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■ **FOOT AND ANKLE**

Comparisons of external fixator combined with limited internal fixation and open reduction and internal fixation for Sanders type 2 calcaneal fractures

FINITE ELEMENT ANALYSIS AND CLINICAL OUTCOME

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Objectives

The aim of this study was to compare the biomechanical stability and clinical outcome of external fixator combined with limited internal fixation (EFLIF) and open reduction and internal fixation (ORIF) in treating Sanders type 2 calcaneal fractures.

Methods

Two types of fixation systems were selected for finite element analysis and a dual cohort study. Two fixation systems were simulated to fix the fracture in a finite element model. The relative displacement and stress distribution were analysed and compared. A total of 71 consecutive patients with closed Sanders type 2 calcaneal fractures were enrolled and divided into two groups according to the treatment to which they chose: the EFLIF group and the ORIF group. The radiological and clinical outcomes were evaluated and compared.

Results

The relative displacement of the EFLIF was less than that of the plate (0.1363 mm to 0.1808 mm). The highest von Mises stress value on the plate was 33% higher than that on the EFLIF. A normal restoration of the Böhler angle was achieved in both groups. No significant difference was found in the clinical outcome on the American Orthopedic Foot and Ankle Society Ankle Hindfoot Scale, or on the Visual Analogue Scale between the two groups (p > 0.05). Wound complications were more common in those who were treated with ORIF (p = 0.028).

Conclusions

Both EFLIF and ORIF systems were tested to 160 N without failure, showing the new construct to be mechanically safe to use. Both EFLIF and ORIF could be effective in treating Sanders type 2 calcaneal fractures. The EFLIF may be superior to ORIF in achieving biomechanical stability and less blood loss, shorter surgical time and hospital stay, and fewer wound complications.

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Article focus

■ The study aimed to design a new treatment for calcaneal fractures and compare the biomechanical stability and clinical outcome of external fixator combined with limited internal fixation and open reduction and internal fixation in treating Sanders type 2 calcaneal fractures.

Key messages

■ This new technique could fix Sanders type 2 calcaneal fractures.

■ The patients were satisfied with the technique.
■ The rate of wound complications was low.

Strengths and limitations

■ A strength of the study was the evaluation of outcomes in a series of patients with a comparison group.
■ As a strength, both the stability and clinical outcomes were evaluated.
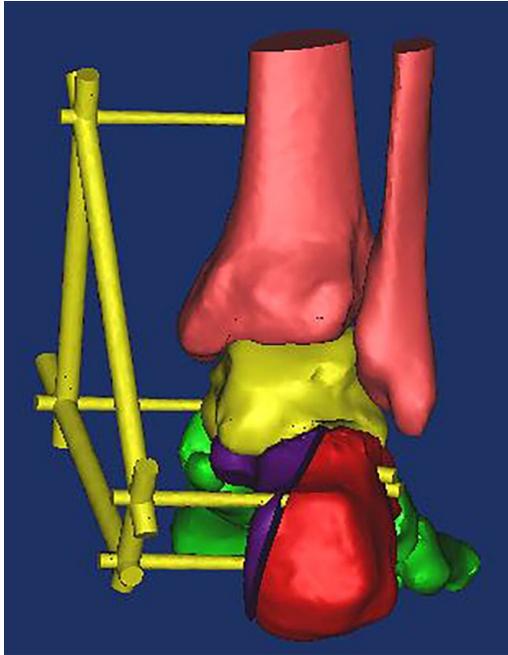■ As a limitation, the study lacked biomechanical analysis.

Fig. 1

The CAD model of the EFLIF for Sanders type 2 calcaneal fractures.

Fig. 2

The CAD model of the plate for Sanders type 2 calcaneal fractures.

