INVESTIGATION

Design and development of an osteosynthesis system for minimally invasive reconstruction-arthrodesis of calcaneal intra-articular fractures.

Centro de Prevención y Rehabilitación FREMAP Majadahonda. Madrid.

Purpose. To develop instruments that can restore the shape of a fractured calcaneus and facilitate minimally invasive primary arthrodesis of the subtalar joint in severe calcaneal intra-articular fractures.

Materials and methods. We studied a new osteosynthesis system for fractures in three consecutive phases: a) system design, b) biomechanical tests and c) prototype testing in cadavers.

Results. The basic characteristics of the original design were validated with minimal changes. From the biomechanical point of view the implant developed has passed strength and fatigue tests and has shown itself to provide good surgical management in cadavers.

Conclusions. The implant designed achieved its purpose, and adapts to the mechanical conditions and dimensions of the calcaneal bone.

Keywords: calcaneal fracture, osteosynthesis, subtalar arthrodesis.

Fractures of the calcaneus represent 60% of tarsal bone fractures and 2% of all fractures. These injuries are usually the result of falling from a height onto the heels and frequently occur in work-related accidents.

The treatment of calcaneal fractures continues to be the subject of discussion and in displaced intra-articular fractures there is no consensus about the best method of treatment, although a conservative trend predominates.

There are no uniform criteria for classification and treatment, with very different solutions being available, particularly as the complexity and severity of the fracture increases. In addition there are frequent complications, which make treatment difficult and worsen the prognosis.

Chronic residual pain is the most common sequela following a comminuted thalamic fracture of the calcaneus. Although there may be various reasons for this, it can be the consequence of compartmental syndrome, reflex sympathetic dystrophy, plantar cushion syndrome, tarsal and peroneal canal syndrome and subtalar arthrodesis. The latter is responsible for most of the long-term problems resulting from the treatment of fractures.

The unanimous view is that the anatomical restoration of the subtalar joint is difficult, and even if this is carried out using an aggressive approach, in most cases the joint loses a great deal of its mobility or may even remain ankylosed.

Problems with cover and post surgery infectious osteitis are fairly common complications and have an effect on the patient's quality of life, including viability of the limb in certain cases.

If the subtalar joint is irreparable or if ankylosis and degeneration is inevitable, primary arthrodesis with reconstruction of the shape of the heel may be a therapeutic option for intra-articular fractures which is very advantageous to the patient, saving him from complications and sequelae.

The aim of this study is to design an osteosynthesis system for the reconstruction-arthrodesis of displaced intra-thalamic fractures of the calcaneus, evaluating its biomechanical behaviour and inserting it in the cadaver as a preliminary stage before its use in clinical practice.

MATERIAL AND METHOD

The Vira system (Biomet, Valencia, Spain) is a method of reconstruction-arthrodesis of fractures of the calcaneus formed by a nail with pins and screws for fixing to the talus. The locked-nail aims to stabilise and reduce the fracture of the calcaneus, at the same time as it fixes in position the posterior subtalar joint. In this way the bone
can be reconstructed and, at the same time, the damaged subtalar joint can be immobilised.

The bone does not need to be integral for the nail to be inserted and its function is to support and strengthen the soft parts of the Achilles-calcaneus-plantar system (figure 1). The implant allows the patient to regain early mobility and weight bearing.

The instrumentation forms an essential part of the system, consisting of a guide to restore the length and height of the fractured calcaneus, with the greater tuberosity being located in its normal anatomical position with the talus. It then allows the latter to be fixed in place by means of introducing the nail and screws.

Definition of the implant and instrumentation

The project has been developed jointly between the Centre for Prevention and Rehabilitation FREMAP Majadahonda and Biomet Spain (Valencia, Spain).

The Vira® system, designated in this way because of its arrow shape, in its definitive form consists of the following:

An implant, which is the nail for the greater tuberosity of the calcaneus crossed by two cannulated screws (tubero-talar) which enter through the heel and are screwed into it and into the body of the talus.

