NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

Assessment report overview

Parafricta Bootees and Undergarments to reduce skin breakdown in people with frail skin or at risk of pressure ulcers

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the External Assessment Centre (EAC) report. It includes key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the Committee may wish to discuss. It should be read along with the sponsor's submission of evidence and with the EAC report. The overview forms part of the information received by the Medical Technologies Advisory Committee when it develops its recommendations on the technology.

Key issues for consideration by the Committee are described in section 7, following the summaries of the clinical and cost evidence.

This report contains information that has been supplied in confidence and will be redacted before publication. This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Comments from professional bodies
- Appendix C: Comments from patient organisations
- Appendix D: Additional information provided by the External Assessment Centre

1 The technology

The Parafricta Bootees and Undergarments (APA Parafricta) are intended to reduce the potential for both the development and progression of skin damage as a result of friction and shear. This includes pressure ulcers and the risk of skin damage in people with frail skin or those who have medical conditions in which skin frailty is a primary factor. The Bootees provide protection for the heel and ankle, and the Undergarments provide protection for the sacrum, buttocks and hips.

The items are made from proprietary Parafricta fabric which is designed to reduce the impact of shear stress and friction associated with movement. It has a friction coefficient value of 0.2, whereas most textiles typically range from 0.3 to 0.7. The Parafricta fabric has an absence of stiction, the additional force needed to overcome skin sticking to a surface before sliding. Because of this, it reduces the ‘jerk’ effect on skin when movement occurs. The lower the friction and stiction, the less likely it is that shear forces will develop and break the skin down, thereby reducing the risk of wound occurrence. This mechanism of action is designed to be distinct from current methods which aim to manage or prevent pressure ulcers by reducing or redistributing pressure. Section 2.1 of the sponsor’s submission describes the principal mechanism of action of the technology.

The Parafricta fabric is used to protect the skin in areas most at risk. Both the Bootees and Undergarments have non-slip areas to assist patient positioning and Velcro opening features. The positioning of the Velcro fasteners and the flat seams is designed to minimise skin creasing or damage. The Bootees are available in a range of sizes in 2 formats, slip-on or Velcro fasteners, and have non-slip soles. The Undergarments are available in several sizes as slip-on garments or with Velcro fasteners, and as briefs or boxer shorts.

The Parafricta fabric is described as breathable but durable. The products are reusable after washing in accordance with garments for NHS use.

Both the Bootees and the Undergarments received a CE mark in 2006 to reduce friction and shear in people with frail skin and those who have, or are at risk of, developing pressure ulcers, and are classified as a class 1 medical device.

The Parafricta Bootees and Undergarments are listed in the Drug Tariff Part IX and can be prescribed on a standard FP10 prescription form.

2 Proposed use of the technology

2.1 Disease or condition

Pressure ulcers (also known as decubitus ulcers or pressure sores) are areas of localised skin damage. Contributing external factors include pressure, friction and shear. They most commonly develop on skin covering bony prominences such as the sacrum, heels, shoulders and hips.

Children and older people may have frail skin. Their thinner skin is likely to sustain injury more easily and take longer to heal. Both children and older people with significantly limited mobility, risk of nutritional deficiency, an inability to reposition, a neurological condition or significant cognitive impairment are at increased risk of skin damage. Maintaining good nutrition, mobility, cognition, preventing falls and managing pain m and continence are essential for managing skin integrity.

2.2 Patient group

For this assessment, the Parafricta Bootees and Undergarments were evaluated in the community or in hospital for adults or children of any age with frail skin or who are at risk of developing a grade 1 or 2 pressure ulcer, or already have a pressure ulcer and are at risk of progressing to a grade 3 or 4 pressure ulcer.

Just under half a million people in the UK develop at least 1 pressure ulcer in any given year. These are usually people with underlying health conditions.

Around 1 in 20 people who are admitted to hospital with an acute (sudden) illness will develop a pressure ulcer. In the UK, chronic wounds represent a significant burden to people and the NHS. Some 200,000 people in the UK have a chronic wound. This includes leg ulcers, foot ulcers, and pressure ulcers.

2.3 Current management

Current options to reduce breakdown of frail skin and to prevent and manage pressure ulcers focus on the reduction or redistribution of pressure and include:

- dynamic or static high-specification pressure-relieving or pressure-redistributing beds, mattresses, overlays and cushions
- sheepskin (numerous products, shapes and sizes available)
- pressure-relieving bootees (numerous shapes and sizes available)
- silicone gel pads.

Pressure ulcer prevention and management (NICE clinical guideline 179) does not consider the prevention or management of pressure ulcers caused by friction or shear. The guideline recommends that when a person presents with, or is at increased risk of developing a pressure ulcer, risk should be assessed and documented first and then reassessed on an ongoing basis.

NICE clinical guideline 179 recommends that once risk has been assessed, mobilising, positioning and repositioning interventions should be considered to prevent damage or further skin damage. Minimum provision is a high-specification foam pressure-relieving mattress, and any ulcer should be closely observed for deterioration. People with a grade 3–4 pressure ulcer should receive a bed with an alternating pressure mattress or high-specification foam mattress with an alternating pressure overlay, or a sophisticated continuous low pressure system.

2.4 Proposed management with new technology

All current interventions used to treat or prevent pressure ulcers relieve or reduce pressure. The Parafricta Bootees and Undergarments are intended to reduce friction and consequent shear damage to skin and underlying tissues, specifically in people who have or are at risk of having pressure ulcers, or for people with frail skin or who have medical conditions where skin frailty is a primary factor.

The scope of this assessment is the use of either the Parafricta Bootees or Undergarments as an adjunct to standard NHS current clinical practice of pressure-reducing devices. The use of the Parafricta Bootees or Undergarments on their own is not included in this evaluation.

2.5 Equality issues

No equality issues were identified.

Groups covered by the Equality Act 2010 include people with chronic wounds. The Parafricta Bootees and Undergarments may have particular advantages for people with chronic wounds or those who have foot ulcers as a result of diabetes. The Parafricta Bootees and Undergarments would not restrict access to treatment for these groups of people.

3 Sponsor's claimed benefits

The benefits to patients claimed by the sponsor are:

- A reduction in pressure ulcer incidence in people who are at high risk of pressure ulcers following assessment, thereby reducing or avoiding adverse impact on quality of life, pain, discomfort, hospital length of stay and morbidity and mortality.
- A reduction in pressure ulcer severity in people who have or develop early (stage I/II) pressure ulcers, thereby reducing or avoiding adverse impact on quality of life, pain, discomfort, hospital length of stay and morbidity and mortality.

- Protection of susceptible skin in people in whom a repetitive, rubbing motion – due to an underlying neurological or other medical condition – can break down the skin.
- The ease of use for patients and carers, combined with a familiarity with the type of products in older people or those with cognitive impairment, may lead to greater compliance with pressure ulcer preventative measures.
- The products can be used in the home or in primary or secondary care, enabling easy transition between these for the patient.