Introduction

Calcaneal fractures are the most common type of tarsal bone fractures in clinical practice. Almost 75% of these fractures are intra-articular, and their management is still controversial.[1] Open reduction and internal fixation (ORIF) has been used as a standard treatment for displaced intra-articular calcaneal fractures, but the rate of complication post-operatively remains very high, and includes superficial wound sloughs or deep infections, cutaneous nerve injury, and hardware removal.[2] In order to reduce complications, minimally invasive techniques have been advocated by many surgeons:[3-5] a minimally invasive surgery was devised using a new external fixator combined with limited internal fixation (EFLIF). A finite element analysis and a dual cohort study were performed both to compare the biomechanical stability of EFLIF and ORIF, and to evaluate the clinical outcome, respectively.

Materials and Methods

Finite element analysis: collection of imaging data. A GE 64-row spiral CT scanner (Siemens, Munich, Germany) supported by the Southern Medical University Fengxian District Central Hospital was used to conduct the helical scan of the male volunteer's right lower limbs (173 cm height and 64 kg weight, the trial had been approved by the hospital's ethic committee, and an informed consent had been signed), and the data were saved in Digital Imaging and Communications in Medicine format. The scanning conditions were as follows: 155 mAs at 120 kV. The thickness from 15 cm above the ankle to the planta pedis was 2 mm. The size of the pixel matrix density in each scanning layer was 512 pixels × 512 pixels.
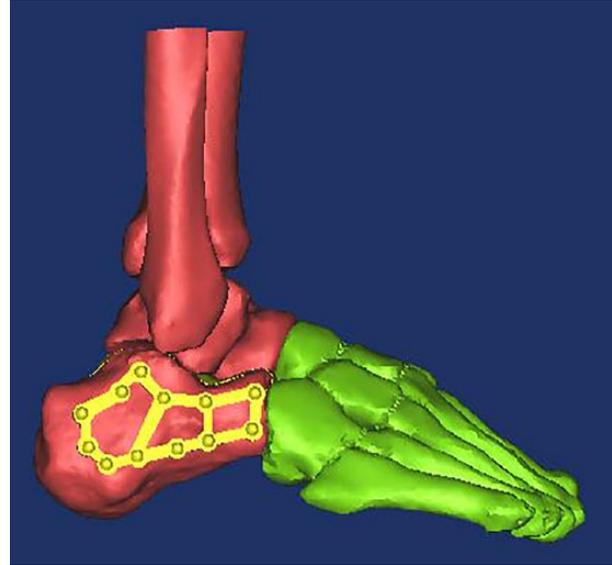
Finite element model of calcaneus construction. The data were inputted into the Mimics 15.01 software (Materialise NV, Leuven, Belgium). A computer-aided design (CAD) model (Figs 1 and 2) was generated by a method proposed by He et al.[6] The model was wrapped and smoothed through the functions of the 3D reconstruction, including region growing, cavity filling and editing masks, to obtain the desired 3D finite element model of the lower extremity. A Sanders type 2 fracture model was created using the cutting tools of SolidWorks 2012 (Dassault Systemes, Boston, Massachusetts). The materials of the external fixator and Schanz screw (Kangli Medical Group, Jiangsu, China), limited internal fixation screws, and plate (Synthes GmbH, Zuchwil, Switzerland) were scanned and transferred to the computed data to be used directly in simulating the fixation of the fracture models after smoothing.

Volume mesh generation. Finite element models were constructed using linear tetrahedrons. In this study, there were 765 848 elements with 163 617 nodes in the EFLIF model after meshing, and 1 323 960 elements with 254 345 nodes in the plate model.

Assignment of material properties. The related material properties of a calcaneal fracture finite element model were set up to establish a 3D finite element model similar to the practical model in material parameters and mechanical behaviour. The ligaments were set up as linear elastic materials sustaining tensile stress only. The material parameters of the fixation devices were obtained from Gefen et al[7] and manufacturers (Table I).

Constraint and loading. Simkin and Stokes[8] found that the Achilles tendon stress sustains about 50% of the force of the foot. The volunteer's weight in this study was 64 kg. While standing stationary, one foot sustained 320 N and the Achilles tendon sustained 160 N of pressure.