The body of the talus is the densest and most resistant spongy bone of the skeleton and the nail provides solidity and support to the fractured calcaneus allowing the tubero-talar screws to maintain the alignment and tension of the soft parts achieved with the instrumentation. In this way it is possible to recover and maintain the anatomical relationship between the talus and the skeleton of the heel by fixing in place and encouraging subtalar arthrodensis.

The nail has a single diameter and length (10 x 38.7 mm), and is made from stainless steel (AISI 316 LVM), with a finely sanded surface finish. It has lateral fins which ensure rotation and maintenance of distraction and reduction of the fracture, as well as facilitating insertion of the implant.

It has two holes for the tubero-talar screws to be inserted and locked. The screws are inclined at 20° in relation to the axis of the nail (fig. 2).

The tubero-talar screws are cannulated with a core of 2.1 mm and double thread. They are available in 7 sizes ranging from 55 - 85 mm in length. They have a cortical thread of 6.5 mm at the end with notches with a self-locking action which are fixed in place in the spongy bone of the talus. The head of the screw has a thread to allow it to be fixed to the nail. The screw is also made of stainless steel (AISI 316 LVM grade 2 UTS min, 860-1100 N/mm²) with finely sanded surface finish.

The Vira® application guide is a complex piece of apparatus for holding the greater tuberosity of the calcaneus which is usually raised and impacted in this type of injury in order to restore axial alignment of the tuberosity, and to recover the length and height of the calcaneus by strengthening the soft parts and releasing the lateral channels.

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holding the greater tuberosity of the calcaneus, and is manufactured in carbon fibre to allow it to be viewed radioscopically; it has an adjustable supporting arch for fixing the guide to the reference pin in the head of the talus which produces distraction against the pin, a system of target guides for the pins, bits and nail implants and the tuberosity-talar screws and, finally, a handling grip (fig. 3).

The Vira® guide is manufactured almost entirely from titanium, except for the carbon fibre clamp and the steel bushes and threads.

In addition to the guide there are other additional instruments for inserting the implant, such as the bits for nail and screws, the guide pins and the tuberosity-talar screw measuring apparatus.

Surgical technique

Prototype tests using plastic replicas of the bones in the foot and ankle allowed the steps of the surgical technique to be defined (fig. 4).

Positioning the patient

The patient must be lying down in a prone decubitus position with preventive ischemia. It is advisable to raise the injured extremity in comparison with the undamaged one in order to obtain a better radioscopic view.

Closed reduction

The recommendation is to carry out manoeuvres to achieve the closed reduction of the fracture prior to surgery, using the technique developed by Omoto et al, especially in cases involving greater displacement.

Positioning the guide pin in the centre of the head of the talus

The guide pin is the spatial reference for the Vira® nail instrumentation, therefore it is essential for it to be positioned correctly. Positioning is carried out from the internal face of the foot, being located using radioscopy in the centre of the head of the talus. The pin must be parallel to the ankle joint interline in the frontal plane, and perpendicular to the axis of the foot in the axial plane. Surgery must not proceed until the correct position of the guide pin has been checked.

Surgical exposure

An external para-Achilles incision of approximately 3 cm is recommended, taking care not to damage the sural nerve which runs along the pre-Achilles portion of the calcaneus. This approach exposes the upper face of the calcaneus and the posterior portion of the subtalar joint.

Preparation of the subtalar joint.

Using a sharp knife we eliminate all of the cartilage from the subtalar facet of the talus and the chondral remains of the fractured facet of the calcaneus.

Positioning of the guide

The guide is initially supported in the guide pin located in the head of the talus. The guide is fitted into the greater tuberosity using the manual screw located at the end of the grip.

Capture the greater tuberosity

A radiographical check of the position is carried out, assisted by the guide pins which simulate the orientation of the screws which are introduced through the holes in the arms of the guide. These pins define the pitch of the definitive screws. If not correctly adjusted in the body of the talus the guide will need to be repositioned.

This allows the axis of the calcaneus to be modified using the grip screw, and also for flexion-extension movement to be applied by mobilising the guide.