The benefits to the health system claimed by the sponsor are:

- The ease of use and practicality of the Parafricta garments imply that the technology may be implemented easily in the community and could be used as a long-term care strategy to improve people's quality of life.
- Prevention of pressure ulcer formation and reduced pressure ulcer incidence would shorten stays in hospital and may allow people to be transferred to lower cost community care. Hospital-acquired pressure ulcers result in lengthened hospital stays and increased complications.
- Reduction in NHS costs including but not limited to:
  - quicker return of people to the community or community long-term care
  - reduced pressure ulcer incidence resulting in lower costs of nursing care, dressings and rehabilitation
  - the reusable nature of the garments.

4 Decision problem

Table 1 Summary of the decision problem

Population	People (adults or children of any age) in the community or in hospital who: • have a grade 1 or 2 pressure ulcer and are at risk of progressing to a grade 3 or 4 pressure ulcer • do not have a pressure ulcer but are at risk of developing pressure ulcers caused by friction and shear forces • have medical conditions where skin frailty is a primary factor and where friction and shear could cause skin damage.
Intervention	In all settings, this is the use of: • a pressure-reducing device (primarily mattresses and overlays) used in standard NHS clinical practice **and** • Parafricta Bootee(s) or Undergarments.
Comparator(s)	In all settings: • a pressure-reducing device (as described in the intervention section) [not Parafricta] **or** • a pressure-reducing device and sheepskin (compared with a pressure-reducing device and a Parafricta Undergarment) **or** • a pressure-reducing device and a pressure-reducing bootee (compared with a pressure-reducing device and a Parafricta Bootee).
Outcomes	Key outcome measures include: • incidence and severity of pressure ulcers or skin breakdown • hospital length of stay • time to healing for those with an existing pressure ulcer • compliance with pressure ulcer management • the person's comfort: including ability to move and self-reposition in bed • quality of life • device-related adverse events.
Cost analysis	The cost analysis should compare the costs and consequences of the use of pressure-reducing devices with and without the use of Parafricta garments in all settings. Parafricta products are reusable, and therefore laundry of the products should be considered.

The External Assessment Centre (EAC) stated that the sponsor's submission conforms to the scope with one exception. The patient population in the scope is adults or children of any age, whereas the sponsor excluded very young

children because the Parafricta Bootees and Undergarments are not available in a suitable size.

The EAC noted that the sponsor submission evaluated the use of pressure-reducing devices with the Parafricta Bootees or Undergarments as an adjunct compared with the use of pressure-reducing devices alone, but no evidence was presented comparing pressure-reducing devices plus the Parafricta Bootees and/or Undergarments against pressure-reducing devices plus sheepskin or pressure-reducing bootees. The External Assessment Centre further noted that although the sponsor did not modify the outcome measures in the NICE final scope, it did not submit evidence for all of the outcomes listed. Information was presented on the following outcomes: incidence of developing pressure ulcers; the incidence of grade 1 or 2 pressure ulcers progressing to grade 3 or 4 pressure ulcers; the incidence of skin breakdown; the severity of pressure ulcers; length of hospital stay and patient comfort.

5 The evidence

5.1 Summary of evidence of clinical benefit

The sponsor's submission included 6 peer-reviewed journal papers and 1 poster that it considered relevant to the scope. It was unclear whether the poster had been peer reviewed. The External Assessment Centre (EAC) conducted additional searches of published clinical data and did not identify any other relevant evidence.

The EAC considered that the following 4 sources presented by the sponsor were relevant to the scope because they included appropriate comparators and outcomes: Hampton et al. 2009, Loehne 2013 (poster), Smith and Ingram 2010, and Stephen-Haynes and Callaghan 2011. These studies were multiple-patient case series, 1 of which had historical controls. The EAC considered that the remaining 3 single-case studies presented by the sponsor – Bree-Aslan and Hampton 2008, Kerr 2008 and Hampton 2007 – did not provide any relevant additional evidence.

One unpublished audit was identified from the sponsor submission (Gleeson 2014) and the Academic –in-Confidence results were obtained for the EAC.

Table 1 Summary of clinical evidence (adapted from assessment report, tables 1 and 2, pages 18–21), presented in author alphabetical order

Study	Study design (country)	Population	Intervention versus comparator	Outcomes considered	EAC comments on study
Full, peer-reviewed articles					
Hampton et al. (2009)	Multiple-patient case series (England)	28 measurements on 25 nursing home residents with grade 1 or above pressure ulcers. Two study arms: • reddened heels (n=10) • reddened sacrum (n=18). No information on ages, medical conditions or durations of pressure ulcers.	**Intervention:** Pressure-reducing cushion or mattress plus a Parafricta Bootee (right heel) or a Parafricta Undergarment **Comparator:** Heel comparator was the patient's untreated left heel. Sacral ulcers comparator was normal skin that was adjacent to the sacrum.	Skin oedema and damage as assessed by: • high frequency ultrasound scans to image and measure oedema • bogginess and redness of skin assessed by tissue viability nurse • colour photographs. The duration of follow-up for Parafricta use was 4 weeks.	High frequency ultrasound: the results of the study are not presented clearly. Bogginess: subjective outcome. Colour photographs: results not presented because they were not always representative of nurse assessment of the skin.
Loehne. (2013). Poster – unclear if peer reviewed	Case series (USA)	Nursing home residents. Number unclear from poster; sponsor states 6. No information on sex, age, current condition, duration, grade or the site of the pressure ulcers. People with or at risk of pressure ulcers on the heel or foot due to	**Intervention:** Standard intervention of pressure-reducing surface plus Parafricta Bootee. **Comparator:** The sponsor states that it is standard intervention of pressure-relieving surface (this is not clear from the	Incidence of pressure ulcer development due to friction and shear.	This does not present any evidence of effectiveness because there is minimal information on patients. Unclear if both feet or only one are included in the analysis.

Study	Study design (country)	Population	Intervention versus comparator	Outcomes considered	EAC comments on study
		pressure only were excluded.	poster alone). Dressings (not specified) were used in some people. Follow-up at 30 days		
Smith and Ingram (2010)	Multiple-patient case series (Isle of Wight)	n=650 recruited. Of these, the following met the criteria: Cohort 1: n=204 Cohort 2: n=165 People were recruited who had a high or very high risk of pressure ulcers (Waterlow score of ≥15), with or without pressure ulcers on admission. All were unable to reposition.	Pressure ulcer incidence data were collected for cohort 1 over 3 months and for cohort 2 over the following 3 months. Incidence data were noted at the end of both 3-month periods in both cohorts. Cohort 1 had standard pressure-reducing mattresses. Cohort 2 had standard pressure-reducing mattresses plus a Parafricta Bootee or Undergarment.	• Reduction in the incidence of pressure ulcers in cohort 2 compared with cohort 1. • Ulcers that occurred after admission that took longer to develop and were less severe. • Cost effectiveness of the low-friction garments (see section 5.2).	No numerical results of length of stay by cohort in published paper. No numbers of deaths in either cohort. No demographic characteristics in either cohort or combined. Cannot tell how similar the cohorts were. If patients could not reposition then movement would be limited, so it is likely that pressure ulcers caused by pressure rather than friction.
Stephen-Haynes and Callaghan (2011)	Multiple-patient case series (England)	n=25 Nursing home patients at-risk of pressure ulcers (n=5) or with a pressure ulcer (n=20, 10 with a category 1 ulcer; 10 with	**Intervention:** Standard NHS pressure ulcer management plus a Parafricta bootee and/or undergarment.	• Skin improvement. • Ease of use. • Garment retention (staying in place). • Patient comfort.	Impossible to tell whether any improvement in pressure ulceration was temporary or permanent or whether it was due to the Parafricta Undergarment or would have happened anyway.