Table I. Material parameters for the bone and fixation systems

Component name	Young's modulus (MPa)	Poisson's ratio	Yield strength (MPa)
Schanz screw	193 400	0.33	225
External fixator connecting rod	69 400	0.31	135
Plate and screw	2 000 000	0.28	225
Cortical bone	7300	0.3	
Cancellous bone	1100	0.26	
Cartilage	1	0.1	
Fracture line	5	0.4	

S, Mises
(Avg: 75%)
+3.088e+01
+2.831e+01
+2.574e+01
+2.316e+01
+2.059e+01
+1.802e+01
+1.544e+01
+1.287e+01
+1.029e+01
+7.721e+00
+5.147e+00
+2.574e+00
+0.000e+00

Fig. 3
External fixator stress nephogram.

Therefore, 160 N was loaded in the direction of the Achilles tendon to simulate the maximum tensile stress that the calcaneus sustained during non-weight-bearing of the lower limb. The relative displacement and stress distribution were calculated to assess the stability of the two fixation systems. The models were implemented into the Abaqus finite element software (Dassault Systemes). When 160 N was loaded, the tibia, fibula, cuboid, wedge and metatarsal bone were fixed in space.

Clinical data. A total of 50 consecutive patients with closed Sanders type 2 calcaneal fractures were included in this study from January 2010 to December 2013, and divided into two groups according to the treatment (as chosen by the patient): the EFLIF group and the ORIF group. The trial had been approved by the hospital's ethic committee, and all patients signed informed consent. The inclusion criteria were as follows: patients with unilateral Sanders type 2 calcaneal fractures, diagnosed by radiograph and CT images; ages from 18 to 58 years; and patients with a clear trauma history, and without any other treatment. The exclusion criteria were as follows: age less than 18 years or more than 58 years; Sanders types 1, 3, and 4 calcaneal fractures; bilateral calcaneal fractures or combined with other damage; open or pathological fracture, and infection near the heel combined with serious medical diseases, cannot tolerate surgery or actively co-operate with the post-operative function of exercisers.

Surgical procedure. All patients were positioned supine with continuous epidural anaesthesia. In the EFLIF group, the use of a tourniquet was not preferred. Two 5 mL syringe needles were used to position the medial side of the non-fractured area of the calcaneal tuberosity. Two Schanz screws were then inserted through a small incision to replace the syringe needle after the most appropriate location was verified by a lateral radiographic view. A Schanz screw was inserted into the tibia and navicular bones in the same way. The fixator rods and clamps were assembled to allow for a full visualisation of the subtalar joint on a lateral radiographic view. The clamps were then locked temporarily under traction. A 2.5 cm incision was made under the lateral malleolus to expose the surface of the subtalar joint. The fracture could be reduced under direct vision. Two cannulated screws were inserted to fix the fractures. Finally,
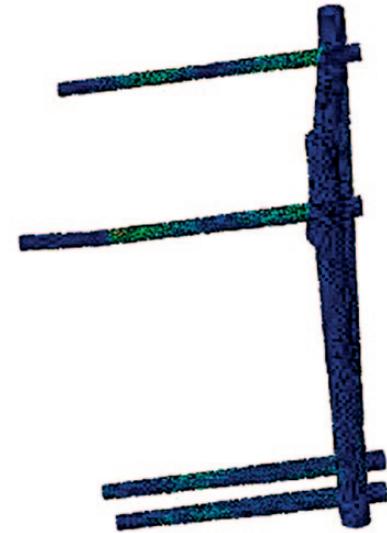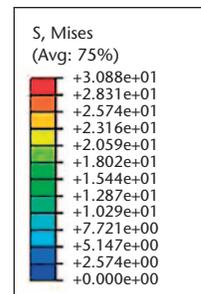
the clamps were locked permanently after the reduction was confirmed by fluoroscopy.

In the ORIF group, the patients underwent a standard procedure as described by Benirschke and Sangeorzan.[9] A thigh tourniquet was used and inflated to 350 mmHg. The fracture was fixed with a calcaneal plate and screws. Finally, the wound was closed in layers with a drain under the flap.