Figure 4. Principal steps in the surgical technique: A) position of the patient; B) external para-Achilles approach; C) cruentation of the subtalar joint; D) application of the guide; E) introduction of the nail, and F) introduction of the tuberosity-talar screws.

Drilling of the greater tuberosity

The housing of the nail in the greater tuberosity is drilled with a 10 mm bit, up to the end stop of the bit. The Achilles tendon must be adequately protected.

In some cases, the serious comminution of the fracture means that we are drilling on top of the fractured bone but this does not pose any problem since the implant does not require an intact bone in order to be fixed in
place. When the bit is removed we have to maintain its rotation in order to extract the bone resulting from drilling in order to use this subsequently as a graft for subtalar arthrodesis. The motor rotation must not be reversed.

**Insertion of the nail**

The nail held by the guide is hammered in order to push it into the previously produced bone tunnel. The guide directs it into the zone below the greater tuberosity, where the plantar fascia is inserted.

The nail must be pushed right in up to the end stop marked by the applicator. In this way correct alignment of the holes in the screws and the guide is obtained.

**Insertion of the locking screws**

With the cannulas in position on top of the guide we make a small 1 cm incision with the bistoury extending right to the bone. The guide pin is inserted and the length of the screws is measured with the depth measuring apparatus. The 4.5 mm cannulated bit is inserted behind the pin in order to position the screws.

**Insertion of bone graft**

Once the system is in position the bone extracted from the nail perforation is applied. It is important to fill the graft well around the tubero-talar screws between the talus and the fractured calcaneus in order to compact the zone and improve the resistance of the assembly. If there is a serious depression in the thalamus it must be filled with an autograft, allograft or bone replacement, at the surgeon's discretion.

After positioning the implant the wounds are sutured and a compression bandage is applied. The ankle and foot do not need to be immobilised, and the system allows immediate partial weight bearing depending on the surgeon's opinion and the patient's tolerance.

**Indications and contraindications**

The Vira® system is indicated for displaced intra-articular fractures of the calcaneus and in sequelae of intra-articular fractures of the calcaneus, such as subtalar arthrosis, vicious consolidation and canalicular syndromes, associated with corrective osteotomy.

However it is contraindicated if there is an infection in the implant zone, in patients with an immature skeleton, in non-articular fractures of the calcaneus or on account of hypersensitivity to the implant material.

**Dimensional study**

An evaluation of the dimensions and fitting of the implant and the instrumentation was carried out, in relation to which x-rays for 30 consecutive patients suffering from unilateral fracture of the calcaneus were analysed.
Lateral x-rays of both feet, the fractured one and the healthy one, were taken. Graduated references provided information about x-ray magnification and by applying the relevant correction the angle between the axes of the talus and calcaneus, the length of the calcaneus, the length of the talus, a height of the body of the talus, the height of the greater tuberosity of the calcaneus, the angle between the axis of the tuberosity of the calcaneus and the centre of the body of the talus and, lastly, the Böhler angle were recorded (fig. 5).

**Biomechanical tests**

On the basis of the biomechanical essentials and with the aim of achieving the established objectives the implant and instrumentation were designed using the AutoCAD assisted design program and resin prototypes were generated using the stereolithographic technique for mechanical and dimensional validation. The second-generation prototypes were made in steel and were subjected to successive modifications until they functioned in compliance with the established targets. At the same time the instrumentation was developed, by manually manufacturing a prototype for the application guide, carrying out a total of 9 tests on the plastic replicas of the bones in the foot.

The implant was subjected to strength and fatigue tests, bearing in mind that the Achilles-calcaneus-plantar system supports loads during walking and lifting up the heel which may reach, in an adult of average weight, up to 3,500 N. The load when standing on both feet is 1,200 N. This is applied to the calcaneus in an axial compression vector using the stresses generated by the Achilles tendon and the plantar fascia. The system dimensions must be capable of supporting these axial loads which coincide with the direction of the tubero-talar screws.

Although the system works by compression, it was tested under flexion in order to determine its strength under unfavourable conditions which do not occur in reality (fig. 6). The tests were carried out at the Biomechanical Institute of Valencia, testing successive prototypes.

