NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of suture fixation of acute disruption of the distal tibiofibular syndesmosis

Suture fixation of acute disruption of the distal tibiofibular syndesmosis is used to treat some types of severe ankle injury, when the ligaments between the2 bones of the lower leg (the tibia and the fibula) become damaged at the ankle joint. The procedure involves drilling a small hole in both bones immediately above the ankle and passing a special strong 'thread' through these holes, before pulling the 'thread' tight and securing it so that it holds the 2 bones in place and allows the injury to heal.

Introduction

The National Institute for Health and Care Excellence (NICE) has prepared this interventional procedure (IP) overview to help members of the Interventional Procedures Advisory Committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This IP overview was prepared in July 2014.

Procedure name

- Suture fixation of acute disruption of the distal tibiofibular syndesmosis

Specialist societies

- British Orthopaedic Foot and Ankle Society
- Orthopaedic Trauma Society
- British Trauma Society.

Description

Indications and current treatment

Syndesmotic injuries are injuries to the ligaments that connect the tibia and fibula at the ankle joint. They are the most severe ligament injuries to the ankle and occur either in isolation or at the same time as an ankle fracture. Typical fractures associated with syndesmotic instability include pronation external rotation fractures (PER or Weber type C), supination external rotation fractures (SER or Weber type B), and proximal fibular fractures with associated syndesmotic injury (Maisonneuve fractures). The most common mechanisms causing syndesmotic injuries are ankle external rotation and/or hyperdorsiflexion. These injuries can occur during activities such as sports or dancing, and from falls or slipping on ice. Patients with isolated syndesmotic injuries such as acute ankle sprains have acute ankle instability, pain and functional problems.

Isolated syndesmotic injuries can sometimes be treated conservatively with immobilisation, limited weight bearing, ankle exercises, compression and elevation. Distal tibiofibular syndesmosis, syndesmotic injuries with persistent symptoms and all syndesmotic injuries occurring with ankle fractures are normally treated by surgical rigid fixation with syndesmotic screws (single or double screws). The screws are often removed at a subsequent operation. Other fixation methods include bolt fixation and syndesmotic hooks, both of which may also be removed at a subsequent operation, and staples or direct repair.

Anatomical reduction and healing of the syndesmosis is desirable because any abnormal shift of the talus in the ankle mortise causes development of early and progressive osteoarthritis.

What the procedure involves

Suture fixation of acute disruption of the distal tibiofibular syndesmosis is done with the patient in the supine position either under general or spinal anaesthesia, with antibiotic prophylaxis and tourniquet control. An incision is made on the lateral aspect of the ankle to access the joint. If there is any associated fracture of the tibia or fibula, this is first openly reduced and internally fixed using standard ankle fixation techniques. After fracture fixation, syndesmosis integrity is evaluated using either a hook test or an external rotation test under intraoperative fluoroscopy. Syndesmosis is reduced by precise anatomical alignment and maintained in position using a clamp with the ankle in a neutral position.

A small tunnel is drilled through the fibula and the tibia under image guidance. A polyethylene-based suture loop, threaded with an oblong metal button, is then inserted through the tunnel (and the vacant hole in a fracture fixation plate, if used) using a needle. After it has passed through the tibia, the button is pulled

back so that it lies flat against the medial cortex of the tibia. The ends of the suture loop on the lateral side of the fibula are then pulled tight against the fibula (or the fracture fixation plate) and secured by drawing a second metal button onto the surface of the fibula or the plate. Once both buttons are seated flush with the bone, a small knot is made with the free ends of the loop to secure the system and stabilise the joint. If additional stability is needed, a second suture loop can be inserted through the same or another tunnel.

The incisions are closed and the ankle is placed in a below-the-knee cast. The ankle should be non-weight bearing for the first 2 weeks, partial weight bearing from 2–6 weeks and full weight bearing after 12 weeks. Rehabilitation is provided once the ankle has healed. The polyethylene-based suture loop is usually left in place. The potential advantages of this procedure include a more rapid return to weight bearing, maintenance of physiological micro-motion between the tibia and the fibula and avoiding further surgery to remove the device.

Outcome measures

Radiographic measurements

Three radiographic parameters are used for evaluation of syndesmotic disruption without diastasis. These include tibiofibular overlap (TFO), tibiofibular clear space (TFCS) and medial clear space (MCS) and they include 3 views of the ankle (anteroposterior, mortise and lateral). TFO should be more than 6 mm in the anteroposterior radiograph and 1 mm in the mortise radiograph as measured 1 cm proximal to the tibial plafond. TFCS should be less than 6 mm in both anteroposterior and mortise radiographs. MCS should be less than or equal to 5 mm on the anteroposterior radiograph and overlap the tibia and fibula more than 1 mm on the mortise view. Decreased TFO and increased TFCS and MCS on either weight bearing or non-weight bearing radiographs indicate syndesmotic disruption.

Imaging modalities, such as CT, are used to detect minor injuries not apparent on radiographs.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to suture fixation of acute disruption of the distal tibiofibular syndesmosis. Searches were conducted of the following databases, covering the period from their commencement to 29.07.2014: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see appendix C for details

of search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The following selection criteria (table 1) were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with distal tibiofibular syndesmosis.
Intervention/test	Suture fixation.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 323 patients from 1 randomised controlled trial[1], 2 non-randomised comparative studies[2,3], 1 retrospective comparative case series[8], 5 case series[4–7,12] and 3 case reports[9–11].

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Table 2 Summary of key efficacy and safety findings on suture fixation of acute disruption of the distal tibiofibular syndesmosis

Study 1 Laflamme M (2014)

Details

Study type	**Randomised controlled study**
Country	Canada (multicentre)
Recruitment period	Not reported
Study population and number	n=**70 (34 dynamic [suture] fixation versus 36 static [screw] fixation) patients with acute ankle syndesmosis** Classification of injury (according to Orthopaedic and Trauma Classification fracture classification): Dynamic suture fixation group: 44-B2 (n=3), 44-B3 (n=2), 44-C1 (n=18), 44-C3 (n=11) Static screw fixation group: 44-B2 (n=6), 44-B3 (n=1), 44-C1 (n=18), 44-C3 (n=11)
Age and sex	Suture fixation group: mean 40 years; screw fixation: 39 years Screw fixation group: 73% (25/34) male; screw fixation: 72% (25/36) male
Patient selection criteria	Inclusion criteria: patients 18–65 years old with recent ankle fracture impairing syndesmotic stability (within 8 days). Exclusion criteria: polytrauma, neurologic impairment, obesity (BMI >40 kg/m^2), poor medical condition limiting rehabilitation or participation.
Technique	Surgeries were done under general anaesthesia (83% versus 70%, p=0.2) by general orthopaedic surgeons. Associated open reduction internal fixation of the malleolus done according to standard principles and syndesmosis stabilised. Dynamic suture fixation: with 1 Arthrex Tightrope Static screw fixation: with 4 cortices and one 3.5 mm quadricortical screw. The routine screw was not allowed in the study. Standardised rehabilitation process used for 2 groups: no weight bearing cast for 6 weeks, then rehabilitation without protection or formal physiotherapy.
Follow-up	**12 months**
Conflict of interest/source of funding	Primary author received grant from manufacturer and was also supported by a training fellowship. 5 authors received institutional support from manufacturer, all co-authors received patient enrolment fee.

Analysis

Follow-up issues: Short follow-up period; 4 patients in the static fixation group and 1 patient in the dynamic fixation group were lost to follow-up immediately after surgery.

Study design issues: Five trauma centres were involved, and concealed randomisation was obtained and stratified by centres. It was a double blind study, and 2 scales were used to measure primary outcome (Olerud and Molander score, AOFAS). Of these, the first was a reliable and validated score for ankle fractures. Pain was assessed on a Visual Analogue Scale. All evaluations (clinical and questionnaires) were done at planned follow-up periods by blinded evaluators trained in orthopaedic clinical assessment studies. Data were analysed using an intention-to-treat procedure. Telephone questionnaires were used in the patients lost to follow-up to assess safety. There was no crossover of patients. CT scans were not done to assess the quality of reduction.

Population issues: The 2 groups were similar for demographic, social and surgical data.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **65 (33 versus 32)**

		Suture fixation n=33	Screw fixation n=32	p value
Olerud and Molander score (mean±SD)*				
3 months		68.8±16.6	60.2±20.6	0.067
6 months		84.2±16.3	76.9±17.4	0.082
12 months		93.3±10.2	87.7±12.2	0.046
Mean AOFAS score (100) (mean±SD)				
3 months		78.6±10.8	70.6±15.3	0.016
6 months		87.1±11.3	83.8±12.3	0.255
12 months		93.1±9.3	89.9±12.9	0.255
Ankle pain (Visual Analogue Scale, range 1–10)				
3 months		1.4 (0–4)	1.7 (0–7)	0.507
12 months		0.6 (0–3)	1.1 (0–5)	0.12
Ankle range of motion				
Plantar flexion (degrees)				
3 months		29.6±8.5	22.8±8.9	0.002
12 months		33.6±7.3	32.0±9.8	0.45
Dorsal flexion (degrees)				
3 months		10.3±6.7	9.2±5.5	0.47
12 months		13.6±4.5	14.8±7.6	0.43
Ankle circumference (cm)				
3 months		28.5±2.8	27.7±1.8	0.18
12 months		26.7±2.0	25.8±4.6	0.27
Earlier return to activities % (n)				
Work	3 months	45.5 (15)	37.5 (12)	0.62
	12 months	97 (32)	87.5 (28)	0.19
Sports	3 months	9.1 (3)	6.3 (2)	1.0
	12 months	78.8 (26)	68.8 (22)	0.41
Radiological mean loss of reduction mm (mean±SD)				
MCS		0.05±0.32	0.41±0.37	0.02
Lateral TFCS		0.32±0.55	1.34±1.36	0.0005

*higher scores indicate better clinical performance

Safety

	Dynamic suture fixation % (n)	Static screw fixation % (n)
Screw removal for discomfort after mean 6.3 months without loss of reduction – surgery not needed.	No screw used	36 (13/36) p<0.05
Implant removal without loss of reduction	6 (2/34) After 14 weeks due to superficial infection secondary to local subcutaneous knot irritation.	3 (1/36) At 10 days for technically insufficient screw fixation; new screw positioned.
Loss of reduction needing reoperation	0	11 (3/36) p=0.006
Partial syndesmosis ossification without complete synostosis	3 (1/34)	3(1/36)

Overall reoperation rate was higher in static group (for screw removal and loss of reduction 4/36, p=0.06).

