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National Clinical Guideline developed by the National Collaborating Centre for Acute Care.

Faecal Incontinence

The Management of Faecal Incontinence in Adults

Appendices A- N

Contents

APPENDIX A: SCOPE

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Scope

1 Guideline title

The management of faecal incontinence in adults

1.1 Short title

Faecal incontinence

2 Background

a) The National Institute for Health and Clinical Excellence ('NICE' or 'the Institute') has commissioned the National Collaborating Centre for Acute Care to develop a clinical guideline on the management of faecal incontinence for use in the NHS in England and Wales. This follows referral of the topic by the Department of Health and Welsh Assembly Government (see Appendix). The guideline will provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness.

b) The Institute's clinical guidelines will support the implementation of National Service Frameworks (NSFs) in those aspects of care where a Framework has been published. The statements in each NSF reflect the evidence that was used at the time the Framework was prepared. The clinical guidelines and technology appraisals published by the Institute after an NSF has been issued will have the effect of updating the Framework.

c) NICE clinical guidelines support the role of healthcare professionals in providing care in partnership with patients, taking account of their individual needs and preferences, and ensuring that patients (and their carers and families, where appropriate) can make informed decisions about their care and treatment.

3 Clinical need for the guideline

a) It is difficult to measure the prevalence of faecal incontinence accurately. This is because the definitions of different degrees of incontinence are, in part, subjective and people under-report the problem because of the associated embarrassment. Best estimates suggest that the prevalence of clinically significant faecal incontinence in the UK is highest in elderly populations and those in institutional care.

b) Faecal incontinence can have a major negative impact on physical and psychological health and lifestyle; in many cases it causes severe social restriction.

c) Faecal incontinence has many possible contributing causes, including damage caused to the body when giving birth, anal surgery, neurological disease, bowel impaction, congenital disorders, overflow incontinence due to faecal impaction and diarrhoea.

d) It is estimated that incontinence in adults (both urinary and faecal) accounts for 2% of the total annual healthcare budget of the UK. The annual NHS bill for treating and managing incontinent persons is estimated at £500 million.

4 The guideline

a) The guideline development process is described in detail in two publications which are available from the NICE website (see 'Further information'). *The Guideline Development Process – An overview for stakeholders, the public and the NHS* describes how organisations can become involved in the development of a guideline. *Guideline Development Methods – Information for National Collaborating Centres and guideline developers* provides advice on the technical aspects of guideline development.

b) This document is the scope. It defines exactly what this guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health and Welsh Assembly Government (see Appendix).

c) The areas that will be addressed by the guideline are described in the following sections.

1.1 Population

1.1.1 Groups that will be covered

a) The guideline will cover adults (age 18 and older) with a diagnosis of faecal incontinence (defined as any involuntary loss of faeces that is a social or hygienic problem).

1.1.2 Groups that will not be covered

a) Patients under the age of 18 years.

1.2 Healthcare setting

a) This guideline will be relevant to patients and their carers in the community (home and care homes) and hospital (all departments).

1.3 Clinical management

a) The guideline will review the clinical and cost effectiveness, and possible morbidity, of interventions to manage faecal incontinence in the populations listed in 4.1.1.

b) Interventions to be considered (used singly or in combination) will include the following.

- *Clinical/continence assessment.*
- *Patient and carer education and support.*
- *Lifestyle changes such as diet and exercise.*
- *Adaptations to home toilet facilities and other measures (for example, clothing adaptations).*
- *Provision of information to patients and, where appropriate, their carers, on clinical and practical aspects of their condition.*
- *Bowel management programmes (for example, abdominal massage, toileting).*
- *Medical treatment (for example, stool bulking agents, constipating agents, evacuation aids, laxatives and anti-diarrhoeal agents).*
- *Manual evacuation/digital stimulation.*
- *Biofeedback and/or sphincter exercises.*
- *Anal electrical stimulation.*
- *Surgical procedures with or without electrical stimulation.*
- *Use of absorbent products.*
- *Skin care management.*
- *Other products such as bags and plugs.*
- *Irrigation via anus or surgically constructed port.*
- *Other specialised products for managing faecal incontinence.*

c) Note that guideline recommendations on prescribing will normally fall within licensed indications; exceptionally, and only where clearly supported by evidence, using a drug outside its licensed indication may be recommended. The guideline will assume that prescribers will use the Summary of Product Characteristics to inform their decisions for individual patients.

1.4 Status

1.4.1 Scope

This is the final scope.

Related NICE guidance:

National Institute for Clinical Excellence (2004) Sacral nerve stimulation for urge incontinence and urgency-frequency. *NICE Interventional Procedure* No. 64. London: National Institute for Clinical Excellence. Available from: www.nice.org.uk

National Institute for Clinical Excellence (2004) Artificial anal sphincter transplantation. *NICE Interventional Procedure* No. 66. London: National Institute for Clinical Excellence. Available from: www.nice.org.uk

National Institute for Clinical Excellence (2004) Sacral nerve stimulation for faecal incontinence. *NICE Interventional Procedure* No. 99. London: National Institute for Clinical Excellence. Available from: www.nice.org.uk

1.4.2 Guideline

The development of the guideline recommendations will begin in June 2005.

2 Further information

Information on the guideline development process is provided in:

- The Guideline Development Process – An overview for stakeholders, the public and the NHS
- Guideline Development Methods – Information for National Collaborating Centres and guideline developers

These booklets are available as PDF files from the NICE website (www.nice.org.uk). Information on the progress of the guideline will also be available from the website.

Appendix – Referral from the Department of Health and Welsh Assembly Government

The Department of Health and Welsh Assembly Government asked the Institute:

To prepare a guideline for the NHS in England and Wales on the management of faecal incontinence.

APPENDIX B: CLINICAL QUESTIONS

Good practice in managing faecal incontinence

1. Do any educational interventions improve outcomes for patients with faecal incontinence?

Baseline assessment and initial management

2. What does a structured assessment add to the assessment of patients with faecal incontinence?
3. What does clinician examination add to the assessment of the patient with faecal incontinence?
4. What does patient reporting add to the assessment of the patient with faecal incontinence?
5. What is the effectiveness of modifying diet or fluid intake at managing faecal incontinence?
6. What is the effectiveness of modifying drug administration at managing faecal incontinence?
7. What is the effectiveness of any combination of dietary, fluid or drug administration in managing faecal incontinence?
8. What are the most effective products (absorbent products, containment products and plugs) to manage faecal incontinence?
9. What are the most effective skin care products to manage faecal incontinence?
10. What is the best practice goal setting (including involving patients) for satisfactory treatment of faecal incontinence?

Specialised management

11. What is the effectiveness of pelvic floor/ anal sphincter exercises vs all other conservative therapies?
12. What is the effectiveness of biofeedback vs all other conservative therapies?
13. Which modality of biofeedback is most effective at managing faecal incontinence?
14. What is the effectiveness of external electrical stimulation to manage faecal incontinence?

Specialist assessment

15. What does functional testing add to the assessment of the patient with faecal incontinence?

16. What do imaging techniques add to the assessment of patients with faecal incontinence?

17. What does endoscopy add to the assessment of patients with faecal incontinence?

18. Are any investigation techniques better than others?

19. Which combinations of tests effectively select patients for specific treatment strategies?

Surgical Interventions in all patient groups

20. Is surgery effective and does it last compared with no surgery (conservative treatment)?

21. Are any surgical interventions more effective than others?

22. Do any interventions, pre or post surgery, affect the outcome of surgery for faecal incontinence?

Specific patient groups

23. What procedures are effective in patients or residents in care homes with faecal incontinence related to faecal loading, impaction or constipation?

24. What procedures are effective in patients with limited mobility and faecal incontinence?

25. In patients who report FI who are using enteral nutritional support, what is the effect of lactose free nutritional intervention vs nutritional intervention containing lactose on patient related outcomes?

26. In patients who report FI using antibiotics, what is the effect of probiotics vs no probiotics on patient related outcomes?

APPENDIX C: SEARCH STRATEGIES

Searches were conducted in the following databases:

- Medline (Dialog Datastar) 1951 to 2 October 2006
- Embase (Dialog Datastar) 1974 to 2 October 2006
- Cinahl (Dialog Datastar) 1982 to 2 October 2006
- Allied & Complementary Medicine - 1985 to 2 October 2006
- British Nursing Index - 1994 to 2 October 2006
- PsycINFO - 1806 to 2 October 2006
- The Cochrane Library Issue 3, 2006 (including NHS EED)
- Health Economic and Evaluations Database (HEED)

All faecal incontinence systematic reviews, RCTs, observational studies and diagnostic accuracy studies were searched for in Medline, Embase, Cinahl, Allied & Complementary Medicine, British Nursing Index and PsycInfo by combining the following two groups of search terms:

1. Faecal incontinence AND
2. Study design (i.e. systematic reviews, RCTs, observational and diagnostic accuracy studies)

The Cochrane Library (including NHS EED) was searched for all studies using the following group of search terms:

1. Faecal incontinence

Surgical case series searches for some procedures used in treating faecal incontinence were searched for in Medline and Embase using the following 3 groups of search terms:

1. Faecal incontinence AND
2. Surgical procedures AND
3. Case series

Patient views, information and education searches in Medline, Embase, Cinahl, AMED and the British Nursing Index were constructed using the following groups of search terms:

1. Faecal incontinence AND

2. Patient information, patient views and education

Economic studies were searched for in Medline and Embase using the following 2 groups of terms:

1. Faecal incontinence AND
2. Economic studies

Economic studies were searched for in NHS EED and HEED (Health Economic Evaluations Database) using the following groups of terms:

1. Faecal incontinence

Terms for each of the above groups of terms are listed below

Faecal incontinence search terms:

Medline

1 Fecal-Incontinence.DE.

2 ((faecal OR fecal OR faeces OR feces OR fecally OR faecally OR anal OR anally OR stool OR stools OR bowel OR double OR defecat$ OR defaecat$) WITH (incontinence OR incontinent OR urge$ OR leak OR leaking OR leakage OR soiling OR seeping OR seepage OR impacted OR impaction)).TI,AB.

3 1 OR 2

Embase

1 Feces-Incontinence.DE.

2 ((faecal OR fecal OR faeces OR feces OR fecally OR faecally OR anal OR anally OR stool OR stools OR bowel OR double OR defecat$ OR defaecat$) WITH (incontinence OR incontinent OR urge$ OR leak OR leaking OR leakage OR soiling OR seeping OR seepage OR impacted OR impaction)).TI,AB.

3 1 OR 2

Cinahl

1 Fecal-Incontinence.DE.

2 ((faecal OR fecal OR faeces OR feces OR fecally OR faecally OR anal OR anally OR stool OR stools OR bowel OR double OR defecat$ OR defaecat$) WITH (incontinence OR incontinent OR urge$ OR leak OR leaking OR leakage OR soiling OR seeping OR seepage OR impacted OR impaction)).TI,AB.

3 1 OR 2

Allied & Complementary Medicine

1 Fecal-Incontinence.DE.

2 ((faecal OR fecal OR faeces OR feces OR fecally OR faecally OR anal OR anally OR stool OR stools OR bowel OR double OR defecat$ OR defaecat$) WITH (incontinence OR incontinent OR urge$ OR leak OR leaking OR leakage OR soiling OR seeping OR seepage OR impacted OR impaction)).TI,AB.

3 1 OR 2

British Nursing Index

1 Faecal-Incontinence.DE.

2 ((faecal OR fecal OR faeces OR feces OR fecally OR faecally OR anal OR anally OR stool OR stools OR bowel OR double OR defecat$ OR defaecat$) WITH (incontinence OR incontinent OR urge$ OR leak OR leaking OR leakage OR soiling OR seeping OR seepage OR impacted OR impaction)).TI,AB.

3 1 OR 2

PsycINFO

1 Fecal-Incontinence.DE.

2 ((faecal OR fecal OR faeces OR feces OR fecally OR faecally OR anal OR anally OR stool OR stools OR bowel OR double OR defecat$ OR defaecat$) WITH (incontinence OR incontinent OR urge$ OR leak OR leaking OR leakage OR soiling OR seeping OR seepage OR impacted OR impaction)).TI,AB.

3 1 OR 2

The Cochrane Library

1 *MeSH descriptor* Fecal Incontinence

2 ((faecal OR fecal OR faeces OR feces OR fecally OR faecally OR anal OR anally OR stool OR stools OR bowel OR double OR defecat* OR defaecat*) NEAR (incontinence OR incontinent OR urge* OR leak OR leaking OR leakage

OR soiling OR seeping OR seepage OR impacted OR impaction)) *in Title*

3 ((faecal OR fecal OR faeces OR feces OR fecally OR faecally OR anal OR anally OR stool OR stools OR bowel OR double OR defecat* OR defaecat*) NEAR (incontinence OR incontinent OR urge* OR leak OR leaking OR leakage OR soiling OR seeping OR seepage OR impacted OR impaction)) *in Abstract*

4 #1 OR #2 OR #3

Systematic review search terms:

Medline

1 Meta-Analysis.DE. OR Review-Literature#.DE.

2 Meta-Analysis.PT. OR ((selection ADJ criteria).AB. OR (data ADJ extraction).AB.) AND Review.PT.

3 (cochrane OR embase OR psychlit OR psyclit OR psychinfo OR psycinfo OR cinahl OR cinhal OR science ADJ citation ADJ index OR bids OR cancerlit).AB.

4 (reference ADJ ('LIST' OR lists) OR bibliograph$ OR hand ADJ search$ OR manual ADJ search$ OR relevant ADJ journals).AB.

5 meta ADJ (analysis OR analyse OR analyses OR analysed OR analytic$) OR metaanaly$ OR meta-analy$ OR systematic ADJ (review OR overview)

6 1 OR 2 OR 3 OR 4 or 5

7 Comment.PT. OR Letter.PT. OR Editorial.PT. OR (Animals#.DE. NOT Humans.DE.)

8 6 NOT 7

Embase

1 Meta-Analysis#.DE. OR Systematic-Review.DE.

2 ((selection ADJ criteria).AB. OR (data ADJ extraction).AB.) AND Review.AT.

3 (cochrane OR embase OR psychlit OR psyclit OR psychinfo OR psycinfo OR cinahl OR cinhal OR science ADJ citation ADJ index OR bids OR cancerlit).AB.

4 (reference ADJ ('LIST' OR lists) OR bibliograph$ OR hand ADJ search$ OR manual ADJ search$ OR relevant ADJ journals).AB.

5 meta ADJ (analysis OR analyse OR analyses OR analysed OR analytic$) OR metaanaly$ OR meta-analy$ OR systematic ADJ (review OR overview)

6 1 OR 2 OR 3 OR 4 OR 5

7 Letter.AT. OR Editorial.AT. OR ((Animal#.DE. OR Nonhuman.DE. OR Animal-Experiment#.DE.) NOT Human#.DE.)

8 6 NOT 7

Cinahl

1 Meta-Analysis.DE. OR Literature-Review#.DE.

2 Systematic-Review.PT. OR ((selection ADJ criteria).AB. OR (data ADJ extraction).AB.) AND Review.PT.

3 meta ADJ (analysis OR analyse OR analyses OR analysed OR analytic$) OR metaanaly$ OR meta-analy$ OR systematic ADJ (review OR overview)

4 1 OR 2 OR 3

5 Commentary.PT. OR Letter.PT. OR Editorial.PT. OR Animals.DE.

6 4 NOT 5

Allied & Complementary Medicine

1 Meta-Analysis.DE.

2 meta ADJ (analysis OR analyse OR analyses OR analysed OR analytic$) OR metaanaly$ OR meta-analy$ OR systematic ADJ (review OR overview)

3 1 OR 2

British Nursing Index

1 meta ADJ (analysis OR analyse OR analyses OR analysed OR analytic$) OR metaanaly$ OR meta-analy$ OR systematic ADJ (review OR overview)

PsycINFO

1 Meta-Analysis.DE. OR Literature-Review.DE.

2 ((selection ADJ criteria).AB. OR (data ADJ extraction).AB.) AND Review.PT.

3 meta ADJ (analysis OR analyse OR analyses OR analysed OR analytic OR analytical) OR metaanalysis OR metaanalyses OR meta-analysis OR meta-analyses OR systematic ADJ (review OR overview)

4 1 OR 2 OR 3

Randomised controlled trial search terms:

Medline

1 Randomized-Controlled-Trials.DE. OR Random-Allocation.DE. OR Double-Blind-Method.DE. OR Single-Blind-Method.DE. OR Clinical-Trials#.DE. OR Cross-Over-Studies.DE. OR Prospective-Studies.DE. OR Placebos.DE.

2 Randomized-Controlled-Trial.PT. OR Clinical-Trial.PT. OR Controlled-Clinical-Trial.PT.

3 ((clinical OR control OR controlled) ADJ (study OR trial) OR (single OR double OR triple) ADJ (blind$3 OR mask$3) OR randomi$6 OR (random OR randomly) WITH (assign$5 OR allocat$4 OR group OR groups OR grouped OR patients OR study OR trial OR distribut$4) OR crossover NEXT (design OR study OR trial) OR placebo OR placebos).TI,AB.

4 1 OR 2 OR 3

5 Case-Reports.PT. NOT Randomized-Controlled-Trial.PT. OR Letter.PT. OR Historical-Article.PT. OR Review-Of-Reported-Cases.PT. OR Animals#.W..DE. NOT Humans.DE.

6 4 NOT 5

Embase

1 Clinical-Trial.DE. OR Randomized-Controlled-Trial.DE. OR Randomization.W..DE. OR Single-Blind-Procedure.DE. OR Double-Blind-Procedure.DE. OR Crossover-Procedure.DE. OR Prospective-Study.DE. OR Placebo.DE.

2 ((clinical OR control OR controlled) ADJ (study OR trial) OR (single OR double OR triple) ADJ (blind$3 OR mask$3) OR randomi$6 OR (random OR randomly) WITH (assign$5 OR allocat$4 OR group OR groups OR grouped OR patients OR study OR trial OR distribut$4) OR crossover NEXT (design OR study OR trial) OR placebo OR placebos).TI,AB.

3 1 OR 2

4 Case-Study.DE. OR case ADJ report OR Abstract-Report.DE. OR Letter.DE. OR (Animal#.DE. OR Nonhuman.DE. OR Animal-Experiment#.DE.) NOT Human#.DE.

5 3 NOT 4

Cinahl

1 Clinical-Trials#.DE. OR Random-Assignment.DE. OR Quantitative-Studies.DE. OR Crossover-Design.DE. OR Placebos.DE.

2 Clinical-Trial.PT.

3 ((clinical OR control OR controlled) ADJ (study OR trial) OR (single OR double OR triple) ADJ (blind$3 OR mask$3) OR randomi$6 OR (random OR randomly) WITH (assign$5 OR allocat$4 OR group OR groups OR grouped OR patients OR study OR trial OR distribut$4) OR crossover NEXT (design OR study OR trial) OR placebo OR placebos).TI,AB.

4 1 OR 2 OR 3

Allied & Complementary Medicine

1 Clinical-Trials#.DE. OR Double-Blind-Method.DE. OR Random-Allocation.DE. OR Placebos.W..DE.

2 ((clinical OR control OR controlled) ADJ (study OR trial) OR (single OR double OR triple) ADJ (blind$3 OR mask$3) OR randomi$6 OR (random OR randomly) WITH (assign$5 OR allocat$4 OR group OR groups OR grouped OR patients OR study OR trial OR distribut$4) OR crossover NEXT (design OR study OR trial) OR placebo OR placebos).TI,AB.

3 1 OR 2

British Nursing Index

1 ((clinical OR control OR controlled) ADJ (study OR trial) OR (single OR double OR triple) ADJ (blind$3 OR mask$3) OR randomi$6 OR (random OR randomly) WITH (assign$5 OR allocat$4 OR group OR groups OR grouped OR patients OR study OR trial OR distribut$4) OR crossover NEXT (design OR study OR trial) OR placebo OR placebos).TI,AB.

PsycINFO

1 Clinical-Trials.DE. OR Placebo.W..DE.

2 ((clinical OR control OR controlled) ADJ (study OR trial) OR (single OR double OR triple) ADJ (blind$3 OR mask$3) OR randomi$6 OR (random OR randomly) WITH (assign$5 OR allocat$4 OR group OR grouped OR patients OR study OR trial OR distribut$4) OR crossover NEXT (design OR study OR trial) OR placebo OR placebos).TI,AB.

3 1 OR 2

Economic studies search terms:

Medline

1 Economics.W..DE. OR Economics-Hospital#.DE. OR Economics-Medical#.DE. OR Economics-Nursing.DE. OR Economics-Pharmaceutical.DE.

2 Costs-and-Cost-Analysis.DE. OR Cost-Allocation.DE. OR Cost-Benefit-Analysis.DE. OR Cost-Control.DE. OR Cost-Savings.DE. OR Cost-Of-Illness.DE. OR Cost-Sharing.DE. OR Health-Care-Costs.DE. OR Direct-Service-Costs.DE. OR Drug-Costs.DE. OR Employer-Health-Costs.DE. OR Hospital-Costs.DE.

3 Health-Expenditures.DE. OR Capital-Expenditures.DE. OR Fees-and-Charges#.DE. OR Budgets#.DE. OR Deductibles-and-Coinsurance.DE. OR Medical-Savings-Accounts.DE. OR Value-Of-Life.DE. OR Quality-Adjusted-Life-Years.DE.

4 ((low OR high OR unit OR healthcare OR health ADJ care OR health-care OR hospital OR benefit) ADJ (cost OR costs OR costing OR costings)).TI,AB. OR ((cost OR costs OR costing OR costings) ADJ (estimat$ OR variable OR effectiv$ OR benefit$)).TI,AB.

5 fiscal OR funding OR financial OR finance OR economic$ OR pharmacoeconomic$ OR price OR prices OR pricing OR (QALY$ OR life-year$ OR costeffectiv$ OR cost-effectiv$ OR costbenefit$ OR cost-benefit$).TI,AB.

6 1 OR 2 OR 3 OR 4 OR 5

Embase

1 Socioeconomics.W..DE. OR Cost-Benefit-Analysis.DE. OR Cost-Effectiveness-Analysis.DE. OR Cost-Of-Illness.DE. OR Cost-Control.DE. OR Economic-Aspect.DE. OR Financial-Management.DE. OR Health-Care-Cost.DE. OR Health-Care-Financing.DE. OR Health-Economics.DE. OR Hospital-Cost.DE. OR Cost-Minimization-Analysis.DE.

2 fiscal OR financial OR finance OR funding OR (cost ADJ (estimate$ OR variable$)).TI,AB. OR (unit ADJ (cost OR costs OR costing OR costings)).TI,AB.

3 1 OR 2

Observational studies search terms:

Medline

1 Evaluation-Studies.DE. OR Epidemiologic-Studies.DE. OR Case-Control-Studies.DE. OR Cohort-Studies.DE. OR Cross-Sectional-Studies.DE. OR Intervention-Studies.DE. OR Prospective-Studies.DE. OR Observation.W..DE. OR Follow-Up-Studies.DE. OR Longitudinal-Studies.DE.

2 Evaluation-Studies.PT. OR Multicenter-Study.PT. OR Validation-Studies.PT.

3 (cohort OR case ADJ control OR prospective OR retrospective OR longitudinal OR cross ADJ sectional OR cross-sectional).TI,AB.

4 ((follow ADJ up OR follow-up OR observational OR epidemiology OR epidemiologic OR epidemiological) ADJ (study OR studies)).TI,AB.

5 (time ADJ series OR pre-test OR pre ADJ test OR post-test OR post ADJ test OR before ADJ after OR quasirandomised OR quasirandomized OR quasi-randomised OR quasi-randomized OR quasi ADJ (randomised OR randomized OR randomisation OR randomization) OR quasiexperimental OR quasi-experimental OR quasi ADJ (experimental OR experimentation)).TI,AB.

6 1 OR 2 OR 3 OR 4 OR 5

Embase

1 Evaluation-and-Follow-Up.DE. Or Evaluation.W..DE. OR Clinical-Study.DE. OR Case-Control-Study.DE. OR Family-Study.DE. OR Longitudinal-Study.DE. OR Prospective-Study.DE. OR Retrospective-Study.DE. OR Cohort-Analysis.DE. OR Follow-Up.DE. OR Comparative-Study.DE.

2 (cohort OR case ADJ control OR prospective OR retrospective OR longitudinal OR cross ADJ sectional OR cross-sectional).TI,AB.

3 ((follow ADJ up OR follow-up OR observational OR epidemiology OR epidemiologic OR epidemiological) ADJ (study OR studies)).TI,AB.

4 (time ADJ series OR pre-test OR pre ADJ test OR post-test OR post ADJ test OR before ADJ after OR quasirandomised OR quasirandomized OR quasi-randomised OR quasi-randomized OR quasi ADJ (randomised OR randomized OR randomisation OR randomization) OR quasiexperimental OR quasi-experimental OR quasi ADJ (experimental OR experimentation)).TI,AB.

5 1 OR 2 OR 3 OR 4

Cinahl

1 Case-Control-Studies#.DE. OR Correlational-Studies.DE. OR Cross-Sectional-Studies.DE. OR Prospective-Studies.DE. OR Nonconcurrent-Prospective-Studies.DE. OR Nonexperimental-Studies.DE. OR Observational-Methods.DE. OR Comparative-Studies.DE.

2 (cohort OR case ADJ control OR prospective OR retrospective OR longitudinal OR cross ADJ sectional OR cross-sectional).TI,AB.

3 ((follow ADJ up OR follow-up OR observational OR epidemiology OR epidemiologic OR epidemiological) ADJ (study OR studies)).TI,AB.

4 (time ADJ series OR pre-test OR pre ADJ test OR post-test OR post ADJ test OR before ADJ after OR quasirandomised OR quasirandomized OR quasi-randomised OR quasi-randomized OR quasi ADJ (randomised OR randomized OR randomisation OR randomization) OR quasiexperimental OR quasi-experimental OR quasi ADJ (experimental OR experimentation)).TI,AB.

5 1 OR 2 OR 3 OR 4

Allied & Complementary Medicine

1 Follow-Up-Studies.DE. OR Comparative-Study.DE.

2 (cohort OR case ADJ control OR prospective OR retrospective OR longitudinal OR cross ADJ sectional OR cross-sectional).TI,AB.

3 ((follow ADJ up OR follow-up OR observational OR epidemiology OR epidemiologic OR epidemiological) ADJ (study OR studies)).TI,AB.

4 (time ADJ series OR pre-test OR pre ADJ test OR post-test OR post ADJ test OR before ADJ after OR quasirandomised OR quasirandomized OR quasi-randomised OR quasi-randomized OR quasi ADJ (randomised OR randomized OR randomisation OR randomization) OR quasiexperimental OR quasi-experimental OR quasi ADJ (experimental OR experimentation)).TI,AB.

5 1 OR 2 OR 3 OR 4

British Nursing Index

1 (cohort OR case ADJ control OR prospective OR retrospective OR longitudinal OR cross ADJ sectional OR cross-sectional).TI,AB.

2 ((follow ADJ up OR follow-up OR observational OR epidemiology OR epidemiologic OR epidemiological) ADJ (study OR studies)).TI,AB.

3 (time ADJ series OR pre-test OR pre ADJ test OR post-test OR post ADJ test OR before ADJ after OR quasirandomised OR quasirandomized OR quasi-randomised OR quasi-randomized OR quasi ADJ (randomised OR randomized OR randomisation OR randomization) OR quasiexperimental OR quasi-experimental OR quasi ADJ (experimental OR experimentation)).TI,AB.

4 1 OR 2 OR 3

PsycINFO

1 Cohort-Analysis.DE. OR Followup-Studies.DE. OR Longitudinal-Studies.DE. OR Prospective-Studies.DE.

2 (cohort OR case ADJ control OR prospective OR retrospective OR longitudinal OR cross ADJ sectional OR cross-sectional).TI,AB.

3 ((follow ADJ up OR follow-up OR observational OR epidemiology OR epidemiologic OR epidemiological) ADJ (study OR studies)).TI,AB.

4 (time ADJ series OR pre-test OR pre ADJ test OR post-test OR post ADJ test OR before ADJ after OR quasirandomised OR quasirandomized OR quasi-randomised OR quasi-randomized OR quasi ADJ (randomised OR randomized OR randomisation OR randomization) OR quasiexperimental OR quasi-experimental OR quasi ADJ (experimental OR experimentation)).TI,AB.

5 1 OR 2 OR 3 OR 4

Case series search terms:

Medline

1 Time-Factors.DE.

2 (change$4 or evaluat$3 or reviewed or baseline or case ADJ series).TI,AB.

3 1 or 2

Embase

1 Treatment-Outcome.DE.

2 (change$4 or evaluat$3 or reviewed or baseline or case series).TI,AB.

3 1 OR 2

Diagnostic studies search terms:

Medline

1 Diagnosis.W..DE. NOT Di.DE.

2 Diagnostic-Errors#.DE.

3 Sensitivity-and-Specificity#.DE.

4 diagnostic.TI,AB.

5 (sensitivity OR specificity OR predictive ADJ value$ OR accuracy OR likelihood ADJ (ratio OR ratios) OR false ADJ negative$ OR false ADJ positive$ OR true ADJ positive$ OR true ADJ negative$).TI,AB.

6 1 OR 2 OR 3 OR 4 OR 5

Embase

1 Diagnosis.W..DE. NOT Di.DE.

2 Diagnostic-Error#.DE.

3 Sensitivity-and-Specificity#.DE.

4 diagnostic.TI,AB.

5 (sensitivity OR specificity OR predictive ADJ value$ OR accuracy OR likelihood ADJ (ratio OR ratios) OR false ADJ negative$ OR false ADJ positive$ OR true ADJ positive$ OR true ADJ negative$).TI,AB.

6 1 OR 2 OR 3 OR 4 OR 5

Cinahl

1 Diagnosis.W..DE. NOT Di.DE.

2 Diagnostic-Errors#.DE.

3 Sensitivity-and-Specificity#.DE.

4 diagnostic.TI,AB.

5 (sensitivity OR specificity OR predictive ADJ value$ OR accuracy OR likelihood ADJ (ratio OR ratios) OR false ADJ negative$ OR false ADJ positive$ OR true ADJ positive$ OR true ADJ negative$).TI,AB.

6 1 OR 2 OR 3 OR 4 OR 5

Allied & Complementary Medicine

1 Diagnosis.W..DE.

2 Diagnostic-Errors#.DE.

3 Sensitivity-and-Specificity#.DE.

4 diagnostic.TI,AB.

5 (sensitivity OR specificity OR predictive ADJ value$ OR accuracy OR likelihood ADJ (ratio OR ratios) OR false ADJ negative$ OR false ADJ positive$ OR true ADJ positive$ OR true ADJ negative$).TI,AB.

6 1 OR 2 OR 3 OR 4 OR 5

British Nursing Index

1 Diagnosis.W..DE.

2 diagnostic.TI,AB.

3 (sensitivity OR specificity OR predictive ADJ value$ OR accuracy OR likelihood ADJ (ratio OR ratios) OR false ADJ negative$ OR false ADJ positive$ OR true ADJ positive$ OR true ADJ negative$).TI,AB.

4 1 OR 2 OR 3

PsycINFO

1 Diagnosis.W..DE.

2 diagnostic.TI,AB.

3 (sensitivity OR specificity OR predictive ADJ value$ OR accuracy OR likelihood ADJ (ratio OR ratios) OR false ADJ negative$ OR false ADJ positive$ OR true ADJ positive$ OR true ADJ negative$).TI,AB.

4 1 OR 2 OR 3

Patient views search terms:

Medline

1 Patients.W..DE. OR Inpatients.W..DE. OR Outpatients.W..DE. OR Survivors.W..DE.

2 Caregivers.W..DE. OR Family#.W..DE. OR Parents#.W..DE. OR Legal-Guardians#.DE.

3 1 OR 2

4 Anxiety.W..DE. OR Perception.W..DE. OR Body-Image.DE. OR Social-Perception.DE. OR Attitude.W..DE. OR Attitude-To-Health#.DE. OR Emotions#.W..DE. OR Depression.W..DE. OR Empathy.W..DE. OR Morale.W..DE. OR Stress.W..DE. OR Confidentiality.W..DE.

5 Religion#.W..DE. OR Culture#.W..DE.

6 Focus-Groups.DE. OR Questionnaires.W..DE. OR Health-Surveys#.DE. OR Health-Care-Surveys.DE. OR Interviews.W..DE.

7 4 OR 5 OR 6

8 3 AND 7

9 Consumer-Satisfaction#.DE. OR Personal-Satisfaction.DE. OR Patient-Acceptance-Of-Health-Care#.DE. OR Consumer-Participation#.DE. OR Patient-Rights#.DE.

10 Hospital-Patient-Relations.DE. OR Nurse-Patient-Relations.DE. OR Physician-Patient-Relations.DE. OR Professional-Patient-Relations.DE.

11 9 OR 10

12 (patient OR patients OR inpatient$ OR outpatient$ OR client$ OR survivor$ OR consumer OR consumers OR user OR users).TI,AB.

13 (caregiver$ OR care ADJ giver$ OR carer$ OR family OR families OR parent OR parents OR guardian$).TI,AB.

14 12 OR 13

15 (accept$ OR anxious OR anxiet$ OR attitud$ OR compassion$ OR concern$ OR confid$ OR cope OR coped OR copes OR coping OR depressed OR depression OR emot$ OR empath$ OR experienc$ OR fear$ OR feeling$ OR issue OR issues OR journey$ OR morale OR opinion$ OR participat$ OR perceiv$ OR percept$ OR perspective$ OR prefer$ OR right OR rights OR satisf$ OR stress OR stressed OR uncertain$ OR view$ OR worri$ OR worry).TI,AB.

16 (quality NEXT life OR self ADJ esteem OR body ADJ image).TI,AB.

17 (culture OR custom$ OR ethnic$ OR faith$ OR religio$ OR spiritual$ OR belief$ OR believ$).TI,AB.

18 (focus ADJ (group OR groups) OR observational ADJ (method OR methods) OR questionnaire OR questionnaires OR survey OR surveys OR interview$).TI,AB.

19 15 OR 16 OR 17 OR 18

20 14 WITH 19

21 8 OR 11 OR 20

Embase

1 Patient#.W..DE. OR Consumer.W..DE.

2 Caregiver.W..DE. OR Family.W..DE. OR Parent#.W..DE. OR Custody.W..DE.

3 1 OR 2

4 Anxiety.W..DE. OR Perception.W..DE. OR Attitude.W..DE. OR Emotion#.W..DE. OR Depression#.W..DE. OR Empathy.W..DE. OR Stress#.W..DE. OR Adaptive-Behavior.DE. OR Body-Image.DE. OR Coping-Behavior.DE. OR Confidentiality.W..DE. OR Trust.W..DE.

5 Religion.W..DE. OR Cultural-Anthropology.DE.

6 Questionnaire.W..DE. OR Health-Survey.DE. OR Interview.W..DE.

7 4 OR 5 OR 6

8 3 AND 7

9 Patient-Attitude#.DE.

10 Doctor-Patient-Relation.DE. OR Nurse-Patient-Relationship.DE.

11 9 OR 10

12 (patient OR patients OR inpatient$ OR outpatient$ OR client$ OR survivor$ OR consumer OR consumers OR user OR users).TI,AB.

13 (caregiver$ OR care ADJ giver$ OR carer$ OR family OR families OR parent OR parents OR guardian$).TI,AB.

14 12 OR 13

15 (accept$ OR anxious OR anxiet$ OR attitud$ OR compassion$ OR concern$ OR confid$ OR cope OR coped OR copes OR coping OR depressed OR depression OR emot$ OR empath$ OR experienc$ OR fear$ OR feeling$ OR issue OR issues OR journey$ OR morale OR opinion$ OR participat$ OR perceiv$ OR percept$ OR perspective$ OR prefer$ OR right OR rights OR satisf$ OR stress OR stressed OR uncertain$ OR view$ OR worri$ OR worry).TI,AB.

16 (quality NEXT life OR self ADJ esteem OR body ADJ image).TI,AB.

17 (culture OR custom$ OR ethnic$ OR faith$ OR religio$ OR spiritual$ OR belief$ OR believ$).TI,AB.

18 (focus ADJ (group OR groups) OR observational ADJ (method OR methods) OR questionnaire OR questionnaires OR survey OR surveys OR interview$).TI,AB.

19 15 OR 16 OR 17 OR 18

20 14 WITH 19

21 8 OR 11 OR 20

Cinahl

1 Patient#.W..DE. OR Consumer.W..DE.

2 Caregivers.W..DE. OR Family#.W..DE. OR Parents#.W..DE. OR Guardianship-Legal.DE.

3 1 OR 2

4 Anxiety.W..DE. OR Perception.W..DE. OR Body-Image#.DE. OR Attitude.W..DE. OR Attitude-To-Health#.DE. OR Attitude-To-Illness.DE. OR Uncertainty.W..DE. OR Emotions#.W..DE. OR Depression#.W..DE. OR Empathy.W..DE. OR Morale.W..DE. OR Stress#.W..DE. OR Privacy-and-Confidentiality.DE.

5 Religion-and-Religions#.DE. OR Culture#.W..DE.

6 Focus-Groups.DE. OR Questionnaires#.W..DE. OR Surveys.W..DE. OR Interviews#.W..DE.

7 4 OR 5 OR 6

8 3 AND 7

9 Personal-Satisfaction.DE. OR Patient-Attitudes.DE. OR Patient-Autonomy.DE. OR Decision-Making-Patient.DE. OR Patient-Access-To-Records.DE. OR Patient-Rights#.DE.

10 Professional-Patient-Relations.DE. OR Physician-Patient-Relations.DE. OR Nurse-Patient-Relations.DE.

11 9 OR 10

12 (patient OR patients OR inpatient$ OR outpatient$ OR client$ OR survivor$ OR consumer OR consumers OR user OR users).TI,AB.

13 (caregiver$ OR care ADJ giver$ OR carer$ OR family OR families OR parent OR parents OR guardian$).TI,AB.

14 12 OR 13

15 (accept$ OR anxious OR anxiet$ OR attitud$ OR compassion$ OR concern$ OR confid$ OR cope OR coped OR copes OR coping OR depressed OR depression OR emot$ OR empath$ OR experienc$ OR fear$ OR feeling$ OR issue OR issues OR journey$ OR morale OR opinion$ OR participat$ OR perceiv$ OR percept$ OR perspective$ OR prefer$ OR right OR rights OR satisf$ OR stress OR stressed OR uncertain$ OR view$ OR worri$ OR worry).TI,AB.

16 (quality NEXT life OR self ADJ esteem OR body ADJ image).TI,AB.

17 (culture OR custom$ OR ethnic$ OR faith$ OR religio$ OR spiritual$ OR belief$ OR believ$).TI,AB.

18 (focus ADJ (group OR groups) OR observational ADJ (method OR methods) OR questionnaire OR questionnaires OR survey OR surveys OR interview$).TI,AB.

19 15 OR 16 OR 17 OR 18

20 14 WITH 19

21 8 OR 11 OR 20

Allied & Complementary Medicine

1 (patient OR patients OR inpatient$ OR outpatient$ OR client$ OR survivor$ OR consumer OR consumers OR user OR users).TI,AB.

2 (caregiver$ OR care ADJ giver$ OR carer$ OR family OR families OR parent OR parents OR guardian$).TI,AB.

3 1 OR 2

4 (accept$ OR anxious OR anxiet$ OR attitud$ OR compassion$ OR concern$ OR confid$ OR cope OR coped OR copes OR coping OR depressed OR depression OR emot$ OR empath$ OR experienc$ OR fear$ OR feeling$ OR issue OR issues OR journey$ OR morale OR opinion$ OR participat$ OR perceiv$ OR percept$ OR perspective$ OR prefer$ OR right OR rights OR satisf$ OR stress OR stressed OR uncertain$ OR view$ OR worri$ OR worry).TI,AB.

5 (quality NEXT life OR self ADJ esteem OR body ADJ image).TI,AB.

6 (culture OR custom$ OR ethnic$ OR faith$ OR religio$ OR spiritual$ OR belief$ OR believ$).TI,AB.

7 (focus ADJ (group OR groups) OR observational ADJ (method OR methods) OR questionnaire OR questionnaires OR survey OR surveys OR interview$).TI,AB.

8 4 OR 5 OR 6 OR 7

9 3 WITH 8

British Nursing Index

1 (patient OR patients OR inpatient$ OR outpatient$ OR client$ OR survivor$ OR consumer OR consumers OR user OR users).TI,AB.

2 (caregiver$ OR care ADJ giver$ OR carer$ OR family OR families OR parent OR parents OR guardian$).TI,AB.

3 1 OR 2

4 (accept$ OR anxious OR anxiet$ OR attitud$ OR compassion$ OR concern$ OR confid$ OR cope OR coped OR copes OR coping OR depressed OR depression OR emot$ OR empath$ OR experienc$ OR fear$ OR feeling$ OR issue OR issues OR journey$ OR morale OR opinion$ OR participat$ OR perceiv$ OR percept$ OR perspective$ OR prefer$ OR right OR rights OR satisf$ OR stress OR stressed OR uncertain$ OR view$ OR worri$ OR

worry).TI,AB.

5 (quality NEXT life OR self ADJ esteem OR body ADJ image).TI,AB.

6 (culture OR custom$ OR ethnic$ OR faith$ OR religio$ OR spiritual$ OR belief$ OR believ$).TI,AB.

7 (focus ADJ (group OR groups) OR observational ADJ (method OR methods) OR questionnaire OR questionnaires OR survey OR surveys OR interview$).TI,AB.

8 4 OR 5 OR 6 OR 7

9 3 WITH 8

PsycINFO

1 (patient OR patients OR inpatient$ OR outpatient$ OR client$ OR survivor$ OR consumer OR consumers OR user OR users).TI,AB.

2 (caregiver$ OR care ADJ giver$ OR carer$ OR family OR families OR parent OR parents OR guardian$).TI,AB.

3 1 OR 2

4 (accept$ OR anxious OR anxiet$ OR attitud$ OR compassion$ OR concern$ OR confid$ OR cope OR coped OR copes OR coping OR depressed OR depression OR emot$ OR empath$ OR experienc$ OR fear$ OR feeling$ OR issue OR issues OR journey$ OR morale OR opinion$ OR participat$ OR perceiv$ OR percept$ OR perspective$ OR prefer$ OR right OR rights OR satisf$ OR stress OR stressed OR uncertain$ OR view$ OR worri$ OR worry).TI,AB.

5 (quality NEXT life OR self ADJ esteem OR body ADJ image).TI,AB.

6 (culture OR custom$ OR ethnic$ OR faith$ OR religio$ OR spiritual$ OR belief$ OR believ$).TI,AB.

7 (focus ADJ (group OR groups) OR observational ADJ (method OR methods) OR questionnaire OR questionnaires OR survey OR surveys OR interview$).TI,AB.

8 4 OR 5 OR 6 OR 7

9 3 WITH 8

Patient Information and education search terms:

Medline

1 Patients.W..DE. OR Inpatients.W..DE. OR Outpatients.W..DE. OR Survivors.W..DE.

2 Caregivers.W..DE. OR Family#.W..DE. OR Parents#.W..DE. OR Legal-Guardians#.DE.

3 1 OR 2

4 Popular-Works-Publication-Type.DE. OR Information-Services#.DE. OR Publications.W..DE. OR Books.W..DE. OR Pamphlets.W..DE. OR Counseling.W..DE. OR Directive-Counseling.DE.

5 3 AND 4

6 ((patient OR patients) WITH (education OR educate OR educating OR information OR literature OR leaflet$ OR booklet$ OR pamphlet$)).TI,AB.

7 Patient-Education.DE. OR Patient-Education-Handout-Publication-Type.DE.

8 5 OR 6 OR 7

Embase

1 Patient#.W..DE. OR Consumer.W..DE.

2 Caregiver.W..DE. OR Family.W..DE. OR Parent#.W..DE. OR Custody.W..DE.

3 1 OR 2

4 Information.W..DE. OR Medical-Information.DE. OR Publication.W..DE. OR Book.W..DE. OR Counseling.W..DE.

5 3 AND 4

6 ((patient OR patients) WITH (education OR educate OR educating OR information OR literature OR leaflet$ OR booklet$ OR pamphlet$)).TI,AB.

7 Consumer-Health-Information.DE. OR Patient-Information.DE. OR Patient-Education.DE. OR Patient-Counseling.DE. OR Patient-Guidance.DE.

8 5 OR 6 OR 7

Cinahl

1 Patient#.W..DE. OR Consumer.W..DE.

2 Caregivers.W..DE. OR Family#.W..DE. OR Parents#.W..DE. OR Guardianship-Legal.DE.

3 1 OR 2

4 Health-Information.DE. OR Print-Materials.DE. OR Literature.W..DE. OR Pamphlets.W..DE. OR Drug-Information.DE. OR Audiovisuals#.W..DE. OR Electronic-Publications.DE. OR Books.W..DE. OR Counseling.W..DE.

5 3 AND 4

6 ((patient OR patients) WITH (education OR educate OR educating OR information OR literature OR leaflet$ OR booklet$ OR pamphlet$)).TI,AB.

7 Consumer-Health-Information.DE. OR Patient-Education.DE.

50 5 OR 6 OR 7

Allied & Complementary Medicine

1 ((patient OR patients) WITH (education OR educate OR educating OR information OR literature OR leaflet$ OR booklet$ OR pamphlet$)).TI,AB

British Nursing Index

1 ((patient OR patients) WITH (education OR educate OR educating OR information OR literature OR leaflet$ OR booklet$ OR pamphlet$)).TI,AB

PsycINFO

1 ((patient OR patients) WITH (education OR educate OR educating OR information OR literature OR leaflet$ OR booklet$ OR pamphlet$)).TI,AB

HEED (Health Economic Evaluations Database) search terms:

1 AX=(faecal OR fecal OR faeces OR feces OR fecally OR faecally OR anal OR anally OR stool OR stools OR bowel OR double OR defecat* OR defaecat*)

2 AX=(incontinence OR incontinent OR urge* OR leak OR leaking OR leakage OR soiling OR seeping OR seepage)

3 CS = (1 AND 2)

Surgical search terms for for case series in some procedures used in the treatment of faecal incontinence:

Medline and Embase

1 (anal ADJ surgery OR sphincteroplasty OR levatorplasty OR levator ADJ sphincteroplasty OR direct ADJ sphincter ADJ repair OR overlapping ADJ

anterior ADJ anal ADJ sphincter ADJ repair OR postanal ADJ repair OR post ADJ anal ADJ sphincter ADJ repair).TI,AB.

2 (direct ADJ apposition ADJ sphincter ADJ repair OR sphincter ADJ reconstruction OR external ADJ anal ADJ sphincter ADJ plication OR neoanal ADJ sphincter OR colonic ADJ conduit OR gracilis ADJ muscle ADJ augmentation).TI,AB.

3 (gracilis ADJ neosphincter OR perineal ADJ puborectalis ADJ sling ADJ operation OR pelvic ADJ floor ADJ repair OR SECCA ADJ procedure OR SECCA ADJ device OR radio ADJ frequency ADJ energy ADJ delivery OR bioinjectibles).TI,AB.

4 (collagen OR teflon OR silicone OR durasphere OR macroplastique OR PTP OR bioplastique OR colostomy OR stoma ADJ creation OR temporary ADJ stoma OR permanent ADJ stoma OR perioperative ADJ management ADJ regimes OR post ADJ surgical ADJ regimes).TI,AB.

5 1 OR 2 OR 3 OR 4

APPENDIX D: EVIDENCE TABLES

Abbreviations used in these evidence tables

ABS	Artificial bowel sphincter
Cont	Control
df	Degrees of freedom
EAUS	Endoanal ultrasound
EMG	Electromyography
FI	Faecal incontinence
FU	Follow-up
GP	Group
HRQL	Health related quality of life
IBD	Irritable bowel disease
IBS	Irritable bowel syndrome
ICER	Incremental cost-effectiveness ratio
INT	Intervention
LE	Life expectancy
LoS	Length of stay (in hospital)
M/F	Male/female
MRI	Magnetic resonance imaging
N	Total number of patients in study
NA	Not available
NR	Not reported
PNTML	Pudendal nerve terminal motor latency
Preop	Preoperative
Postop	Postoperative
QoL	Quality of life
RCT	Randomised controlled trial
SD	Standard deviation
SEM	Standard error of the mean
Sig	Statistically significant
UI	Urinary incontinence
US	Ultrasound
VS	versus

Evidence tables for chapter 2: good practice in management of faecal incontinence

Evidence Table 1: Patient views

Study details	Patients	Context	Methods of data collection	Data analysis	Findings	Comments
Paterson et al, 2003 [1] **Study design:** interviews and focus groups **Duration of follow-up:** Not applicable	**All patients** **N: 82 N with FI:** NR **Age (mean):** NR **M/F:** NR **Dropouts:** NR **Patient group:** Participants included people who had incontinence or cared for someone with incontinence, or were part of an advocacy group that had significant numbers of people with incontinence in its membership **Cause of FI:** Varied widely and included congenital malformations, chronic debilitating diseases, sever spinal cord injuries and degenerative diseases. **Recruitment and selection of participants:** Possible selection bias as method of recruitment not reported.	**Country and further details:** Australia, culturally and linguistically diverse groups from rural/metropolitan/remote areas. **Details of intervention, if appropriate, including timing:** NA **Setting:** Not specified.	**Methods:** Semi structured interviews and focus groups to inform development of comprehensive Australian consumer guide to continence products. **Specific tools used:** N/A	**Data analysis methods:** Used qualitative technique of constant comparison, thematic data analysis was commenced concurrently with data collection enabling the opportunity to follow up an emerging theme. Three researchers undertook data analysis and results cross-validated by an additional researcher. **Synthesis methods:** Integrated into common themes, shared meanings, similarities and difference. The investigators reported striking similarities in experiences and concerns of consumers across the group. They reported the issues raised by the group.	All participants raised the same issues about selection of continence products. 1. Did not know where to seek information, 2. Hard to find info 3. Info from products themselves, books, magazines, interne, networks, community service providers, clubs/churches, health professionals, state-funded subsidy schemes. 4. Vulnerability, embarrassment, sensitivity of Health professionals very important. 5. Lack of confidence in Health professionals knowledge. 6. Difficulty in identifying products, unaware professional assessment and advice for management existed, inconsistent advice, product choice influenced by cost, availability, quality, comfort and design. 7. Problems identified with products 8. suggestion for improvement included detailed product information, working capacity, instructions etc, also general info about incontinence in simple language, better marketing and distribution of information sources in general	**Funding:** National Continence Management Strategy, an initiative of the Commonwealth of Australia Department of Health and Aged Care **Notes:** Not clear whether their target group of 'incontinent' patients is for urinary or faecal incontinence or both.

Patient views continued

Study details	Patients	Context	Methods of data collection	Data analysis	Findings	Comments
Jarrett et al, 2005[2] **Study design:** Survey **Duration of follow-up:** N/A	**All patients** **N:** 16 **N with FI:** 16 **Age (mean):** 56 **M/F:** NR **Dropouts:** NR **Patient group:** Sixteen consecutive patients with permanent sacral neuromodulation (SNM) for faecal incontinence **Cause of FI:** Not stated. Median duration of FI was 8 years prior to SNM plantation. **Recruitment and selection of participants:** 16 consecutive female patients who had had temporary and subsequent permanent sacral neuromodulation, who had been resistant to conservative treatments., recruited at follow-up visit	**Country and further details:** UK **Details of intervention, if appropriate, including timing:** At the time of the questionnaire, the patients had been implanted for a median of 24 months (3-36). **Setting:** Presumably in health care setting although not explicitly stated.	**Methods:** Patients were asked to complete a questionnaire at follow-up visit. Questions asked if they had any altered sensation in the pelvic viscera, and for an estimate of the percentage improvement in sex-life after implantation. **Specific tools used:** (questionnaire included in paper, both open- and closed- questions).”sex Life questionnaire”. No details of reliability, validity or piloting given.	**Data analysis methods:** Statistical analysis was performed using the Wilcoxon signed rank test and the Pearson coefficient. **Synthesis methods:** No details given.	9/16 were sexually active, 5/9 were worried about incontinence during coitus, 4/9 had actually experienced it. All said their sexual activity had been hampered by FI. Of the 9, 7 said SNS had improved their sex life (med 40%) with greater improvement for younger patients. Percentage improvement was inversely correlated with age (r = -0.834, p = 0.005)	**Funding:** Not stated. **Notes:**

Patient views continued

Study details	Patients	Context	Methods of data collection	Data analysis	Findings	Comments
Malouf et al, 2000[3] **Study design:** Survey **Duration of follow-up:** Median of 5 years post-repair.	**All patients** **N:** 47 **N with FI:** 47 **Age (mean):** **M/F:** 0/47 **Dropouts:** **Patient group:** anterior anal sphincter repair. **Cause of FI:** **Recruitment and selection of participants:** 55 patients 47 were contacted, one had a proctectomy.27 reported improved bowel function without need for further surgery, 23 50% improved or more.	**Country and further details:** UK **Details of intervention, if appropriate, including timing:** 5 yrs+ after overlapping anterior anal sphincter repair for obstetric trauma. Post-operative. **Setting:** N/A postal survey	**Methods:** Open- and closed-questionnaires. **Specific tools used:** Specific questionnaire developed for the study	**Data analysis methods:** " Patients were classified as having good or poor long-term outcome, and each variable was compared between the two groups by use of an unpaired two-tailed r test it the data were parametric, or a Mann-Whitney U test if the data were non-parametric". No details were given on narrative synthesis. **Synthesis methods:** NR	8/46 had a failed outcome. Of the remaining 38, 71% reported improvement, 13% no improvement, 16% deterioration. Decrease in time with 85% at 15 months to 50% at 77 months. No patient was fully continent. Patients rated own outcome before and after, postoperative. Affected by perception of success, e.g. unsuccessful ops more likely to rate before as better. demonstrates difficulty in subjective assessment	**Funding:** Not reported **Notes:**

Patient views continued

Study details	Patients	Context	Methods of data collection	Data analysis	Findings	Comments
Norton et al, 2005[4] **Study design:** Survey **Duration of follow-up:**	**All patients** **N:** 69 **N with FI:** **Age (mean):** **M/F:** 11/58 **Dropouts:** N/a **Patient group:** People with previous formation of a colostomy to manage faecal incontinence **Cause of FI:** NR **Recruitment and selection of participants:** People with previous formation of a colostomy to manage faecal incontinence were recruited via an advertisement in the magazine of the British colostomy association (BCA) or from the author's own hospital (identified through hospital records). Stoma formed solely to manage FI. Self-selected.	**Country and further details:** UK **Details of intervention, if appropriate, including timing:** Post-colostomy, median of 59 months later. **Setting of intervention or data collection, as appropriate:** Not applicable – postal questionnaire	**Methods:** Participants were sent four questionnaires which were then posted back, or recruited through hospital. Results were combined. **Specific tools used:** Specific questionnaire developed for the study, SF-36, HADS (Hospital Anxiety Depression Scale), FIQL (Faecal Incontinence Quality of Life)	**Data analysis methods:** Not stated **Synthesis methods:** Not stated	A majority thought that a stoma restricted their life a little or not at all (83%). Satisfaction was med 9/10. A minority intensely hated it. Bowel control had restricted life before stoma in following ways: focussed round toilets, housebound, restricted in social, personal, work lives. 5 described life as nightmare/hating self. Most people felt that the stoma had changed quality of life 4.5 (-5 to 5).	**Funding:** NR **Notes:** Self-selected populations, and no details given on data analysis means results probably biased.

