Design and Development of an Osteosynthesis System for Minimally Invasive Reconstruction-Arthrodesis of Calcaneal Intra-articular Fractures

F. López-Oliva Muñoz, T. Sánchez-Lorente, G. López-Hernández, M.J. Rodríguez-Macías and F. Forriol
FREMAP Prevention and Rehabilitation Center, Majadahonda. Madrid, Spain.

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 intraarticular fractures.
Materials and methods. We studied a new osteosynthesis system for calcaneal 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 achieves its purpose, and adapts to the mechanical conditions and dimensions of the calcaneal bone.

Key words: *calcaneal fracture, osteosynthesis, subtalar arthrodesis.*

Diseño y desarrollo de un sistema de osteosíntesis para la reconstrucción-artrodesis mínimamente invasiva de fracturas intraarticulares de calcáneo

Objetivo. Desarrollar una instrumentación que restaure la forma del calcáneo fracturado y facilite la artrodesis primaria de la articulación subastragalina mínimamente invasiva en las fracturas intraarticulares graves del calcáneo.
Material y método. Se estudió un nuevo sistema de osteosíntesis para las fracturas de calcáneo en tres fases consecutivas: a) diseño del sistema, b) ensayos biomecánicos y c) prueba de los prototipos en el cadáver.
Resultados. Los fundamentos del diseño original han sido validados con mínimos cambios. Desde el punto de vista biomecánico el implante desarrollado ha superado las pruebas de resistencia y fatiga y ha demostrado un buen manejo quirúrgico en el cadáver.
Conclusiones. El implante diseñado cumple sus objetivos, se adapta a las condiciones mecánicas y dimensionales del calcáneo.

Palabras clave: *fractura de calcáneo, osteosíntesis, artrodesis subastragalina.*

Calcaneal fractures are 60% of fractures of the ankle bones and 2% of all fractures[1].Usually, they are caused by falls from a height on to the heels of the feet, and they are frequently seen in work accidents[2,3]. The treatment of calcaneal fractures continues to be an object of discussion and in the case of displaced intraarticular fractures there is no consensus as to the best treatment method although the predominant tendency is to use conservative treatment. There are no uniform criteria for the classification and treatment of these fractures, and very different solutions are applied, especially in the case of complex and severe fractures. It is important to remember the frequent complications that make treatment even more difficult and are the reason for poor prognoses.

Chronic residual pain is the most common sequelae after a comminuted calcaneal fracture. Although there are different causes, these fractures may be a consequence of compartmental syndrome, reflex sympathetic dystrophy, plantar pad syndrome, tarsal tunnel syndrome and personal and subtalar

Corresponding author:
F. López-Oliva Muñoz.
FREMAP Prevention and Rehabilitation Center, Majadahonda.
Ctra. Pozuelo n.o 61.
28220 Majadahonda. Madrid, Spain.
Email: felipe_lopez@fremap.es

Received: June 2006.
Accepted: June 2006..

arthritis. The most frequent cause of poor results of treatment of these fractures in the long term is subtalar arthritis.

There is unanimous agreement that it is difficult to achieve anatomical restoration of the subtalar joint, although it may be achieved with an aggressive approach, in most cases the joint loses its mobility and may even become ankylosed[9].

Coverage problems and postoperative infectious osteitis are not rare complications and affect the patient's quality of life, and even member viability in some cases[10]. When the subtalar joint is irreparable or is condemned to ankylosis and degeneration, primary arthrodesis with reconstruction of the heel may be a therapeutic option for intraarticular fractures, which may be of great advantage to the patient and prevent complications and sequelae.

The aim of this study is to design an osteosynthesis system for the reconstruction of arthrodesis of displaced intrathalamic fractures of the calcaneus, assessing its biomechanical characteristics and placing it in cadavers as a prior step to clinical use.

MATERIALS AND METHODS

The Vira® system (Biomet, Valencia, Spain) is a method for the reconstruction of calcaneal fracture arthrodesis. It comprises a nail with holes and screws for fixation to the talus. The purpose of the locking nail is to stabilize and reduce the calcaneal fracture, and at the same time fixate the posterior subtalar joint. In this way it is possible to reconstruct the bone and simultaneously immobilize the damaged subtalar joint.

It is not necessary for the bone to be whole at the point of nail insertion, since the function of the nail is to support and tense soft tissues of the plantar Achilles-calcaneal system (Figure 1). The implant makes it possible for the patient to load-bear and move sooner.