Abbreviations used: AOFAS, American Orthopaedics Foot and Ankle Society; CT, computed tomography; MCS, medial clear space; SD, standard deviation; TFCS, tibiofibular clear space.

Study 2 Cottom JM (2009)

Details

Study type	**Prospective non-randomised comparative study (cohort study)**
Country	USA
Recruitment period	Not reported
Study population and number	n=**50 (25 suture fixation versus 25 screw fixation) patients with disruption of the distal tibiofibular articulation** Classification of injury (according to Lauge–Hansen and Danis–Weber ankle fracture classification systems): Suture fixation group: SER/Weber B (n=8), PER/Weber C (n=5), Maisonneuve (n=4), pure ligament injuries (n=8) Screw fixation group: SER/Weber B (n=4), PER/Weber C (n=11), Maisonneuve (n=3), pure ligament injuries (n=7)
Age and sex	Suture fixation group: mean 35 years; screw fixation: 37 years Suture fixation group: 56% (14/25) male; screw fixation: 76% (19/25) male
Patient selection criteria	Patients with diabetes and/or neuroarthropathic changes in the foot or ankle were excluded.
Technique	Associated ankle fractures were first treated using ankle fixation techniques. In 10 patients before fixation methods, the disrupted syndesmosis was reduced with arthroscopic guidance. Suture fixation group: 25 patients had treatment with an Arthrex Tightrope. Standard method of fixation used. In 21 cases, a single Tightrope was placed, and in 4 cases, 2 Tightropes were used. Mean distance from tibial plafond was 3.3 cm in 21 cases, and in 4 double fixation cases it was 2.3 cm distal and 3.6 cm proximal. Traditional screw fixation: in 25 patients, 12 had a single fixation and the mean distance from tibial plafond was 2.0 cm, 13 had double fixation and the mean distance was 1.6 cm distal and 2.7 cm proximal. Patients were immobilised in a non-weight bearing splint for 10 days and weight bearing cast for 3 weeks until full weight bearing tolerance was reached.
Follow-up	**Suture fixation group: mean 11 months** **Screw fixation group: mean 8 months**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: Short follow-up period.

Study design issues: There were a small number of patients, and it is not clear how patients were selected between groups; diagnosis was based on radiographs, MRI or CT. Postoperative evaluation parameters included radiographic measurements, a modified AOFAS scoring system (without the physical exam components and a maximum of 63 points) and SF-12. Preoperative parameters were assessed at first patient visit; postoperative scores were obtained by telephone interview by 1 author who has done the procedure. Reliability and construct validity of the modified AOFAS questionnaire was not established.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **50 (25 versus 25)**

	Suture fixation n=25	**Screw fixation n=25**	**p value**
Mean modified AOFAS score (maximum 63 points)			
Preoperative (range)	29.8 (0–35)	33.4 (0–40)	NR
Postoperative 6 months (range)	50.6 (30–63) (p<0.05)	53.4 (25–63) (p<0.05)	NR
SF-12			
Preoperative			
Physical component summary	32.4	33.7	NR
Mental component summary	51.9	50.1	NR
Postoperative (6 months)			
PCS	47.0	46.8	NR
MCS	55.3	54.6	NR
Total	102.3	101.5	NR
Mean time to full weight bearing (weeks)			
All patients (range)	5.5 (2–8)	10.5 (8–14)	NS
Maisonneuve/soft tissue group (range)	4.9 (2–8)	9.5 (8–14)	NS
Mean MCS mm (range)			
Preoperative	5.4 (3–9)	6.4 (4–10)	
Postoperative	3.0 (3–4)	3.0 (2–4)	NS
Mean TFO mm (range)			
Postoperative	6.8 (4–11)	7.9 (4–11)	NS
Mean TFCS mm (range)			
Postoperative	3.8 (3–5)	4.7 (2–8)	<0.05

Safety

	Suture fixation % (n)	**Screw fixation % (n)**
Screw loosening	No screw used	29 (5/25)
Screw breakage	No screw used	41 (7/25)
Implant removal at an average of 4.4 months	0 (0/25)	68 (17/25)
Implant failure	0	0

Abbreviations used: AOFAS, American Orthopaedics Foot and Ankle Society; ASIF, Association for the Study of Internal Fixation; CT, computed tomography; MCS, medial clear space; MRI, magnetic resonance imaging; NR, not reported; NS, not significant; PER, pronation external rotation; PCS, physical component summary; SF-12, Short Form-12 Health Survey; SER, supination external rotation; TFCS, tibiofibular clear space; TFO, tibiofibular overlap.

Study 3 Naqvi GA (2012)

Details

Study type	**Non-randomised comparative study (cohort study)**
Country	Ireland (single centre)
Recruitment period	2007–09
Study population and number	n=**46 (23 suture fixation versus 23 screw fixation) patients with ankle syndesmotic diastasis** Classification of injury: Suture fixation group: Weber B (n=2), Weber C (n=13), Maisonneuve (n=8) Screw fixation group: Weber B (n=2), Weber C (n=15), Maisonneuve (n=6) Mechanism of injury: sports, fall from height, trip and fall, slipped on ice, dancing
Age and sex	Suture fixation group: mean 42 years; screw fixation: mean 40 years Suture fixation group: 74% (17/23) male; screw fixation: 70% (16/23) male
Patient selection criteria	Inclusion criteria: patients with acute ankle injuries involving distal tibiofibular syndesmosis. Exclusion criteria: patients with compound fractures, multiple injuries, neuropathic arthropathy, bilateral injuries and chronic or missed syndesmotic injuries excluded.
Technique	Patients diagnosed by clinical examination and radiographic parameters (TFCS and TFO) preoperatively, followed by intraoperative confirmation under image intensifier using external rotation stress test or hook test. Suture fixation group done with Tightrope done by 3 consultants. In a few cases the technique was modified: once the 2 buttons were seated flush with the bone, the free ends of the suture were hand tied on the lateral side and cut 1 cm long and buried into the periosteal recess made (this modified step was done to reduce complications related to the prominent lateral knot). Two Tightropes were used in 7 cases depending on the fracture configuration. Standard transosseous screw fixation done by 3 consultants. 1 screw used on 20 patients and 2 screws used in 3 patients depending on the fracture configuration and all screws removed 10 weeks after surgery. Patients immobilised in a below-the-knee non-weight bearing cast for 6 weeks followed by physiotherapy and weight bearing as tolerated. Patients were followed up at 2 and 6 weeks and then at 5–6 months clinically and radiologically.
Follow-up	**Mean 2.5 years (range 1.5–3.5 years)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: Complete follow-up.

Study design issues: It was a prospective study with appropriate sample size; it was not clear how patients were selected between groups; STROBE guidelines were followed in conducting the study. Procedures were done by different surgeons, irrespective of patient demographics or type of injury, depending on surgeons' preference; clinical examination was done by an independent clinician blinded to the interventions. Diagnosis of malreduction (primary outcome) was based on predetermined standard radiographic parameters and CT scans done by a single radiographer and blinding assessor was not possible. CT scans were not done immediately after the surgery.

There might be some overlap of suture fixation patients with study 5 (Naqvi 2012).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **46 (23 versus 23)**

Syndesmotic mean width between the operated and contralateral ankle in the 2 groups (assessed on CT)

	Syndesmotic width (mm)		
	Operated ankle (mean±SD)	**Contralateral ankle –control (mean±SD)**	**p value**
Suture fixation (n=23)	4.37±1.12	4.04±0.95	0.30
Screw fixation (n=23)	5.16±1.92	4.02±0.87	0.01

Average width of normal syndesmosis was 4.03±0.89 mm.

Radiographic, clinical and functional outcomes

	Suture fixation (n=23)	**Screw fixation (n=23)**	**p value**
Malreduction of syndesmosis* between the 2 groups (assessed on CT) (p=0.04)			
No malreduction % (n)	100 (23/23)	78 (18/23)	
Malreduction % (n)	0	21.7 (5/23)	
MCS mm			
Preoperative	5.86±2.3	6.67±1.7	
Postoperative	3.36±0.5	3.23±0.6	0.48
TFCS mm			
Preoperative	7.04±2.1	7.82±1.6	
Postoperative	4.04±0.8	5.0±1.8	<0.05
TFO mm			
Preoperative	3.95±2.0	3.78±2.3	
Postoperative	8.21±2.0	7.47±2.0	0.22
Time to full weight bearing (weeks)	8.0±1.2 (range 6–10)	9.1±1.8 (range 6–13)	0.11
Postoperative AOFAS score (0–100) (mean±SD)	89.56±8.6	86.52±9.6	0.26
Postoperative FADI score (0–100) (mean±SD)	82.42±11.2	81.22±15.6	0.76

*Malreduction was diagnosed on the basis of predefined criteria of a >2 mm difference in width between treated and untreated sides.