Three months after healing, two examiners assessed pain, walking ability, gait, ankle activity, ankle stability, and alignment, respectively. Hospital stay, blood loss, operation time, intra-operative fluoroscopy times, subtalar joint range of movement, return to previous work, patient satisfaction, and subtalar arthritis were recorded and compared between the two groups.

Statistical analysis. Means (and standard deviations) were calculated for each variable of interest, and t-tests were used to compare the treatment group. The Fisher's exact test was used to compare the complications between groups, as well as gender and type of accident. A p value of < 0.05 was considered significant.

Results

Finite element analysis: displacement of fractures. In a neutral loading of 160 N, the relative displacement was as follows: 0.1363 mm for the EFLIF in treating a Sanders type 2 calcaneal fracture; 0.1808 mm for the plates and less than 1 mm for both fixation systems.[10]

Finite element analysis: von Mises stress on fixation. There was no fixation failure in either fixation system. The highest value of von Mises stress of the external fixator was 30.88 MPa on the Schanz screw (Fig. 3). The highest value of the stress on the screws was 21.16 MPa in the fracture area (Fig. 4). The highest stress value of the
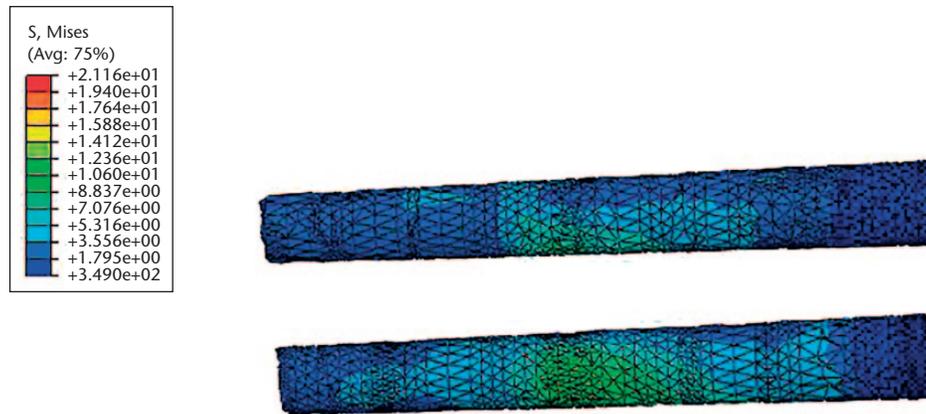
S, Mises
(Avg: 75%)

| +2.116e+01 |
| +1.940e+01 |
| +1.764e+01 |
| +1.588e+01 |
| +1.412e+01 |
| +1.236e+01 |
| +1.060e+01 |
| +8.837e+00 |
| +7.076e+00 |
| +5.316e+00 |
| +3.556e+00 |
| +1.795e+00 |
| +3.490e+02 |

Fig. 4

Screw stress nephogram.

S, Mises
(Avg: 75%)

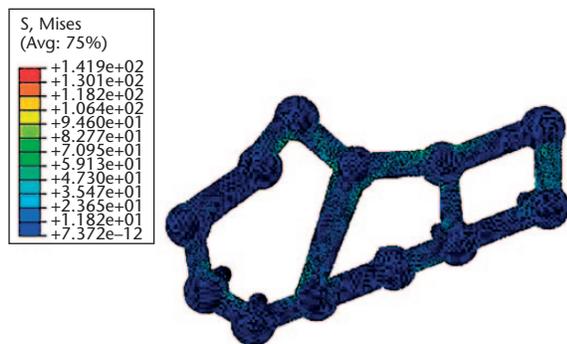| +1.419e+02 |
| +1.301e+02 |
| +1.182e+02 |
| +1.064e+02 |
| +9.460e+01 |
| +8.277e+01 |
| +7.095e+01 |
| +5.913e+01 |
| +4.730e+01 |
| +3.547e+01 |
| +2.365e+01 |
| +1.182e+01 |
| +7.372e–12 |

Fig. 5

Plate stress nephogram.

plate was 141.9 MPa on the connection of the screws and the plate (Fig. 5). The stress value of the plate was 33% higher than the stress value of the EFLIF.