Patient views continued

Study details	Patients	Context	Methods of data collection	Data analysis	Findings	Comments
Chelvanayagam and Norton, 2000[5] **Study design:** Focus groups **Duration of follow-up:** n/a	**All patients** **N:** 12 **N with FI:** **Age (mean):** **M/F:** 0/12 **Patient group:** females aged 27-71 (median age 51), **Cause of FI:** IBD (3), IBS (1), failed sphincter repair after obstetric trauma (3), scleroderma (1) **Recruitment and selection of participants:** "The more homogenous a group is in terms of social background, education, knowledge and experience, the more likely member will be to contribute to the discussion For this reason, we decided to invite female participants with long-standing faecal incontinence problems that had failed to respond to treatment. . Author states: small female sample may not be representative, but themes were recurrent and most agreed with them all. good agreement in general between participants."	**Country and further details:** UK **Details of intervention, if appropriate, including timing:** N/A **Setting:**	**Methods:** 2 focus groups, 5 and 7 participants respectively The draft questionnaire [not provided] was used as a topic guide. Each group lasted 90 minutes and was tape recorded. The participants were given an explanation of the purpose of the group and signed a consent form, including permission to record the session. They were reassured about confidentiality. **Specific tools used:** "validated questionnaire" A draft questionnaire was developed, based on clinical experience with this patient group, the available literature on faecal continence problems and quality of like, and more developed work in the effect of urinary continence problems on quality of life. Focus groups were then convened to discuss the draft and quality of life issues. This was the first	**Data analysis methods:** Analysis of the data involved the facilitators listening independently, reading a verbatim transcription and identifying recurrent themes. **Synthesis methods:** Not stated.	TOILETS: Major topic of discussion. Availability and cleanliness of public conveniences, lack of facilities, women able to list all PTs on way to work, lack of privacy. PSYCHEMOTIONAL EFFECTS: range of emotional and coping strategies. Stress, distress, tearfulness, anxiety, exhaustion, fear of being caught out, feeling dirty, body image all discussed. Need to be in control of all aspects of life to compensate. Low self-esteem, fear of public humiliation. FOOD: discussed in relation to bowel function; timing of meals and restriction of intake; diets to help symptoms; fruit and vegetables avoided. SKIN: soreness and ramifications, obsessive cleaning, constrained sexual activity. SHOPPING: all participants reported difficulties; anticipatory fear increased chance of episode; avoidance of supermarkets - not always customer toilets; communal changing rooms also a concern. APPEARANCE: governs clothing choice; compensation by concentrating on hair/face; difficult to wear attractive clothes or underwear; dark clothing, ease of removal, trousers better for some, skirts others. EXERCISE: reduced or stopped by many patients; walking precipitated bowel activity for	**Funding:** NR **Quality:** very good. Limitations of methodology discussed. Only potential problem is that questionnaire not provided and therefore don't know to what extent parameters of discussion were pre-supposed. **Notes:** Other: Women's approaches varied a lot. Public attitudes seen as a barrier to coping effectively (lack of understanding etc) Focus groups easy to facilitate. Discussion focussed on problems mostly but also lots of mutual support. Questionnaire

Study details	Patients	Context	Methods of data collection	Data analysis	Findings	Comments
			stage in the validation of the questionnaire.		many and was avoided. EMPLOYMENT: many got up early to empty bowels before work; difficulty in explaining need for flexible working especially to male colleagues; using toilets at work feared. RELATIONSHIPS: singles feared new relationships; couples recalled concealing symptoms from partners; although most families were supportive on disclosure; many felt less sexy due to staining or protective clothing. TRAVEL: restricted, required detailed planning; car preferred - no toilets on public transport; practicalities of coping exacerbated away from home; hotels preferred to staying at a friends as less embarrassing. SOCIAL LIFE: planned around availability of toilets; certain activities; especially theatre/cinema avoided; fear of flatus increased anxiety in company.	revised in view of findings. 'Bowel control' identified by participants as being most comprehensible term. Focus groups so beneficial to women in terms of support, centre is considering setting up permanent support groups.

Patient views continued

Study details	Patients	Context	Methods of data collection	Data analysis	Findings	Comments
Collings & Norton, 2004[6] **Study design:** Survey **Duration of follow-up:**	**All patients** **N:** 20 **N with FI:** **Age (mean):** **M/F:** 0/20 **Dropouts:** **Patient group:** 20 participants. 15 married, 1 in a long-term relationship. Other 4 singe. 18 had 1+ children. **Cause of FI:** childbirth injury, Crohn's disease an a variety of bowel gynaecological disorders **Recruitment and selection of participants:** women attending a "specialist clinic" to whom it was explained that this was an exploratory study to ascertain the need for a psychosexual therapist at St Marks Hospital. The group of women were al those who opted to participate in the study. The women were asked if they would be willing to see a psychosexual therapist after their appointment.	**Country and further details:** UK **Details of intervention, if appropriate, including timing:** N/A **Setting:** "specialist clinic"	**Methods:** a semi-structured interview format was deemed the most appropriate **Specific tools used:** Not stated	**Data analysis methods:** notes were taken throughout the sessions and each session was writing up immediately afterwards in the traditions of the case study. **Synthesis methods:** The notes from the interviews were analysed to find common themes and differences.	NEGATIVE ISSUES: in addition to physical symptoms: life restricted by bowel problem; anger with doctors who misdiagnosed or misinformed; pain; heterosexual intercourse; shame; embarrassment; fear of incontinence; stress; depression; isolation; secrecy; poor self-image; sexual avoidance/aversion; concerns regarding starting new relationships. PERCEIVED COPING STRATEGIES: privacy in the bathroom; faith/religion; counselling; restricting activity (6) carrying change of clothes; humour; denial (5) knowing location of toilets when out (5) diet/fasting; moving to new home; new job; choosing clothes carefully; biofeedback; working (6), medication; faith in medics; taking own car; control of sex; obsession with washing; separate bedrooms; pads (5) SUPPORT STRUCTURES: most felt they had at least some social and emotional support: partner (12 children (12) family (4) friends (8) colleagues (2) hospital (1). 1 participant stated had no support. PSYCHOSEXUAL ISSUES: lack of arousal (6); lack of desire (6); abstinence (4); however, unexpectedly not all said this was a problem, 7 said not a problem unless it occurred during intercourse.	**Funding:** North West London hospitals R&D fund **Notes:**

Patient views continued

Study details	Patients	Context	Methods of data collection	Data analysis	Findings	Comments
Forbat, 2004[7] **Study design:** Interviews **Duration of follow-up:** N/A	**All patients** **N:** NR **N with FI:** NR **Age (mean):** NR **M/F:** NR **Dropouts:** NR **Patient group:** Carers. not stated **Cause of FI:** Not stated **Recruitment and selection of participants:** people were recruited primarily through the community support groups for south Asian and Afro-Caribbean elders. These groups acted as the gatekeepers to potential respondents. Also states: further details on the methodology have been published elsewhere, highlighting the difficulties in accessing this client group.	**Country and further details:** UK **Details of intervention, if appropriate, including timing:** N/A **Setting:** Not stated	**Methods:** the research aimed to involve either small group discussion or individual interviews. The use of vignettes enables speakers to talk about care generally without the need for personal/private stories. …..the gatekeepers to potential respondents for this research indicated that conversations with south Asian and Afro-Caribbean carer were likely to be limited to public accounts, drawing on vignettes to illustrate issues because personal accounts were generally not be forthcoming. this turned out to be far from that happened. Interviews were held to hear about the difficulties arising in the family as a consequence of caring and to connect the findings with recent policy relating to adult protection and race relations. The topic of continence emerged from the	**Data analysis methods:** The interviews were tape-recorded (apart from one instance where the interviewee preferred not to be recorded. They were then transcribed and analysed **Synthesis methods:** Not stated	TOILETS: Many carers spoke at length about continence and difficulties about getting relatives to toilet o having appropriate facilities. Themes arising: 1. clean-up operations (importance of managing continence, great burden on carers, continence related to huge washing tasks, cleaning person themselves. annoyance and frustration) 2. Changing nature of space in the house (need for structural changes in their homes. annoyance and frustration) 3. Use of toilets as indicating competence. Warm and sympathetic to relative's needs .If can use toilet, considered competent by carer and also by health visitors. Toilet use influences relationships and is even used to validate need for care.4. Embarrassment about incontinence. On individual level and in relationships. CONC: continence is component of family care seen as very important. Awareness of how continence impacts on care and caring relationships can enable practitioners to respond more effectively to carers.	**Funding:** Not stated. **Notes:** OK quality - limitations of methodology not discussed. Also no discussion of data analysis or synthesis. OK - methods of analysis not discussed so possible that bias entered. Also vignettes and case studies not used with all interviewees "not necessary".

Study details	Patients	Context	Methods of data collection	Data analysis	Findings	Comments
			interviewees rather than from the interviewer. The interviews were tape-recorded (apart from one instance where the interviewee preferred not to be recorded. They were then transcribed and analysed. Most of the interviews were in English, others, conducted with the aid of interpreters were in Urdu and Mirpuri. **Specific tools used:**			

Patient views continued

Study details	Patients	Context	Methods of data collection	Data analysis	Findings	Comments
Rizk et al, 2001[8] **Study design:** Survey **Duration of follow-up:** N/A	**All patients** **N:** 450 **N with FI:** 450 **Age (mean):** **M/F:** 0/450 **Dropouts:** **Patient group:** authors state sample "at risk of having FI, such as multiparous females" to increase the detection rate. **Cause of FI:** Not reported, although perceptions of causes reported. **Recruitment and selection of participants:** A representative sample of mulitparous UAE females aged 20+ (450) were randomly selected from the community (225) and healthcare centres (225) patients were interviewed about inappropriate stool loss in the past year using a structured and pre-tested questionnaire.	**Country and further details:** United Arab Emirates **Details of intervention, if appropriate, including timing:** N/A **Setting:** Community and health care centres	**Methods:** Pre-tested questionnaire used during interview. Intervention divided into 3 parts: 1. pilot study to find out local terms for FI and attitudes, structured interviews with women attending hospital for reasons other than FI. 2. Community-based qualitative survey to determine prevalence and get in of on social aspects of condition such as taboos, coping mechanisms, and local remedies. 3. Primary healthcare based descriptive study (not included in this analysis) data collected by 2 trained health physicians and one researcher. Good description of survey and questions clearly pre-tested and so forth. **Specific tools used:** Described above.	**Data analysis methods:** Description of analysis techniques given. SPSS, statistical tests used, however, not stated how interview data was analysed. **Synthesis methods:** NR	FI defined as "inability to control the passage of liquid or solid faeces or accidental loss of control of defecation in inappropriate places or at inappropriate times regardless of its severity, frequency or social or hygienic consequences in the last year". Most data given is quantitative, i.e. designed to show that demographics do not differ between continent and incontinent women. However, interesting comparisons made between incontinent and continent women. Consequences of having FI as perceived by incontinent and continent (%) respectively: Interference with regular praying (92.2;82.4), feeling disgusted and dirty (84.3;72.6); feeling self-conscious ashamed and embarrassed especially with husband and children (76.4;64.7); inability to have sex (43.1;32.3); limitations of social activity (27.4;24.3); difficulty in performing physical activity including housework and chores (19.6;15.3); Reasons for not seeking treatment as perceived by incontinent and continent women respectively: embarrassed to consult doctor (64.7;54.3); male physician (54.9;42.2) female physician (7.8;11.1) prefer to discuss with relatives in case resolves	**Funding:** Not reported **Notes:** OK quality-limitations of methodology not discussed. Does not say if these were pre-defined answers - seems unlikely. How do these figures compare to clinical records?

Study details	Patients	Context	Methods of data collection	Data analysis	Findings	Comments
					spontaneously (47.1;39.8) unaware need for help as assumed is normal in old age (31.3;26.1) belief in self-treatment as medicine unlikely to help (23.5;23.8). DIFFERENCES NOT STATISTICALLY DIFFERENT> 83.3% believed FI abnormal, but only 20% had been asked about it by doctor. Coping mechanisms: frequent washing (52.9%) regular undergarment changing(49.1) protective pad (37.2) decreasing food intake (25.4) stopping all work (7.8%) Perceptions of causes of FI paralysis/neurologic (90.2;87.9) old age (80.4;83.2) childbirth (23.5;27.1) menopause (19.6;16.2)	

Patient views continued

Study details	Patients	Context	Methods of data collection	Data analysis	Findings	Comments
Wong 1995[9] **Study design:** Survey **Duration of follow-up:** N/A	**All patients** **N:** 9 **N with FI:** **Age (mean):** **M/F:** 3/6 **Dropouts:** **Patient group:** Incontinence patients were defined as patients who lost control of their bladders of bowels at least once a day.. I 10female, 10 male. Mean age 79.6 (65-101), 12 patients had UI, 8 UI and FI, further details about treatment etc are given. Mean level of incontinence-related stress was 52.8 (incontinence stress questionnaire-patient). Of these 20 patients, 11 dropped out (too embarrassed, or deteriorating physical health leaving 9 (6m 3f) for in-depth interviews. **Cause of FI:** **Recruitment and selection of participants:** Charge nurses of a metropolitan geriatric teaching hospital nominated 67 of the hospitals 208 incontinent patients as being mentally alert and able to communicate in English. The sample comprised 20 of the 67	**Country and further details:** Australia **Details of intervention, if appropriate, including timing:** hospitalised but not wrt a specific intervention **Setting:** Geriatric ward on a hospital.	**Methods:** Each of the nine patients was interviewed for 1 hour. Aims and confidentiality discussed. Interview guide and tested for validity and reliability. Patients asked about incontinence history, interactions with nurses following incontinent episode, perceptions/attitudes incontinence and management plans. All interviews video taped so verbal and non-verbal cues could all be coded. After interviews, patients were asked if they wanted to be helped to the toilet, 8/9 accepted. Researcher observed patients' physical and psychological responses to toileting and	**Data analysis methods:** Qualitative data sorted in 4 files: and original copy of the video, a transcript file, researchers journal and researchers analytical file. Approx 5000 words/interview. Verbal and non-verbal cues analysed. **Synthesis methods:** Strauss's coding system was used to identify major themes.	Patient's responses to their incontinence varied according to their level of incontinence-related stress. The most common of the various strategies used to cope with incontinence were: 1. fighting against incontinence; 2. putting up with incontinence; 3. accepting and living positively with incontinence; 1. Characteristics of patients employing this strategy included being seen by hospital staff as uncooperative, aggressive, or trouble-making, angry, paranoid. Resentment and anger towards hospital staff. 2. Patients given up hope, had faith in doctors, as a result of doctor's eventual disinterest they became depressed and blamed self for wetting bed. Apathetic, humiliated, complained of lack of appropriate care from nursing staff e.g. not being checked by night nurse. Also saw nurses as subordinate to doctors and not really worth discussing problem with. 3. "Learn to live with it" comment made by cheerful and positive patients who " as a result" had better relationships with their carers. Assertive, diplomatic skills allowed her to manage	**Funding:** Study sponsored by the John Allison/Monkhouse Scholarship for Nurses. **Notes:** Good quality. Limitations of patient groups given, but no discussion of methodology or analysis.

Study details	Patients	Context	Methods of data collection	Data analysis	Findings	Comments
	patients. [Further details given - looks like a very well-defined patient group although representativeness is debatable - all over 65, some patients excluded because denied incontinent, lack of mental clarity.]		compared impressions with the observations reported in the patients' nursing and medical files. **Specific tools used:** Incontinence Stress Questionnaire-patient, Hodgkinsons mental test		her incontinence better and win cooperation and affection of staff. Have other interests e.g. music, occupations. In general study revealed little evidence that health professionals tackled incontinence and associated social and psychological problems proactively. Study indicates patients can participate actively in their incontinence management.. Professional passivism led to patient's perceptions that they lacked professional guidance and support. Lack of guidance meant that patients dealt with incontinence according to their general outlook on life, e.g. those with negotiating skills and positive outlook were better off. Older patients adjusted better in general. Communication with HEALTH PROFESSIONALS major barrier to effective management. Avoidance behaviour on both patients and health professionals part has negative effect. Many patients inhibited when faced with apathetic and uncaring health professionals.	

Evidence tables for chapter 3: baseline assessment and initial management

Evidence Table 2: What does clinician examination add to the assessment of the patient with faecal incontinence?

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Keating et al, 1997 [10] **Study design:** Diagnostic study A **Evidence level:** II **Duration of follow-up:** NA	**Patient group:** consecutive patients with a diagnosis of faecal incontinence **Cause of FI:** neuropathy 18 patients, external sphincter disruption 7 patients, internal sphincter disruption 7 patients, full thickness rectal prolapse 5 patients, haemorrhoids/ local anus causes 5 patients, rectocele 4 patients, other causes 4 patients. **<u>All patients</u>** **N:** 50 **N with FI:** 50 **Age (mean):** NR **M/F:** NR **Dropouts:** NR	**Assessment tool under investigation:** clinical assessment **Gold standard:** anal ultrasound, anal manometry, external sphincter electromyography and defecating proctography.	**Neuropathy** Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 86% 97% NR NR 18 (36%)	**Funding:** NR **Limitations:** Not possible to calculate the 'two by 'two' table and prevalence was not recorded. **Additional outcomes:** Variations or provisional management plan based on the history and examination from the final plan. **Notes:** Unclear if 'clinical assessment' refers to history, general examination and anorectal examination or anorectal examination alone.
			External sphincter disruption Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 93% 94% NR NR 7 (14%)	
			Internal sphincter disruption Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 64% 100% NR NR 7/ 50 (14%)	
			Rectal prolapse Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 100% 96% NR NR 5 (10%)	
			Haemorrhoids/ local anus causes Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 90% 100% NR NR 5/50 (10%)	

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
			Rectocele Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 100% 97% NR NR 4/50 (8%)	

Clinician examination continued

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Sultan et al, 1994[11] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** consecutive unselected patients with faecal incontinence undergoing sphincter repair. **Cause of FI:** 4 women had undergone surgery previously for obstetric tear. 1 man became incontinent after surgery **All patients** **N:** 12 **N with test for FI:** 12 **Age (mean):** 46 (30-64) years **M/F:** 1/11 **Dropouts:** 0	**Assessment tool under investigation:** Clinical assessment Decision to perform sphincter repair based on patient symptoms, clinical examination and anorectal physiology. **Gold standard:** Surgery and histology	**External sphincter defects by clinical assessment:** Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 56% 33% 71% 20% 9/12 (75%)	**Funding:** Joint Research Board of St Bartholomew's Hospital and The Wellcome Trust, St Mark's Research Foundation **Limitations:** very small and highly selected patient group.

Evidence Table 3: What is the effectiveness of modifying diet or fluid intake at managing faecal incontinence?

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Bliss et al, 2001[12] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 8 days prior to study plus 31 days fibre supplement-ation period	**Patient group:** Adult volunteers who were incontinent of loose or liquid stools at least weekly were eligible. Subjects were excluded if they had been diagnosed with a rectal prolapse, colon cancer, or a rectal fistula because these conditions require therapies other than fibre, ulcerative colitis, or had some portion of their gastrointestinal tract removed. None of the subjects participated in biofeedback training for pelvic muscle exercises. **Cause of FI:** NR **<u>All patients</u>** **N:** 39 **N with FI:** 39 **Age (mean):** NR **M/F:** 8/31 **Dropouts:** 0 **<u>Group 1</u>** **N:** 13 **N with FI:** 13 **Age (mean ± SD):** 61 ± 3 years **Range:** 30-89 years **Body Weight**: 89 ± 5kg **M/F:** 4/9 **Dropouts:** 0 **<u>Group 2</u>** **N:** 13 **N with FI:** 13 **Age (mean):** 62 ± 3 years	**Group 1** 25 g of Metamucil containing 7.1 g of psyllium/d and is typical dose for FI. This supplemented their normal diet for 31 days. **Group 2** 25 g of Gum Arabic. The amount of Psyllium and Gum Arabic were progressively increased over the first 6 days of supplementation to decrease the risk of flatus and worsening FI. **Each of the fibres was mixed in 360 ml of half-strength fruit juice divided into 2 servings and ingested at the**	**Faecal Incontinence** (proportion of stool that were incontinent)	**Group1:** 0.17±0.07 **Group 2:** 0.18±0.07 **Group 3**: 0.50±0.05 F(2,38)=7.9, p=0.002	**Funding:** Funded in part by R15 NR04028-01 from NINR, NIH, the American Federation for Aging Research, Sigma Theta Tau Zeta Chapter, and a University of Minnesota Grant-in-Aid of Research. **Limitations:** Single blinded study **Additional Outcomes:** The study also reports other outcomes like fibre fermentation and tolerance and in vitro fibre fermentation Anti diarrhoeal medications: Group 1:3 Group 2: 2 Control: 3 Subjects maintained same type of anti diarrhoeal medications during both periods which include atropine CI, loperamide HCI, bismuth subsalicylate kaolin pectin. **Notes:** Te review Bliss, McLaughlin 2000 study for outcome dietary intake Each of the fibres was mixed in 360 ml of half-strength fruit juice divided into 2 servings and ingested at the morning and evening meal.
			Average flatus	**Group 1:** 1.3±0.3 **Group 2:** 1.1±0.3 **Group 3:** 0.8±0.3; F(2,38) =0.87; p=0.4	
			Stool frequency: baseline (average daily) Supplementation period (adjusted mean stool frequency per day	**Group 1:** 1.8±0.2 **Group 2:** 1.7±0.2 **Group 3:** 1.7 ±0.2 F(2,38) = 0.2, p=0.9	
			Stool wet weight (g/d)	**Group 1:** 198.2±1.9 **Group 2:** 159.0±1.4 **Group 3:** 139.0±1.5	
			Total stool solids (g/d)	**Group 1:** 34.1±3.2 **Group 2:** 35.6±3.3 **Group 3:** 31.6±3.2	
			% water content (by freeze drying)	**Group 1:** 78.8±1.3 **Group 2:** 75.8±1.3 **Group 3:** 77.0±0.3	
			% water insoluble solids (per g stool/d)	**Group 1:** 25.3±2.2 **Group 2:** 25.1±2.2 **Group 3:** 22.9±2.2	
			Water holding capacity (WHC) per g water – insoluble solids	**Group 1:** 3.0±0.1 **Group 2:** 2.6±0.1 **Group 3:** 2.3±0.1	
			Total water holding capacity (calculated as WHC per g	**Group 1:** 46.6±2.5 **Group 2:** 43.4±2.5	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Range: 34-76 years **Body weight**: 83 ± 5 kg **M/F:** 2/11 **Dropouts:** 0 **Group 3**: Control **N:** 13 **N with FI:** 13 **Age (mean ± SD):** 61 ± 6 years **Range:** 30-89 years **Body Weight**: 68 ± 6kg **M/F:** 2/11 **Dropouts:** 0	**morning and evening meal.** **Comparison:** 0.25g of Pectin/d given as placebo	insoluble solids x g insoluble solids in 100g stool)	**Group 3:** 37.6±2.5	Originally 42 subjects at baseline but 3 dropouts. Reasons hysterectomy, clinical depression and treatment for diverticulitis.

Diet or fluid intake continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Lauti et al, 2006[13] **Study design:** Randomised cross-over trial **Evidence level:** 1+ **Duration of follow-up:** Between 3 months and 3 years after the study completion.	**Patient group:** Adults that were referred to an outpatient colorectal service with the primary presenting problem of chronic incontinence to mucus, liquid and/or solid stool. Excluded: full thickness rectal prolapse, inflammatory bowel disease, other pathologies requiring surgery, diabetes and previous treatment for FI. **Cause of FI:** NR **All patients** **N:** 63 **N with FI:** 63 **Age (mean):** 58.8 ± 14.8 yrs **M/F:** 6/57 **Dropouts:** 16	**Treatment A** Loperamide, an untitled dietary advice sheet for a balanced low residue diet and placebo supplement. **Treatment B** Loperamide, an untitled dietary advice sheet for a balanced diet consisting of both high and low residue items and fibre supplement. **Duration:** Each intervention was assessed for 6 weeks and then cross-over to the other intervention for a further 6 weeks.	**Mean (SD) (95% CI) Faecal Incontinence Severity Index (FISI)** (0-61; the lower the better)	**Baseline (n=59):** 31.2± 10.3 **After treatment A (n=48):** 18.4±13.2 **After treatment B (n=48):** 18.8±14.1 **Mean difference (n=47): -0.8 (-4.9 to 3.3)** **P value: NS**	**Funding:** Grant support from University of Otago Research Grant, Otago Medical Research Foundation. **Limitations:** Bar chart of FIQL and SF-36 results without exact figures or scale. **Additional outcomes:** Follow-up questionnaire for FISI from 30 patients and the regimen they are currently following. FIQL and SF-36 reported. **Notes:** Awaiting publication – report on prelimary results. Overall results showed no difference for each treatment arm. However, examination of individual patient results demonstrate marked variability.
			Adverse events	None reported Several patients reported a dry mouth or struggled with the palatability of the supplements.	

Evidence Table 4: What is the effectiveness of modifying drug administration at managing faecal incontinence?

Anti-diarrhoeal drugs

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Read et al, 1982[14] **Study design:** randomised crossover study **Evidence level:** 1+ **Duration of follow-up:** 2 weeks	**Inclusion criteria:** Adults with persistent diarrhoea for more than 3 months and complained of episodes of faecal incontinence and severe urgency sufficient to limit their life style. **Cause of faecal incontinence:** irritable bowel syndrome: 11 ulcerative colitis: 2 Crohn's disease: 3 diabetes mellitus: 2 hypothyroidism: 1 duodenal diverticulae and bacterial overgrowth: 1 postvagotamy diarrhoea: 1 not able to diagnose cause: 5 **Frequency of faecal incontinence**: 6/26 >1/month up to 1/year 3/26 >1/week to 1/month 9/26 =3/week to 1/week 6/26 =1/day to 3/day **<u>All patients:</u>** **N:** 26 **Age (mean):** 45 ±18 (24-82) years **M/F:** 10/16 **Dropouts:** 0	**Group 1** Loperamide 2 x 2 mg three times/day for 8 days **Group 2** Placebo 2 identical capsules three times/day for 8 days **Washout periods:** not specified	**Mean (range) no. episodes of faecal incontinence per week**	**Group 1:** 0.6 (0-6) **Group 2:** 0.9 (0-6) **p value:** <0.01	**Funding:** Special Trustees of the Former United Sheffield Hospitals and Janssen Pharmaceutica, Belgium **Additional outcomes:** maximum squeeze pressure (numbers not given but difference reported as not significant); 24 hour stool weight, bowel movements per week and % uniformed stools per week – significantly higher in placebo group.
			Mean (range) no. episodes of urgency per week	**Group 1:** 1.52 (0-7) **Group 2:** 5.3 (0-27) **p value:** <0.001	
			No. of people with constipation	**Group 1:** 11/26 **Group 2:** 0/26 **p value:** NR	
			No. of people with exacerbation of diarrhoea	**Group 1:** 4/26 **Group 2:** 0/26 **p value:** NR	
			No. of people with abdominal discomfort or pain	**Group 1:** 2/26 **Group 2:** 1/26 **p value:** NR	
			Basal pressure (cm H_2O	**Group 1:** 84 ±6 (n=26) **Group 2:** 73 ±6 (n=26) **p value:** <0.05	
			No. of people with nausea and vomiting	**Group 1:** 3/26 **Group 2:** 0/26 **p value:** NR	

Anti-diarrhoeal drugs continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Sun et al, 1997[15] **Study design:** randomised crossover study **Evidence level:** 1+ **Duration of follow-up:** 3 weeks	**Inclusion criteria:** Chronic diarrhoea and faecal incontinence (more than once per month). Excluded patients with volume of diarrhoea >500 ml/day. **Reasons for FI:** Irritable bowel syndrome: 9/11 Chronic diarrhoea and FI after cholecystectomy and partial gastrectomy: 2/11 **All patients:** **N:** 11 **Age (median):** 56 **M/F:** 3/8 **Dropouts:** 0	**Group 1** Loperamide oxide. 2 x 2 mg tablets 2x/day for 1 week **Group 2** Placebo for 1 week Washout period of 1 week between the drug and placebo	**Mean visual analogue scale for incontinence** (mm)**	**Group 1:** 26 ±36 (n=11) **Group 2:** 43 ±37 (n=11) **p value:** 0.12	**Funding:** Jansen Research Foundation, Belgium **Additional outcomes:** Minimum basal pressure and whole gut transit time significantly higher in loperamide group. Mouth to caecum transit time, maximum basal pressure, squeeze increment, total squeeze pressure – no significant difference. **Notes:** All medication stopped for the week preceding the trial. Measurements taken at the end of this 1
			Mean visual analogue scale for urgency (mm)*	**Group 1:** 40 ±35 (n=11) **Group 2:** 70 ±25 (n=11) **p value:** 0.01	
			Mean visual analogue scale for diarrhoea (mm)*	**Group 1:** 23 ±33 (n=11) **Group 2:** 48 ±39 (n=11) **p value:** 0.01	
			Mean visual analogue scale for abdominal pain (mm)	**Group 1:** 30 ±37 (n=11) **Group 2:** 31 ±31 (n=11) **p value:** 0.95	
			No. of participants with "pasty" stools at day 6	**Group 1:** 8/11 **Group 2:** 3/11 **p value:** <0.05	
			Percentage days with stools	**Group 1:** 67 ±27 (n=11) **Group 2:** 88 ±17 (n=11) **p value:** 0.02	
			Total no. stools/week	**Group 1:** 10 ±7 (n=11) **Group 2:** 14 ±7 (n=11) **p value:** 0.02	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Percentage days with "formed" stools	**Group 1:** 67 ±39 (n=11) **Group 2:** 34 ±31 (n=11) **p value:** 0.002	week run in period. * Values for both groups are also different from values at the end of run in period implying that the placebo had some effect too. P values not provided for these values. ** Visual analogue scale is a patient rating of the severity of urgency, incontinence, diarrhoea and abdominal pain before the study, after the run in period and after each intervention.

Anti-diarrhoeal drugs continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Hallgren et al, 1994[16] **Study design:** randomised crossover study **Evidence level:** 1+ **Duration of follow-up:** 23 days	**Inclusion criteria:** Patients after restorative proctocolectomy for ulcerative colitis. 16 patients operated with endoanal mucosectomy, starting with a dentate line, and a **handsewn** ileal pouch-anal anastomosis. Median (range) time since closure: 18 (12-72) months 14 patients operated by an abdominal approach, **stapling** pouch to top of anal canal. Median (range) time since closure: 20 (6-48) months 24/30 patients regularly used loperamide (6-16 mg/day) **<u>All patients:</u>** **N:** 30 **Age (mean):** not reported **M/F:** 22/8 **Dropouts:** 2 (1 handsewn, 1 stapled)	**Group 1** restorative proctocolectomy + loperamide hydrochloride 2 x 2 mg three times/day for 8 days **Group 2** restorative proctocolectomy + placebo 2 identical capsules three times/day for 8 days **Washout periods:** 7 days before starting study and 7 days between each interventions	**No. people with leaking/soiling during the day**	**Group 1:** 3/28 **Group 2:** 7/28 **p value:** 0.14	**Funding:** Swedish Medical Research Council, University of Göteborg, Göteborgs Läkarsällskap, Assar Gabrielssons Fond, AB Skandias 100-årsfond & Ingabritt och Arne Lundbergs Forskningsfond **Limitations:** 24/30 patients taking loperamide (different doses) before the study.
			No. people with leaking/soiling during the night	**Group 1:** 1/28 **Group 2:** 11/28 **p value:** 0.007	
			No. of people using protective pads during the day	**Group 1:** 1/28 **Group 2:** 3/28 **p value:** 0.27	
			No. of people using protective pads at night	**Group 1:** 1/28 **Group 2:** 6/28 **p value:** 0.07	
			Median (range) frequency of defaecation per 24 hours	**<u>Handsewn patients</u>:** **Group 1:** 3 (2.9-4.8) n=15 **Group 2:** 6 (5.3-7.1) n=15 **p value:** <0.001 **<u>Stapled patients</u>:** **Group 1:** 5 (3.7-5.7) n=13 **Group 2:** 7 (5.5-7.9) n=13 **p value:** <0.01	
			Median (range) frequency of defaecation during the daytime	**<u>Handsewn patients</u>:** **Group 1:** 3 (2.9-4.2) n=15 **Group 2:** 5 (4.8-6.2) n=15 **p value:** <0.01 **<u>Stapled patients</u>:** **Group 1:** 4 (3.4-5.1) n=13 **Group 2:** 5 (4.7-6.6) n=13 **p value:** <0.01	
			Median (range) resting anal pressure (mm Hg)	**<u>Handsewn patients</u>:** **Group 1:** 65 (52.3-72.4) n=15 **Group 2:** 58 (50.8-60.2) n=15 **p value:** <0.05	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				<u>Stapled patients</u>: **Group 1:** 65 (56.0-69.1) n=13 **Group 2:** 55 (49.7-59.6) n=13 **p value:** <0.05	
			Maximal squeeze pressure (mm Hg)	**<u>Handsewn patients</u>:** **Group 1:** 240 (195.7-272.8) n=15 **Group 2:** 245 (186.6-282.4) n=15 **p value:** not sig **<u>Stapled patients</u>:** **Group 1:** 210 (160.9-257.6) n=13 **Group 2:** 165 (151.4-249.3) n=13 **p value:** not sig	

Drugs enhancing sphincter tone

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Carapeti et al, 2000[17] **Study design:** randomised crossover study **Evidence level:** 1+ **Duration of follow-up:** 9 weeks	**Inclusion criteria:** Consecutive patients with passive faecal incontinence and a structurally intact sphincter. Excluded patients with underlying treatable causes for incontinence such as irritable bowel syndrome or surgically repairable external sphincter injury **All patients:** **N:** 36 **Age (mean):** 58 (28-81) years **M/F:** 14/22 **Dropouts:** 0 **Mean duration of symptoms**: 5 years **Mean ±SD baseline Wexner Scale incontinence score**: 14 ±4	**Group 1** 10% phenylephrine gel 0.5 ml applied to anus twice per day for 4 weeks. **Group 2** Placebo gel 0.5 ml applied to anus twice per day for 4 weeks. **Washout periods:** 1 week in between each intervention 15 patients using loperamide before the study were permitted to continue using it during the study as it had not controlled the episodes of FI.	**Mean ±SD change in Wexners incontinence score (0-20; 0=normal, 20 incontinent)**	**After 1st treatment period** **Group 1:** 12.5 ±3.4 (n=18) **Group 2:** 13.0 ±4.7 (n=18) **p value:** not sig **After 2nd treatment period:** **Group 1:** 13.4 ±4.7 (n=18) **Group 2:** 12.6 ±4.2 (n=18) **p value:** not sig **p value for both treatment periods**: 0.7	**Funding:** Slaco Pharmaceuticals (UK) Ltd **Additional outcomes:** anodernal blood flow **Notes:** Means and standard deviations were given for the two treatment periods
			Mean ±SD percentage improvement in symptom scores	**After 1st treatment period** **Group 1:** 28 ±38 (n=18) **Group 2:** 9 ±21 (n=18) **p value:** NR **After 2nd treatment period:** **Group 1:** 14 ±27 (n=18) **Group 2:** 21 ±31(n=18) **p value:** NR **p value for both treatment periods**: 0.5	
			Mean ±SD maximum anal resting pressure (cmH_20)	**After 1st treatment period** **Group 1:** 65 ±21 (n=18) **Group 2:** 54 ±21 (n=18) **p value:** NR **After 2nd treatment period:** **Group 1:** 55 ±16 (n=18) **Group 2:** 61 ±18 (n=18) **p value:** NR **p value for both treatment periods**: 0.3	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			No. of people with adverse events (only side effect was mild dermatitis)	**Group 1:** 3/36 **Group 2:** 0/36 **p value:** NR	

Drugs enhancing sphincter tone continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Carapeti et al, 2000 [18] **Study design:** randomised crossover study **Evidence level:** 1+ **Duration of follow-up:** 9 weeks	**Inclusion criteria:** Patients who had had an ileoanal pouch construction for previous ulcerative colitis. Their pouch had been created a median of 4 (range: 1 to 13) years previously. The episodes of faecal incontinence had been present for a median of 3 (range: 1 to 13) years previously. All patients had tried loperamide without complete relief. 8 out of 12 patients were still taking loperamide at entry to the study and continued throughout. All patients were viewed by endoscope to exclude pouchitis as a contributory cause for their incontinence. **<u>All patients:</u>** **N:** 12 (Gp 1: n=7; Gp 2: n=5) **Median (range) age:** 44 (29-67) years **M/F:** 5/7 **Dropouts:** 0 **Mean ±SD baseline Wexner Scale incontinence score**: 17 ±4	**Group 1** 10% phenylephrine gel 0.5 ml applied to anal margin (not intra-anally) twice per day for 4 weeks. **Group 2** Placebo gel 0.5 ml applied to anal margin (not intra-anally) twice per day for 4 weeks. **Washout periods:** 1 week in between each intervention	**No. patients with complete cessation of faecal incontinence**	**Group 1:** 4/12 **Group 2:** 0/12 **p value:** <0.05	**Funding:** Slaco Pharmaceuticals (UK) Ltd **Limitations:** Study reports that incontinence data only measured for first intervention study period because "washout period was insufficient". **Additional outcomes:** anodermal blood flow **Notes:** * Incontinence and symptom scores assessed the frequency, amount and nature of incontinence, urgency, the need to wear a pad, alteration in lifestyle, and the use of constipating drugs.
			No. patients with "subjective" improvement in faecal incontinence	**Group 1:** 6/12 **Group 2:** 1/12 **p value:** 0.07	
			Mean ±SD change in incontinence score* (based on a validated modification of the Wexner Scale*: worst incontinence =24, no incontinence =0)	**After 1st treatment period** **Group 1:** -6 ±3 (n=7) **Group 2:** 0 ±1 (n=5) **p value:** 0.015 **After 2nd treatment period:** not reported	
			Mean ±SD (confidence interval) symptom scores* (based on a patient symptom diary scoring 0 to 10 daily: no symptoms =0, maximum number of symptoms after 28 days =280)	**After 1st treatment period** **Group 1:** 117 ±36 (83-150) (n=7) **Group 2:** 208 ±31 (169-247) (n=5) **p value:** 0.001 **After 2nd treatment period:** not reported	
			Mean ±SD maximum anal resting pressure	**After 1st treatment period** **Group 1:** 91 ±7 (n=7) **Group 2:** 71 ±9 (n=5) **After 2nd treatment period:** **Group 1:** 86 ±27 (n=5) **Group 2:** 78 ±17 (n=7) **p value after both treatments:** 0.012	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Adverse events (no side effects reported for any participant during study)	**Group 1:** 0/12 **Group 2:** 0/12 **p value:** not sig	

Drugs enhancing sphincter tone continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Kusunoki et al, 1990[19] **Study design:** randomised crossover study **Evidence level:** 1+ **Duration of follow-up:** 17 days	**Inclusion criteria:** Patients over 18 years of age with ulcerative colitis (n=8) or adenomatosis coli (n=9) treated with an ileoanal pouch 12/17 reported soiling before the study, no other indication of faecal incontinence **All patients:** **N:** 17 **Mean ±SD (range) age:** 33.9 ±1.58 (21-45) years **M/F:** 13/4 **Dropouts:** 0	**Group 1** Ileoanal pouch + Sodium valproate 400 mg 4x /day for 7 days **Group 2** Ileoanal pouch + placebo for 7 days **Washout periods:** 3 days in between each intervention	**No. people with soiling**	**Group 1:** 3/17 **Group 2:** 10/17 **p value:** 0.0324	**Funding:** Ministry of Education, Science and Culture, Japan, Japanese Society for the Promotion of Science (Fujita Foundation) **Notes**: 10 patients had hard stools during the application of Valproate Sodium.
			Stool frequency (mean ± SEM of the 4th, 5th &6th days)	**Group 1:** 5.98 ±0.72 (n=17) **Group 2:** 9.65 ±0.87 (n=17) **p value:** NR	
			No. of people perianal skin problems	**Group 1:** 3/17 **Group 2:** 9/17 **p value:** 0.0707	

Evidence Table 5: What are the most effective products (absorbent products, containment products and plugs) to manage faecal incontinence?

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Brown, 1994[20] **Study design:** RCT with a non-randomised crossover phase within each intervention (see interventions) **Evidence level:** 1+ **Duration of follow-up:** 6-12 weeks (see interventions)	**Patient group:** hospitalised medical nursing unit adults with urinary, faecal or double incontinence from 3 acute care facilities. **Cause of FI:** NR **All patients** **N:** 166 **N with FI & UI:** 48 (29%) **Age (mean):** 74.5 **M/F:** 86/80 **Dropouts:** NR (166 is for participants who completed study) **Type of incontinence**: new onset (incontinence) 48% occasional 12% occasional urinary 7% routine urine 5% routine urine & faeces 29% 2,190 incontinence clean up events. 66% of participants no skin alteration	**Group A** n=82 (includes Groups 1 & 2): Diapers for 12 weeks **Group 1**: Non polymer diapers (wings briefs) (1st 6 weeks phase) **Group 2**: polymer diapers (durasorb briefs) (2nd 6 weeks phase of intervention) **Group B** n=84 (includes groups 3-5): Underpads for 12 weeks **Group 3**: disposable non-polymer underpads (valusorb) (1st 6 weeks) **Group 4**: disposable polymer underpads (maxima) – 2nd 6 weeks phase **Group 5:** cloth underpads (geripad) for entire 12 weeks)	**Mean skin integrity scores - colour** (Perineal Dermatitis Grading Scale – none=0, mild=1, moderate=2 severe=3)	**Group A:** 1.9 (n=82) **Group B:** 1.5 (n=84) **p value:** not sig Group 1: 2.9 Group 2: 0.4 Group 3: 1.4 Group 4: 1.2 Group 5: 3.1 p value: 0.0001	**Funding:** Kaiser Permanente Northern California Region Innovation Program. Products donated by Professional Medical Products Inc **Limitations:** 1. Only 29% or participants were *routinely* doubly incontinent. Prevalence of FI amongst *new cases* was not reported. 2. Sometimes various products off-protocol products were used in cleaning up, but numbers not reported. **Notes:** Reported in Brazzelli 1999[21] (systematic review)
			Mean skin integrity scores - integrity (Perineal Dermatitis Grading Scale – none=0, slight swell=1, swollen=2, bullae=3, open=4, crusting=5)	**Group A:** 1.3 (n=82) **Group B:** 1.8 (n=84) **p value:** not sig Group 1: 2.1 Group 2: 0.4 Group 3: 1.6 Group 4: 2.3 Group 5: 1.9 p value: 0.003	
			Mean skin integrity scores – patient symptoms (Perineal Dermatitis Grading Scale – none=0, tingling=1, itching=2, burning=3, pain=4)	**Group A:** 0.6 (n=82) **Group B:** 1.2 (n=84) **p value:** not sig Group 1: 0.7 Group 2: 1.0 Group 3: 1.5 Group 4: 0.9 Group 5: 0.7 P value: NS	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Mean skin score: aggregate of colour, integrity and symptom scores (reported in Brown1994)	Group 1: 5.6 Group 2: 1.7 Group 3: 4.5 Group 4: 4.3 Group 5: 5.4 P=NR	

Products continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Harper, 1995[22] **Study design:** (randomised crossover study) **Evidence level:** 1+ **Duration of follow-up:** 6 weeks	**Patient group:** Incontinent chronic care (primarily) geriatric patients from 2 contiguous units. **Cause of incontinence:** orthopaedic problems (n=12) neuological problems (n=43) cerebral vascular (n=15) dementia/Alzheimer's (n=12) Mean no. of diagnoses per participant: 2.6 **<u>All patients</u>** **N:** 50 **N with FI:** not reported **Age (mean):** 75.5 years **M/F:** 25/21 **Dropouts:** 4	**Group 1** Disposable briefs worn for 3 weeks **Group 2** Reusable briefs worn for 3 weeks **Period in between interventions:** No period between interventions reported. Participants checked for incontinence at least 6 times per 24 hour period. Not stated if cream was used.	**Mean number of briefs used per patient per day**	**Group1:** 4.27 (n=46) **Group 2:** 4.47 (n=46) **p value:** not sig	**Funding:** Disposable briefs supplied by Independent Linen Inc. Financial support the Saint-Vincent Hospital Foundation & Chawkers Foundation **Limitations:** No indication whether urinary, faecally or doubly incontinent. Poor method of randomisation but all patients received both interventions. **Additional outcomes:** Preference of intervention type from 40 respondents (18 nurses, 8 patients, 14 visiting family members). (nurses preferred disposable) **Notes:** Reported in Brazzelli 1999 [21] (systematic review)
			Skin classification – red (19/46 participants with red skin at start of study)	**Group1:** 17/46 **Group 2:** 16/46 **p value:** not sig	
			Skin classification – rash (3/46 participants with a rash at start of study)	**Group1:** 1/46 **Group 2:** 3/46 **p value:** not sig	
			Skin classification – excoriation (1/46 participants with excoriation at start of study)	**Group1:** 2/46 **Group 2:** 1/46 **p value:** not sig	

Products continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Hu et al, 1988[23] **Study design:** RCT (randomised by **matched pairs**) **Evidence level:** 1+ **Duration of follow-up:** 5 weeks	**Patient group:** nursing home residents with double incontinence. All participants used reusable cloth products before study. **Cause of FI:** not reported but participants recruited regardless of sex, age, cognitive/mental health status. **Group 1** **N:** 42 (all doubly incontinent) **Age (mean):** NR **M/F:** 6/28 **Dropouts:** 8 **Mean no. of FI episodes/day**: 1.1 **Mean no. of UI episodes/day**: 6.9 44% could stand/walk **Group 2** **N:** 42 (all doubly incontinent **Age (mean):** NR **M/F:** 6/28 **Dropouts:** 8 **Mean no. of FI episodes/day**: 1.2 **Mean no. of UI episodes/day**: 6.5 41% could stand/walk	**Group 1** Disposable pads (Promise). A completely closed system Duration: 5 weeks **Group 2** Cloth products: partially open - snap brief during day & evening, underpad during night (n=22) completely open – underpad 24 hours per day (n=12) Duration: 5 weeks Home policy concerning skin care maintained during trial: routine washing, no perineal care unless some skin breakdown.	**Number of patients with deterioration in skin condition**	**Group1:** 5/34 **Group 2:** 27/34 **p value:** Sig	**Funding:** NR **Notes:** Skin assessment based on 5 criteria (erythema, rash, excoriation, blisters and skin) assessed at 8 areas of the body (upper thigh, inner thigh buttocks, coccyx, hips, rectal area, groin, perineum - for females, scrotum - for males). Intensity of conditions: 1=slight, 2=moderate, 3=moderately severe, 4 severe. Grades for each area (0=excellent, 1=good, 2=fair, 3=poor) based on the no. of conditions, severity of condition and size of area affected: Study reported in Brazzelli 1999[21] – Systematic Review.
			Number of patients with improvement in skin condition	**Group1:** 22/34 **Group 2:** 1/34 **p value:** Sig	
			Number of patients without change in skin condition	**Group1:** 7/34 **Group 2:** 6/34 **p value:** Sig	
			Change in mean ±SD skin assessment scores	**Group1:** 0.13 ±0.30 (n=34) **Group 2:** -0.35 ±0.35 (n=34) **p value:** Sig	
			Change in mean ±SD skin assessment scores for disposable pads with open cloth users 16 cloth users of completely open pads or who used only 1 snap brief could be compared to their matched pair with a disposable pad	**Group1:** 0.16 ±0.29 (n=16) **Group 2:** -0.19 ±0.23 (n=16) **p value:** Sig	

Products continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Silberg, 1977[24] **Study design:** Randomised crossover study **Evidence level:** 1+ **Duration of follow-up:** 21 days	**Patient group:** doubly incontinent hospitalised and bedridden geriatric females **Cause of FI:** NR **All patients** **N:** 32 **N with FI:** 32 **Age (mean):** NR **M/F:** 0/32 **Dropouts:** 0	**Group 1** Absorbent pad (Kylie) Duration: 7 days **Group 2** Absorbent pad impregnated with an antimicrobial agent (Kylie impregnated with Resiguard containing 1% picloxydine & 12% benzalkonium chloride in a surfactant base), 20 ml per pad Duration: 7 days **Group 3** Heavy cotton draw sheet Duration: 7 days	**Number of bedding changes for faeces alone**	**Group1:** 17 **Group 2:** 22 **Group 3:** 20 **p value:** NR	**Funding:** Pads supplied by Nicholas Ply Ltd, Chadstone, Victoria **Limitations:** Results heavily influenced by the urinary incontinence. **Additional outcomes:** micro-organisms per square centimetre of soiled pads and under sheets; odour of urine; presence of creasing or wrinkling of pads; total incidence of presence of erythema (not easy to relate to number of participants) **Notes:** Nurses perceived damp skin to be due to perspiration.
			Number of bedding changes for double incontinence	**Group1:** 37 **Group 2:** 19 **Group 3:** 40 **p value:** NR	
			Number of bedding changes for urinary incontinence alone	**Group1:** 189 **Group 2:** 252 **Group 3:** 597 **p value:** Sig	
			Number of recordings of dry skin	**Group1:** 292/976 **Group 2:** 359/1004 **Group 3:** 386/1046 **p value group1 vs group 3:** <0.001	
			Number of recordings of damp skin	**Group1:** 458/976 **Group 2:** 352/1004 **Group 3:** 1/1046 **p value group1 vs group 3:** <0.001	
			Number of recordings of wet skin	**Group1:** 226/976 **Group 2:** 264/1004 **Group 3:** 659/1046 **p value group1 vs group 3:** <0.001	

Evidence Table 6: patient views table for products

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Paterson et al, 2003[1] **Study design:** Qualitative Study **Evidence level:** 3 **Duration of follow-up:** NR	**Patient group:** Participants included people who had incontinence or cared for someone with incontinence, or were part of an advocacy group that had significant numbers of people with incontinence in its membership, from metropolitan, rural and remote Australia **Cause of FI:** Varied widely and included congenital malformations, chronic debilitating diseases, sever spinal cord injuries and degenerative diseases. **<u>All patients</u>** **N: 82 N with FI:** NR **Age (mean):** NR **M/F:** NR **Dropouts:** NR	Semi structured interviews and focus groups to inform development of comprehensive Australian consumer guide to continence products. Used qualitative technique of constant comparison, thematic data analysis was commenced concurrently with data collection enabling the opportunity to follow up an emerging theme.	Integrated into common themes, shared meanings, similarities and difference.	Participants did not know how to begin to search for information. Difficulties to obtain information and most consumers gathered information themselves. Generally had to travel to obtain information required as not in a central place. People who were less capable of travelling had very limited product knowledge.	**Funding:** National Continence Management Strategy, an initiative of the Commonwealth of Australia Department of Health and Aged Care **Limitations:** Possible selection bias as method of recruitment not reported. Not clear whether their target group of 'incontinent' patients is for urinary or faecal incontinence or both. **Notes:** Three researchers undertook data analysis and results cross-validated by an additional researcher
			The investigators reported striking similarities in experiences and concerns of consumers across the group. They reported the issues raised by the group.	Had lack of confidence in the health professionals and they had not received much helpful advice on products or sources of advice. Most satisfactory help was from specialist continence nurse advisers. Local doctor knew little about assessment and management. Several participants of focus group were shocked to discover that there are many options for incontinence treatment and management. Participants expressed need for standardised and coordinated assessment and management strategy. Most consumers said they had limited product knowledge in early stages and selected from limited range accessible to them in shops, hospital suppliers and recommendations of professionals. However, participants in support networks benefited from exchange of information.	
				Key factors influencing selection of continence products were availability, cost, quality, comfort and design. Other queries regarded best methods for care and disposal of products.	
				Suggestions for content and format of the consumer guide to products: detailed product description and more information in general about incontinence (causes, treatments and sources of help) and in simple layman's language throughout guide. They requested variety of formats and wide distribution throughout the community were suggested.	

Patient views table for products continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Norton & Kamm, 2001 [25] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 4 weeks	**Patient group:** Outpatients attending a specialist colorectal hospital who failed to respond to previous treatment for FI. All were ambulant adults. **Cause of FI:** Spinal injury, MS, sphincterotomy, obstetric trauma, anal fistula, rectal resection, ileoanal pouch, Idiopathic, rectal prolapse surgery, constipation, spina bifida and imperforate anus. **<u>All patients</u>** **N:** 34 **N with FI:** 34 **Age (mean):** 53.5 years (of subjects who completed the study) **M/F:** 4/16 (of subjects who completed the study) **Dropouts:** 23	All patients tested the two sizes of anal plug, in a random order, each for two weeks. 11 patients used the larger plug and 9 the smaller one first. Patients received an individual instruction session with nurse specialist. Patients were to use the plug while continuing their daily activities, for up to a maximum of 12 hours wear time per plug. A fresh plug used each day.	**Degree of continence when using the plug:** Patients continent: Improved continence (5 wore plug for too short a time to report continence and 1 subject could not retain the plug)	 10 4	**Funding:** NR **Limitations:** 1 subject was aged 17 years. **Additional outcomes:** Anorectal sensation reported in some patients (n=11) Comfort of inserting, use and removal of plug were rated on a scale of 1-10. No difference was found between the plugs in efficacy or comfort and only one patient expressed a preference. **Notes:** 9 patients dropped out after using first plug and refused to trial the second plug. Additional 14 patients considered for study. 4 refused as disliked the idea of the plug, 2 failed to attend first appointment and 8 dropped out immediately after trying a plug on one or two occasions only due to discomfort.
			Patients that completed study (n=11) Patients refused to use plug after study Patients wishing to use on a regular basis Patients wishing to use on an occasional basis	 5 4 2	

Evidence Table 7: What are the most effective skin care products to manage faecal incontinence?