Instruments are a basic component of the system since they act as a guide that makes it possible to reestablish the length and height of the fractured calcaneus, once more placing the greater tuberosity in its normal anatomical relation to the talus. Subsequently, they allow fixation by means of a nail and screws.

Definition of Implant and Instruments

The project was carried out jointly by the FREMAP Majadahonda Prevention and Rehabilitation Center and Biomet Spain (Valencia, Spain). The Vira® system, given this name because of its arrow-shape, is made up of:

– an implant, which is the nail for the greater tuberosity of the calcaneus that is perforated by two cannulated screws (tuberotalar) that enter through the heel and fixate it to the talar body.

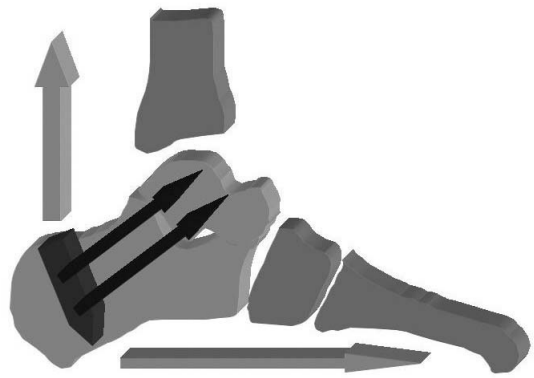

Figure 1. *Biomechanical characteristics of the Vira nail. It does not require the bone it is inserted in to be whole. Its function is to support and tense the soft tissues of the plantar Achilles-calcaneal system.*

– the talus is the densest and most resistant cancellous bone of the skeleton and the nail supplies firmness and support to the fractured calcaneus allowing the tuberotalar screws to maintain soft tissue alignment and tension once they have been achieved by instrumentation. In this way it is possible to recover and maintain the anatomical relationship between the talus and the heel skeleton, fixating and supporting the subtalar arthrodesis.

– the nail is of a single diameter and length (10 x 38.7 mm), and is made of stainless steel (AISI 316 LVM), with a fine-sanded surface. It has lateral wings that ensure the rotation and maintenance of the distraction, fracture reduction and assists implant insertion. It has two holes for the tuberotalar screws that have a metal-metal thread on the distal smooth face and on the proximal face. The smooth area acts as a centering ramp so the screw can be screwed in with greater ease. The holes have an angle of 20º to the axis of the nail (Figure 2). 2).

– The tuberotalar screws are cannulated with a core of 2.1 mm and a double thread. They are available in 7 sizes from 55-85 mm in length. They have a spongy thread on the end of 6.5 mm with selftapping inlets that fixate on the spongy bone of the talus. The head of the screw has a metal-metal thread so that it can be fixated to the nail. the screw is also made of stainless steel (AISI 316 LVM grade 2 UTS min, 860-1100 N/mm2) with a fine-sanded surface finish.

– The Vira® application guide is a complex device to capture the calcaneal tuberosity that is usually ascended and impacted in this type of lesion, so as to restore the axial alignment of the tuberosity and recover the length and height of the calcaneal, tensing the soft tissues and freeing the lateral tunnels. It makes it possible to perform a safe implant, and to achieve nail and screw placement. It comprises a pincers with nails to capture the greater tuberosity of the calcaneus. It is made of carbon fiber to allow visibility on X-ray and has a support arch that can be regulated for the fixation of the guide to the reference needle in the head of

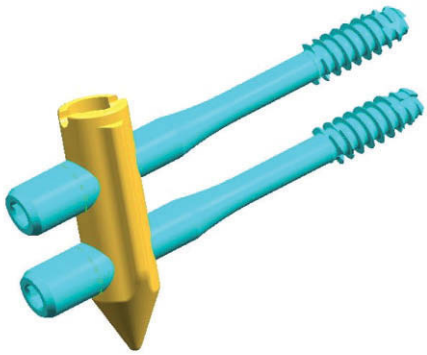

Figure 2. *Image of the Vira® implant.*

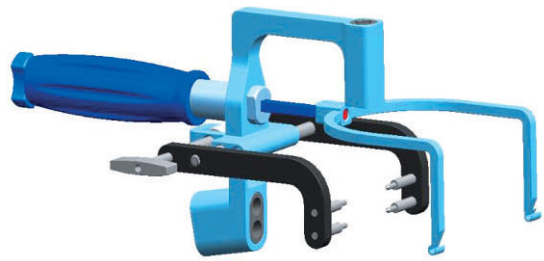

Figure 3. *Guide for calcaneus reconstruction using osteosynthesis and a Vira® implant.*

the talus that carries out distraction with relation to the needle. It has a guide system for the needles, drill bits and implants of the needle and the tuberotalar screws and finally a handle to hold and direct it (Figure 3).

