NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of autologous blood injection for plantar fasciitis

Treating plantar fasciitis by injecting patients with their own blood

Plantar fasciitis occurs when the connective tissue between the heel and the middle of the foot deteriorates. This usually happens because of overuse or injury, and it causes foot pain. In autologous blood injection, blood is taken from the patient and injected into the area around the affected tissue. Sometimes the blood is separated into red blood cells and platelets (cell fragments that produce substances called growth factors) before injecting the sample containing mainly platelets. The aim is to supply the connective tissue with growth factors that promote the healing process.

Introduction

The National Institute for Health and Clinical Excellence (NICE) has prepared this 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 overview was prepared in May 2012 and updated in November 2012.

Procedure name

Autologous blood injection for plantar fasciitis.

Specialist societies

British Orthopaedic Association

British Society of Skeletal Radiologists

British Society of Rheumatology

Description

Indications and current treatment

Plantar fasciitis is generally a self-limiting condition characterised by a painful inflammatory process involving the plantar fascia, causing pain on the underside of the heel. It is usually caused by overuse, injury or biomechanical abnormalities and may be associated with microtears, or fibrosis.

Conservative treatments include rest, analgesics, anti-inflammatory medication, use of orthotic devices, eccentric exercise, stretching and physiotherapy. Local injection of steroids, extracorporeal shockwave therapy and surgery to release the plantar fascia from the bone or to relieve muscular tightness are sometimes used for patients with refractory symptoms.

What the procedure involves

Autologous blood injection (using whole blood or platelet-rich plasma) is claimed to promote healing through the action of growth factors.

A variable amount of blood is withdrawn from the patient by standard venesection and injected into the area around the damaged plantar fascia. There is a lot of variation in how the procedure is performed. Sometimes the blood is centrifuged to produce a platelet-rich sample, which aims to deliver a greater concentration of growth factors. About 2–3 ml of whole blood or platelet-rich plasma is injected into the plantar fascia, sometimes with ultrasound guidance. Local anaesthetic is usually used; it is sometimes mixed with the blood before it is re-injected. Before injection, 'dry needling' (repeatedly passing a needle through the plantar fascia to disrupt the fibres and induce bleeding) may be performed. A peppering technique is sometimes used to inject the autologous blood; this involves inserting the needle into the fascia, injecting some of the blood, withdrawing without emerging from the skin, slightly redirecting and reinserting. After the procedure, patients are usually advised to avoid high-impact activities for approximately 2 weeks, and to follow a programme of stretching exercises. The procedure may be repeated if needed (usually after 3 months).

Outcome measures

Roles and Maudsley score

The Roles and Maudsley score is a subjective 4-point patient assessment of pain and limitations of activity:

- excellent: no pain, patient satisfied with treatment outcome, and unlimited walking without pain
- good: substantially decreased symptoms, patient satisfied with treatment outcome, and ability to walk without pain for >1 hour

- acceptable: symptoms somewhat decreased, pain at a more tolerable level, and patient slightly satisfied with treatment outcome
- poor: symptoms identical or worse and patient not satisfied with the treatment outcome.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to autologous blood injection for plantar fasciitis. Searches were conducted of the following databases, covering the period from their commencement to 20 September 2012: 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 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 plantar fasciitis.
Intervention/test	Autologous blood injection.
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 overview

This overview is based on approximately 278 patients from 3 randomised controlled trials, 2 non-randomised comparative study and 3 case series[1–8].

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 autologous blood injection for plantar fasciitis

Abbreviations used: ABI, autologous blood injection; PRP, platelet-rich plasma; SD, standard deviation; TT, tenderness threshold; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Lee TG (2007)[1]

Randomised controlled trial
Malaysia
Recruitment period: 2005–6
Study population: adults with plantar fasciitis for more than 6 weeks
n=64 (33 ABI vs 31 corticosteroid)
Age range (years): 28–66
Sex: 91% (57/63) female
Mean duration of symptoms: 8 months

Patient selection criteria: inclusion criteria were plantar heel pain (worse on rising in the morning and/or after periods of sitting or lying) for more than 6 weeks and maximal tenderness at the attachment of the plantar fascia on the medial tubercle of the calcaneus. Exclusion criteria were previous surgery for heel pain, nerve-related symptoms, regional pain syndrome, Achilles tendon pathology, rheumatoid arthritis, diabetes, local or systemic infection, peripheral vascular disease, metabolic disease (such as gout), clotting disorder, anticoagulant therapy, pregnancy, dysfunction of the knee, ankle or foot, and work-related or compensable injury.

Technique: For ABI, 1.5 ml of autologous blood was mixed with 1 ml of lignocaine hydrochloride 2%. For corticosteroid injection, 0.5 ml of triamcinolone acetonide was mixed with 2 ml of lignocaine hydrochloride 1%. After injection all patients were allowed to walk but were advised to avoid impact-loading activities, such as running or jumping, for at least 10 days. Non-steroidal anti-inflammatory drugs were prescribed for not more than 3 days. All patients were instructed to follow a standardised stretching programme for the Achilles tendon and the plantar fascia. No additional form of</td>
<td>Number of patients analysed: 61 (30 vs 31)

Mean pain scores (VAS, lower scores indicate less pain)
<table>
<tr><th>Follow-up period</th><th>ABI</th><th>Cortico-steroid</th><th>p value (between groups)</th></tr>
<tr><td>Baseline</td><td>7.3±1.8</td><td>6.9±1.7</td><td>0.306</td></tr>
<tr><td>6 weeks</td><td>4.6±2.3</td><td>2.9±2.8</td><td>0.011</td></tr>
<tr><td>3 months</td><td>4.3±2.7</td><td>2.3±2.6</td><td>0.005</td></tr>
<tr><td>6 months</td><td>3.6±2.6</td><td>2.4±3.0</td><td>0.094</td></tr>
</table>
At 6 months, the reduction in pain levels from baseline was statistically significant in both groups (p<0.0001).

Repeated measures F test showed no significant difference in improvement between the two groups over time (p=0.093).