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Cooper and Gray 2001[26] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 14 days	**Patient group:** Long term elderly or dependent hospital patients or nursing home residents. Majority both faecally and urinary incontinent, numbers not given. **Cause of FI:** NR **Group 1** **N:** 44 **Age (median):** 85 **M/F:** 9/35 **Dropouts:** 3/44 **Skin condition:** Healthy skin: 33/44 Erythema: 5/44 Broken skin: 3/44 **Group 1** **N:** 49 **Age (median):** 79 **M/F:** 22/27 **Dropouts:** 3/49 **Skin condition:** Healthy skin: 33/49 Erythema: 9/49 Broken skin: 5/49	**Group 1** Clinisian foam cleanser, pH = 5.5, contains emollient, water repellent deodorant and water repellent barrier. Applied for 14 days **Group 2** Soap and water Applied for 14 days	No. of participants with healthy skin before and after intervention	**Group 1**: 27/41 **Group 2**: 17/44 **p value**: 0.012*****	***** p values calculated by NCC-AC reviewer using Pearsons Chi square **Funding:** Venture health care **Limitations:** Initially, patients were individually randomised, then, after the first 11 patients the treatments were randomised by ward. Each of these eleven patients had their own bathroom, not clear whether the other patients had their own bathroom. 1 patient in each group had healthy skin at the start and end of the study but developed erythema after the study. **Additional outcomes:** Change in motility, change in undersheets or pad use
			No. of participants with deterioration in skin condition	**Group 1**: 5/41 **Group 2**: 14/44 **p value**: 0.03*****	
			No. of participants with improvement in skin condition	**Group 1**: 4/41 **Group 2**: 6/44 **p value**: 0.49*	
			No. of participants with no change in skin condition	**Group 1**: 2/41 **Group 2**: 1/44 **p value**: 0.51	
			Number of patients with healthy skin before intervention and erythema after	**Group 1**: 5/33 **Group 2**: 10/33 **p value**: 0.14*	
			Number of patients with healthy skin before intervention and broken skin after	**Group 1**: 0/33 **Group 2**: 4/33 **p value**: 0.039*	

Skin care products continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Anthony et al, 1987[27] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 14 days	**Patient group:** Incontinent geriatric ward patients requiring pads Type of incontinence not recorded but participants appear to have some faecal incontinence. **<u>All participants</u>** **N:** 67 **Age (median):** 81 **M/F:** 10/54 (3 not accounted for) **Dropouts:** 10 **<u>Group 1</u>:** **N:** 33 **Dropouts:** 4 **No. subjects with inflammatory lesions**: 13 **No. subjects without inflammatory lesions**: 16 **<u>Group 2</u>:** **N:** 34 **Dropouts:** 6 **No. subjects with inflammatory lesions**: 17 **No. subjects without inflammatory lesions**: 11	**Group 1** Sudocrem: zinc oxide: 15.25% hydrous wool fat (hypo-allergenic): 4% benzyl benzoate: 1.01% benzyl cinnamate: 0.15% benzyl alcohol: 0.39% Applied for 14 days **Group 2** Zinc cream: zinc oxide: 32% arachis oil: 32% calcium hydroxide: 0.045% oleic acid: 0.5% wool fat: 8%	Percent of participants showing reduction in redness at day 7 Percent of participants showing reduction in redness at day 14	**Group 1**: 92.3% **Group 2**: 37.5% **p value**: <0.01 **Group 1**: 84.6% **Group 2**: 50.0% **p value**: <0.01	**Funding:** not reported **Limitations:** No indication as to the percentage of people with faecal incontinence. Actual results/values not provided. Study does not provide number of subjects improving

Economic evaluations of conservative interventions

Evidence Table 8: Economic evaluations of conservative interventions

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Brazzelli et al, 2002[28] UK **Economic analysis:** Cost-consequences **Study design** Decision analysis using data collected through systematic review **Time-horizon:** 1 year. **Discount rates:** Costs: NA Effects: NA	**Patient group:** Adults with urinary and/or faecal incontinence. **Cause of FI:** NR **<u>All patients</u>** **N:** NR **N with FI:** NR **Age (mean):** NR **M/F:** NR **Dropouts:** NR	**Group 1:** Disposable underpads **Group 2:** Disposable superabsorbent bodyworns **Group 3:** Nondisposable bodyworns **Group 4:** Disposable bodyworns **Group 5:** Nondisposable underpads **Clinical effectiveness data presented for 4 comparisons:** **4 vs 3** **1 vs 5** **2 vs 4** **2+3+4 vs 1+5**	**Skin complaints** (no. people experiencing deterioration in skin problems)	**4 vs 3** OR 0.08 (95% CI: 0.03 to 0.20) **1 vs 5** OR 2.68 (95% CI: 0.81 to 8.83) **2 vs 4** One study reported OR 0.55 (95% CI: 0.21 to 1.41) Not sig. **2+3+4 vs 1+5** Not enough data	**Funding:** NR **Limitations:** 1.Authors note that since the trials used in this review were published, products have developed considerably suggesting the results of this review may not be applicable to currently available products. 2. Not all costs have been considered e.g. cost of disposal of soiled products. **Notes** Also reported in Brazzelli 1999[21]
			Mean cost per patient (UK £, 1999/2000, costs include product, cleaning, linen, skin treatments)	**Product (per year):** **1.** £1478 **2:** £515 **3:** £40 **4:** £249 **5:** £161 **Clean-up episode (per year):** **1.** £3601 **2:** £3538 **3:** £3139 **4:** £3139 **5:** £2698 **Cleaning and linen (per year):** **1.** £189 **2:** £206 **3:** £579 **4:** £209 **5:** £697 **Skin complaints (per year):** **1.** £78 **2:** £78 **3:** £161 **4:** £78 **5:** £78 **Total cost (per year):** **1.** £5345 **2:** £4337 **3:** £3919 **4:** £3675 **5:** £3633	
			Cost-effectiveness	4. dominates 3.	
			Sensitivity analysis one-way SA	High and low values were presented for all costs. Variables which influenced total cost the most included cost of supplying superabsorbent bodyworns and disposable underpads (total costs increased > 13%) and the number of disposable underpads used (if 10 pads were used per episode costs increased 50%).	

Economic evaluations of conservative interventions continued

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Brown, 1994[29] USA **Economic analysis**: Cost-effectiveness **Study design:** **Study design:** RCT with a non-randomised crossover phase within each intervention [20] **Duration of follow-up:** 6-12 weeks (see interventions) **Duration of follow-up:** 6-12 weeks (See interventions) **Discount rates:** NA	**Patient group:** hospitalised medical nursing unit adults with urinary, faecal or double incontinence from 3 acute care facilities. **Cause of FI:** NR **<u>All patients</u>** **N:** 166 **N with FI:** NR (see below) **Age (mean):** 74.5 **M/F:** 86/80 **Dropouts:** NR (166 is for participants who completed study) **Type of incontinence**: new onset (incontinence) 48% occasional 12% occasional urinary 7% routine urine 5% routine urine & faeces 29%	**Group 1.** Diapers without polymer (6 weeks) **Group 2.** Diapers with polymer (6 weeks) **Group 3**. Underpads without polymer (6 weeks) **Group 4.** Underpads with polymer (6 weeks) **Group 5.** Cloth underpads (12 weeks)	**Mean skin score:** aggregate of colour (0-3), integrity (0-5)and symptom (0-4) scores – See Brown 1994a[20]	**1:** 5.6 **2:** 1.7 **3:** 4.5 **4:** 4.3 **5:** 5.4 p=NR	**Funding:** Kaiser Permanente Northern California Region Innovation Program. Products donated by Professional Medical Products Inc **Limitations:** 1. Only 29% or participants were *routinely* doubly incontinent. Prevalence of FI amongst *new cases* was not reported. 2. Sometimes various products off-protocol products were used in cleaning up, but numbers not reported. 3. Inadequate sensitivity/statistical analysis 4. Difficult to assess whether the health gain from polymer diapers is enough to justify the increased cost
			Mean cost per clean-up episode (US$, incontinence supplies, staff, laundry, linen)	**1:** $4.40 (£2.80) **2:** $4.93 (£3.10) **3:** $5.07 (£3.20) **4:** $3.81 (£2.40) **5:** $3.87 (£2.40) p=0.0003	
			Cost-effectiveness:	Polymer pads dominated cloth and non-polymer pads. Polymer diapers improved skin scores compared with non-polymer diapers but at an increased cost.	
			Sensitivity analysis:	NR	

Economic evaluations of conservative interventions continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Byers et al, 1995[30] USA **Economic analysis:** Cost **Study design** **Clinical study**: randomised cross-over study **Cost study** Unclear **Duration of follow-up:** **Clinical study:** 15 weeks **Cost study:** NR **Discount rates:** NA	**Inclusion criteria:** Nursing home residents, who did not have thigh-length amputations and were expected to survive the study period. Timings /cost Results were presented separately for patients with FI. **Clinical study:** **N:** 12 **Age (mean):** 87 **M/F:** 0/12 **Dropouts:** 2 (1 died, 1 moved away) Mean Braden scale score=9 indicating a risk for pressure sores. Mean duration of incontinence was 8 months. None of the survivors were acutely ill and all had intact perineal skin. All were white. **Cost study** **N:** NR **Details:** NR	**Group 1** No-rinse incontinence cleanser **Group 2** Soap and water	**Mean cleansing time** (minutes)	**Group 1:** 2.95±1.16 **Group 2:** 12.63±2.26 **p value:** <0.001	**Funding:** Smith and Nephew United Inc. **Limitations:** 1. Clinical outcomes could not be extracted since they did not distinguish between FI and UI patients, 2. Sample size and methods of estimating cleansing time were not reported. **Additional outcomes:** TEWL, Erythema & pH were reported but not specifically for FI patients. **Notes:** They hypothesised additional product cost savings.
			Mean cost savings per patient per week ($US, Nursing assistant time; PPP=0.623)	**Group 1 vs Group 2:** $23.71 (£15) **p value:** NR	
			Cost-effectiveness	NR	
			Sensitivity analysis	NR	

Economic evaluations of conservative interventions continued

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Hu et al, 1990[31] USA **Economic analysis:** Cost-consequences **Study design** Randomised, controlled, matched-pair cohort **Duration of follow-up:** 5 weeks **Discount rates:** Costs: NA Effects: NA	**Patient group:** Elderly care home residents with urinary and/or faecal incontinence, with at least one wet episode per day. **Cause of FI:** NR **All patients** **N:** 68 **N with FI:** NR **Age (mean):** NR **M/F:** 18%/82% **Dropouts:** NR **Group 1** **N:** 34 **N with FI:** NR **Age (mean):** NR **M/F:** 18%/82% **Dropouts:** NR **Group 2** **N:** 34 **N with FI:** NR **Age (mean):** NR **M/F:** 18%/82% **Dropouts:** NR	**Group 1:** Disposable diapers **Group 2:** Reusable diapers	**Skin condition** (0=excellent, 1=good, 2=fair, 3=poor) (Pre minus post assessment)	**1:** 0.13 (±0.30) (an improvement) **2:** -0.30 (±0.35) (a deterioration) p value = 0.01	**Funding:** Scott Healthcare products (manufacturer of disposable products) **Limitations:** 1. FI incidence NR 2. Cost data limited to perspective of one nursing home. **Additional Outcomes:** Incontinence related laundry usage.
			Mean cost per patient (year not specified, assume 1989, US dollars, nursing home costs only) (PPPs used for conversion 1989 0.573)	**Product costs (per day)** **1:** $2.48 (£1.42**) 2:**$2.61 (£1.50) NS **Cost of Laundry (per day)** **1:** $0.87 (0.50p) **2:** $1.40 (0.80p) NR	
			Sensitivity analysis (one-way SA)	Cost per lb of laundry varied from 23¢ to 36¢. As cost increased, magnitude of savings by using disposables increased. At 23¢ annual savings per patient = $161, at 36¢ savings increased to $248	

Economic evaluations of conservative interventions continued

Bibliographic reference	Patients	Interventions	Outcome measures	Effect size	Comments
McCormick et al, 1990 [32] USA **Economic analysis**: Cost-consequences **Study design:** Case series (before and after) **Duration of follow-up:** Mean 68.5 days **Discount rates:** NA	**Patient group:** 10 severely mobility-impaired long term residents **Mean age:** 78 **M/F:**0/10	**Intervention:** two-hourly staff-provided toilet prompts using a Clinilift, a pneumatic lift that allows residents to be transferred from bed to commode. Mean duration was 68.5 days **1:** Last 10 days of treatment **2:** First 10 days **3 Pre-baseline**: Usual care	**'Faecal continence'**	**1:** 95%±10% **2:** 92%±12% (p<0.05)	**Funding:** National Institute on Aging; Health Care Financing Administration L**imitations:** 1. The intervention was actually taking place during the control period. 2. As a before and after study, there is a large potential for bias. 3. The statistical method (t-test) is not applicable in such a small sample and the p-values should be disregarded. 4. Costs were not subjected to statistical analysis or sensitivity analysis. 5. The measures of faecal incontinence, dryness, etc were inadequately described. 6. Baseline period was inadequately described
			'Dryness'	**1:** 47%±27% **2:** 33%±28% (p<0.05)	
			Bedsore	**1:** 20% **2:** 80% (p<0.05)	
			Urinary tract infection	**1:** 0% **2:** 60% (p<0.05)	
			Mean Activities of Daily Living score	**1:** 56.66±6.68 **2:** 64.00±13.81 (p<0.05)	
			Mean Cost per patient per day (US$ 1986-8)	**Toileting/continence** **1:** $12.68, **2:** $14.31 **3:** $9.78 **Treatment of bedsores** **1:** $2.43, **2:** $9.70 **Treatment of UTI** **1:** $0, **2:** $9.00	
			Cost-effectiveness:	Intervention dominates – it both reduced FI and reduced cost	
			Sensitivity analysis:	NR	

Economic evaluations of conservative interventions continued

Bibliographic reference	Patients	Interventions	Outcome measures	Effect size	Comments
Schnelle et al, 2003 [33] USA **Economic analysis**: cost-consequences **Study design:** RCT[34] **Duration of follow-up:** Baseline phase 6 months Intervention phase 8 months **Discount rates:** NA	**Patient group:** Incontinent residents in long-stay beds at 4 nursing homes **Intervention** N=92 Mean age: 87.3+-8.0 M/F:20%/80% **Control** N=98 Mean age: 88.6+-6.7 M/F:10%/90%	**Group 1:** Every 2 hours patients were prompted to toilet and encouraged to exercise (staff time was 21 minutes per episode) **Group 2:** Usual care	**Faecal incontinence frequency** (based on 8 checks per day)	**Baseline phase** **Group 1:** 7%±10 **Group 2:** 6%±11 **Intervention phase** **Group 1:** 3%±8 **Group 2:** 7%±10 ($p<0.05$)	**Funding:** National Institutes of Health
			Appropriate faecal toileting ratio (number of successful toilet visits / total number of episodes of defecation)	**Baseline phase** **Group 1:** 17%±33 **Group 2:** 31%±43 **Intervention phase** **Group 1:** 73%±35 **Group 2:** 28%±36 ($p<0.01$)	
			13 other functional outcomes	All favoured the intervention, some were statistically significant	
			Incidence of 31 acute conditions grouped into 11 categories	No significant differences were found for any of the 11 categories. Overall reduction of 10% was also not significant	
			Mean cost per day (1997/8 US$ for diagnosing and treating 31 acute conditions; not incl the cost of the intervention)	**Baseline phase** **Group 1: $**4.34, **Group 2: $**5.26 **Intervention phase** **Group 1:** $3.49, **Group 2:** $5.48 (not significantly different)	
			Cost-effectiveness:	NA	
			Sensitivity analysis:	NR	

Economic evaluations of conservative interventions continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Warshaw et al, 2002[35] USA **Economic analysis:** Cost-consequences **Study design** Case series (before and after) **Duration of follow-up:** Intvn: 7 days Comp: NR **Discount rates:** NR	**Inclusion criteria:** Elderly residents at a long-term hospital and a care home). Incontinent but low-risk on the Perineal Assessment Tool (PAT≤6). **All patients:** **N:** 19 **Age (mean):** 73.1±11.9 **M/F:** 14/5 **Dropouts:** 3 ('intention to treat analysis was performed by using the last observation carry-forward technique') **FI:** 11/19	**Intervention** One-step: single product cleanser and barrier cream for 7 days **Comparison** Two-step: Separate cleanser and barrier (Duration: NR)	**Mean erythema Grade** (0=clear, no redness…4=Non-intact with redness)	**Intervention (day 7):** 2.3±0.5 **Comparison (day 1):** 0.6±0.8 **p value:** p<0.002	**Funding:** Coloplast Corp **Limitations:** 1. Study design has a large potential for bias, 2. Duration of control period was not reported, 3. Study duration was quite short.
			Mean pain Score (0=No pain…4=Extreme pain)	**Intervention (day 7):** 1.5±1.0 **Comparison (day 1):** 0.3±0.8 **p value:** <0.01	
			Mean care-giver time (seconds per application)	**Intervention:** 94±45 **Comparison:** 117±47 **p value:** NR	
			Mean cost savings per patient per year ($US, product cost and caregiver time; PPP=0.623)	**Intervention vs comparison:** $136 (£85) **p value:** NR	
			Cost-effectiveness	The one-step product both reduced costs and improved health outcomes	
			Sensitivity analysis	NR	

Economic evaluations of conservative interventions continued

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
Zehrer et al, 2004[36] USA **Economic analysis:** Cost-consequences **Study design** Cohort study **Duration of follow-up:** 90 days **Discount rates:** Costs: NA Effects: NA	**Patient group:** Elderly care home residents with urinary and/or faecal incontinence without incontinence dermatitis. **Cause of FI:** NR **<u>All patients</u>** **N:** **N with FI:** NR **Age (median):** 81 to 90 **M/F:** 37%/76% **Dropouts:** NR **<u>Group 1</u>** **N:** 56 **N with FI:** NR **Age (mean):** NR **M/F:** NR **<u>Group 2</u>** **N:** 41 **N with FI:** NR **Age (mean):** NR **M/F:** NR **<u>Group 3</u>** **N:** 87 **N with FI:** NR **Age (mean):** NR **M/F:** NR **<u>Group 4</u>** **N:** 87 **N with FI:** NR **Age (mean):** NR **M/F:** NR	**Group 1:** Ointment (1) – ConvaTec Aloe Vesta Protective Ointment **Group 2:** Ointment (2) – Secura Protective ointment **Group 3:** Barrier film applied once daily (3M Cavilon). **Group 4:** Barrier film applied trice weekly (3M Cavilon).	**Incidence of incontinence dermatitis**	**1:** NR **2:** 2.6% (n=1) **3:** 3.9% (n=3) **4:** 3.0% (n=2) Not sig (p=0.44)	**Funding:** NR **Limitations:** 1. FI episodes were relatively infrequent and not included separately in this economic analysis. 2. Small sample size, limited to three nursing homes. **Additional outcomes:** Annual cost of each product based on a 150-bed nursing home with an incontinence rate of 50%
			Mean cost per patient ($US, 2003, costs include: product, staff costs) (PPPs used for conversion 2003 0.627)	**Cost of barrier (daily):** **1:** $0.73 **2:** $0.76 **3:** $0.39 **4:** $0.17 **Cost of barrier + staff costs (daily):** **1:** $1.37 (86p) **2:** $1.40 (88p) **3:** $0.60 (38p) **4:** $0.26 (16p)	
			Sensitivity analysis	NR	

Evidence tables for chapter 4: specialised conservative management

Evidence Table 9: What is the effectiveness of pelvic floor/ sphincter exercises vs all other conservative therapies?

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Glazener et al, 2001[37] and Glazener et al, 2005[38] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** Glazener et al, 2001 follow up 9 months. Glazener et al, 2005 follow up 6 years**.** At 6 years (n=516) response rate 69.5%	**Patient group:** women with urinary incontinence 3 months postnatally. **Cause of FI:** NR **All patients** **N:** 747 **N with FI:** 111 **Age (mean):** NR **M/F:** 0/747 **Dropouts:** 223 **Group 1** **N:** 371 **N with FI:** 57 **Age (mean):** 29.6 (SD: 5.2) **M/F:** 0/371 **Dropouts:** 92 **Group 2** **N:** 376 **N with FI:** 54 **Age (mean):** 29.4 (SD: 5.1) **M/F:** 0/376 **Dropouts:** 131	**Group 1** Assessment by nurses of UI with conservative advice on pelvic floor exercises at 5, 7 and 9 months after delivery supplemented with bladder training if appropriate at 7 and 9 months. Characteristics: Primiparous: 134 (36.7%) Method of delivery: spontaneous vaginal: 285 (78.3%); assisted vaginal: 50 (13.7%); caesarean section: 29 (8.0%) Perineum: Intact: 124 (34.4%); tear: 154 (42.8%); Episiotomy (with or without tear): 82 (22.8%). **Group 2** Control group did not receive any visits from research nurses. Like intervention group they had received peripartum preparation, which sometimes included pelvic floor exercises and could seek medical advice. Characteristics: Primiparous: 139 (37.6%) Method of delivery: spontaneous vaginal: 291 (78.6%); assisted vaginal: 51 (13.8%); caesarean section: 28(7.6%) Perineum: Intact: 128 (35.9%); tear: 160 (44.8%); Episiotomy (with or without tear): 69 (19.3%).	**Baseline (3 months after delivery):** Any FI (motions) (%) at entry	**Group1:** (57/371) 16.3% **Group 2:** (54/376) 15.1% **p value:** NR	**Funding:** 2001: WellBeing (grant sponsored by GlaxoWellcome) and Health Research Council of New Zealand. 2005: Birthright, Royal College of Obstetricians and Gynaecologists; New Zealand Lottery Grant Board; Health Services Research Unit, Aberdeen. **Limitations:** Higher response rate to 12 month questionnaire in intervention group (75% in group 1 vs 65% in group 2). **Additional outcomes:** Primary outcome is persistence and severity of urinary incontinence 12 months after delivery. Secondary outcome: Performance of pelvic floor exercises, change in co-existing FI, anxiety and depression.
			12 months post delivery (after 9 months follow up) Any FI (to motions):	**Group1:** 12/273 (4.4%) **Group 2:** 25/237 (10.5%) **Absolute difference (95%CI for difference):** 6.1 (1.6 to 10.8); x^2=6.25, p=0.012	
			Severe FI (to motions):	**Group1:** 5/273 (1.8%) **Group 2:** 12/237 (5.1%) **Absolute difference (95%CI for difference):** 3.3 (0.02 to 6.4); x^2=3.17, p=0.075	
			6 year Follow up: **Any FI** [numbers (%) of women]	**Group1:** 32/261 (12%) **Group 2:** 32/248 (13%) **Difference (95%CI):** -0.6% (-6.4 to 5.1); p=0.932	
			Severe FI [Numbers (%) of women]	**Group1:** 15/261 (6%) **Group 2:** 8/248 (3%) **Difference (95%CI):** 2.5% (-1.1 to 6.1); p=0.248	

Pelvic floor/ sphincter exercises continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Solomon et al, 2003[39] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 4 months treatment programme	**Patient group:** Patients with mild to moderate FI with at least mild neuropathy on single fibre, 4 quadrant sampling of external sphincter with electromyography and no anatomic defect in the external sphincter. **Cause of FI:** NR **<u>All patients</u>** **N: 120 N with FI:** 120 **Age: mean (SD):** 62.0 (12.8) **M/F:** 13/107 **Dropouts:** 18 **<u>Group 1</u>** **N:** 40 **N with FI:** 40 **Age: mean (SD):** 60.1 (13.7) **M/F:** 5/35 **Dropouts:** 4 **<u>Control 2</u>** **N: 39 N with FI:** 39 **Age: mean (SD):** 63.4 (13.6) **M/F:** 3/39 **Dropouts:** 8 **<u>Group 3</u>** **N:** 41 **N with FI:** 41 **Age: mean (SD) :** 62.7 (11.0) **M/F:** 5/36 **Dropouts: 6**	**Group 1** Biofeedback with transanal ultrasound **Group 2** Biofeedback with anal manometry **Group 3** Pelvic floor exercises with feedback from digital examination Commencing one week after an initial 45 minute assessment session, all patients attended monthly treatments for a total of five sessions (30 minutes per session) and involved sphincter exercises with biofeedback that involved instrumentation or digital examination alone and patients were encouraged to perform identical exercises twice per day between outpatient visits.	**'Quality of life (10-0) – where 10 is full quality of life and 0 is no quality of life.** **INITIAL:** **Median (25th, 75th percentiles)** **FINAL:** **Median (25th, 75th percentiles)**	**Group 1:** 3.8 (2.7,5.6) **Group 2**: 5 (3, 6.4) **Group 3:** 4.2 (3.5,5.3) **p value: NR** **Group 1:** 6.3 (5,8.6) **Group 2:** 6.5 (4, 7.9) **Group 3:** 6.7 (5,7.1) **p value: NR**	**Funding:** Supported by a research grant from the ANZAC Health and Medical Research Foundation. **Additional outcomes:** Pescatori, St. Marks, Self-rating, investigator rating scores were found before and after treatment for each group. Additionally, the isotonic fatigue time and isotonic fatigue contractions were reported for each group before and after the intervention. **Notes:** 102 patients completed the final tests (85% response rate).
			Mean change in QOL outcome measures (10-0) – defined above	**Group 1:** 2.6 **Group 2:** 1.69 **Group 3:** 2.01 **p value: NS**	
			Rest pressure (mmHg) **INITIAL:** **Median (25th, 75th percentiles)** **FINAL:** **Median (25th, 75th percentiles)**	**Group 1:** 38 (33,51) **Group 2:** 38 (33,47**)** **Group 3:** 45 (39,52) **Group 1:** 44 (34,57) **Group 2:** 45 (37,55) **Group 3:** 48 (38,57)	
			Mean change in rest pressure outcome measures (mmHg)	**Group 1:** 2.54 **Group 2:** 6.84 **Group 3:** 2.8 **p value:** NS	
			Squeeze pressure (mmHg) **INITIAL:** **Median (25th, 75th percentiles)** **FINAL:** **Median (25th, 75th percentiles)**	**Group 1:** 80 (60,101) **Group 2:** 73 (59,92**)** **Group 3:** 90 (57,100) **Group 1:** 95 (77,121) **Group 2:** 78 (70,106) **Group 3:** 90(67, 120)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Mean change in squeeze pressure outcomes measures (mmHg)	**Group 1:** 11.66 **Group 2**: 10.45 **Group 3**: 10.69 **P value: NS**	

Pelvic floor/ sphincter exercises continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Norton et al, 2003[40] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 12 months	**Patient group:** Patients referred to a specialist colorectal hospital with episodes of FI. **Cause of FI:** NR Exclusion criteria were: patients who had previously undergone a treatment of biofeedback or exercises for FI, patients under 18 years, patients with major neurologic disease, or significant cognitive impairment, active inflammatory bowel disease, patients who appeared distressed, patients needing urgent treatment and patients with insufficient written English skills to complete questionnaires. **All patients** **N:** 171 **N with FI:** 171 **Age (mean):** 56 (26-85) **M/F:** 12/159 **Dropouts:** 31 **Group 1** **N:** 43 **N with FI:** 43 **Age (mean):** 55 (26-76) **M/F:** 5/38 **Dropouts:** 11 **Group 2** **N:** 37 **N with FI:** 37 **Age (mean):** 58 (28-84)	**Group 1** Up to 9, 40-60 minutes sessions over 3-6 months with a specialist nurse offering advice on standard range of issues such as diet, fluids, techniques to improve evacuation, bowel training programme, titration of dose of anti diarrhoeal medication (if previously prescribed) and practical management. **Group 2** Patients taught anal sphincter exercises verbally and by digital examination and given leaflet on exercises. Patients were instructed to perform at least 50 maximal voluntary sustained sphincter contractions and 50 fast-twitch contractions per day plus up to 9, 40-60 minutes sessions over 3-6 months with a specialist nurse offering advice on standard range of issues such as diet, fluids, techniques to improve evacuation, bowel training programme, titration of dose of anti diarrhoeal medication (if previously prescribed) and	**Completed protocol and questionnaires**	**Group1:** 29 (78%) **Group 2:** 32 (74.4%) **Group 3:** 44 (90%) **Group 4:** 35 (83.3%) **p value:** NS	**Funding:** Supported by Action Research. **Additional outcomes:** Comparison of all patients before and after treatment. Additional interventions of biofeedback were recorded but not included in this clinical question. . **Notes:**
			Rating of bowel control (0-10 scale) median:	**Group1:** 6 (3) **Group 2:** 7 (2.5) **Group 3:** 6 (5) **Group 4:** 6 (3) **p value:** NS	
			Diary bowel actions per week: median (IQ range)	**Group1:** 10 (8) **Group 2:** 11 (11) **Group 3:** 9 (8) **Group 4:** 10 (11) **p value:** NS	
			Diary accidents per week: median (IQ range)	**Group1:** 1 (2) **Group 2:** 0 (2) **Group 3:** 0 (3) **Group 4:** 0 (3) **p value:** NS	
			Diary pad changes per week: median (IQ range)	**Group1:** 1 (2) **Group 2:** 0 (0) **Group 3:** 0 (2) **Group 4:** 0 (1) **p value:** NS	
			Continence score: median (IQ range)	**Group1:** 13 (6.5) **Group 2:** 11 (6) **Group 3:** 13 (7) **Group 4:** 14 (11) **p value:** NS	
			Anorectal physiology test results: a) resting pressure: median (IQ	**Group1:** 50 (18)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	M/F: 1/36 **Dropouts:** 8 **<u>Group 3</u>** **N: N with FI:** **Age (mean):** **M/F:** **Dropouts:** **<u>Group 4</u>** **N: N with FI:** **Age (mean):** **M/F:** **Dropouts:**	practical management. **Group 3** Patients were provided with computer assisted biofeedback during sessions to attempt to teach the patient increased rectal sensitivity to distention, improved coordination of sphincter activity, decreased delay in sensation and isolation of the anal sphincter, concentrating on improving both muscle strength and endurance. The external sphincter contraction pressure was shown on a computer screen plus up to 9, 40-60 minutes sessions over 3-6 months with a specialist nurse offering advice on standard range of issues such as diet, fluids, techniques to improve evacuation, bowel training programme, titration of dose of anti diarrhoeal medication (if previously prescribed) and practical management. **Group 4** Patients were asked to use a home biofeedback device once daily for 20 minutes.	range) b) squeeze pressure: median (IQ range) cm H20 c) 5 second squeeze increment: median (IQ range) cmH2O	**Group 2:** 49 (43) **Group 3:** 66 (36) **Group 4:** 54 (45) **p value:** NS **Group1:** 71 (67) **Group 2:** 60 (103) **Group 3:** 46 (43) **Group 4:** 37 (40) **p value:** NS **Group1:** 35 (70) **Group 2:** 37 (44) **Group 3:** 30 (45) **Group 4:** 35 (50) **p values:** NS	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
		This device involves insertion of an intra-anal electromyelogram electrode, connected to a battery box, with increasing muscle contraction showing as an increased number of lights illuminated plus up to 9, 40-60 minutes sessions over 3-6 months with a specialist nurse offering advice on standard range of issues such as diet, fluids, techniques to improve evacuation, bowel training programme, titration of dose of anti diarrhoeal medication (if previously prescribed) and practical management.			

Pelvic floor/ sphincter exercises continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Ilnyckyj et al, 2005[41] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 2 months	**Patient group:** women with regular and frequent idiopathic FI were recruited through poster and newspaper advertisement. Women with diabetes complicated by neuropathy or a neurological disorder were excluded. Women who were less than 6 months post vaginal or caesarean birth were also excluded. Patients with Irritable Bowel Syndrome were also excluded. **Cause of FI:** Idiopathic FI **<u>All patients</u>** **N:** 23 **N with FI:** 23 **Age (mean):** 59 (26-75) **M/F:** 0/23 **Dropouts:** 5 (no data on which group these were assigned - 4 did not complete study and 1 did not provide complete data for analysis) **<u>Group 1</u>** **N:** 11 **N with FI:** 11 **Age (mean):** NR **M/F:** 0/11 **Dropouts:** 0 **<u>Group 2</u>** **N:** 7 **N with FI:** 7 **Age (mean):** NR **M/F:** 0/7 Dropouts: 0	**Group 1** Patients received education and exercise instruction. They determined their own maximal squeeze duration and tone. **Group 2** Received same educational programme as group 1. In addition they were instructed in pelvic floor exercises using visual biofeedback, physical (hand application) and verbal cueing. Both groups were given an equal number of sessions for treatments.	**Complete responder** (defined as a participant who during the 2 week baseline period before treatment had at least one weekly episode of any degree of incontinence and then reported no incontinence at all during the last week of the study)	**Group1** (n=11): 45% **Group 2** (n=7): 86% **p value:** 0.1507	**Funding:** NR **Limitations:** Bias – group selection from advertisements. Small and unequal numbers of participants. There is also an imbalance in the base-line readings between the two groups. **Additional outcomes:** P values were reported for manometric results for each group comparing results before and after treatments. **Notes:** Originally excluded as underpowered and imbalance of base-line readings.
			Resting pressure (mmH20) Before:	**Group1** (n=11): 32.9 **Group 2** (n=7): 44.4 **p value:** NR	
			Resting pressure (mmH20) After:	**Group1** (n=11): 34.1 **Group 2** (n=7): 51.6 **p value:** NR	
			Squeeze pressure (mmH20) Before:	**Group1** (n=11): 80.7 **Group 2** (n=7): 72.2 **p value:** NR	
			Squeeze pressure (mmH20) After:	**Group1** (n=11):**:** 81.3 **Group 2** (n=7): 91.7 **p value:** NR	
			Squeeze duration (mmH20) Before:	**Group1** (n=11):**:** 8 **Group 2** (n=7)**:** 7.2 **p value:** NR	
			Squeeze duration (mmH20) After:	**Group1** (n=11): 14 **Group 2** (n=7): 19.4 **p value:** NR	

Evidence Table 10: What is the effectiveness of biofeedback vs all other conservative therapies?

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Ilnyckyj et al, 2005[41] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 2 months	**Patient group:** Women with regular and frequent idiopathic FI recruited through poster and newspaper advertisement. Women with diabetes complicated by neuropathy or neurological disorder were excluded. Women who were less than 6 months post vaginal or caesarean birth also excluded. Patients with Irritable Bowel Syndrome also excluded. **Cause of FI:** Idiopathic FI **<u>All patients</u>** **N:** 23 **N with FI:** 23 **Age (mean):** 59 (26-75) years **M/F:** 0/23 **Dropouts:** 5 (no data on which group these were assigned – 4 did not complete study and 1 did not provide complete data for analysis) **<u>Group 1</u>** **N:** 11 **N with FI:** 11 **Age (mean):** NR **M/F:** 0/11 **Dropouts:** 0 **<u>Group 2</u>** **N:** 7 **N with FI:** 7 **Age (mean):** NR **M/F:** 0/7 Dropouts: 0	**Group 1** Patients received education and exercise instruction. They determined their own maximal squeeze duration and tone. **Group 2** Received same educational programme as group 1. In addition they were instructed in pelvic floor exercises using visual biofeedback, physical (hand application) and verbal cueing. Both groups were given an equal number of sessions for treatments.	**Complete responder** (defined as a participant who during the 2 week baseline period before treatment had at least one weekly episode of any degree of incontinence and then reported no incontinence at all during the last week of the study)	**Group1** (n=11**):** 45% **Group 2**(n=7**):** 86% **p value:** 0.1507	**Funding:** NR **Limitations:** Bias – group selection from advertisements. Small and unequal numbers of participants. There is also an imbalance in the base-line readings between the two groups. **Additional outcomes:** P values were reported for manometric results for each group comparing results before and after treatments. **Notes:** Originally excluded as underpowered and imbalance of base-line readings.
			Resting pressure (mmH20) Before:	**Group1**(n=11)**:** 32.9 **Group 2**(n=7**:** 44.4 **p value:** NR	
			Resting pressure (mmH20) After:	**Group1**(n=11)**:** 34.1 **Group 2**(n=7**:** 51.6 **p value:** NR	
			Squeeze pressure (mmH20) Before:	**Group1**(n=11)**:** 80.7 **Group 2**(n=7**:** 72.2 **p value:** NR	
			Squeeze pressure (mmH20) After:	**Group1**(n=11)**:** 81.3 **Group 2**(n=7**:** 91.7 **p value:** NR	
			Squeeze duration (mmH20) Before:	**Group1**(n=11)**:** 8 **Group 2**(n=7**:** 7.2 **p value:** NR	
			Squeeze duration (mmH20) After:	**Group1**(n=11)**:** 14 **Group 2**(n=7**:** 19.4 **p value:** NR	

Biofeedback vs other conservative therapies continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Solomon et al, 2003[39] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 4 months treatment programme	**Patient group:** Patients with mild to moderate FI with at least mild neuropathy on single fibre, 4 quadrant sampling of external sphincter with electromyography and no anatomic defect in the external sphincter. **Cause of FI:** NR **<u>All patients</u>** **N:** 120 **N with FI:** 120 **Age: mean (SD):** 62.0 (12.8) **M/F:** 13/107 **Dropouts:** 18 **<u>Group 1</u>** **N:** 40 **N with FI:** 40 **Age: mean (SD):** 60.1 (13.7) **M/F:** 5/35 **Dropouts:** 4 **<u>Control 2</u>** **N: 39 N with FI:** 39 **Age: mean (SD):** 63.4 (13.6) **M/F:** 3/39 **Dropouts:** 8 **<u>Group 3</u>** **N:** 41 **N with FI:** 41 **Age: mean (SD) :** 62.7 (11.0) **M/F:** 5/36 **Dropouts: 6**	**Group 1** Biofeedback with transanal ultrasound **Group 2** Biofeedback with anal manometry **Group 3** Pelvic floor exercises with feedback from digital examination Commencing one week after an initial 45 minute assessment session, all patients attended monthly treatments for a total of five sessions (30 minutes per session) and involved sphincter exercises with biofeedback that involved instrumentation or digital examination alone and patients were encouraged to perform identical exercises twice per day between outpatient visits.	**'Quality of life (10-0) – where 10 is full quality of life and 0 is no quality of life.** **INITIAL:** **Median (25th, 75th percentiles)** **FINAL:** **Median (25th, 75th percentiles)**	**Group 1:** 3.8 (2.7,5.6) **Group 2**: 5 (3, 6.4) **Group 3:** 4.2 (3.5,5.3) **p value: NR** **Group 1:** 6.3 (5,8.6) **Group 2:** 6.5 (4, 7.9) **Group 3:** 6.7 (5,7.1) **p value: NR**	**Funding:** Supported by a research grant from the ANZAC Health and Medical Research Foundation. **Additional outcomes:** Pescatori, St. Marks, Self-rating, investigator rating scores were found before and after treatment for each group. Additionally, the isotonic fatigue time and isotonic fatigue contractions were reported for each group before and after the intervention. **Notes:** 102 patients completed the final tests (85% response rate).
		Mean change in QOL outcome measures (10-0) – defined above	**Group 1:** 2.6 **Group 2:** 1.69 **Group 3:** 2.01 **p value: NS**	
		Rest pressure (mmHg) **INITIAL:** **Median (25th, 75th percentiles)** **FINAL:** **Median (25th, 75th percentiles)**	**Group 1:** 38 (33,51) **Group 2:** 38 (33,47**)** **Group 3:** 45 (39,52) **Group 1:** 44 (34,57) **Group 2:** 45 (37,55) **Group 3:** 48 (38,57)	
		Mean change in rest pressure outcome measures (mmHg)	**Group 1:** 2.54 **Group 2:** 6.84 **Group 3:** 2.8 **p value:** NS	
		Squeeze pressure (mmHg) **INITIAL:** **Median (25th, 75th percentiles)** **FINAL:** **Median (25th, 75th percentiles)**	**Group 1:** 80 (60,101) **Group 2:** 73 (59,92**)** **Group 3:** 90 (57,100) **Group 1:** 95 (77,121) **Group 2:** 78 (70,106) **Group 3:** 90(67, 120)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Mean change in squeeze pressure outcomes measures (mmHg)	**Group 1:** 11.66 **Group 2**: 10.45 **Group 3**: 10.69 **P value: NS**	

Biofeedback vs other conservative therapies continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Norton et al, 2003[40] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 12 months	**Patient group:** Patients referred to a specialist colorectal hospital with episodes of FI. **Cause of FI:** NR Exclusion criteria were: patients who had previously undergone a treatment of biofeedback or exercises for FI, patients under 18 years, patients with major neurologic disease, or significant cognitive impairment, active inflammatory bowel disease, patients who appeared distressed, patients needing urgent treatment and patients with insufficient written English skills to complete questionnaires. **All patients** **N:** 171 **N with FI:** 171 **Age (mean):** 56 (26-85) **M/F:** 12/159 **Dropouts:** 31 **Group 1** **N:** 43 **N with FI:** 43 **Age (mean):** 55 (26-76) **M/F:** 5/38 **Dropouts:** 11 **Group 2** **N:** 37 **N with FI:** 37 **Age (mean):** 58 (28-84)	**Group 1** Up to 9, 40-60 minutes sessions over 3-6 months with a specialist nurse offering advice on standard range of issues such as diet, fluids, techniques to improve evacuation, bowel training programme, titration of dose of anti diarrhoeal medication (if previously prescribed) and practical management. **Group 2** Patients taught anal sphincter exercises verbally and by digital examination and given leaflet on exercises. Patients were instructed to perform at least 50 maximal voluntary sustained sphincter contractions and 50 fast-twitch contractions per day plus up to 9, 40-60 minutes sessions over 3-6 months with a specialist nurse offering advice on standard range of issues such as diet, fluids, techniques to improve evacuation, bowel training programme, titration of dose of anti diarrhoeal medication (if previously prescribed) and	**Completed protocol and questionnaires**	**Group1:** 29 (78%) **Group 2:** 32 (74.4%) **Group 3:** 44 (90%) **Group 4:** 35 (83.3%) **p value:** NS	**Funding:** Supported by Action Research. **Additional outcomes:** Comparison of all patients before and after treatment. Additional interventions of biofeedback were recorded but not included in this clinical question. . **Notes:**
			Rating of bowel control (0-10 scale) median:	**Group1:** 6 (3) **Group 2:** 7 (2.5) **Group 3:** 6 (5) **Group 4:** 6 (3) **p value:** NS	
			Diary bowel actions per week: median (IQ range)	**Group1:** 10 (8) **Group 2:** 11 (11) **Group 3:** 9 (8) **Group 4:** 10 (11) **p value:** NS	
			Diary accidents per week: median (IQ range)	**Group1:** 1 (2) **Group 2:** 0 (2) **Group 3:** 0 (3) **Group 4:** 0 (3) **p value:** NS	
			Diary pad changes per week: median (IQ range)	**Group1:** 1 (2) **Group 2:** 0 (0) **Group 3:** 0 (2) **Group 4:** 0 (1) **p value:** NS	
			Continence score: median (IQ range)	**Group1:** 13 (6.5) **Group 2:** 11 (6) **Group 3:** 13 (7) **Group 4:** 14 (11) **p value:** NS	
			Anorectal physiology test results: a) resting pressure: median (IQ	**Group1:** 50 (18)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	M/F: 1/36 **Dropouts:** 8 **<u>Group 3</u>** **N: N with FI:** **Age (mean):** **M/F:** **Dropouts:** **<u>Group 4</u>** **N: N with FI:** **Age (mean):** **M/F:** **Dropouts:**	practical management. **Group 3** Patients were provided with computer assisted biofeedback during sessions to attempt to teach the patient increased rectal sensitivity to distention, improved coordination of sphincter activity, decreased delay in sensation and isolation of the anal sphincter, concentrating on improving both muscle strength and endurance. The external sphincter contraction pressure was shown on a computer screen plus up to 9, 40-60 minutes sessions over 3-6 months with a specialist nurse offering advice on standard range of issues such as diet, fluids, techniques to improve evacuation, bowel training programme, titration of dose of anti diarrhoeal medication (if previously prescribed) and practical management. **Group 4** Patients were asked to use a home biofeedback device once daily for 20 minutes.	range) b) squeeze pressure: median (IQ range) cm H20 c) 5 second squeeze increment: median (IQ range) cmH2O	**Group 2:** 49 (43) **Group 3:** 66 (36) **Group 4:** 54 (45) **p value:** NS **Group1:** 71 (67) **Group 2:** 60 (103) **Group 3:** 46 (43) **Group 4:** 37 (40) **p value:** NS **Group1:** 35 (70) **Group 2:** 37 (44) **Group 3:** 30 (45) **Group 4:** 35 (50) **p values:** NS	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
		This device involves insertion of an intra-anal electromyelogram electrode, connected to a battery box, with increasing muscle contraction showing as an increased number of lights illuminated plus up to 9, 40-60 minutes sessions over 3-6 months with a specialist nurse offering advice on standard range of issues such as diet, fluids, techniques to improve evacuation, bowel training programme, titration of dose of anti diarrhoeal medication (if previously prescribed) and practical management.			

Evidence Table 11: which modality of biofeedback is the most effective at managing faecal incontinence?

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Fynes et al, 1999[42] reported in systematic review Norton et al, 2000[43] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 12 weeks	**Patient group:** Females with faecal incontinence presenting to a dedicated perineal clinic. Mean duration of symptoms 4 months (range 3-28 months). 37 females were symptomatic after primary repair of recognised anal sphincter disruption and 3 after traumatic instrumental delivery with no attempt at repair. 24 were primiparous 16 were multiparous. No significant difference between the two groups in age, parity or duration of symptoms. **Cause of FI:** obstetric trauma **All patients** **N:** 40 **N with FI:** 40 **Age (mean):** 32 **M/F:** 0/40 **Dropouts:** 0 There no significant difference between the groups in terms of age, parity or duration of symptoms.	**Group 1:** Weekly 30 minute sessions for 12 weeks of vaginal pelvic floor manometric pressure biofeedback conducted by a continence nurse plus 'standard Kegel pelvic floor exercises'. **Group 2:** Weekly sessions of anal EMG biofeedback plus anal electrical stimulation conducted by a physiotherapist plus 'standard Kegel pelvic floor exercises'.	**Proportion of patients to become asymptomatic**	OR 4.54 95% CI 1.30-15.83 in favour of electrical stimulation group	**Funding:** Irish Health Research Board, the mater College of Education and Research and the Friends of the Rotunda Hospital, Ireland. **Limitations:** Study was not only comparing different modalities of biofeedback but also the addition of electrical stimulation. **Additional outcomes:** Other outcomes were presented a median values and range (continence score) or as mean values and range (resting pressure, squeeze pressure, squeeze increment and vector symmetry). **Notes:** The estimation of the standard deviation was not computed since this method can results in over-estimation of the standard deviation.
			Proportion of patients to improve in their incontinence status	OR 12.38 95% CI 2.67-57.46 in favour of electrical stimulation group	

Biofeedback vs biofeedback continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Miner et al, 1990[44] reported in systematic review Norton et al, 2000[43] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 4 weeks	**Patient group:** consecutive patients referred to unit for assessment of faecal incontinence **Cause of FI:** heterogeneous diagnoses. 5 had previous post-anal repair, 2 inflammatory bowel disease, many also had irritable bowel symptoms **All patients** **N:** 25 **N with FI:** **Age (mean):** 55 **M/F:** 8/17 **Dropouts:** **Group 1** **N:** **N with FI:** **Age (mean):** **M/F:** **Dropouts:** **Group 2** **N:** **N with FI:** **Age (mean):** **M/F:** **Dropouts:**	**Group 1** Biofeedback. Trained to perceive small rectal volumes (active sensory training to teach to discriminate progressively smaller volumes of rectal balloon distension with decreasing delay) **Group 2** Carried out the same manoeuvres but were not given any information or instruction.	**Incontinent episodes per week (Weighted Mean Difference (WMD))** **People achieving full continence** **Improving incontinence status** **Rectal sensory threshold**	**WMD: -1.40; 95%CI: -1.51 to -1.29** **OR: 0.11; 95%CI: 0.01 to 0.90** **OR: 0.17; 95%CI: 0.03 to 0.83** **WMD: -12.90; 95%CI: -14.10 to -11.70**	**Funding:** NR **Limitations:** **Additional outcomes:** A number of outcomes were reported within each group.

Biofeedback vs biofeedback continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Heyman et al, 2000[45] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** not reported	**Patient group:** Patients with incontinence identified as non-surgical candidates based on clinical, manometric and electrophysiological parameters. These parameters include co-morbid disease with high operative risk, severe neuropathy or diffuse sphincter injury as noted by EMG and poor sphincter pressures with no evidence of sphincter defects on ultrasonography. Attempts were made to treat patient conservatively with education, dietary modification prior to inclusion. Patients with neurologically intact pelvic floor muscles that were either too weak to maintain continence or who demonstrated poor perception and control of these muscles were referred for biofeedback training of the pelvic floor muscles. **All patients** **N:** 40 **N with FI:** **Age (mean):** 74years **M/F:** 11/23 **Dropouts:** 6	**Group 1** Feedback display of EMG activity of pelvic floor muscles, education as to pelvic floor physiology and operant conditioning techniques to retrain this function. (Outpatient) **Group 2** Out-patient EMG biofeedback training plus balloon distension sensory training plus pelvic floor exercises. **Group 3** Out-patient EMG biofeedback training plus home trainer EMG biofeedback until for the home practice portion of the training programme. **Group 4** Out-patient EMG biofeedback training plus home trainer EMG biofeedback until for the home practice portion of the training programme plus balloon distension sensory training.	**Mean (±SD) number of days per week with incontinent episodes.**	**Group 1:** 1.66 ±2.36 (n=8) **Group 2:** 0.22 ±0.31 (n=8) **Group 3:** 1.59 ±2.33 (n=8) **Group 4:** 1.95 ±1.53 (n=10) **All groups:** 1.39 ±1.86 (n=34) **No significant different across patient groups.**	**Funding:** supported in part by a research grant from David G. Jagelman Research Fund **Limitations:** the duration of the study is not reported.
			Percentage reduction in mean number of days per week with incontinent episodes	**Group 1**: 64% (p=0.001) **Group 2**: 96% (p=0.004) **Group 3**: 73% (p=0.001) **Group 4**: 67% (p=0.028) p values relate to the change in mean number of days per week with incontinent episodes	

Biofeedback vs biofeedback continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Norton et al, 2003[40] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 12 months	**Patient group:** Patients referred to a specialist colorectal hospital with episodes of FI. **Cause of FI:** NR Exclusion criteria were: patients who had previously undergone a treatment of biofeedback or exercises for FI, patients under 18 years, patients with major neurologic disease, or significant cognitive impairment, active inflammatory bowel disease, patients who appeared distressed, patients needing urgent treatment and patients with insufficient written English skills to complete questionnaires. **All patients** **N:** 171 **N with FI:** 171 **Age (mean):** 56 (26-85) **M/F:** 12/159 **Dropouts:** 31 **Group 1** **N:** 43 **N with FI:** 43 **Age (mean):** 55 (26-76) **M/F:** 5/38 **Dropouts:** 11 **Group 2** **N:** 37 **N with FI:** 37 **Age (mean):** 58 (28-84) **M/F:** 1/36	**Group 1** Up to 9, 40-60 minutes sessions over 3-6 months with a specialist nurse offering advice on standard range of issues such as diet, fluids, techniques to improve evacuation, bowel training programme, titration of dose of anti diarrhoeal medication (if previously prescribed) and practical management. **Group 2** Patients taught anal sphincter exercises verbally and by digital examination and given leaflet on exercises. Patients were instructed to perform at least 50 maximal voluntary sustained sphincter contractions and 50 fast-twitch contractions per day plus up to 9, 40-60 minutes sessions over 3-6 months with a specialist nurse offering advice on standard range of issues such as diet, fluids, techniques to improve evacuation, bowel training programme, titration of dose of anti diarrhoeal medication (if previously prescribed) and practical management.	**Completed protocol and questionnaires**	**Group1:** 29 (78%) **Group 2:** 32 (74.4%) **Group 3:** 44 (90%) **Group 4:** 35 (83.3%) **p value:** NS	**Funding:** Supported by Action Research. **Additional outcomes:** Comparison of all patients before and after treatment. Additional interventions of biofeedback were recorded but not included in this clinical question. . **Notes:**
			Rating of bowel control (0-10 scale) median:	**Group1:** 6 (3) **Group 2:** 7 (2.5) **Group 3:** 6 (5) **Group 4:** 6 (3) **p value:** NS	
			Diary bowel actions per week: median (IQ range)	**Group1:** 10 (8) **Group 2:** 11 (11) **Group 3:** 9 (8) **Group 4:** 10 (11) **p value:** NS	
			Diary accidents per week: median (IQ range)	**Group1:** 1 (2) **Group 2:** 0 (2) **Group 3:** 0 (3) **Group 4:** 0 (3) **p value:** NS	
			Diary pad changes per week: median (IQ range)	**Group1:** 1 (2) **Group 2:** 0 (0) **Group 3:** 0 (2) **Group 4:** 0 (1) **p value:** NS	
			Continence score: median (IQ range)	**Group1:** 13 (6.5) **Group 2:** 11 (6) **Group 3:** 13 (7) **Group 4:** 14 (11) **p value:** NS	
			Anorectal physiology test results: a) resting pressure: median (IQ range)	**Group1:** 50 (18) **Group 2:** 49 (43)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Dropouts: 8 **<u>Group 3</u>** **N: N with FI:** **Age (mean):** **M/F:** **Dropouts:** **<u>Group 4</u>** **N: N with FI:** **Age (mean):** **M/F:** **Dropouts:**	**Group 3** Patients were provided with computer assisted biofeedback during sessions to attempt to teach the patient increased rectal sensitivity to distention, improved coordination of sphincter activity, decreased delay in sensation and isolation of the anal sphincter, concentrating on improving both muscle strength and endurance. The external sphincter contraction pressure was shown on a computer screen plus up to 9, 40-60 minutes sessions over 3-6 months with a specialist nurse offering advice on standard range of issues such as diet, fluids, techniques to improve evacuation, bowel training programme, titration of dose of anti diarrhoeal medication (if previously prescribed) and practical management. **Group 4** Patients were asked to use a home biofeedback device once daily for 20 minutes. This device involves	b) squeeze pressure: median (IQ range) cm H20 c) 5 second squeeze increment: median (IQ range) cmH2O	**Group 3:** 66 (36) **Group 4:** 54 (45) **p value:** NS **Group1:** 71 (67) **Group 2:** 60 (103) **Group 3:** 46 (43) **Group 4:** 37 (40) **p value:** NS **Group1:** 35 (70) **Group 2:** 37 (44) **Group 3:** 30 (45) **Group 4:** 35 (50) **p values:** NS	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
		insertion of an intra-anal electromyelogram electrode, connected to a battery box, with increasing muscle contraction showing as an increased number of lights illuminated plus up to 9, 40-60 minutes sessions over 3-6 months with a specialist nurse offering advice on standard range of issues such as diet, fluids, techniques to improve evacuation, bowel training programme, titration of dose of anti diarrhoeal medication (if previously prescribed) and practical management.			