Clinical outcome. Age, gender, type of accident, accompanying injuries and comorbidities were similar for the two groups. Follow-up time in the ORIF group was 23.66 months and 25.03 months in EFLIF group, and no significant differences were observed between the two groups (t = 1.686, p = 0.096). The external fixator and the plate were removed at the last follow-up. The timing of surgery, operation time, blood loss, and hospital stay were significantly less in the EFLIF group (p < 0.05). The intraoperative fluoroscopy times were greater in the EFLIF group (4.43 to 6.75, t = 8.070, p = 0.000). The Böhler angle was reconstructed anatomically (Fig. 6); a significant decrease in the Böhler angle was not encountered during the follow-up period.[11]

No significant differences were noted in the Böhler angle between the two groups pre-operatively, post-operatively, or at last follow-up (p > 0.05); nor were any significant differences found in the American Orthopedic Foot and Ankle Society (AOFAS) ankle hindfoot scale (83.83 to 84.40, t = 0.994, p = 0.324) or the Visual Analogue Scale (1.63 to 1.56, t = 0.389, p = 0.698) between the two groups. The subtalar joint range of movement, return to previous work, patient satisfaction, and subtalar arthritis were similar between the two groups (Table II).

One external fixation pin tract infection (2.85%) occurred in the EFLIF group, while six superficial infections and one deep infection (22.22%) occurred in the ORIF group, complications in the EFLIF group was significantly lower than ORIF group (p = 0.028, chi-squared). Administration of oral antibiotics and dressing changes were performed to treat the external fixation by pin tract and superficial infections. Implant removal, operative debridement and administration of intravenous antibiotics were performed to treat the deep infection at the sixth week post-operatively.

Discussion

ORIF is a standard technique for calcaneal fractures that can effectively restore the anatomy and allows for early weight-bearing and functional exercise.[12] However, extensive soft-tissue exposure aggravates the tissue damage and increases the risk of wound complications post-operatively.[12] Swelling after calcaneal fractures often delays surgical time, which can lead to a fracture haematoma mechanisation and scar tissue formation, influencing the exposure, reduction, and implant of the plate. The operative time, blood loss and hospital stay were significantly less in the EFLIF group.

Many scholars have reported the use of an external fixator in treating calcaneal fractures,[13-18] with the advantage of reduced soft-tissue injury and without the limitation of surgical timing and fracture types, thereby facilitating the treatment of open wounds and avoiding incision complications effectively.[19] However, if the fractures were treated solely with the external fixator, the subtalar joint could not be restored anatomically. In recent years, the EFLIF techniques were devised for

Fig. 6

A patient with Sanders type 2 calcaneal fractures treated with EFLIF. From left to right: a) pre-operatively in the lateral view; b) CT pre-operatively; one week post-operatively in the c) lateral and d) axial view; and e) one year post-operatively in the lateral view.