Mean TT scores (kg/cm^2, higher scores indicate less tenderness)
<table>
<tr><th>Follow-up period</th><th>ABI</th><th>Cortico-steroid</th><th>p value (between groups)</th></tr>
<tr><td>Baseline</td><td>3.1±1.2</td><td>3.7±2.0</td><td>0.167</td></tr>
<tr><td>6 weeks</td><td>4.1±1.8</td><td>6.4±3.5</td><td>0.003</td></tr>
<tr><td>3 months</td><td>5.5±2.7</td><td>7.9±3.2</td><td>0.003</td></tr>
<tr><td>6 months</td><td>6.5±2.9</td><td>8.6±3.1</td><td>0.008</td></tr>
</table>
At 6 months, the increase in TT from baseline was statistically significant in both groups (p<0.0001).

Repeated measures F test showed no significant difference in improvement between the two groups over time (p=0.051).

Non-responders (no change in VAS score):
• ABI=10.0% (3/30)
• Corticosteroid=9.7% (3/31)

Non-responders (no change in TT score):
• ABI=3.3% (1/30)
• Corticosteroid=3.2% (1/31)

Number of patients who received a second injection</td>
<td>The report states that there was no fat atrophy, infections or rupture of the plantar fascia.

All patients found the injection painful.

Post-injection pain (requiring analgesia, ice application or both):
• ABI=53.3% (16/30)
• Corticosteroid= 12.9% (4/31)
(Mean duration of symptoms was 7 days in the ABI group and 5 days in the corticosteroid group).</td>
<td>Follow-up issues:
• 4.7% (3/64) of patients were lost to follow-up, all of whom were treated by autologous blood injection.

Study design issues:
• Computer-generated randomisation was used.
• The assessment was done by a doctor who was blinded to the treatment allocation.
• Pain was rated in a visual analogue scale, with 0 indicating no pain and 10 the worst imaginable pain.
• TT was measured using a pressure algometer. The maximal pressure applied was 11 kg/cm^2 and if no pain could be elicited at this pressure, TT was defined as 11 kg/cm^2.

Study population issues:
• The two groups were similar with regard to age, gender, weight, body mass index, range of dorsiflexion of the ankle joint, presence of a calcaneal spur and duration of symptoms before treatment.</td>
</tr>
</table>

Abbreviations used: ABI, autologous blood injection; PRP, platelet-rich plasma; SD, standard deviation; TT, tenderness threshold; VAS, visual analogue scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
treatment was permitted during the study period, including orthoses, night splints and non-steroidal anti-inflammatory drugs. Repeat injection was offered if necessary (all repeat injections were given at 3 months from baseline treatment). **Follow-up: 6 months** Conflict of interest/source of funding: not reported	**(given at 3 months from baseline):** • ABI=10.0% (3/30) • Corticosteroid=6.5% (2/31)		

Abbreviations used: ABI, autologous blood injection; PRP, platelet-rich plasma; SD, standard deviation; TT, tenderness threshold; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Kiter E (2006)[2]

Randomised controlled trial
Turkey
Recruitment period: not reported
Study population: patients with plantar heel pain
n=45 (15 ABI vs 15 corticosteroid injection vs 15 peppering technique alone)
Mean age: 51 years (range 26–70)
Sex: 69% (31/45) female
Mean duration of symptoms: 19 months

Patient selection criteria: patients whose conservative treatment for a minimum of 6 months failed. Exclusion criteria included corticosteroid injection for heel pain within the last year, presence of inflammatory or severe metabolic disease, morbid obesity and presence of lower-limb deformity with functional deficit.

Technique: in the peppering technique group, after infiltration of 1 ml of 2% prilocaine, the needle was inserted, withdrawn, slightly redirected and reinserted 10 to 15 times without emerging from the skin. In the ABI group, a mixture of 2 ml of autologous blood and 1 ml of 2% prilocaine was infiltrated. In the corticosteroid group, 40 mg of methylprednisolone acetate mixed with 1 ml of 2% prilocaine was injected (repeat injections were done at 1-month intervals).

Follow-up: 6 months
Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 44 (15 vs 14 vs 15)

Number of injections needed by group (timing of injections not reported for ABI and peppering; corticosteroid injections were given at 1-month intervals)
<table>
<tr><td></td><td colspan="4">Number of patients</td></tr>
<tr><td>Group</td><td>Total</td><td>First injection</td><td>Second injection</td><td>Third injection</td></tr>
<tr><td>ABI</td><td>15</td><td>2</td><td>3</td><td>10</td></tr>
<tr><td>Cortico-steroid</td><td>14</td><td>7</td><td>7</td><td>0</td></tr>
<tr><td>Peppering technique</td><td>15</td><td>4</td><td>4</td><td>7</td></tr>
</table>
VAS score at baseline and 6-month follow-up (mean±SD)
<table>
<tr><td></td><td colspan="2">VAS score</td><td></td></tr>
<tr><td>Group</td><td>Baseline</td><td>6-month follow-up</td><td>p value</td></tr>
<tr><td>ABI</td><td>7.6±1.3</td><td>2.4±1.8</td><td><0.001</td></tr>
<tr><td>Cortico-steroid</td><td>7.3±1.2</td><td>2.6±2.9</td><td><0.001</td></tr>
<tr><td>Peppering technique</td><td>6.4±1.1</td><td>2.0±2.2</td><td><0.001</td></tr>
</table>
Rearfoot score at baseline and 6-month follow-up (mean±SD)
<table>
<tr><td></td><td colspan="2">Rearfoot score</td><td></td></tr>
<tr><td>Group</td><td>Baseline</td><td>6-month follow-up</td><td>p value</td></tr>
<tr><td>ABI</td><td>71.6±14</td><td>80.9±13.9</td><td>0.025</td></tr>
<tr><td>Cortico-steroid</td><td>65.7±12.7</td><td>80.1±17.5</td><td>0.030</td></tr>
<tr><td>Peppering technique</td><td>64.1±15.1</td><td>78.2±12.4</td><td>0.018</td></tr>
</table>
There were no statistically significant differences between the groups.</td>
<td>No complications were reported.