Biofeedback vs biofeedback continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Solomon et al, 2003[39] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 4 months	Patient group: Patients with mild to moderate FI. Patients were excluded if they had a defunctioning stoma, inflammatory bowel disease, acute perianal inflammation, a potentially reversible cause of incontinence (e.g. diarrhoea) or untreated full thickness rectal prolapse. All patients had initially been referred to a colorectal surgeon for investigation and management for focal incontinence. Investigations for all patients included anal manometry, transanal ultrasound and electromyography to confirm neuropathy and exclude anatomic defects. Management included dietary advice and medical treatment which included loperamide where appropriate. Patients were referred to the biofeedback program by the treating colorectocal surgeon of they had not had success with maximal medical and dietary treatment. During the biofeedback programme patients were asked to continence their previously established regimen. (e.g. elderly care home residents with urinary or faecal	Group 1 Biofeedback with transanal ultrasound Group 2 Biofeedback with anal manometry	Mean change in Pescarti faecal incontinence score (full continence 0-complete incontinence 6)	Intervention: -1.06 comparison: -0.68 NS	**Funding:** Supported by a research grant from the ANZAC Health and Medical Research Foundation.
			Mean change in St Marks faecal incontinence score (full continence 0 -complete incontinence 13)	Intervention: -2.14 comparison: -0.94 NS	
			Mean change in patients self-assessment of faecal incontinence severity using a visual analogue scale N=(No continence problems 0 - 'the worst it could be' 10)	Intervention:-1.94 comparison: -2.23 NS	
			Mean change in investigator rating (0-10)	Intervention: -1.47 comparison: -1.12 NS	
			Mean change in quality of life using Direct Questioning of Objectives (0 no quality of life – full quality of life 10)	Intervention: 2.6 comparison: 1.69 NS	
			Mean change in resting anal canal manometric pressure (mmHg)	Intervention: 2.54 comparison: 6.84 NS	
			Mean change in maximal squeeze anal canal manometric pressure	Intervention: 11.66 comparison: 10.45 NS	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	incontinence) Cause of FI: Patients with at least mild neuropathy on single fibre. <u>All patients</u> N: 120 N with FI: 120 Age (mean): M/F: Dropouts: <u>Group 1</u> N: N with FI: Age (mean): **M/F:** **Dropouts:** **<u>Group 2</u>** **N: N with FI:** **Age (mean):** **M/F:** **Dropouts:**		(mmHg)		
			Mean change in isotonic fatigue time	**Intervention: 32.42 comparison: 8.94 NS**	
			Mean change in isometric fatigue contractions	**Intervention: 1.58 comparison: 3.79**	

Biofeedback vs biofeedback continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Byrne et al, 2005[46] **Study design:** Non-randomised controlled trial **Evidence level:** 2+ **Duration of follow-up:** Not reported	**Patient group:** 239 consecutive patients with faecal incontinence. All had been assessed by a colorectal surgeon, had undergone anal manometry and transanal ultrasound and had not improved with the usual conservative treatment modalities, including standard dietary advice, use of fibre supplements, constipating medications, and enemas. **Cause of FI:** NR **<u>All patients</u>** **N:** 239 **N with FI:** NR **Age (mean):** **M/F:** **Dropouts:** **<u>Group 1</u>** **N:** 55 **N with FI:** NR **Age (mean):** 58.7 **M/F:** 4/51 **Dropouts:** 8 **<u>Group 2</u>** **N:** 184 **N with FI:** NR **Age (mean):** 62.2 **M/F:** 20/164 **Dropouts:** 56	**Group 1** Initial face-to-face assessment and treatment with transanal manometry and ultrasound biofeedback, followed by three treatments conducted via telephone and a final face-to-face assessment. **Group 2** Standard treatment involved five face-to-face treatment sessions with manometry and ultrasound. The treatment protocol involved and identical initial assessment and biofeedback. The subsequent treatment sessions consisted of the patients' general well-being and compliance with treatment being assess. Additional advice re incontinence, including dietary and medication was given.	**Incontinence** (Pescatori – decrease in percentages)	**Group1:** 26% **Group 2:** 34% **p value:** Not significant	**Funding:** Notaras Fellowship from the University of Sydney and the Training board of the Colorectal Surgical Society of Australasia **Limitations:** Bias in allocation of patients to treatment programs – rural participants were offered the telephone option. Duration of study not reported **Additional outcomes:** Quality of life, between groups and pre-and post measure for each group. Isotonic external sphincter fatigue, isotonic external sphincter repeats, compliance. **Notes:** Does not give p values.
			Incontinence (Pescatori – changes pre and post-trial for each group.	**Group1** **Pre:** 4.7 **Post:** 3.4 **p value:** NR **Group 2:** **Pre:** 4.5 **Post:** 3.2 **p value:** NR	
			Incontinence (St Marks – changes pre and post-trial for each group.	**Group1** **Pre:** 7.9 **Post:** 4.7 **p value:** Significant **Group 2:** **Pre:** 7.4 **Post:** 4.2 **p value:** Significant	
			Incontinence (St Marks – decrease in percentages)	**Group1:** 39% **Group 2:** 43% **p value:** Not significant	
			Incontinence (Patient visual analogue score – changes pre and post-trial for each group.	**Group1** **Pre:** 5.7 **Post:** 2.9 **p value:** Significant **Group 2:** **Pre:** 5.4 **Post:** 2.5 **p value:** Significant	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Incontinence (Patient visual analogue score – decrease in percentages)	**Group1:** NR **Group 2:** NR **p value:** Not sig	
			Incontinence (Investigator visual analogue score – changes pre and post-trial for each group.	**Group1** **Pre:** 6.6 **Post:** 3.6 **p value:** NR **Group 2:** **Pre:** 6.0 **Post:** 3.2 **p value:** NR	
			Incontinence (Investigator visual analogue score – decrease in percentages)	**Group1:** NR **Group 2:** NR **p value:** Not sig	
			Resting pressure (mmHg)	**Group1** **Pre:** 48 **Post:** 50 **p value:** NR **Group 2:** **Pre:** 47 **Post:** 51 **p value:** NR	
			Maximum pressure (mmHg)	**Group1** **Pre:** 97 **Post:** 111 **p value:** NR **Group 2:** **Pre:** 89 **Post:** 104	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				p value: NR	

Evidence Table 12: What is the effectiveness of external electrical stimulation at managing faecal incontinence?

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Fynes et al, 1999[42] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 12 weeks	**Patient group:** Females with FI caused by obstetric trauma presenting to a dedicated perineal clinic. Mean duration of symptoms 4 months (range 3-28 months). 24 were primiparous and 16 were mulitparous. No significant difference between the two groups in age, parity or duration of symptoms. **Cause of FI:** Obstetric trauma **All patients** **N:** 40 **N with FI:** 40 **Age (mean):** 32 (18-48) **M/F:** 0/40 **Dropouts:** 1 **Group 1** **N:** 20 **N with FI:** 20 **Age (mean):** NR **M/F:** 0/20 **Dropouts:** 0 **Group 2** **N:** 20 **N with FI:** 20 **Age (mean):** NR **M/F:** 0/20 Dropouts: 1	**Group 1** Augmented biofeedback training which combined audiovisual feedback and anal electrical stimulation conducted by continence physiotherapist plus 'standard Kegel pelvic floor exercises' Static (slow twitch) and dynamic (fast twitch) exercises were alternated over a 15 min period comprising 13 – second cycles (5 seconds activity and 8 seconds rest). The beginning of each 13 second cycle was announced by a buzzer sound. **Group 2** Weekly 30 minutes sessions each week for 12 weeks of vaginal pelvic floor manometric pressure biofeedback conducted by a continence nurse plus 'standard Kegel pelvic floor exercises'.	**Proportion of patients to become asymptomatic**	Group 1: 15/20 = 75% Group 2: 7/19 =37% p = 0.0248	**Funding:** Irish Health Research Board, the mater College for Education and Research, and the Friends of the Rotunda Hospital, Ireland.
			Proportion of patients to improve in their incontinence status	Group 1: 20/20 Group 2: 11/19 p = 0.0012	
			Median faecal incontinence score after treatment	Group 1: 0 (range, 0-12) Group 2: 4.2 (range, 0-19)	

External electrical stimulation continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Mahony et al, 2004[47] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 12 weeks	**Patient group:** women with FI symptoms after obstetric injury at 12 weeks after delivery. Patients with history of diabetes mellitus, inflammatory bowel disease, irritable bowel disease, previous anorectal surgery or malignancy were excluded. **Cause of FI:** obstetric injury **All patients** **N:** 60 **N with FI:** 60 **Age (mean):** NR **M/F:** 0/60 **Dropouts:** 6 **Group 1** **N:** 30 **N with FI:** 30 **Age (mean):** 32 (range 22–42) years **M/F:** 0/30 **Dropouts:** 2 **Group 2** **N:** 30 **N with FI:** 30 **Age (mean):** 35 (23-39) years **M/F:** 0/30 **Dropouts:** 4	**Group 1** Intra-anal EMG biofeedback with electrical stimulation of anal sphincter once weekly for 12 weeks and kegel exercises. Median parity (n): 1 (1-3) Mode of delivery (n): a) spontaneous vaginal:15 b) vacuum extraction:5 c) Forceps: 4 d)Vacuum/forceps: 6 **Group 2** Intra-anal EMG biofeedback training of pelvic floor once weekly for 12 weeks and kegel exercises. Median parity (n):1 (1-3) Mode of delivery (n): a) spontaneous vaginal:19 b) vacuum extraction: 2 c) forceps: 6 d) vacuum/forceps: 3	**Median continence score** (scale 0-20) **Baseline:** **Median continence score** (scale 0-20) **After treatment:** **Median resting pressure (mmHg) Baseline:** **Median resting pressure (mmHg) After treatment:** **Median squeeze pressure (mmHg) Baseline:** **Median squeeze pressure (mmHg) After treatment:**	**Group1 (n=28):** 4 (range: 2-14) **Group 2 (n=26):** 4.5 (range: 2-11) **p value:** NR **Group1(n=28):** 2 (range: 0-10) **Group 2(n=26):** 2 (range: 0-10) **p value:** NR **Group1(n=28):** 28 (range: 4-43) **Group 2(n=26):** 29 (range: 11-54) **p value:** NR **Group1(n=28):** 30 (range: 2-66) **Group 2(n=26):** 31 (range: 8-64) **p value:** NR **Group1(n=28):** 42 (range: 6-71) **Group 2(n=26):** 44 (range: 20-83) **p value:** NR **Group1(n=28):** 47 (range: 17-91) **Group 2(n=26):** 59 (range: 25-110) **p value:** NR	**Funding:** NR **Limitations:** Cause of dropouts not stated. **Additional outcomes:** The study also reports FIQL Scores on lifestyle, coping/behaviour, depression/self perception and embarrassment before and after treatment. **Notes:** Continence scores: 0 indicated complete continence and a score of 20 indicated complete incontinence. The investigators acknowledge the lack of a placebo group. However, they felt that it would not be moral to not treat women 12 weeks after delivery with FI following obstetric injury.

External electrical stimulation continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Norton et al, 2005[48] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 8 weeks	**Patient group:** Patients referred to tertiary referral hospital. Reported median history of 3 years incontinence (range, 6 months to 30 years). Women had a median parity of 2 (range, 0-7). Main complaint of urge FI: 30; passive faecal soiling: 34; both urge and passive incontinence: 26. **Cause of FI:** NR **<u>All patients</u>** **N:** 90 **N with FI:** 90 **Age (mean):** 55 (range, 30-77) yrs **M/F:** 9/81 **Dropouts:** 20 **M/F after dropouts**: 6/64 **<u>Group 1</u>** **N:** 47 **N with FI:** 47 **Age (mean):** NR **M/F:** NR **Dropouts:** 10 **<u>Group 2</u>** **N:** 43 **N with FI:** 43 **Age (mean):** NR **M/F:** NR Dropouts: 10	**Group 1** 'Active' stimulation. Involved the use of a home electric stimulation unit (Elpha 4 conti danmeter A/S Denmark) with an "Anuform" anal plug electrode for 8 weeks. This was at 35 Hz with 0.5 second ramped pulse, 5 seconds on, 0.5 second ramp down, and a 5 second off-duty cycle. Pulse width was 300 µs. **Group 2** 'Sham' stimulation. The stimulator was identical to active stimulator, had the same ramping duty cycle, and was used to the same protocol, but with stimulation at 1 Hz, a frequency that can be felt but does not produce any voluntary muscle contraction. Patients were not offered advice on diet, medication and lifestyle, exercises or biofeedback.	**Bowel control** (scale: 0-10, where 0 was no control and 10 was perfect control) - Median	**Group1:** 4.0 **Group 2:** 5.0 **p value:** 0.10	**Funding:** Supported by Action Medical Research, a medical research charity. **Limitations:** Drop out rate was 10 per group (response rate 78%) **Additional outcomes:** Frequency of defecation, incontinent episodes and use of pads before and after intervention. Effect on their life was also scored before and after treatment. Outcomes for all patients was also assessed. **Notes:** Exclusion criteria: patients refusing informed consent, children under 18 years, pregnant women or those within six weeks o vaginal delivery, patients with a history of pelvic malignancy, patients with active inflammatory bowel disease, active perianal sepsis or painful haemorrhoids or fissure and patients with previous experience of using an electric stimulator to treat urinary or FI
			Comfort of using the stimulator (scale: 0-10, where 0 was very uncomfortable and 10 was completely comfortable) – Median rating	**Group1:** 7.0 **Group 2:** 6.0 **p value:** 0.93	
			Satisfaction with the electrical stimulation (scale: 0-10, where 0 was very dissatisfied and 10 was completely satisfied) – Median rating	**Group1:** 5.5 **Group 2:** 5.0 **p value:** 0.46	
			Resting pressure at baseline (cmH2O) Median (IQ range)	**Group1:** 41.5 (28.5) **Group 2:** 46.0 (37.5) **p value:** 0.80	
			Resting pressure after intervention (cmH2O) Median (IQ range)	**Group1:** 49.0 (44.0) **Group 2:** 38.5 (23.0) **p value:** 0.76	
			Squeeze pressure increment at baseline (cmH2O) Median (IQ range)	**Group1:** 57.0 (70.0) **Group 2:** 29.0 (61.0) **p value:** 0.10	
			Squeeze pressure increment after intervention (cmH20) Median (IQ range)	**Group1:** 50.0 (54.5) **Group 2:** 36.5 (57.8) **p value:** 0.31	
			Cough pressure increment at baseline (cmH20) Median (IQ range)	**Group1:** 60.0 (45.5) **Group 2:** 47.0 (45.5) **p value:** 0.10	
			Cough pressure increment after intervention (cmH20) Median (IQ range)	**Group1:** 56.0(43.25) **Group 2:** 40.5 (58.0) **p value:** 0.14	

External electrical stimulation continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Norton et al, 2006[49] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 8 weeks	**Patient group:** Patients referred and waiting for biofeedback **Cause of FI:** (e.g. rectal prolapse / sphincter tear / idiopathic / all / NR / etc) **All patients** **N:** 90 **N with FI:** 90 **Age (median):** 55 (30-77) **M/F:** 6/64 **Dropouts:** 20 **Group 1** **N:** 47 **N with FI:** 47 **Age (mean):** **M/F:** NR **Dropouts:** 10 **Group 2** **N:** 43 **N with FI:** 43 **Age (mean):** **M/F:** NR **Dropouts:** 10 Analysis was by intention to treat. Dropouts were given a score of 0 for the outcomes measures on a -5 to +5 scale.	**Group 1** Active electrical stimulation of sphincter. For the first three weeks, stimulator used 2 0 mins/day, then from weeks 4-8 40 mins/day. Stimulation at 35Hz with a 0.5 second ramped pulse, 5 seconds on, 0.5 secs ramp down, 5 secs off. **Group 2** Sham stimulation used the same cycle and was used to the same protocol, but the a 1Hz frequency, which causes no muscle contraction.	**Frequency of urge**	**Group1:** NR **Group 2:** NR **Relative risk:** NR **Interquartile range:** NR **p value:** 0.47	**Funding:** NR **Additional outcomes:** Patient-rated outcomes: comfort, satisfaction, bowel control, effect of symptoms on life. Also completion rates **Notes:** Same as paper above.
			Passive urge	**Group1:** NR **Group 2:** NR **Relative risk:** NR **Interquartile range:** NR **p value:** 0.61	
			Flatus incontinence	**Group1:** NR **Group 2:** NR **Relative risk:** NR **Interquartile range:** NR **p value:** 0.45	
			Frequency of defaecation after stimulation	**Group1:** NR **Group 2:** NR **Relative risk:** NR **Interquartile range:** NR **p value:** 0.79	
			Frequency of incontinent episodes after stimulation	**Group1:** NR **Group 2:** NR **Relative risk:** NR **Interquartile range:** NR **p value:** 0.60	
			Frequency of use of pads after stimulation	**Group1:** NR **Group 2:** NR **Relative risk:** NR **Interquartile range:** NR **p value:** 0.65	
			Resting pressure before (cmH2O) All median values	**Group1:** 41.5 **Interquartile range:** 28.5 **Group 2:** 37.5	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				Interquartile range: 37.5 **p value:** 0.80	
			Resting pressure after (cmH2O) All median values	**Group1:** 49.0 **Interquartile range:** 44.0 **Group 2:** 37.5 **Interquartile range:** 23.0 **p value:** 0.76	
			Squeeze pressure increment before (cmH2O) All median values	**Group1:** 57.0 **Interquartile range:** 70.0 **Group 2:** 29.0 **Interquartile range:** 61.0 **p value:** 0.10	
			Squeeze pressure increment after (cmH2O) All median values	**Group1:** 50.0 **Interquartile range:** 54.5 **Group 2:** 36.5 **Interquartile range:** 57.8 **p value:** 0.31	
			Cough pressure increment before (cmH2O) All median values	**Group1:** 60.0 **Interquartile range:** 455 **Group 2:** 47.0 **Interquartile range:** 45.5 **p value:** 0.10	
			Cough pressure increment after (cmH2O) All median values	**Group1:** 56.0 **Interquartile range:** 43.25 **Group 2:** 40.5 **Interquartile range:** 58.0 **p value:** 0.14	

External electrical stimulation continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Osterberg et al, 2004[50] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up (mean):** 3, 12 and 24 months	**Patient group:** Patients with neurogenic disabling FI and no sphincter defect, rectal prolapse or intra-anal intussusception. **Cause of FI:** NR **All patients** **N:** 59 **N with FI:** 59 **Age (median):** 66 **M/F:** 7/52 **Dropouts:** NR **Group 1** **N:** 31 **N with FI:** 31 **Age (mean):** 68 (52-80) **M/F:** 2/29 **Dropouts:** NR **Group 2** **N:** 28 **N with FI:** 28 **Age (mean):** 64 (43-81) **M/F:** 5/23 **Dropouts:** NR	**Group 1:** Anterior Levatorplasty (post anal repair for men) **Group 2** Anal plug electrical stimulation of the pelvic floor	**Improvement in incontinence (number of patients) at 3 months:**	**Group1:** 28 **Group 2:** 19 **p value**=0.032	**Funding:** Study supported by the Swedish research council **Limitations:** The physical and social handicap was assessed by asking yes/no question. **Notes:** Visual analogue scale not described. The bowel function questionnaire included 49 questions relating to FI, constipation and general symptom. Based on the answers given an evaluation was performed according to Miller's incontinence score system (0- total continence and 18 (maximum incontinence)
			Improvement in incontinence (number of patients) at 12 months:	**Group1:** 28 **Group 2:** 22 **p value**=0.210	
			Improvement in incontinence (number of patients) at 24 months:	**Group1:** 26 **Group 2:** 19 **p value**=0.149	
			Less use of pads (number of patients) at 3 months:	**Group1:** 14 **Group 2:** 9 **p value**=0.306	
			Less use of pads (number of patients) at 12 months:	**Group1:** 17 **Group 2:** 9 **p value**=0.078	
			Less use of pads (number of patients) at 24 months:	**Group1:** 15 **Group 2:** 8 **p value**=0.119	
			Improvement in physical handicap (number of patients) at 3 months:	**Group1:** 18 **Group 2:** 6 **p value**=0.004	
			Improvement in physical handicap (number of patients) at 12 months:	**Group1:** 23 **Group 2:** 7 **p value**=0.001	
			Improvement in physical handicap (number of patients) at 24 months:	**Group1:** 20 **Group 2:** 6 **p value**=0.001	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Improvement in social handicap (number of patients) at 3 months:	**Group1:** 20 **Group 2:** 8 **p value**=0.006	
			Improvement in social handicap (number of patients) at 12 months:	**Group1:** 23 **Group 2:** 10 **p value**=0.003	
			Improvement in social handicap (number of patients) at 24 months:	**Group1:** 17 **Group 2:** 8 **p value**=0.041	
			Deferring time, loose stool, median (range) score on visual – analogue scale at 3 months:	**Group1:** 15 (0-35) **Group 2:** 11 (0-55) **p value**=0.731	
			Deferring time, loose stool, median (range) score on visual – analogue scale at 12 months:	**Group1:** 22 (0-32) **Group 2:** 13(0-70) **p value**=0.431	
			Deferring time, loose stool, median (range) score on visual – analogue scale at 24 months:	**Group1:** 14 (0-36) **Group 2:** 10 (0-54) **p value**=0.582	
			Deferring time, solid stool, median (range) score on visual – analogue scale at 3 months:	**Group1:** 32 (0-73) **Group 2:** 25 (0-100) **p value**=0.114	
			Deferring time, solid stool, median (range) score on visual – analogue scale at 12 months:	**Group1:** 34 (0-58) **Group 2:** 33 (0-98) **p value**=0.295	
			Deferring time, solid stool, median (range) score on visual – analogue scale at 24 months:	**Group1:** 30 (0-49) **Group 2:** 27 (0-88) **p value**=0.317	
			Morbidity (number of patients):	**Group1:** 1(wound infection) **Group 2:** 1(burning	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				sensation in vagina)	

Evidence tables for chapter 5: specialist assessment

Evidence Table 13: What does functional testing add to the assessment of patients with faecal incontinence?

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Sultan et al, 1994[11] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** consecutive unselected patients with faecal incontinence undergoing sphincter repair. **Cause of FI:** 4 women had undergone surgery previously for obstetric tear. 1 man became incontinent after surgery **<u>All patients</u>** **N:** 12 **N with test for FI:** 9 **Age (mean):** 46 **M/F:** 1/11 **Dropouts:** 0	**Assessment tool under investigation:** Anal manometry **Gold standard:** Surgery and histology	**External sphincter defects (maximum squeeze pressure <40cm water)** Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 67% 67% 86% 40% 9/12 (75%)	**Funding:** Joint Research Board of St Bartholomew's Hospital and The Wellcome Trust, St Mark's Research Foundation Limitations: very small and highly selected patient group. **Notes:** **2/12 patients could not tolerate multiple needle insertions so suspected defect not confirmed**
		Assessment tool under investigation: **Concentric needle electromyography** **Gold standard:** **Surgery and histology**	**External sphincter defects** **Sensitivity** **Specificity** **Positive predictive value** **Negative predictive value** **Prevalence**	 89% 33% 80% 50% 9/12 (75%)	

Evidence Table 14: What do imaging tests add to the assessment of patients with faecal incontinence?

MRI

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Pinta et al, 2004[51] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** female patients with anal incontinence **Cause of FI:** obstetric injury (18 patients) anorectal surgery (1 patient). **All patients** **N:** 19 **N with FI:** 19 **Age (mean):** 32 **M/F:** 0/19 **Dropouts:**	**Assessment tool under investigation:** endovaginal MRI **Gold standard:** surgeons judgment	**Condition of the external anal sphincter** Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 91.7% 14.3% 64.7% 50.0% 12/19 (63%)	**Funding:** NR **Limitations:** small study with selected patients. Surgeon's judgment is not gold standard for outcomes reported.
			Condition of the internal anal sphincter Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 57.1% 42.6% 36% 63% 9/19 (47%)	

MRI continued

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Briel et al, 2000[52] **Study design:** Diagnostic study A Prospective **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** Unselected women with faecal incontinence. **Cause of FI:** Obstetric trauma. **All patients** **N:** 25 **N with FI:** 25 **Age (mean):** 48 **M/F:** 0/48 **Dropouts:**	**Assessment tool under investigation:** endoanal MRI **Gold standard:** histopathology	**External sphincter atrophy** Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 89% 94% 89% 94% 36%	**Funding:** NR **Limitations:** small study with selected patients.

MRI continued

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Rociu et al, 1999[53] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** Consecutive non-selected women with faecal incontinence who underwent surgical repair of the sphincter. **Cause of FI:** Childbirth (19 patients), anorectal surgery (2 patients), sexual assault (1 patient). **All patients** **N:** 22 **N with FI:** 22 **Age (median):** 49 **M/F:** 0/22 **Dropouts:** 0	**Assessment tool under investigation:** endoanal MRI **Gold standard:** Surgical diagnosis	**Demonstration of damage to external anal sphincter** Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 NR NR 90 100 20/22 (91%)	**Funding:** NR **Limitations:** unclear if outcomes "demonstration of damage to internal and external anal sphincter" are calculated with US (not surgery) as gold standard.
			Demonstration of defect to external anal sphincter Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 85 78 85 78 13/22 (63%)	
			Demonstration of scarring to external anal sphincter Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 100 94 80 100 2/22 (9%)	
			Demonstration of thinning to external anal sphincter Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 0 100 0 91 4/22 (18%)	

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
			Demonstration of normal external anal sphincter		
			Sensitivity	33	
			Specificity	85	
			Positive predictive value	25	
			Negative predictive value	89	
			Prevalence	3/22 (14%)	
			Demonstration of damage to internal anal sphincter		
			Sensitivity	NR	
			Specificity	NR	
			Positive predictive value	80%	
			Negative predictive value	50%	
			Prevalence	20/22 (91%)	
			Demonstration of defect to internal anal sphincter		
			Sensitivity	83	
			Specificity	80	
			Positive predictive value	83	
			Negative predictive value	80	
			Prevalence	12/22 (55%)	
			Demonstration of scarring to internal anal sphincter		
			Sensitivity	100	
			Specificity	100	
			Positive predictive value	100	
			Negative predictive value	100	
			Prevalence	1/22 (5%)	

MRI continued

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Meyenberger et al, 1996[54] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** 1 – 11 (mean 5.3) months	**Patient group:** consecutive patients with faecal incontinence that had lasted from one month to 362 months (median 12 months) **Cause of FI:** obstetric trauma (n=8), surgical trauma (n=17), rectal prolapse (n=1), **All patients** **N:** 28 **N with FI:** 28 **Age (median):** 40 **M/F:** 15/13 **Dropouts:** 0	**Assessment tool under investigation:** endoanal ultrasound **Gold standard:** surgery carried out within 2 months of the endoanal ultrasound	**Internal anal sphincter defect** Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence **External anal sphincter defect** Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 100% 100% 100% 100% 25/28 (89%) 100% 83% 77% 100% 10/28 (36%)	**Funding:** not reported **Limitations:** small study.

Ultrasonography

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Pinta et al, 2004[51] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** female patients with anal incontinence **Cause of FI:** obstetric injury (18 patients) anorectal surgery (1 patient). **All patients** **N:** 19 **N with FI:** 19 **Age (mean):** 32 **M/F:** 0/19 **Dropouts:**	**Assessment tool under investigation:** endoanal ultrasound **Gold standard:** surgeon's judgement.	**Condition of the external anal sphincter** Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence 12/19 (63%)	 91.6% 14.2% 65% 50%	**Funding:** NR **Limitations:** small study with selected patients. Surgeon's judgment is not gold standard for outcomes reported.
			Condition of the internal anal sphincter Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence 12/19 (63%)	 58.3 100% 100% 58%	

Ultrasonography continued

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Sultan et al, 1994[11] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** consecutive unselected patients with faecal incontinence undergoing sphincter repair. **Cause of FI:** 4 women had undergone surgery previously for obstetric tear. 1 man became incontinent after surgery **All patients** **N:** 12 **N with test for FI:** 12 **Age (mean):** 46 **M/F:** 1/11 **Dropouts:** 0	**Assessment tool under investigation:** Anal endosonography **Gold standard:** Surgery and histology	**External anal sphincter defect** Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 100% 100% 100% 100% 9/12 (75%)	**Funding:** Joint Research Board of St Bartholomew's Hospital and The Wellcome Trust, St Mark's Research Foundation **Additional outcomes:** Internal sphincter defects (8/9 with external defects). Not confirmed/assessed by surgery and histology.

Ultrasonography continued

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Romano et al, 1996[55] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** patients undergoing overlapping sphincteroplasty or total pelvic floor repair for faecal incontinence. **Cause of FI:** trauma (iatrogenic 11, obstetric 9, road accident 2) and neurogenic. **All patients** **N:** 30 **N with FI:** 30 **Age (median):** NR (range 26-68) **M/F:** 9/21 **Dropouts:** 0	**Assessment tool under investigation:** anal endosonography **Gold standard:** appearance at surgery	**External anal sphincter defects** Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 95.5 89 95 89 100%	**Funding:** NR

Ultrasonography continued

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Deen et al, 1993[56] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** patients with faecal incontinence undergoing pelvic floor repair. **Cause of FI:** Post-obstetric trauma (n=35), rectal prolapse (n=5), iatrogenic injury (n=3) unknown cause of sphincter damage (n=1). **All patients** **N:** 44 **N with FI:** 44 **Age (median):** 56 **M/F:** 4/40 **Dropouts:** 0	**Assessment tool under investigation:** Endoanal ultrasound **Gold standard:** Surgical exploration	**External anal sphincter defects** Sensitivity Specificity Positive predictive value Negative predictive value Prevalence **Internal anal sphincter defects** Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 100 100 NR NR 52% 100 95.5 NR NR 50%	**Funding:** NR

Ultrasonography continued

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Rociu et al, 1999[53] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** Consecutive non-selected women with faecal incontinence who underwent surgical repair of the sphincter. **Cause of FI:** Childbirth (19 patients), anorectal surgery (2 patients), sexual assault (1 patient). **All patients** **N:** 22 **N with FI:** 22 **Age (median):** 49 **M/F:** 0/22 **Dropouts:** 0	**Assessment tool under investigation:** endoanal ultrasound **Gold standard:** Surgical diagnosis	**Demonstration of damage to external anal sphincter** Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 NR NR 83 25 82%	**Limitations:** unclear if outcomes demonstration of damage to internal and anal sphincter are calculated with MRI (not surgery) as gold standard.
			Demonstration of defect to external anal sphincter Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 85 78 85 78 59%	
			Demonstration of scarring to external anal sphincter Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 100 94 80 100 18%	
			Demonstration of thinning to external anal sphincter Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 0 100 0 91 9%	

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
			Demonstration of normal external anal sphincter		
			Sensitivity	33	
			Specificity	85	
			Positive predictive value	25	
			Negative predictive value	89	
			Prevalence	14%	
			Demonstration of damage to internal anal sphincter		
			Sensitivity	NR	
			Specificity	NR	
			Positive predictive value	86	
			Negative predictive value	38	
			Prevalence	64%	
			Demonstration of defect to internal anal sphincter		
			Sensitivity	83	
			Specificity	80	
			Positive predictive value	83	
			Negative predictive value	80	
			Prevalence	55%	
			Demonstration of scarring to internal anal sphincter		
			Sensitivity	100	
			Specificity	100	
			Positive predictive value	100	
			Negative predictive value	100	
			Prevalence	5%	
			Demonstration of thinning to internal anal sphincter		
			Sensitivity	20	
			Specificity	100	
			Positive predictive value	100	
			Negative predictive value	81	
			Prevalence	23%	

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
			Demonstration of normal internal anal sphincter		
			Sensitivity	75	
			Specificity	72	
			Positive predictive value	38	
			Negative predictive value	93	
			Prevalence	18%	
			Sphincter injury – using video pictures		
			Sensitivity	100%	
			Specificity	NR	
			Positive predictive value	NR	
			Negative predictive value	NR	
			Prevalence	100%	
			Sphincter injury – using static pictures limited to the distal 1.5cm of the anal canal		
			Sensitivity	100%	
			Specificity	NR	
			Positive predictive value	NR	
			Negative predictive value	NR	
			Prevalence	100%	

Ultrasonography continued

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Sentovich et al, 1998[57] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** Incontinent women with probable sphincter injury. **Cause of FI:** NR **All patients** **N:** 62 **N with FI:** 22 **Age (median): NR** **M/F:** 0/62 **Dropouts:** 0	**Assessment tool under investigation:** Transanal ultrasound **Gold standard:** Surgery – all incontinent women underwent subsequent sphincteroplasty and thus had operatively verified anal sphincter injury.	**Sphincter injury – using static pictures** Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 100% NR NR NR 100%	**Funding:** NR **Limitations:** Not possible to calculate the 'two by 'two' table and specificity was not recorded. **Additional outcomes:** Agreement between sonographers. **Notes:** data extracted from incontinent patient group only. Possible to calculate specificity only by including data from continent patients. TAUS gave false positives in these groups.

Ultrasonography continued

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Frudinger et al, 1997[58] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** **Cause of FI:** **All patients** **N:** 48 **N with FI:** 36 **Age (median):** 41.3 **M/F:** 0/48 **Dropouts:** 3	**Assessment tool under investigation:** Transvaginal endosonography **Gold standard:** Transanal endosonography	**Internal Sphincter Defects** Sensitivity Specificity Positive predictive value Negative predictive value Prevalence **External Sphincter Defects** Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 44% 96% 88% 72% 40% 48% 88% 77% 66% 47%	**Funding:** Austrian Ministry of Science, Research and Arts. **Limitations:** NR **Additional outcomes:** NR **Notes:** Not all patients were faecally incontinent, and results were not divided up to give prevalence among this group. Therefore the findings do not reflect sensitivity or specificity in incontinent patients.

Evidence Table 15: Are any investigation techniques better than others in the assessment of patients with faecal incontinence?

Study details	Patients	Diagnostic tools	Measure of Disorder	Results	Comments
Buch et al, 1998[59] **Study design:** Diagnostic study A Retrospective **Evidence level:** III **Duration of follow-up:** NR	**Patient group:** Patients with faecal incontinence at least monthly. **Cause of FI:** Sphincter muscle defect or pundendal neuropathy confirmed by electrophysiological study, excluding patients with altered rectal distensibility (inflammatory bowel disease, rectal tumours etc) isolated alterations in evacuation rhythm, diabetes and patients with neurological or systemic disease. **All patients** **N:** 191 **N with FI:** 106 **Age (mean):** NR **M/F:** NR **Dropouts:** NA **Sub-group: Patients with FI** **N:** 106 **N with FI:** 106 **Age (mean):** 51.3 **M/F:** 28/ 78 **Dropouts:** NR	**Assessment tool under investigation:** digital examination **Gold standard:** manometry	**Anal tone at rest** Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence **Anal tone at squeeze** Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 92% 31% 86% 45% NR 94%% 44% 88% 39% NR	**Funding:** NR **Limitations:** Unclear if the outcomes were calculated using the results from all 3 patient groups. **Additional outcomes:** See below **Notes:** Healthy controls and patients with constipation were recruited into groups 2 and 3. Patient's groups were compared to correlate results for other outcomes.

Are any investigations better than others continued

Study details	Patients	Diagnostic tools	Measure of Disorder	Results	Comments
Hill et al, 1994[60] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NR	**Patient group:** patients with idiopathic faecal incontinence **Cause of FI:** idiopathic **All patients** **N:** 237 **N with FI:** 237 **Age (mean):** 54.8 **M/F:** 27/210 **Dropouts:** NR	**Assessment tool under investigation:** digital examination **Gold standard:** anal manometry	**Leakage** Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 98.8% 11.2% 50.8% NR NR	**Funding:** NR **Limitations:** Not possible to calculate the 'two by 'two' table and prevalence was not recorded. **Notes:** Unclear if clinical accuracy reported relies on history, general examination and anorectal examination or anorectal examination alone.
			Gaping anus Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 73.0% 80.7% 80.7% NR NR	
			Resting tone Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 95.8% 51.4% 66.7% NR NR	
			Incontinence en route Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 72.6% 47.8% 80.3% NR NR	
			Anorectal angle Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 73.0% 51.3% 79.3% NR NR	

Study details	Patients	Diagnostic tools	Measure of Disorder	Results	Comments
			Voluntary contraction Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 94.3% 42.9% 80.6% NR NR	

Are any investigations better than others continued

Study details	Patients	Diagnostic tools	Measure of Disorder	Results	Comments
Frudinger et al, 1997[58] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** consecutive women with a history of forceps assisted delivery. **Cause of FI:** NR **All patients** **N:** 48 **N with FI:** 36 **Age (median):** 41.3 **M/F:** 0/48 **Dropouts:** 3 3 patients had inadequate transvaginal images and were excluded from the calculations	**Assessment tool under investigation:** Transvaginal ultrasonography **Gold standard:** Transanal ultrasonography	**Internal sphincter defect** Sensitivity Specificity Positive predictive value Negative predictive value Prevalence **External sphincter defect** Sensitivity Specificity Positive predictive value Negative predictive value Prevalence	 44% 96% 88% 72% 18/45 (40%) 48% 88% 77% 66% 21/45 (47%)	**Funding:** Austrian Ministry of Science, Research and Arts

Are any investigations better than others continued

Study details	Patients	Diagnostic tools	Measure of Disorder	Results	Comments
Keating et al, 1997[10] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** patients with a diagnosis of faecal incontinence **Cause of FI:** neuropathy 50 patients, external sphincter disruption 7 patients, internal sphincter disruption 7 patients, full thickness rectal prolapse 5 patients, haemorrhoids/ local anus causes 5 patients, rectocele 4 patients, other causes 4 patients. **All patients** **N:** 50 **N with FI: 50** **Age (mean):** NK **M/F:** NK **Dropouts:** NR	**Assessment tool under investigation:** clinical assessment **Gold standard:** anal ultrasound, anal manometry, external sphincter electromyography and defecating proctography.	**Anorectal angle** Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 86% 97% NR NR NR	**Funding:** NR **Limitations:** Not possible to calculate the 'two by 'two' table and prevalence was not recorded. **Additional outcomes:** Variations or provisional management plan based on the history and examination from the final plan. **Notes:** Unclear if 'clinical assessment' refers to history, general examination and anorectal examination or anorectal examination alone.
			External sphincter disruption Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 93% 94% NR NR 7 (14%)	
			Internal sphincter disruption Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 64% 100% NR NR 7/ 50 (14%)	
			Rectal prolapse Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 100% 96% NR NR 5 (10%)	
			Haemorrhoids/ local anus causes Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 90% 100% NR NR 5/50 (10%)	

Study details	Patients	Diagnostic tools	Measure of Disorder	Results	Comments
			Rectocele Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 100% 97% NR NR 4/50 (8%)	

Are any investigations better than others continued

Study details	Patients	Diagnostic tools	Measure of Disorder	Results	Comments
Eckardt et al, 1993[61] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NR	**Patient group:** Patients with constipation or incontinence **All patients** **N:** 64 **N with FI:** 40 **Age (mean):** NR **M/F:** NR **Dropouts:** NR	**Assessment tool under investigation:** digital examination **Gold standard:** anorectal manometry	**External anal sphincter dysfunction** Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 84% 57% NR NR NR	**Funding:** NR **Limitations:** Not possible to calculate the 'two by 'two' table and prevalence was not recorded. **Additional outcomes:** Sensitivity and specificity of digital examination in diagnosing an incompetent interval anal sphincter, using observations in 'normal persons as gold standard. **Notes:** 24 patients were constipated and included in the analysis.

Evidence Table 16: Which combinations of tests effectively select patients with faecal incontinence for treatment strategies?

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Keating et al, 1997[10] **Study design:** Diagnostic study A **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** patients with a diagnosis of faecal incontinence **Cause of FI:** neuropathy 50 patients, external sphincter disruption 7 patients, internal sphincter disruption 7 patients, full thickness rectal prolapse 5 patients, haemorrhoids/ local anus causes 5 patients, rectocele 4 patients, other causes 4 patients. **<u>All patients</u>** **N:** 50 **N with FI: 50** **Age (mean):** NK **M/F:** NK **Dropouts:** NR	**Assessment tool under investigation:** clinical assessment **Gold standard:** anal ultrasound, anal manometry, external sphincter electromyography and defecating proctography.	**Anorectal angle** Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 86% 97% NR NR NR	**Funding:** NR **Limitations:** Not possible to calculate the 'two by 'two' table and prevalence was not recorded. **Additional outcomes:** Variations or provisional management plan based on the history and examination from the final plan. **Notes:** Unclear if 'clinical assessment' refers to history, general examination and anorectal examination or anorectal examination alone.
			External sphincter disruption Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 93% 94% NR NR 7 (14%)	
			Internal sphincter disruption Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 64% 100% NR NR 7/ 50 (14%)	
			Rectal prolapse Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 100% 96% NR NR 5 (10%)	
			Haemorrhoids/ local anus causes Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 90% 100% NR NR 5/50 (10%)	

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
			Rectocele Sensitivity Specificity Positive predictive value (PPV) Negative predictive value (NPV) Prevalence	 100% 97% NR NR 4/50 (8%)	
		Assessment tool under investigation: clinical assessment **Gold standard:** clinical assessment + anal ultrasound, anal manometry, external sphincter electromyography and defecating proctography.	**Total number of variations of provisional management plan based on the history and exam vs final management plan:**	16/50 (32%)	
			Clinician unable to formulate a management plan without physiology	3/50 (6%)	
			Repair of prolapse incorrectly advised for neuropathic patient	3/50 (6%)	
			Patient not offered anoplasty for keyhole deformity	2/50 (4%)	
			Rectocele repair incorrectly advised for internal sphincter defect	1/50 (2%)	
			Rectocele repair incorrectly advised for neuropathic patient	1/50 (2%)	
			Rectocele repair incorrectly advised for patient with irritable bowel syndrome	1/50 (2%)	
			External sphincter defect not repaired	1/50 (2%)	
			Significant neuropathy not treated	1/50 (2%)	
			External sphincter repair advised for patient with internal sphincter defect	1/50 (2%)	

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
			Biofeedback offered to patient with prolapse	1/50 (2%)	
			Excess alcohol intake not addressed	1/50 (2%)	

Which combination of tests effectively select patients for tests continued

Study details	Patients	Diagnostic tools	Measure of Disorders	Results	Comments
Liberman et al, 2001[62] **Study design:** before/ after **Evidence level:** III **Duration of follow-up:** NA	**Patient group:** consecutive patients with faecal incontinence. **Cause of FI:** NR **All patients** **N:** 95 **N with FI:** 95 **Age (mean):** 51 **M/F:** 6/ 84 **Dropouts:** 5	**Assessment tool under investigation:** interview and examination **Gold standard:** interview and examination + physiologic testing with transanal ultrasound, pudendal nerve terminal motor latency and anorectal manometry	**Total number of patients with a change in management plan**	9/90 (10%)	**Funding:** NR **Limitations:** **Additional outcomes:** Comparisons of the results of tests between the medical and surgical patient groups.
			Number of patients within medical management group changing to surgical management	5/45 (11%)	
			Number of patients within the surgical group changed from surgical to medical therapy	3/45 (7%)	
			Number of patients changing form sphincteroplasty to neosphincter procedure	1/45 (2%)	

Evidence tables for chapter 7: specific groups

Evidence Table 17: What procedures are effective in patients with limited mobility and faecal incontinence?

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Schnelle et al, 2002[34] and Schnelle et al,2003[33] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** Base line period 6 months and intervention period 8 months.	**Patient group:** Incontinent long stay nursing home residents. **Cause of FI:** NR **All patients** **N:** 190 **N with FI:** NR **Age (mean):** NR **M/F:** NR **Dropouts:** 43 (data not available at 32 weeks assessment). **Group 1** **N:** 92 **N with FI:** NR **Age (mean):** 87.3 ± 8 **M/F (%):** 20/80 **White** (%): 90 **Ambulatory**: 60% **LOS** in nursing home, years, mean ± SD: 2.1± 2.6 **Dropouts:** 19 **Group 2** **N:** 98 **N with FI:** NR **Age (mean):** 88.6 ± 6.7 **M/F(%):** 10/90 **White** (%): 90 **Ambulatory**: 63% **LOS** in nursing home, years, mean ± SD: 2.4± 2.6 Dropouts: 24	**Group 1** Low intensity, functionally orientated exercise and incontinence caser provided every two hours from 8am to 4pm for five days a weeks for eight months. Residents encouraged to walk or, if non-ambulatory, to wheel their chairs to repeat sit to stands up to eight times using the minimum level of human assistance possible. During one care episode per day each resident was given upper body resistance training (arm curls or arm raises) usually while in bed. Before and after each care episode, residents were offered fluids. **Group 2** Usual care.	**Faecal incontinence frequency:**	**Pre-intervention:** **Group 1 (n=73):** 7%±10 **Group 2 (n=74):** 6% ± 11 **Post 32 weeks:** **Group 1 (n=73):** 3%± 8 **Group 2 (n=74):** 7% ± 10 P<0.05	**Funding:** National Institutes of Health. **Limitations:** UI and FI participants. Unclear how many were FI patients at baseline. **Additional outcomes:** 13 other outcomes favouring intervention reported. Cost also considered.
			Appropriate faecal toileting ratio (ratio calculated by dividing number of times resident used a toilet or toilet substitute by the total number of voids)	**Pre-intervention:** **Group 1 (n=73):** 17%± 33 **Group 2 (n=74):** 31% ± 43 **Post 32 weeks:** **Group 1 (n=73):** 73%± 35 **Group 2 (n=74):** 28% ± 36 P<0.01	

Evidence Table 18: What treatments are effective in patients or residents in care homes with faecal incontinence related to faecal loading, impaction or constipation?

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Chassagne et al, 2000[63] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 8 weeks	**Inclusion criteria:** Long term care residents aged 65 years or older with faecal incontinence and impaired rectal emptying. 130 participants cognitively impaired 117 participants with a history of impaction **Frequency of FI**: > once/day: 76 > once/week: 91 not reported: 11 **Duration of FI:** <6 months: 48 6-24 months: 37 >24 months: 93 **Group 1: N:** 104 **N after 1 week:** 85 **N after 5 weeks:** 62 **N after 8 weeks:** 62 **Age (mean):** 84.7 years **M/F:** 17/68 **Dropouts by week 5**: 23 **Dropouts by week 8**: 23 **Group 2: N:** 102 **N after 1 week:** 93 **N after 5 weeks:** 61 **N after 8 weeks:** 39 **Age (mean):** 85.9 years **M/F:** 16/77 **Dropouts by week 5**: 32 **Dropouts by week 8**: 54	**Group 1** 30g/day single osmotic laxative (lactulose) PLUS daily glycerine suppository AND a tap-water enema once/week for 8 weeks **Group 2** 30g/day of a single osmotic laxative (lactulose) for 8 weeks	Mean (SD) no. of faecal incontinence episodes per patient (loss of faeces)	**Group 1**: 24 ±10.8 (n=62) **Group 2**: 24 ±11.5 (n=61) not significant	**Notes:** all outcomes reporte at week 5 **Funding:** Solvay Pharma Laboratories **Limitations:** High dropout: 28 were excluded before the end of the first week. 19 because of severe diarrhoea 1 died and 8 refused to participate. Between week 1 and week 5 of the study 55 participants dropped out: death (10), diarrhoea (10) missed follow-up (35). Significantly more of the 35 who missed the follow up we in group 2. At week 8 a further 22 participants had dropped ou all from group 2
			Total no. of faecal incontinence episodes (loss of faeces)	**Group 1**: 1492 (n=62) **Group 2**: 1461 (n=61) not significant	
			Mean (SD) no. of faecal incontinence episodes per patient (soiling)	**Group 1**: 12 ±12.7 (n=62) **Group 2**: 12 ± 9.9 (n=61) not significant	
			Total no. of faecal incontinence episodes (soiling)	**Group 1**: 766 (n=62) **Group 2**: 702 (n=61) not significant	
			Mean (SD) no. of soiled items (bedding and/or clothing)	**Group 1**: 78 ±20.7 (n=62) **Group 2**: 80 ±60.1 (n=61) not significant	
			No. of soiled items (bedding and/or clothing)	**Group 1**: 4843 (n=62) **Group 2**: 4881 (n=61) not significant	
			No. of incidents of loss of faeces per day per patient	**Group 1**: 0.84 (n=62) **Group 2**: 0.85 (n=61) not significant	
			No. of incidents of loss of changes of bedding or clothing per day per patient	**Group 1**: 2.8 (n=62) **Group 2**: 2.9 (n=61) not significant	

Faecal loading related faecal incontinence continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Tobin and Brocklehurst, 1986[64] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 2 months	**Patient group**: 52 patients were randomly selected from a list of patients with FI from 30 residential care homes. A further 30 patients with FI were selected from the remaining patients on the list as controls. **Cause of FI:** NR **Patients** **N:** 82 **N with FI:** 82 **Age (mean):** NR **M/F:** 22/60 **Dropouts:** 9 **Group 1** **N:** 52 **N with FI:** 52 **Age (mean):** 82.3 **M/F:** 14/38 **Dropouts:** 7 **Group 2** **N:** 30 **N with FI:** 30 **Age (mean):** 81.4 **M/F:** 8/22 **Dropouts:** 2 There was no significant difference between study and control residents in age or sex	**Group 1** FI patients from residential care homes. Allocated to two groups for treatment based on cause of FI: (a) diagnosed as being incontinent of faeces secondary to faecal impaction (n=27). Treatment included daily enemas until no response and lactulose twice daily and then weekly enema (b) Idiopathic FI patients (n=25) - treated with codeine phosphate and then given two enemas per week **Group 2** Control group with FI where no recommendation was given for treatment .	**Number of patients (%):** No longer incontinent: Incontinent less than once/week: Incontinent equal to or more than once a week:	**Group 1 (n=45):** 27(60%) **Group 2(n=28):** 9 (32%) **Group 1(n=45):** 2 (4.4%) **Group 2(n=28):** 4 (14.3%) **Group 1(n=45):** 16 (35.6%) **Group 2(n=28):** 15 (53.6%) **Significance:** $\chi^2(2)=6.07$ P=0.047 **Fishers Exact = 0.048**	**Funding:** Grant from the North West Regional Health Authority **Limitations:** Different care homes so treatment received (excluding medical intervention) may differ between patients. **Additional outcomes:** Impaction vs idiopathic outcomes of no longer incontinent, incontinence less than once/week and more than once/week (NS) **Notes:** Dropouts due to death or admission to hospital.
			Patients in who full compliance obtained: No longer incontinent: Incontinent less than once/week: Incontinent equal to or more than once a week:	**Group 1(n=30):** 26 (86.6%) **Group 2(n=28):** 9 (32.0%) **Group 1(n=30):** 1 (3.3%) **Group 2(n=28):** 4 (14.3%) **Group 1(n=30):** 3 (10.0%) **Group 2(n=28):** 15 (53.6%) **Significance:** $\chi^2(2)=18$ P=0.001	

Evidence tables for chapter 6: surgery

Evidence Table 19: Is surgery effective and does it last compared to no surgery?

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
O'Brien et al 2004[65] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 6 months	**Patient group**: Adults with severe faecal incontinence **Cause of FI:** 4 in the intervention group and 5 in comparison group had post-obstetric incontinence. 2 in each group had anal surgery before onset of incontinence. 1 patient in each group had apparent neurological lesion with prolonged pudendal nerve latency. 2 patients in each group had direct sphincter repair and one had post anal repair **<u>All patients</u>** **N:** 14 **N with FI:** 14 **Age :** 44 - 75 **M/F:** 1/ 13 **Dropouts:** 0 **<u>Group 1</u>** **N:** 7 **N with FI:** 7 **Age (mean):** 59 (44-75) **M/F:** 1/6 **Dropouts:** 0	**Group 1:** Placement of artificial bowel sphincter (Acticon neosphincter) **Group 2:** Supportive care. Patients were provided with a program of advice and supervision with respect to optimal conservative management. This included physiotherapy for pelvic floor/ anal sphincter muscle rehabilitation, which may include biofeedback, electrical stimulation and defecation retraining. There was a judicious use of laxatives, bulking agents and antidiarrhoeals and use of aids and appliances to maintain firm consistency of stool and minimise impact of incontinence episodes.	**Cleveland continence score -mean (SD)** [Scale: 0-20; 0- perfect control and 20 – total incontinence]	**Baseline:** **Group1:** 19 (1.2) **Group 2:** 17.4 (2.3) **6 months post-op:** **Group1:** 4.8 (4.0) **Group 2:** 14.3 (4.6) **p value =** 0.002	**Funding:** Supported by a grant from the Australian Governments department of health and ageing **Limitations:** Small sample size **Additional outcomes:** NR **Notes:** Beck depression inventory mean and SF-36 scales not described.
			American medical systems QOL score -mean (SD) [Scale: 0-100; 0 – worst and 100 – best result]	**Baseline:** **Group1:** 38.8 (6) **Group 2:** 42.5 (22) **6 months post-op:** **Group1:** 82.7 (14) **Group 2:** 54.7(26) **p value =** 0.04	
			SF – 36 physical component summary - mean (SD) [Scale: 0-100]	**Baseline:** **Group1:** 37 (10) **Group 2:** 41.6 (13) **6 months post-op:** **Group1:** 45 (7) **Group 2:** 41(11) **p value =** 0.43	
			SF – 36 mental component summary -mean (SD) [Scale: 0-100]	**Baseline:** **Group1:** 45 (9) **Group 2:** 40.3 (10) **6 months post-op:**	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Group 2 **N:** 7 **N with FI:** 7 **Age (mean):** 66 (46-75) **M/F:** 0/7 **Dropouts:** 0			**Group1:** 52 (4) **Group 2:** 44.4(5) **p value =** 0.02	
			Beck depression inventory-mean (SD) [Scale: 0-100]	**Baseline:** **Group1:** 10.8 (9) **Group 2:** 7.3 (2) **6 months post-op:** **Group1:** 6.8 (9) **Group 2:** 0.3 (10) **p value =** 0.65	
			Number of patients with perioperative complications (Failed surgery)	**Group1:** 3 **Group 2:** 0	

Surgery vs no surgery continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Osterberg et al, 2004[50] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up** (mean): 3, 12 and 24 months	**Patient group:** Patients with neurogenic disabling FI and no sphincter defect, rectal prolapse or intra-anal intussusception. **Cause of FI:** NR **All patients** **N:** 59 **N with FI:** 59 **Age (median):** 66 **M/F:** 7/52 **Dropouts:** N **Group 1** **N:** 31 **N with FI:** 31 **Age (mean):** 68 (52-80) **M/F:** 2/29 **Dropouts:** NR **Group 2** **N:** 28 **N with FI:** 28 **Age (mean):** 64 (43-81) **M/F:** 5/23 **Dropouts:** NR	**Group 1:** Anterior Levatorplasty (post anal repair for men) **Group 2** Anal plug electrical stimulation of the pelvic floor	**Improvement in incontinence** (number of patients) **at 3 months**	**Group1:** 28 **Group 2:** 19 **p value**=0.032	**Funding:** Study supported by the Swedish research council **Limitations:** The physical and social handicap was assessed by asking yes/no question. **Additional outcomes:** NR **Notes:** Visual analogue scale not described. The bowel function questionnaire included 49 questions relating to FI, constipation and general symptoms. Based on the answers given an evaluation was performed according to Miller's incontinence score system (0- total continence and 18 (maximum incontinence)
			Improvement in incontinence (number of patients) **at 12 months**	**Group1:** 28 **Group 2:** 22 **p value**=0.210	
			Improvement in incontinence (number of patients) **at 24 months**	**Group1:** 26 **Group 2:** 19 **p value**=0.149	
			Less use of pads (number of patients) **at 3 months**	**Group1:** 14 **Group 2:** 9 **p value**=0.306	
			Less use of pads (number of patients) **at 12 months**	**Group1:** 17 **Group 2:** 9 **p value**=0.078	
			Less use of pads (number of patients) **at 24 months**	**Group1:** 15 **Group 2:** 8 **p value**=0.119	
			Improvement in physical handicap (number of patients) **at 3 months**	**Group1:** 18 **Group 2:** 6 **p value**=0.004	
			Improvement in physical handicap (number of patients) **at 12 months**	**Group1:** 23 **Group 2:** 7 **p value**=0.001	
			Improvement in physical handicap (number of patients) **at 24 months**	**Group1:** 20 **Group 2:** 6 **p value**=0.001	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Improvement in social handicap (number of patients) **at 3 months**	**Group1:** 20 **Group 2:** 8 **p value**=0.006	
			Improvement in social handicap (number of patients) **at 12 months**	**Group1:** 23 **Group 2:** 10 **p value**=0.003	
			Improvement in social handicap (number of patients) **at 24 months**	**Group1:** 17 **Group 2:** 8 **p value**=0.041	
			Deferring time, loose stool, median (range) score on visual – analogue scale (see notes section) **at 3 months**	**Group1:** 15 (0-35) **Group 2:** 11 (0-55) **p value**=0.731	
			Deferring time, loose stool, median (range) score on visual – analogue scale (see notes section) **at 12 months**	**Group1:** 22 (0-32) **Group 2:** 13(0-70) **p value**=0.431	
			Deferring time, loose stool, median (range) score on visual – analogue scale (see notes section) **at 24 months**	**Group1:** 14 (0-36) **Group 2:** 10 (0-54) **p value**=0.582	
			Deferring time, solid stool, median (range) score on visual – analogue scale at 3 months	**Group1:** 32 (0-73) **Group 2:** 25 (0-100) **p value**=0.114	
			Deferring time, solid stool, median (range) score on visual – analogue scale at 12 months	**Group1:** 34 (0-58) **Group 2:** 33 (0-98) **p value**=0.295	
			Deferring time, solid stool, median (range) score on visual – analogue scale at 24 months	**Group1:** 30 (0-49) **Group 2:** 27 (0-88) **p value**=0.317	
			Morbidity (number of patients):	**Group1:** 1(wound	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				infection) **Group 2:** 1(burning sensation in vagina)	

Surgery vs no surgery continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Leroi et al, 2005[66] **Study design:** Randomised cross-over trial **Evidence level:** 1+ **Duration of follow-up:** 3 months	**Patient group:** Patients with faecal incontinence to solid or liquid stools (or urgency episodes causing patients to remain at home to avoid incontinence accidents) at least once per week, documented on a prospectively recorded diary card, for at least 3 months. Conservative methods had failed in all patients. **Cause of FI:** idiopathic (n=18), pudendal neuropathy (n=14), post-operative IAS fragmentation (n=1), primary IAS degeneration (n=1). **<u>All patients</u>** **N:** 34 **N with FI:** 34 **Age (median):** 57 **M/F:** 3/31 **Drop outs:** 10 7 patients dropped out before the cross over period and 3 during the final period. The two main reasons for discontinuation were device related adverse events (4 device explanations, 3 for unresolved pain and 1 for recurrent infection) and protocol violation (patients used the handheld programmer).	**Post implantation period** Each patient had a 1-3 month phase when the stimulator was turned 'on' to optimise effectiveness of stimulation by determining most effectiveness parameters of stimulation for each patient. **Cross over period** Patients were randomised to 'on' or 'off' stimulation for the first one month period. At the end of the first period, the neurostimulator was programmed to the opposite mode 'on' or 'off' and monitoring continued for the second month. There was no interval between the treatment periods. **Final period** At the end of the second period, patients chose which period of stimulation they preferred and the neurostimulator was programmed accordingly	**Median frequency of FI episodes per week during cross over period**	**Baseline:** 7 (range 0-17) **Post-implantation:** 0.8 (range 0-10) **Stimulation 'on':** 0.8 (range 0-11) **Stimulation 'off':** 1.9 (range 0-11) **Baseline vs post implantation period:** <0.05 **'On' vs 'off':** 0.03 **Baseline vs 'on':** 0.0003 **Baseline vs 'off':** 0.001 **post implantation period vs 'on':** <0.05	**Funding:** Medronic **Limitations:** Possibility of contamination from post implantation period and 'on' phase of cross over period. **Additional outcomes:** Delay in postponing defecation, frequency of urgency episodes, number of bowel movements per week, duration of voluntary contraction. **Notes:** Patients with external anal sphincter damage on ultrasound were included in the study if the defect was not considered to be the main cause of FI (i.e. limited defect ≥30° or limited to 1 part, superficial, middle or deep part, of the external anal sphincter. All patients had at least a demonstrable
			Cleveland continence score during cross over period	**Baseline:** 16 (range 8-20) **Post-implantation:** 9 (range 0-19) **Stimulation 'on':** 8.5 (range 3-18) **Stimulation 'off':** 10.5 (range 4-17) **Baseline vs post implantation period:** 0.0002 **'On' vs 'off':** 0.2 **Baseline vs 'on':** 0.0005 **Baseline vs 'off':** 0.0004	
			Number of patients who felt they had improved during cross over period	**Baseline:** **Post-implantation:** **Stimulation 'on':** 24/ 27 (89% **Stimulation 'off':** 17/ 27 (63%) Four patients (0.1%) could not decide if they had improved or not (3 during the 'off' period and 1 during the 'on' period) **p value:** 0.02	
			Number of patients who expressed a preference for a specific stimulation period during cross over period	**Baseline:** **Post-implantation:** **Stimulation 'on':** 18/27 **Stimulation 'off':** 6/ 27 Three patients had no preference **p value:** 0.02	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
		for the final period (3 months). If the patient could not choose 1 of the 2 periods, the stimulator was turned on.	**Maximum anal resting pressure**	**p value:** Not sig	unilateral bulbo(clitorido)-cavernosus reflex, indicating existing conducting pathways between the sacral plexus and the pelvic floor. All patients underwent temporary percutaneous stimulation to assess their probable response to treatment. Patients received either a temporary percutaneously placed test stimulation lead or by placement of a permanent quadripolar lead, both of which were connected to an external pulse generator. All patients were tested for between 8 and 15 days. All patients fulfilled the necessary criteria for permanent implantation which was a 50% reduction in the number of episodes of incontinence per week and or 50% reduction in number of urgencies per week.
			Squeeze pressure increment	**p value:** Not sig	

Surgery vs no surgery continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Vaizey et al, 2000[67] **Study design:** Cross-over study **Evidence level:** 1+ **Duration of follow-up:** 4 weeks	**Patient group:** patients with passive faecal incontinence. One patient had a three year history of passive faecal leakage which occurred more than once per day. Ultrasound showed an intact, normal external sphincter and an intact but very thin internal anal sphincter. The second patient had two and a half year history of passive faecal leakage occurring more than three times per week. Ultrasound showed an intact, normal external sphincter and a thin, hyperchoic internal sphincter. **Cause of FI:** One patient had a weak internal sphincter secondary to scleroderma. The second patient was a 61 year old female with a weak internal sphincter caused by primary internal sphincter degeneration. **All patients** **N:** 2 **N with FI:** 2 **Age (mean):** 63 **M/F:** 0/2 **Drop outs:** 0	**Post-implantation period:** both patients had been implanted with permanent sacral electrodes and a stimulator for 9 months to ensure that the clinical benefit was maintain in the medium term and so that he optimal stimulation parameters for each patients had been determined. **Test period:** the study consisted of two two-week treatment periods. Patients had their stimulators turned 'on' or 'off' for a two week period. After two weeks, patients had their stimulators changed to the opposite setting. There was no interval between the treatment periods.	**Median episodes of incontinence of solid or liquid stool during two weeks**	**Pre-stimulation:** 15 **Stimulation off:** 12 **Stimulation on:** 1 **P-value:** NR	**Funding:** Medtronic INTERSTIM **Limitations:** Previous treatment had shown that continence was maintained with the stimulation parameters set below the sensory threshold. Also possibility of contamination from 9 month post-implantation period. **Additional outcomes:** Episodes of faecal incontinence, maximum resting and squeeze anal pressures, rectal sensation to distension, threshold/ urge/ maximum-tolerated volumes reported and SF-36 scale were reported individually for both patients.