Regression analysis to determine the predictors of functional outcome (AOFAS score used as a measure of functional outcome)

	Regression coefficient	**t**	**p > t**
Syndesmotic malreduction	−12.39	−2.43	0.02
Fixation technique	0.29	0.1	0.91
Duration since surgery	−0.05	−0.34	0.73
Age	0.008	0.08	0.93

Safety

No safety outcomes reported

Abbreviations used: AOFAS, American Orthopaedics Foot and Ankle Society; ASIF, Association for the Study of Internal Fixation; CT, computed tomography; FADI, Foot and Ankle Disability Index; MCS, medial clear space; STROBE, strengthening the reporting of observational studies in epidemiology; TFCS, tibiofibular clear space; TFO, tibiofibular overlap.

Study 4 Storey P (2012)

Details

Study type	**Retrospective case series**
Country	UK
Recruitment period	2007–10
Study population and number	n=**102 patients with unstable ankle fractures (either non-specific twisting injury or during sporting activity)** Type of fractures: Weber C/pronation external rotation (n=60), Weber B/supination external rotation (n=31), Weber B/pronation abduction (n=1), Maisonneuve-type syndesmotic non-bony injuries (n=8), minimally displaced pilon fracture associated with a pronation external rotation injury (n=1) and open talus dislocation (n=1).
Age and sex	Mean 31 years; 63% (64/102) male
Patient selection criteria	Patients identified from surgical log books and hospital notes were reviewed. Patients with no record of follow-up were excluded from review.
Technique	Suture fixation: patients were treated with Tightrope by 15 trauma and orthopaedic surgeons (doing a median of 5 cases each; range 1–28). 61 patients had stabilisation using 1 Tightrope and in 41 patients 2 Tightropes were used. Device inserted through a fibular plate in 61 patients. 8 of these were 3-hole plates inserted to act as a washer for the fibula button. In 12 patients a plate was used to stabilise a fibula fracture but the device was not inserted through the plate.
Follow-up	**Median 85 days (range 17–1292 days)** **Between surgery and final radiographic follow-up: median 71 days (range 7–1265 days)**
Conflict of interest/source of funding	Not reported.

Analysis

Study design issues: Retrospective case series review of complications (not efficacy). An independent observer did the classification and data collection. Fractures were classified using the Weber and Lauge–Hansen systems.

Other issues: The authors recommend meticulous attention and modification of the surgical technique. These included:

1. Cut the Fiberwire loop at least 1 cm beyond the knot and bury sharp edges adjacent to the fibula to prevent skin irritation, stitch abscess and osteomyelitis.
2. Remove Tightropes for painful aseptic osteolysis.
3. A small medial incision to position endobutton directly abutting the tibial cortex to prevent soft tissue necrosis between endobutton and medial tibial cortex and rediastasis (failed stabilisation)
4. Insert the Tightrope through a fibula plate to prevent lateral button pull through and diastasis.

Key efficacy and safety findings

<table>
<tr><th>Efficacy</th><th>Safety</th></tr>
<tr><td>Number of patients analysed:
102</td><td>
Complications after intervention* (timing not reported)
<table>
<tr><th></th><th>% (n)</th></tr>
<tr><td>Superficial wound infection</td><td>3 (3/102)</td></tr>
<tr><td>Osteomyelitis</td><td>3 (3/102)</td></tr>
<tr><td>Aseptic osteolysis (surrounding the Tightrope)</td><td>3 (3/102)</td></tr>
<tr><td>Intraosseous migration of the lateral endobutton</td><td>3 (3/102)</td></tr>
<tr><td>Malpositioning of the medial endobutton</td><td>3 (3/102)</td></tr>
</table>
*10 of these occurred in patients with Weber C/pronation external rotation injuries.
Complications at final follow-up (mean 85 days)
<table>
<tr><th></th><th>% (n)</th></tr>
<tr><td>Ankle pain, swelling, stiffness or combination of 3 symptoms</td><td>44 (44/102)</td></tr>
<tr><td>Non-fatal pulmonary emboli</td><td>2 (2/102)</td></tr>
<tr><td>Symptomatic deep vein thrombosis</td><td>2 (2/102)</td></tr>
<tr><td>Further surgery (unrelated to the Tightrope):
1 delayed wound closure of an open fracture with split skin grafting
1 ankle arthroscopy to assess the articular cartilage because of ongoing ankle pain
1 fibular plate removal for hardware prominence.</td><td>3 (3/102)</td></tr>
<tr><td>Device removal</td><td>8 (8/102)</td></tr>
<tr><td colspan="2">Reasons for removal</td></tr>
<tr><td>Osteomyelitis surrounding the Tightrope</td><td>3</td></tr>
<tr><td>Radiological track widening (aseptic osteolysis) and pain</td><td>2</td></tr>
<tr><td>Failed stabilisation of the syndesmosis</td><td>2</td></tr>
<tr><td>Unexplained pain</td><td>1</td></tr>
</table>
Management not reported.
</td></tr>
</table>

Study 5 Naqvi GA (2012)

Details

Study type	**Retrospective case series**
Country	Ireland (single centre)
Recruitment period	2007–09
Study population and number	n=**49 patients with ankle syndesmotic diastasis** Injury type: sports (n=13), fall from height (n=8), trip and fall (n=20), slipped on ice (n=3), dancing (n=3), motor vehicle accident (n=2). Classification of injury: Weber B (n=6), Weber C (n=29), Maisonneuve (n=11), soft tissue (n=3).
Age and sex	Mean 38 years; 65% (32/49) male
Patient selection criteria	Inclusion criteria: patients with acute ankle injuries involving distal tibiofibular syndesmosis. Exclusion criteria: patients with open fracture, multiple trauma, neuropathic arthropathy and associated the pilon fracture.
Technique	Patients diagnosed based on both clinical examination and radiographic parameters, including widening of the MCS, increased TFCS and reduction of TFO preoperatively and intraoperative assessment under fluoroscopy using external rotation stress test or hook test after fixation of fractures. All fractures were fixed according to Association for the Study of Internal Fixation principles by 3 surgeons. Syndesmosis stabilised using single (in 36 cases) or double (in 13 cases) Arthrex Tightropes depending on the fracture. 18 patients were operated with standard technique. 31 patients had modified technique. The periosteum over the posterior surface of the fibula was elevated using sharp dissection in the area of proposed Tightrope placement to create a recess to bury the knot later. Once both the buttons were seated flush with the bone, the free ends of the Fiberwire on the lateral side were hand tied and cut 1 cm long. The knot was then buried posterior to the fibula in the periosteal recess made previously (this modified step was done to reduce complications related to the prominent lateral knot). Patients were immobilised in a below-the-knee non-weight bearing cast for 6 weeks followed by physical therapy and weight bearing as tolerated. Patients were followed up at 2 weeks, 6 weeks and then after 3 months.
Follow-up	**Mean 24 months (range 12–38 months)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: Short clinical follow-up.

Study design issues: This was a retrospective study with limited patients. Procedures were done by different surgeons and, after a certain point in time, operative technique was slightly modified (to bury the knot subperiosteally) by the authors to reduce or avoid soft tissue complications. Radiographic data were limited to standard ankle views and up to an average of 6 months.

The authors stated that there is a learning curve.

There might be some overlap of patients with study 2 (Naqvi 2012).

Key efficacy and safety findings

Efficacy

Number of patients analysed: **49**

Clinical, radiological and functional outcomes (n=49)

	Mean±SD
Clinical and functional outcomes	
Time to full weight bearing (weeks)	7.76±1.16 (range 5–10)
Time to normal activities (weeks)	11.20±1.88 (range 7–16)
AOFAS score at mean 6 months	85.57±16.71 (95% CI 77.96–93.18)
FADI score* at mean 24 months	81.20±16.11 (95% CI 73.86–88.53)
Patient satisfaction*	**n**
Excellent	26
Very good	16
Good	6
Fair	0
Poor (with persistent pain and stiffness)	1
Radiographic measurements	
MCS mm	
Preoperative	6.71±3.15
Postoperative (at 6 months)	3.33±0.63
TFCS mm	
Preoperative	7.45±2.29
Postoperative (at 6 months)	4.37±0.76
TFO mm	
Preoperative	3.37±2.28
Postoperative	8.88±1.60

*Self-administered confidential questionnaire

Safety

Device removal due to soft tissue complications:

Standard technique % (n)	**Modified technique % (n)**	**p value**
17 (3/18) • 1 removed due to deep wound infection on lateral side after surgery that did not resolve with antibiotics • 1 removed after 5 months due to a prominent knot causing skin irritation • 1 removed after 6 months due to infectious sinus formation over the lateral knot	0	0.04

Abbreviations used: AOFAS, American Orthopaedics Foot and Ankle Society; CI, confidence interval; FADI, Foot and Ankle Disability Index; MCS, Medial clear space; TFCS, Tibiofibular clear space; TFO, Tibiofibular overlap.