The authors noted that pain was a major complaint of patients treated by peppering without local anaesthetic (performed early in the study).</td>
<td>Follow-up issues:
1 patient in the corticosteroid injection group discontinued the study at 3 months (moved to another city).
Study design issues:
Patients were allocated to 1 of 3 groups by drawing lots.
Results of the outcome measure scores were collected by an independent observer who had no information about the patients.
Clinical improvement was evaluated using a 10 cm VAS and the Rearfoot score of the American Orthopaedic Foot and Ankle Society. The Rearfoot score includes subjective and objective measures and has a scale of 0–100 with higher scores indicating less pain and better function (the scoring system was not described in the paper).
Study population issues:
The groups were similar with regard to age, sex, body mass index, duration of complaints and pain level before the injections.</td>
</tr>
</table>

Abbreviations used: ABI, autologous blood injection; PRP, platelet-rich plasma; SD, standard deviation; TT, tenderness threshold; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Kalaci A (2009)[3]

Non-randomised comparative trial
Turkey
Recruitment period: not reported
Study population: patients with plantar fasciitis
n=100 (25 ABI vs 25 local anaesthetic combined with peppering vs 25 corticosteroid injection vs 25 corticosteroid combined with peppering)
Mean age: 51 years (range 30–79)
Sex: 70% (70/100) female
Mean duration of symptoms: 9 months

Patient selection criteria: exclusion criteria included previous injections for plantar fasciitis, surgery for plantar fasciitis in the previous 6 months, associated conditions involving the lower limb and abnormal erythrocyte sedimentation rate or C-reactive protein level.

Technique: ABI involved local injection of autologous blood alone. Each patient had only a single injection. No restriction of activity was advised.

Follow-up: 6 months

Conflict of interest/source of funding: none</td>
<td>Number of patients analysed: 100 (25 vs 25 vs 25 vs25)

Pain in the affected heel (VAS)
<table>
<tr><td></td><td colspan="3">Mean VAS score (SD)</td></tr>
<tr><td></td><td>Baseline</td><td>3 week follow-up</td><td>6 month follow-up</td></tr>
<tr><td>ABI</td><td>6.84 (2.27)</td><td>4.32 (2.93)</td><td>3.53 (3.06)</td></tr>
<tr><td>Local anaesthetic with peppering</td><td>6.72 (1.74)</td><td>4.56 (2.45)</td><td>3.40 (2.88)</td></tr>
<tr><td>Corticosteroid injection</td><td>6.96 (2.71)</td><td>3.04 (2.32)</td><td>1.52 (2.14)</td></tr>
<tr><td>Corticosteroid with peppering</td><td>7.24 (2.22)</td><td>2.20 (2.45)</td><td>0.96 (1.24)</td></tr>
</table>
‘The rates of success in all groups were higher after injections compared with the pre-treatment condition (p=0.000).’

VAS scores of pain at 6 months were significantly higher in the ABI and local anaesthetic with peppering groups than the groups receiving corticosteroid injections (p<0.05).

Outcomes according to modified Roles and Maudsley scores at 6 months
<table>
<tr><td></td><td colspan="4">Modified Roles and Maudsley score (number of patients)</td></tr>
<tr><td>Group</td><td>Excellent</td><td>Good</td><td>Acceptable</td><td>Poor</td></tr>
<tr><td>ABI</td><td>6</td><td>9</td><td>6</td><td>4</td></tr>
<tr><td>Local anaesthetic with peppering</td><td>4</td><td>9</td><td>4</td><td>8</td></tr>
<tr><td>Corticosteroid injection</td><td>10</td><td>10</td><td>5</td><td>0</td></tr>
<tr><td>Corticosteroid with peppering</td><td>16</td><td>6</td><td>3</td><td>0</td></tr>
</table>
There was a statistically significant difference between corticosteroid injection and ABI and local anaesthetic with peppering (p<0.05). The difference between the 2 corticosteroid groups was not statistically significant (p=0.24).</td>
<td>All patients found the injection to be painful.

No complications attributable to the injections (such as hypopigmentation of the skin, haematoma or infection) were observed during the study.

No complications attributable to local effects of corticosteroids (such as tendon rupture) were observed in the corticosteroid groups.</td>
<td>Follow-up issues:
No losses to follow-up were described.
Study design issues:
Prospective study.
The paper described this as a randomised controlled trial but there is no mention of any randomisation. The first 25 consecutive patients were allocated to ABI, the second to local anaesthetic and peppering, the third to corticosteroid alone, and the last 25 to corticosteroid combined with peppering.
Patients were blinded to the type of injection they received.
Patients were evaluated by reviewers who were ‘blinded to the study method’.
Patient-assessed pain was measured using a VAS from 0 to 10, where 0 is no pain and 10 is the worst imaginable pain or stiffness, and modified Roles and Maudsley scores (‘excellent’, ‘good’, ’acceptable’ or ’poor’).
Study population issues:
There was no statistically significant difference between groups with regard to age, body mass index and baseline VAS.
Other issues:
The authors noted that 2 additional groups of patients</td>
</tr>
</table>

Abbreviations used: ABI, autologous blood injection; PRP, platelet-rich plasma; SD, standard deviation; TT, tenderness threshold; VAS, visual analogue scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
	An 'excellent' or 'good' score was considered to be a successful outcome.		were formed as part of the study. Peppering was used with saline in 1 group and with autologous blood in the other. However, these were discontinued after the first few patients because the procedures caused too much pain.

Abbreviations used: ABI, autologous blood injection; PRP, platelet-rich plasma; SD, standard deviation; TT, tenderness threshold; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Aksahin E (2012)[4]

Non-randomised comparative trial
Turkey
Recruitment period: not reported
Study population: patients with plantar fasciitis
n=60 (30 ABI vs 30 corticosteroid injection)
Mean age: 46 years
Sex: 58% (35/60) female
Mean duration of symptoms: 9 months

Patient selection criteria: patients with plantar fasciitis refractive to ≥3 months of conservative treatment. Exclusion criteria: history of any previous injection treatment or surgery for heel pain, any other associated pathology involving the lower limb, calcaneal fracture, calcaneal bone cysts, bone tumour, osteomyelitis, Achilles tendinopathy, abnormal erythrocyte sedimentation rate or C-reactive protein level, any systemic disorders (such as diabetes, rheumatoid arthritis) haematological diseases, gout and pregnancy.

Technique: a double centrifugation technique was used to concentrate platelets from 25 ml autologous blood (activated using calcium). ABI involved injecting 3 ml PRP after local anaesthetic injection. Each patient had only a single injection of PRP. After the procedure, patients were not allowed to bear weight for 3 days. They were advised to wear comfortable shoes and avoid all running and other high impact activities for 10 days. A standardised stretching programme for the Achilles tendon and plantar fascia was given to all patients. No additional treatment was permitted during the study period.