Study	Study design (country)	Population	Intervention versus comparator	Outcomes considered	EAC comments on study
		category 2 ulcer). Characteristics included steroid use (n=1), cerebrovascular accident (n=6), dementia (n=3) and multiple sclerosis (n=3).			
Unpublished					
Gleeson (2014)	Clinical audit (England)	[redacted]	**Intervention:** [redacted] [redacted] on pressure ulcers plus [redacted]people.	[redacted]	The decrease in pressure ulcers was probably not due to a decrease in hospital activity but may be related to education and training initiatives and investment in a range of pressure-reducing products. It is unclear how much of [redacted] was due to Parafricta bootees and how much was due to the other initiatives taking place at the NHS trust.

Hampton et al. (2009)

A case series of 25 nursing home residents by Hampton et al. (2009) evaluated whether the use of the Parafricta Bootees and Undergarments could reduce the degree of oedema and inflammation in pressure ulcers. All residents had restricted mobility and each had redness and a 'boggy' feel to the tissues, either over the sacrum and/or 1 or 2 heels. A total of 28 pressure ulcers of grade 1 or above were analysed, all of which were related to friction or shear. Of the 28 people included in the study, 10 used a Parafricta Bootee on the right heel (the left heel without the Bootee was used as a comparator) and 18 used a Parafricta Undergarment ('normal' skin adjacent to the sacrum was used as a comparator).

The degree of oedema and inflammation of the wounds were measured using 3 methods: high frequency ultrasound (HFU) scan data, colour photographs and tissue assessment by a tissue viability nurse. Measurements were taken on day 1 to provide a baseline and at 2 and 4 weeks post-treatment with the Parafricta garments. The HFU test was considered by the authors and the EAC to be the most reliable measure.

Statistical analysis of the HFU data was conducted using the Kolmogorov–Smirnov 2-sample test (sponsor's submission page 135). It is not clear from the information provided, but it appears that for the heel analysis a distribution from a 'normal' heel was used as the baseline. At the start of the study, results from the heel data showed that both the treated heel ($D=29.7$, $p<0.001$) and the control heel ($D=30.4$, $p<0.001$) were statistically significantly different from the normal heel. By the end of the 4 weeks, the difference between the treated heel and the 'normal' heel had reduced ($D=9.4$, $p=0.2$) whereas the difference between the control heel and the 'normal' heel was still statistically significant ($D=30.0$, $p<0.001$). Analysis of the treated heel results at week 0 compared with week 4 showed a statistically significantly difference ($D=31.25$, $p<0.001$). Based on these results, the authors concluded that the heel treated

with the Parafricta Bootee became more similar to the ‘normal’ heel and therefore the Parafricta garments could be effective in reducing oedema. The tissue viability nurse assessment found that bogginess and redness was reduced in the treated heels of all 10 residents and that there was no change in the control heel. Results from the analysis of the HFU for the sacral data for baseline compared with week 4 showed a statistically significant difference (D=14.84, p=0.006). The bogginess and redness was reduced in all 18 residents. The colour photographs for both the heels and sacral areas were not clear enough to validate the results.

The EAC found it difficult to understand the rationale for the Kolmogorov–Smirnov test used and considered that the statistical results were reported poorly. It considered that a 2-sample test was inappropriate; because each patient has 2 heels that were compared, a paired-sample statistical test should have been used. The EAC has suggested that an alternative summary measure such as area under the curve should have been used instead (see appendix D).

Loehne (2013; poster)

The case series by Loehne (2013) evaluated the use of the Parafricta Bootees to prevent pressure ulcers from developing in nursing home residents at risk of developing heel pressure ulcers caused by friction and shear. The poster does not report how many people were involved. The sponsor submission stated that the study included 6 people and the intervention was a standard pressure-reducing surface plus a Parafricta Bootee, but this could not be verified by the EAC. After 30 days, none of the residents had developed pressure ulcers or experienced any closed wounds re-opening. This included 1 person who had a recurrent wound for 2 years. However, the EAC stated that the results were unclear and impossible to verify.

Smith and Ingram (2010)

Smith and Ingram (2010) investigated the effectiveness of the Parafricta garments in reducing the incidence and prevalence of pressure ulcers in

hospital. The study incidence data were collected over 6 consecutive months from 2 medical wards and 1 orthopaedic ward. The first 3 months provided the data for cohort 1 (n=204) and the next 3 months were used for cohort 2 (n=165). People in both cohorts received identical care using the hospital standard pressure ulcer prevention protocol, except that those in cohort 2 were also given a Parafricta Bootee or Undergarment. Analysis of the Waterlow scores suggested that they did not differ between the 2 cohorts.

The authors reported the results as percentage differences in incidence between the cohorts (see the assessment report table 4, page 26). For additional ease of interpretation, the EAC recalculated the results as relative risks (see table 2). The results showed that at-risk people who were admitted to hospital without a pressure ulcer were more likely to develop a pressure ulcer in the no Parafricta cohort than in the Parafricta cohort (relative risk [RR] 1.64, 95% confidence interval [CI] 1.05 to 2.59). For at-risk people admitted without a pressure ulcer who then developed one, those in the no Parafricta cohort were more likely to have an ulcer that deteriorated or did not improve compared with those in the Parafricta cohort (RR 2.53, 95% CI 1.16 to 5.52). A similar result was found for people who were admitted with an existing pressure ulcer; the risk of deterioration of an existing ulcer was more likely in the no Parafricta cohort than in the Parafricta cohort (RR 4.90, 95% CI 1.75 to 13.75). There was no statistically significant difference between the cohorts in the risk of developing an additional ulcer in people who were admitted with a pressure ulcer (RR 1.55, 95% CI 0.87 to 2.75).

Table 2 Incidence of pressure ulcers in the Smith and Ingram (2010) study

Patient group	Risk	Cohort risk results		Relative risk (95% confidence interval)
		No Parafricta	With Parafricta	
No pressure ulcer on admission	Developed pressure ulcer	46/113 (41%)	19/77 (25%)	1.65 (1.05 to 2.59)

No pressure ulcer on admission but one developed during hospital stay	Pressure ulcer same or deteriorated	32/48 (67%)	5/19 (26%)	2.53 (1.16 to 5.52)
Pressure ulcer on admission	That pressure ulcer deteriorated	18/67 (27%)	4/73 (6%)	4.90 (1.75 to 13.75)
Pressure ulcer on admission	Developed an additional pressure ulcer	24/91 (26%)	15/88 (17%)	1.55 (0.87 to 2.75)

The Smith and Ingram (2010) study reported median lengths of stay. The EAC obtained the study data from the sponsor and reanalysed it to generate mean lengths of stay for each group with confidence intervals (see appendix 4 of the assessment report page 73). The average length of stay was calculated by weighting the length of stay in each treatment group by the proportion of people in the group. Results showed a weighted mean length of stay of 20.31 days for the no Parafricta group and 16.27 days with Parafricta, giving a statistically significant difference of 4.05 days (p=0.019). The EAC also used the limited information on confounding factors to estimate adjusted length of stay values, which take into account known baseline characteristics between the groups. Results showed a weighted mean length of stay of 14.94 days for the no Parafricta group and 12.47 days with Parafricta, giving a difference of 2.47 days.