Study 6 Rigby RB (2013)

Details

Study type	**Retrospective case series**
Country	USA
Recruitment period	2007–11
Study population and number	n=**37 (64 Tightropes) patients with distal tibiofibular syndesmosis** Injury type: isolated syndesmotic injuries (n=3), trimalleolar fractures (n=10), bimalleolar fractures (n=7), Weber C fractures (n=3), Weber B fractures (n=7), Salter Harris type 3 fracture (n=1), Maisonneuve fractures (n=4).
Age and sex	Mean 41 years, 57% (21/37) male
Patient selection criteria	Inclusion criteria: patients with preoperative radiographic evidence (decreased TFO and an increase in the MCS and TFS) confirmed by intraoperative syndesmotic instability. Exclusion criteria: diabetic and neuropathic patients excluded.
Technique	Tightrope suture fixation In 27% (10/37) of patients 1 suture button was placed. In 73% (27/37) of patients 2 suture buttons were placed.
Follow-up	**Mean 23.6±4.3 months**
Conflict of interest/source of funding	One of the authors was a paid consultant for Arthrex (manufacturer).

Analysis

Study design issues: Medical records were reviewed retrospectively. The study mainly assessed radiographic outcomes and the radiographic examination was done by 1 reviewer on an anteroposterior radiograph. Non-weight bearing radiographs were excluded. Maximum threshold width of the syndesmosis for acceptable widening of the syndesmosis used in the study was 1.5 mm.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **37 (64 Tightropes)**

	Mean±SD
Clinical and functional outcomes	
Time to full weight bearing (days)	33.2±12.7
Mean postoperative AOFAS score	97 (range 90–100)
Radiographic measurements	
MCS mm	
Preoperative	2.9±0.5
Postoperative	3.0±0.5
TFCS mm	
Preoperative	4.1±1.1
Postoperative	4.2±1.3
TFO mm	
Preoperative	7.2±2.7
Postoperative	7.4±2.8

The calculated measurable differences from the initial to final TFCS, TFO and MCS were significantly less than the maximum threshold for allowable widening of the syndesmosis (TFCS 0.48±0.5, p<0.001; TFO 1.02±0.92, p<0.002; MCS 0.27±0.22, p<0.001).

Safety

Complications

	% (n)
Skin irritation caused by the subcutaneous knot (3 resolved without removal)	19 (7/37)
Superficial infection (resolved with oral antibiotics)	8 (3/37)
Device removal (6 devices in 4 patients with knot irritation were removed)	11 (4/37)
Additional fracture revision surgery (secondary to severity of the initial fracture injury)	5 (2/37)

Abbreviations used: AOFAS, American Orthopaedics Foot and Ankle Society; MCS, medial clear space; TFCS, tibiofibular clear space; TFO, tibiofibular overlap.

Study 7 DeGroot H (2011)

Details

Study type	**Retrospective case series**
Country	Jordan, Egypt
Recruitment period	2007–09
Study population and number	n=**24 patients with acute distal tibiofibular syndesmosis injuries** Classification of injury: PER 4 type/Weber C fracture (n=10), SER/Weber B (n=9), PAB/Weber B (n=2), tibial plafond fracture (n=1), high ankle sprain with syndesmotic disruption (n=1), Maisonneuve fracture with syndesmotic disruption (n=1).
Age and sex	Mean 43 years; 42% (10/24) male
Patient selection criteria	Inclusion criteria: all patients who had suture fixation of syndesmosis during the collection period. Exclusion criteria: not reported
Technique	Suture fixation (Arthrex Tightrope) was done after the injury was radiographically confirmed. In 20 patients open reduction and internal fixation of the ankle fracture was done by standard techniques. 3 patients had minimally displaced fractures of the distal fibula combined with syndesmotic injury, and surgery for these included percutaneous fixation of the syndesmosis using suture fixation or a combination of suture fixation and a fibular plate. 1 patient with Maisonneuve injury had a percutaneous suture fixation of the distal syndesmosis and non-operative treatment. 1 patient with recent bimalleolar fracture had a second surgery for unreduced syndesmosis. Once placement was done, 1 limb of the pull through suture on the medial side was cut so that the entire pull through suture could be removed on the medial side. Single Tightrope (n=7), double Tightrope (n=16), triple Tightrope (n=1). Distance from tibial plafond – single: 2.2 cm; double: most distal 1.2 cm, proximal 2.7 cm; triple: most distal 1.0 cm, middle 1.8 cm, proximal 3.4 cm. 18 devices were placed through a tibiofibular plate, 6 against the bone. Patients were placed in a splint, removed after 1–2 weeks, immobilised in a below-the-knee non-weight bearing cast for 1–2 weeks followed by fracture boot and physical therapy by the 3rd week. Weight bearing as allowed after sufficient healing (within 1–2 weeks for isolated injuries, at 6–10 weeks for unstable fractures). Radiographic parameters were assessed postoperatively at follow-up periods.
Follow-up	**Mean 20 months (range 12–38 months)**
Conflict of interest/source of funding	None

Analysis

Follow-up issues: A short clinical follow-up. Patients with subsidence had longer follow-up (32 months) than those who did not (mean 17 months).

Study design issues: This was a retrospective study with limited patients and different types of ankle injuries. Functional outcomes were prospectively collected, and radiographical outcomes were retrospectively analysed. Fractures were classified according to Lauge–Hansen classification. In most patients (with Maisonneuve injuries, severe disruption of syndesmosis) 2 Tightropes were used. All procedures were done by a single surgeon.

Preoperative AOFAS scores were not obtained in these patients with acute trauma. Postoperative scores were calculated at each clinical follow-up visit. Measurements obtained from non-weight bearing radiographs.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **24**

Clinical, radiological and functional outcomes (n=24)

	Mean±SD
Clinical and functional outcomes	
Time to full weight bearing (weeks)	5.7±2.1 (range 2–10)
AOFAS score at last follow-up (mean 20 months)	
Average pain sub-score (out of 40)	35 (range 20–40)
Average functional score (out of 60)	59.17 (range 51–60)
Average total score	94.17 (range 71–100)
Radiographic measurements	
MCS mm	
Preoperative	8.0±2.7
Postoperative	3.7±0.41
Last follow-up	3.8±0.39
TFCS mm	
Preoperative	8.5±3.6
Postoperative	3.2±0.7
Last follow-up	3.3±0.7
TFO mm	
Preoperative	3.4±2.4
Postoperative	8±1.2
Last follow-up	7.9±1.2

Safety

Complications

	% (n)
Device removal (4 were removed between 12 and 35 months after surgery because of prominence and local irritation of the skin 1 had persistent pain with activity and restriction of motion in the ankle, relieved by removal after 12 weeks 1 patient with severe PER type fracture had a second severe open fracture at 8 weeks after surgery, lateral suture button and sutures were removed at second surgery and metallic screws fixed. A later patient had local irritation over the medial suture button. All devices were removed at patient's request.)	25 (6/24)
Osteolysis and subsidence of the bone (Due to lysis of the bone adjacent to the metallic portions of the device seen on final radiographs at mean 32 months (24–38 months) – suture buttons subsided 2–4 mm into the cortex of fibula or tibia.)	17 (4/24)
Heterotopic ossification of syndesmosis ligaments^ at 5, 14 and 18 months (1 moderate heterotopic bone was seen within the substance of the intraosseous ligament adjacent to the sutures. 2 had extensive ossification of the intraosseous ligament and posterior tibiofibular ligament with local bridging of syndesmotic interval by the heterotopic bone seen on CT scans.)	12.5 (3/24)
Delayed healing of the skin on lateral side of ankle (needed dressing)	4 (1/24)

^No effect on clinical outcomes or cause any pain. AOFAS score 97 points.

Enlargement of suture tunnels noted in some cases.

Abbreviations used: AOFAS, American Orthopaedics Foot and Ankle Society; ASIF, Association for the Study of Internal Fixation; CT, computed tomography; MCS, medial clear space; PER, pronation external rotation; TFCS, tibiofibular clear space; TFO, tibiofibular overlap.

Study 8 Maempel J (2014)

Details

Study type	**Retrospective comparative case series**
Country	UK
Recruitment period	2008–09
Study population and number	n=**35 (12 suture fixation vs 23 screw fixation) patients with ankle syndesmotic disruption** Classification of injury: Suture fixation group: Weber B (n=1), Weber C (n=5), Maisonneuve (n=6) Screw fixation group: Weber B (n=2), Weber C (n=15), Maisonneuve (n=6)
Age and sex	Suture fixation group: mean 41.5 years; screw fixation: mean 41 years Suture fixation group: 83% (10/12) male; screw fixation: 70% (16/23) male
Patient selection criteria	Inclusion criteria: all patients having treatment for primary tibiofibular syndesmotic injury. Exclusion criteria: patients who had previous ankle pathology or fixation and those whose first intervention during the study period was a revision procedure for their syndesmotic injury were excluded.
Technique	All associated ankle fractures were managed according to AO principles. The syndesmosis stabilised using either Arthrex Tightrope or syndesmotic screw. Suture fixation group had 13 procedures (mean 1.08 procedures per patient). In 7 patients a single Tightrope was used. In 5 patients, 2 Tightropes were used (4 Maisonneuve and 1 high Weber C fracture) 23 screw fixation group patients had 45 procedures (mean 1.96 procedures per patient): 19 were for screw removals, 2 were revisions in 1 patient. Patient progress was noted until discharge from the trauma outpatient service and thereafter progress of those who had Tightrope was followed through contact with their GP.
Follow-up	**Mean 12.4 weeks (range 6–35) in clinic; GP contacted at mean 14.6 months (range 5.16–22.86)**
Conflict of interest/source of funding	Not reported.

Analysis

Follow-up issues: 1 patient was lost to clinic follow-up; however, his GP was contacted for data. GPs of 3 patients could not be traced.

Study design issues: This was a retrospective review of all medical records and radiographs.