– the Vira® guide is almost totally made of titanium, with the exception of the carbon fiber pincers and the caps and threads of steel. As well as the guide there are other supplementary instruments for implant placement, such as bits for the nail and screws, guide wires and calibrating instruments for the tuberotalar screws.

Surgical Technique

The trials carried out with plastic prototypes of the bones of the foot and ankle made it possible to define the steps to follow during the surgical technique (Figure 4).

Patient positioning

The patient must be lying down with preventive ischemia. It is convenient to elevate the damaged limb with relation to the healthy one so as to have a better X-ray view.

Closed reduction

Before surgery it is advisable to carry out closed reduction fracture maneuvers according to the Omoto et al[11], technique, especially in cases with greater displacement.

Placement of the needle in the center of the talar head

The guiding needle is the instrument used as a spatial reference for placement of the Vira® needle, therefore its correct placement is indispensable. The procedure is performed from the internal side of the foot, locating the center of the head of the talus using X-ray. The needle must follow, in the frontal plane a direction parallel to the joint line of the ankle, and on the axial plane a direction perpendicular to the axis of the foot. Surgery must not continue until it is ascertained that the needle guide is in the correct position.

Surgical Incision

It is advisable to make an external para-Achilles incision of approximately 3 cm, taking care not to damage the sural nerve that runs by the pre-Achilles portion of the calcaneus. This approach exposes the upper part of the calcaneus and the posterior portion of the subtalar joint.

Rasping the subtalar joint

With a rasp all cartilage is removed from the subtalar facet of the talar and the chondral remains from the fractured facet of the calcaneus.

Guide positioning

The guide is initially placed on the guiding needle on the head of the talus. The guide is fixated to the greater tuberosity by means of a manual screw at the tip of the handle.

Capture of the greater tuberosity

The position is checked using X-rays, with the help of the guiding needles that simulates the direction the screws will have when they are placed through the holes of the guiding arms. These needles determine the positions of the permanent screws.

If they are not appropriately fixated to the body of the talus, it is necessary to relocate the guide. This makes it possible to modify the axis of the calcaneus using the screw with the handle and also to apply flexion-extension movements by moving the guide.

Burring of the greater tuberosity

The housing of the nail in the greater tuberosity is burred using a 10 mm bit, up to the limit of the bit. The Achilles tendon must be appropriately protected. In some cases, due to severe fracture comminution, burring must be performed on fractured bone. This is not a problem as the