The EAC critique of this study noted that no demographic characteristics were reported for either cohort. This made it difficult to assess how similar the cohorts were because there is no information on confounding factors. The EAC noted that the adjusted length-of-stay results are still subject to potential bias because confounders may well have biased the results in either direction.

Stephen-Haynes and Callaghan (2011)

Stephen-Haynes and Callaghan (2011) described a case series of 25 nursing home residents who used the Parafricta Bootees and Undergarments in addition to the standard approach for the Prevention and management of pressure ulcers as outlined in NICE clinical guideline 179. At the start of the study 20 people had an existing pressure ulcer of category 2 or below and 5 had intact skin. Those with intact skin were considered at risk of developing a pressure ulcer through friction due to repetitive movements caused by their medical condition (including Parkinson's disease). The outcomes that were considered included skin improvement, ease of use, garment retention and patient comfort. No information about the timescale of the study was provided.

The results are shown in table 3. There was skin improvement in 76% (n=19) of people; 24% (n=6) remained the same. Clinicians found the garments very easy to use for most people (64%, n=16), and 88% (n=22) of clinicians stated that the Parafricta garment had a positive impact on clinical outcomes. All people in the study found the garment comfortable (24%, n=6) or very comfortable (76%, n=19). Elsewhere, 48% (n=12) of clinicians reported that it was very easy to keep the garments in place, and 16% (n=4) did not find it easy.

The EAC noted that this was an uncontrolled study so it is impossible to tell whether any improvement in pressure ulceration or skin improvement was temporary or permanent, or even whether it was due to the Parafricta undergarment.

Table 3 Results from the Callaghan and Stephen-Haynes (2011) study

Outcome	Classification results (%) (n)			
	Very easy	**Easy**	**Fairly easy**	**Difficult**
Ease of use	64 (16)	16 (4)	16 (4)	4 (1)
Remaining in place	48 (12)	16 (4)	20 (5)	16 (4)

	Very comfortable	**Comfortable**	**Uncomfortable**	**Very uncomfortable**
Patient comfort	76 (19)	24 (6)	–	–
	Yes	**No**	**No difference**	
Skin improvement	76 (19)	16 (4)	8 (2)	
Prevented friction	88 (22)	12 (3)		

Summary of results from the unpublished audit

Gleeson (2014)

This was a clinical audit evaluating the use of the Parafricta Bootees in people [redacted]. The number of people included [redacted] were made during the year. There were [redacted] purchased during the year. At the NHS trust there was also a general investment in pressure-reducing products including 4-sectional electric profiling beds, pressure-reducing foam, alternating air mattresses, heel troughs and cushions. There was also an initiative for policy development driven through education, training and key performance indicators which may have affected the results. [redacted].

The EAC stated that this is an unpublished manuscript of an interim report and some details are missing. For example, there was no information on the number of people who were allocated the Parafricta Bootees. It is also unclear how much of the reduction in pressure ulcers reported was due to the Parafricta Bootees and how much was due to the other initiatives taking place at the NHS trust.

Adverse events

The sponsor found no adverse event reports relating to the Parafricta garments in a search of the Medicines and Healthcare Products Regulatory Agency database.

5.2 Summary of economic evidence

The sponsor identified 1 relevant study (Smith and Ingram 2010) using the search strategy described in section 10.1 (appendix 3) of the sponsor's submission. The EAC agreed with this inclusion and did not identify any further studies.

The clinical outcomes and patient population of the Smith and Ingram study are described in section 5.1 of this report. The study also considered the cost effectiveness of the Parafricta garments to see if any reduction in treatment costs outweighed the initial item cost. Costs were calculated for each treatment pathway, and it was estimated that the Parafricta garments could save more than £63,000 per 100 at-risk people. The EAC has provided a critique of this study (assessment report appendix 3, page 72).

Sponsor's de novo analysis

The sponsor submitted a de novo cost analysis to assess potential cost savings associated with using the Parafricta Bootees and Undergarments as an adjunct to current clinical care. Separate analyses were conducted to reflect their use in either hospital or the community. In hospital, potential cost savings were based on expected reductions in length of stay for people using the Parafricta garments. In the community setting, potential cost savings were based on a reduced prevalence rate among those using the Parafricta garments. The sponsor presented deterministic and probabilistic sensitivity analyses for both the hospital and community models.

The patient group in both models was defined as adults or children in the community or in hospital who have or are at risk of developing a pressure ulcer. This is consistent with the scope, although no distinction was made

between adults and children, or between pressure ulcers and frail skin damage in the cost analysis. The intervention and comparator in both models were consistent with the scope.