Key efficacy and safety findings

Efficacy

Number of patients analysed: **35 (12 versus 23)**

Clinical and functional outcomes

	Suture fixation (n=9)	**Screw fixation (n=23)**
Time to full weight bearing (weeks)	4.4 (range 2–6)	NR
Recurrent diastasis	0	1
Satisfactory syndesmotic reduction	100	NR

Safety

	Suture fixation (n)	**Screw fixation (n)**
Small stitch abscess in the medial ankle wound (Resolved after removal of suture material and infected metalwork.)	1	0
Peroneal nerve injury (Due to fracture was present prior to surgery. Electrography after 3 months revealed injury to the common peroneal nerve with neurapraxia and early re-innervation.) Patient had treatment, and arthroscopy revealed an osteochondral defect. Suture fixation was removed.	1	0
1 dehisced wound (as a result of screw removal)	0	1
1 superficial infection (as a result of screw removal)	0	1

Abbreviations used: NR, not reported.

Study 9 Welck MJ (2013)

Details

Study type	**Case report**
Country	UK
Recruitment period	2010
Study population and number	n=**1 patient with Weber B, bimalleolar ankle fracture**
Age and sex	45 years, female
Patient selection criteria	
Technique	The fracture was internally fixed with 2 partially threaded screws for the medial malleolus and a tubular plate for the fibular fracture. Patient sustained a further fall in 2011, radiographs showed a refracture of the medial malleolus with some bending of the screws and a proximal fibula fracture. There was also distal tibiofibular diastasis. This was treated with double Tightrope fixation. 1 screw from the plate was removed to place the Tightrope, and the second was inserted 1 cm distal to the first, at the posterior edge of the plate, in order to obtain axial divergence.
Follow-up	**Immediate postoperative period**
Conflict of interest/source of funding	Not reported

Key efficacy and safety findings

Safety
Number of patients analysed: **1** **Tendon entrapment from medial suture button** Patient suffered from severe anterior ankle pain immediately after the procedure. This was exacerbated by ankle dorsiflexion and plantar flexion. The patient also had a sharp pain on the dorsomedial aspect of the foot. There was paraesthesia in the distribution of deep peroneal nerve. Patient was taken to theatre and on exploration, the distal and medial button was found to be entrapping the tibialis anterior muscle and in close proximity to the deep peroneal nerve. This was because the surgeon altered the angle of the second suture in the coronal plane. The Tightrope and a further screw were removed and the second Tightrope was put through the plate. The patient had an uneventful recovery and returned back to her pre-fracture mobility after 6 weeks. Paraesthesia resolved completely.

Study 10 Mason LW (2010)

Details

Study type	**Case report**
Country	UK
Recruitment period	2010
Study population and number	n=**1 patient with pronation-external rotation ankle injury (displaced trimalleolar fracture with talar shift and syndesmotic diastasis)**
Age and sex	25 years, male
Patient selection criteria	
Technique	Suture syndesmosis fixation. Fracture was reduced and placed in a below the knee posterior splint and admitted with ice and elevation. Surgery was postponed for 8 days as the ankle was too swollen. The fibular was fixed with a screw and plate, and medial malleolus with 2 screws. A Tightrope was placed for syndesmotic instability. The patient remained in a cast for 6 weeks, non-weight bearing and mobilised successfully.
Follow-up	**1 year**
Conflict of interest/source of funding	Not reported

Key efficacy and safety findings

Safety
Number of patients analysed: **1** **Tibiofibular synostosis** Some signs of callus formation between the tibia and fibular were seen on radiographs at 6 weeks. Patient regained full range of motion and was therefore discharged at 12 weeks. After 1 year, the patient returned complaining of anterior ankle pain while weight bearing. Range of motion was well preserved. Radiograph showed a bony union between the distal tibia and fibula accounting for the symptoms.

Study 11 Hohman DW (2011)

Details

Study type	**Case report**
Country	USA
Recruitment period	2011
Study population and number	n=**1 patient with sustained fracture to left lower extremity** Injury mechanism: a lateral side impact upon contact with his leg by a fellow football player who fell down
Age and sex	18 years, male
Patient selection criteria	
Technique	Radiographs demonstrated acute fracture of the tibia and fibula through the superior tract of the suture button device which was placed for syndesmotic injury repair 2 years before. Open reduction and internal fixation was done after anatomical reduction under fluoroscopy. 2 screws from anterior to posterior and a medial distal tibial locking plate along the medial border of the tibia were used. The previous suture device was removed without difficulty. The distal aspect of the fracture was found to have propagated through the suture button tract. Suture tracts were curetted. Stability of the syndesmosis was confirmed on imaging. The proximal fibular fracture was treated non-operatively owing to appropriate overall alignment and no appreciable shortening to the fibula distally.
Follow-up	**1 year**
Conflict of interest/source of funding	None

Key efficacy and safety findings

Safety
Number of patients analysed: **1** **Pathologic tibia/fibula fracture through the suture fixation of a previously well-healed syndesmotic disruption** At 6 months follow-up the wound was well healed, and weight bearing was well tolerated. Range of motion was 15° with dorsiflexion and 35° at plantar flexion. Radiographic evaluation demonstrated callus formation and appreciable healing at the fracture sites. At 12 months, the patient had returned to high-intensity sport activity, and radiographs revealed a well-healed tibia and fibula. Authors conclude that the pathologic tibia/fibula fracture resulted from a persistent stress riser related to the suture button fixation drill holes 2 years after syndesmotic repair.

Study 12 Treon K (2011)

Details

Study type	**Case series (abstract only)**
Country	UK (single centre)
Recruitment period	2006–09
Study population and number	n=**18 patients with ankle syndesmosis**
Age and sex	Range 16–58 years; 72% (13/18) male
Patient selection criteria	Not reported
Technique	Tightrope fixation of ankle syndesmosis. 5 had Tightrope fixation alone, 13 had fracture fixation according to AO recommendations. Time in cast mobilisation ranged from 5–8 weeks, time to full weight bearing 6–10 weeks and time to discharge 8 weeks to 15 months.
Follow-up	**Not reported**
Conflict of interest/source of funding	Not reported

Key efficacy and safety findings

Safety
Number of patients analysed: **18** Overall complication rate was 44% (8/18). • Tightropes were removed secondary to wound breakdown or knot prominence: 22% (4/18). • Syndesmotic widening: 11% (2/18). • Knot prominence without removal: 5.5% (1/24). • Synostosis: 5.5% (1/18).
Abbreviations: AO, American Orthopaedic.

Efficacy

Time to full weight bearing

A non-randomised comparative study of 50 patients with distal tibiofibular diastasis comparing suture fixation (n=25) against screw fixation (n=25) reported no significant difference in the average time to full weight bearing between the suture fixation group and the screw fixation group at an average follow-up of 10.8 months and 8.2 months respectively (mean time 5.5 weeks versus 10.5 weeks, but the difference was not significant)[2].

A non-randomised comparative study of 46 patients with ankle syndesmotic diastases comparing suture fixation (n=23) against screw fixation (n=23) reported no significant difference in the average time to full weight bearing between the suture fixation group and the screw fixation group (8 weeks versus 9.1 weeks, p=0.11)[3].

A retrospective case series of 49 patients with ankle diastasis treated with suture fixation reported that the average time to full weight bearing was 7.7 weeks[5].

A retrospective case series of 37 patients (with 64 devices) with distal tibiofibular syndesmosis treated with suture fixation reported that the mean time to full weight bearing was 33.2±12.7 days[6].

A retrospective case series of 24 patients with distal tibiofibular syndesmosis treated with suture fixation reported that the mean time to full weight bearing was 5.7±2.1 weeks[7].

Time to return to activities

The retrospective case series of 49 patients with ankle diastasis reported that the average time to return to normal activities was 11.2 weeks[5].

A randomised controlled trial of 70 patients with acute ankle syndesmosis rupture compared dynamic suture fixation (n=34) against static screw fixation (n=36) for 12 months. Sixty-five patients completed the study (dynamic suture fixation, n=33; static screw fixation, n=32) and were included in the analysis. The study reported that there were no significant differences in return to previous work or sporting activities between the suture fixation and screw fixation groups at 12-month follow-up (return to work, 97% versus 88%, p=0.19; return to sporting activities, 79% versus 69%, p=0.41)[1].

Clinical performance (measured by Olerud and Molander, AOFAS or FADI scores)

The randomised controlled trial of 70 patients with acute ankle syndesmosis rupture compared suture fixation (n=34) against screw fixation (n=36). Sixty-five patients completed the study (suture fixation, n=33; screw fixation, n=32) and

were included in the analysis. The study reported that patients with suture fixation had significantly better functional scores than those in the screw fixation group (measured with the Olerud and Molander Ankle Score) at 12 months (93.3 versus 87.6, p=0.046), but the difference was not significant at 3 months (68.8 versus 60.2, p=0.067) or 6 months (84.2 versus 76.9, p=0.082). Significantly higher American Orthopaedic Foot and Ankle Society (AOFAS) scores were seen at 3 months in the suture fixation group compared with the screw fixation group (78.6 versus 70.6, p=0.016), but these were not significant at 6 months (87.1 versus 83.8, p=0.260) or 12 months (93.1 versus 89.9, p=0.260)[1].

The non-randomised comparative study of 50 patients comparing suture fixation (n=25) against screw fixation (n=25) reported that there was no significant difference between the 2 groups in mean postoperative modified AOFAS scores (50.64 and 53.45, p=not significant) respectively at 6-month follow-up. Improvements were noted in SF-12 subjective scores for both fixation groups between the preoperative and 6-month postoperative measurements (suture fixation 84.44 versus 102.36; screw fixation 83.87 versus 101.56)[2].