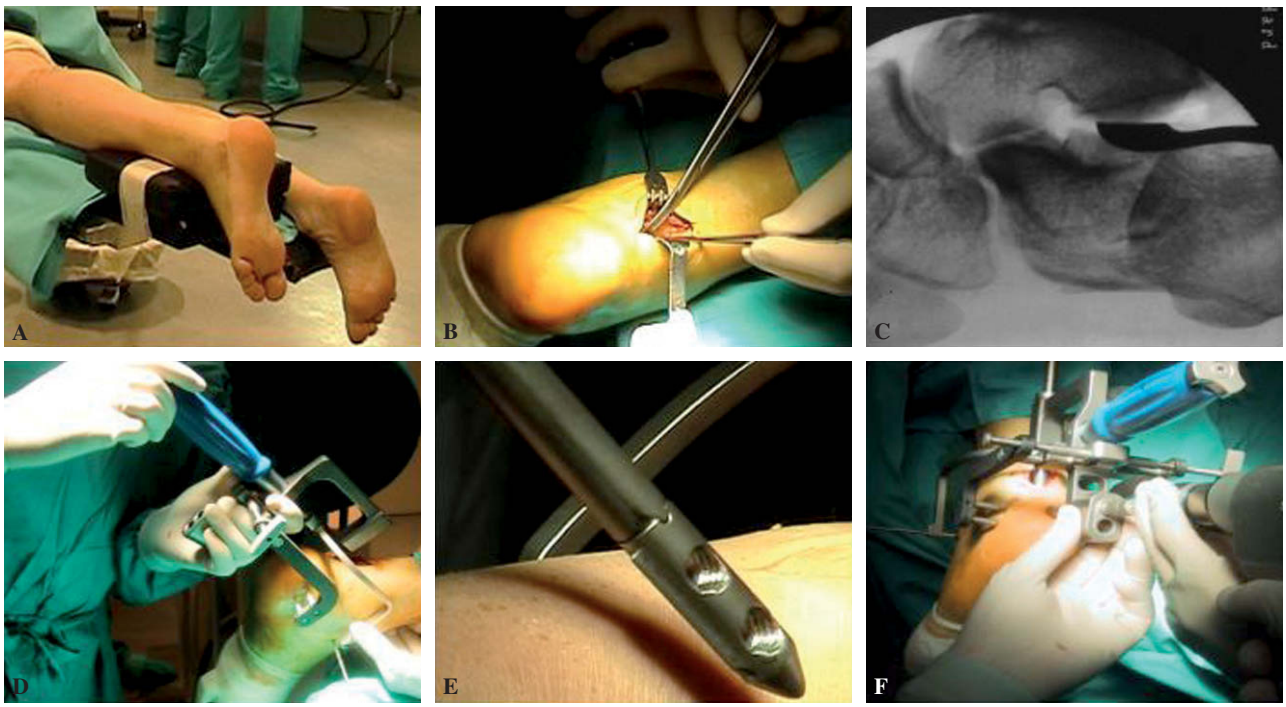

Figure 4. *Main steps in this surgical technique: A) Position the patient; B) External para-Achilles approach; C) Rasping of the subtalar joint; D) Guide application; E) Nail placement, and F) Placement of tuberotalar screws.*

implant does not require intact bone for its fixation. On withdrawing the bit, it must be kept whirling so as to extract the bone from the perforation, as this will later be used as a graft for the subtalar arthrodesis. The motor rotation direction must not be inverted.

Nail insertion

With the nail fixed to the guide, it is hammered into the bone tunnel previously created. The guide directs the nail towards the lower area of the greater tuberosity, where it is inserted into the plantar fascia. The nail must be completely introduced up to the limit marked by the applicator. In this way correct alignment of the holes for the screws and the guide is obtained.

Blocking screw placement

With the cannula positioned on the guide a small 1 cm incision is made with the scalpel down to the bone. The guide needle is passed through and the depth caliber measures the length of the screws. After the guide needle, the cannulated 4.5 mm bit is passed through so that the screws can be placed.

Bone graft placement

Once the system is in place, the bone extracted from the perforation is put in place. It is important to achieve good graft filling around the tubero-talar screws between the fractured calcaneus and the talus to compact the area and improve resistance. If there is a severe subsidence of the thalamus, it must be filled with autograft, allograft or bone substitutes according to the surgeon's preference. After the implant has been put in place, the incisions are sutured and a compressive bandage is used. It is not necessary to immobilize the ankle and foot, and the system allows immediate partial weight-bearing according to the surgeon's criterion and the patient's tolerance.

Indications and contraindications

The Vira® system is indicated in calcaneal displaced intraarticular fractures and in sequelae of calcaneal intraarticular fractures such as subtalar arthritis, malunion and tunnel syndromes associated with corrective osteotomies. On the other hand, it is contraindicated when there is implant infection, in patients with immature skeletons, in non-articular calcaneal fractures or when the patient is sensitive to the implant material.

It is also necessary to keep in mind the conditions that may increase risk of failure in patients that do not cooperate or suffer from neurological disorders and are incapable of following instructions. Also care must be taken in metabolic disorders that decrease bone formation or increase bone loss and are a poor prognosis for wound healing, bed sores, terminal diabetes, severe protein deficiency and/or malnutrition.