Follow-up: 6 months
Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 60 (30 vs 30)

Pain in the affected heel (VAS)
<table>
<tr><td></td><td colspan="3">Mean VAS score (SD)</td><td>p value*</td></tr>
<tr><td></td><td>Baseline</td><td>3 week follow-up</td><td>6 month follow-up</td><td></td></tr>
<tr><td>ABI</td><td>7.3 (0.62)</td><td>5.6 (1.64)</td><td>3.93 (2.02)</td><td>0.001</td></tr>
<tr><td>Corticosteroid injection</td><td>6.2 (1.61)</td><td>4.4 (2.09)</td><td>3.4 (2.32)</td><td>0.001</td></tr>
</table>
* baseline compared with after treatment

Patient satisfaction – outcomes according to modified Roles and Maudsley scores
<table>
<tr><td></td><td colspan="4">Modified Roles and Maudsley score (number of patients)</td></tr>
<tr><td>Group</td><td>Excellent</td><td>Good</td><td>Acceptable</td><td>Poor</td></tr>
<tr><td colspan="5">3 week follow-up</td></tr>
<tr><td>ABI</td><td>1 (3%)</td><td>10 (33%)</td><td>13 (43%)</td><td>6 (20%)</td></tr>
<tr><td>Corticosteroid injection</td><td>2 (7%)</td><td>8 (27%)</td><td>14 (47%)</td><td>6 (20%)</td></tr>
<tr><td colspan="5">6 month follow-up</td></tr>
<tr><td>ABI</td><td>6 (20%)</td><td>4 (13%)</td><td>16 (53%)</td><td>4 (13%)</td></tr>
<tr><td>Corticosteroid injection</td><td>8 (27%)</td><td>6 (20%)</td><td>12 (40%)</td><td>4 (13%)</td></tr>
</table>
There were no statistically significant differences between the groups.</td>
<td>No complications attributable to the injections were observed.</td>
<td>Follow-up issues:
• No losses to follow-up were described.

Study design issues:
• Prospective study.
• Patients were blinded to the type of injection they received.
• Patients were evaluated by a reviewer who was blinded to the injection type.
• Patient-assessed pain was measured using a VAS from 0 to 10, where 0 is no pain and 10 is the worst imaginable pain or stiffness, and modified Roles and Maudsley scores (‘excellent’, ‘good’, ’acceptable’ or’ poor’).

Study population issues:
There was no statistically significant difference between groups with regard to age, body mass index and baseline VAS.</td>
</tr>
</table>

Abbreviations used: ABI, autologous blood injection; PRP, platelet-rich plasma; SD, standard deviation; TT, tenderness threshold; VAS, visual analogue scale			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Scioloi MW (2011)[5] **Case series** USA Recruitment period: not reported Study population: patients with proximal plantar fasciitis **n=30 feet** Age: not reported Sex: not reported Mean duration of symptoms: not reported Patient selection criteria: patients with proximal plantar fasciitis refractory to treatment with corticosteroid injection, night splints, strapping and orthoses. Exclusion criteria included neural entrapment, earlier surgery including endoscopic plantar fascial release or open plantar fascial release, excessive or reactive scar formation and cutaneous neuroma. Technique: harvested blood (20–60 ml) was centrifuged to produce PRP, using the Harvest® system (Terumo Corporation). The posterior tibial nerve and medial calcaneal branch were injected with local anaesthetic before injection of PRP. Dry needling was used and 1 ml PRP was injected in a 'peppering' manoeuvre at 3 to 4 sites of maximal tenderness. No aggressive running or jumping activities were allowed for 2 weeks. Stretching was advised and night splints were used for comfort. **Mean follow-up: not reported** Conflict of interest/source of funding: not reported	Number of patients analysed: **30 feet** **Success of procedure** All but 2 patients had marked reduction in first-step pain and post-rest pain, and improved ability to stand and walk (outcome measures not described). 2 patients needed open surgery. 2 patients had repeat injections, 1 at 6 months and the other at 9 months after the initial PRP injection, with 'good relief of pain' at 1 year.	No complications were reported.	**Follow-up issues**: • The report states that patients were followed up at 6 and 12 weeks, but several patients appear to have been followed up for a longer period. **Study design issues**: • The report states that 30 feet were treated; it is unclear if this also refers to the number of patients.

Abbreviations used: ABI, autologous blood injection; PRP, platelet-rich plasma; SD, standard deviation; TT, tenderness threshold; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Ragab EMS (2012)[6]

Case series
Egypt
Recruitment period: 2010–11
Study population: patients with chronic plantar fasciitis
n=25
Mean age: 44 years
Sex: 56% (14/25) female
Mean duration of symptoms: not reported

Patient selection criteria: patients aged >18 years with chronic plantar fasciitis after failure of conservative treatment for at least 6 months and VAS pain in the morning higher than 5. Exclusion criteria included local steroid injection within 6 months, physical therapy within 6 weeks or non-steroidal anti-inflammatory drugs within 1 week, active bilateral plantar fasciitis, previous surgery for plantar fasciitis, vascular insufficiency or neuropathy related to heel pain, diabetes or other painful or function-limiting disorders of the foot and ankle, pregnancy, history of severe anaemia (haemoglobin <5) and significant cardiovascular, renal or hepatic disease.

Technique: harvested blood (approximately 50 ml) was centrifuged to produce PRP. A peppering technique was used to inject 5 ml PRP into the most tender area of the plantar fascia. Patients were instructed to limit their activities for 48 hours after the procedure. After 2 days, patients were sent to a physiotherapist to start stretching exercises for 2 weeks. At 4 weeks, patients were allowed to start normal recreational activities.