The non-randomised comparative study of 46 patients with ankle syndesmotic diastases comparing suture fixation (n=23) against screw fixation (n=23) reported that there was no significant difference between the 2 groups in mean postoperative AOFAS scores (89.56 and 86.52, p=0.26) or Foot and Ankle Disability Index (FADI) score (82.42 and 81.22, p=.76) respectively[3].

The retrospective case series of 49 patients with ankle diastasis treated with suture fixation (a slightly modified technique was used in 31 patients) reported that the mean AOFAS score was 85.57 and the mean FADI score was 81.20 at a 24-month average follow-up[5].

The retrospective case series of 37 patients (with 64 devices) reported that the mean postoperative AOFAS score was 97 (range 90–100)[6]. The retrospective case series of 24 patients reported that the mean postoperative AOFAS score was 94 (range 90–100 points) at a mean follow-up of 20 months[7].

Radiographic outcomes

The randomised controlled trial of 70 patients reported that adequate syndesmosis reduction was achieved in both groups. Patients in the screw fixation group had a statistically significantly higher mean radiological ‘loss of reduction’ compared with those in the suture fixation group (medial clear space 0.41 mm versus 0.05 mm, p=0.02; lateral tibiofibular clear space 1.34 mm versus 0.32 mm, p=0.0005)[1].

The non-randomised comparative study of 46 patients with ankle syndesmotic diastases comparing suture fixation (n=23) against screw fixation (n=23) reported no malreduction of syndesmosis on CT scans in the suture fixation group compared with 22% (5/23) malreduction in the screw fixation group (p=0.04). The

study also reported that the mean width of syndesmosis (on CT measurement) was 4.37±1.12 mm (p=0.30) in the suture fixation group compared with 5.16±1.92 mm in the screw fixation group (p=0.01).The average width of normal syndesmosis in the contralateral ankle in these patients was 4.03±0.89 mm. Regression analysis showed that malreduction of syndesmosis predicted the clinical outcome (regression coefficient, −12.39; t=−2.43; p=0.02)[3].

The non-randomised comparative study of 50 patients with distal tibiofibular diastasis comparing suture fixation (n=25) against screw fixation (n=25) reported that postoperative radiographic measurements for medial clear space (MCS) and tibiofibular overlap (TFO) each showed no significant difference (3.0 mm versus 3.1 mm; 6.8 mm versus 8.0 mm). The only significant difference between the 2 groups was the tibiofibular clear space (TFCS; 3.8 mm versus 4.8 mm, p<0.05)[2].

The retrospective case series of 49 patients with ankle diastasis reported that postoperative radiographic measurements showed satisfactory reduction of syndesmosis (MCS 6.7 mm to 3.3 mm; TFCS 7.5 mm to 4.4 mm; TFO 3.4 mm to 8.9 mm) at 6-month follow-up[5].

The retrospective case series of 37 patients reported that initial measurements for TFCS, TFO and MCS were 4.1, 7.2, and 2.9 mm respectively. The final measurements were 4.2, 7.4, and 3.0 mm respectively. The mean differences from initial to final measurements were 0.09 mm, 0.53 mm and 0.11 mm respectively. The measureable differences from initial to final weight bearing radiographic measurements for TFCS, TFO and MCS were significantly less than the maximum threshold for acceptable widening of the syndesmosis (TFCS 0.48mm, p<0.001; TFO 1.02, p<0.002; MCS 0.27, p<0.001)[6].

The retrospective case series of 24 patients reported that the preoperative syndesmotic radiographic parameters returned to normal after the suture fixation and remained normal (MCS 8.0 mm to 3.8 mm; TFCS 8.5 mm to 3.3 mm; TFO 3.4 mm to 7.9 mm) at a mean follow-up of 20 months[7].

Ankle range of motion

The randomised controlled trial of 70 patients comparing dynamic suture fixation (n=34) against static screw fixation (n=36) reported no significant difference in the ankle range of motion (dorsal and plantar flexion and ankle circumference) between the 2 groups at 6- and 12-month follow-up[1].

Ankle pain

The randomised controlled trial of 70 patients comparing dynamic suture fixation (n=34) against static screw fixation (n=36) reported no significant difference in ankle pain (determined with a Visual Analogue Scale) between the 2 groups at 3-, 6- and 12-month follow-up[1].

Recurrent diastasis

A retrospective comparative case series of 35 patients (12 in the suture fixation group and 23 in the screw fixation group) reported that no patients in the suture fixation group had recurrent diastasis at discharge, while 1 patient in the screw fixation group had syndesmotic diastasis[8].

Safety

Device removal due to infection, irritation or pain

Device removal at patients' request was reported in 25% (6/24) of patients in a retrospective case series of 24 patients at a mean follow-up of 20 months. Reasons for removal include prominence and local irritation of the skin between 12 and 35 months after surgery (n=4), persistent pain with activity and restriction of motion in the ankle (n=1), and local irritation over the medial suture in a patient who had a second surgery for severe fracture after 8 weeks during which lateral buttons and sutures were removed (n=1)[7].

Device removal was reported in 8% (8/102) of patients in a case series of 102 patients at a median follow-up of 85 days. Reasons for removal were: osteomyelitis surrounding the device (n=3), painful radiological track widening (aseptic osteolysis) (n=2), failed stabilisation of the syndesmosis (n=2) and unexplained pain (n=1)[4].

Device removal was reported in 17% (3/18) of patients treated with a standard suture technique compared to none treated with a modified suture technique (n=31) in a case series of 49 patients. Reasons for removal were deep wound infection on the lateral side after surgery that did not resolve with antibiotics (n=1), infectious sinus formation over the lateral knot after 6 months (n=1) and prominent knot causing skin irritation after 5 months (n=1)[5].

Skin irritation caused by the subcutaneous knot was reported in 19% (7/37) of patients in a case series of 37 patients at a mean follow-up of 24 months. Six per cent (6/64) of the devices (used in 4 patients) needed removal and 3 resolved without device removal[6].

Device removal was reported in 2 patients in the suture fixation group (n=12) in a retrospective comparative case series of 35 patients[8].Reasons for removal were small stich abscess in the medial ankle wound in 1 patient and peroneal nerve injury with neurapraxia and osteochondral defect in 1 patient 3 months after suture fixation.

Superficial wound infection

Superficial infection (resolved with oral antibiotics) was reported in 8% (3/37) of patients in the case series of 37 patients with sustained distal tibiofibular disruption at a mean follow-up of 24 months[6].

Superficial wound infection was reported in 3% (3/102) of patients in the case series of 102 patients (further details were not reported)[4].

Delayed skin healing

Delayed healing of the skin on the lateral side of the ankle (that needed dressing to promote healing) was reported in 1 patient in the case series of 24 patients[7].

Device migration and subsidence

Intraosseous migration of the lateral endobutton was reported in 3% (3/102) of patients in the case series of 102 patients (further details were not reported)[4].

Subsidence of the suture buttons into the bone (due to osteolysis of the bone adjacent to the metallic buttons) was reported in 17% (4/24) of patients in the case series of 24 patients. The suture buttons subsided 2–4 mm into the cortex of the fibula or tibia and this was seen on final radiographs at mean 32 month follow-up[7].

Osteolysis

Osteolysis of the bone was reported in 17% (4/24) of patients in the case series of 24 patients (further details were not reported)[7].

Radiological track widening (aseptic osteolysis) and pain surrounding the device was reported in 3% (3/102) of patients in the case series of 102 patients. Devices were removed in 2 of the 3 patients[4].

Pain, swelling or stiffness

Ankle pain, swelling or stiffness or a combination of these 3 symptoms were reported in 44% (44/102) of patients in the case series of 102 patients at a median follow-up of 85 days (further details were not reported)[4].

Thromboembolic events

Non-fatal pulmonary emboli were reported in 2% (2/102) of patients in the case series of 102 patients at a median follow-up of 85 days (further details were not reported)[4].

Symptomatic deep vein thrombosis was reported in 2% (2/102) of patients in the case series of 102 patients at a median follow-up of 85 days (further details were not reported)[4].

Tendon entrapment from the medial button

Tibialis anterior tendon entrapment from the medial suture button (in close proximity to the peroneal nerve) in the immediate postoperative period was reported after double suture fixation in a case report of 1 patient with refracture of a Weber B, bimalleolar ankle fracture and distal tibiofibular diastasis. This was because the surgeon altered the angle of the second suture in the coronal plane. The offending suture and a screw were removed and a second suture was

inserted through the plate. Paraesthesia resolved completely and the patient returned to prefracture mobility after 6 weeks[9].

Heterotopic ossification of syndesmosis ligaments

Heterotopic ossification within syndesmosis intraosseous ligaments adjacent to the sutures (seen on CT) at 5, 14 and 18 months was reported in13% (3/24) of patients in the case series of 24 patients. One patient had moderate heterotopic bone within the substance of the intraosseous ligament adjacent to the sutures. Two patients had extensive ossification of the intraosseous ligament and posterior tibiofibular ligament with local bridging of syndesmotic interval by the heterotopic bone[7].

Partial syndesmosis ossification without complete synostosis was reported in 1 patient each in the dynamic suture fixation and static screw fixation groups in a randomised controlled trial of 70 patients[1].

Distal tibiofibular synostosis

Distal tibiofibular synostosis following suture fixation of an ankle fracture with syndesmotic instability was reported in a case report of 1 patient. At 6 weeks radiographs showed some signs of callus formation between the tibia and the fibular, with synostosis and anterior ankle pain occurring by 1 year (management details were not reported)[10].