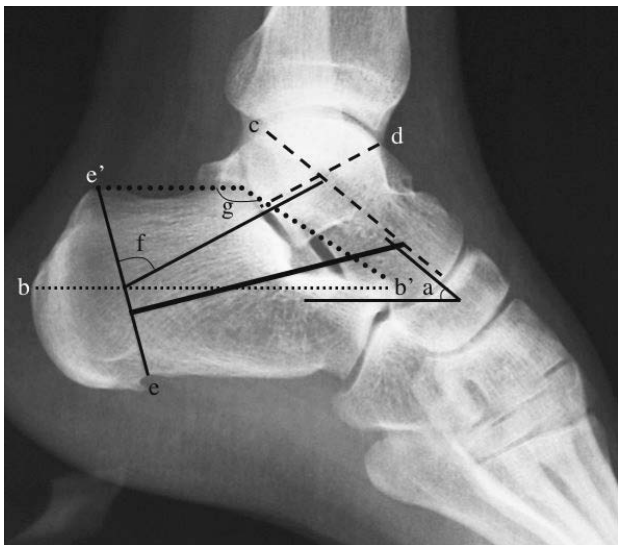

Figure 5. *Size Determination: a: Angle between the axis of the calcaneus and the talus; b-b': length of the calcaneus; c: length of the talus; d: Height of the body of the talus; e-e': Height of the greater tuberosity of the calcaneus; f: Angle between the axis of the tuberosity of the calcaneus and the center of the body of the talus; g: Böhler angle.*

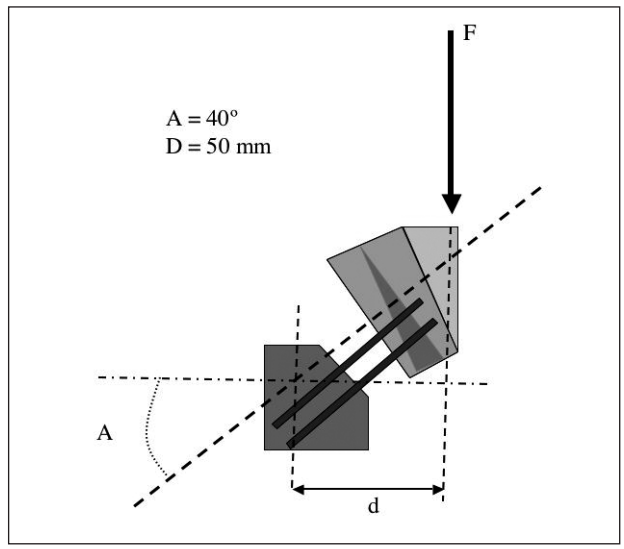

Figure 6. *Instrument positioning during resistance and fatigue testing.*

Size Assessment

An assessment was made of the sizes of the implants and the instruments by analyzing X-rays of 30 consecutive patients with unilateral calcaneal fractures. Lateral X-rays of both feet were taken, the fractured foot and the healthy one. By means of graded references it was possible to determine the magnification of the X-rays and apply the corresponding corrections to register the angle between the talus and calcaneal axis, the length of the calcaneus, the length of the talus, the height of the body of the talus, the height of the greater tuberosity of the calcaneus, the angle between the axis of the calcaneal tuberosity and the center of the talar body and, lastly, the Böhler[12] angle (Figure 5).

Biomechanical Tests

Taking into account biomechanical characteristics and the aims to achieve, implants and instruments were designed using an AutoCAD assisted design program and resin prototypes were made using a stereolithographic technique for mechanical and size validation. The second generation of prototypes were made of steel and underwent successive modifications until they were functional according to the aims to achieve. Simultaneously instruments were developed, an application guide was made manually, and 9 plastic replicas of the bones of the foot were made. The implant underwent resistance and fatigue testing, keeping in mind that the calcaneo-plantar-Achilles system supports weight during gait and the lifting of the heel that may, in a medium weight adult, reach 3,500 N. When both feet are weight-bearing the load is 1,200 N, these are applied to the calcaneus by means of an axial compression vector due to the tensions generated by the Achilles tendon and the plantar fascia. The system must be of a size to support these axial forces that coincide with the direction of the tuberotalar screws. Although the system works under compression, it has been tested in flexion to determine its resistance under unfavorable conditions that do not arise in the real world (Figure 6). The trials were carried out at the Valencia Biomechanical Institute where successive prototypes were tested.

The resistance test was done in a universal trial machine (Instron®, UK) with an actuator displacement speed of 0.09 mm/sec until system failure or until 3,500 N was achieved. Fatigue tests were carried out in a pneumatic machine with cyclic loads of 1,200 and 900 N and a frequency of 1 Hz, the test was ended at failure or when 1 million cycles were achieved.