Mean follow-up: 10 months (range 9–13)
Conflict of interest/source of funding: not reported</td>
<td>Number of patients analysed: 25

Mean VAS:
• Baseline=9.1
• ‘late’ follow-up=2.1

Mean thickness of the plantar fascia (mm) (assessed by ultrasound)
<table>
<tr><td></td><td colspan="2">Mean thickness of bands (mm)</td></tr>
<tr><td></td><td>Baseline</td><td>3 months after injection</td></tr>
<tr><td>Medial band</td><td>7.1</td><td>4.8</td></tr>
<tr><td>Central band</td><td>6.6</td><td>5.4</td></tr>
<tr><td>Lateral band</td><td>4.6</td><td>4.6</td></tr>
</table>
p<0.001 for medial and central bands

Limitation of activities
<table>
<tr><td></td><td>Baseline</td><td>At ‘late’ follow-up</td></tr>
<tr><td>No limitation</td><td>0/25</td><td>60% (15/25)</td></tr>
<tr><td>Minimal limitation</td><td>0/25</td><td>32% (8/25)</td></tr>
<tr><td>Moderate limitation</td><td>28% (7/25)</td><td>8% (2/25)</td></tr>
<tr><td>Severe limitation</td><td>72% (18/25)</td><td>0/25</td></tr>
</table>
Patient satisfaction
• Completely satisfied=88% (22/25)
• Satisfied with reservations=8% (2/25)
• Unsatisfied=4% (1/25)

Between 6 weeks and 3 months, 24% (6/25) of the patients took oral non-steroidal anti-inflammatory drugs. Between 3 and 6 months, 4% (1/25) of patients took oral non-steroidal anti-inflammatory drugs.

Mean return to work or daily activities=2 weeks</td>
<td>None of the patients experienced any complications.</td>
<td>Follow-up issues:
• Questionnaires were completed at baseline and after 2 weeks, 3 months, 6 months and 1 year.
• No losses to follow-up were reported.

Study design issues:
• Prospective data collection.</td>
</tr>
</table>

Abbreviations used: ABI, autologous blood injection; PRP, platelet-rich plasma; SD, standard deviation; TT, tenderness threshold; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Barrett SL (2004)[7]

Case series
USA
Recruitment period: not reported
Study population: patients with chronic plantar fasciitis
n=9
Age: not reported
Sex: not reported
Mean duration of symptoms: not reported

Patient selection criteria: willingness to forgo any other concomitant conservative treatment modality and not having had a cortisone injection within 90 days prior to the procedure.

Technique: harvested blood (20 ml) was prepared using the Smart Prep® system (Harvest Technologies Inc.). Approximately 3 ml PRP was injected into the most hypoechoic areas within the medial and central bands of the affected fascia (using ultrasound guidance). The affected areas were needled several times before infiltration. Anaesthesia involved a block of the posterior tibial peripheral nerve and sural nerve. After the procedure, patients were instructed to wear a below-knee cast immobilisation boot, and to avoid weight bearing for 48 hours with a subsequent increase in walking over the next several days. Patients were allowed to return to a comfortable shoe after 2 days.

Follow-up: 1 year
Conflict of interest/source of funding: the first author is a consultant and speaker for Harvest Technologies Inc.</td>
<td>Number of patients analysed: 9

Resolution of symptoms
6 patients had complete resolution of symptoms after 2 months; 1 patient had resolution of pain after an injection of corticosteroid; 1 patient had complete resolution after a second injection of PRP and the remaining patient had only occasional pain when walking barefoot.

At 1 year, 7 out of 9 patients had complete resolution of plantar fascial pain. The procedure was considered to have failed in 1 patient and the other patient was dismissed from the study because of a subsequent corticosteroid injection.

Mean thickness of medial and central bands of the plantar fascia (mm) (assessed by ultrasound)
<table>
<tr><td></td><td colspan="2">Mean thickness of bands (mm)</td></tr>
<tr><td></td><td>Baseline</td><td>3 months after injection</td></tr>
<tr><td>Symptomatic medial band</td><td>7.02</td><td>5.03</td></tr>
<tr><td>Asymptomatic medial band</td><td>4.88</td><td>4.63</td></tr>
<tr><td>Symptomatic central band</td><td>6.59</td><td>5.39</td></tr>
<tr><td>Asymptomatic central band</td><td>4.27</td><td>4.20</td></tr>
</table>
Mean reduction in thickness of the medial band of the plantar fascia (assessed by ultrasound) at follow-up:
• 1 week=1.45 mm
• 4 weeks =1.99 mm
• 3 months=2.29 mm
All patients had improvement that was noted on ultrasound.</td>
<td>No complications were reported.</td>
<td>Follow-up issues:
• 1 patient was dismissed from the study because of a subsequent corticosteroid injection.

Study population issues:
• Details of patient selection criteria were not described.</td>
</tr>
</table>

Abbreviations used: ABI, autologous blood injection; PRP, platelet-rich plasma; SD, standard deviation; TT, tenderness threshold; VAS, visual analogue scale

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Omar AS (2012)[8]

Randomised controlled trial
Egypt
Recruitment period: 2009–10
Study population: adults with plantar fasciitis
n=30 (15 ABI [PRP] vs 15 corticosteroid)
Age: mean 43 vs 45 years
Sex: 100% (30/30) female

Patient selection criteria: inclusion criteria were plantar heel pain (worse on rising in the morning and/or after periods of sitting or lying) with maximal tenderness over the anteromedial aspect of the inferior heel. Exclusion criteria were previous surgery for plantar fasciitis; vascular insufficiency or neuropathy related to heel pain; hypothyroidism; diabetes; history of anaemia, thrombocytopaenia or bleeding dyscrasias; significant cardiovascular, renal or hepatic disease; local malignancy.

Technique: For ABI, PRP was prepared from 150 ml withdrawn blood. After injection all patients were instructed to avoid weight bearing for 48 hours. Non-steroidal anti-inflammatory drugs were prohibited. Patients were allowed to return to a comfortable shoe after 2 days.

Follow-up: 6 weeks

Conflict of interest/source of funding: none</td>
<td>Number of patients analysed: 30 (15 vs 15)

Mean pain scores (VAS, lower scores indicate less pain)
<table>
<tr><th>Follow-up period</th><th>ABI</th><th>Corticosteroid</th></tr>
<tr><td>Baseline</td><td>8.2±1.3</td><td>8.8±0.9</td></tr>
<tr><td>6 weeks</td><td>2.6±2.1</td><td>6.5±2.6</td></tr>
</table>
At 6 weeks, the reduction in pain levels from baseline was statistically significant in both groups (p<0.001 and p=0.005 respectively).