Enlargement of suture tunnels

Enlargement of suture drill holes in the tibia and fibula were reported in some patients in the case series of 24 patients[7]. Further details were not reported.

Pathologic tibia/fibula fracture

Acute fracture of the tibia and fibula through the suture button fixation tunnel, previously done for syndesmotic disruption, which resulted from a persistent stress riser related to the suture button fixation drill holes was reported after 2 years in a case report of 1 patient. The suture device was removed without difficulty and open reduction and internal fixation was done. At 12 months the patient returned to high-intensity sport activity and radiographs revealed a well-healed tibia and fibula[11].

Syndesmosis widening

Syndesmosis widening was reported in 11% (2/18) of patients in a case series of 18 patients[12].

Validity and generalisability of the studies

- There is only 1 high-quality study (randomised controlled trial) comparing suture fixation against screw fixation[1].

- Studies were mainly case series with small number of patients and short-term follow-up. The longest available follow-up is an average of approximately 26 months.
- Two studies[2,5] used a modified technique to prevent soft tissue complications and subsequent device removal.
- Three studies used more than 1 suture fixation device in some patients[2,5,7].

Existing assessments of this procedure

There were no published assessments from other organisations identified at the time of the literature search.

Related NICE guidance

There is currently no NICE guidance related to this procedure.

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society.

Mr Bill Harris, Mr Ronald Russell, Mr Solan Matthew, British Orthopaedic Foot and Ankle Society; Mr Anish Amin, Mr Robert Elliot, Orthopaedic Trauma society.

- Two specialist advisers have done this procedure regularly, 2 advisers have done it at least once and 1 adviser has never done this procedure.
- Two specialist advisers considered this procedure as an established practice and no longer new as the device has been used to treat syndesmosis injuries for 10 years. Two advisers considered that the procedure is definitely novel and of uncertain safety and efficacy. One adviser considered it to be a minor variation of an existing procedure which is unlikely to alter the procedure's efficacy and safety.
- Syndesmotic fixation with screws is the comparator for this procedure.
- One specialist adviser stated that fewer than 10% of specialists are engaged is this area of work. Three advisers stated that 10–50% of specialists are

engaged in this area of work. One adviser stated that he cannot give an estimate.

- Efficacy outcomes include maintaining ankle stability and anatomical reduction of the tibiofibular syndesmosis (assessed on X-rays or CT postoperatively) and assessment of ankle pain, function and range of movement using common foot and ankle scoring systems (the American Orthopaedic Foot and Ankle Society [AOFAS] score, Olerud and Molander Ankle Score [OMAS] and The Manchester–Oxford Foot Questionnaire [MOXFQ]). Advisers stated that there is uncertainty whether there is an advantage over existing stabilisation methods and for use in chronic injuries. Some other concerns include fixation strength, ability to maintain reduction of syndesmosis, knot prominence, concerns about soft tissue irritation, number of devices needed, infection risk and device removal difficulties.
- Theoretical adverse events listed include bone tunnel enlargement, infection, aseptic osteolysis, unexplained pain, painful aseptic osteolysis, knot prominence, soft tissue irritation, loss of fixation or stability of the syndesmosis (rediastasis, especially in the elderly with osteopenia or osteoporosis), malreduction of the syndesmosis prior to fixation, suture failure, need for removal, and fracture after bone tunnel widening.
- Anecdotal events reported include problems tightening the device sufficiently and malreduction or failure due to soft tissue interposition (medial endobutton).
- Specialist advisers stated that minimal specific training (with operative technique) is needed for surgeons before they do this procedure. Image intensifier guidance is also needed.
- Four advisers stated that the procedure is likely to be carried out in most district general hospitals and trauma centres managing ankle injuries as it is widely known or recognised. One adviser stated that he cannot predict the proportion of doctors likely to perform the procedure. One adviser stated that usage is likely to spread quickly if an efficacy and safety profile is established. One adviser stated that speed of diffusion of this procedure is high, if cost

effective. It would have the distinct advantage of avoiding a second operation to remove the metallic screw and avoiding problems with broken syndesmotic screws.

- Two advisers stated that the potential impact on the NHS is minor. One of the advisers stated that the device has significant resource- and cost-saving potential, but the volume of cases for which it is used is modest. One adviser stated that the impact on the NHS is moderate while another considered it as major because the primary cost of the device is significantly higher than the traditional screw fixation and will be primarily used in the acute setting for syndesmotic disruption associated with ankle fractures.

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Issues for consideration by IPAC

- One of the studies used a modified technique in some cases at a certain point during the study which involves burying the lateral knot subperiosteally. In these cases, there were good results with no cases of soft tissue irritation at follow-up.
- The same device is used elsewhere in orthopaedic and trauma surgery.
- Ongoing trials:
  - NCT01275924: Tightrope or screw fixation of acute tibiofibular syndesmotic injury (TIGHTROPE-SS). Randomised controlled trial (TightRope vs syndesmotic screw); study type: randomised trial; estimated enrolment: n=100; primary outcome: modified AOFAS score; location: Norway; completion date: December 2014 (not published).
  - NCT01742650: Screw versus Tightrope syndesmotic injury fixation in Weber C ankle fractures; study type: prospective study; estimated enrolment: n=38; primary outcome: malreduction of the tibiofibular joint in

intraoperative computed tomography; location: Finland; completion date: December 2011 (study completed).

References

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2. Cottom JM, Hyer CF et al (2009). Transosseous fixation of the distal tibiofibular syndesmosis: comparison of an interosseous suture and endobutton to traditional screw fixation in 50 cases. Journal of Foot & Ankle Surgery 48: 620-630.
3. Naqvi GA, Cunningham P et al (2012). Fixation of ankle syndesmotic injuries: comparison of tightrope fixation and syndesmotic screw fixation for accuracy of syndesmotic reduction. American Journal of Sports Medicine 40: 2828-2835.
4. Storey P, Gadd RJ et al (2012). Complications of suture button ankle syndesmosis stabilization with modifications of surgical technique. Foot & Ankle International 33: 717-721
5. Naqvi GA, Shafqat A, and Awan N (2012). Tightrope fixation of ankle syndesmosis injuries: clinical outcome, complications and technique modification. Injury 43: 838-842
6. Rigby RB and Cottom JM (2013). Does the Arthrex TightRope provide maintenance of the distal tibiofibular syndesmosis? A 2-year follow-up of 64 TightRopes in 37 patients. Journal of Foot & Ankle Surgery 52: 563-567.
7. DeGroot H, Al-Omari AA et al (2011). Outcomes of suture button repair of the distal tibiofibular syndesmosis. Foot & Ankle International. 32: 250-256
8. Maempel J, Ward A et al (2014). Use of tightrope fixation in ankle syndesmotic injuries. Chinese Journal of Traumatology 17: 8-11
9. Welck MK and Ray P (2013). Tibialis anterior tendon entrapment after ankle tightrope insertion for acute syndesmosis injury. Foot & Ankle Specialist 6: 242-246.
10. Mason LW, Dodds A et al (2010). Tibiofibular synostosis following syndesmosis fixation: A case report. The Foot and Ankle Online Journal 3: 3.
11. Hohman DW, Alfonso J et al (2011). Pathologic tibia/fibula fracture through a suture button screw tract: case report. The American journal of sports medicine. 39: 645-648.
12. Treon K, Beastall JE et al (2011). Complications of ankle syndesmosis stabilisation using a tightrope. The Journal of Bone and Joint Surgery. 1: 62.

Appendix A: Additional papers on suture fixation of acute disruption of the distal tibiofibular syndesmosis

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article	Number of patients/follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Coetzee JC and Ebeling P (2008).Treatment of syndesmosis disruptions with TightRope fixation. Techniques in Foot and Ankle Surgery.7:196-202	Provide an overview of the important anatomical and biomechanical issues relating to syndesmosis injuries and to present the surgical technique and potential advantages of fixation with the TightRope implant (Arthrex Inc, Naples, Fla). The short-term results of an ongoing prospective, randomized clinical trial are also presented.		Mainly technical description paper. Discusses results from Thornes 2005.
Cottom JM, Hyer CF et al (2008). Treatment of syndesmotic disruptions with the Arthrex Tightrope: a report of 25 cases. Foot & Ankle International. 29: 773-780	Prospective case series n=25 patients with disruption of the distal tibiofibular articulation Treatment with an Arthrex Tightrope (in 21 a single Tightrope was placed, and in 4, two Tightropes used). Follow-up: average 10.8 months.	The mean time to full weight bearing was 5.5 (range, 2 to 8) weeks. Postoperative radiographic analysis of the mean distance from the tibial plafond to the placement of the Tightrope(s), medial clear space, average postoperative tibiofibular overlap and the mean tibiofibular clear space demonstrated no evidence of re-displacement of the syndesmotic complex at an average of 10.8 (range, 6 to 12) months. The modified AOFAS hindfoot scoring scale and SF-12 both demonstrated significant improvements; preoperative values were assessed in the office with the first patient visit as they are incorporated into the patient intake form that each patient fills out at the initial visit.	Small number of cases and short term follow-up. There is an overlap, with Cottom 2009 (same series was compared to a series of syndesmosis screw fixation patients).
den Daas A, van Zuuren WJ et al (2012). Flexible stabilization of the distal tibiofibular syndesmosis: clinical and biomechanical	Review orthopaedic trauma literature, both biomechanical and clinical, and present the current knowledge on suture-button fixation	5 biomechanical and 6 clinical studies were reviewed. The suture button demonstrated good resistance to axial and rotational loads (equivalent to screws) and resistance to	Narrative review (systematic) but literature not up to date.