Surgery vs no surgery continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Tillin et al, 2005[68] **Study design:** Non randomised controlled trial **Evidence level:** 2+ **Duration of follow-up:** 24 months.	**Patient group:** patients with stomas or refractory FI undergoing dynamic graciloplasty at the royal London Hospital between April 1997 and December 2002. **Cause of FI:** anorectal agenesis, previous surgery, neurogenic causes or idiopathic. **Intervention** **N:** 48 **N with FI:** NR **Age (mean):** 42 (15-71) yrs **M/F:** 12/36 **Dropouts:** 9 **Comparison** **N:** 40 **N with FI:** NR **Age (mean):** 10/30 **M/F:** 49 (16-81) yrs **Dropouts:** 5 (not returned questionnaires)	**Intervention:** Dynamic graciloplasty **Comparison:** Usual care (not offered surgery). **Analysis periods for outcomes:** Intervention: pre-op and 24 months post op (up to 5 years follow-up) Comparison: baseline and 24 months post-baseline.	**Mean changes of Cleveland Incontinence score at 24 months** (0-20; 20 being the worst)	**Int (n=17):** +24 (CI: +11 to +37) **Cont (n=13): -**8 (CI: -19 to +3) **p value:** 0.001	**Funding:** National Specialist Commissioning Advisory group. **Additional outcomes:** Success rates of intervention over time of study (non-comparative). Frequency of incontinence and evacuation difficulties for intervention group. Patient's opinions of success of surgery were reported. Changes in health status, pain scale, social isolation, anxiety and psychosocial scales were compared between groups from postoperatively to 24 month follow-up. Analyses excluding atresia patients and cancer patients. Comparisons of patients with preoperative stomas versus non-stoma patients. Secondary outcomes also measured were health status visual analogue scale, emotional reaction scale, energy scale, physical mobility scale, sleep scale, bowel-specific questionnaire item 'effect on my sex life' and general satisfaction with life. Comparison of outcomes for intervention patients with patients that underwent dynamic graciloplasty at 3
			Mean changes in HADS depression (HADS defined as Hospital Anxiety and Depression Scale)	**Int (n=17):** +6.0 (CI: -3 to +15) **Cont (n=13):** -4 (CI: -8 to +1) **p value=** 0.05	
			Mean changes in Royal London Hospital lifestyle scale	**Int (n=17):** +31 (CI: +19 to +43) **Cont (n=13):** -3 (CI: -11 to +5) P<0.0001	
			Complications	Intervention: Evacuations difficulties or pain (n=33), and infective (n=31) or circuitry problems (n=23) after primary treatment. Following completion of primary treatment admissions to hospital resulted in an average of 20 impatient bed days per patient during follow-up period.	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
					Northern UK centres. These additional patients did not have preoperative data. **Notes:** Outcome comparisons of 24 month follow-up but intervention also assessed at 36 months postoperatively.

Evidence Table 20: Are any surgical interventions more effective than others?

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Oya et al, 1994[69] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up** (mean): 24 months	**Patient group**: Female patients with neuropathic faecal incontinence and a history of obstetric trauma. **Cause of FI:** Post obstetric incontinence. **<u>All patients</u>** **N:** 36 **N with FI:** 36 **Age :** NR **M/F:** 0/ 36 **Dropouts:** NR **<u>Group 1</u>** **N:** 12 **N with FI:** 12 **Age (mean):** NR **M/F:** 0/12 **Dropouts:** NR **<u>Group 2</u>** **N:** 12 **N with FI:** 12 **Age (mean):**NR **M/F:** 0/12 **Dropouts:** NR	**Group 1:** Total pelvic floor repair (TPFR) **Group 2:** Anterior levatorplasty (AL) **Group 3:** Post Anal repair (PAR)	**Continence of solids and liquids for more than 6 months (number of patients)**	PAR=4; AL=4; TPFR=9 PAR vs TPFR p=0.05; AL vs TPFR p=0.05	**Funding:** NR **Additional outcomes:** Other outcomes like anal canal length, pelvic floor position, perineal position, anorectal angle, change in pelvic floor position and changes in perineal position also reported. **Notes:** Patient group also reported in Deen et al, 1993[70]
			Median (range) frequency of incontinence per month	PAR= 10(0-30); AL= 2.5 (0-30; TPFR= 0 (0-12) PAR vs AL p= 0.01; PAR vs TPFR p= 0.01; AL vs TPFR p< 0.01	
			Median (range 1-7; 1 being never and 7 being always) continence score	PAR= 4(2-7); AL= 4 (1-7); TPFR= 1 (1-5) PAR vs TPFR p< 0.01; AL vs TPFR p< 0.05	
			Manometry **a) Maximum basal pressure cm H2O**	Pre- PAR: 73±11 Post-PAR: 84±9 Pre- AL: 70±9 Post-AL: 74±7 Pre- TPFR: 74±9 Post-TPFR: 85±7	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Group 3 **N:** 12 **N with FI:** 12 **Age (mean):** NR **M/F:** 0/12 **Dropouts:** NR		**Maximum squeeze pressure cm H2O**	Pre- PAR: 132±17 Post-PAR: 123±10 Pre- AL: 121±15 Post-AL: 141±17 Pre- TPFR: 136±15 Post-TPFR: 131±10	

Surgery vs surgery continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
van Tets et al, 1998[71] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 42 months	**Patient group:** Female patients with neurogenic FI treated at a surgical centre in the Netherlands between 1992-5. All patients had no control of solid stood (Type D on Browning and Parks Incontinence scoring system). **Excluded:** if had anal sphincter defect. **Cause of FI:** Neuropathic **<u>All patients</u>** **N:** 20 **N with FI:** 20 **Age (mean):** 55 (range, 34-74) yrs **M/F:** 0/20 **Dropouts:** 0 **<u>Group 1</u>** **N:** 11 **N with FI:** 11 **Age (mean):** NR **M/F:** 0/11 **Dropouts:** 0 **<u>Group 2</u>** **N:** 9 **N with FI:** 9 **Age (mean):** NR **M/F:** 0/9 **Dropouts:** 0	**Group 1** Post anal repair **Group 2** Total pelvic floor repair (combination of post anal repair, anterior levatorplasty and anterior sphincter placation).	**Continence score: (N)** (Browning and Parks Incontinence scores: Grade A=continent for solid and liquid stool, Grade B=continent for solid and liquid stool but not flatus Grade C=Continent for solid stool, no control of liquid stool/flatus Grade D=complete incontinence).	**Group1:** **Pre-operative** Grade A: 0 Grade B: 0 Grade C: 0 Grade D: 11 **Post-operative: 12 weeks** Grade A: 0 Grade B: 3 Grade C: 2 Grade D: 6 **Group 2:** **Pre-operative** Grade A: 0 Grade B: 0 Grade C: 0 Grade D: 9 **Post-operative: 12 weeks** Grade A: 0 Grade B: 2 Grade C: 1 Grade D: 6 **p value:** NS	**Funding:** NR **Limitations:** Randomisation concealment not reported. Not known if surgeons, patients or assessors were blinded to treatment received. **Additional outcomes:** Manometric and defecography results were reported for both groups pre and post-operatively. **Notes:** No significant results were found when the manometric and radiological results were compared between the two groups. Long-term follow up (mean 42 months) found deterioration of clinical results. 25% of patients who had an improvement in continence score (2 of 8 patients) after surgery became incontinent again within a few years after surgery. RCT study from the SR by Bachoo1999.
			Patients that remained incontinent after surgery: (from SR by Bachoo 1999)	**Group 1:** 6/11 (55%) **Group 2:** 6/9 (67%) **OR 0.62 (95%CI 0.11 to 3.57)**	

Surgery vs surgery continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Deen et al, 1995[72] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** Group 1 at mean 15.4 (±5.5) months. Group 2 at mean 16.8 (±4.5) months	**Patient group:** female patients with a history of prolonged or difficult vaginal delivery and neuropathic faecal incontinence, experiencing 6 or more accidents each month from one centre in the UK. Excluded: if patients had external anal sphincter defects. **Cause of FI:** Neuropathic **<u>All patients</u>** **N:** 33 **N with FI:** **Age (median):** 57.5 (range, 27-72) years **M/F:** 0/33 **Dropouts:** 0 **<u>Group 1</u>** **N:** 18 **N with FI:** 18 **Age (mean):** 57 years **M/F:** 0/18 **Dropouts:** 0	**Group 1** Total pelvic floor repair. **Group 2** Total pelvic repair with placation of internal anal sphincter.	**Median (range) hospital stay after surgery:**	**Group1:** 5 (3-10) days **Group 2:** 5 (3-7) days **p value=** 0.75	**Funding:** Supported by MRC of GB. **Limitations:** Functional scores are within group and not comparing the groups. Study does not mention whether participants, surgeons or outcome assessors were blinded. **Notes:** Group 1 were found to have a longer duration of symptoms compared to group 2. * Reported in SR (Bachoo 1999) Maximum resting anal pressure showed a statistically significant difference in favour of the total pelvic floor repair alone group after surgery, Weighted Mean Difference
			Functional length of anal canal	**Group1:** Increased: 12/18 (67%), p<0.05 Unchanged: 6/18 (33%) **Group 2:** Increased: 5/15 (33%) Unchanged: 5/15 (33%) **p>0.05 (**between groups)	
			Improvement in mean functional score: (continence quality 1-7;1=satisfactory, 7=poor)	**Group1:** 3.61 (±1.82), p<0.01 **Group 2:** 2.80 (±1.66), p<0.01 **P>0.05** (between groups)	
			Maximum resting pressure: Mean (SD)	**Group1:** Preoperatively: 94.0 (±31.72) cm H2O Postoperatively: 86.89 (±31.53) cm H2O P=0. 5 **Group 2:** Preoperatively: 80.67 (±22.2) cm H2O Postoperatively: 63.2 (±18.5) cm H2O P<0.05 *** see notes**	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Group 2 **N:** 15 **N with FI:** 15 **Age (mean):** 55 years **M/F:** 0/15 **Dropouts:** 0		**Maximum squeezing pressure:** Median (range)	**Group1:** Preoperatively: 152 (78-235) cm H2O Postoperatively: 140 72-287) cm H2O P=0.75 **Group 2:** Preoperatively: 126 (68-294) cm H2O Postoperatively: 92 (42-200) cm H2O P<0.05	(WMD) 23.69 (95% CI 6.37 to 41.0).
			Rectal capacity: Mean (SD)	**Before surgery:** **Group 1:** 203.9 (±63.1) ml **Group 2:** 175.7 (±340) ml P=0.114 **After surgery:** **Group 1:** 207.2 (±60.5) ml **Group 2:** 189 (±38.7) ml P=0.32	
			Anal mucosal electrosensitivity improvement in the upper anal canal	**Improvement in threshold sensation after surgery:** **Group 1:** 0.47 (±6.56) mA **Group 2:** 2.22 (±8.74) mA P=0.53	
			Complications:	**Group 1:** Posterior rectal wall inadvertently opened (n=1), minor wound infection (n=1). **Group 2:** There was a postoperative urinary tract infection (n=1).	

Surgery vs surgery continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Yoshioka et al, 1999[73] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** Median 10 (range 6-27) months.	**Patient group:** consecutive women with FI and history of obstetric trauma recruited between 1994-6 from one centre in UK. No evidence of sphincter damage. **Cause of FI:** post-obstetric neuropathic FI **All patients** **N:** 24 **N with FI:** 24 **Age (mean):** NR **M/F:** 0/24 **Dropouts:** 0 **Group 1** **N:** 12 **N with FI:** 12 **Age (mean):** 59.6 (30-77) **M/F:** 0/12 **Dropouts:** 0 **Group 2** **N:** 12 **N with FI:** 12 **Age (mean):** 60.36 (48-70) **M/F:** 0/12 **Dropouts:** 0	**Group 1** Total Pelvic Floor Repair **Group 2** Gluteus transposition (GMT)	**Length of hospital stay (days)**	**Group1:** 9.1 (4-16) **Group 2:** 13.0 (5-35) **p value:** NR	**Funding:** NR **Limitations:** Study does not mention whether participants, surgeons or outcome assessors were blinded. **Additional outcomes:** Subjective assessment of functional results by patients for both groups. **Notes:** No significant differences between the groups in continence score, adverse effects, mean resting anal pressure, mucosal electro-sensitivity, maximum squeeze pressure and length of high-pressure zone). * Reported in SR (Bachoo 1999)
			Cleveland Clinic Incontinence score (0-20; higher the worse)	**Group1:** Preoperatively: 13.1 ± 2.7 Postoperatively: 6.6 ± 4.5 p=0.004 **Group 2:** Preoperatively: 13.8 ± 3.8 Postoperatively: 7.7 ± 6.1 P=0.033	
			Number of patients failing to achieve full continence:	**Group1:** 5/12 **Group 2:** 4/12	
			Number of patients with no improvement in faecal urgency:	**Group1:** 5/12 **Group 2:** 3/12	
			Complications:	Group 1: Faecal impaction (n=1) Group 2: Wound sepsis (n=2) and wound haematoma (n=1).	

Surgery vs surgery continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Rongen et al, 2001[74] **Study design:** Prospective matched control study **Evidence level:** 2 **Duration of follow-up:** 521 days (mean)	**Patient group:** patients with end-stage faecal incontinence for both liquid and solid stool. Group one comprised 13 consecutive patients from a waiting list. In the same period (September 1996-June 1997) 13 patients matched for gender, age, and aetiology comprised group two. Prior incontinence surgery had been performed in group one eight times vs eight times in group two (anal repairs four times vs five times, post-anal repair twice vs once, surgery for anorectal malformations twice in both groups). Biofeedback had been given to nine vs seven patients. **Cause of FI:** trauma (n=14), idiopathic (n=8), anal atresia (4). **<u>All patients</u>** **N:** 26 **N with FI:** 26 **Age (mean):** 45.8 **M/F:** 4/ 22 **Drop outs:** NR **Mean duration of incontinence:** 15.0 years	**Group 1** One-step procedure for graciloplasty: muscle wrap, implant of the electrodes and implanted pulse generator during the same operation. **Group 2** Two-step procedure for graciloplasty: the implant was performed during a separate procedure 6 weeks after the gracilis transposition.	**Proportion of patients in which continence was achieved**	**Group1:** 11/13 (85%) **Group 2:** 9/13 (69%) **Relative risk:** **95% CI:** **p value:** Not sig	**Funding:** NR **Additional outcomes:** Defaecation frequency pre-operative, postponement defecation, amplitude, basal pressure **Notes:** In both groups stimulation was started 6 weeks after the gracilis transposition. All patients underwent the same training protocol; intermittent stimulation with an increase of actual stimulation time every 2 weeks during two months. Stimulation amplitude was adjusted until continence was achieved.
			Proportion of patients with a functional dynamic graciloplasty (measured by palpitation, anal manometry and defaecography)	**Group1:** 12/13 (92%) **Group 2:** 13/13 (100%) **p value:** Not sig	
			Quality of life (SF-36)	Not sig.	
			Quality of life (SDS)	Not sig.	
			Quality of life (STAI)	Not sig.	
			Quality of life (VAS)	Not sig.	
			Proportion of patients with failures	**Group1:** 2/ 13 (15%) Both due to infections and subsequent implant removal. **Group 2:** 4/13 (31%) One attributable to chronic diarrhoea, one due to a serious disturbance in anorectal sensation, with lack of urge. One patient due to diarrhoea secondary to evacuation problems. One patient due to anal atresia with persistent diarrhoea. **p value:** Not sig	
			Morbidity	**Group 1: one** patient had necrosis of the distal part of the wrap. One patient had a too loose wrap and persistent superficial infection located at the IPG site requiring implant removal. Three patients had evacuation difficulties after the procedure. One patient had to undergo	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Group 1 **N:** 13 **N with FI:** 13 **Age (mean):** 44.6 **M/F:** 2/ 11 **Drop outs:** NR **Mean duration of incontinence:** 15.2 years **Group 2** **N:** 13 **N with FI:** 13 **Age (mean):** 47.0 **M/F:** 2/ 11 **Drop outs:** NR			emergency resection of the sigmoid for diverticulitis. **Group 2:** one patient had urinary retention. One patient had pain at the donor site due to stimulation. One patient had pain due to periosteal reaction at the pubic bone during stimulation. Two patients had evacuation problems.	
			Hospital stay	**Group1:** 5 days **Group 2:** 8 days (5 days for transposition and 3 days for implantation)	
			Operation time	**Group1:** 94 minutes **Group 2:** 95 minutes	
			Stimulated squeeze pressure	**Group1:** 100mmHg **Group 2:** 118mmHg	
			Post-operative voluntary squeeze pressure	**Group1:** 151 mmHg **Group 2:** 146 mmHg	

Surgery vs surgery continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Tan et al, 2001[75] **Study design:** Non randomised controlled trial **Evidence level:** 2+ **Duration of follow-up:** Mean 22.4 (SD 16.1) months	**Patient group:** patients had sphincter injuries, and all patients had significant external anal sphincter injury seen on preoperative endosonography. **Cause of FI:** obstetric **All patients** **N: 50 N with FI:** NR **Age (mean):** 40.8 (SD 11.5) yrs **M/F:** 0/50 **Group 1** **N: 32 N with FI:** NR **Age (mean):** NR **M/F:** 0/32 **Group 2** **N:** 18 **N with FI:** NR **Age (mean):** NR **M/F:** 0/18	Anterior overlap anal sphincter repair was performed over a five year period. : Group 1: the first 32 patients underwent conventional perineal approach Group 2: Subsequent patients underwent surgery with a posterior fourchette approach	**Incidence of wound complication:**	**Group1:** 44% **Group 2:** 11% **p value:** <0.05	**Funding:** NR **Limitations:** Patients with rectovaginal fistula had sphincter reconstruction combined with a rectal mucosal advancement flap. 26 patients had a rectocele. 11 patients had an anterior levatorplasty. A loop colostomy was formed in three patients, who had had previous unsuccessful delayed repairs elsewhere. **Additional outcomes:** Continence scores improved post operatively in all patients except one patient who had a persistent large defect in external anal sphincter postoperatively. Age, symptoms, parity, fistula and dehiscence was not significantly different between the two groups. Minimum resting pressure, vector symmetry index, functional length and squeeze pressure had no significant different pre and post operation for both groups. The squeeze pressure increment was significantly increased after operation in both groups.
			Mean continence score (modified Pescatori incontinence score; 0-20; 0=continent)	**Group1:** Preoperatively: 15.5 Postoperatively: 8.1 P<0.001 **Group 2:** Preoperatively: 15.7 Postoperatively: 7.3 **p value = 0.005** **Postoperatively:** **Gp 1: 8.1** **Gp2: 7.3** **P=0.6**	
			Complications:	Minor consisting of erythema or minor degrees of discharge that did not delay the patients discharge from the hospital. A greater than twofold difference was seen in the incidence of wound breakdown, 16 vs 6%, but not significant. No difference in final outcome related to occurrence of wound complications.	

Evidence Table 21: Do any interventions, pre or post surgery (including stoma), affect the outcome of surgery for faecal incontinence?

Biofeedback

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Davis et al, 2004[76] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up:** 12 months	**Patient group**: Adult female patients, above 18 years with FI at least for the last 12 months. All patients had an external anal sphincter defect identifiable on endoanal ultrasound. **Cause of FI:** NR **<u>All patients</u>** **N:** 31 **N with FI:** 31 **Age (mean):** 60.48 **M/F:** 0/ 31 **Dropouts:** 7 **<u>Group 1</u>** **N:** 14 **N with FI:** 14 **Age (mean):** 60.71 **M/F:** 0/ 14 **Dropouts:** 4 **<u>Group 2</u>** **N:** 17 **N with FI:** 17 **Age (mean):** 60.29 **M/F:** 0/17 **Dropouts:** 3	**Group 1:** Sphincter surgery plus biofeedback. Biofeedback was commenced 3 months after surgery and conducted by the same therapist in all patients. Sessions lasting for an hour per week extending over a period of 6 weeks. **Group 2:** Sphincter surgery. (Direct sphincter repair and levatorplasty).	**Mean difference in continence scores from 3 (baseline) to 12 months between groups** (measured on a composite continence score ranging from 0 (no incontinence) to 20 (complete incontinence)).	**Group 1 vs Group 2:** -0.48 **95% CI:** -3.30 to 2.33 **p value:** 0.73	**Funding:** NR (Mediplus Ltd provided biofeedback equipment) **Additional outcomes:** Within group comparisons for mean resting anal pressures, squeeze anal pressures, Continence grading scale score and quality of life.
			Mean change in patient satisfaction scores from 3 (baseline) to 12 months between groups (measured on a visual analogue sliding scale ranging from 0 (not satisfied) to 10 (very satisfied)).	**Group 1 vs Group 2:** 1.03 **95% CI:** -0.59 to 4.70 **p value:** 0.12	
			Mean difference in quality of life parameters (lifestyle, coping, depression and embarrassment) between groups from 3 (baseline) to 6 months.	Lifestyle, coping and depression scores did not reach significance between the groups. **Mean difference for embarrassment score for group 1 vs group 2:** 0.56 **95% CI:** 0.12 to 0.99 **p value:** 0.014	
			Mean difference between the mean resting anal canal pressures from 3 (baseline) to 12 months.	**Group 1 vs Group 2:** -2.99 cmsH_20 **95% CI:** -19.33 to 13.35 **p value:** 0.711	
			Mean difference between the mean squeeze anal canal pressures from 3 (baseline) to 12 months.	**Group 1 vs Group 2:** -4.94 cmsH_20 **95% CI:** -29.19 to 19.30 **p value:** 0.68	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Number of patients failing to gain symptom control at 12 months (symptom control was defined as having mixed stool consistency, urgency and an inability to defer defecation).	**Group 1:** 1 **Group 2:** 2 **p value:** NR	
			Number of patients taking antidiarrhoeal medication at 12 months	**Group 1:** 3 **Group 2:** 6 **p value:** NR	

Bowel confinement

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Nessim et al, 1999[77] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up (mean):** 13 months	**Patient group:** Patients without stomas undergoing anorectal reconstructive surgery. Indications for surgery are as follows: faecal incontinence (n=32); complicated fistulas (n=17); anal stenosis (n=4); Whitehead deformity (n=1); Chronic unhealed fissure (n=1). **Cause of FI:** NK **All patients** **N:** 54 **N with FI:** 32 **Age (mean):** 49.1 **M/F:** 8/46 **Dropouts:** 0 **Group 1** **N:** 27 **N with FI:** 17 **Age (mean):** 51 **M/F:** NR **Dropouts:** 0 **Group 2** **N:** 27 **N with FI:** 15 **Age (mean):** 47.2 **M/F:** NR **Dropouts:** 0	**Group 1:** anorectal reconstructive surgery (sphincter repair for patients with faecal incontinence) + medical bowel confinement (a clear liquid diet with loperamide 4 mg by mouth 3 times a day and Codeine phosphate 30 mg by mouth 4 times a day until the third post-op day). **Group 2** anorectal reconstructive surgery (sphincter repair for patients with faecal incontinence) + regular diet (beginning the day of surgery)	**Complications**	**Group 1 vs Group 2** Wound infection: 2/27 vs 0/27 Abscess: 0/27 vs 1/27 Wound dehiscence: 0/27 vs 1/27 Urinary retention: 2/27 vs 1/27 Nausea & vomiting: 7/27 vs 3/27 Faecal impaction: 7/27 vs 2/27 Bleeding from wound: 2/27 vs 0/27 None were statistically significant	**Funding:** Caporella family **Notes:** All patients in both groups underwent the identical preoperative oral mechanical preparation, preoperative oral and parenteral antibiotics and postoperative antibiotics. Wound closure and wound care was identical in both groups.
			First post-operative bowel movement	**Group 1:** Mean 3.9 days **Group 2:** Mean 2.8 days ($p<0.05$)	
			Frequency of pain medication	**Group1:** none: 2/27(7%) oral analgesic 8/27 (30%) oral/ intramuscular narcotic 9/27 (30%) patient control analgesia/ morphine 8/27 (30%) **Group 2:** none: 7/27(26%) oral analgesic 9/27 (33%) oral/ intramuscular narcotic 7/27 (26%) patient control analgesia/ morphine 4/27 (15%) **p value:** Not statistically significant.	
			Incontinence score for those undergoing sphincteroplasty for FI (n=32)	**Group 1:** Pre vs post-op, 10 **Group 2:** Pre vs post-op, 11 NS	
			Hospital stay	**Group 1:** Mean 4.4 days **Group 2:** Mean 3.7 days Not tested for significance	

Faecal diversion

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Hasegawa et al, 2000[78] **Study design:** RCT **Evidence level:** 1+ **Duration of follow-up (mean):** 34 months	**Patient group:** Patients with faecal incontinence. **Cause of FI:** localized sphincter damage, obstetric (n=20), fistula operation (n=4), haemorrhoidectomy (n=1) **All patients** **N:** 27 **N with FI:** 27 **Age (mean):** 45.7 **M/F:** 1/26 **Dropouts:** NR **Group 1** **N:** 13 **N with FI:** 14 **Age (mean):** 45.69 **M/F:** 1/12 **Dropouts:** 0 **Group 2** **N:** 14 **N with FI:** 14 **Age (mean):** 45.64 **M/F:** 0/ 14 **Dropouts:** 0	**Group 1** Sphincter repair + stoma **Group 2** Sphincter repair + psyllium and lactulose	**Incontinence score on Cleveland Continence score (SD)**	**Pre-operative** **Group 1:** 13.5 (3.1) **Group 2:** 14 (2.9) **Post-operative** **Group 1:** 7.8 (5.5) **Group 2:** 9.6 (6.8) **p value:** 0.457	**Funding:** NR **Additional outcomes:** Wound infection, fistula, parastomal hernia, prolapsed stoma, incisional hernia at stoma site.
			Total number of patients with complications	**Group1:** 12/13 **Group 2:** 3/14 **p value:** 0.4197	
			Number of patients with faecal impaction	**Group1:** 0 **Group 2:** 1 **p value:** 1.0	
			Readmission for complications	**Group1:** 0 **Group 2:** 1 **p value:** 1.0	
			Mean hospital stay (SD)	**Group1:** 8.9 (2.2) **Group 2:** 8 (1.9) **p value:** 0.8725	

Evidence Table 22: Surgical case series for sphincter repair

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Gutierrez et al, 2004[79] **Study design:** Historical Case series **Evidence level:** 3 **Duration of follow-up:** Median 10 (range 7-16) years	**Patient group:** women who underwent anterior sphincter repair for anal sphincter disruption at University of Minnesota affiliated hospitals from 1985-1994. **Cause of FI:** 91% of patients incontinence caused by obstetric injuries. **<u>All patients</u>** **N:** 191 **N with FI:** 86% **Age (mean):** NR **M/F:** 0/182 **Dropouts:** 9 medically were unable to be included and 52 did not respond to questionnaire. **<u>Responders:</u>** **N:** 130 **N with FI:** NR **Age (mean):** 47 years **Age at Surgery (mean):** 37 **M/F:** 0/130	**Intervention:** Anterior sphincteroplasty.	**Continence outcomes reported by patients:**	**3 year follow up:** **No incontinence:** 18% **Incontinent of gas only:** 25% **Soiling only:** 21% **Incontinent of solid stool:** 36% **10 year follow up: (n=130)** **No incontinence:** 6% **Incontinent of gas only:** 16% **Soiling only:** 19% **Incontinent of solid stool:** 57% **P value:** NR	**Funding:** NR **Additional outcomes:** Patient satisfaction, comparison of responders and non responders. **Notes:** Results of same group of patients at shorter follow-up reported in Buie2001[80]. 62% considered bowel control better than before surgery and 74% were satisfied with results. 18 patients had Biofeedback after surgery and eight felt they had benefited. Poor outcomes were significantly associated to increased age and worse function at 3 years. No correlations between anorectal physiology and outcome found. Quality of life scores reported and patients with incontinence had worse scores on all scales of the FIQL, indicating a poorer quality of life.
			Continence outcomes reported by patients	**No incontinence:** 3 years (n=110): 15% 10 years (n=104): 6% p value: NS **Incontinent to gas only:** 3 years(n=110): 21% 10 years(n=104): 17% p value: NS **Soiling only:** 3 years(n=110): 27% 10 years(n=104): 19% p value: P<0.002 **Incontinent of solid stool:** 3 years(n=110): 36% 10 years(n=104): 58% p value: p<0.006	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Londono-Schimmer et al, 1994[81] **Study design:** Historical case series **Evidence level:** 3 **Duration of follow-up:** Median 58.5 (range 12-98) months. Post operative manometry performed at a mean of 22 months	**Patient group:** Patients with FI due to sphincter injury underwent an overlapping sphincter repair from 1984-89. **Cause of FI:** Obstetric trauma, operations for fistula, external trauma and iatrogenic after other anorectal procedures. **<u>All patients</u>** **N:** 128 **N with FI:** 128 **Age (mean):** 43.4 (16-77) years **M/F:** 28/100 **Excluded**: 34 (did not respond to postal questionnaire).	**Intervention:** Sphincter repair [Anterior repair (n=88), posterior repair (n=16) and lateral repair (n=24)].	Continence outcomes: (defined in notes section)	Excellent: 13/94 (13.8%) Good: 34/94 (36.2%) Fair: 24/94 (25.5%) Poor: 23/94 (24.5%)	**Funding:** NR **Limitations:** In 16 patients another procedure was simultaneously performed including placation of the puborectalis muscle (n=7), repair of a rectovaginal fistula (n=4), a posterior vaginal repair in 2 and other miscellaneous procedures in 3. **Additional outcomes:** Outcomes correlated to cause of sphincter injury were reported. **Notes:** 71 (75.5%) reported that subjectively they had become normal (fully continent) or were improved after the repair, and that their quality of life was definitely better. Patients having an anterior repair had better results compared with those located posteriorly or laterally (χ^2=15.9, df=6, P<0.025). There was no difference in the long term functional result among those who received a colostomy at the time of the repair with those who did not (χ^2=0.004, P>0.5). **Continence Scores:** Considered excellent when full control of
			Manometry: Mean resting pressure (cmH20):	Preoperative n=40):40.5 Post operative (n=40): 51.0 P=0.0396	
			Mean voluntary contraction (cmH20)**:**	Preoperatively: 32.3 Postoperatively: 47.4 P=0.0451	
			Patients with improved continence outcomes (a) Mean resting pressure (cmH20)	Preoperatively (n=21): 37.1 Postoperatively (n=21): 54.5 p=0.0510	
			(b) Mean voluntary Contraction: (cmH20)	Preoperatively: 29.6 Postoperatively: 54.5 P=0.0038	
			Patients with poor continence outcomes (a) Mean resting pressure (cmH20)	Preoperatively (n=19): 44.2 Postoperatively (n=19): 47.1 P=1.8301	
			(b) Mean voluntary contraction:	Preoperatively: 35.2 cmH20 Postoperatively: 40.1 cmH20 P=1.9433	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Complications	Early complications (<30 days) developed in 32 patients. Wound infection in 20 cases that led to breakdown of the repair in 3. Two of these were re-operated and 1 still has a colostomy. Impaction occurred in 9 patients and led to breakdown of the repair in 1, who required re-operation. Two patients developed a haematoma and 1 developed cellulites which resolved spontaneously. Late complications in 12 cases (recurrence of fistula-in-ano (n=4), stricture (n=3) and formation of a sinus (n=3). Other late complications were small bowel obstruction in one patient sand pain which required removal of wire in one case.	solid and liquid faeces and flatus was achieved. Good when there was continence to faeces but not to flatus or when a leak of liquid stool occurred less or equal to one episode per week. Fair when patients could control solid faeces only or suffered incontinent episodes more than once a week and Poor when only partial control of solid faeces was obtained when a permanent colostomy required. 144 patients had the surgery but 16 were excluded from this study as there was no follow up recorded after the surgery.

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Zorcolo et al, 2005[82] **Study design:** Historical case series **Evidence level:** 3 **Duration of follow-up:** ***Last clinic visit median 10*** (1-39) ***months*** and long-term follow up by questionnaire median 70 (48-112) months	**Patient group:** Patients that underwent anterior anal sphincter repair from 1991-1999. **Cause of FI:** Sphincter injury from obstetric injury **Patients at last clinic visit:** **N:** 93 **N with FI:** NR **Age (median):** 56 (27-80) **M/F:** 0/93 **Dropouts**: 31 (11 had further operations and were considered failed results and included)	**Intervention:** External sphincter repair that was reinforced with levatorplasty (n=51) and the internal sphincter was plicated (n=31)	**Changes in continence scores:**	**10 months follow-up:** Excellent: 36 (39%) Good: 24 (26%) Fair: 8 (9%) No benefit or worse: 25 (27%) **P value: NR**	**Funding:** NR **Limitations:** The wound was closed in 82 patients and none of the patients had a planned stomas as part of the repair. **Additional outcomes:** Quality of life improvement was reported: Need to wear a pad was reported pre-operatively. **Notes:** Previous surgery for anal incontinence or prolapse had been performed in seven patients and two had undergone post anal repair before referral. Predictive variables were compared to outcomes in long-term results (no significant results found). Internal sphincter placation and levatoroplsty was performed mainly in the patients who achieved a good result (excellent or good outcome, n39) (36 vs 26% and 61 vs 47%, NS, respectively) compared to worse
			Continence scores: Mean St Marks Score	**70 months follow-up:** **Before:** 18 (5-23) **After:** 11 (1-22) **p value:** <0.001	
			Changes in continence Score: (defined in notes)	**70 months follow-up:** Excellent: 7/62 (11%) Good: 32/62 (52%) Fair: 12/62 (19) No benefit: 4 (6%) Worse: 7(11%) P value: NR	
			Patient satisfaction reported:	**70 months follow-up:** Fully Satisfied: 20 (22.5%) Satisfied: 17 (23%) Moderately satisfied: 7 (10%) Not satisfied: 17 (23%) P value: NR	
			Incontinence to solid stools:	Preoperatively: 43 10 months postoperatively: 13 70 months postoperatively: 18 P value: NR	
			Incontinence to liquid stools:	Preoperatively: 51 10 months postoperatively: 10 70 months postoperatively: 21 P value: NR	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Urgency:	Preoperatively: 52 Short-term follow-up: 20 Long-term follow-up: 50	outcome. 40 patients considered that their bowel control had improved. **<u>St Marks Incontinence Score</u>** (0-24); 0=total control and 24=totally incontinent. Outcome - grade of improvement from pre to post surgery: **Excellent:** an improvement of 12 points plus **Good**: an improvement of 6-11 points **Fair**: 2-5 points **No improvement:** 0-1 **Worse** when postoperative score higher than preoperative one.
			Wound complications:	Occurred in 24 patients. Five patients needed an examination under anaesthesia, one patient developed perineal sepsis and required a colostomy that was closed two months later. 18 of 24 reported improved continence. 4 who did not improve had repeat repairs for persistent defects. Five patients had repeat repairs who recovered without local complications. Seven of 93 experience prolonged anal pain and six had dyspareunia.	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Karoui et al, 2000[83] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** mean 40 (range, 9-98) months	**Patient group:** consecutive patients with FI with an ultrasound defect of the external anal sphincter that did not extend over more than one-half the anal circumference. **Cause of FI:** vaginal delivery, after proctologic surgery or trauma or unidentified cause in women with a history of at least one vaginal delivery. **<u>All patients (short-term follow-up)</u>** **N:** 86 **N with FI:** 86 **Age (mean):** 52.9 (21-85) years **M/F:** 9/77 **Dropouts**: NR **<u>Long-term follow up</u>** **N:** 74 **N with FI:** 74 **Age (average):** 56 (28-85) years **M/F:** 6/68 **Dropouts**: NR	Overlapping anal sphincter repair	**Continence outcomes:**	**3 months post surgery:** No incontinence: 42/86 (49%) Incontinent for gas: 28/86 (32%) FI: 16/86 (19%) **P value: NR**	**Funding:** NR **Limitations:** **Additional Outcomes: NR** **Notes:** KEY: * 7 of these were patients with FI
			Continence outcomes:	**40 months follow-up:** Totally continent: 21/74(28%) Incontinent for gas: 17/74 (23%) FI: 36/74 (49%) **P-value: NR**	
			Frequency of incontinence in FI patients	More than once a week: 18/36 (50%) Less than once a week: 10/36 (28%) Only if diarrhoea: 6/36 (17%) No information: 2/36 (5%) Significantly different compared with those observed three months after surgery (p=0.02).	
			Subjective patient views of surgery	Cured: 13 (18%) Clearly improved: 21 (28%)* Slightly better: 22 (30%) Surgery failed: 18 (24%) **p-value: NR**	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Engel et al, 1994[84] **Study design:** Historical case series **Evidence level:** 3 **Duration of follow-up:** Median follow-up of 15 (range 6-36) months.	**Patient group:** Consecutive women that underwent anterior sphincter repair for FI following obstetric anal sphincter damage. **Cause of FI:** obstetric **All patients** **N: 55 N with FI:** 55 **Age (median):** 42 (26-67) yrs **M/F:** 0/55 **Dropouts:** 0	Overlapping anterior sphincter repair and 13 patients had a covering colostomy, depending on the preference of the surgeon.	**Parks continence classification:**	**Pre-operative:** Grade 1: n=0 Grade 2: n=0 Grade 3: n=17 Grade 4: n=38 P values: NR	**Funding:** Supported by joint research board of St Bartholomew's Hospital and St Mark's Hospital. Support also from St mark's Research Foundation. **Limitations:** **Additional outcomes:** **Notes:** Subjective improvement scores were significantly greater in patients in grades 1 and 2 compared with those in grades 3 and 4. Included in systematic review Jarrett 2004[85]. Anorectal physiology (n=47): Patients assessed as grades 1 and 2 had significantly larger change in voluntary contraction pressure increment than those assessed as grades 3 and 4. No other significant differences measured. Patients with improved confidence had a significantly higher postoperative voluntary
			Parks continence classification:	**Follow up:** Grade 1: n=25 Grade 2: n=17 Grade 3: n=9 Grade 4: n=2 P values: NR Awaiting colostomy closure=2	
			Postoperative endosonography of EAS (intact: not intact)	Grades 1 & 2 (n=35): 32:3 Grades 3 & 4 (n=11): 5:6 P=0.0029	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
					contraction pressure than those whose confidence had not improved. **Park's Classification** Grade 1: continent to stool and flatus Grade 2: incontinent to flatus, some urgency Grade 3: incontinent to liquid stood Grade 4: incontinent to formed stool.

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Fleshman et al, 1991[86] **Study design:** Historical case series **Evidence level:** 3 **Duration of follow-up:** 1-2 years follow up.	**Patient group:** women with anal sphincter incontinence between 1973 and 1987 at the Jewish Hospital of St. Louis, US. **Cause of FI:** obstetric injury (n=48), fistulotomy (n=6) fistulotomy for Crohn's disease (n=1). **All patients** **N:** 55 **N with FI:** 52 **Age (mean):** 34 (22-75) years **M/F:** 0/55 **Dropouts**: 0 Charts reviewed and follow-up by telephone interview.	Overlap muscle repair for anal sphincter reconstruction.	Incontinence after surgery:	Incontinent: 3/55 (6%) Liquid and flatus: 12/55 (22%) Flatus only: 12/55 (22%) None: 28/55 (50%) P-value: NR	**Funding:** NR **Limitations:** A rectovaginal fistula present in 15 patients and repaired at same time as surgery. **Additional outcomes:** Clinical impression and functional results from surgeon reported (based on overall patient function and the patients own assessment of outcome). Outcome compared to aetiology of incontinence. **Notes:** An improvement from preoperative symptoms reported in 48 (87%). Six patients reported no change and one was symptomatically worse. Included in systematic review Chapman 2002[87]
			Complications	Wound infection 8/55 patients. Infection occurred in 5/22 (22%) without perineal drain but in only 3/33 (9%) with perineal drain in place. In the majority of these patients opening the skin incision to drain the perineal body was adequate treatment. Only one patient required repeat repair after treatment of the infection. On e patient suffered urinary tract infection postoperatively. No patient required a colostomy.	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Young et al, 1998[88] **Study design:** Historical case series **Evidence level:** 3 **Duration of follow-up:** Mean follow up 27.2 (range 1-77) months.	**Patient group:** patients with FI and sphincter defect requiring sphincteroplasty. **Cause of FI:** obstetric, penetrating trauma and anal surgery. **All patients** **N:** 56 **N with FI:** 55 **Age (median):** 42 (range, 10-78) yrs **M/F:** 2/54 **Dropouts**: NR	Overlapping anal sphincter repair	**Median St Mark's Incontinence Scores** (range 0-13; 0=complete continence and 13=complete incontinence):	Preoperatively: 13/57 Postoperatively: 3/57 P<0.0001	**Funding:** NR **Limitations:** Sphincter repair performed alone in 36 repairs and in conjunction with a colostomy in 21 repairs. Youngest age 10 yrs. **Additional outcomes:** Patients rated as success or failure. Repairs failures and incontinence scores were compared between those with evidence of an associated neuropathy (no significance). Comparison of rated as failure between repairs with a colostomy and without.
			Median Pescatori Incontinence Scale (0-6; 0=complete continence and 6= complete incontinence):	Preoperatively: 6/57 Postoperatively: 2/57 P<0.0001	
			Surgery success/failure: (Rated success if patients felt continence improved or became normal and failed if same or became worse)	Success: 49/56 (86%) Failure: 8/56 (14%)	
			Success of repairs reported by patients	Under 40 years of age: 21/27 (78%) Older than 40 years: 28/30 (93%) P=0.10	
			Complications	22 patients had local skin morbidity, with one small bowel obstruction, one paracolostomy hernia, one parastomal wound infection and two large bowel obstructions following colostomy closure that required laparotomy.	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Oliveira et al, 1996[89] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Mean 29 (3-61) months.	**Patient group**: All patients that underwent anterior sphincteroplasty for anterior defects between 1989 and 1994 **Cause of FI:** obstetric (84%), surgical procedure (15%) and trauma (2%). **<u>All patients</u>** **N:** 55 **N with FI:** 55 **Age (mean):** 48 (27-72) years Age > 60y: 16 patients **M/F:** NR	Anterior sphincteroplasty.	**Surgery outcome** (rated by patients)	Excellent: 13/55 (24%) Good: 26/55 (47%) Fair: 5/55 (9%) Poor: 11/55 (20%) P value NR	**Funding:** NR **Additional outcomes:** Subjective analysis of outcome for over and under 60yrs. Significant change in frequency and type of incontinence was reported by authors in patients who had a successful repair (improvement not seen in patients that had a failed repair). Difference in functional results between both age groups. Results of endoanal ultrasonography reported. **Notes:** The successful patients mean (and maximal) resting and squeeze pressures and high-pressure zone significantly increased from pre to post operative. The failed patients did not have significant changes pre and post operation. Incontinence grade (0-20; 0 perfect continence) reported by questionnaire before and 3-6 months following surgery.
			Mean incontinence score: (defined in notes section)	**Successful procedures: excellent or good outcomes (n=39)** Preoperative: 15.3 Postoperative: 5.8 P=0.0001 **Failed procedure: fair or poor outcomes (n=16):** Preoperative: 14.2 Postoperative: 13.1 P=NS	
			Complications:	Minor complications occurred in 3 patients and consisted of bleeding during the night following the procedure, faecal impaction and a chronic perineal sinus; all treated conservatively. NO infectious complications occurred.	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Morren et al, 2001[90] **Study design:** Historical case series **Evidence level:** 3 **Duration of follow-up:** Median 40 (5-137) months.	**Patient group:** patients with FI that underwent external anal sphincter repair. All had signs of sphincter defect and in 43 this was confirmed by ultrasound or EMG. Cause of FI: obstetric injury, surgical trauma or combination of both. **<u>All patients</u>** **N:** 67 **N with FI:** 67 **Age (median):** 39 (24-73) years **M/F:** 12 **Dropouts**: NR	External anal sphincter repair. Three techniques used (1) end to end repair (n=13), (2) overlapping repair (n=26) and (3) imbrication or placation (n=16).	**Patient's subjective analysis of operation:** (success defined as an excellent or good result)	Excellent: 10 Good: 21 Some improvement: 14 Unchanged: 6 Worse: 1 (n=52; as 3 had stoma after surgery) Successful: 31/55 (56%)	**Funding:** NR **Limitations:** Incontinent scores were not reported pre-operatively but subjectively at time of follow-up. 3 had repeat sphincter repair and 1 had post anal repair and results assessed after second operation. **Additional outcomes:** Manometry reported in 42 patients: PNTML reported in 25 patients comparing successful to failed repairs. **Notes:** 3 patients who finally had a colostomy were included and regarded as failures in the analysis. 4 patients had two consecutive repair procedures due to failure of first. Assessment carried out after second repair. No correlation between preoperative degree of incontinence and success rate. **Parks continence classification:** Grade I: fully continent; Grade II: soiling or incontinence for gas; Grade III: incontinence for liquid stools; Grade IV: incontinence for solid stool. Patients subjective result of surgery classified as worse, unchanged, some improvement good or excellent. **Operation defined as successful when classified as**
			Changes in patients continence scores.	Improved: 19 (35%) Unchanged: 17 (30%) Worse: 19 (35%) **P value: NR**	
			Symptoms of urgency:	Successful repair: 12/31 Failed: 16/24 P=0.01	
			Patients with loose stools (post operative symptoms in relation to outcome)	Success: 2/31 Failed: 7/24 P=0.02	
			Complications	No mortality. Complications occurred in 13 patients. One developed a deep infection with breakdown of the plasty. Second attempt of repair done after healing but with poor result. 12 patients had minor complications: superficial wound infection (5), perineal haematoma (1), faecal impaction post-operatively (2), urinary tract infection (1). Two patient s suture granuloma (2) and persistent pain at site of repair (1). No difference in success rate between patient with minor complications and	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				those without.	**good or excellent.**