Mean Foot Health Status questionnaire scores (not further described in the paper)
<table>
<tr><th>Follow-up period</th><th>ABI</th><th>Corticosteroid</th></tr>
<tr><td>Baseline</td><td>58.5±9.6</td><td>57.5±9.4</td></tr>
<tr><td>6 weeks</td><td>25.1±12.4</td><td>49.0±19.1</td></tr>
</table>
At 6 weeks, the difference from baseline was statistically significant in both groups (p<0.001 and p=0.03 respectively).</td>
<td>No complications were described in the paper.</td>
<td>Study design issues:
Method of randomisation was not described.
Pain was rated in a visual analogue scale, with 0 indicating no pain and 10 the worst imaginable pain.</td>
</tr>
</table>

Efficacy

Relief of symptoms

A randomised controlled trial of 64 patients treated by autologous blood injection or corticosteroid injection reported that the mean pain scores decreased from 7.3 and 6.9 at baseline to 3.6 and 2.4 respectively at 6 month follow-up ($p<0.0001$ for both groups; measured on a visual analogue scale from 0–10, with 0 indicating no pain and 10 the worst imaginable pain)[1]. The proportion of patients with no change in score was 10% in both groups (3/30 and 3/31 respectively). In the same study, the mean tenderness threshold improved from 3.1 kg/cm^2 at baseline to 6.5 kg/cm^2 in the autologous blood injection group and from 3.7 kg/cm^2 to 8.6 kg/cm^2 in the corticosteroid group at 6 month follow-up ($p<0.0001$ for both groups).

A randomised controlled trial of 45 patients treated by autologous blood injection, corticosteroid injection or peppering alone reported that mean pain scores reduced from 7.6, 7.3 and 6.4 at baseline to 2.4, 2.6 and 2.0 respectively at 6 month follow-up ($p<0.001$ for all groups; measured on a visual analogue scale from 0–10)[2]. The Rearfoot scores (scale 0–100 with higher scores indicating less pain and better function) improved from 72, 66 and 64 at baseline to 81, 80 and 78 respectively at 6 month follow-up ($p=0.025$, 0.030 and 0.018 respectively). There were no statistically significant differences between the groups.

A randomised controlled trial of 30 patients treated by platelet-rich plasma or corticosteroid injection reported that the mean pain scores decreased from 8.2 and 8.8 at baseline to 2.6 and 6.5 respectively at 6 week follow-up ($p<0.001$ and <0.05 respectively; measured on a visual analogue scale from 0–10, with 0 indicating no pain and 10 the worst imaginable pain)[8].

A non-randomised comparative trial of 100 patients treated by autologous blood injection, local anaesthetic with peppering, corticosteroid injection or corticosteroid injection with peppering reported that mean pain scores reduced from 6.8, 6.7, 7.0 and 7.2 at baseline to 3.5, 3.4, 1.5 and 1.0 respectively at 6 month follow-up ($p<0.001$ for all groups; measured on a visual analogue scale from 0–10)[3]. A non-randomised comparative trial of 60 patients treated by autologous blood injection or corticosteroid injection reported the mean pain scores reduced from 7.3 and 6.2 at baseline to 3.9 and 3.4 respectively at 6 month follow-up ($p=0.001$ for both groups; measured on a visual analogue scale from 0–10)[4].

In a case series of 30 feet treated by platelet-rich plasma injection, all but 2 patients had marked reduction in first-step pain and post-rest pain, and improved ability to stand and walk (outcome measures not described, follow-up period not stated)[5].

In a case series of 9 patients treated by platelet-rich plasma injection, 7 had complete resolution of plantar fascial pain at 1-year follow-up[7].

Patient satisfaction

The non-randomised comparative trial of 100 patients treated by autologous blood injection, local anaesthetic with peppering, corticosteroid injection or corticosteroid injection with peppering reported an 'excellent' or 'good' outcome in 60% (15/25), 52% (13/25), 80% (20/25) and 88% (22/25) of patients respectively at 6 month follow-up (measured using a modified Roles and Maudsley scale)[3]. There was a statistically significant difference between corticosteroid injection and autologous blood injection and local anaesthetic with peppering, with more successful outcomes in the corticosteroid groups ($p<0.05$).

The non-randomised comparative trial of 60 patients treated by autologous blood injection or corticosteroid injection reported an 'excellent', 'good' or 'acceptable' outcome in 87% (26/30) of patients in both groups at 6 month follow-up (measured using a modified Roles and Maudsley scale)[4].

A case series of 25 patients reported that 88% (22/25) of patients were 'completely satisfied' and 8% (2/25) of patients were 'satisfied with reservations' after the procedure[6].

Mean thickness of fascial bands

The case series of 25 patients and the case series of 9 patients both reported a mean reduction in thickness of the medial band of the plantar fascia of 2.3 mm at 3 month follow-up (assessed by ultrasound)[6,7].

Repeat procedures

The randomised controlled trial of 45 patients treated by autologous blood injection, corticosteroid injection or peppering alone reported that 67% (10/15), 0% (0/14) and 47% (7/15) of patients respectively needed a third injection[2]. In the case series of 30 feet, 2 patients had repeat injections (1 at 6 months and the other at 9 months after the initial platelet-rich plasma injection, with 'good relief of pain' at 1 year)[5]. In the same series, 2 patients needed open surgery.

Safety

Pain

The randomised controlled trial of 64 patients and the non-randomised comparative trial of 100 patients both reported that all patients found the procedure painful[1,3]. The randomised controlled trial of 64 patients treated by autologous blood injection or corticosteroid injection reported post-injection pain (requiring analgesia, ice application or both) in 53% (16/30) and 13% (4/31) of patients respectively (p value not reported). The mean duration of symptoms was

7 days in the autologous blood injection group and 5 days in the corticosteroid injection group[1].

A non-randomised comparative study of 60 patients treated by autologous blood injection or corticosteroid injection and a case series of 25 patients reported that there were no adverse events.

Validity and generalisability of the studies

- There is a lack of long-term follow-up; only 2 small case series reported outcomes beyond 6 months[6,7].
- None of the comparative studies included a control group to show the natural history of the disease without intervention.
- Rehabilitation protocols after the procedure varied between studies; 1 study instructed patients to wear a below-knee cast immobilisation boot and to avoid weight bearing for 48 hours[7] whereas another imposed no restriction on activity[3].
- The main outcome measures used by the studies were subjective visual analogue scales.
- The mean duration of symptoms before treatment was not reported in 3 studies[5–7]. In the remaining 3 studies, the mean duration of symptoms was 8 months or longer.
- Some studies used multiple injections and this may have had an impact on the efficacy.
- There were variations in the blood product being used (platelet-rich plasma compared with whole blood), the use of imaging and the injection technique (some studies used peppering to administer the autologous blood).