The strength test was carried out on a universal test machine (Instron®, United Kingdom) with an activator displacement speed of 0.09 mm/sec until system breakdown or until 3,500 N were reached. The fatigue tests were carried out on a multi-position pneumatic machine with cyclic loads of 1,200 and 900 N and frequency of 1 Hz, with the test being completed on reaching a million cycles or failure.

**Prototype test on a cadaver**

Once the definitive prototype was produced tests were carried out on cadavers, on 4 specimens of foot and ankle dissected from the lower third of the leg, taken from 2 cadavers (Chair of Anatomy, Professor Rodriguez, Faculty of Medicine of the Complutense University of Madrid).

The specimens were mounted and held in place on a bench lathe and positioned, as takes place during surgery, in a prone decubitus position (fig. 7). The instrumentation and the implant were developed in accordance with the protocol designed for the latter, taking note of any problems and improvements which arose. In order to check the potential for reconstruction and reduction of the instrumentation and the implant, a fracture of the calcaneus was simulated by cutting out a 1 cm section of bone in the subtalar joint, making it independent of the greater tuberosity of the body of the calcaneus and anterior tuberosity of the calcaneus.

**RESULTS**

**Design of the system for the reconstruction-arthrodesis of fractures of the calcaneus**

**Dimensional study**

The magnification factor was 1.2 and the results obtained are presented in table 1.

**Biomechanical tests**

The results of the strength test are presented in table 2, showing satisfactory performance towards static loads withstanding up to 2,400 N. In the fatigue tests a million cycles with a load of 1,200 N could not be supported and...
the test at 900 N was successful.

**Table 1. Dimensions of the calcaneus and talus**

<table>
<thead>
<tr>
<th></th>
<th>X</th>
<th>Min.</th>
<th>Max.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angle between talus-calcaneus (°)</td>
<td>40.3</td>
<td>36.3</td>
<td>42.1</td>
</tr>
<tr>
<td>Length of calcaneus (mm)</td>
<td>87</td>
<td>68</td>
<td>90</td>
</tr>
<tr>
<td>Length of talus (mm)</td>
<td>62</td>
<td>52</td>
<td>73</td>
</tr>
<tr>
<td>Height of body of talus (mm)</td>
<td>31</td>
<td>27</td>
<td>37</td>
</tr>
<tr>
<td>Height of greater tuberosity of the calcaneus (mm)</td>
<td>46</td>
<td>39</td>
<td>55</td>
</tr>
<tr>
<td>Angle of the axis of tuberosity of the calcaneus and body of talus (°)</td>
<td>69.3</td>
<td>65</td>
<td>75</td>
</tr>
<tr>
<td>Length between axis of greater tuberosity and centre of talus head (mm)</td>
<td>68</td>
<td>58</td>
<td>75</td>
</tr>
<tr>
<td>Normal Böhler angle (°)</td>
<td>152</td>
<td>145</td>
<td>155</td>
</tr>
<tr>
<td>Fracture Böhler angle (°)</td>
<td>171</td>
<td>-133</td>
<td>+122</td>
</tr>
</tbody>
</table>

X: mean

**Table 2. Results of the rigidity test**

<table>
<thead>
<tr>
<th>Rigidity (N/mm)</th>
<th>Elastic limit force (N)</th>
<th>Deformity of elastic limit (mm)</th>
<th>Fracture force (N)</th>
<th>Fracture deformity (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>551.25</td>
<td>2,403.00</td>
<td>5.54</td>
<td>2,607.87</td>
<td>7.99</td>
</tr>
</tbody>
</table>

N: Newtons; mm: millimetres

**Test of prototypes on cadavers**

The four surgical procedures carried out on cadavers showed that the biomechanical essentials of the implant were correct and it was not necessary to modify either the instrumentation or the implant.

The problems registered were minor in nature and required the modification of two dimensional problems and four mechanical problems without affecting strength. With regard to the guide we discovered two dimensional problems, five mechanical problems and three problems with strength, while in the instrumentation we found three dimensional problems, five mechanical problems and three involving strength.