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Giordano et al, 2002[91] **Study design:** Historical case series **Evidence level:** 3 **Duration of follow-up:** Group 1: median 13 (1-64) months. Group 2: median follow-up 20 (range 2-96) months	**Patient group:** Female patients with obstetric sphincter damage who underwent anterior overlapping sphincter repair from 1988-2000 were reviewed. **Cause of FI:** obstetric damage **Group 1:** **N:** 115 **N with FI:** NR **Age (median):** NR **M/F:** 0/115 **Dropouts**: NR **Group 2:** **N:** 36 **N with FI:** NR **Age (median):** 46 (20-68) **M/F:** 0/36 Dropouts: NR	**Group 1:** Patients who had not had previous sphincter repair surgery **Group 2:** Patients who had one or more previous failed repairs and presented with residual anterior anal sphincter damage.	**Continence score at follow up:**	**Group 1:** Good: 67 (58%) Adequate: 19 (16.5%) Poor: 29 (25.5%) **Group 2:** Good: 18 (50%) Adequate: 4 (11%) Poor: 14 (39%) Chi-squared test P=0.2646 **All patients: (n=151)** Good: 85 (56%) Adequate: 23 (15%) Poor: 43 (28%)	**Funding:** Supported in part by a generous grant fro the Eleanor Naylor Dana Charitable Trust. **Additional outcomes:** Manometry before surgery and after surgery. **Notes:** Post operative improvement in median IS equally statistically significant for both groups (P<0.0001). Number of previous repairs did not statistically affect outcome (spearman's r=0.2460, 95% CI, -0.09983 to 0.5389; 2-tailed p value=0.1480). No significant difference in success of operation when compare patients that have undergone 1 or 2 previous repairs (n=31, good or adequate outcome 68%) compared to patients with more than 3 (n=5, good or adequate outcome 20%) repairs (p=0.0637). **Continence scores:** Cleveland Clinic Florida FI Score (IS) (rating 0-20 with 0 being completely continent) **Good** clinical outcomes defined as an IS 0-5, **adequate** 6-10 and **poor** between 11 and 20
			Cleveland Clinic Florida Faecal Incontinence (IS) score (median)	**Group 1 (n=115)** Preoperative: 18 Postoperative: 5 P value: <0.0001	
			IS score (median) [see notes for definition of score]	**Group 2 (n=36)** Preoperative: 17.5 Postoperative: 7 P value: <0.0001	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Arnaud et al, 1991[92] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** average 17 (range, 2-96) months.	**Patient group:** patients with traumatic sphincter lesions treated by sphincter repair treated at one surgery between 1974-88. **Cause of FI:** Surgical (n=22), obstetric (n=14), and accidental (n=4). **All patients** **N:** 40 **N with FI:** 40 **Age (mean):** 49.5 (17-75) years **M/F:** 15/25 **Dropouts:** 0	**Intervention:** Sphincter repair (end to end apposition – without any overlapping). Diverting sigmoid colostomy was also carried out on 11 patients.	**Functional results:** (continence reported by patients defined as: **excellent**: patient fully continent, **good:** occasional leaks of liquid stool; **fair:** continent for solid stool only or **bad**: no improvement of preoperative state)	**Excellent:** 25/40 (62.5%) **Good:** 6/40 (15%) **Fair:** 4/40 (10%) **Bad:** 5/40 (12.5%)	**Funding:** NR **Limitations:** Subjective results of patients following surgery. **Additional outcomes:** Functional results by aetiology of trauma (surgical, obstetric and accidental). Functional results reported by site of division of sphincter muscle ring (anterior and posterolateral). **Notes:** Anterior disruptions had a better outcome after surgery than posterolateral disruptions.
			Complications:	5 patients developed wound sepsis. In 3 patients this resulted in complete breakdown of the repair and treatment by further colostomy.	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Bartolo & Duthie, 1990[93] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Traumatic incontinence follow up 5 (1-18) years and in idiopathic incontinence group the follow up was 4 (2-12) years	**Patient group:** female patients with idiopathic or traumatic incontinence were operated on at Bristol Royal Infirmary. **Cause of FI:** idiopathic or traumatic incontinence. 14 patients had an anterior sphincter defect and 16 had an intact sphincter at surgery. **All patients** **N:** 30 **N with FI:** 30 **Age (mean):** NR **M/F:** 0/30 **Dropouts:** 15 (Pre and post operative tests carried out on 15 patients)	**Intervention:** Anterior sphincter repair with an additional levatorplasty or posterior colporrhaphy was performed.	**Continence** (defined as restoration of continence to solid and liquid stool)	**Traumatic incontinent (n=14)** Before: 7% After: 72% **Idiopathic incontinent (n=16)** Before: 0% After: 69%	**Funding:** NR **Additional outcomes:** Mucosal electrosensitivity, anorectal angle and perineal descent were measured pre and post operatively. **Notes:** Patients with rectal prolapse underwent rectopexy.
			Sphincter length (cm)	**Traumatic incontinent** Before: 3 (2-4) After: 3 (1-3.5) P=not sig **Idiopathic incontinent** Before: 3 (0-4) After: 3 (0-4**)** **P=Not sig**	
			Maximum resting pressure (cmH2O)	**Traumatic incontinent** Before: 55.4 (28-105) After: 62 (33-80) P=Not sig **Idiopathic incontinent** Before: 55.5 (0-100) After: 56 (30-137) P=Not sig	
			Maximum voluntary contraction (cmH2))	**Traumatic incontinent** Before: 80 (50-115) After: 115 (75-290) P<0.005 **Idiopathic incontinent** Before: 107 (5-200) After: 117 (45-230) P=Not sig	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Elton & Stoodley, 2002[94] **Study design:** Historic case series **Evidence level:** 3 **Duration of follow-up:** 13 (3-61) months.	**Patient group:** Patient with FI and confirmed anterior anal sphincter defect involving both external and internal sphincters. None of patients had undergone previous sphincter repair. **Cause of FI:** Obstetric injury (n=14), gynaecological surgery (n=2) and anal surgery (n=4). **All patients** **N:** 20 **N with FI:** 20 **Age (mean):** 55.5 (range, 32-79) years **M/F:** 1/19 **Dropouts:** 0	**Intervention:** Overlapping anterior anal sphincter repair	**Median (range) Continence Score** (defined by Cleveland continence score (0-20); 0 being perfect continence and 20 being complete incontinence):	**Before:** 14 (4-15) **After:** 7 (0-15) **P<0.001**	**Funding:** NR **Additional outcomes:** Continence score of sub-group (n=12) with mesh reinforcement. **Notes:** Normal MRP: 46-96 cmH20 Normal MSP: 60-120 cm H20
			Patient-reported subjective improvement of symptoms:	**Improvement:** 16/20 (80%) **No improvement:** 4/20 (20%)	
			Mean resting anal canal pressure (MRP) (cmH20)	**Before:** 29.6 **After:** 32.74 **p value:** NS, p>0.2	
			Mean maximum squeeze pressure (MSP) (cmH20)	**Before:** 29.89 **After:** 32.25 **p value:** >0.5	
			Mean sphincter length (cm)	**Before:** 3.45 **After:** 3.65 **p value:** >0.1	
			Complications:	Two wound infections which settled on oral antibiotics and analgesia. One patient subsequently underwent removal of the mesh 5 months after sphincter repair because of severe perineal pain.	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Engel et al, 1994[95] **Study design:** Historical case series **Evidence level:** 3 **Duration of follow-up:** Median 46 (15-116) months	**Patient group:** consecutive patients underwent anterior sphincter plictation for FI. Patients had a defect in the external anal sphincter. **Cause of FI:** obstetric injury (n=15), previous anorectal operation (n=8), direct trauma to the sphincter (n=2), posterior vaginoplasty (n=3). **All patients** **N:** 28 **N with FI:** 28 **Age (mean):** 41 (22-66) years **M/F:** 3/25 **Dropouts:** 0	**Intervention:** Overlapping sphincter repair. Additional levatorplasty (n=16).	**Number of patients in each clinical outcome grade:** (Defined as: Grade 4: no improvement, Grade 3: improvement but frequent loss of liquid and solid stools, therefore dissatisfied, Grade 2: improvement but infrequent loss of liquid and solid stools, satisfied and Grade 1: perfect continence for liquid and solid stools).	**Before:** Grade 4: 28 **After:** Grade 1: 16 Grade 2: 5 Grade 3: 1 Grade 4: 6	**Funding:** NR **Limitations:** Not all patients had manometry following surgery. Additional levatorplasty (n=16). **Additional outcomes:** Comparison of postoperative resting pressure, squeeze pressure and length of high pressure zone in satisfied and dissatisfied patients (n=26).
			Median age of satisfied and dissatisfied patients: (satisfied = grades 1 & 2)	**Satisfied:** 32 years **Dissatisfied:** 55 years p = 0.0073, CI 5 to 27	
			Complications:	Two patients had postoperative complications: abdominal wall dehiscence after covering colostomy and haematoma of the rectovaginal septum.	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Gibbs and Hooks, 1993[96] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** average 43 months (range, 4 months-9.5 years).	**Patient group:** patients with FI operated on by one surgeon from 1981 to 1990. **Cause of FI:** obstetric (n=21), previous anorectal surgery (n=7), trauma (n=1), gynaecologic surgery (n=1) and multiple factors (n=1) and idiopathic (n=5). **<u>All patients</u>** **N:** 36 **N with FI:** 36 **Age (mean):** 47 (20-74) yrs **M/F:** 2/34 **Dropouts:** 3	**Intervention:** Overlapping sphincter repair.	**Functional long-term results:**	**Excellent:** 10/33 (30%) **Good:** 14/33 (43%) **Fair:** 5/33 (15%) **Poor:** 4/33 (12%)	**Funding:** NR **Limitations:** **Additional outcomes:** Number of patients that considered themselves better off after surgery and in the same circumstances would repeat surgery**.** <u>Functional results defined:</u> Excellent: reliable control of solid and liquid stool and occasional loss of gas, Good: occasional loss of liquid stool or gas, Fair: frequent loss of control necessitation use of a pad, but improved from preoperative state, Poor: little or no benefit from surgery.
			Functional results (patients with FI due to obstetric, previous surgery or trauma only (n=29)	**Follow up for n=26/29** **Excellent:** 9/26 (35%) **Good:** 13/26 (50%) **Fair:** 3/26 (12%) **Poor:** 1/26 (3%)	
			Complications:	11 patients had post operative complications. Five patients had temporary voiding difficulties, three had urinary tract infection, one had a perianal sinus tract, and three had anal stenosis. One patient had postoperative congestive heart failure, which resolved with diuretics and fluid restriction. Another patient had fever and diarrhoea. Two patients required colostomy for wound sepsis.	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Gilliland et al, 1998[97] **Study design:** Historical case series **Evidence level:** 3 **Duration of follow-up:** Median 24 months (2-96 months).	**Patient group:** patients who underwent surgery at one centre between 1988 and 1996. **Cause of FI:** obstetric (n=53), perineal surgery (n=6), haemorrhoidectomy (n=6), fistula surgery (n=4), unknown (n=4), mixed (n=2) and assault (n=2). **<u>All patients</u>** **N:** 77 **N with FI:** NR **Age (mean):** 47 (25-80) yrs **M/F:** NR **Dropouts:** 0	**Intervention:** Anterior overlapping sphincteroplasty. A concomitant levatorplasty was performed in 58 of the 77 patients.	**Patients grade subjective outcome of surgery:** (successful outcome defined as patients with excellent or good result)	**Excellent:** 20 (26%) **Good:** 22 (29%) **Fair:** 11 (14%) **Poor:** 24 (31%) Successful outcome: 42 Failed outcome: 35	**Funding:** Grant from Eleanor Naylor Dana Charitable Trust. Gilliland supported in part by the Northern Ireland Postgraduate Council for medical Education. **Limitations:** 58 of 77 patients had a levatorplasty performed as well as the sphincteroplasty. No correlation between the surgical procedure and outcome. 30 patients had had a previous attempted repair elsewhere. **Additional outcomes:** Correlation between manometric parameters and outcome. EAUS, EMG and PNTMLS results compared to outcomes.
			Median incontinence score (0-20; where 0=perfect continence)	**Successful patients:** **Preop:** 15 (range, 1-20) **After:** 3 (range, 0-15) **p value:** <0.0001 **Failed patients:** **Preop:** 17 (range, 6-20) **After:** 16 (range, 0-20) **p value=0.35**	
			% of patients incontinence score (0-20; where 0=perfect continence)	**After surgery:** **Score 0-5:** 42% **Score 6-10**: 18% **Score 11-15**: 19% **Score 16-20**: 21%	
			Complications:	Constipation n=4), wound infection (n=3) urinary retention (n=2). Persistent sinus (n=2), dyspareunia (n=1), rectal prolapse (n=1), and pneumonia (n=1).	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Malouf et al, 2000[3] **Study design:** Historical case series **Evidence level:** 3 **Duration of follow-up:** 77 (60-96) months	**Patient group:** consecutive women patients undergoing anterior overlapping sphincter repair at one hospital between 1990 and 1992. **Cause of FI:** obstetric damage. **<u>All patients</u>** **N:** 55 **N with FI:** 55 **Age (mean):** NR **M/F:** 0/55 **Dropouts:** 17 Eight lost to follow up. One excluded as ileostomy for Crohn's disease. From the 47 responders a further eight patients were excluded as repair failed outright (7 needed further surgery and one had a colostomy).	**Intervention:** Anterior overlapping sphincter repair.	**Median bowel control** (scale 0-10; where 0=no control to 10=perfect control)	**Before** (n=38)**:** 2 (0-10) **After** (n=38)**:** 6.5 (0-9)	**Funding:** NR **Limitations:** Cleveland clinic scale measured postoperatively but not preoperatively so no comparison available. **Additional outcomes:** Patient's satisfaction and quality of life reported. Study compared long term outcomes with short term outcomes (Engel 1994b) at 15 months with physiological and endosonograhic variables. **Notes:** 14 patients reported an evacuation disorder that was not present after delivery but occurred after sphincter repair. Engel 1994b reports some patients follow up at 15 months.
			Patients subjective improvement of bowel control:	**Improvement:** 27/38 (71%) **No improvement:** 5/38 (13%) **Deterioration:** 6/38 (16%)	
			Patients perceived change in episodes of incontinence, compared to preoperative state.	**Median 15 months post operatively: (**n=31): 85% improvement **Median 77 months postoperatively: (**n=36): 50% improvement	
			Median (range) continence scores (modified Parks score) (1=continent to stool and flatus, 2=incontinent to flatus, some urgency but no incontinence; 2=incontinent to liquid stool, 4=incontinent to solid stool)	**Preoperatively:** 4 (3-4) **15 months follow-up**: 2 (1-4) **77 months follow-up:** 3 (2-4)	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Osterberg et al, 2000[98] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 12 months	**Patient group:** women with FI who were unsuccessfully treated conservatively with bulking agents for a period of at least two months. **Cause of FI:** traumatic anal sphincter injury. All had a history of at least one ocomplicated delivery. **<u>All patients</u>** **N:** 20 **N with FI:** 20 **Age (median):** 47 (30-69) yrs **M/F:** 0/20 **Dropouts:** NR	**Intervention:** Overlapping anal sphincteroplasty	**Incontinence per se**	**Pre-op:** 18 **3 months post op:** 11 **p value:** <0.01 **12 months post -op:** 10 **p value:** <0.01	**Funding:** Swedish Medical Research Council. **Limitations:** Not clear what 'incontinence per se' refers to. **Additional outcomes:** Use of pads, % straining, deferring time (loose stool, solid stool), resting pressure, squeeze pressure, high-pressure zone, rectoanal inhibitory reflex, rectal compliance.
			Median incontinence score (0-18, lower score indicates improved incontinence)	**Pre-op:** 8.5 **3 months post op:** 5 **p value:** <0.01 **12 months post -op:** 3.5 **p value:** <0.01	
			Impact on lifestyle – social handicap	**Pre-op:**18 **3 months post op:** 5 **p value:** <0.001 **12 months post -op:** 5 **p value:** <0.001	
			Impact on lifestyle – physical handicap	**Pre-op:** 20 **3 months post op:** 10 **p value:** <0.001 **12 months post -op:** 7 **p value:** <0.001	
			Maximum rest pressure	**Pre-op:** 37 **3 months post op:** 41 **p value:** NS **12 months post -op:** 40 **p value:** NS	
			Maximum squeeze pressure	**Pre-op:** 58 **3 months post op:** 66 **p value:** NS **12 months post -op:** 65 **p value:** NS	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Rothbarth et al, 2000[99] **Study design:** Historical case series **Evidence level:** 3 **Duration of follow-up:** mean 39.3 (12-114) months.	**Patient group:** consecutive patients with FI due to obstetric injury undergoing anterior sphincter repair at one centre. Patients had a period of biofeedback training which was unsuccessful eventually. **Cause of FI:** obstetric injury **<u>All patients</u>** **N:** 39 **N with FI:** 39 **Age (mean):** 50.6 (29-74) yrs **M/F:** 0/39 **Dropouts:** 0	**Intervention:** Anterior sphincter repair (overlapping) with a puborectal muscle plasty in 32 patients. Additional procedures included posterior vaginal wall repair (n=5) and colostomy (n=6).	**Continence** (Success = Grade 1 or Grade 2 of modified Park's Continence Score (see notes for classification)	**3 months follow-up:** 30/39 (77%) **9 months follow-up:** 26/39 (67%) **12 months plus:** 24/39 (62%)	**Funding:** NR **Limitations:** *EMG performed in 30 patients (77%): therefore some data missing **Additional outcomes:** Mean duration of surgery and mean hospital stay. Age, duration of FI, episiotomy, rupture, rectopexy, hysterectomy and addition of puborectal muscle plasty were compared with successful or failed outcomes. **Notes:** modification of **Parks classification;** grade 1, continent for stool and flatus; grade 2, continent for stool, incontinent for flatus; grade 3, incontinence for liquid stool; grade 4, incontinent for solid stool.
			Complications	Urinary tract infection (n=1), pulmonary tract infection (n=1) and wound infection (n=3)	
			Prolonged pudendal latency: *	**At least 12 months post surgery:** **Success (Parks Grades 1 & 2) (n=24**): 7 (29%) **Failure (Parks Grades 3 & 4) (n=15):** 11 (73%) p=0.025	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Simmang et al, 1994[100] **Study design:** Historic case series **Evidence level:** 3 **Duration of follow-up:** 12 months	**Patient group:** women aged 55 years or older who underwent anal sphincter reconstruction between 1986 and 1991. **Cause of FI:** obstetric injury (n=11), hemorrhoidectomy (n=2) and fistulotomy (n=1). **All patients** **N:** 14 **N with FI:** 14 **Age (mean):** 66 (55-81) yrs **M/F:** 0/14 **Dropouts:** 0	**Intervention:** Overlapping sphincter repair	**Continence**	**Preoperative:** Continent: 0 (0%) Gas only: 0 (0%) Liquid, gas: 4 (29%) Solid, liquid, gas: 10 (71%) **Postoperative:** Continent: 7 (50%) Gas: 3 (21%) Liquid, gas: 4 (29%) Solid, liquid, gas: 0 (0%)	**Funding:** NR **Additional outcomes:** Comparison of these results with a previous study by the authors on younger women. Manometry (n=10) preoperatively and at 6 months postoperatively. Also compared to functional outcomes and group of younger women in previous study.
			Patients that continence rating improved:	Improved: 13/14 (93%) No change: 1/14 (7%) Worse: 0/14 (0%)	
			Preoperative PNTML categories:	**Normal PNTML: (n=7)** Improved continence: 7 Unimproved continence: 0 **Unilateral abnormal: (n=2)** Improved continence: 2 Unimproved continence: 0 **Bilateral abnormal: (n=1)** Improved continence: 0 Unimproved continence: 1	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Ternent et al, 1997[101] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Mean 12 (3-48) months	**Patient group:** female patients with FI underwent sphincteroplasty between 1991 and 1995. **Cause of FI:** FI secondary to obstetric anal sphincter trauma <u>**All patients**</u> **N:** 35 **N with FI:** 35 **Age (mean):** 44 (range, 26-75) yrs (excluding dropouts) **M/F:** 0/35 **Dropouts:** 19	**Intervention:** anterior overlapping sphincteroplasty	**Patients continence score** (modified Millers scale: ranges 0-5; where 0=continence and 5=incontinent to solid stool, daily or more and wears a pad)	**Preoperatively: (n=16)** **Score 1:** 0 **Score 2:** 1 **Score 3:** 3 **Score 4:** 4 **Score 5:** 8 **Postoperatively: (n=16)** **Score 1**: 4 **Score 2:** 4 **Score 3:** 2 **Score 4:** 2 **Score 5:** 4	**Funding:** NR **Additional outcomes:** Endosonograhic and anorectal physiology were reported before and after surgery and compared to change in continence scores. Change in continence scores was correlated to endosonograhic size of sphincter defects, manometry, PNTM and age. Sphincter defects postoperatively and existence of pudendal neuropathy were reported. Pudendal neuropathy was stratified into absence of pudendal neuropathy, unilateral and bilateral and their mean change in continence scores were compared between the groups. **Notes:**
			Mean continence scores	**Preoperatively:** 4.2 ± 0.2 **Postoperatively:** 2.9 ± 0.4 **P=0.005**	
			Patients with changes in continence scores:	**Postopertively:** Worse score: 1 (6%) No change: 5 (32%) Improvement: 10 (62%)	
			Postoperative satisfaction (score: 1-5; the lower the score the lower the satisfaction)	Score 5: 4 (25%) Score 4: 3 (19%) Score 3: 5 (31%) Score 2: 0 (0%) Score 1: 4 (25%) **Group postoperative:** 3.2 ± 0.4 (range, 1-5)	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Briel et al, 1998[102] **Study design:** Before and after study – reported as case series **Evidence level:** 3 **Duration of follow-up:** 24 months	**Patient group:** female patients with FI as result of obstetric trauma. **Cause of FI:** obstetric **All patients** **N:** 55 **N with FI:** 55 **Age (mean):** NR **M/F:** 0/55 **Dropouts:** NR 7 patients had undergone previous attempt at surgical correction.	Direct sphincter repair (n=24) and anterior overlapping external anal sphincter repair with internal anal sphincter imbrication (n=31)	**Preoperatively degree of incontinence:** **Parks Incontinence grade** Grade I: fully continent Grade II: soiling and incontinence for gas Grade III: incontinence for liquids Grade IV: incontinence for solid stool	Grade I: 0 Grade II: 0 Grade III: 24 Grade IV: 31	**Funding:** NR **Limitations:** Two patients with rectovaginal fistulas, which were treated simultaneously with the repair. **Additional outcomes:** Comparison of successful results between patients that had previous repairs.
			24 months following surgery: (Restoration of continence from Grade IV to Grade II or I or from Grade III to grade I was defined as successful outcome).	Follow-up Successful: 36/55 (65%)	
			Complications:	Three patients in group 1 and three in group 2 had wound abscess. Two patients suffered a urinary tract infection in group 1. Long-term complications comprised one perineovaginal fistula and one rectovaginal fistula in Group 2. one patient complained about disabling dyspareunia after repair. In this patient the anterior sphincteroplasty was broken down and a postanal repair was performed.	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Sangwan et al, 1996[103] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Mean 15.9 months	**Patient group:** Patients with anterior sphincter defects. **Cause of FI:** Obstetric **All patients** **N:** 15 **N with FI:** 15 **Age (mean):** 36.9 **M/F:** 15F **Dropouts:** NR	**Intervention:** Overlapping sphincter repair	**Mean continence score:** Grade 1: continent Grade 2: Incontinent to flatus Grade 3:Incontinent to liquid stool and flatus Grade 4: Incontinent to solid stool	**Before:** 3.4 **After:** 2.3 **p value:** NR	**Funding:** NR **Additional outcomes:** PNTML (ms) Resting pressure (mmHg) and squeeze pressure (mmHg) postoperative data only reported. Subjective improvement scores.
			Operative outcome (excellent/good/improved/failed)	**Excellent:** 6/15 **Good:** 3/15 **Improved:** 4/15 **Failed:** 2/15	
			Complications	None reported.	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Fleshman et al, 1991[104] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Mean 12.5 months	**Patient group:** Consecutive patients at one hospital that underwent anterior anal sphincter reconstruction between 1985 and 89. **Cause of FI:** obstetric **All patients** **N:** 28 **N with FI:** 28 **Age (mean): 37.8 (22-75) yrs** **M/F:** 0/28 **Dropouts:** 0	**Intervention:** Overlapping anal sphincter repair.	**Continence Grade** (defined by: Grade I: complete continence, Grade II: Incontinent to flatus, Grade III: Incontinent to liquid stools and flatus, Grade IV: Incontinent to solid and liquid stools and flatus).	**Before:** Grade I = 0 Grade II = 0 Grade III = 7 (25%) Grade IV = 21 (75%) **After:** Grade I = 15 (54%) Grade II = 6 (21%) Grade III = 6 (21%) Grade IV = 1 (4%) **p value:** NR	**Funding:** NR **Limitations:** A concomitant sliding flap repair of a rectovaginal fistula was performed in five patients. **Additional outcomes:** Changes in manometric findings for patients in each grade of continence after surgery. Anal manometry before sphincter repair compared with functional results after repair. Anal manometry after repair compared between patients with different grades of continence after surgery. **Notes:** Included in systematic review Chapman 2002[87]
			Mean ± SEM maximal resting pressure (mmHg)	**Before:** 33.0±1.8 **After:** 42.0±2.6 **p value:** <0.01	
			Mean ± SEM maximal squeeze pressure (mmHg)	**Before:** 55.4 ± 3.7 **After:** 80.8 ± 6.5 **p value:** <0.001	
			Mean ± SEM Anterior sphincter length (cm)	**Before:** 2.3 ± 0.2 **After:** 3.3 ± 0.1 **p value:** <0.001	
			Mean ± SEM Anterior resting pressure profile (cm2)	**Before: 2.7** ± 0.3 **After:** 4.4 ± 0.3 **p value:** <0.001	
			Complications	Urinary retention (n=2) Superficial wound infection (n=2)	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Briel et al, 1999[105] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Median 1 year	**Patient group:** consecutive women with FI due to obstetric injury had anal sphincter defect and underwent repair by one surgeon. **Cause of FI:** obstetric **<u>All patients</u>** **N:** 20 **N with FI:** 20 **Age (median):** 50 (28-75) years **M/F:** 0/20 **Dropouts:** 0	**Intervention:** Anterior anal repair	**Continence restored:**	**After surgery:** 13/20 (65%)	**Funding:** NR **Limitations:** Complications not reported. **Additional outcomes:** Magnetic resonance imaging measurements in patients with poor and good outcome after repair. **Notes:** Continence classified by parks: Grade I, fully continent; Grade II, soiling and incontinence for gas; grade III, incontinence for liquids; and grade IV, incontinence for solid stool. Restoration of continence from grade IV to grade II or I, or from grade III to grade I, was defined as a successful outcome.
			Number of patients with or without external sphincter atrophy	**Atrophy:** 8/20 (40%) **Without**: 12/20 (60%)	
			Number of patients with restored continence with and without atrophy:	**With atrophy**: 2/8 **Without atrophy:** 11/12 **P=0.004**	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Chen et al, 1998[106] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 49.7 (20.4-72.6) months	**Patient group:** patients with an anterior anal sphincter defect that underwent anal sphincteroplasty. **Cause of FI:** obstetric – PNTL was prolonged unilaterally I seven patients, and prolonged bilaterally in four patients. Only one patient had a normal PNTL result. **All patients** **N:** 15 **N with FI:** 15 **Age (mean):** 45 (27-75) yrs **M/F:** 0/15 **Dropouts:** 3 (not responded to questionnaire follow-up)	**Intervention:** Anterior anal sphincter repair by the plication method.	**Mean ± SD continence scores** (defined by modified score 0-20; where 0=perfect continence).	**All patients (n=12)** **Preoperatively:** 15.8 ± 3.5 **Postoperatively:** 5.0± 5.1 **p value:** <0.05	**Funding:** Supported by Ferguson-Blodgett Digestive Disease Institute, Michigan. **Limitations:** one patient had a failed prior sphincteroplasty and two patients had an anal fistula operation 20 years previously. Select group of patients as only included those that underwent electrophysiological studies prior to surgery. These patients were only referred if they had suspected nerve injury. **Additional outcomes:** Continence scores were also reported immediately after surgery. Surgical outcomes (excellent, good, fair and poor continence scores) reported for patients subgrouped by prolonged unilateral and bilateral and normal PNTML. **Notes:**
			Mean ± SD continence scores (defined by modified score 0-20; where 0=perfect continence).	**Patients with prolonged bilateral PNTML (n=4)** **Preoperatively:** 15.0 ± 4.2 **Postoperatively:** 6.0± 6.1 **p value:** <0.05	
			Mean ± SD continence scores (defined by modified score 0-20; where 0=perfect continence).	**Patients with prolonged unilateral PNTML (n=7)** **Preoperatively:** 16.3 ± 3.5 **Postoperatively:** 5.1± 4.9 **p value:** <0.05	
			Mean ± SD continence scores (defined by modified score 0-20; where 0=perfect continence).	**Patients with external sphincter denervation (n=11)** **Preoperatively:** 15.5 ± 3.5 **Postoperatively:** 5.5 ± 5.0 **p value:** <0.05	
			Mean ± SD continence scores (defined by modified score 0-20; where 0=perfect continence).	**Patients with puborectalis denervation (n=2)** **Preoperatively:** 19.5 ± 0.7 **Postoperatively:** 2.5 ± 3.5 **p value:** <0.05	
			Complications	Perineal wound abscess (n=2)	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Engel et al, 1997[107] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 12 (4-30) months	**Patient group:** consecutive patients that underwent sphincter repair. The cause of the FI was from previous fistula surgery. **Cause of FI:** from previous fistula surgery performed at a median of 8 (4-42) months previously. **<u>All patients</u>** **N:** 20 **N with FI:** 20 **Age (median):** 42 (22-62) **M/F:** 13/7 **Dropouts:** 0	**Intervention:** Overlapping sphincter repair and six patients had a defunctioning colostomy.	**Patients parks continence scores** (defined by: Grade I continent to all stool and flatus, Grade II incontinent to flatus, some urgency but no incontinence, Grade III incontinent to liquid stool, Grade IV incontinent to formed stool).	**Before:** **Grade IV:** 20/20 (100%) **Post surgery:** **Grade I:** 4/19 **Grade II:** 9/19 **Grade III:** 6/19 **Grade IV:** 0/19 One patient awaiting colostomy closure.	**Funding:** NR **Additional outcomes:** Comparison of patients sex, complications, colostomy, location of EAS defect, endosonography results were compared between good and poor clinical results. **Notes:** No difference in maximum resting pressures, maximum voluntary contractile pressures, and maximum total pressures either pre or postoperatively between patients with a good outcome and those with a poor outcome (good outcome grades 1 & 2 and poor outcomes grades 3 & 4).
				Required packing of the surgical wound under general anaesthesia for persistent bleeding (n=1). Minor infective complication (n=3) Major infective (n=1) Ano-rectal sepsis during follow-up (n=2)	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Steele et al, 2006[108] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 33.8 months	**Patient group:** patients with sphincter defects undergoing surgery. **Cause of FI:** concomitant defects (pelvic floor disorders). 20 had obstetric-related FI **All patients** **N:** 28 **N with FI:** 28 **Age (mean):** 52.3 **M/F:** f **Dropouts:**	**Intervention:** Sphincteroplasty, with or without pelvic floor repair.	**Continence** (Wexner scores)	**Before:** 14.2 **After:** 5.1 **p value:** <0.001	**Funding:** NR **Additional outcomes:** Manometry, PMNTL, previous surgery etc. **Notes:** Compares PFR patients with non-PFR patients. Combined here as irrelevant to the analyses.
			Complications	**12 (43%) infection, faecal impaction, urinary retention,**	

Sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Jensen & Lowry, 1997[109] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 32 months	**Patient group:** 28 patients with at least one previous sphincteroplasty, 3 had had 2 repairs and one patient had had 3. 9 patients had an accompanying levatorplasty. **Cause of FI:** obstetric **All patients** **N:** 28 **N with FI:** 28 **Age (mean):** 34 **M/F:** f **Dropouts:** none reported	**Intervention:** Biofeedback after sphincteroplasty	**Continence (0- 30, best-worst)**	**(self rated as) failed: 3 (10%)** **Before:** 22 **After:** 16 **p value:** Not sig	**Funding:** NR **Additional outcomes:** Number of incontinence episodes per week, age, time between sphincter repairs and biofeedback, rectal sensations, PNTLM.
				(self rated as)Improved: 25 (89%) **Before:** 16.5 **After:** 13.5 **p value:** <0.001	
			Complications	**0 (0%)**	
			Continence (0- 30, best-worst) overall	**Before:** 20 **After:** 3 **p value:** <0.0001	

Evidence Table 23: surgical case series for repeat sphincter repair

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Pinedo et al, 1999[110] **Study design:** Historical case series **Evidence level:** 3 **Duration of follow-up:** Median follow up was 20 (5-42) months.	**Patient group:** patients underwent repeat sphincter repair of an anterior obstetric sphincter injury from May 1994 to May 1997. Inclusion criteria were adequate contraction of the remaining external sphincter muscle. **Cause of FI:** obstetric injury **<u>All patients</u>** **N: 26 N with FI:** 26 **Age (median):** 43 (23-63) yrs **M/F**: 0/26 **Drop out:** 3 1 previous repair surgery=19 2 previous repair surgery=4	Repeat sphincter repair and 9 had a covering colostomy.	Patients felt improved by 50% or more:	N= 15/23 (65%)	**Funding:** NR **Limitations:** Manometry conducted in 21 patients before operation and 17 after the operation. **Additional outcomes:** Relationship between patient age, number or previous repair of the use of a covering colostomy and clinical outcome after the repair. **Notes:** There was a significant correlation between the improvement in the Wexner incontinence score and the improvement in ability to defer defaecation and the patients assessment of improvement and satisfaction (p<0.001). No relationship between pre-operative anorectal sensation or pudendal nerve latencies and outcome of surgery
			Median satisfaction scale (1-10)	**Satisfaction:** 7 (range 1-10)	
			Median Wexner continence grading scores (1-20, higher the worse)	**Before:** 19 (range, 17-20) **After:** 12 (range, 1-20) **p value:** <0.001	
			Median time reported able to defer defaecation:	**Before:** <1 min **After:** 5 min **p value:** <0.001	
			Median resting anal pressure: cmH2O	**Before:** 46 (range, 0-120) **After:** 55 (range, 20-105) **p value:** >0.5	
			Median squeeze pressure: cmH2O	**Before:** 36 (range, 8-70) **After:** 45 (range, 20-110) **p value:** >0.5	

Repeat sphincter repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Vaizey et al, 2004[111] **Study design:** Case Series **Evidence level:** 3 **Duration of follow-up:** Median = 20 months	**Patient group:** 23 patients undergoing repeat obstetric anterior sphincter repair, previously assessed. **Cause of FI:** Persistent sphincter defect (obstetric) **All patients** **N:** 23 **N with FI: 23** **Age (mean):** Median age 47 **M/F:** 0/23 **Dropouts:** 2	**Intervention:** Repeat anterior sphincter repair	**Continence** (Wexner continence grading score 0-10, no control to perfect control)	**Before:** 12 **After:** 7 **p value:** 0.81	**Funding:** NR **Limitations:** Subjective assessment **Additional outcomes:** Physiologic findings and ultrasound, satisfaction with operation (20 and 60 months following op), median hospital stay,
			Symptom improvement (20 and 60 months following op)	**20 months follow-up:** 62% **60 months follow-up:** 61% **p value:** 0.62	
			Ability to defer defecation	**Before:** < 1 minute **After:** 4 minutes **p value:** 0.16	
			Complications	Not stated. 2 patients underwent further surgery for faecal incontinence.	

Evidence Table 24: Surgical case series for post-anal repair

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Engel et al, 1994[112] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up (median):** 43 months	**Patient group:** Patients reporting faecal incontinence. Eight women had had successful operation for complete rectal prolapse by abdominal rectopexy (n=4) and low anterior resection (n=4), 2 other women unspecified operations on their anterior sphincters. **Cause of FI:** idiopathic. **All patients** **N:** 38 **N with FI:** 38 **Age (mean):** 57 **M/F:** 4/ 34 **Dropouts:** 0	**Intervention:** post-anal repair.	**Grade of incontinence** (grade 1: perfect continence to liquid and solid stool, grade 2: improvement but infrequent loss of liquid and solid stool, therefore satisfied, grade 3: improvement but frequent loss of liquid and solid stool therefore dissatisfied, grade 4: no improvement)	**Before:** Grade 1: 0 Grade 2: 0 Grade 3: 0 Grade 4: 38 **After:** Grade 1: 8 Grade 2: 11 Grade 3: 6 Grade 4: 13 **p value:** NR	**Funding:** NR **Additional outcomes:** Anorectal manometry scores for patients who are satisfied and not satisfied. **Notes:** 8/38 patients required a covering colostomy. Patients without a colostomy were kept on a liquid diet for 5 days after which liquid paraffin was used to ensure easy passage of soft stool.
			Mean clinical score of incontinence	**Before:** 4 **After:** 2.6 **p value:** NR	
			Complications	3 patients had post-operative complications; pulmonary embolus, angina and wound infection that necessitated a permanent colostomy.	

Post-anal repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Setti et al, 1994B[113] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up (median):** 73 months after operation.	**Patient group:** Patients with faecal incontinence (median duration of symptoms was 72 months). **Cause of FI:** Neurogenic **All patients** **N:** 54 **N with FI:** 54 **Age (mean):** 64 **M/F:** 3/51 **Dropouts:** 12 patients were not available for follow-up (nine patients had died from unrelated conditions, one patient had dementia, one had undergone proctectomy and one was in hospital for other reasons) and 7 declined to return for assessment. The remaining male patient was 3 excluded from the analysis.	**Intervention:** post-anal repair	**Continence score on Browning and Parks scale** (4 categories: A= normal continence for solid and liquid stool and flatus, B=continence for solid and liquid stool but not for flatus, C= control over solid stool but incontinence for liquid stool or flatus and D=incontinence for solid and liquid stool and flatus.	**Before:** A: 0 patients B: 0 patients C: 12 patients D: 22 patients **6 months post-operative:** A: 2 patients B: 12 patients C: 16 patients D: 1 patient **p value:** NR **12 months post-operative:** A: 2 patients B: 9 patients C: 18 patients D: 0 patients **p value:** NR **>60 months post-operative:** A: 4 patients B: 5 patients C: 21 patients D:4 patients **p value:** NR	**Funding:** Ospedale Maggiore Policlinico, IRCCS, Milan, Italy and the St Marks Research Foundation. **Additional outcomes:** Anal canal length, resting pressure, voluntary contraction pressure, perineal descent (at rest and strain), mean pundendal nerve terminal latency and fibre density were all reported for various subgroups of patients.

Post-anal repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Orrom et al, 1991[114] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 15 months	**Patient group:** patients with idiopathic faecal incontinence. **Cause of FI:** NR **All patients** **N:** 17 **N with FI:** 17 **Age (mean):** 65 (39-88) **M/F:** NR, assumed F **Dropouts:**	**Intervention:** Postanal repair	**Faecal incontinence** (Browning and Parks grading systems, A-D, A = continent, B = incontinent to flatus, C = incontinent to flatus and liquid, D = incontinent to flatus, liquid and solid)	**A:** **Before:** 0/17 **After:** 4/17 **p value:** NR **B:** **Before:** 0/17 **After:** 6/17 **p value:** NR **C:** **Before:** 1/17 **After:** 3/17 **p value:** NR **D:** **Before:** 16/17 **After:** 4/17 **p value:** NR	**Funding:** NR **Limitations:** Reported that there was a significant difference between groups but not actual figures. **Additional outcomes:** Sphincter length (cm), Anorectal angle, Pelvic descent (cm), Mucosal electrosensitivity (mA) **Notes:** 2 case series reported in one paper. Controls also, but excluded for this review. Complications not discussed.
			Maximum resting pressure (cmH20)	**Before:** 40 **After:** 50 **p value:** p<0.05	
			Maximum squeeze pressure (cmH20)	**Before:** 55 **After:** 95 **p value:** p<0.01	
			Success (Success defined as grade A or B.)	59% of patients had a successful result.	

Post-anal repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Rieger et al, 1997[115] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 8 years (median; range 2-10)	**Patient group:** NR **Cause of FI:** NR **All patients** **N:** 22 **N with FI:** 22 **Age (mean):** 60 (31-82) **M/F:** 2/20 **Dropouts:** 3	**Intervention:** Postanal repair	**Faecal incontinence** (Flinders scoring system Nature of incontinence: 0-3, best-worst Degree of incontinence 0-3 best-worst Frequency 0-4 best-worst Maximum possible score = 10)	**Before:** (mean) 8.8 **After:** (mean) 5.2 **p value:** NR	**Funding:** NR **Limitations:** (e.g. FI incidence/score NR, or name potential biases) **Additional outcomes:** Subjective assessment by patient, Faecal incontinence Browning and Parks grading systems, manometry, data given only for six patients.
			Patients subjective outcomes of surgery	**Success: 7** **Improved: 4** **Failure: 8**	

Post-anal repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Matsuoka et al, 2000[116] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 3 (1-7.5) years	**Patient group:** patients with an FI score of at least 12/20, with failed conservative, medical and biofeedback management. **Cause of FI:** idiopathic or neurogenic **<u>All patients</u>** **N:** 21 **N with FI:** 21 **Age (mean):** 68 **M/F:** 0/21 **Dropouts:** 1 (unknown cause)	**Intervention:** Post-anal repair	**Continence (0- 20, best-worst)**	**(clinician-rated as) Cured: 7 (35%)** **Before:** 16.7 **After:** 2.6 **p value:** <0.001 **(clinician-rated as) Improved: 13 (65%)** **Before:** 16.5 **After:** 13.5 **p value:** Not sig	**Funding:** NR **Additional outcomes:** Length of hospital stay, prior vaginal delivery, history of previous surgery for FI, PNTML damage, sphincter damage – none of which correlated with a successful outcome.
			Complications	**1/21 (5%) wound infection**	

Post-anal repair continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Abbas et al, 2005[117] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 3 years range 2-9)	**Patient group:** patients who had not responded to dietary and pharmacological treatment and underwent a post-anal repair for faecal incontinence at Auckland Hospital between 1994 and 2001 (identified from the hospital databases and admission records and operative notes). All patients were parous (median number of vaginal deliveries: 2) **Cause of FI:** (e.g. rectal prolapse / sphincter tear / idiopathic / all / NR / etc) **<u>All patients</u>** **N:** 47 **N with FI:** 66 **Age (median):** 63 years **M/F:** 0/47 66 originally had operation but only 47 responded to questionnaire.	**Intervention:** post-anal repair	**Median FISI score**	**(n=44)** **Before:** 35 (range 10-61) **After:** 23 (range 0-56) **p value:** 0.001	**Funding:** NR **Additional outcomes:** Separate scores for Gas, mucus, liquid and solid reported. **Notes:** 16 patients had perianal rectocele repair (10 of which were done at the same time as the post-anal repair)
			Proportion of patients with improved FISI score	30/44 (68%)	
			Number of patients fully continent to liquid and solid stools and flatus	4	
			Number of patients fully incontinent to flatus only	6	
			Median hospital stay	6 days (range 2-14)	
			Post-operative complications	3 patients had wound breakdown and 1 patient had urinary retention	

Evidence Table 25: Surgical case series for levatorplasty

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Osterberg et al, 2000[98] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 12 months	**Patient group:** Patients who had failed conservative treatment (administration of bulking agents for at least 2 months). **Cause of FI:** idiopathic (neurogenic) **All patients** **N:** 31 **N with FI:** 31 **Age (median):** 68 **M/F:** 0/31 **Dropouts:** 0	**Intervention:** Anterior levatorplasty (post-anal repair in men).	**Incontinence per se**	**Pre-op:** 29 **3 months post op:** 15 **p value:** <0.001 **12 months post -op:** 13 **p value:** <0.001	**Funding:** Swedish Medical Research Council. **Limitations:** Not clear what 'incontinence per se' refers to. **Additional outcomes:** Use of pads, % straining, deferring time (loose stool, solid stool), resting pressure, squeeze pressure, high-pressure zone, rectoanal inhibitory reflex, rectal compliance.
			Median incontinence score (0-18, lower score indicates improved incontinence)	**Pre-op:** 14 **3 months post op:** 3 **p value:** <0.001 **12 months post -op: 3** **p value:** <0.001	
			Impact on lifestyle – social handicap	**Pre-op:** 25 **3 months post op:** 12 **p value:** <0.001 **12 months post -op:** 12 **p value:** <0.001	
			Impact on lifestyle – physical handicap	**Pre-op:** 28 **3 months post op:** 14 **p value:** <0.001 **12 months post -op:** 12 **p value:** <0.001	
			Maximum rest pressure	**Pre-op:** 42 **3 months post op:** 43 **p value:** NS **12 months post -op:** 42 **p value:** NS	
			Maximum squeeze pressure	**Pre-op:** 63 **3 months post op:** 61 **p value:** NS **12 months post -op:** 64 **p value:** NS	
			Complications	Two patients had post-operative wound infection, treated successfully with drainage and antibiotics.	

Levatorplasty continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Aitola et al, 2000[118] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Mean 12 months (2-54 range)	**Patient group:** **Cause of FI:** 27 idiopathic 17 traumatic **All patients** **N:** 45 **N with FI:** 45 **Age (mean):** **M/F:** f **Dropouts:** 1	**Intervention:** Anterior levatorplasty combined with external anal sphincter placation for faecal incontinence.	**Wexner score** (0-20, best-worst) FI, Trauma patients	**Before:** 13 **After:** 7 **p value:** 0.0001	**Funding:** Grant from the Medical Research Fund of the Tampere University Hospital **Additional outcomes:** Incontinence according to Kirwan's scale. Averages not given, raw data only Satisfaction with results. **Notes:** Complications not discussed.
			Wexner score (0-20, best-worst) FI, Idiopathic patients	**Before:** 13 **After:** 7 **p value:** 0.0006	
			Mean resting pressures (cmH20) Trauma Idiopathic	**Before:** 38 **After:** 39 **p value: NR** **Before:** 48 **After:** 43 **p value: NR**	
			Mean squeeze pressures (cmH20) Trauma Idiopathic	**Before:** 55 **After:** 72 **p value: <0.04** **Before:** 49 **After:** 52 **p value: NR**	
			Functional anal canal (cm) Trauma Idiopathic	**Before:** 2.7 **After:** 2.8 **p value:** NR **Before:** 2.8 **After:** 2.5 **p value:<0.02**	

Evidence Table 26: surgical case series for total pelvic floor repair

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Korsgen et al, 1997[119] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up (median):** 36 months	**Patient group:** patients with faecal incontinence (duration of incontinence before presentation ranged from 10-98 months). 55 patients had at least weekly incontinence to stools, 2 patients suffered from solid stool incontinence less than once per month. **Cause of FI:** post-obstetric neuropathic **<u>All patients</u>** **N:** 75 **N with FI:** 75 **Age (mean):** 57 **M/F:** 0/75 **Dropouts:** 9 patients could not be traced, 6 patients required re-operation for persistent incontinence (which included a stoma in 4 and graciloplasty in 2), and 3 patients were too old and frail to complete the questionnaire.	**Intervention:** total pelvic floor repair	**Patient's assessment of outcome (%)**	**Worse than before operation:** 6/57 (11%) **Not improved:** 11/57 (19%) **Slight improvement:** 13/57 (23%) **Greatly improved:** 27/57 (47%) **p value:** NR	**Funding:** NR **Limitations:** (e.g. FI incidence/score NR, or name potential biases) **Additional outcomes:** Difference between squeeze and resting pressures, anal canal sensation (lower and upper), threshold rectal sensation in ml of air, maximum rectal sensation in ml of air, Pundendal nerve latency in milliseconds, anorectal physiology of those with mild or no improvement vs those with marked improvement.
			Patient satisfaction:	**Not at all satisfied:** 11/57 (19%) **Moderately satisfied:** 25.57 (44%) **Very satisfied:** 21/57 (37%) **p value:** NR	
			Mean maximum resting pressure (SD)	**Before:** 80 (30) **After:** 68 (30) **p value:** <0.01	
			Mean maximum squeeze pressure (SD)	**Before:** 138 (52) **After:** 119 (47) **p value:** <0.05	

Evidence Table 27: surgical case series for sacral nerve stimulation

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Rosen et al, 2001[120] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up (median):** 15 months	**Patient group:** Patients who had a minimum of 1 incontinent episode per week for solid stool, an intact anal sphincter documented by endoanal ultrasound and/ or MRI, a minimum history of FI for one year after a neurological event (surgery, trauma, stroke) and had failed a 6 week course of a standardised biofeedback protocol. Two patients with idiopathic faecal incontinence had undergone post-anal repair procedures with no improvement. For 3 patients SNS was the first surgical treatment for their incontinence. **Cause of FI:** neurologic (n= 15) and idiopathic (n= 5). **All patients** **N:** 20 **N with FI:** 20 **N with typical visual positive response at acute testing and underwent permanent implantation:** 16 **Age (mean):** 50.1 **M/F:** 6/ 14 **Dropouts:** 4 Acute testing failed to show any response in 4 patients (2 patients with FI cause by spinal cord trauma after a car accident, 1 with spinal stroke and 1 with meningomyelocele).	**Intervention:** After temporary external stimulation over 10-14 days, patients in whom continence improved underwent implantation of a permanent quadripolar lead and subcutaneous pulse generator.	**Median number of incontinence episodes for solid or liquid stool per 21 days for all patients (range)**	**Before:** 6 (3-15) **After:** 2 (0-15) **p value:** NR	**Funding:** NR **Limitations:** small group of patients. **Additional outcomes:** Time of rentention of a volume of saline, anal canal length, resting and squeeze pressure for all patients. **Notes:** The Fecal Incontinence Quality of Life Scale is composed of a total of 29 items; these items form four scales: Lifestyle (10 items), Coping/Behaviour (9 items), Depression/Self-Perception (7 items), and Embarrassment (3 items). Larger numbers indicate improved quality of life. “of 20 total patients, 16 (80%) reported improvement of continence after acute testing and in the early post-operative period after permanent implantation.” p539
			Median number of incontinence episodes for solid or liquid stool per 21 days for all 12 patients with neurologic events (range)	**Before:** 7(4-15) **After:** 2(0-5) **p value:** Sig (<0.01)	
			Median QOL score (The Faecal Incontinence Quality of Life Scale) - lifestyle	**Before:** 2.1 (1.0-2.8) **6 months after:** 3.9 (2.7-4.4) **p value:** Sig (<0.01)	
			Median QOL score (The Faecal Incontinence Quality of Life Scale) – coping/ behaviour	**Before:** 2.0 (1.3-2.5) **6 months after:** 3.7 (3.0-4.1) **p value:** Sig (<0.01)	
			Median QOL score (The Faecal Incontinence Quality of Life Scale) – depression/ self perception	**Before:** 2.6 (1.7-3.1) **6 months after:** 3.7 (3.2-4.3) **p value:** Sig (<0.01)	
			Median QOL score (The Faecal Incontinence Quality of Life Scale) questionnaire - embarrassment	**Before:** 1.7 (1.0-2.2) **6 months after:** 3.8 (3.0-4.6) **p value:** Sig (<0.01)	
			Resting pressure in patients with idiopathic cause of FI (n=4)	**Before:** 36.3 mmHg (19-39) **3 months after:** 54.2 mmHg (46-76) **p value:** 0.1	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Resting pressure in patients with neurological cause of FI (n=12)	**Before:** 21.4 mmHg (16-37) **3 months after:** 46.7 mmHg (29.9 – 75) **p value:** 0.01	
			Squeeze pressure with idiopathic cause of FI (n=4)	**Before:** 50 mmHg (30-61) **3 months after:** 110 mmHg (57-115) **p value:** 0.10	
			Squeeze pressure in patients with neurological cause of FI (n=12)	**Before:** 68 mmHg (28-87) **3 months after:** 126 mmHg (81-193) **p value:** 0.01	
			Post-operative complications	3 patients had severe infections of the implanted systems that had to be treated with explanation of the leads and generator and drainage of the wounds 3-6 months after implantation. After consolidation of infectious site, all 3 patients were rated as candidates for renewed SNS. 1 patient had dislocation of the permenant electrode that led to reintervention and new placement. When dislocation occurred for the second time 3 months later, the patient underwent dynamic graciloplasy using the already implanted pulse generator. Post-operative pain was controlled by mild analgetics	

SNS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Matzel et al, 2004[121] **Study design:** case series **Evidence level:** 3 **Duration of follow-up (mean):** 23.9 months. 32 (94.1%) of 34 patients with permanent implants were followed up for 6 months, 30 (88.2%) for 12 months and 23 (67.6%) for 24 months.	**Patient group:** adult patients (18-75 years) with faecal incontinence with either no previous sphincter surgery or had persistent incontinence despite a surgically repaired sphincter. Patients had involuntary passage of liquid of solid stool at least once a week, intact anal sphincter (if previous repair intact at least 50% of its length), incontinence was refractory to medical or biofeedback therapy. **Cause of FI:** idiopathic (n= 19), scleroderma (n=2), obstetric trauma (n=10), perineal surgery (n=6). **<u>All patients</u>** **N:** 37 **N with FI:** 37 **N who had implantation of permanent stimulation system:** 34 **Age (mean):** 54.3 **M/F:** 4/33 **Dropouts:** non-adherence, repeat lead dislodgement and infection despite successful screening obviation permanent implantation in 3 patients.	**Intervention:** staged diagnostic procedure with acute and subchronic percutaneous stimulation for a minimum of 10 days. Patients with at least 50% reduction in number of incontinent episodes per week or 50% reduction in number of days with incontinence per week underwent implantation of a permanent neurostimulation device.	**Mean incontinence episodes per week** (SD)	**Baseline:** 16.4 (19.3) **3 months:** 1.2 (1.9) **p value:** <0.0001 **6 months:** 1.6 (2.2) **p value:** <0.0001 **12 months:** 3.1 (5.5) **p value:** <0.0001 **24 months:** 20. (3.3) **p value:** <0.0001 **36 months:** 1.8 (2.2) **p value:** 0.0034	**Funding:** Bakken Research Centre BV **Limitations:** Not clear if any of the patients in this study attending St Marks Hospital, London were also reported in Jarrett2004A[122]. **Additional outcomes:** urgency episodes per week, passive incontinent episodes per week, days with stains per week, SF-36 quality of life assessment. Outcomes reported in the table were also reported after screening. **Notes:** The Fecal Incontinence Quality of Life Scale is composed of a total of 29 items; these items form four scales: Lifestyle (10 items), Coping/Behavior (9 items), Depression/Self-Perception (7 items), and Embarrassment (3 items). Larger numbers indicate improved quality of life. Doesn't show calculations but says 83% of patients with
			Mean number of days with incontinence per week (SD)	**Baseline:** 4.5 (1.8) **3 months:** 0.8 (1.1) **p value:** <0.0001 **6 months:** 1.1 (1.4) **p value:** <0.0001 **12 months:** 1.4 (2.0) **p value:** <0.0001 **24 months:** 1.2 (1.8) **p value:** 0.0004 **36 months:** 1.3 (1.7) **p value:** 0.0016	
			Number of patients with improvement in faecal incontinence episodes (100% full continence, 75-99% improvement, 50-75% improvement, <50% improvement) (%)	**Screening** **100%:** 11/ 37 (30%) **75-99%:** 19/37 (51%) **50-75%:** 3/ 37 (8%) **<50%:** 3/ 37 (8%) **3 months** **100%:** 12/37 (27%) **75-99%:** 13/37 (35%) **50-75%:** 3/37 (8%) **<50%:** 3/37 (8%)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				6 months **100%:** 11/37 (30%) **75-99%:** 13/37 (35%) **50-75%:** 3/37 (8%) **<50%:** 3/37 (8%) **12 months** **100%:** 17/37 (46%) **75-99%:** 4/37 (11%) **50-75%:** 4/37 (11%) **<50%:** 5/37 (13%) **24 months** **100%:** 9/37 (24%) **75-99%:** 6/37 (16%) **50-75%:** 4/37 (11%) **<50%:** 2/37 (5%) **36 months** **100%:** 3/37 (8%) **75-99%:** 1/37 (3%) **50-75%:** 1/37 (3%) **<50%:** 1/37 (3%) **p-values:** NR	the primary two outcomes had a 50% or greater improvement in symptoms.
			Number of patients with improvement in days with faecal incontinence (100% full continence, 75-99% improvement, 50-75% improvement, <50% improvement) (%)	**Screening** **100%:** 11/37 (30%) **75-99%:** 11/37 (30%) **50-75%:** 10/37 (27%) **<50%:** 4/37 (11%) **3 months** **100%:** 12/37 (32%) **75-99%:** 9/37 (24%) **50-75%:** 5/37 (13%)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				<50%: 4/37 (11%) **6 months** **100%:** 11/37 (30%) **75-99%:** 7/37 (19%) **50-75%:** 8/37 (22%) **<50%:** 4/37 (11%) **12 months** **100%:** 17/37 (46%) **75-99%:** 2/37 (5%) **50-75%:** 3/37(8%) **<50%:** 8/37 (22%) **24 months** **100%:** 9/37 (24%) **75-99%:** 5/37 (13%) **50-75%:** 1/37 (3%) **<50%:** 6/37 (16%) **36 months** **100%:** 3/37 (8%) **75-99%:** 1/37 (3%) **50-75%:** 2/37 (5%) **<50%:** 0/37 (0%) **p-values:** NR	
			Mean QOL score (The Faecal Incontinence Quality of Life Scale) – lifestyle (SD)	**Baseline:** 2.7 (0.9) **3 months:** 3.6 (0.7) **p value:** <0.0001 **6 months:** 3.5 (0.6) **p value:** <0.0001 **12 months:** 3.5 (0.6) **p value:** <0.0001 **24 months:** 3.4 (0.7) **p value:** 0.0004	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				36 months: 3.5 (0.6) **p value:** 0.0012	
			Mean QOL score (The Faecal Incontinence Quality of Life Scale) – coping/ behaviour (SD)	**Baseline:** 1.7 (0.6) **3 months:** 2.9 (0.8) **p value:** <0.0001 **6 months:** 2.9 (0.8) **p value:** <0.0001 **12 months:** 2.8 (0.8) **p value:** <0.0001 **24 months:** 2.9 (0.8) **p value:** <0.0001 **36 months:** 2.9 (1.1) **p value:** 0.0161	
			Mean QOL score (The Faecal Incontinence Quality of Life Scale) – depression/ self perception (SD)	**Baseline:** 2.8 (1.0) **3 months:** 3.7 (0.8) **p value:** <0.0001 **6 months:** 3.9 (1.0) **p value:** <0.0001 **12 months:** 4.0 (0.9) **p value:** <0.0001 **24 months:** 3.5 (1.0) **p value:** 0.0082 **36 months:** 3.6 (0.8) **p value:** 0.0327	
			Mean QOL score (The Faecal Incontinence Quality of Life Scale) questionnaire – embarrassment (SD)	**Baseline:** 1.8 (0.9) **3 months:** 3.1 (0.9) **p value:** <0.0001 **6 months:** 2.9 (0.9) **p value:** <0.0001 **12 months:** 3.0 (0.9) **p value:** <0.0001 **24 months:** 3.1 (0.9) **p value:** 0.0003 **36 months:** 3.1 (0.9) **p value:** 0.0347	

SNS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Kenefick et al, 2002[123] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Median 24 (range 3-60) months.	**Patient group:** consecutive patients underwent temporary and subsequent permanent, stimulation over a five year period in one institution. All patients had failed to improve with maximal conventional treatment, including antidiarrhoeal agents and behavioural therapy. **Cause of FI:** obstetric (n=7), scleroderma (n=4), idiopathic (n=2), fistula surgery (n=1) and repaired rectal prolapse (n=1). **All patients** **N:** 15 **N with FI:** 15 **Age (median):** 60 (range 37-71) yrs **M/F:** 1/14 **Dropouts:**	**Intervention:** Sacral nerve stimulation.	Median (range) number of mean episodes of FI per week	**Before (n=15):** 11 (2-30) **Percutaneous nerve evaluation (PNE)** (n=15): 0 (0-7) P<0.001 **Post implant of permanent device:** 3 months (n=15): 0 (0-5) p<0.001 6 months (n=13): 0 (0-4) p<0.001 12 months (n=10): 2 (0-8) p <0.01 24 months (n=9): 0 (0-4) p<0.01 36 months (n=5): 0 (0-1) p<0.05 48 months (n=4):0 (0-0) p=NS 60 months (n=2):0 (0-1) p=NS	**Funding:** Medtronic **Notes:** All patients responded to temporary stimulation and had permanent implantation.
			Median (Range) minutes able to defer defaecation:	**Before:** Less than 1 (0-1) **After:** 8 (1-15) **p value:** 0.01	
			Mean (SD) resting pressure (cmH2O)	**Before:** 35 (17) **PNE:** 49 (21) **P<0.05** **After:** 41 (19) **P=NS**	
			Mean (SD) squeeze pressure increment (cmH20)	**Before:** 43 (40) **PNE:** 74 (47) **P<<0.01** **After:** 69 (49)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Mean (SD) threshold volume (ml air)	**P<0.05** **Before:** 47 (19) **PNE:** 65 (33) **P=ns** **After:** 34 (15) **P <0.05**	
			Mean (SD) urge volume (ml air)	**Before:** 82 (31) **PNE:** 106 (48) **P=ns** **After:** 74 (41) **P=ns**	
			Mean (SD) maximum tolerated volume (ml air)	**Before:** 127 (43) **PNE:** 150 (52) **P=ns** **After:** 103 (49) **P=ns**	
			Complications	Superficial skin infection (n=1), permanent lead dislodgement occurred (n=2) pain at the iliac crest over the subcutaneous connecting wires (n=3). Some patients occasionally experienced electric shocks when passing electrical or magnetic fields.	