Existing assessments of this procedure

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

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B gives details of the recommendations made in each piece of guidance listed.

Interventional procedures

- Extracorporeal shockwave therapy for refractory plantar fasciitis. NICE interventional procedures guidance 311 (2009). Available from www.nice.org.uk/guidance/IPG311
- Autologous blood injection for tendinopathy. NICE interventional procedures guidance 279 (2009). This guidance is currently under review and is expected to be updated in 2012. For more information, see www.nice.org.uk/guidance/IPG279

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 does not represent the view of the society.

Mr T Clough (British Orthopaedic Association); Mr K Hariharan, Mr W Harries, Mr M Solan (British Orthopaedic Foot and Ankle Society); Dr H Tahir (British Society of Rheumatology); Dr S Babar, Dr S Ganeshalingham and Dr S Jayaraman (British Society of Skeletal Radiologists).

- Four Specialist Advisers have performed the procedure at least once, 1 Specialist Adviser performs it regularly and 3 have never performed it.
- Five Specialist Advisers consider the procedure to be a minor variation on an existing procedure; 2 consider it to be definitely novel and of uncertain safety and efficacy; 1 considers it to be first in a new class of procedure.
- Standard practice would be orthotics and conservative measures, which would be complemented with steroid injections and dry needling.
- Theoretical adverse events include rupture of the plantar fascia, local neurovascular damage, infection, bruising, and bleeding in patients on anticoagulants.
- Adverse events reported in the literature include increased pain.
- Key efficacy outcomes include reduction in heel pain (measured using VAS), reduction in pain induced by pressure on the heel and changes in the appearance of the plantar fascia after the procedure.
- Some radiologists will perform dry needling as well.
- Some radiologists will use a local anaesthetic. The type of local anaesthetic may vary.
- Some radiologists may give local anaesthetic into the subcutaneous fascia as well, which may improve patient acceptance of the procedure.
- Depending on the referral source, there will be different conservative measures.
- Plantar fasciitis is a very common condition and in most cases it is self-limiting.
- One Specialist Adviser noted that interpreting results of treatment is difficult because so many cases would resolve with rest, time and physiotherapy.
- One Specialist Adviser noted that interventions of any sort should be reserved for patients who have had the condition for at least 6 months and it has not responded to first-line therapy. Another Adviser noted that 80% of people with plantar fasciitis get better without treatment in approximately 3 months. Of those people that do not, physiotherapy and specific stretches help another 80%.The remaining 4% of people with plantar fasciitis are the only ones who should be considered for this type of treatment.
- Two Specialist Advisers considered the procedure to have a major potential impact on the NHS, in terms of numbers of patients and use of resources; 2 Specialist Advisers considered the procedure to have a moderate potential impact; 4 Specialist Advisers thought the potential impact would be minor.

Patient Commentators' opinions

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

Issues for consideration by IPAC

Ongoing trials:

- NCT01509274 Treatment of plantar fasciitis with injection of platelet-rich plasma into the origin of the plantar fascia; location: Denmark; type: randomised controlled trial (platelet-rich plasma compared with saline compared with physiotherapy and heel cups); estimated enrolment: 90 patients; estimated primary completion date: June 2012.
- NCT00758641 Platelet rich plasma to treat plantar fasciitis; location: Netherlands; type: randomised controlled trial (platelet-rich plasma compared with corticosteroid injection); estimated enrolment: 120 patients; estimated study completion date: December 2013.
- NCT01127672 Treatment of plantar fasciitis with platelet rich plasma; location: USA; type: randomised controlled trial (platelet-rich plasma compared with corticosteroid injection); estimated enrolment: 50 patients; estimated study completion date: May 2011.

References

1. Lee TG, Ahmad TS (2007) Intralesional autologous blood injection compared to corticosteroid injection for treatment of chronic plantar fasciitis. A prospective, randomized, controlled trial. Foot and Ankle International 28: 984–90

2. Kiter E, Celikbas E, Akkaya S et al. (2006) Comparison of injection modalities in the treatment of plantar heel pain: a randomized controlled trial. Journal of the American Podiatric Medical Association 96: 293–6

3. Kalaci A, Cakici H, Hapa O et al. (2009) Treatment of plantar fasciitis using four different local injection modalities: a randomized prospective clinical trial. Journal of the American Podiatric Medical Association 99: 108–13

4. Aksahin E, Dogruyol D, Yuksel HY et al. (2012) The comparison of the effect of corticosteroids and platelet-rich plasma (PRP) for the treatment of plantar fasciitis. Archives of Orthopaedic and Trauma Surgery 132: 781–5

5. Scioli MW (2011) Platelet-rich plasma injection for proximal plantar fasciitis. Techniques in Foot and Ankle Surgery 10: 7–10

6. Ragab EMS, Othman AMA (2012) Platelets rich plasma for treatment of chronic plantar fasciitis. Archives of Orthopaedic and Trauma Surgery May 4 (Epub ahead of print)

7. Barrett SL, Erredge SE (2004) Growth factors for chronic plantar fasciitis. Podiatry Today 17: 36–42

8. Omar AS, Ibrahim ME, Ahmed AS et al. (2012) Local injection of autologous platelet rich plasma and corticosteroid in treatment of lateral epicondylitis and plantar fasciitis: Randomized clinical trial. The Egyptian Rheumatologist 34: 43–9

Appendix A: Additional papers on autologous blood injection for plantar fasciitis

The following table outlines the studies that are considered potentially relevant to the 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
Chitre AP, Pancholi V, Archik S et al. (2011) Extra-venous use of autologous platelet concentrate: beginning of a new era of therapy of transfusion medicine? Indian Journal of Hematology and Blood Transfusion 27: 152–56	n=8 (2 with plantar fasciitis) Follow-up=3 months	Both patients had 100% relief from pain with restoration of mobility at follow-up.	Larger studies are included.
de Vos RJ, van Veldhoven PL, Moen MH et al. (2010) Autologous growth factor injections in chronic tendinopathy: a systematic review. British Medical Bulletin 95: 6–7	n=11 studies (3 for plantar fasciitis)	There is strong evidence that autologous blood injections do not improve pain and/or function compared with other treatment options. There is only limited evidence that platelet-rich plasma injections are beneficial. Further studies using a proper control group, randomisation, blinding and validated disease-specific outcome measures for pain and function are needed.	Systematic review with no meta-analysis – all included studies are described in detail in table 2.
Jia X, Peters PG, Schon L (2011) The use of platelet-rich plasma in the management of foot and ankle conditions. Operative Techniques in Sports Medicine 19: 177–84	n=634 patients with a range of conditions (including 82 patients with tendonosis some of which were plantar fasciitis) Follow-up=not reported	Overall, the results were favourable with very limited morbidity. Painful donor site=0.8% (5/634)	The number of patients with plantar fasciitis was not stated. Results were not reported separately by indication.