considerations: a review of the literature. Strategies in Trauma & Limb Reconstruction. 7:123-129	and put emphasis on advantages and disadvantages. Searched databases up to March 2011 according to selection criteria.	failure. Physiologic motion of the syndesmosis was restored in all directions. The clinical studies (149) ankles demonstrated good functional results using the AOFAS score, indicating faster rehabilitation with flexible fixation than with screws. There were few complications. Preliminary results from the current literature support the use of suture-button fixation for syndesmotic ruptures. This method seems secure and safe. As there is no strong evidence for its use, prospective randomized controlled trials to compare the suture-button to the screw fixation for ankle syndesmotic ruptures are required.	
Hong CC, Lee WT and Tan KJ (2015). Osteomyelitis After TightRope Fixation of the Ankle Syndesmosis: A Case Report and Review of the Literature. Journal of Foot & Ankle Surgery 54 (1) 130-134.	Case report n=1 Fixation of ankle syndesmosis injuries using Ankle TightRope	The procedure has shown good results, facilitated early weight bearing, reduced the need for implant removal, and allowed an earlier return to work and, possibly, a more anatomic syndesmotic reduction compared with screw fixation. However, it has been associated with complications such as soft tissue irritation, infection and wound breakdown, suture-button subsidence, and pathologic fracture from the screw tract. We describe a case of chronic osteomyelitis and suture-button migration associated with TightRope fixation and a limited contact-dynamic compression plate for ankle syndesmosis disruption and lateral malleolus fracture.	Larger studies included in table 2.
Qamar F, Kadakia A, and Venkateswaran B (2011). An anatomical way of treating ankle syndesmotic injuries. Journal of Foot & Ankle Surgery. 50: 762-765	Retrospective case series n=16 patients (ankles) with evidence of tibiofibular syndesmotic injury Treated by ankle fracture open reduction with internal fixation, combined with use of the Ankle TightRope Mean follow-up: 26 months.	The mean American Orthopaedic Foot and Ankle Society score at 2-year follow-up was 86.88 + 11.49 (range 48 to 100). The mean time to full weight-bearing was 4.5 + 0.87 weeks. Two (12.5%) patients had postoperative superficial wound infections, each of which was treated with oral antibiotics. One (6.25%) patient had the TightRope removed because of irritation from the knot. There was no failure of	Larger studies with similar follow-up included in table 2.

		syndesmotic fixation, despite early weight-bearing in the postoperative phase.	
Schepers T (2012). Acute distal tibiofibular syndesmosis injury: a systematic review of suture-button versus syndesmotic screw repair. [Review] International Orthopaedics. 36: 1199-120	Systematic review Tightrope (6 biomechanical studies 7 clinical studies 4 abstracts) screw/bolt fixation (27 studies)	AOFAS score for 133 patients treated with Tightrope was 89.1 points. Average study follow-up was 19 months. AOFAS score for 253 patients treated with screws/bolts was 86.3 points with an average follow-up of 42 months. 2 studies reported earlier return to work in the Tightrope group. Implant removal was reported in 10% (22/220) treated with a Tightrope (range 0-25%), in the screw group, it was 51% of 866 patients (range 5.8-100%)	Although a systematic review, this is not a meta-analysis and included only 7 clinical studies and 4 abstracts as well. There are no detailed information/analyses about safety events and the reasons for device removal.
Thornes, B and McCartan, D (2006). Ankle syndesmosis injuries treated with the TightRope suture-button kit. Techniques in Foot and Ankle Surgery.5: 45-53	Technical description, Case series n=12 +case review. Patients with Weber Type C ankle fractures (5 had ankle fracture dislocations, 9 had fibular plate fixation in addition to syndesmosis fixation, 3 patients with Maisonneuve injuries had syndesmosis fixation only). Tightrope syndesmosis fixation. Follow-up: 6 months.	Rehabilitation is faster, an obvious advantage to the professional athlete, but also benefits the average patient, who will be able to return to the workplace sooner. There were no major complications, loss of reduction, wound problems, implant loosening or osteolysis. Mean AOFAS score was 87 at follow-up. Joint dislocations, age older than 50 years, female sex, were all associated with a poorer outcome. Outcome in patients with fracture comminution type C2 was worse than simple fractures (C1) or Maisonneuve fractures. Mean ankle dorsiflexion at follow-up was 4.3 degrees beyond neutral and 8.7 degrees on the uninjured side. All 8 patients who were in employment returned to work at an average 11 weeks. No patient needed second surgery for any reason, including removal.	Paper mainly describes the technique. It also reports a short section on outcomes in 12 patients and a case review. Not sure if these patients overlap with the study above (Thornes 2005).
Thornes B, Shannon F, Guiney AM et al (2005). Suture-button syndesmosis fixation: accelerated rehabilitation and improved outcomes. Clinical Orthopaedics & Related Research. 431: 207-212	Prospective comparative case series Patients with Weber type C ankle fractures n=16 suture-button fixation versus 16 screw fixation for syndesmosis (Tightrope prototype device was used)	Mean American Orthopaedic Foot and Ankle Society ankle scores were significantly better in patients who had suture-button fixation than in a comparative group of 16 patients who had syndesmosis screw fixation at 3 months (91 versus 80, respectively) and at 12	Small study with short term follow-up. A prototype device was used in this study.

	Follow-up: 3 months and 12 months.	months postoperatively (93 versus 83, respectively). Return to work was faster (2.8 months in patients who had suture-button fixation versus 4.6 months who had syndesmosis screw fixation), and no patients who had suture-buttons required secondary surgery for implant removal. Axial computed tomography scanning at 3 months showed maintenance of reduction. Suture-button fixation is simple, safe, and effective. Patients have had improved outcomes and faster rehabilitation, without needing routine implant removal. It may become the treatment of choice in patients with a syndesmosis injury.	
Van J and Lafferty M (2014). Injuries to the ankle syndesmosis. Journal of Bone & Joint Surgery, American Volume. 96: 603-614		Despite being common, syndesmotic injuries are challenging to diagnose and treat. Anatomic reduction of the ankle syndesmosis is critical for good clinical outcomes. Intraoperative three-dimensional radiography and direct syndesmotic visualization can improve rates of anatomic reduction. The so-called gold-standard syndesmotic screw fixation is being brought increasingly into question as new fixation techniques emerge. Syndesmotic screw removal remains controversial, but may allow spontaneous correction of malreductions.	Review of different treatments and a summary of recommendations for care.
Willmott HJ, Singh B, and David LA (2009). Outcome and complications of treatment of ankle diastasis with tightrope fixation. Injury. 40:1204-1206	Retrospective case series n=6 Patients with ankle diastasis (4 Weber C fractures, 1 Maisonneuve fracture and 1 isolated diastasis without fracture) Suture fixation (Tightrope) applied through a plate in 3 cases and directly through the fibula in 3 cases. Mean follow-up: 5.3	In 2 cases device caused soft-tissue irritation with granuloma formation, necessitating subsequent removal, 1 after six months, and 1 after 10 months. Histological examination revealed refractile material within giant cells, suggestive of foreign-body reaction. Average time to weight bearing was 6 weeks (range 4-8). In all cases the syndesmosis was reduced and held, even after device removal. Functional outcome was good and patients were satisfied. This series shows that there is a significant	Larger studies with longer follow-up included in table 2.

	months.	incidence of soft-tissue complications with the use of Tightrope fixation and subsequent need for removal.	

Appendix B: Related NICE guidance for suture fixation of acute disruption of the distal tibiofibular syndesmosis

There is currently no NICE guidance related to this procedure.

Appendix C: Literature search for suture fixation of acute disruption of the distal tibiofibular syndesmosis

Databases	Date searched	Version/files	No. retrieved
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	08/01/2015	Issue 1 of 12, January 2015	3
Database of Abstracts of Reviews of Effects – DARE (Cochrane Library)	08/01/2015	Issue 4 of 4, October 2014	0
HTA database (Cochrane Library)	08/01/2015	Issue 4 of 4, October 2014	0
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	08/01/2015	Issue 12 of 12, December 2014	11
MEDLINE (Ovid)	08/01/2015	1946 to November Week 3 2014	10
MEDLINE In-Process (Ovid)	08/01/2015	January 07, 2015	14
EMBASE (Ovid)	08/01/2015	1974 to 2015 Week 01	16
CINAHL (NLH Search 2.0)	08/01/2015	n/a	31
PubMed	08/01/2015	n/a	13
JournalTOCS	08/01/2015	n/a	1

Trial sources searched

- National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC) Portfolio Database
- Current Controlled Trials *meta*Register of Controlled Trials – *m*RCT
- Clinicaltrials.gov

Websites searched on

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- French Health Authority (FHA)
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)

- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- Conference websites
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

1	arthrex.tw.
2	tightrope.tw.
3	fibrewire.tw.
4	Suture Techniques/
5	Suture Anchors/
6	Internal Fixators/
7	((sutures or suture) adj4 (endobutton* or button* or anchor*)).tw.
8	or/1-7
9	Ankle Joint/
10	ankle fractures/
11	Ankle Injuries/
12	((ankle* or malleolus or trimalleolar or bimalleolar or syndesmosis or syndesmoses or syndesmotic or tibiofibular) adj4 (broke* or fracture* or diastasis or rupture* or disrupt* or injur* or sprain*)).tw.
13	((maissonneuve or galeazzi) adj4 (fracture* or injur*)).tw.
14	or/9-13
15	8 and 14
16	animals/ not humans/

17	15 not 16