SNS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Ganio et al, 2001[124] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 15.5 months (mean)	**Patient group:** faecally incontinent with intact or surgically repaired anal sphincter. **Cause of FI:** scleroderma (2), trauma (2), spastic paraparesis (1), idiopathic (5), neuropathy (3), others not reported. **All patients** **N:** 16 **N with FI:** 16 **Age (mean):** 51.4 (27-79) **M/F:** 4/12 **Dropouts:**	**Intervention:** Sacral nerve stimulator implantation.	**Faecal incontinence** (William's score)	**Before:** 4.1± 0.96 **After:** 1.25±0.5 **p value:** 0.01 (Wilcoxon)	**Funding:** NR **Limitations:** Manometry not pre- and post-implantation figures, but on whether the generator is turned on or not. Complications not mentioned. Patients selected were those most likely to have positive outcomes. **Additional outcomes:** Rectal sensitivity, length of stay, duration of surgery, stimulation parameters, rectal volume, urinary incontinence.
			Number of incontinence accidents (per fortnight)	**Before:** 11.5±4.8 **After:** 0.6±0.9 **p value:** NR	
			Mean maximal resting pressure (mmHg)	**Before:** 38±14.9 **After:** 49±19 **p value:** 0.04	
			Maximum squeeze pressure (mmHg)	**Before:** 67±21 **After:** 81±21 **p value:** 0.09	

SNS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Jarrett et al, 2005[125] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 12 (6-24) months	**Patient group:** NR **Cause of FI:** NR **All patients** **N:** 13 **N with FI:** 13 **Age (median):** 58.5 (39-73) **M/F:** 4/9 **Dropouts:** 1 unsuccessful implantation	**Intervention:** Sacral nerve stimulator implantation.	**Mean number of incontinent episodes per week**	**Before:** 9.33 **After:** 2.39 **p value:** 0.012	**Funding:** Medtronic, Nakken Research centre BV. **Additional outcomes:** Ability to defer defecation. Number of days per week pads used. Quality of life., resting and squeeze pressure, length of stay, mean operating time.
			Number of days per week with incontinence or staining	**Before:** NR **After:** NR **p value:** <0.001	
			Complications	6 patients (46%) experienced complications, including pain, device migration or breakage. Infections, constipation and impaction.	

SNS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Ganio et al, 2006[126] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 12 months	**Patient group:** Patients with faecal incontinence to solid or liquid stool at least once per week who did not respond to conventional behavioural and or medical treatments and possessed a structurally intact external anal sphincter on anal endosonography and or pudendal nerve terminal motor latency assessment. **<u>All patients</u>** **N:** 116 **N with FI:** 116 **Age (mean):** NR **M/F:** 18/98 **Drop outs:** **<u>Patients selected for definitive implant</u>** **N:** 36 **N with FI:** 36 **Age (mean):** 55.2 **M/F:** 7/29 **Drop outs: 5** **Cause of FI:** idiopathic (n=15), pelviperineal surgery (n=11), spinal cord surgery (n=2), incomplete D8 lesion (n=1), scleroderma (n=1) and spastic paraparesis (n=1).	Sacral Nerve Modulation **Peripheral nerve evaluation (PNE):** all patients underwent PNE for a mean of 13 days (range 7-20). Patients with 50% reduction in leakage episodes for liquid or solid stools during test period and a rapid return to pre-PNE condition when stimulation was discontinued. **Definitive implant:** 31 patients had a permanent implant, 14 with a two-stage technique	**Mean number of incontinence episodes for sold or liquid stools (per 14 days)**	**Baseline:** 15 (range 2-22) **12 months:** 0.3 (range 0-4) **p value:** NR	**Funding:** NR **Additional outcomes:** Number of bowel movements, results from SF36 compared to healthy population. **Notes:** Included in systematic review Jarrett 2004[85].
			Mean number of episodes of minor incontinence (incontinence to gas and soiling)	**Baseline:** 41.6 (range 2-65) **12 months:** 12.6 (0-19) **p value:** NR	
			Cleveland Clinic Florida Faecal Incontinence Scoring System	**Baseline:** 14.6 (range 6-20) **12 months:** 4.6 (3-9) **p value:** <0.1	
			Anorectal manometry	NS	
			Pad use	**Baseline:** 1.3 **12 months:** 1.95	
			Complications	One patient complained of pain at implant site when IPG was used as anode (unipolar impulse) and another necessitated electrode repositioning for displacement after 3 months.	

Evidence Table 28: Surgical case series for dynamic graciloplasty

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Wexner et al, 2002[127] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 24 months	**Patient group:** adult patients with end stage faecal incontinence (14% of patients had no continent bowel movements). Average symptom duration was 11.7 years. 95% of patients had refractory incontinence to standard treatments (including antidiarrhoeal medications, bulking supplements, biofeedback, enemas, laxatives and surgery). 29 patients entered the trial with a stoma. **Cause of FI:** congenital (n=15), idiopathic (n=34), obstetric trauma (n=35), other direct trauma (n=31). **All patients** **N:** 115 **N with FI:** 115 **Age (mean):** 50.3 **M/F:** 23/ 92 **Dropouts:** 24	**Intervention:** graciloplasty and implantation of the stimulating device (pacemaker and leads) was performed by one or two stages by the surgeon. Eight weeks of muscle conditioning with increasing levels of neuromuscular stimulation followed.	**Mean incontinent solid bowel movements per week (SD) in non-stoma patients**	**Before:** 9.3 (9.1) **12 months:** 2.5 (7.0) **p value:** Not sig. **24 months:** 1.3 (3.1) **p value:** NR	**Funding:** Interstim Division of Medtronics **Limitations:** it was not always clear if outcomes reported were comparing results for stoma and non-stoma patients or baseline and follow-up. **Additional outcomes:** Average number of continent bowel movements per week, average number of pads used per week, enema retention, SF-36 quality of life questionnaire, general health questionnaire, Zung self-rating depression scale and TyPE specification. Change in stimulated and non-stimulated resting and squeeze pressure from baseline was also reported however, it was not clear when during follow-up these outcomes were measured again. **Notes:** Patients were recruited from May 1993 to November 1999. Baeten et al, 2000[128] report results of same study although patients were recruited from September 1994 to January 1999. Matzel et al,
			Mean incontinent liquid bowel movements per week in non-stoma patients	**Before:** 9.1 (12.0) **12 months:** 3.0 (6.2) **p value:** Not sig. **24 months:** 3.5 (5.9) **p value:** NR	
			Overall success (defined as at least 50% reduction in the number of incontinent episodes compared to baseline) in non-stoma patients	**12 months:** 47/76 (62%) **18 months:** 37/67 (55%) **24 months:** 35/62 (56%)	
			Analysis of function in non-stoma patients at 24 months	**100% continence:** 9/ 62 (15%) **50-99% continence:** 26/62 (42%) **1-49% continence:** 6/62 (10%) **Patients opting for permanent stoma:** 4/ 62 (6%)	
			Overall success (defined as at least 50% reduction in the number of incontinent episodes compared to baseline) in stoma patients	**12 months:** 9/24 (37.5%) **18 months:** 13/21 (62%) **24 months:** 9/21 (43%)	
			Analysis of function in stoma patients at 24 months	**100% continence:** 7/21 (33%) **50-99% continence:** 4/21 (17%) **1-49% continence:** 5/21 (22%) **Patients opting for permanent stoma:** 1/21 (6%)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
					2001[129] reports results from same study although patients were recruited September 1994 to November 1999. Wexner et al, 1996[130] report results of same group of patients recruited from march 1993 to December 1995. Mavrantonis et al, 1999[131] report results from same patient group from may 1993 to February 1998. Konsten et al, 1993[132] report same patient group. Geerdes et al, 1996[133] report some of same patients. Baeten et al, 1995[134] report some of the same group of patients.

Graciloplasty continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Madoff et al, 1999[135] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up (median):** 24 months	**Patient group:** Patients with faecal incontinence. One or more previous attempts at sphincter repair had failed in 65 of 104 patients; 16 patients had stomas at time of enrolment. Overall 76/104 patients had undergone previous surgery to address their faecal incontinence. Patients who did not undergo prior surgical therapy either had severe neuropathy or such extensive sphincter damage that direct reconstruction was not possible. All patients had been treated with conservative measures such as dietary modification and constipating drugs. 24 patients had failed biofeedback therapy. **Cause of FI:** acquired, congenital and secondary to sphincter repair. **<u>All patients</u>** **N:** 139 **N with FI:** 104 **N undergoing graciloplasty:** 128 **Age (median):** 50 **M/F:** 47/ 92	**Intervention:** Graciloplasty.	**Mean maximum rest pressure (SD)**	**Pre-operative:** 40 (33) **Post-operative, stimulator on:** 80 (936) **p value:** 0.0001	**Funding:** NR **Limitations:** Patients were recruited from June 1992 to November 1994. Potentially some of the patients reported in this study could also be reported in Wexner2002[127]. **Additional outcomes:** Enema retention times. **Notes:** Age range of patients was 15-79. Gluteoplasty was undertaken in 11 patients but results not reported here.
			Mean maximum contraction pressure (SD)	**Before:** 57 (35) **After:** 101 (50) **p value:** 0.0001	
			Complications (%)	**Major wound complications:** 41/ 128 (32%) **Minor wound complications:** 37/ 128 (29%) **Pain:** 28/ 128 (22%) **Device/ stimulation problems:** 14/ 128 (11%) **Tendon detachment:** 4/ 128 (3%) **Other:** 14/ 128 (11%)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Dropouts: NR				

Graciloplasty continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Penninckx, 2004[136] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Median 48 (13-117) months	**Patient group:** consecutive patients from seven Belgian university hospitals. Conservative treatments had failed in all patients. **Cause of FI:** congenital (n=14), acquired (n=40) or after total anorectal construction (n=6) **All patients** **N:** 60 **N with FI:** 60 **Age (mean):** 43 (9-73) yrs **M/F:** NR **Dropouts:** NR	**Intervention:** Dynamic graciloplasty	**Operation outcome:**	**Failure:** 27/60 (45%)	**Funding:** NR **Additional outcomes:** Outcome compared to when muscle stimulation began after surgery. **Notes:** Failure of operation was reported as non-closure of a stoma or postoperative construction of a stoma, use of antegrade continence enema (ACE) or retrograde colonic irrigation, loss of gracilis stimulation with pacemaker turned off (or removed). Continence results unclear as number reported differently in study: Perfect continence reported in 37 patients. Perfect continence to solid stool reported in 43 patients. ACE or other measures to augment continence proved necessary in 44%.
			Mean (SD) continence score (defined by Cleveland continence score: 0-20; where 20 is complete incontinence)	**Before (n=47):** 18.4 (1.9) **After (n=47):** 5.5 (4.6) **p value<0.001**	
			Complications	75 complications that required 61 re-interventions under general anaesthesia (n=44). [Stoma closed (n=17), battery replaced (n=8), loss of muscle stimulation (n=22), repeat operation (n=4), faecal evacuation problems (n=12). 21 non-infective wound problems (n=19), inactivation of pacemaker due to pain (n=3), inflammatory or infective complications (n=9), battery leakage (n=1)].	

Graciloplasty continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Sielezenff et al, 1999[137] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Mean 20 (SD 10.2) months	**Patient group:** consecutive patients in a single centre between July 1994 and February 1998. **Cause of FI:** obstetric, anal fistula, anal atresia and prolapse **All patients** **N:** 16 **N with FI:** 16 **Age (mean):** 42.1 (range, 22-57) yrs **M/F:** 5/11 **Dropouts:** 0	**Intervention:** Dynamic graciloplasty. Stimulation began with low-voltage and low-frequency settings 14 days after electrical implantation. The muscle was then trained progressively over 12 weeks according to a standard stimulation protocol.	**Mean continence score** (Cleveland score: 0-20; where 0 is complete continence)	**Before:** 17.7 **After:** 4.0 p<0.001	**Funding:** NR **Notes:** 13 patients reported significant improvement or full continence following operation with increased social mobility and improvement in general confidence and perceived quality of life. *4 of these require daily enemas and laxatives to complete evacuation. Two required a repeat procedure so initially successful in 11/16 patients. Included in systematic review Chapman 2002[87]
			Success: *	Continent: 10/16 Improved: 3/16	
			Complications	8/16 (50%) had at least one postoperative complication (mean 2.9 (range 1-6). Minor wound infections (n=6) 23 additional operations were required to treat complications, to correct technical problems or to manage outcome failures.	
			Mean rise in anal canal pressure on stimulator activation	**Mean:** 35.9 cm H2O P<0.001	

Graciloplasty continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Thornton et al, 2004[138] **Study design:** Historical case series **Evidence level:** 3 **Duration of follow-up:** Median 60 months	**Patient group:** consecutive patients undergoing dynamic graciloplasty in one institution between 1993 and 2003. **Cause of FI:** obstetric (n=21), direct perineal trauma (n=4), congenital perineal anomalies (n=2), perineal injury from previous anal surgery (n=6) and those patients that underwent neo-sphincter reconstruction after abdominoperineal resection of the rectum for carcinoma (n=5). **<u>All patients</u>** **N:** 38 **N with FI:** NR **Age (median):** 62 (18-76) **M/F:** 6/32 **Dropouts:** 5	**Intervention:** Dynamic graciloplasty	**Median (range) continence score** (classified by modified St Mark's continence score, 0-24; where 24=totally incontinent)	**Postoperatively:** 16 (2-22)	**Funding:** NR **Additional outcomes:** Time able to defer defaecation. Impact of bowel function on daily activity and quality of life was assessed at follow-up. **Notes:** Eleven patients converted to an end colostomy. A stoma formed for ongoing FI in six, obstructed defaecation in four and one had an emergency stoma. The remaining 22 patients have a function graciloplasty. Dropouts due to deaths (n=3) from unrelated causes, lost to follow-up (n=1) and awaiting closure of a pre-existing colostomy (n=1).
			Defaecation difficulties	Postoperatively (n=22) n=11 (50%)	
			Sexual function	Sexual activity=2 No sexual activity=9 Not sexually active (for unrelated reasons to the surgery)=22	
			Number of patients reporting some degree of daily FI	Postoperatively (n=22): n= 13/22(59%)	
			Patient satisfaction (% of patients):	Satisfaction 50% or better: 60% Correlated with the continence score at time of assessment (p<0.001)	
			Complications	**Perioperative morbidity (n=38):** Patients required revision of the gracilis transposition (n=2). Wound infections (n=13) Deep vein thrombosis and pulmonary embolus (n=1). **Long-term complications:** 15 surgical procedures were required to replace pacemaker components (n=10). Morbidity in donor leg occurred frequently with long-term complications (n=24). Patients experienced pain (n=8), swelling (n=7) and paraesthesia (n=18).	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				Complications following stoma formation (n=2).	

Graciloplasty continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Christiansen et al, 1998[139] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 7 to 27 months	**Patient group:** patients with severe anal incontinence previously treated surgically for anal incontinence **Cause of FI:** Obstetric lesion: 6 Other trauma: 2 Idiopathic: 2 Anal atresia: 3 **All patients** **N:** 13 **N with FI:** 13 **Age (median):** 48 (range: 26-74) **M/F:** 3/10 **Dropouts:** 0	**Intervention:** Graciloplasty	**Continence score** (modified Williams scale) Score 1: Continence with regard to solids, liquid and flatus Score 2: Continence with regard to solids and liquid but not flatus Score 3: Continence with regard to solids, but occasional incontinence of liquids Score 4.:Occasional episodes of incontinence of solids Score 5: Frequent episodes of incontinence of solids and liquid	**Before:** Score 1: 0 Score 2: 0 Score 3: 0 Score 4: 0 Score 5: 13 **After:** Score 1: 3 Score 2: 3 Score 3: 5 Score 4: 1 Score 5: 1 **p value:** NR	**Funding:** Not reported **Limitations:** Not stated if the patients were selected consecutively. The reason why the follow up period is not the same for all patients is not stated. **Additional outcomes:** pre- and postoperative resting anal and squeeze pressure by individual; patient satisfaction with defaecatory function **Notes:** Included in systematic review Chapman 2002[87]
			Side effects Total no. patients	**Total**: 10/13 Pain at stimulator site: 5/13 Infection around leads: 1/13 Impaired rectal evacuation: 3/13 Perianal pain: 1/13	

Graciloplasty continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Rongen et al, 2003 [140] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Minimum of 2 years	**Patient group:** Faecally incontinent people after graciloplasty **Cause of FI:** Congenital: 28 Trauma: 98 Idiopathic: 58 Neurological: 16 **All patients** **N:** 200 **N with FI:** 200 **Age (mean):** 48 (range: 15-77) **M/F:** 47/153 **Dropouts:** 9	**Intervention:** Graciloplasty No patients received a protective stoma but when patients had already had a colostomy the stoma was temporarily left in place.	**Continence score of 1 or 2 at a median follow up period of 261 weeks** (modified Williams scale 1 or 2 is continent or incontinent to flatus only)	All patients: 145/191 (76%) **By cause of FI:** congenital: 52% trauma: 82% idiopathic: 72% neurological: 80%	**Funding:** Not reported **Additional outcomes:** **Notes:** Previous anal surgery performed in 130/200 patients
			Complications (total: 138) **by no. of patients**	Disturbed evacuation: 32 (16%) Pain caused by stimulation: 16 (8%) Infection: 24 (12%) Implantable pulse generator displacement 12 (6%) Rectal perforation: 10 (5%) Failure of contraction with stimulation: 9 (4.5%) Lead problems: 6 (3%) Perianal pain: 6 (3%) Urinary retention: 5 (2.5%) Wound abscess, leg: 5 (2.5%) Other: 13 (6.5%)	

Graciloplasty continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Faucheron et al, 1994[141] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 63 months (median)	**Patient group:** NR **Cause of FI:** Surgical trauma (8), nonsurgical trauma (5), anal atresia (6), neurologic disease (1), anal sphincter drug-induced damage (2) **All patients** **N:** 22 **N with FI:** 22 **Age (mean):** 34 (12-65) **M/F:** 10/12 **Dropouts:** 6 =4 patients lost to follow-up, 18 left. 2 more died.	**Intervention:** Nonstimulated gracilis muscle transposition.	**Continence** (Browning and Park's system) **Complications**	**Before:** NR **After:** 81% improved **4/16 (25%) had wound sepsis** **6/16 (37.5%) difficulties in faecal evacuation**	**Funding:** NR **Additional outcomes:** Type of anatomic lesion **Notes:** Impossible to extract meaningful data, very poorly written, statistical analysis methods given but no results, for example. Included in systematic review Chapman 2002[87]

Graciloplasty continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Christiansen et al, 1990[142] **Study design:** Case control series **Evidence level:** 3 **Duration of follow-up:** 14 months (4-37)	**Patient group:** NR **Cause of FI:** trauma (4), idiopathic (4), neurologic (2), radiation damage (1), anal atresia (1) **All patients** **N:** 13 **N with FI:** 13 **Age (mean):** 44 (18-55) **M/F:** 1/12 **Dropouts:** 1 death (unrelated)	**Intervention:** Gracilis muscle transposition	**Continence**	**Not improved: 2 (17%)** **Improved: 4 (33%)** **Cured: 6 (50%)**	**Funding:** NR **Additional outcomes:** Comparisons made with a control group, but almost certainly an inappropriate comparison group as MSP significantly better in control group pre and post. Also reported, liquid retention time. **Notes:** Included in systematic review Chapman 2002[87]
			Complications	**2 (17%) patients developed minor infections**	
			Maximum squeeze pressure (mmHg)	**Before:** 38 **After:** 59 **p value:** 0.041	
			Resting anal pressure (mmHg)	**Before:** 35 **After:** 35 **p value:** Not sig	

Evidence Table 29: Surgical case series for gluteoplasty

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Madoff et al, 1999[135] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Median 24 months	**Patient group:** Multi centre report of patients with faecal incontinence that underwent gluteoplasty. **Cause of FI:** acquired, congenital or surgical **All patients** **N:** 11 **N with FI:** 11 **Age (mean):** NR **M/F:** NR **Dropouts: 0**	**Intervention:** Dynamic Gluteoplasty – gluteus wraps were anchored by suturing to the contralateral muscle.	**Successful continence outcome**: (success defined as 70% reduction in incontinence incidents to solid stools compared to baseline. Or if no baseline data then successful if had complete control of solid stools).	All patients (n=11) had successful outcome at some point during the follow-up period, but only 5/11 (45%) were able to maintain that level of success.	**Funding:** NR **Limitations:** Device complications reported but not stated whether these occurred in patients having gluteoplasty or graciloplasty. **Notes:** Patients results following graciloplasty also reported in this case series and reported separately in this review. Included in systematic review Chapman 2002[87]
			Complications	Major wound complications (n=4), Minor wound complications (n=2), pain (n=3), miscellaneous complications (n=2)	

Evidence Table 30: Surgical case series for artificial bowel sphincter

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Altomare et al, 2001[143] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Median of 19 (7-41) months	**Patient group:** Patients with severe faecal incontinence not amenable to conservative treatment and able to manage and understand the device. **Cause of FI:** NR **All patients** **N:** 28 **N with FI:** 28 **Age (mean):** 58 (35-79) **M/F:** F **Dropouts:** 7	**Intervention:** Implantation of artificial anal sphincter (Acticon TM prosthetic device)	**Faecal incontinence** (measured using the American Medical System, percentiles where negative scores are worse, positive better)	**Before:** (median) 98.5 (75-120) **After:** 5.5 (0-49) **p value:** p < 0.001	**Funding:** NR **Additional outcomes:** Quality of life **Notes:** Included in systematic review Mundy 2004[144]
			Faecal incontinence (measured using the Continence Grading scale, no further information given)	**Before:** 14.9 (11-20) **After:** 2.6 (0-6) **p value:** p < 0.001	
			Median resting anal pressure (mmHg)	**Before:** 27 (5-71) **After:** 32 (11-59) **p value:** Not Sig.	
			Median squeezing anal pressure (with cuff activated (mmHg)	**Before:** 42 (11-110) **After:** 67 (14-145) **p value:** p < 0.061	
			Complications Infection and/or anal erosion (4/28) Cuff breakage (1)	Obstructed defecation (2) Pain (2)	

ABS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Altomare et al, 2004[145] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 50 months	**Patient group:** Patients with severe faecal incontinence not amenable to conservative treatment and able to manage and understand the device. **Cause of FI:** NR **All patients** **N:** 28 **N with FI:** 28 **Age (mean):** 58 (35-79) **M/F:** F **Dropouts:** 7	**Intervention:** Implantation of artificial anal sphincter (Acticon TM prosthetic device)	**Faecal incontinence** (measured using the American Medical System, percentiles where negative scores are worse, positive better) Only 14 patients available for follow-up	**Before:** 94 **After:** 96 **p value:** NR	**Funding:** NR **Additional outcomes:** Incontinence measured using the Continence Grading System (CGS) and the constipation scoring system. No data given or explanation of scales. Manometry given but no preoperative data. **Notes:** Same patients as Altomare 2001 (above) with a longer follow-up period. 21/28 had a functioning device
			Complications (including earlier outcomes from previous paper) Device breakage (8/28) Infection (5/28)	Pain (3/28) Obstructed defecation (10/28)	
			Satisfaction (1-10, ten best)	**7>5** **7>7**	

ABS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Casal et al, 2004[146] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Av: 29 months	**Patient group:** patients with severe anal incontinence **Cause of FI:** obstetric (4) neuropathy (3) sphincter injury from previous anal surgery (3) **All patients** **N:** 10 **N with FI: 10** **Age (mean):** 56 **M/F:** 8F 2M **Dropouts:**	**Intervention:** Artificial bowel sphincter	**Faecal incontinence** (measures using the faecal incontinence scoring system FISS 0-120 best-worst)	**Before:** 99.9 (83-120) **After:** 28.4 (0-58) **p value:** p<0.001	**Funding:** NR **Additional outcomes:** AMS scale (not reported what it measures), length of anal canal. **Notes:** Other complications not noted in their summary included perineal pain and faecal impaction.
			Maximum resting pressure (mmHg)	**Before:** 45 (3.4-106) **After:** 81 (27-124) **p value:** p<0.001	
			Complications	6/10 displayed complications: Infection (2) Haematoma (2) Dehiscence (2)	

ABS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Christiansen et al, 1999[147] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Median 7 years (5-10 years)	**Patient group:** NR **Cause of FI:** neurological disorder (10), anal atresia (1), failed previous treatment for anal incontinence (6). **<u>All patients</u>** **N:** 17 **N with FI:** 17 **Age (mean):** 46 (32-65) **M/F:** 6/11 **Dropouts:**	**Intervention:** First 6 patients received a urinary sphincter (AMS 800), last 11 received a modified version with a stronger cuff-tab, wider and enlarged pressure-regulating balloon.	**Faecal incontinence** (modified William's scale, 1-5, 1 = full continence, 5 = frequent episodes of incontinence to solid and liquid stool)	**Before:** 5 **After:** 2.5 **p value:** NR	**Funding:** NR **Limitations:** Postoperative data on 8 patients only, those with a malfunctioning device or explanted devices do not have reported outcomes. **Additional outcomes:** Manometry, postoperative only, revision procedures. **Notes:** Included in systematic review Mundy 2004[144]
			Complications	Infection (3) Malfunction (3) Obstructed defecation (1)	

ABS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Devesa et al, 2002[148] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 26.5 months	**Patient group:** **Cause of FI:** congenital (13), iatrogenic (13) obstetric (10), neurogenic (9) trauma (2) idiopathic (2) perineal colostomy (2) **All patients** **N:** 53 **N with FI:** 53 **Age (median):** 46 **M/F:** 35f, 18m **Dropouts:**	**Intervention:** Acticon Neosphincter implantation.	**Incontinence:** (measured using the Cleveland Clinic Score 0-20, best-worst)	**Before:** 17 **After:** 4 **p value: p=** 0.000	**Funding:** NR **Additional outcomes:** Quality of life, explanation rates. **Notes:** Included in systematic review Mundy 2004[144]
			Average resting pressures:	**Before:** 32 **After:** 55 **p value:** p=0.000	
			Squeeze pressure:	**Before:** 61 **After:** 94 **p value:** p=0.000	
			Complications	Infection/fever (6) Dehiscence (1) Erosion (2) Pain (1) Fistula (1) Total:10/53 (19%)	

ABS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Lehur et al, 1996[149] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** median 20 (4-60) months	**Patient group:** consecutive patients between 1989 and 1995 with FI had an artificial urinary sphincter implanted. **Cause of FI:** anal atresia (n=3), neurological (n=2), anal/rectal surgery (n=6), obstetric (n=1), idiopathic (n=1). **All patients** **N:** 13 **N with FI:** 13 **Age (mean):** 44 (22-63) years **M/F:** 4/9 **Dropouts:** 0	**Intervention:** Artificial bowel sphincter (AMS 800 – artificial urinary sphincters implanted). The prosthesis was left deactivated for six weeks after implantation. Then the cuff was pressurised and the patient instructed to manipulate the control pump.	**Number of patients with functioning device** (for more than four months)	**Functioning:** 10/13 **Not functioning:** 3/13	**Funding:** NR **Additional outcomes:** Mean anal pressures before and 4 months after surgery. **Notes:** A single patient had colostomy before implantation.
			Clinical outcomes of patients with functioning device	**Continent: 9/10** **Continence for gas: 5/10** **Failure (incontinent for liquid stool): 1/10** **Difficulties with evacuation: 4/10**	
			Complications	Sepsis (n=2), skin erosion (n=1), intense perineal pain (n=1), rupture of cuff (n=1), control pump position modified (n=2).	

ABS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Lehur et al, 1998[150] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 30 months	**Patient group:** patients with severe faecal incontinence. **Cause of FI:** anal agenesia, trauma, neurogenic. **All patients** **N:** 13 **N with FI:** 13 **Age (median):** 40 **M/F:** 4/9 **Dropouts: NR**	**Intervention:** Neoanal sphincter construction – 9 unmodified artificial urinary sphincters (AMS 800) implanted, 6 artificial anal sphincters implanted.	**Faecal incontinence** (measured using the Cleveland Clinic score 0-20, best-worst)	**Before:** 17 (14-20) **After:** 4 (0-4) **p value:** NR	**Funding:** NR **Additional outcomes:** Subjective assessment of quality of life and manometric evaluation were performed annually. Anal canal length also measured. **Notes:** Included in systematic review Mundy 2004[144]
			Resting pressure (mmH2O)	**Before:** 41 **After:** 72 **p value:** NR	
			Complications	Pain (1) Impaction (1)	

ABS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Lehur et al, 2000[151] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 20 months	**Patient group:** (e.g. elderly care home residents with urinary or faecal incontinence) **Cause of FI:** anal trauma (9), neuropathy (6), neurological (4), congenital malformation (3), prolapse (2). **<u>All patients</u>** **N:** 24 **N with FI:** 24 **Age (median):** 44 **M/F:** 7/17 **Dropouts:**	**Intervention:** Artificial anal sphincter implantation (Acticon Neosphincter TM)	**Faecal incontinence at 6 months** (measured using Faecal incontinence Score 0-120, best-worst)	**Before:** 106 **After:** 19 **p value:** p<0.0001	**Funding:** Not reported **Additional outcomes:** Explantation/ reimplantation rates. Satisfaction. Length of stay. **Notes:** Reported in Mundy 2004
			Faecal incontinence at 12 months (Faecal incontinence Score 0-120, best-worst)	**Before:** 106 **After:** 25 **p value:** p<0.0001	
			Faecal incontinence at end of follow-up (Faecal incontinence Score 0-120, best-worst)	**Before:** 106 **After:** 25 **p value:** p<0.0001	
			Median anal pressure (mmHg)	**Before:** 28 **After:** 60 **p value:** p<0.0001	
			Complications	Dehiscence (2) Urinary tract infections (5) Haematomas (NR)	

ABS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Lehur et al, 2002[152] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 25 months	**Patient group:** Not reported **Cause of FI:** Anal trauma, neurological, rectal prolapse, pudendopathy, anal agenesis **All patients** **N:** 16 **N with FI:** 16 **Age (mean):** 43 **M/F:** 2/14 **Dropouts:** 0	**Intervention:** Artificial anal sphincter implantation (Acticon Neosphincter TM)	**Faecal incontinence at 6 months** (Faecal incontinence Score 0-120, best-worst)	**Before:** 105 **After:** 24 **p value:** <0.05	**Funding:** Not reported **Additional outcomes:** Quality of Life, correlation between quality of life score and faecal incontinence score. **Notes:** Included in systematic review Mundy 2004[144]
			Faecal incontinence at 12 months (Faecal incontinence Score 0-120, best-worst)	**Before:** 105 **After:** 32 **p value:** <0.05	
			Faecal incontinence at 24 months (Faecal incontinence Score 0-120, best-worst)	**Before:** 105 **After:** 32 **p value:** <0.05	
			Faecal incontinence at >24 months (Faecal incontinence Score 0-120, best-worst)	**Before:** 105 **After:** 23 **p value:** <0.05	
			Mean maximum resting pressure (cmH2O)	**Before:** 42 **After:** 97 **p value:** <0.0001	

ABS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Michot et al, 2003[153] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 34.1 months	**Patient group:** (e.g. elderly care home residents with urinary or faecal incontinence) **Cause of FI:** Sphincter disruption (19), congenital malformations (2), neurologic disease (16). **<u>All patients</u>** **N:** 37 **N with FI:** 37 **Age (mean):** 52 **M/F:** 15/22 **Dropouts:**	**Intervention:** Implantation of artificial sphincter.	**Incontinence**	**Before:** "severe and complete". **After:** **100%** continent for solid stool, no leakage **78.9%** continent for liquid stool **63.1%** continent for gas **12%** "failures"	**Funding:** NR **Additional outcomes:** Explantation/ reimplantation rates. Length of occlusion of sphincter. Manometric data postoperatively only. **Notes:** 6 patients had had previous surgery for faecal incontinence. Contraindications discussed. Included in systematic review Mundy 2004[144]
			Complications	Obstructive internal rectal procidentia (2) Device change/migration (4)	

ABS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Ortiz et al, 2002[154] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 26 (7-48) months	**Patient group:** (e.g. elderly care home residents with urinary or faecal incontinence) **Cause of FI:** neuropathy (5), anal atresia (3) perineal trauma (3) direct sphincter disruption from operative trauma (4), obstetric (6), myotonic dystrophy (1) **All patients** **N:** 22 **N with FI:** 22 **Age (mean):** 47 **M/F:** 5/17 **Dropouts:**	**Intervention:** Artificial anal sphincter implantation.	**Continence Score** (Cleveland Clinic Score, 0-20 best-worst)	**Before:** 18 **After:** 4 **p value:** <0.001	**Funding:** NR **Additional outcomes:** Complications associated with surgery, re-operation rate at immediate postoperative period and at follow-up due to high frequency of complications. **Notes:** Included in systematic review Mundy 2004[144]
			Resting anal pressure (mmHg)	**Before:** 35 **After:** 54 **p value:** <0.01	
				Infection, explantation and reimplantation rates, and obstruction of defecation all noted but no figures given.	

ABS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Parker et al, 2003[155] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Group 1: 91 months (29-143) Group 2: 24 months	**Patient group:** Two groups: Group 1: n=10 Group 2: n=35 (although 37 actually treated, only 35 analysed as operation only successful in these 35) **Cause of FI:** (group 2 only): Obstetric (11), anorectal trauma (11), congenital defect (7), prolapse (4), back surgery (2), neurogenic (2) **<u>All patients</u>** **N:** 45 **N with FI:** 45 **Age (mean):** 43.7 yrs **M/F:** 18/27 **Dropouts:** 2	**Intervention:** Artificial bowel sphincter implantation.	**Faecal incontinence severity scores** (Faecal Incontinence Scoring System FISS 0-120, best-worst)	**Group 1: unavailable data** **Group 2:** **Before:** 103 **After (1 year):** 59 **After (2+ years):** 23 **p value:** <0.01	**Funding:** NR **Additional outcomes:** Manometry results – raw data not given.
			Complications	13 group 2 patients required re-operation, although no more detail about complications given – successful implantation is focus of paper rather than incontinence scoring.	

ABS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Savoye et al, 2000[156] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** Mean 16 (4-28) months	**Patient group:** Faecally incontinent patients in whom conventional treatment had failed. **Cause of FI:** neurological (7), sequalae of anorectal surgery (2) , obstetric (1), multiple associated causes (1). **All patients** **N:** 12 **N with FI:** 12 **Age (mean):** 51 **M/F:** 7/5 **Dropouts:**	**Intervention:** Artificial bowel sphincter implantation.	**Continence**	**Before:** All incontinent for solids and liquids **After:** All continent for solids (100%), 8 for liquid and solid (67%). 5 were incontinent for gas(42%).	**Funding:** NR **Additional outcomes:** Manometry, duration of cuff opengin and closing times. Pressure etc.

ABS continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Wong et al, 2002[157] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 12 months	**Patient group:** NR **Cause of FI:** NR **All patients** **N:** 115 **N with FI:** 115 **Age (mean):** 49 **M/F:** 26/89 **Dropouts:** 14	**Intervention:** Artificial bowel sphincter implantation.	**Faecal incontinence scoring system (FISS)** 0: Fully continent 1-30:Incontinent to gas 31-60: Incontinent to seepage 61-72: Incontinent to liquids or solids rarely 73-84: Incontinent to liquids or solids> monthly 85-96: Incontinent to liquids or solids > weekly 97-108: Incontinent to liquids or solids daily 109-120: Incontinent to liquids or solids > daily	**Before:** 106 **After:** 51 **p value:** NR Mean scores given for differing numbers of patients before and after.	**Funding:** American Medical systems. **Additional outcomes:** Faecal incontinence quality of life, health status, manometry at activation and 6 months. **Notes:** Authors describe study as 'multicentre, prospective, nonrandomised clinical trial', but no control group: therefore treated as a case series even though carried out in US, Canada and Europe. Attrition through missed follow-ups, unable to carry out surgery. Included in systematic review Mundy 2004[144]
			Resting pressure (mmHg) **Before:** 26 (0-70)	**After (I yr):** 46 (14-77) **p value:** <0.0001	
			Complications	Included: pain, infection, impaction, constipation, erosion, FI, surgical injury, wounds problems, device migration or fit, Percentages affected not given. 383 device-related or potentially device-related events occurred in 99 patients.	

Evidence Table 31: Surgical case series radio-frequency energy (Secca procedure)

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Takahashi et al, 2003[158] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 24 months	**Patient group:** (e.g. elderly care home residents with urinary or faecal incontinence) **Cause of FI:** haemorrhoidectomy (3), vaginal delivery (1), perirectal abscess drainage (1), idiopathic (8). **All patients** **N:** 10 **N with FI:** 10 **Age (mean):** 55.9 yrs **M/F:** 10 F **Dropouts:**	**Intervention:** Radio-frequency energy for faecal incontinence (Secca procedure)	**Faecal incontinence:** (Cleveland Clinic Florida Incontinence Score 0-20, best-worst)	**Before:** 13.8. **After:** 7.3 **p value:** 0.002	**Funding:** NR **Additional outcomes:** Faecal incontinence-related quality of life scores, PNTML values. **Notes:** Results of same group of patients reported at earlier follow-up in Takahashi2002A[158]. Patients were excluded if they had had prior surgery for faecal incontinence, IBS or other conditions. Complications not reported.
			Anorectal Resting pressure (mmHg) Measured after 6 months (median)	**Before:** 39 **After:** 39 **p value:** Not sig	
			Anorectal voluntary squeezing pressure (mmHg) Measured after 6 months (median)	**Before:** 66 **After:** 63 **p value:** Not sig	
			Median initial rectal sensation vol (ml)	**Before:** 20 **After:** 15 **p value:** 0.046	
			Median maximum tolerable rectal sensation vol (ml)	**Before:** 245 **After:** 110 **p value:** 0.0009	

Evidence Table 32: surgical case series bioinjectibles/ sphincter bulking agents

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Davis et al, 2003[159] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up (mean):** 28.5 months	**Patient group:** Patients with persistent faecal leakage/ soiling, greater than once a week for at least 6 months. All patients had previously tried a range of conservative measures including dietary and fluid manipulation, anti diarrhoeal medication and stool bulking. **Cause of FI:** internal sphincter defect identifiable on endoanal ultrasound (n=17) and significant neuropathy but 'normal' sphincter complex on endoanal ultrasound (n=1). (Seven females also had additional partial, anterior disruption of the external anal sphincter that did not need surgical repair.) **<u>All patients</u>** **N:** 18 **N with FI:** 18 **Age (mean):** 60 **M/F:** 9/ 9 **Dropouts:** 3 (2 patients exited the study at 6 months perceiving no symptomatic improvement. One patient who reported initial improvement had to withdraw from the study following unrelated colorectal surgery performed in another health district 10	**Intervention:** Durasphere was injected into the submucosal anal plane (using a pre-loaded 1 ml Durasphere syringe) at the site of the defect until adequate anal sphincter symmetry was restored. The sphincter bulking injections were performed under direct vision with the aid of a proctoscope and guided by information provided by the pre-injection anal ultrasound. A mean volume of 1.28 ml was injected at one to four sites.	**Mean score on Cleveland Clinic continence scale -** 0 (perfect continence) to 20 (complete incontinence) (SD)	**Baseline:** 11.89 (5.10) **12 months:** 8.07 (3.682) **p value:** 0.002	**Funding:** Carbon Medical Technologies. **Limitations:** Baseline scores for patient satisfaction were not reported. **Notes:** All patients were treated in the out-patient department and no local anaesthetic or antibiotic cover was required. The presence of Durasphere at injection sites was confirmed on ultrasound for 16/18 patients.
			Patient satisfaction measured on visual analogue scale (SD)	**3 months:** 4.889 (3.160) **vs 6 months:** 6.000 (2.051) **p value:** 0.055 **3 months:** 4.889 (3.160) **vs 12 months:** 6.933 (2.055) **p value:** 0.053	
			Mean quality of life assessment score – lifestyle (SD)	**Baseline:** 2.19 (1.162) **12 months:** 3.18 (0.837) **p value:** 0.004	
			Mean quality of life assessment score – coping (SD)	**Baseline:** 1.83 (0.825) **12 months:** 2.73 (0.825) **p value:** 0.011	
			Mean quality of life assessment score – depression (SD)	**Baseline:** 2.53 (1.07) **12 months:** 3.19 (0.952) **p value:** 0.024	
			Mean quality of life assessment score – embarrassment (SD)	**Baseline:** 2.16 (1.22) **12 months:** 3.10 (0.908) **p value:** 0.023	
			Mean anal resting pressure (SD)	**Baseline:** 69.68 cmH_2O (35.788) **3 months:** 86.52 cmH_2O (43.949 **p value:** 0.094 **12 months:** 73.39cmH_2O (31.515)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	months after bulking. One patient was unable to perform the 6 month assessment measures but was able to perform the 12 month assessment measures.		**Mean squeeze pressure (SD)**	No change at any time interval.	
			Mean rectal volume sensation - maximal tolerable volume (SD)	**3 months:** 218.82 ml (63.011) **vs 12 months:** 165.76 ml (53.340) **p value:** 0.036 **Baseline:** 216.66 ml (65.439) **vs 12 months:** 165.76 ml (53.340) **p value:** 0.033	
			Adverse events	2 patients reported mild anal discomfort for 2-3 days post-procedure that resolved spontaneously with out medical intervention. One patient reported a slight worsening of longstanding puritis ani for 5 days post procedure but symptoms resolved spontaneously. Two patients reported the passage of Durasphere with the stool and on the toilet paper during the first few days post injection. Subsequently in these two patients we found no identifiable Durasphere in place on the post-treatment ultrasound.	

Evidence Table 33: Island advancement flap anoplasty

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Morgan et al, 1997[160] **Study design:** Case series **Evidence level:** 3 **Duration of follow-up:** 34 months	**Patient group:** treated for incontinence during November 1989 to February 1995 **Cause of FI:** internal anal sphincter injury **All patients** **N:** 15 **N with FI:** 15 **Age (median):** 48 (32-69) yrs **M/F:** 12/3 **Dropouts:** 0 None of the patients were incontinent to solid stool preoperatively.	**Intervention:** **Anoplasty** – filling the defect in the anal canal with skin and subcutaneous fat which was achieved by raising a flap of perianal and buttock skin and subcutaneous tissue using a rotation (n=5), an advancement (n=4) or an island (n=5) technique. The remaining patients (n=2) had a direct internal anal sphincter repair.	**Median Continence Score** (Cleveland continence score: 0-20): where 0 is perfect continence and 20 is complete incontinence)	**Preoperatively: (n=15)** Score: 14 (11-16) **Postoperatively: (n=13)** Score: 2 (0-4)*	**Funding:** NR **Limitations:** Postoperative continence score only includes patients that had anoplasty. **Notes:** 14 of the 15 patients had undergone previous anal surgery; haemorrhoidectomy (n=7), posterior sphincterotomy (n=3), anal fistulotomy (n=3) and local excision of a radiation-induced ulcer (n=1). Remaining patient had internal anal sphincter division due to penetrating trauma.
			Results of direct internal anal sphincter repair patients	Both failed to exhibit symptomatic improvement. One patient had anoplasty but failed to improve after 20 months follow up.	
			Complications	Wound infection (n=3) and wound resuture and temporary loop colostomy after flap dislodgement occurred due to inadvertent suture removal on the third postoperative day. All complications in anoplasty group and none seen in patients that had direct internal sphincter repair.	

Economic evaluations of surgical interventions

Evidence Table 34: Economic evaluations of surgical interventions

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Adang et al, 1998[161] Netherlands **Economic analysis:** Cost-consequences **Study design** Decision model based on two cohorts **Duration of follow-up:** 52 weeks, costs extrapolated to lifetime. **Discount rates:** Costs: 5% Effects: NA	**Cost analysis:** Group 1: Patients undergoing dynamic graciloplasty **N:** 43 **Age (median):** 48 **M/F:** 26%/74% Group 3: Patients who have previously had colostomy **N:** 7 **Age (mean):** 47 **M/F:** 29%/71% **Quality of life analysis:** Before and after comparisons in group 1	**Intervention** **1.** Dynamic graciloplasty **Comparison** *Cost analysis* **2.** Conventional treatment (diapers and enemas) **3.**Colostomy *Quality of life analysis* 2.Conventional treatment	**Median difference in Nottingham Health Profile, Part 1 and 2*** (pre-op vs 12 months post op)	**Part 1:** (Mobility 0, pain 3, energy 0, sleep 0, emotional reaction 0) = NS (Social isolation 0) p=0.048. **Part 2** (daily living)**:** -2, p=0.0003	**Funding:** NR **Limitations:** 1. QOL based on successful patients only. 2. Colostomy patients were not included in the QOL analysis. 3. As a before and after study there is a large potential for bias. 4.Colostomy costs were based on only 7 patients 5. Calculation of cost of complications unclear 6. Costs not subjected to statistical analysis **Notes:** Quality of life data described in full elsewhere (Baeten, 1995[134])
			Median difference in State Trait Anxiety Inventory* (pre-op vs 12 months post op)	-6, p=0.0016	
			Median difference in Zung's self-rating depression scale* (pre-op vs 12 months post op)	-2, NS	
			Mean cost per patient (US$, hospital costs) (PPP used for conversion 1997 0.624)	**Initial operation costs** **1:** $16,291, **2:** none, **3:** $3,805 **Cost per year (excl. operation costs)** **1:** $957, **2:** $793 **3:** $4,393 **Lifetime costs** **1:** $31,733 (£19,801) **2:** $12,181 (£7,601) **3:** $71,577 (£44,664) **Lifetime costs (intent to treat)** **1:** $35,960 (£22,439)	
			Indirect cost savings (due to improved productivity, US$)	**1 vs 3:** $6,331 (£3,925)	
			Cost-effectiveness	NR	
			Sensitivity analysis A.discount rate, B.price of neurostimulator C.hospital stay	A. +10% = 3.9% change in direct costs B.+10% = 6.5% change in direct costs C. +50% = 5% change in direct costs	

Economic evaluations of surgical interventions continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Buttafuoco & Keighley, 2000 [162] UK **Economic analysis:** Cost-consequences **Study design** Retrospective cohort **Duration of follow-up:** Group 1: 9.7 years Group 2: 6.6 years **Discount rates:** NR	**Inclusion criteria:** Patients with FI who had undergone pelvic floor repair with at least 5 years of follow-up. Rectal prolapse was excluded. **All** **Age (mean):** 51 **Group 1** **N:** 47 **Age (mean):** NR **M/F:** 15%/85% **Group 2:** **N:** 32 **Age (mean):** NR **M/F:** 13%/87%	**Group 1:** Post anal repair **Group 2:** Total pelvic floor repair	**Faecal continence**	**Fully continent** 1. 28% 2. 53% **Improved but still incontinent** 1. 28% 2. 41% **Unimproved or required end stoma** 1. 45% 2. 6%	**Funding:** NR **Limitations:** 1. Cohorts not controlled for baseline 2. Follow-up periods different for the two groups 3. Costs are charges not actual costs. 4. Baseline characteristics (e.g. age) were not reported for each arm 5. No statistical analysis on costs or outcomes 6. No sensitivity analysis 7. Cost not discounted
			Mean number of operations (initial and re-operations)	1. 2.12 2. 1.15	
			Mean cost per patient (Euro, 1999. Charges include initial and repeat operations, length of stay, out-patient visits, staff and theatre cost) (Exchange rate 1999 0.659)	**Hospital (€102/day)** 1. €2159 2.€2032 **Out-patients (pre-op, €109/visit)** 1. €229 2. €220 **Outpatients (post-op, €61/visit)** 1. €515 2.€285 **Surgeon (€188/hour)** 1. €528 2 €333 **Theatre costs (€217/hour)** 1.€612 2 €541 **Total mean cost per patient** 1. **€**4043 (£2,664) 2. **€**3411 (£2,248)	
			Cost-effectiveness	NA	
			Sensitivity analysis	NR	

Economic evaluations of surgical interventions continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Creasey & Dahlberg, 2001[163] USA **Economic analysis:** Cost analysis **Study design** Retrospective case series (Before and after) **Duration of follow-up:** One year **Discount rates:** NR	**Inclusion criteria:** All patients with complete suprasacral spinal cord injuries and neurogenic bladder and bowel who had undergone neuroprosthesis between 1993 and 1998 at 2 centres in Cleveland, US. Proportion with FI not reported **<u>All patients:</u>** **N:** 17 **Age (mean):** 39 **M/F:** 50%/50% **Drop-outs:** 5	**Intervention** Implanted neuroprosthesis for bladder and bowel control The following periods were used in the analysis: **1.** Cost 1 year before intervention. **2.** Cost 1 year after intervention	**Mean cost per patient** (US$ 1998) (PPPs used for conversion 1998 0.634)	**Medication** **1.** $1834 **2.** $282 **Medical supplies-bladder** **1.** $3701 **2.** $309 **Medical supplies-bowel** **1.** $344 **2.** $130 **Medical care** **1.** $1820 **2.** $564 **Total** **1.** $7698 (£4,880) **2.** $1285 (£815) **Cost of intervention** $35,200 (£22,317) **Cost of maintenance** $465 per year (£295)	**Funding:** NR **Limitations:** 1. No health outcomes measured. 2. Before and after design can lead to bias. 3. Retrospective cost data based on interviews with patients with checks for reliability, therefore potential for recall bias. 4. Costs not subjected to statistical or sensitivity analysis. 5. Small patient sample
			Cost-effectiveness	NA	
			Sensitivity analysis	Break-even analysis – the intervention would pay for itself in 4.8 years due to the reduction in other direct costs.	