Hospital model structure

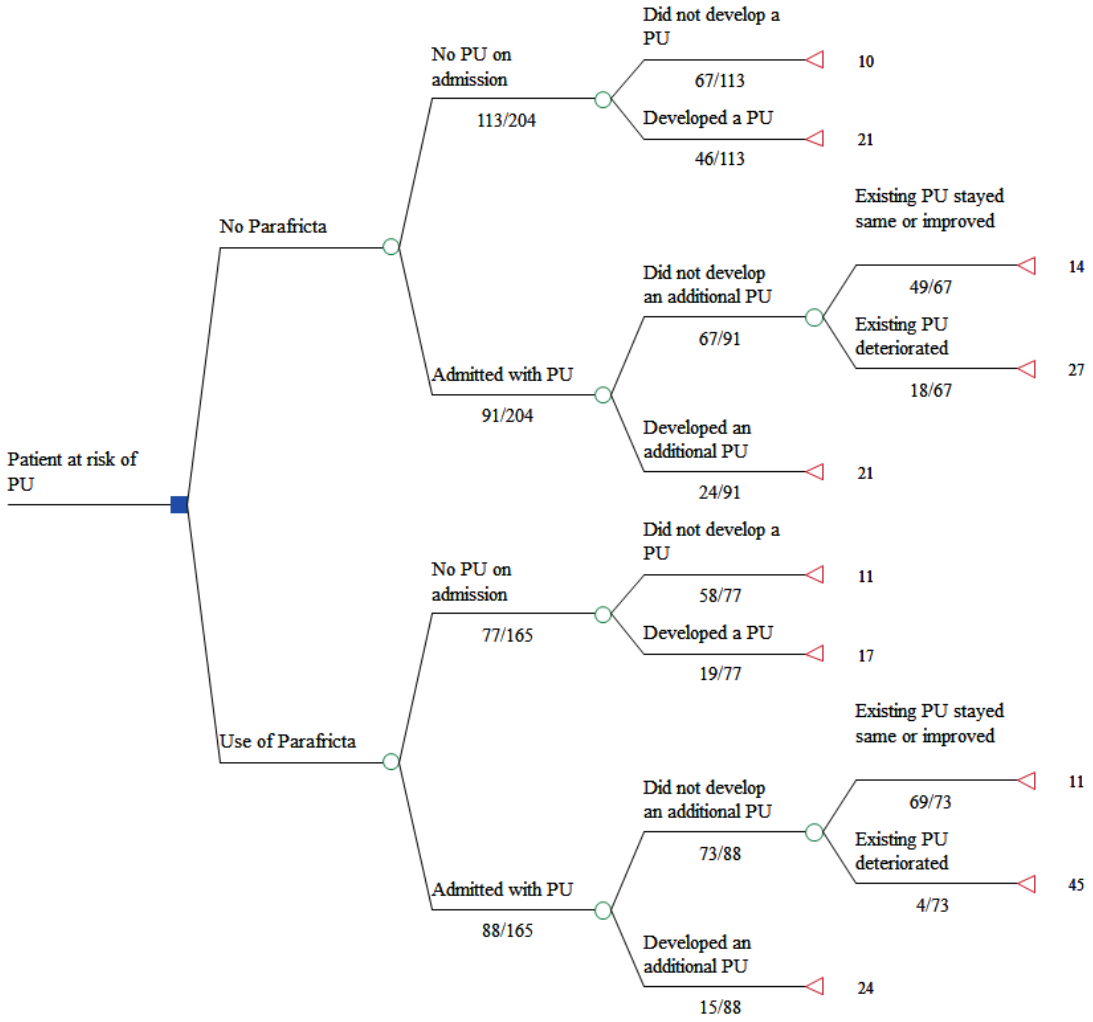
The sponsor's hospital model structure reflected the Smith and Ingram (2010) data and was based on 5 potential pathways for at-risk people. The pathways considered were as follows:

- Admitted without pressure ulcer(s) and remained without.
- Admitted without pressure ulcer(s) but developed ulcer in hospital.
- Admitted with pressure ulcer(s) which did not deteriorate.
- Admitted with pressure ulcer(s) which deteriorated.
- Admitted with pressure ulcer(s) and developed an additional ulcer in hospital.

The EAC presented the pathways in the hospital model as a decision tree for additional clarity (figure 1), with the observed proportions and median length of stay associated with the pathway. All data were taken from the Smith and Ingram (2010) study results.

The sponsor's submission stated that the time horizon for the model was 1 year. However, the EAC noted that the time horizon in the hospital model was based on the inpatient stay in the Smith and Ingram study, which was up to 4 months.

Figure 1 Sponsor model shown as a decision tree (redrawn by the EAC)



Notes: median length of stay (days) is shown at the end of pathways. The proportion of patients on each pathway is shown under each pathway.

Hospital model parameters

Parameters in the hospital model were based on data from the Smith and Ingram study. The probability of each patient having an outcome in the decision tree was based on the proportion of people in the study who moved into each pathway. The median length of stay in each pathway was also taken from the same study. These parameters are shown in table 8 of the assessment report (page 42). Weighted median lengths of stay of 13.7 days for the Parafricta group and 16.2 days for the no Parafricta group were calculated.

Hospital costs and resource use

In the hospital model, the cost of treating each group was calculated by applying the appropriate day costs to the relevant weighted length of stay. Costs differ for those days spent without a pressure ulcer when only general hospital costs are incurred and days with a pressure ulcer when there is an additional dressing cost. The general hospital costs were £326.33 per day, which included a bed day cost of £325, a £0.59 per day mattress cost and a £0.74 general dressing cost. The additional dressing cost applicable to days with a pressure ulcer was £0.74. Further details can be found in section 4.7.6.1 of the assessment report and table 10 (page 46). The EAC amended the costs used in the revised model.

The total cost associated with use of the Parafricta garments was £72.28 per patient episode. This cost was based on the following assumptions:

- Each person is allocated 6 garments.
- Each garment is washed on average twice over the person's length of stay.
- Each set of 6 garments is used by an average of 3 different people over the garment's lifetime.

The cost of each Parafricta garment was £35.14 and the laundry cost was £0.50 per garment.

Hospital model sensitivity analysis

The sponsor's submission did not explicitly investigate the potential impact of structural uncertainty. The sponsor stated that face validity had been sought through its clinical advisers, and also that it was implied by the peer review of the published paper on which the sponsor's model was based.

The sponsor conducted a series of probabilistic and deterministic sensitivity analyses to explore the impact of uncertainty in the parameters on the results. A multi-way deterministic analysis was presented by varying 4 parameters to produce results for 26 different scenarios. The parameters investigated were

the weighted lengths of stay when the Parafricta garments are used and not used, the cost of the Parafricta garments and the hospital general costs. For each parameter, the base case value was varied by ±25% in the deterministic analysis. A probabilistic sensitivity analysis was also presented.

Hospital model results

The sponsor's base-case results suggested that use of the Parafricta garments saved £757 per at-risk person based on costs of £5307 per at-risk person when Parafricta is not used and £4550 per at-risk person when Parafricta is used.

Results from the multi-way deterministic sensitivity analyses presented by the sponsor confirmed that the modelled cost savings were most sensitive to the weighted length of stay values used. In these results, the Parafricta garments were cost saving in all cases, except when the median weighted length of stay without Parafricta garments was reduced to 14.8 days and the median weighted length of stay with Parafricta garments was increased to 14.9 days. The cost savings were greatest when the median weighted length of stay without Parafricta garments was increased to 17.7 days and the median length of stay with Parafricta garments was reduced to 12.5 days. Further details can be found in the assessment report (parameters in table 11, page 51 and results in figure 3, page 54). The results from the sponsor's probabilistic sensitivity analysis suggested that there was very little uncertainty, with the Parafricta garments always being cost saving. The EAC considered that the lack of uncertainty in the probabilistic analysis results was due to assumptions used in the analysis that did not reflect the random nature of the input parameters.

Community model structure

The community model considered the potential reduction, and therefore cost savings, in pressure ulcer prevalence in the community if the Parafricta Bootees or Undergarments are used as an adjunct to current clinical practice. The model calculated steady-state costs for treating pressure ulcers in a

community setting with a time horizon of 1 year. The model adopted a per prevalence approach rather than an at-risk patient. It assumed that if a Parafricta garment is not used, there will be 2 other at-risk people without a pressure ulcer for every person in the community with a pressure ulcer (see assessment report page 40). The benefits of the Parafricta garments were included as a fixed reduction in the prevalence of pressure ulcers when the garments are used.

Community model parameters

The prevalence of pressure ulcers in the community model was estimated from the hospital data obtained in the Smith and Ingram (2010) study. The difference between median length of stay when a pressure ulcer has developed and time to develop a pressure ulcer was used as a proxy for pressure ulcer duration. The incidence per at-risk person (0.25 in the Parafricta group and 0.41 in the no Parafricta group) and the pressure ulcer duration were used to calculate a point prevalence in the Parafricta and no Parafricta groups. The ratio of these prevalences (Parafricta to no Parafricta) was 0.37, and this was used in the community model to estimate the reduction in pressure ulcer prevalence in those who used the Parafricta garments.