Article	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Kampa RJ, Connell DA (2010) Treatment of tendinopathy: is there a role for autologous whole blood and platelet rich plasma injection? International Journal of Clinical Practice 64: 1813–23	n=15 studies (4 for plantar fasciitis)	More studies are needed to elucidate the difference between autologous whole blood and platelet-enriched blood. Early results look promising, especially in refractory cases of tendinopathy that have been unresponsive to traditional treatments. Longer term well-conducted studies of sufficient sample size are needed.	Review with no meta-analysis – all relevant studies have been described in the overview.
Logan LR, Klamar K, Leon J et al. (2006) Autologous blood injection and botulinum toxin for resistant plantar fasciitis accompanied by spasticity. American Journal of Physical Medicine and Rehabilitation 85: 699–703	n=1 Follow-up=21 days	Patient was pain-free at 21 days follow-up. Autologous blood injection combined with botulinum toxin A may be an alternative treatment for resistant plantar fasciitis accompanied by spasticity.	Autologous blood injection treatment combined with botulinum toxin A. Case report with no adverse events reported.
Nguyen RT, Borg-Stein J, McInnis K (2011) Applications of platelet-rich plasma in musculoskeletal and sports medicine: an evidence-based approach. Physical Medicine and Rehabilitation 3: 226–50	n=1 study on plantar fasciitis	Platelet-rich plasma shows promise and the authors' own patients' outcomes have been 'quite positive'. Further randomised controlled trials are needed.	No original results are presented. The single study on plantar fasciitis that is reviewed is described in table 2 (Barrett et al. 2004).
Soomekh DJ (2011) Current concepts for the use of platelet-rich plasma in the foot and ankle. Clinics in Podiatric Medicine and Surgery 28: 155–70	n=1 study on plantar fasciitis	The author has found promising results using platelet-rich plasma for patients with chronic recalcitrant plantar fasciitis.	No original results are presented. The single study that is reviewed is described in table 2 (Barrett et al. 2004).

Appendix B: Related NICE guidance for autologous blood injection for plantar fasciitis

Guidance	Recommendations
Interventional procedures	**Extracorporeal shockwave therapy for refractory plantar fasciitis. NICE interventional procedures guidance 311 (2009)** 1.1 The evidence on extracorporeal shockwave therapy (ESWT) for refractory plantar fasciitis raises no major safety concerns; however, current evidence on its efficacy is inconsistent. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake ESWT for refractory plantar fasciitis should take the following actions. • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG311publicinfo). • Audit and review clinical outcomes of all patients having ESWT for refractory plantar fasciitis (see section 3.1). 1.3 NICE encourages further research into ESWT for refractory plantar fasciitis. Future research should take the form of clinical studies with clearly described patient selection and treatment protocols, including a description of local anaesthesia use and the type of energy applied (see section 2.5). The studies should include validated outcome measures and be based on a minimum of 1-year follow-up. NICE may review the procedure on publication of further evidence. **Autologous blood injection for tendinopathy. NICE interventional procedures guidance 279 (2009)** 1.1 Current evidence on the safety and efficacy of autologous blood injection for tendinopathy is inadequate in quantity and quality. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake autologous blood

	injection for tendinopathy should take the following actions: • Inform the clinical governance leads in their Trusts. • Ensure that patients understand the uncertainty about the procedure's efficacy, especially in the long term, make them aware of alternative treatments and provide them with clear written information. In addition, use of NICE's information for patients ('Understanding NICE guidance') is recommended. • Audit and review clinical outcomes of all patients having autologous blood injection for tendinopathy (see section 3.1). 1.3 Future research should be in the context of randomised controlled trials that define chronicity of tendinopathy and clearly describe any previous or adjunctive treatments (including physiotherapy and 'dry needling') as well as the tendons treated. They should address the role of ultrasound guidance and include functional and quality of life outcomes with a minimum follow-up of 1 year. NICE may review the procedure upon publication of further evidence.

Appendix C: Literature search for autologous blood injection for plantar fasciitis

Databases	Date searched	Version/files	No. retrieved
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	20/09/2012	September 2012	12
Database of Abstracts of Reviews of Effects – DARE (CRD website)	20/09/2012	-	1
HTA database (CRD website)	20/09/2012	-	1
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	20/09/2012	-	28
MEDLINE (Ovid)	20/09/2012	1946 to September Week 2 2012	7
MEDLINE In-Process (Ovid)	20/09/2012	September 19, 2012	17
EMBASE (Ovid)	20/09/2012	1974 to 2012 September 19	23
CINAHL (NLH Search 2.0)	20/09/2012	N/A	10
BLIC (Dialog DataStar)	25/09/2012	N/A	0

Trial sources searched on 4 May 2012

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

Websites searched

- National Institute for Health and Clinical Excellence (NICE)
- 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 search
- 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	Fasciitis, Plantar/
2	(Plant* adj3 Fasciit*).tw.
3	(plant* adj3 fascia*).tw.
4	(Plant* adj3 fasciopath*).tw.
5	(heel adj2 spur).tw.
6	or/1-5
7	Blood Transfusion, Autologous/
8	platelet-rich plasma/
9	(blood* or platelet* or plasma* or autologous or homologous).tw.
10	Blood Platelets/
11	7 or 8 or 9 or 10
12	exp injections/
13	(inject* or needle*).tw.
14	12 or 13
15	11 and 14
16	6 and 15
17	6 and 11
18	6 and 14
19	16 or 17 or 18
20	animals/ not humans/
21	19 not 20