Economic evaluations of surgical interventions continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Hetzer 2006A[164] Switzerland **Economic analysis:** Cost analysis **Study design** Cohort study for Groups 1 and 2 and the other 3 arms are taken from another study's decision model[161] **Time-horizon:** 5 years; Follow-up period of cohorts is unclear. **Discount rates:** Costs: 5%	**Patient group:** Patients with incapacitating FI with more than one FI episode per week for at least a year who have failed medical therapy including medication and biofeedback. **Cause of FI:** anal sphincter defect (16), idiopathic (9), pelvic surgery (6), neurogenic (5) **Group 1** **N:** 36 **N with FI:** 36 **Median Age:** 61 (Range 15, 88) **M/F:** 7/29 **Drop outs:** 0 **Group 2** **N:** 13 **N with FI:** 13 **Median age:** 58 (Range 37, 78) **M/F:** **Drop outs: NR** **Groups 3-5** see Adang1998B	**Group 1:** Sacral nerve stimulation Stage 1: temporary Stage 2: permanent **Group 2:** Sphincter repair **Group 3:** Dynamic graciloplasty **Group4:** Colostomy **Group 5:** Conservative treatment (pads, diapers and enema)	**'Success' rate of SNS**	**Group 1** After stage 1: 33/36 After stage 2: 31/36	**Funding:** NR **Limitations:** 1. No comparative health outcomes. 2. Sphincter repair is not an appropriate comparator for all patients undergoing SNS. 3. No statistical analysis 4. Median costs reported instead of means 5. The costs of further treatment after failed SNS were not included. **Additional outcomes:** Detailed info about costs and complications but only for Group 1.
			Complications associated with SNS	**Group 1** After stage 1: 8/36 (all minor) After stage 2: 8/36 (infection, pain or loss of effect)	
			Median cost per patient – 1st Year (2005 Euro, hospital costs, including operations, complications, follow-up & battery replacement)	**Group 1:** €15,345 (Range: €11,974, €28,346) **Group 2:** €5,327 (Range: €4,294, €13,040) **Group 3:** €28,317 **Group 4:** €14,609 **Group 5:** €779 **p value:** NR	
			Median cost per patient – 5 years (2005 Euro, hospital costs, including operations, complications, follow-up & battery replacement)	**Group 1:** €22,150 (£14,800) **Group 2:** €5,327 (£3,600) **Group 3:** €31,590 (£21,100) **Group 4:** €33,996 (£22,700) **Group 5:** €3,234 (£2,200) **p value:** NR	
			Cost-effectiveness	NA	
			Sensitivity analysis	NR	

Economic evaluations of surgical interventions continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Nessim et al, 1999[77] USA **Economic analysis:** Cost-consequences **Study design** RCT **Duration of follow-up:** Mean 13 months **Discount rates:** NA	**Inclusion criteria:** Patients without stomas who underwent anorectal reconstructive surgery 32 (70%) patients had FI (17 in the intervention arm and 15 in the comparison arm) **Group 1:** **N:** 27 **Age (mean):** 51.0 **M/F:** NR **Group 2:** **N:** 27 **Age (mean):** 47.2 **M/F:** NR	**Group 1** Medical bowel confinement (clear liquid diet, loperamide 4 mg 3/day, codeine phosphate 30 mg 3/day, until the 3rd post-op day) **Group 2** Regular diet starting the day of surgery	**Complications**	**Group 1 vs Group 2** Wound infection: 2/27 vs 0/27 Abscess: 0/27 vs 1/27 Wound dehiscence: 0/27 vs 1/27 Urinary retention: 2/27 vs 1/27 Nausea & vomiting: 7/27 vs 3/27 Faecal impaction: 7/27 vs 2/27 Bleeding from wound: 2/27 vs 0/27 None were statistically significant	**Funding:** NR **Limitations:** 1. Source of cost data not described. 2. Costs were hospital charges not actual costs. 3. No sensitivity analysis. 4. No statistical analysis on cost or length of stay
			First post-operative bowel movement	**Group 1:** Mean 3.9 days **Group 2:** Mean 2.8 days ($p<0.05$)	
			Frequency of pain medication	**Group1:** none: 2/27(7%) oral analgesic 8/27 (30%) oral/ intramuscular narcotic 9/27 (30%) patient control analgesia/ morphine 8/27 (30%) **Group 2:** none: 7/27(26%) oral analgesic 9/27 (33%) oral/ intramuscular narcotic 7/27 (26%) patient control analgesia/ morphine 4/27 (15%) **p value:** Not statistically significant.	
			Incontinence score for those undergoing sphincteroplasty for FI (n=32)	**Group 1:** Pre vs post-op, 10 **Group 2:** Pre vs post-op, 11 NS	
			Hospital stay	**Group 1:** Mean 4.4 days **Group 2:** Mean 3.7 days Not tested for significance	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
			Mean cost per patient (US $, year not specified) (PPPs used for conversion 1998 0.634)	**Hospitalisation:** **Group 1:** Mean $12,586 (Range: $3,436 to $20,375) (£7,980) **Group 2:** Mean $10,685 (Range: $3,954 to $18,574) (£6,774) NS	
			Cost-effectiveness	NA	
			Sensitivity analysis	NR	

Economic evaluations of surgical interventions continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Tillin et al, 2005[68] UK **Economic analysis:** Cost-utility **Study design** *Outcomes*: Longitudinal, prospective cohort study *Costs*: As above, plus model to extrapolate results **Duration of follow-up:** *Outcomes*: 2 years, *Costs*: 25 year Time-horizon. **Discount rates:** Costs: 6% Effects: 1.5%	**Inclusion criteria:** Patients with stomas or refractory FI ***Cohort study*** **Intervention arm** Electrically stimulated gracilis neosphincter surgery: **N:** 51 **Age (mean):** 42 **M/F:** 25%/75% **Dropouts:** 3 **Comparison arm** Usual care (not-offered neosphincter surgery surgery): **N:** 40 **Age (mean):** 49 **M/F:** 25%/75% **Dropouts**: 5	**1.**Electrically stimulated gracilis neosphincter surgery **2.**Usual care (not-offered surgery) 2a Stoma care 2b.Conservative management **3.** Stoma placement *Analysis periods for clinical outcomes:* Intervention (1): pre-op and 24 months post op. Comparison (2): baseline and 24 months post-baseline	**Cleveland clinical incontinence score**	1. +24 (CI: +11 to +37) 2. -8 (CI: -19 to +3) p=0.001	**Funding:** National Specialist Commissioning Advisory Group. **Limitations:** 1. Outcome and cost elements are based on slightly different populations. 2. Caution required with ICERs due to small patient numbers and small changes seen in the EQ5D. **Considerable additional outcomes listed, including:** 1. Intervention outcomes up to 4 years; 2. Detailed costs; 3. Details of a separate retrospective cross-sectional analysis done to confirm results due to small patient numbers. **Notes:** NHP pain scale & social isolation, HADS anxiety and depression, RLH psychosocial scale and lifestyle scale
			Mean change in EQ-5D (Euroqol)	**12 months** p=NR 1. +4% (CI:-5 to +13) (n=23) 2. -1% (CI:-8 to +5) (n=13) **24 months** p=0.92 1. +7% (CI:-3 to +18) (n=17) 2. +7% (CI:-3 to +16) (n=13)	
			Other quality of life scores (see Notes)	Significantly in favour of neosphincter surgery in all but the NHP scale.	
			Mean QALY	**Conservative at outset** **1.** 12.796 **2b.** 12.460 **Stoma at outset** **1.** 12.796 **2a.** 12.460	
			Mean cost per patient (£ 2003, NHS perspective)	**Cost of intervention:** **1.** £23,253 **Cost post intervention:** **1.** £1,864 per year **2a**. £2,125 per year (with stoma) **2b**. £442 per year (with no stoma)	
			Cost-effectiveness - Incremental cost per QALY gained; range depends on costs used (RLH or other NHS Trusts)	**Conservative at outset: 1 vs 2b** ICER = £30,000 to £40,000 **Conservative at outset: 1 vs 3** 1 dominates **Stoma at outset: 1 vs 2a** ICER = £5,000 to £15,000	
			Sensitivity analysis (all model parameters)	Results not sensitive apart from Time-horizon. A horizon of only 5 years results in considerably higher ICERs.	

Evidence tables for chapter 7: specific groups (continued)

Evidence Table 35: patient views evidence for faecal impaction

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Gosselink et al, 2005[165] **Study design:** Historical Case series **Evidence level:** 3 **Duration of follow-up:** Mean 56 months (range, 8-154 months)	**Patient group:** Consecutive series of patients with disturbed continence or obstructed defaecation were offered retrograde colonic irrigation on an ambulatory basis. These patients had not responded to medical treatment and biofeedback. **Cause of FI:** NR **<u>All patients</u>** **N: 169 N with FI:** 103 **Age (mean):** NR **M/F:** 49/54 (for FI patients) **Dropouts:** 98 In follow up it was found that of the 267 original patients, 15 patients had died and 13 could not be contacted as moved. Therefore, 239 questionnaires sent out to patients. 190 patients responded but 21 of these did not receive the irrigation so the final patient response was 169.	Not applicable – all patients received retrograde colonic irrigation on an ambulatory basis.	**Effective Retrograde Colonic Irrigation in patients soiling:**	**(n=32): 15 (47%)**	**Funding:** NR **Limitations:** Low response rate (169/267) 63% **Additional outcomes:** The Kaplan-Meier curves show that the discontinuation rate among patients with soiling and FI is significantly higher than in the obstructed defaecation and defaecation disturbances after LAR or Pouch surgery groups (all P<0.058) Patient with soiling stopped because of the time consuming aspect and irrigation related problems. Patients with incontinence stopped due to irrigation related problems and loss of irrigation fluid during the day. Also reported best times to perform the irrigation and the irrigation-related problems reported by the patients still performing irrigation on a regular basis.
			Effective Retrograde Colonic Irrigation in FI patients:	**(n=71): 29 (41%)**	
			Discontinuation rate for soiling patients despite effectiveness:	**(n=15): 10 (67%)**	
			Discontinuation rate for FI patients despite effectiveness:	**(n=29): 5 (17%)**	

Patient views on faecal impaction continued

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Crawshaw et al, 2004[166] **Study design:** Historical Case series **Evidence level:** 3 **Duration of follow-up:** Median follow up 11 months (range 4-27 months)	**Patient group:** Patient who had been offered rectal irrigation for symptomatic relief at some time in their management **Cause of FI:** NR **All patients** **N:** 48 **N with FI:** 33 **Age (mean):** 54 **M/F:** 13/35 **Dropouts:** Initially 92 patients received the rectal irrigation but response rate to the follow up questionnaire was 48 (52%)	**Not applicable**	**Successful treatment of rectal irrigation at relieving their symptoms (n=33)**	**Successful: 16 (48.5%)** **Unsuccessful: 17 (51.5%)**	**Funding:** Salt and Son provided travel funding and irrigation tubing and connectors used were supplied free of charge by Coloplast. **Limitations:** Possible selection bias as low response rate. High rate of continued use of irrigation in responders (92%) may have higher motivation to respond to the questionnaire **Additional outcomes:** Anorectal physiological variables for some of the patients (n=36). Reported visual analogue score, incontinence scores and quality of life score for the entire group and not separately for patients with FI or constipation.

APPENDIX E: SUMMARY RESULT TABLES FOR SURGICAL CASE SERIES

Key:
CR – clinician reported
PR – patient reported

Summary Results Table 1: Sphincter Repair

Study	Surgery type	Follow-up (months)	N	N. at follow-up	Faecal Incontinence:						Complications			Comments
					Cured		improved		Not improved		Wound infection?	Bleeding?	Unknown or other?	
					CR	PR	CR	PR	CR	PR				
Engel1994b[84]	Anterior sphincter repair (wrap-over)	15	55	55		45%		31%		24%				External sphincter defect
Giordano 2002[91]	Anterior overlapping sphincter repair	20		151										External sphincter defect. Poorer results in patients with repeat repairs (not significant)
Oliveria1996[89]	Anterior overlapping sphincter repair	29	55	55				71%		29%		2%	4%	Anterior defects
Morren1997[90]	Direct and overlapping sphincter repair.	40	67	55				35%		65%	11%	2%	11%	External sphincter defect. Surgery combined with an anterior levator plasty (n=45), internal sphincter placation (n=24) and postanal repair (n=1)

Study	Surgery type	Follow-up (months)	N	N. at follow-up	Faecal Incontinence:						Complications			Comments
					Cured		improved		Not improved		Wound infection?	Bleeding?	Unknown or other?	
					CR	PR	CR	PR	CR	PR				
Young1998[88]	Overlapping sphincter repair	27	56	56				86%		14%	2%		38%	Anterior and laterally placed single anal sphincter defects
Karoui2000[83]	Overlapping sphincter repair	40	86	74		18%		58%		24%				External and associated internal sphincter defect
Fleshman1991a[86]	Overlapping sphincter repair	24	55	55		50%		22%		28%	15%		2%	Rectovaginal fistula (n=15) also repaired during surgery. 22% of cured are incontinent to gas
Londonoschimmer1994[81]	Overlapping sphincteroplasty	59	128	94		14%		36%		50%	16%	2%	8%	External sphincter defect. In addition to repair: plication (n=7), repair of rectovaginal fistula (n=4), posterior vaginal repair (n=2) and miscellaneous (n=3).
Zorcolo2005[82]	Anterior anal sphincter repair	70	93	73				82%		17%	1%		25%	Internal and external sphincter defects. Repair reinforced with levatoplasty (n=51) and had better outcomes than group without levatorplasty (not significant)
Gutierrez et al[79]	Overlapping sphincteroplasty	120	191	130		6%		16%		76%				16% of cured patients incontinent to gas. Sphincter defect.
Arnaud1	Direct sphincter	17	40	40		63%		15%		22%	13%			

991[92]	repair													
Study	**Surgery type**	**Follow-up (months)**	**N**	**N. at follow-up**	**Faecal Incontinence:**						**Complications**			**Comments**
					Cured		**improved**		**Not improved**		**Wound infection?**	**Bleeding?**	**Unknown or other?**	
					CR	**PR**	**CR**	**PR**	**CR**	**PR**				
Bartolo1990[93]	Anterior sphincter repair	60	30	30		67%								Additional levatorplasty or posterior colporrhaphy was performed
Elton2002[94]	Overlapping anterior sphincter repair	13	20	20				80%		20%	10%		5%	
Engel1994a[95]	Overlapping sphincter repair	46	28	28		58%		21%		21%		4%	4%	Additional levatorplasty (n=16)
Gibbs1993[96]	Overlapping sphincter repair	43	36	33				88%		12%	6%		25%	
Gilliland1998[97]	Overlapping sphincter repair	24	105	77				55%		45%	4%		14%	Levatorplasty performed in 58 of the patients
Malouf2000c[3]	Overlapping sphincter repair	77	55	36				50%		50%				
Osterberg2000[98]	Overlapping sphincter repair	12	20	20										
Rothbarth2000[99]	Overlapping sphincter repair	39	39	39				62%		38%	7%		5%	Combined with puborectal muscle plasty (n=32) and additional posterior vaginal wall repair (n=5)
Simmang1994[100]	Overlapping sphincter repair	12	14	14				93%		7%				
Ternent1	Anterior	12	35	35				62%		38%				

997[101]	overlapping sphincteroplasty													
Study	**Surgery type**	**Follow-up (months)**	**N**	**N. at follow-up**	**Faecal Incontinence:**						**Complications**			**Comments**
					Cured		**improved**		**Not improved**		**Wound infection?**	**Bleeding?**	**Unknown or other?**	
					CR	**PR**	**CR**	**PR**	**CR**	**PR**				
Briel1998[102]	Direct sphincter repair and overlapping with internal imbrication	24	55	55				65%		35%	11%		9%	
Fleshman1191[104]	Overlapping	13	28	28				75%		25%	7%		7%	
Chen1998[106]	Sphincter repair by plication method	50	15	15				95%		5%	13%			
Engel1997[107]	Overlapping repair	12	20	20							30%	5%		
Briel1999[105]	Anterior anal sphincter repair	12	20	20				65%		35%				
Sangwan 1996[103]	Overlapping sphincter repair	16	15	15	40		47		13					
Jensen1997[109]	Biofeedback after sphincteroplasty	32	28	28				89%		10%	0%	0%	0%	
Steele2006[108]	overlapping anal sphincteroplasty	33.8	28	28							43%			
Weighted mean					40%	29%	47%	52%	13%	36%	20%	2%	12%	

Summary Results Table 2: Repeat Sphincter Repair

Study	Surgery type	Follow-up (months)	N	N. at follow-up	Faecal Incontinence:						Complications			Comments
					Cured		improved		Not improved		Wound infection?	Bleeding?	Unknown or other?	
					CR	PR	CR	PR	CR	PR				
Pinedo1999[110]	Overlapping repair	20	26	23				65%		35%				External sphincter defect
Vaizey 2004[111]	Repeat obstetric anterior sphincter repair	20	23	23				62%		38%			2 patients underwent further surgery for FI	
Weighted mean								64%		36%				

N.B no reviewed studies on repeat sphincter repair reported outcomes at ≥4 years Follow-up (months)

Summary Results Table 3: Levatorplasty

Study	Surgery type	Follow-up (months)	N	N. at follow-up	Faecal Incontinence:						Complications			Comments
					Cured		Improved		Not improved		Wound infection?	Bleeding?	Unknown or other?	
					CR	PR	CR	PR	CR	PR				
Osterberg2000[98]	Anterior levatorplasty (post-anal repair in men)	12	31	31					6%		6%			
Aitola 2000[118]	Anterior levatorplasty combined with external anal sphincter placation	12 months	45	45 Idiopathic: 27 Trauma:17		I: 19% T:24%		I:67 % T:59 %		:				
Weighted mean						21%		63%	6%		6%			

N.B no reviewed studies on levatorplasty reported outcomes at ≥4 years follow-up

Summary Results Table 4: Post-anal repair

Study	Surgery type	Follow-up (months)	N	N. at follow-up	Faecal Incontinence:						Complications			Comments
					Cured		Improved		Not improved		Wound infection?	Bleeding?	Unknown or other?	
					CR	PR	CR	PR	CR	PR				
Engel1994[112]	Post-anal repair	43	38	38		21%		45%		34%	3%	-	5%	
Setti1994[113]	Post-anal repair	73	54	34		12%		14%		74%				
Orrom 1991[114]	Postanal repair	15	17	17				59%		41%				
Rieger 1997[115]	Postanal repair	96	22	19				58%		32%				
Abbas2005a[117]	Postanal repair	36	47	44		9%		59%		32%	7%		2%	
Matsuoka2000[116]	Post-anal repair	36	21	20	35%		65%				5%			
Weighted mean					35%	14%	65%	45%		43%	5%		3%	

Summary Results Table 5: Total pelvic floor repair

Study	Surgery type	Follow-up (months)	N	N. at follow-up	Faecal Incontinence:						Complications			Comments
					Cured		Improved		Not improved		Wound infection?	Bleeding?	Unknown or other?	
					CR	PR	CR	PR	CR	PR				
Korsgen1997[119]	Total pelvic floor repair	36	75	57			70		30					
Weighted mean							70%		30%					

Summary results table 6: Bioinjectibles/ sphincter bulking agents

Study	Surgery type	Follow-up (months)	N	N. at follow-up	Faecal Incontinence:						Complications			Comments
					Cured		Improved		Not improved		Wound infection?	Bleeding?	Unknown or other?	
					CR	PR	CR	PR	CR	PR				
Davis2003[159]	Durasphere	29	18	15									33%	
Weighted mean													33%	

Summary Results Table 7: Island Advancement flap anoplasty

Study	Surgery type	Follow-up (months)	N	N. at follow-up	Faecal Incontinence:						Complications			Comments
					Cured		Improved		Not improved		Wound infection?	Bleeding?	Unknown or other?	
					CR	PR	CR	PR	CR	PR				
Morgan1997[160]	Island Advancement flap anoplasty	34	15	15							20%			
Weighted mean											20%			

Summary Results Table 8: Sacral Nerve Stimulation (SNS)

Study	Surgery type	Follow-up (months)	N	N. at follow-up	Faecal Incontinence:						Complications			Comments
					Cured		Improved		Not improved		Wound infection?	Bleeding?	Unknown or other?	
					CR	PR	CR	PR	CR	PR				
Kenefick2002a[167]	SNS	24	15	15							7%		33%	
Jarrett2005[2]	SNS	12	13	13									46%	
Rosen2001[120]	SNS	15	20	16			80%				15%		5%	
Matzel2004A[121]	SNS	24	37	34			83%				3%		8%	
Ganio2006[126]	SNS	12	116	31									6%	
Ganio 2001[124]	SNS	15.5	16	16										
Weighted mean							89%				5%		15%	

Summary Results Table 9: Graciloplasty

Study	Surgery type	Follow-up (months)	N	N. at follow-up	Faecal Incontinence:						Complications		
					Cured		Improved		Not improved		Major wound complication	Minor wound complications	Device/ stimulation problems? Or other.
					CR	PR	CR	PR	CR	PR			
Wexner2002[127]	graciloplasty	24	86 non-stoma patients	64			56%						
			29 stoma patients	21	33%								
Penninckkx2004[136]	Dynamic graciloplasty	48	60	60					45%		32%	15%	50%
Sielezenff19999a[137]	Dynamic graciloplasty	20	16	16		19%		63%		19%		38%	
Thornton 2004[138]	Dynamic graciloplasty	60	38	38							63%	34%	32%
Christiansen1998a[139]	Dynamic graciloplasty	27	13	13		23%		69%		8%			77%
Madoff1999[135]	graciloplasty	24	128	128							32%	29%	11%
Fauchero n[141]	graciloplasty	63	22	16				81%				25%	38%
Rongen2003[140]	Gracilopasty	24	200	191				76%				15%	55%
Christiansen1990[142]	graciloplasty	14	13	12		50%		33%		17%		17%	
Weighted mean					33%	29%	56%	73%	45%	15%	37%	22%	40%

Summary Results Table 10: Gluteoplasty

Study	Surgery type	Follow-up (months)	N	N. at follow-up	Faecal Incontinence:						Complications			Comments
					Cured		Improved		Not improved		Major wound complication	Minor wound complications	Device/ stimulation problems? Or other.	
					CR	PR	CR	PR	CR	PR				
Madoff1999[135]	Gluteoplasty	24	11	11				45%		55%	36%	18%	45%	

Summary Results Table 11: Artificial Bowel Sphincter

Study	Surgery type	Follow-up (months)	N	N. at follow-up	Faecal Incontinence:						Complications			
					Cured		Improved		Not improved		Wound infection ?	Bleeding ?	Unknown or other?	
					CR	PR	CR	PR	CR	PR				
Altomare 2004[168]	AAS	50	28	14									46%	
Casal 2004[146]	ABS	29	10	10							60%			
Christiansen 1999[147]	ABS	84	17	17							18%		24%	
Devesa 2002[148]	ABS	26.5	53	53							11%		9%	
Lehur1996[149]	AUS	20	13	13	38%		31%		31 %		15%		38%	
Lehur 1998[150]	AAS	30	13	13									15%	
Lehur 2000[151]	AAS	20	24	24				75%			21%		8%	
Lehur 2002[152]	AAS	25	16	16										
Michot 2003[153]	AAS	34.1	37	19			100						16%	
Ortiz 2002[154]	AAS	26	22	22										
Parker 2003[155]	AAS	24	45	45									29%	
Savoye2000	ABS	16	12	12			100							Improvement taken to mean continent for solids but not

														necessarily for gas or liquid.
Wong 2002[157]	ABS	12	115	101									98%	
Weighted mean							80%	75%			19%		47%	

APPENDIX F: UNIT COSTS FOR INTERVENTIONS

Economic data presented as part of the consensus development process

Methods

After the published clinical and economic evidence had been reviewed, it was clear that evidence base for this guideline was very limited. Given the absence of good quality clinical evidence, the health economist and the GDG agreed that cost-effectiveness modelling would be difficult and would be unlikely to inform recommendations. All the recommendations in this guideline were developed using consensus methods. To encourage the GDG to reach a consensus that was underpinned by the principles of cost-effectiveness, the guideline health economist presented unit cost data and discussed the implications with the Group. This was carried out both at the subgroup meetings where recommendations were proposed and at the meetings where the recommendations were formally agreed.

Unit costs were extracted from standard NHS sources, from the literature already reviewed. Other costs were supplied by GDG members from their own Trusts and from the Guideline costing analyst.

In this appendix we outline the data and principles discussed with the GDG.

General principles

The following issues were discussed.

- Where we do not have good evidence for clinical effectiveness…

  - we should be cautious about recommending interventions and consider research recommendations.

- Where we do have some evidence of clinical effectiveness…

  - we should consider whether the magnitude of the effect is large enough

  - consider the net resource costs of alternative interventions

  - target interventions on those most likely to gain.

- The costs of interventions that cure or reduce incontinence may be offset, partially at least, by cost savings from a reduced need for:

  - containment products

  - stoma formation and other types of surgery

  - social care (FI is a major contributing factor to older people being admitted to care homes).

Assessment

We extracted costs of testing from NHS Reference Costs 2003[169] (this is the most recent year that broke down the cost of gastroenterology outpatient visits by type of diagnostic test) (Unit Costs Table 1).

Unit Costs Table 1: Cost of gastroenterological assessment

Medical / Surgical Gastroenterology outpatient visit HRG Label	HRG Code	No. of Attendances	National Average Unit Cost (£)
MRI	F03op	13,510	244
CT	F04op	30,100	189
Colonoscopy Examination Alone	F06op	26,917	171
Endoscopic Ultrasound	F07op	4,285	167
GI Physiology Studies	F13op	17,763	162
Flexible Sigmoidoscopy Examination Alone	F14op	31,055	153
Rigid Sigmoidoscopy with Biopsy or Therapy	F16op	32,957	136
Ultrasound	F18op	48,742	119
Rigid Sigmoidoscopy	F19op	68,442	114
Other Gastroenterological Attendance with Other Investigation or Procedure	F22op	84,332	111
Ultrasound (Gynaecology)	M03op	192,301	111
Referral to PAMS or Specialist Nurse	F17op	14,522	98
Minor Radiology	F20op	36,867	94
Other General Surgical Attendance with Investigation or Procedure	F23ops	299,428	87
New Attendance with No Investigation or Procedure	F24op	164,713	87
Minor Pathology Test	F21op	208,118	81
Follow up Attendance with No	F25op	494,084	68

Investigation or Procedure			

The following questions were discussed.

When is a test likely to be cost-effective? (five links in the chain of evidence)

1. sensitive & specific

2. change clinical practice / patient choice

3. effective treatment

4. health gain (or cost savings) associated with treatment is large enough to justify the cost

5. patient subgroup – baseline risk not too high nor too low

How can we try to ensure cost-effectiveness?

- Think about the five links in the chain
- Be cautious about recommending tests that are more expensive
- Be cautious about recommending multiple tests, when a single test would be sufficient
- Be cautious about recommending tests for patient subgroups that are unlikely to benefit

Conservative management

Unit Costs Table 2 shows some relevant staff costs in the NHS.

Unit Costs Table 2: NHS staff costs per hour

Physiotherapist	£30
Occupational therapist	£30
Dietician	£29
Health care Assistant	£14
Staff nurse	£21
Ward manager	£26
District Nurse	£29
Senior House Officer	£27
Specialist Registrar	£32
Consultant (medical)	£88

Source: PSSRU[170]

From the staff costs, we estimated very approximately the staff costs of specialist conservative treatments:

Pelvic floor exercises: 3 x 20-minute session with hospital physiotherapist = £30

Biofeedback: 10 x 60-minute session with hospital physiotherapist = £300

Of course, we should be taking in to account the cost of equipment, & consumables and potentially cost savings from a reduced need for containment products, etc.

In Unit Costs Table 3 are the costs of some drugs and products used in the management of FI.

Unit Costs Table 3: Product costs

Product	Unit cost	Source
Loperamide - 2mg (capsules)	£0.04	BNF[171]
Loperamide - 2mg (syrup)	£0.10	BNF[171]
Disposable bodyworns	£0.50 each	GDG members
Anal plugs	£2.00 each	NHS electronic drug tariff[172]

Surgical management

In Unit Costs Table 4 we present a sensitivity analysis to show how the price the NHS should be prepared to pay for one episode of FI surgery will be dependent on the quality of life gained each year and on the duration of the health gain. Studies have shown a reduction in health-related quality of life of about 30% attributable to faecal incontinence[173,174]. If a surgery achieved full quality of life then our willing ness to pay would be represented in the left hand side of Unit Costs Table 4. However, if the benefit is much less than that (if the patient's FI is not so limiting or if the surgery is only partially successful), say 10% then the right hand side would be more accurate. All of the willingness to pay figures would be reduced if there are complications associated with surgery.

From a small sample of Trusts we have found the procedural cost of SNS (permanent device) was between £6,500 and £10,500 (Sources: Mark Minchin, NICE and Christine Norton, St Marks Hospital) compared with the £12,000 to £22,000 for DGP reported in the NHS HTA report[68].

Unit Costs Table 4: Willingness to pay for faecal incontinence surgery: A sensitivity analysis

QALYs gained per successful year=1.0	QALYs gained per successful year=0.1

Mean duration of effect	QALYs gained	Maximum willingness to pay for surgery		Mean duration of effect	QALYs gained	Maximum willingness to pay for surgery
1	0.3	£9,000		1	0.1	£3,000
2	0.6	£18,000		2	0.2	£6,000
3	0.9	£27,000		3	0.3	£9,000
4	1.2	£36,000		4	0.4	£12,000
5	1.5	£45,000		5	0.5	£15,000
10	3.0	£90,000		10	1.0	£30,000

Patients with limited mobility and faecal incontinence

We conducted a crude cost-effectiveness analysis on the prompting and exercise intervention evaluated in the study by Schnelle and colleagues [33,34](Chapter 7). In this cost-consequences study, an intervention of 2-hourly prompts plus an exercise programme was compared to standard care. The evaluation was based on an RCT of 190 incontinent residents in long stay beds at four nursing homes. They evaluated potential cost savings from the intervention by measuring the incidence of 31 acute conditions (including: skin irritation, pressure ulceration, respiratory infection, urinary infection, constipation, pain, injury, depression, weight loss, angina, stroke, hyperglycaemia). The overall incidence, for all 31 conditions, was reduced by 10% but this was not statistically significant and therefore costs were not significantly reduced (£2.20/day vs £3.40/day). They did not cost the intervention itself but they note that staff time was considerable (21 minutes per patient per prompt). Assuming the cost of a health care assistant is £11 per hour[170], the cost-effectiveness of the intervention can be expressed as £88 per FI episode averted (Unit Costs Table 5). This cost would be offset in part by savings due to less staff time involved with cleaning and reduced laundry costs. Without quality of life data, it is difficult to assess whether or not this intervention is cost-effective.

Unit Costs Table 5: Cost-effectiveness of prompting and exercise

	Intervention	**Control**		**Difference (intervention-Control)**
FI prevalence* (*a*)	3%	7%		
FI episodes per week (*b*=*a* x 5 days x 5 prompts per day)	**0.8**	**1.8**		**-1.0**
Hours per prompt	0.35	NA		

(*c*)				
Hours per week (d=*c* x 5 days x 5 prompts per day)	8.8	0		
Cost of intervention per week (*e*=*d* x £11)	£96	£0		£96
Cost of acute care per week (*f*)	£15	£24		-£8
Cost per week of intervention & acute care (*g*=*e*+*f*)	**£112**	**£24**		**£88**
Incremental cost-effectiveness	**£88 per FI episode averted (=£88/1.0)**			

* Patients in both arms were checked 5 times per day, 5 days per week. Prevalence is calculated as the number of checks in which FI was observed divided by the total number of checks.

Source: FI prevalence, time per prompt and acute care costs are from Schnelle et al[33,34]. Unit cost of intervention staff time is from Unit costs of Health and Social Care[170].

APPENDIX G: EXCLUDED STUDIES

Excluded assessment studies

Alexander et al, 1996[175]
Barthet et al, 2002[176]
Beer-Gabel et al, 2002[177]
Bielefeldt et al, 1991[178]
Bouchoucha et al, 2002[179]
Braun et al, 1994[180]
Chen et al, 1999[181]
Cheong et al, 1995[182]
Chew et al, 2003[183]
Cornella et al, 2003[184]
Cuesta et al, 1992[185]
Damon et al, 2002[186]
Deen et al, 1993[187]
deSouza et al, 1996[188]
Dobben et al, 2005[189]
Eckardt et al, 1994[190]
Farouk and Bartolo, 1993[191]
Farouk and Bartolo, 1994[192]
Favetta, 2000[193]
Felt-Bersma et al, 1992[194]
Fink et al, 1992[195]
Fletcher et al, 2003[196]
Fowler et al, 2003[197]
Hetzer et al, 2006[198]
Ho and Ho, 1999[199]
Ho and Goh, 1992[200]
Holmberg et al, 1995[201]
Infantino et al, 1995[202]
Jones et al, 1998[203]
Kafka et al, 1997[204]
Malouf et al, 2000[205]
Martínez-Hernández et al, 2003[206]
Mibu et al, 2001[207]
Muñoz-Yagüe et al, 2003[208]
Neill et al, 1981[209]
Nielsen et al, 1993[210]
Nielsen et al, 1993[211]
Oberwalder et al, 2004[212]
Oggianu et al, 1998[213]
Osterberg et al, 1999[214]
Osterberg et al, 2000[215]
Pescatori et al, 1992[216]
Poen et al, 1998[217]
Ramírez et al, 2005[218]
Rasmussen et al, 1992[219]
Rentsch et al, 2001[220]
Rex and Lappas, 1992[221]

Rieger et al, 1996[222]
Rieger et al, 1996[223]
Roberts et al, 1990[224]
Sangwan et al, 1995[225]
Savoye-Collet et al, 2005[226]
Seidel et al, 1994[227]
Sentovich et al, 1995[228]
Sentovich et al, 1998[57]
Shobeiri et al, 2002[229]
Siproudhis et al, 1999[230]
Stojkovic et al, 2002[231]
Stoker et al, 1996[232]
Strijers et al, 1989[233]
Telford et al, 2004[234]
Terra et al, 2005[235]
Vaizey and Kamm, 2000[236]
Vernava, III et al, 1993[237]
West et al, 2005[238]
Williams et al, 1995[239]
Williams et al, 1995[240]
Zbar et al, 1999[241]

Excluded conservative management studies

Attar et al, 1999[242]
Bond et al, 2005[243]
Coulter et al, 2002[244]
Enck et al, 1994[245]
Ernst, 2003[246]
Guillemot et al, 1995[247]
Harford et al, 1980[248]
Heymen et al, 2001[249]
Jeter and Lutz, 1996[250]
Jorge et al, 2003[251]
Lyder et al, 1992[252]
Nix and Ermer-Seltun, 2004[253]
Norton and Kamm, 2001[25]
Norton and Kamm, 2001[254]
Palsson et al, 2004[255]
Sander et al, 1999[256]
Schuren and Becker, 2005[257]
Whitehead et al, 1985[258]
Wilson and Muir, 1975[259]

Excluded surgical studies

Akhtar and Padda, 2005[260]
Altomare et al, 1997[261]
Altomare et al, 2004[262]
Baeten et al, 1991[263]
Baeten et al, 2001[264]

Barisic et al, 2006[265]
Catena et al, 2002[266]
Christiansen and Skomorowska, 1987[267]
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White 1993[421]

APPENDIX H: USEFUL CONTACTS, WEBSITES AND SOURCES OF PATIENT INFORMATION

Alzheimer's Society

Gordon House, 10 Greencoat Place

London SW1P 1PH

Tel: 020 7306 0606

Fax: 020 7306 0808

Helpline: 0845300 0336

Email: infor@alzheimers.org.uk

Website: www.alzheimers.org.uk

Association for Continence Advice (ACA)

102a Astra House, Arklow Road, London SE14 6EB

Tel: 020 8692 4680

Fax: 020 8692 6217

Email: info@aca.uk.com

Website: www.aca.uk.com

Association for Spina Bifida and Hydrocephalus (ASBAH)

ASBAH House, 42 Park Road, Peterborough, PE1 2UQ

Tel: 01733 555988

Fax: 01733 555985

Email: info@asbah.org

Website: www.asbah.org

Beating Bowel Cancer

39 Crown Road, St. Margarets, Twickenham, Middlesex, TW1 3EJ

Telephone: 020 8892 5256

Fax: 020 8892 1008

Email: info@beatingbowelcancer.org

Website: www.beatingbowelcancer.org

Bowel Control

www.bowelcontrol.org.uk

Brain and Spine Foundation

Freepost Lon 10492, London, SW9 6BR

Tel: 0808 808 1000

Website : www.brainandspine.org.uk

Centre for Accessible Environments

70 South Lambeth Road, London SW8 1RL.

Telephone: 020 7840 0125

Email info @cae.org.uk

Website www.cae.org.uk

Colostomy Association (BCA)

15 Station Road

Reading

Berks. RG1 1LG

Website www.colostomyassociation.org.uk

Telephone: 0800 587 6744

British Toilet Association

PO Box 17, Winchester SO23 9WL

Telephone: 01962 850277

Fax: 01962 870220

Email: enquiries@britloos.co.uk

Website: www.britloos.co.uk

Coloplast Ltd.

Peterborough Business Park, Peterborough, Cambridgeshire, PE2 0FX.

Telephone: 01733 392000

Fax: 01733 233348

Website: www.coloplast.co.uk

Continence Foundation.

307 Hatton Square, 16 Baldwin Gardens, London EC1N 7RJ.

Helpline: 0845 345 0165.

Email: continence-help@dial.pipex.com

Website: www.continence-foundation.org.uk

Continence Worldwide Website

Website: www.continenceworldwide.org

Links to national continence organisations in many different countries around the world.

Digestive Disorders Foundation.

3, St. Andrew's Place, London NW1 4LB.

Telephone: 020 7486 0341

Fax: 020 7224 2012

Email: ddf@digestivedisorders.org.uk

Website: www.digestivedisorders.org.uk

(A range of information leaflets on common bowel disorders).

Disability Rights Commission

DRC Helpline Free post, MID 02164

Tel: 08457 622 633

Text phone 08457 622 644

Website www.drc-gb.org

Disabled Living Foundation

380 - 384 Harrow Road, London W9 2HU

Telephone: 0845 130 9177

Email: info@dlf.org.uk

Website: www.dlf.org.uk

Information on equipment and resources for people with disabilities. Includes toilet aid, adaptations and alternatives.

Disabled Living Centres Council (DLCC)

Redbank House, St Chad's Street, Manchester M8 8QA

Telephone: 0161 834 1044

Fax: 0161 839 0802

Email: dlcc@dlcc.co.uk

Website: www.dlcc.co.uk

ERIC (Enuresis Resource & Information Centre)

34 Old School House, Britannia Rd, Kingswood, Bristol, BS15 8DB

Telephone: 0845 370 8008

Fax: 0117 960 0401

Email: info@eric.org.uk

Website: www.enuresis.org.uk

Information for children and parents with childhood soiling; helpline).

Hollister Ltd

Rectory Court, 42 Broad Street, Wokingham, Berkshire RG40 1AB

Telephone: 0800 521 377

Email: samples.uk@hollister.com

Website: www.hollister.co.uk

Faecal collection pouch for bed-bound people with severe incontinence.

INCONTACT

United House, North Road, London NW1 9DP

Telephone: 0870 770 3246

Email: info@incontact.org

Website: www.incontact.demon.co.uk

IBS Network.

Unit 5, 53 Mowbray Street, Sheffield, S3 8EN.

Help line: 0114 272 3253

Website: www.ibsnetwork.org.ukl

Organisation for people with Irritable Bowel Syndrome.

The Ileostomy and Internal Pouch Group

PO BOX 132 Scunthorpe DN15 9YW.

Telephone: 0800 018 4724

www.the-ia.org.uk

International Foundation For Functional Gastrointestinal Disorders

IFFGD PO Box 17864 Milwaukee WI 53217-8076, USA

Telephone: (USA) 001 414 964 1799

Fax: 001 414 964 7176

Email: iffgd@iffgd.org

Website: www.about incontinence.org

Multiple Sclerosis Society

23 Effie Road, Fulham, London SW6 1EE

Tel: 020 8438 0700

Helpline: 0808 800 8000

Website: www.mssociety.org.uk

National Association for Colitis & Crohn's Disease (NACC).

4 Beaumont House, Sutton Road, St Albans, Herts AL1 5HH.

Telephone: 01727 844296

Fax: 01727 862550

Email: nacc@nacc.org.uk

Website: www.nacc.org.uk

Norgine Ltd

Chaplin House, Widewater Place, Moorhall Rd, Harefield, Middlesex, UB9 6NS

Telephone: 01895 453710

Fax: 01895 453711

Website: www.norgine.com

Range of information on IBS and constipation; Bristol stool form chart.

Parkinson's Disease Society

United Scientific House, 215 Vauxhall Bridge Road, London SW1V 1EJ

Telephone: 020 7931 8080

Fax: 020 7233 9908

Helpline: 0808 800 0303

Email: enquiries@parkinsons.org.uk

Website: www.parkinsons.org.uk

Understanding you bladder and bowel in Parkinson's Disease.

Promocon (continence product information sheets and display).

Redbank House, St. Chad's Street, Cheetham, Manchester M8 8QA.

Telephone: 0161 834 2001

Fax: 0161 214 5961

Email: promocon@disabledliving.co.uk

Website: www.promocon.co.uk

RADAR (supplier of keys for National Disabled Toilet Scheme, and other travel /holiday information for people with continence problems.

12 City Forum, 250 City Road, London EC1V.

Telephone: 020 7250 3222

Website www.radar.org.uk

Spinal Injuries Association

2 Trueman Place, Oldbrook,

Milton Keynes. MK6 2HH

Telephone: 0845 678 6633

Fax: 0845 070 6911

Freephone Helpline: 0800 980 0501

e-mail: sia@spinal.co.uk

web: www.spinal.co.uk

www.spinal.co.uk/help/bowel.htm

APPENDIX I: MEDICAL HISTORY

Medical history can be amassed in a personal history, discussed with carers (as appropriate) and information referred from previous clinicians.

Additional information may be obtained from a bowel diary.

Questions to consider:

1. History of bowel habit: Questions to ask patients

What is your normal bowel habit?

Has it changed recently? If so how? Has there been any bleeding from the back passage? Or loss of mucus?

What is the usual consistency of your stools (bowel motions)? (Refer to stool chart such as the Bristol Stool Chart to assist the patient/carer to describe)

Do the stools vary in consistency?

Do you have to strain to empty your bowels? If so, for how long?

Are you able to tell the difference between when you are about to pass wind or stool?

Do you pass much wind?

Can you control this wind?

Are you able to delay emptying your bowels?

If so for how long?

Do you experience any abdominal pain or bloating before passing a bowel motion?

Does that relieve the sensation?

Do you have a feeling of incomplete emptying after an attempted bowel evacuation?

Do you ever have to assist the passage of stool with your finger?

Are you able to clean yourself after passing stools?

Do you have to clean yourself several times after passing stools?

Do you ever leak stools without being aware of it?

When faecal incontinence is reported, ask the following:

How often does it happen?

When has it happened? Is there any pattern to this or any factor that provokes it?

How much leaks? What is the consistency of the leakage? Can it be wiped away easily?

Do you get the sensation of the need to empty your bowels before you leak? Is that sensation an urgent need to empty your bowels? (Passive soiling)

Does soiling occur after a bowel motion has been passed? (post defaecation soiling).

Do you wear pads (or something else) in your underwear? If so, are they effective in preventing soling of clothes / surroundings / furnishing?

2. Previous Medical History

Assess the patient for possible contributory factors:

Constipation/diarrhoea

Acute severe illness

Terminal illness

Severe cognitive impairment

Assess the patient for limited mobility:

Does the patient have adequate toilet facilities (for example, is there limited availability, access problems, lack of privacy, unclean, unsafe?)

Does the patient need assistance for toileting? If so, is there delayed assistance when there is an urgent call to stool?

Is the patient able to communicate when there is a need to defecate?

Are there any physical or environmental difficulties with toilet access, for example, anonymous doors, steps, non-slip shiny floors, patterned carpets, excessive distance?

Is there a history of a neurological disorder(s)?

If yes - how long has it been present?

Is it expected to improve?

Is it permanent?

Does the patient have an obstetric history and/or history of weak pelvic floor (as appropriate)

Parity

Difficult delivery

Large birth weight

Is there a history of perianal trauma or surgery?

Is there a history of urinary continence?

Is there a history of rectal prolapse?

Is there a history of other co-morbidities e.g. diabetes, Parkinson's disease

3. Perform a Medication Review

Is the patient taking any of the drugs which may exacerbate faecal incontinence (see appendix J)?

What treatment alterations have already been made in the management of the problem?

How effective were these alterations?

4. Diet and fluid history

Enquire about meals and snacks taken.

Review food intake versus the list of foods which may exacerbate faecal incontinence (see appendix K)

5. Consequences of faecal incontinence

Do you experience itching or soreness around the back passage?

When is this present?

6. Impact of symptoms on lifestyle / Quality of Life

Does the patients bowel symptoms affect the following?

General lifestyle

Family life

Leisure and Social activity

Work

Sexual activity

Emotions

Self-image

Relationships, particularly any changes in close relationships

Ability to travel

Ability to manage within place of residence, for example does the patient require any structural changes to be made to their residence?

7. Physical examination

General examination (as indicated)

Cognitive and behavioural assessment (if indicated)

Assess patients ability to use toilet, including:

Access

Mobility

Ability to adjust clothing

Ability to wash after using toilet

Anorectal examination:

Visual inspection of anus

Assessment of perineal descent

Digital rectal examination for anal tone, ability to squeeze anal sphincter voluntarily

Assessment of faecal loading

APPENDIX J: DRUGS THAT MAY EXACERBATE FAECAL INCONTINENCE AND LOOSE STOOLS

Drug (and mechanism)	Examples (not exhaustive list)
Drugs altering sphincter tone	Nitrates Calcium channel antagonists Beta-adrenoceptor antagonists (beta-blockers) Sildenafil SSRIs
Broad spectrum antibiotics (multiple mechanisms)	Cephalosporins Penicillins Erythromycin
Topical drugs applied to anus (reducing pressure)	GTN ointment Diltiazem gel Bethanechol cream Botulinum toxin A injection
Drug causing profuse loose stools	Laxatives Metformin Orlistat SSRIs Magnesium-containing antacids Digoxin
Constipating drugs	Loperamide Opioids Tricyclic antidepressants Aluminium-containing antacids Codeine
Tranquilisers or hypnotics (reducing alertness)	Benzodiazepines Tricyclic antidepressants SSRIs Anti-psychotics

APPENDIX K: FOOD/ DRINK WHICH MAY EXACERBATE FAECAL INCONTINENCE IN PATIENTS WHO PRESENT WITH LOOSE STOOLS OR RECTAL LOADING OF SOFT STOOL

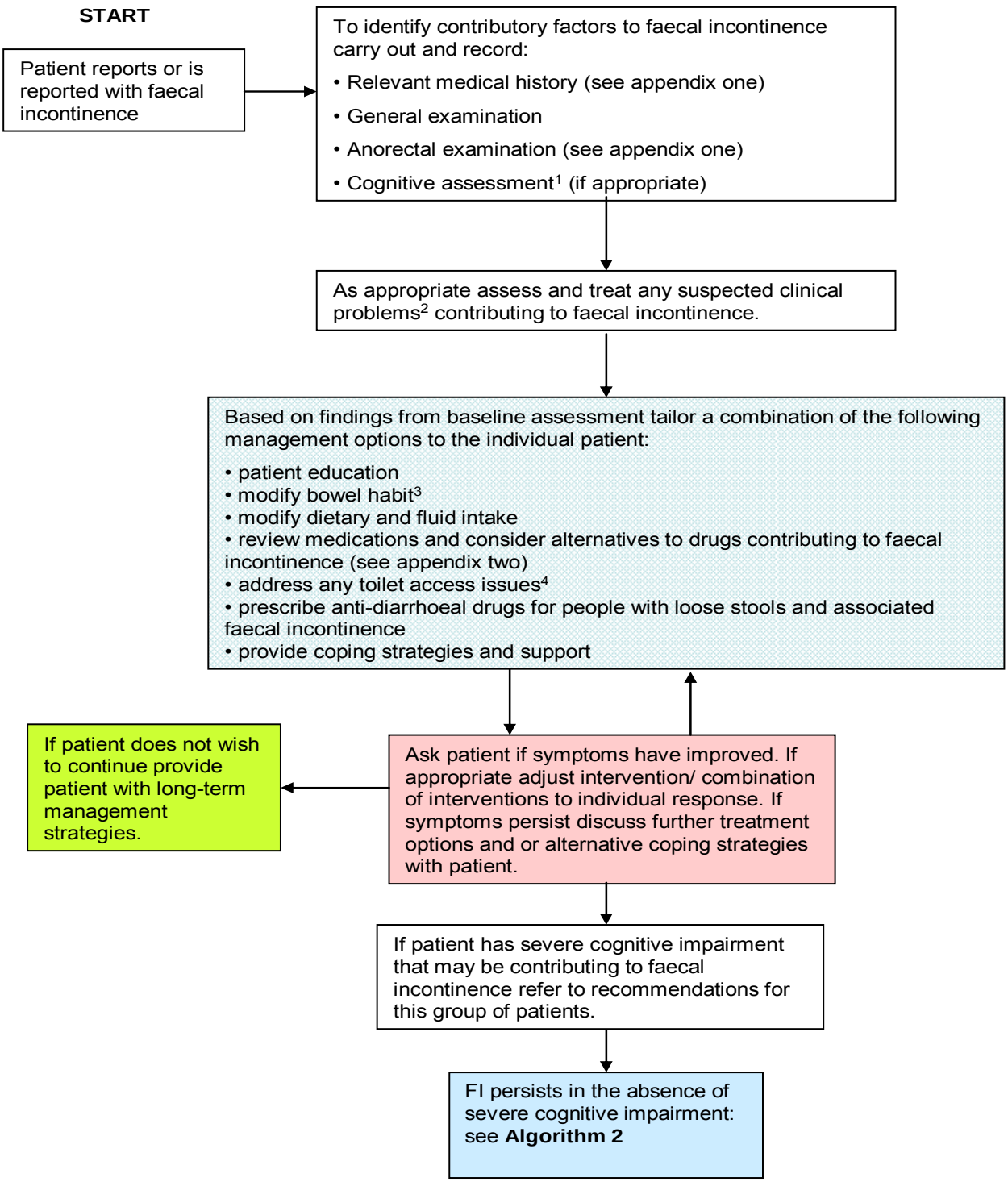
Food Type	Examples/Rationales
Fibre	Fibre supplements for example bulking agents such as ispaghula husk, methylcellulose, sterculia or unprocessed bran Wholegrain cereals/ bread (reduce quantities). Porridge/oats may cause fewer problems than whole wheat based cereals.
Fruit and vegetables	Rhubarb, figs, prunes/plums best avoided as contain natural laxative compounds. Beans, pulses, cabbage and sprouts. Initially limit to the portion sizes given on the DH list www.dh.gov.uk, for example, one apple or 1 tablespoon dried fruit. Space out portions over day.
Spices	For example chilli.
Artificial sweeteners	Sorbitol is best avoided. It is found in special diabetic products such as chocolate, biscuits, conserves and in some sugar free items including many nicotine replacement gums. Aspartamine
Alcohol	Especially stout, beers and ales.
Lactose	A few patients may have some degree of lactase deficiency. Whilst small amounts of milk for example in tea or yoghurt are often tolerated, an increase in the consumption of milk may cause diarrhoea. For more information on lactose intolerance see www.eatwell.gov.uk
Caffeine	Excessive intake of caffeine may loosen stool and thus increase faecal incontinence in some predisposed patients.
Vitamin and mineral supplements	Excessive doses of vitamin C, magnesium, phosphorus and/or calcium supplements may increase faecal incontinence. For more information on lactose intolerance, vitamin and mineral supplements see www.eatwell.gov.uk
Olestra fat substitute	Can cause loose stools.

APPENDIX L: FOOD/ DRINK TO INCREASE SLOWLY IN PATIENTS WITH FAECAL INCONTINENCE AND HARD STOOLS OR CONSTIPATION

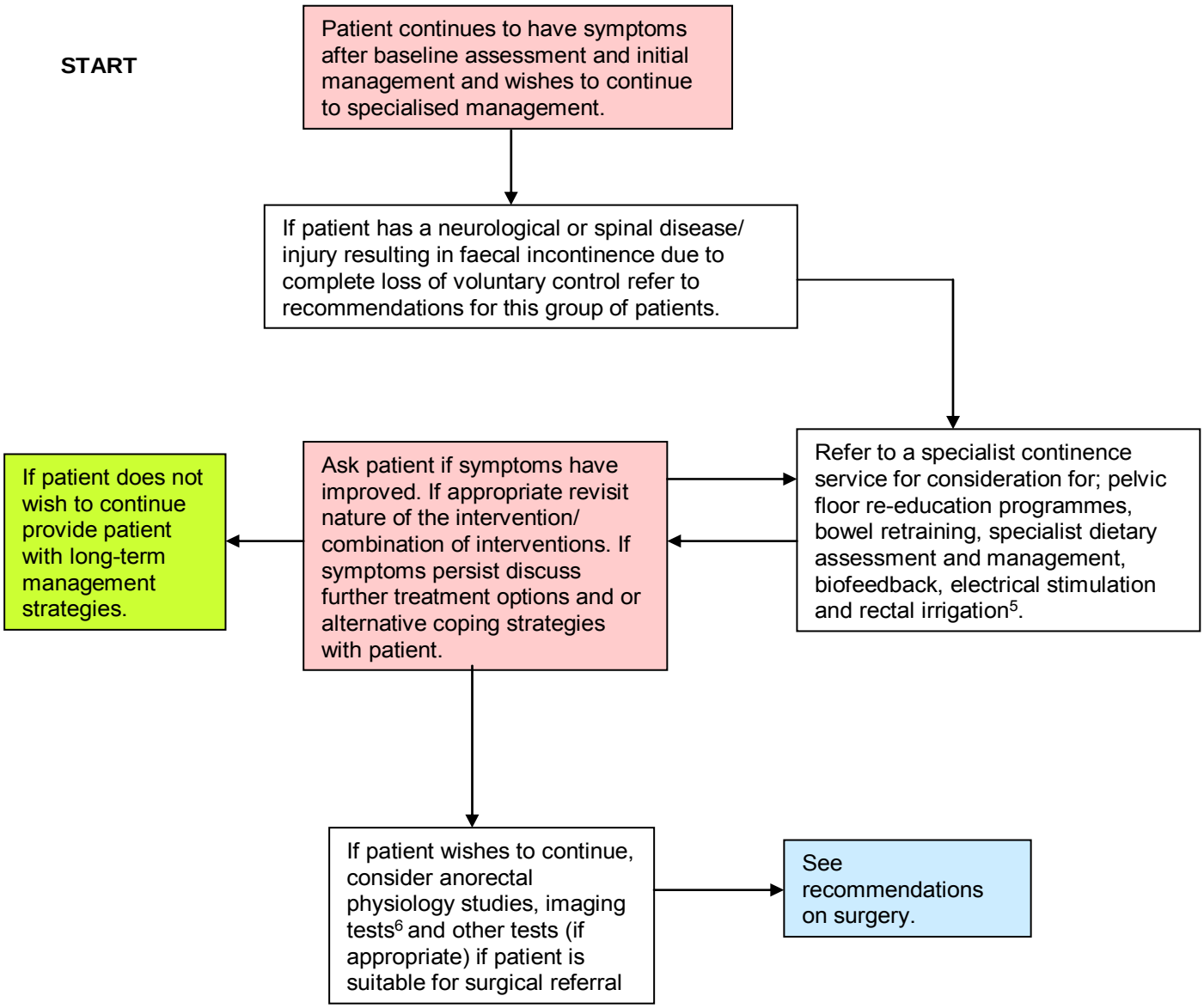
Food Type	Examples/Rationales
Fibre	Current guidelines (DH 1991) are for an average intake of 18 g/ day. Some patients may need an intake of up to 30g /day. Increase intake of wholegrain cereals, wholemeal, wholegrain bread, or white breads with added fibre. Encourage patient to have extra fluid with cereal fibre rich foods. Some patients may require a fibre/bulking agent supplement to be prescribed to achieve a normal stool consistency.
Fruit and vegetables	Fresh, tinned, dried or frozen Encourage a minimum of five portions a day (see www.dh.gov.uk)

APPENDIX M: ALGORITHMS

Algorithm 1



Algorithm 2


START
Patient continues to have symptoms after baseline assessment and initial management and wishes to continue to specialised management.
If patient has a neurological or spinal disease/ injury resulting in faecal incontinence due to complete loss of voluntary control refer to recommendations for this group of patients.
Refer to a specialist continence service for consideration for; pelvic floor re-education programmes, bowel retraining, specialist dietary assessment and management, biofeedback, electrical stimulation and rectal irrigation[5].
Ask patient if symptoms have improved. If appropriate revisit nature of the intervention/ combination of interventions. If symptoms persist discuss further treatment options and or alternative coping strategies with patient.
If patient does not wish to continue provide patient with long-term management strategies.
If patient wishes to continue, consider anorectal physiology studies, imaging tests[6] and other tests (if appropriate) if patient is suitable for surgical referral
See recommendations on surgery.

Footnotes:

- Cognitive assessment: in patients with suspected cognitive impairment contributing to FI it may be appropriate to conduct or refer for more formal cognitive testing.
- For example, faecal loading, treatable causes of diarrhoea, warning signs for lower gastrointestinal cancer (see NICE clinical guideline on referral for suspected cancer (www.nice.org.uk/CG027), rectal prolapse, third degree haemorrhoids, acute anal sphincter injury, acute disc prolapse.
- Aim for ideal stool consistency, and satisfactory bowel emptying at a predictable time.
- If appropriate refer to healthcare professional for assessment of home/mobility.
- This referral may not be appropriate for patients who are unable to understand and/ or comply with instruction, for example, pelvic floor re-education programmes for those with neurological or spinal disease/injury resulting in faecal incontinence due to complete loss of voluntary control.
- Endoanal ultrasound. If this is not available endocoil MRI, endovaginal ultrasound and perineal ultrasound should be considered.

APPENDIX N: DECLARATIONS OF INTEREST

GDG Members, Expert Advisors and Staff Declarations of Interest

GDG Members	Interest
Christine Norton	No interests were declared that required action
James Barrett	No interests were declared that required action
David Bartolo	No interests were declared that required action
Susan Bennett	No interests were declared that required action
Anton Emmanuel	No interests were declared that required action
June Gallagher	No interests were declared that required action
Julie Lang	None
Marlene Powell	No interests were declared that required action
Judith Wardle	No interests were declared that required action

NCC-AC Staff	Interest
Louise Thomas	None
John Browne	None
Clare Jones	No interests were declared that required action
Peter B Katz	None
Veena Mazarello Paes	None
Kathryn Oliver	None
David Wonderling	None

Expert Advisors	Interest
Christopher Chan	None
Graham Scott Duthie	No interests were declared that required action
Scott Glickman	No interests were declared that required action
Christine Kettle	No interests were declared that required action
Frances Przygrodska	None
Graham Stokes	No interests were declared that required action
Abdul Sultan	No interests were declared that required action
Stuart Taylor	No interests were declared that required action
Julie Vickerman	None

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