Community model costs and resource use

Costs in the community model were based solely on the annual cost of the Parafricta garments and the costs associated with nurse visits. All people with pressure ulcers were assumed to need nurse visits. No other resource use or costs were identified as relevant and included in the model.

Based on data from the Smith and Ingram (2010) study, the model assumed that a person with pressure ulcers needed 1.86 visits a week by a nurse. The cost of a nurse visit was £61.

In the community model the annual cost of the Parafricta garments was £80 per at-risk person. This cost is based on an assumption of 2 garments per

person (£35.14 each) and a notional allowance for the average annual cost of washing of £9.72 (appendix D).

Community model sensitivity analysis

A multi-way deterministic sensitivity analysis was presented that considered 3 parameters: Parafricta costs per at-risk person (±£40), a risk to prevalence ratio (±1) and the weekly cost of treating a pressure ulcer (±25%). The impact of reducing the effectiveness of the Parafricta garments by 50% was also considered. A probabilistic sensitivity analysis based on the same parameters was also presented.

Community model results

The base-case calculation in the community model for treating a person with pressure ulcers without the use of the Parafricta garments was £5900 based on 1.86 nurse visits a week at £61 per visit for 52 weeks. Treatment of a prevalent case with the use of the Parafricta garments was estimated at £2445 based on a prevalence ratio of 0.37 and an annual cost of £240 per person with pressure ulcers. This suggested a cost saving of £3455 per a person with pressure ulcers from the sponsor's base-case community model.

Results from the deterministic sensitivity analysis always favoured the use of the Parafricta garments and suggested cost savings of approximately £1500 to £4500 (see assessment report figure 4, page 53). The reduction in the effectiveness of the Parafricta garments – by increasing the prevalence ratio to 0.685 – resulted in the lowest cost savings. Results from the probabilistic sensitivity analysis suggested that there is very little uncertainty and that the Parafricta garments are always cost saving. The EAC considered that the lack of uncertainty in the probabilistic analysis results was due to assumptions used in the analysis that did not reflect the random nature of the input parameters.

Additional cost analysis by the External Assessment Centre

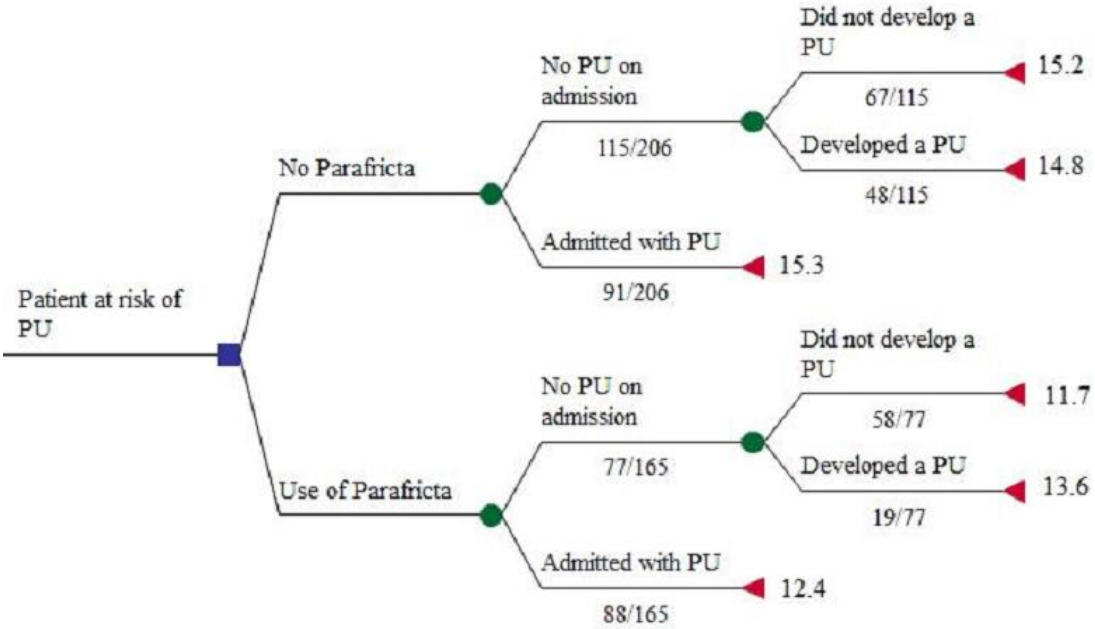
Revised hospital model

The EAC considered that some assumptions and estimates in the sponsor's cost model were incorrect or unlikely, and so modified them to produce a revised model. The EAC noted that the sponsor's model used median rather than mean length of stay values. It also considered that the smaller patient numbers in the pathways reflecting change in pressure ulcer condition increased the uncertainty in the length of stay information. It noted that the daily costs associated with change in pressure ulcer condition for people in the pathways did not incur any different costs. In the revised model, the EAC proposed a simplified structure based on 3 pathways:

- Admitted without pressure ulcer(s) and remained without.
- Admitted without pressure ulcer(s) but developed an ulcer in hospital.
- Admitted with pressure ulcer(s).

The EAC reanalysed the data from the Smith and Ingram (2010) study to obtain mean lengths of stay with confidence intervals adjusted for the limited baseline patient characteristics and mean time to develop an ulcer (see assessment report appendix 4, page 73). The revised hospital cost model is shown in the sponsor model and shown as a decision tree (redrawn by the EAC). Median length of stay (days) is shown at the end of pathways. The proportion of people progressing through each pathway is shown under each individual pathway.

Figure 2 Revised model shown as a decision tree



Mean length of stay (days) is shown at the end of pathways. The proportion of patients on each pathway is shown under each pathway.

The EAC also amended some of the costs in the model, the most noteworthy of which was the revision of the bed day cost. The EAC acknowledged that it is difficult to identify an appropriate bed day cost for 'hospital stay' alone. It calculated a weighted cost using excess bed day cost across a range of wards to obtain an estimate of £234 per day. It used a cost of £328 as an upper limit in the sensitivity analysis (see assessment report page 57).

The EAC considered it was not clear how the sponsor's probabilistic sensitivity analyses added to the understanding of uncertainty. In both models, the distributions were arbitrarily assigned and incorporated no information on the random nature of the parameters. In the revised model the EAC used available information on the mean length of stay and its confidence intervals to recalculate more meaningful probabilistic sensitivity analyses.

Revised hospital model results

The revised hospital model base-case results suggested that use of the Parafricta garments saved £595 per at-risk person. This was based on costs of £3556 per at-risk person if the Parafricta garments are not used and £2960 per at-risk person is the garments are used. In a one-way sensitivity analysis with a bed day costing £328, the cost savings were increased to £863 (assessment report table 16, page 61).