Table II. Clinical outcomes

		ORIF group (mean, sd)	EFLIF group (mean, sd)	p-value
Age (yrs)		41.92 (sd 12.65)	43.80 (sd 12.45)	0.512
Gender (male/female)		29/7	30/5	0.753
Type of accident				
	Fall from height	27	24	0.605
	Traffic accident	9	11	
Accompanying injuries		2 lumbar fractures	4 lumbar fractures	-
Comorbidities		1 diabetes mellitus	2 diabetes mellitus	-
Timing of surgery (days)		7.60 (sd 1.99)	3.08 (sd 0.94)	0.000
Hospital stay (days)		12.83 (sd 2.47)	9.14 (sd 1.61)	0.000
Operation time (mins)		74.77 (sd 7.32)	65.22 (sd 6.48)	0.000
Mean blood loss (mL)		79.14 (sd 11.28)	33.33 (sd 9.35)	0.000
Intra-operative fluoroscopy time (n)		4.43 (sd 1.09)	6.75 (sd 1.32)	0.000
Böhler's angle (°)				
	Pre-operatively	4.01 (sd 7.71)	3.20 (sd 8.26)	0.672
	Post-operatively	31.04 (sd 2.64)	31.81 (sd 3.58)	0.310
	Last follow-up	30.64 (sd 3.30)	30.85 (sd 3.45)	0.793
Follow-up (mths)		23.66 (sd 3.64)	25.03 (sd 3.20)	0.096
Range of movement (°)		26.57 (sd 2.08)	25.81 (sd 2.72)	0.188
Return to previous work		16	17	0.814
Patient satisfaction		32	34	-
Subtalar arthritis		3	2	-
AOFAS (max.; worst pain; 100)		83.83 (sd 7.21)	85.58 (sd 7.67)	0.324
Visual analogue score (max.; worst pain; 10)		1.63 (sd 0.73)	1.56 (sd 0.84)	0.698

AOFAS, American Orthopaedic Foot and Ankle Society Ankle Hindfoot Scale

treating calcaneal fractures as follows: first, the external fixator was used to correct the deformities with ligamentotaxis,[20] restoring the shape, height, length and width of the calcaneus; second, a lateral mini-incision was made to restore the joint surface under direct vision, fixing the fractures with one or two hollow screws to prevent the subsidence of the joint surface; and finally, the external fixator was locked at the ankle in a 90° neutral position, avoiding foot drop and talipes equinovarus. Using these techniques, the decrease in the Böhler angle was not observed during the follow-up period in this study.

With significant development in computer technology, the finite element analysis is widely used in the field of orthopaedic biomechanical research, especially in the foot.[6,21] In the present study, the detailed data of the foot contour were scanned witt the use of spiral CT of a healthy adult foot. The material parameters and properties of the model in this study were based on the published literature[7] that was commonly used in the finite element analysis. Thus, the finite element model would be accurate and reliable.

The stability of the medical apparatus and instruments used in fracture fixation is an important index to evaluate the effect. In this study, the EFLIF and plate for Sanders type 2 calcaneal fracture models were simulated. Under 160 N loading in the direction of the Achilles tendon, the displacement of both fixation systems were less than expected: separating or shifting 1 mm after the treatment of intra-articular calcaneal fractures.[10] Both fixation systems could be used to treat Sanders type 2 calcaneal fractures, however, the EFLIF may be more stable than the plate. In a clinical scenario, the patient should not bear

weight on the foot before healing. The strength of the Achilles tendon might be less than 160 N; that is to say, the displacement between the fracture blocks is less than the experimental value.

The stress distribution of the fixation system is also an important index to evaluate its effect. The stress distribution in the ideal state should be evenly distributed on the medical apparatus and instruments, and should not be overly focused on any single area. To this end, the stress distribution of the external fixator, screws and plate was tested after constraint and loading on the model. The maximum stress values of the two fixation systems were less than the yield strength of medical equipment. Compared with the plate, the maximum stress value on the EFLIF was lower. Although a stress concentration area was found on the two fixation systems, the value of stress was still less than the yield strength of medical devices. As the actual stress in a clinical scenario should be less than the experimental values, failure should not happen on the EFLIF.

Owing to the limitations of the study, we could not compare the finite element model with the cadaver model. While treating calcaneal fractures surgically, the ligaments, muscles and other soft tissues may be damaged during operation and repaired post-operatively. Due to the lack of thin soft-tissue slices of the foot, the reconstruction of ligaments could only be obtained from Gefen et al.[7] The material parameters of bones, ligaments, medical apparatus and instruments were derived from the published literature and device makers, but the exact material parameters of a part of the ligaments were not obtained, thus an average of the values was cited.[7] However, various factors could have some influence on the accuracy of the study.

In conclusion, the EFLIF technique is better, and hence preferable, to the ORIF due to the following advantages: it is more stable, there are lower levels of blood loss, a shorter surgical time and hospital stay, and fewer wound complications.

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