Each incidence was resolved individually by adapting the design and manufacturing new prototypes in compliance with the conclusions of the test. This meant that a definitive prototype could be manufactured for use in clinical procedure.

**DISCUSSION**

Modern surgical treatment of fractures aims to reduce bone fragments, to achieve joint congruence and stable fixing to allow early mobilisation. In fractures of the calcaneus the principles of osteosynthesis are perfectly applicable, but historically the results are controversial. The cause of the problems which have occurred is due to significant technical difficulty, post-surgical morbidity and long-term progress of patients, which does not differ greatly from that of functional treatment. It has been shown that imperfect osteosynthesis is worse than functional treatment, as a greater level of complications is added to its lack of efficacy. Temporary or permanent injury to the sural nerve after open surgery occurs in 50% of cases and the rate of post-surgery infection is between 3 and 5%.
postoperative pain, avoid complications, cuts down the period of convalescence, facilitates rehabilitation and improves aesthetic results and, above all, functional results. Historically, in fractures of the calcaneus, many attempts at minimum aggression surgery have been carried out, but, to date, the results have not been completely satisfactory, except for tongue fractures.

The concept of the Vira® system for reconstruction-arthrodesis of displaced intra-articular fractures of the calcaneus considers that the subtalar joint is irrecoverable, therefore its initial arthrodesis has the advantage of much faster and safer consolidation than if this is carried out at a later date. In our experience, also confirmed in literature, primary arthrodesis consolidates quickly, probably assisted by the reparative biological environment of the recent fracture.

The conceptual development of the Vira® implant is supported experimentally with the use of pins and screws across the posterior subtalar joint, described by numerous authors for the reconstruction-arthrodesis of fractures of the calcaneus. The problem with these screws is that frequently the greater tuberosity collapses and protrudes through the heel. The Vira® nail provides support and solidity to the greater tuberosity, even if this is also fractured. The effect of the implant is to tighten the soft parts and to maintain the anatomical ratios of the calcaneus towards the body of the talus, a reference to which the tuberosity-talar screws are anchored.

The biomechanical tests carried out with the Vira® implant did not reproduce its real working conditions, since this is not possible in the laboratory due to the complexity of the calcaneus-Achilles-plantar system. Actual mechanical conditions subject the system to principal axial compression stresses on the tuberosity-talar screws as a result of the vectors of the loads from body weight and the plantar fascia. In tests we subjected the implant to forces of flexion, instead of compression. The results of these tests confirmed that it would not fail under actual conditions once implanted and demonstrated sufficient strength to allow early weight-bearing for the patient without instrumental failures.

The sizes and dimensions defined by the study required no changes in the dimensional tests on cadavers, and in patients this was perfectly adapted to requirements.

The Vira® guide is definitely responsible for achieving a system involving minimum invasiveness and anatomical reconstruction of the back of the foot. Despite its complex appearance, it is simple to use as it has only two methods of adjustment and because of its weight, since it is manufactured in titanium and carbon fibre. Although correct holding of the greater tuberosity of the calcaneus as the initial manoeuvre is crucial for its positioning, the subsequent instrumental steps are easy and reproducible. Tests on cadavers were essential for final adjustment of the instrumentation, since these were able to detect problems with adjustment and dimensions prior to clinical use. The number of problems detected is greater than usual in other more traditional instrumental designs due to the fact that the Vira® system is opening up a new unexplored route in osteosynthesis and there are no previous references to guide its development.

ACKNOWLEDGEMENTS

The authors would like to highlight the professional work carried out by the engineer Luis Lozano who worked on developing this design. They would also like to thank the company Biomet Spain for having shared and supported the project.

Conflict of interest. The first author (F. López-Oliva Muñoz) has a patent agreement with the company BIOMET, which manufactures the VIRA system for fractures of the calcaneus.
REFERENCES


Conflict of Interests: The first author (P. López-Oliva Muñoz) has a patent agreement with BIOMET, the manufacturer of the VRKA system for calcaneal fractures.