The probabilistic sensitivity analysis suggested that on nearly 8 out of 10 occasions, the use of the Parafricta garments resulted in cost savings. Figure 8 in the assessment report (page 61) shows that most iterations suggested that the Parafricta garments were cost saving, with maximum savings of about £6000 per at-risk person. However, there are some iterations in which the garments add costs, reflecting the uncertainty in length of stay data.

Community model results with revised prevalence ratio

The EAC recalculated a prevalence ratio using the adjusted mean length of stay data and obtained a value of 0.53. No other changes were made to the model.

The base-case results for the revised community model were estimated at £2510 per person with pressure ulcer based on an unchanged cost per person with pressure ulcers of £5900 without the Parafricta garments and £3390 with them. Deterministic sensitivity analysis varying the length of stay data based on lower and upper limits of 95% confidence intervals suggested that the cost savings could be between £2295 and £2799 (see assessment report table 18, page 62). The EAC did not consider that a truly probabilistic analysis incorporating distributions around the time to develop an ulcer and the length of stay was possible.

6 Ongoing research

The sponsor and the External Assessment Centre are not aware of any ongoing research on the Parafricta garments.

7 Issues for consideration by the Committee

Clinical evidence

Quantity and quality of clinical evidence

The clinical evidence for the Parafricta Bootees and Undergarments is limited in both quantity and quality. There are no published randomised controlled trials and the submitted studies were not of high quality. One of the studies was unpublished (Gleeson 2014) and the information given to the External Assessment Centre (EAC) by the author presented neither the full details of how it was conducted nor how many people were included. The EAC stated that the results of the study by Hampton et al. (2009) were difficult to interpret accurately. The EAC concluded that there is insufficient evidence to demonstrate that the Parafricta Bootees and Undergarments are associated with a decreased incidence, improvement, deterioration or better healing of pressure ulcers compared with no Parafricta garments.

Economic evidence

Limitations of Smith and Ingram (2010) data

The driver of the cost savings in the hospital model was the reduced length of stay associated with the use of the Parafricta garments based on the data obtained from the Smith and Ingram (2010) study. The EAC highlighted the uncertainties associated with the data from this study because of its non-randomised design and lack of information about patient characteristics. The EAC has revised the model to make best use of the available low quality evidence, but the uncertainty in the evidence base remains. Probabilistic sensitivity analysis from the EAC revised model suggested that there was

nearly an 8 in 10 chance that the Parafricta Bootees and Undergarments would be cost saving in hospital.

Capture of costs and resources used in pressure ulcer prevention and management

In the hospital model the only additional cost for people with a pressure ulcer apart from the increased length of stay is a daily additional dressing cost. The sponsor noted that the costs of pharmaceuticals used to treat people with pressure ulcers are not included in the model. In addition, the potential costs of complications of pressure ulcers and benefits for people with pressure ulcers are not considered.

Lack of evidence for the community model

There was no available evidence on the effectiveness of use of the Parafricta garments in the community that could be used to inform the community cost model. The sponsor based the estimates on information from the Smith and Ingram (2010) study, which was hospital based. The community model adopted a simple approach in which the costs of treating all pressure ulcers in the community were the same and all pressure ulcers were assumed to need weekly visits from a nurse.

8 Authors

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NICE Medical Technologies Evaluation Programme

May 2014

Appendix A: Sources of evidence considered in the preparation of the overview

A Details of assessment report:

- Meads C, Glover M, Pokhrel S. Parafricta Bootees and Undergarments to reduce skin breakdown in people with frail skin or at risk of pressure ulcers, April 2014

B Submissions from the following sponsors:

- APA Parafricta

C Related NICE guidance

- Diabetic foot - inpatient management of people with diabetic foot ulcers and infection. NICE clinical guideline 119 (2011)
- Management of multiple sclerosis in primary and secondary care. NICE clinical guideline 8 (2003)
- Mega Soft Patient Return Electrode for use during monopolar electrosurgery. NICE medical technologies guidance 11 (2012)
- Metastatic spinal cord compression: diagnosis and management of adults at risk of and with metastatic spinal cord compression. NICE clinical guideline 75 (2008)
- MIST Therapy system for the promotion of wound healing in chronic and acute wounds. NICE medical technologies guidance 5 (2011)
- MoorLDI2 Burns Imager a laser Doppler blood flow imager for the assessment of burn wounds. NICE medical technologies guidance 2 (2011)
- Negative pressure wound therapy for the open abdomen. NICE interventional procedure guidance 322 (2009)
- Pressure ulcers: prevention and management of pressure ulcers. NICE clinical guideline 179 (2014)

- Prevention and treatment of surgical site infection. NICE clinical guideline 74 (2008)
- The PleurX peritoneal catheter drainage system for vacuum-assisted drainage of treatment-resistant, recurrent malignant ascites. NICE medical technologies guidance 9 (2012)
- Type 2 diabetes: prevention and management of foot problems NICE clinical guideline 10 (2004)

D References

Barrett S, Callaghan R, Ivins N, et al. (2012) Case series evaluation: the use of durafiber on exuding wounds. Wounds UK 8:104–13

Bree-Aslan A, Hampton S (2008) Parafricta and the prevention of shearing forces: heel ulcers. Nursing & Residential Care 10: 626–8

Dealey C, Posnett J, Walker A (2012) The cost of pressure ulcers in the United Kingdom. Journal of Wound Care 21: 261–66

Gleeson D (2014). Heel pressure ulcers, where now? Unpublished manuscript

Hampton S (2007) Reducing shearing forces: Parafricta fabric. Nursing & Residential Care 9: 2–4

Hampton S, Young S, Bree-Aslan A et al. (2009) Parafricta material: Can it reduce the potential for pressure ulcer damage? Journal of Community Nursing 23: 28–31

Ingram A, Raynor S, Paulraj R et al. (2014) An assessment of friction and shearing prevention treatment in the management of pressure ulcers based on the study conducted by Hampton et al. (2009) within a long term nursing home environment. Unpublished manuscript.

Kerr A (2008) Reducing shear and friction: Parafricta undergarments. Nursing & Residential Care 10: 626–8

Lahmann NA, Kottner J (2011a) Relation between pressure, friction and pressure ulcer categories: A secondary data analysis of hospital patients using CHAID methods. International Journal of Nursing Studies 248: 1487–94

Lahmann NA, Tannen A, Dassen T et al. (2011b) Friction and shear highly associated with pressure ulcers of residents in long-term care – classification tree analysis (CHAID) of Braden items. Journal of Evaluation in Clinical Practice 17: 168–73

Loehne HB (2013) Clinical study of device to assist in prevention of heel and foot pressure ulcers resulting from friction and shear in patients unable to utilize heel pressure relieving devices. Poster presented at the SAWC Spring Meeting, 1–5 May 2013, Denver, Colorado, USA

NICE (2014) Pressure ulcers: prevention and management of pressure ulcers. A Clinical Practice Guideline (CG179). London: Royal College of Nursing

Smith G, Ingram A (2010) Clinical and cost effectiveness evaluation of low friction and shear garments. Journal of Wound Care 19: 535–42

Stephen-Haynes J, Callaghan R (2011) Clinical outcomes using a low friction and shear garment in the care home setting. Wounds UK 7: 76–84

Young SR, Hampton S, Bree-Aslan C et al. (2008) Parafricta Trial ultrasound scan results. Unpublished manuscript

Appendix B: Comments from professional bodies

Expert advice was sought from experts who have been nominated or ratified by their Specialist Society, Royal College or Professional Body. The advice received is their individual opinion and does not represent the view of the society.