Testing Prototypes in Cadavers

Once the permanent prototype was achieved, it was tested on cadavers, in 4 specimens of foot and ankle sectioned at the bottom third of the leg taken from 2 cadavers (Chair of Anatomy, Professor Rodríguez, School of Medicine of the Complutense University of Madrid). The specimens were mounted and fixated in a bench clamp and placed in the position they would be during surgery if the patient was lying prone (Figure 7). The instruments and the implant were developed according to the protocol designed for this purpose, registering any improvements or problems. With the aim of determining the possibility of reconstruc-

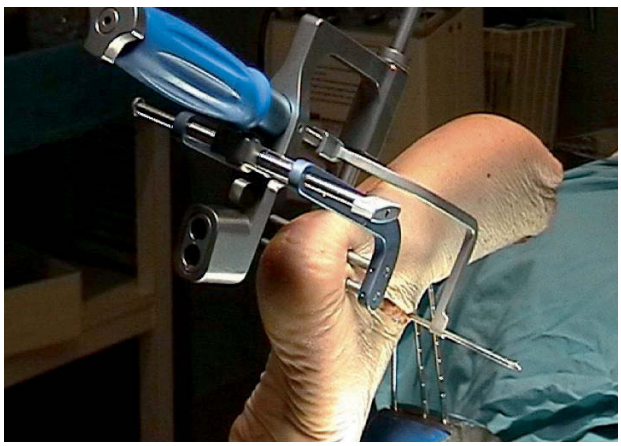

Figure 7. *Image of the trials in cadavers.*

Table 1. Talar and calcaneal sizes

	X	Minimum	Maximum
Talar-calcaneal angle (°)	40.3	36.3	42.1
Length of the calcaneus (mm)	87	68	90
Length of the talus (mm)	62	52	73
Height of talar body (mm)	31	27	37
Height of calcaneal greater tuberosity (mm)	46	39	55
Angle of the calcaneal tuberosity axis and talar body (°)	69,3	65	75
Length between the axis of the greater tuberosity and the center of the talar head (mm)	68	58	75
Normal Böhler angle (°)	152	145	155
Fracture Böhler angle (°)	171	–133	+122

x: media.

Table 2. Rigidity test results

Rigidity (N/m)	Force Yield strength (N)	Deformity Yield strength (mm)	Force Fracture (N)	Deformity Fracture (mm)
551.25	2,403.00	5.54	2.607.67	7.99

N: Newtons; mm: millimeters.

tion and reduction using instruments and an implant, calcaneal fracture was simulated in two specimens and a section of 1 cm of bone was dissected in the subtalar joint, separating the greater tuberosity from the body and the anterior tuberosity of the calcaneus.

RESULTS

Design of the System for Reconstruction-Arthrodesis of Calcaneal Fractures

Size assessment

The magnification factor was 1.2 and the results can be seen in Table 1.

Biomechanical tests

The results of the resistance tests can be seen in Table 2. There was good resistance to static loads and up to 2,400 N were supported. During fatigue testing 1 million cycles were not supported with a load of 1,200 N and there was no failure with the 900 N test.

Testing prototypes in cadavers

In the four procedures carried out on cadavers it was possible to determine that the biomechanical rationale of the implant was correct and it was not necessary to modify the instruments or the implants. The problems that arose were minor and made it necessary to change two dimensions and four mechanical characteristics that did not affect resistance. On the other hand, we encountered 2 size problems, 5 mechanical problems and 3 resistance problems in the guide, whereas in the instruments we encountered 3 size problems, 5 mechanical problems and 3 resistance problems. Each case was solved individually, adapting the design and making new prototypes according to the results of the tests. This made it possible for us to make a final prototype to use clinically.

DISCUSSION

Modern treatment of fractures has as its aim the reduction of the bone fragments, joint congruence and stable fixation that will allow early movement. In calcaneal fractures the principles that apply to osteosynthesis are perfectly applicable, but historically the results have been the object of controversy[4,13-17]. The reasons for poor results have been technical difficulties, postoperative morbidity and patient evolution in the long term.

Thalamic fractures frequently cause complications such as tarsal tunnel syndrome, especially of the external branch and entrapment of the peroneal tendons (external submalleolar pain). In 70% of these fractures there is chronic posterior subtalar joint pain cue to lack of congruence in this joint that causes arthritis in the medium term[18].

Although the most recent literature supports open reduction and internal fixation of the calcaneal fractures, there are many who are in favor or orthopedic treatment. In other cases a conservative approach is used initially and sequelae are treated as they appear.