Emma Bond
Vascular Clinical Nurse Specialist, The Vascular Society

Professor Michael Clark
Professor, European Wound Management Association

Mr George Dunn
Specialist Podiatrist, The Society of Chiropodists and Podiatrists

Ms Deborah Gleeson
Tissue Viability Nurse, Wound Care Alliance UK

Ms Judy Harker
Nurse Consultant, Royal College of Nursing

Samantha Holloway
Senior Lecturer, European Wound Management Association

Dr Jane McAdam
Principle Podiatrist, The Society of Chiropodists and Podiatrists

Mr Glenn Smith
Clinical Nurse Specialist Nutrition and Tissue Viability, Southern Alliance of Tissue viability Nurses

Professor Jackie Stephen-Haynes
Professor and Consultant Nurse, Wound Care Alliance UK

Professor Peter Vowden

Professor of Wound Healing Research, European Wound Management Association

Expert advice was received from 9 people from 6 societies at the scope stage. This advice is summarised below:

- Of the 9 advisers, 3 had used the Parafricta technology, referred patients for its use and had managed patients for whom it is used in another part of their care pathway. The remaining 6 would like to use the technology but it is not currently available to them. Three had been involved in research on this technology.
- Eight advisers considered the Parafricta garments to be either a significant modification of an existing technology or thoroughly novel.
- All the advisers considered that the most appropriate use was for pressure ulcer avoidance by preventing skin damage due to friction and shear. Of the experts, 3 stated that it may be particularly beneficial in high-risk patients, 2 advised that it may be particularly useful for patients who are unable to reposition themselves, 2 stated it would be useful for bed-bound people, and 2 said that the technology may be useful for people who have uncontrolled repetitive spasms.
- In terms of comparators, 5 expert advisers stated that there was no comparator and 4 suggested that the comparator may be standard support surface covers and heel protectors. All the experts believed there was no competing product. One expert stated that most mattress and seating manufacturers include a low friction cover with their products but that this surface is rarely incorporated into garments.
- When asked about possible benefits for patients, 5 experts stated that the reduction in the likelihood of developing a pressure ulcer would be the most beneficial. Four expert advisers said that it would reduce skin damage and 1 stated that it should offer greater protection than current clinical care. Five experts believed that the additional benefits were likely to be realised in practice. One stated that the products may be lost on a hospital ward

and 1 stated that the product addressed only part of the pressure ulceration cause because it is not pressure-relieving.

- Most of the experts stated that using the Parafricta garments would be cost saving due to lower pressure ulcer incidence, with 2 in particular believing that the benefits are likely to be realised in practice. The 2 experts who had collected local data were happy with the available evidence. The other 2 experts believed that the evidence was very limited.
- In terms of facilities, training and functioning, the experts stated that there would need to be a laundering service and education on the cleaning and decontamination of the products. Five experts believed that standard training would be sufficient to use these products.
- The advisers believed that there would be an initial cost as the product does not replace any direct comparators but would be used as an adjunct. However, they anticipated overall reduced costs if pressure ulceration were reduced.
- All the experts commented that it would be useful for NICE to produce guidance on these products. Two believed it would be particularly useful to enable procurement of the products.

Appendix C: Comments from patient organisations

The following patient organisations were contacted and no response was received.

- British Skin Foundation
- Disability Rights UK
- Disabled Living Foundation
- Ethnic Health Foundation
- European Pressure Ulcer Advisory Panel
- Independent Age
- James Lind Alliance Pressure Ulcer Priority Setting Partnership
- Leg Ulcer Forum
- Limbless Association
- Lindsay Leg Club Foundation
- Multiple Sclerosis Resource Centre
- Multiple Sclerosis Society
- Multiple Sclerosis Trust
- Muscular Dystrophy Campaign
- Posture and Mobility Group
- Shine
- Spinal Injuries Association

Appendix D: Additional information from the External Assessment Centre

The External Assessment Centre (EAC) provided some additional information during the preparation of the assessment report overview by the NICE technical team.

A Assessment of the statistical analysis of the results of the Hampton et al. (2009) study (see sponsor's submission appendix 5 page 135)

The EAC found the reporting of the original study and further analysis to be of such poor quality that it was difficult to understand exactly what the authors had done. It was difficult to understand the rationale for the test chosen and statistical results were reported poorly. The EAC's understanding of what was done is given below, but may reflect poor reporting.

In the study, 10 people were included as heel cases and 18 as sacrum cases with some overlap. All people had grade 1 tissue damage over the sacrum and 1 or 2 heels, but no further information was given. For the heel cases, the right but not the left heel was treated with the Parafricta Bootee. No description of the right and left heels at baseline was provided, but results refer to 'normal' and 'treated' heel. It is not clear how many right heels had grade 1 ulcers.

Results were expressed as pixel intensity spectra derived from an ultrasound scan (both heels scanned for heel patients). Normal skin was scanned to provide a standard for comparison. Mean spectra for normal skin, time 0, time 2 weeks and time 4 weeks were calculated, and these mean spectra were then expressed as cumulative percentage distributions. This allowed the authors to calculate 2-sample Kolmogorov–Smirnov tests to assess whether these distributions were statistically different. This test assesses difference on

the basis of the maximum difference between 2 cumulative distributions and does not assume any particular distributional shape.

This statistical approach was incorrect on a number of counts.

- A 2-sample test was inappropriate, because each patient has 2 heels that were compared, so a paired sample statistical test should have been used.
- The cumulative distribution used for the Kolmogorov–Smirnov test should be based on a single observation for subject (for example a cumulative distribution of a pressure ulcer score could have been constructed). The cumulative distributions here seem to be based on averaged distributions for each subject. An alternative summary measure such as the area under the curve should have been used.
- Multiple tests at different time points are presented. Ideally, a repeated measures analysis should have been used, but the small sample would have been a limitation.
- Similar considerations apply to the sacral results. This study was also uncontrolled as normal skin cannot be considered an adequate control site.

B Additional information relating to economic evidence

The EAC confirmed the following:

- The time horizon for the hospital model was limited to the inpatient stay in the Smith and Ingram (2010) study and was up to 4 months.
- The £80 cost of the Parafricta garments in the community model is the average annual cost per at-risk person. This is a rounded figure in view of the nature and accuracy of the model. It was based on the cost of 2 garments at £35.14 each and a £9.72 notional allowance for the average annual cost of washing.
- The sensitivity analysis of the community model investigated the impact of assuming that the Parafricta garments were 50% less effective. This meant that the prevalence ratio was changed from 0.370 to 0.685 in the model.

- In the revised community model, the prevalence ratio used was based on the adjusted mean length of stay values calculated by the EAC. A value of 0.530 was obtained.