In view of all the above we believe that it is important to develop new osteosynthesis systems that have greater ad-

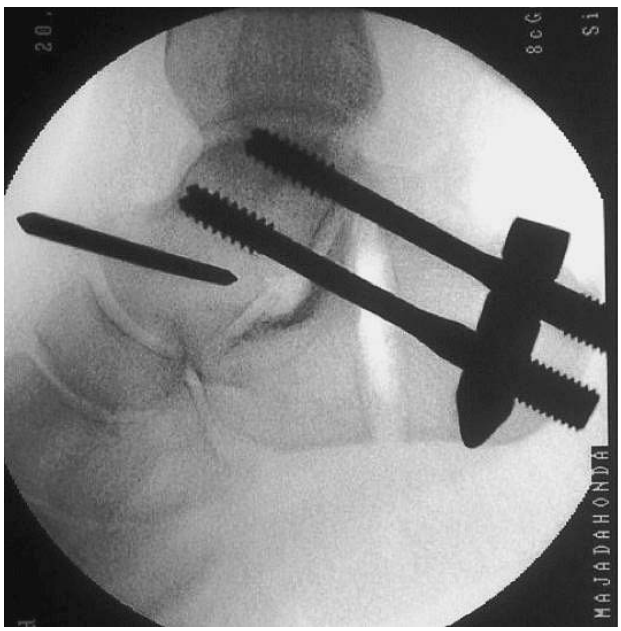

Figure 8. *X-ray image of an implant in a cadaver with a simulated fracture*

vantages than the systems already in existence. Current surgery is clearly moving towards less aggressive procedures, which expect the surgeon to achieve a perfect technique and leave a minimal scar. Surgical procedures that cause minimum damage, decrease postoperative pain, prevent complications, shorten recovery, help rehabilitation and improve cosmetic results, and above all, are functional. Historically, many attempts have been made to perform minimally aggressive surgery in cases of calcaneal fractures[19,20], but up to date, the results have not been satisfactory, with the exception of tongue fractures.

The concept of the Vira® system for reconstruction-arthrodesis of displaced intraarticular fractures of the calcaneal considers the subtalar joint irrecoverable, therefore its initial arthrodesis achieves a quicker, safer union than if it is deferred in time. In our experience, and this has been confirmed in the literature[21-23], primary arthrodesis has a rapid union rate, probably helped by the repair-oriented environment of the recent fracture.

The development of the concept of the Vira® implant is based on experiences with nails and screws in the posterior subtalar joint, described by many authors, for the reconstruction-arthrodesis of calcaneal fractures[22,24]. The problem with these screws is that they frequently cause a collapse of the greater tuberosity and suffer protrusion through the heel. The Vira® nail provides a solid support for the greater tuberosity, even if this is also fractured. The effect of the implant is to tense soft tissues and maintain the anatomical relationship of the calcaneus and the body of the talus, as a reference for the anchorage of the tuberotalar screws.

Biomechanical tests using the Vira® implant have not duplicated true working conditions which are impossible to duplicate in the laboratory due to the complexity of the plantar-Achilles-calcaneal system. Real mechanical conditions cause the main forces to exert axial compression on the tuberotalar screws due to the resultant vector of the forces of body weight and plantar fascia. During testing we have made the implant undergo flexion forces instead of compression forces. The results of these trials ensure that the implants once they are in place will not suffer failures in real conditions and they have shown sufficient resistance to allow early weight-bearing without instrument failure. The sizes determined in this study have not needed to be changed for carrying out tests in cadavers and in patients have adapted perfectly to requirements.

The Vira® guide is the device responsible for achieving a minimally invasive procedure and anatomical reconstruction of the hindfoot. In spite of its complex aspect, it is easy to manage because it has only 2 possibilities of regulating it and its weight, since it is made of titanium and carbon fiber. Although correct capture of the greater tuberosity of the calcaneus is crucial for its placement as an initial maneuver, the following steps using instruments are easy to duplicate. Tests in cadavers have been indispensable for the testing of the instruments, and have allowed the detection of sizing and fixation problems before attempting clinical use. The number of problems detected is greater than is usual with more conventional instruments due to the fact that the Vira® system opens up a new unexplored route in osteosynthesis without previous references to guide its development.

ACKNOWLEDGEMENTS

The authors wish to acknowledge the professional work of Luis Lozano for his engineering work developing this design. They also wish to thank Biomet Spain for having supported and contributed to this project.

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Conflict of interests: The first author (F. López-Oliva Muñoz) has a patent agreement with BIOMET, the manufacturers of the VIRA system for calcaneal fractures.