# Polyaxially-locked plate screws increase stability of fracture fixation in an experimental model of calcaneal fracture

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**Different calcaneal plates with locked screws were compared in an experimental model of a calcaneal fracture. Four plate models were tested, three with uniaxially-locked screws (Synthes, Newdeal, Darco), and one with polyaxially-locked screws (90° ± 15°) (Rimbus). Synthetic calcanei were osteotomised to create a fracture model and then fixed with the plates and screws. Seven specimens for each plate model were subjected to cyclic loading (preload 20 N, 1000 cycles at 800 N, 0.75 mm/s), and load to failure (0.75 mm/s).**

**During cyclic loading, the plate with polyaxially-locked screws (Rimbus) showed significantly lower displacement in the primary loading direction than the plates with uniaxially-locked screws (mean values of maximum displacement during cyclic loading: Rimbus, 3.13 mm (SD 0.68); Synthes, 3.46 mm (SD 1.25); Darco, 4.48 mm (SD 3.17); Newdeal, 5.02 mm (SD 3.79); one-way analysis of variance, $p < 0.001$).**

**The increased stability of a plate with polyaxially-locked screws demonstrated during cyclic loading compared with plates with uniaxially-locked screws may be beneficial for clinical use.**

The treatment of calcaneal fractures is challenging, even to the most experienced of trauma surgeons.[1,2] Plate fixation is an available treatment option, but technical difficulties and failure of fracture reduction have been reported.[3-8] Following the successful use of contoured plates and locking screws for other complex fractures[9,10] these designs have recently been introduced for calcaneal fractures.

A previous experimental study showed that plates with locked screws provide higher stability during cyclic loading than plates without locked screws.[11] However, the angle between the plate and the uniaxial locking screws, and the locking process itself, can prevent compression of the plate to the bone.[11] This has not proved to be a problem for similar designs used for other fractures.[9-12]

Consequently, a plate with polyaxially locking screws (90° ± 15°) and a special screwdriver system which prevents the screws from locking before the plate is compressed to the bone, was developed.[10,12,13]

In this experimental study we aimed to compare the stability of a calcaneal plate with polyaxially-locked screws with three plates fixed with uniaxially-locked screws during cyclical loading up to the point of failure. Our null hypothesis was that the different locking plates do not differ in mechanical stability during experimental fixation of calcaneal fractures.

## Materials and Methods

Left-sided calcanei (model Calcaneus Foam Cortical Shell, Sawbones, Pacific Research Laboratories, Vashon, Washington) were used (Fig. 1). The fracture pattern described by Lin et al[6] was created using a standard oscillating saw (Powerdrive, Synthes Inc., Bochum, Germany).

Four different plates were used (Fig. 1). The locking mechanisms of all systems include a conically-shaped complete thread at the screw head. The plates with uniaxially-locked screws (Newdeal (Newdeal Inc., Vienne, France), Darco (Darco Inc., Diessen, Germany) and Synthes (Synthes Inc.)) include a non-conically shaped complete thread at the screw holes. The plate with polyaxially-locked screws (Rimbus; (Intercus Inc., Rudolstadt, Germany) includes a non-conically-shaped interrupted thread at the screw holes. The locking mechanism of all implants prevents cold welding. The Rimbus screwdriver system (Intercus Inc.) has a sleeve which covers the thread of the screw head during initial insertion of the screw. The sleeve is equipped with a spring, which allows the sleeve to slide back and release the thread of

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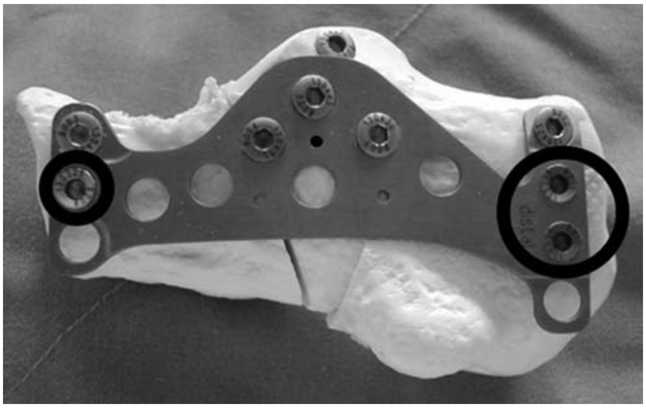

Fig. 1a

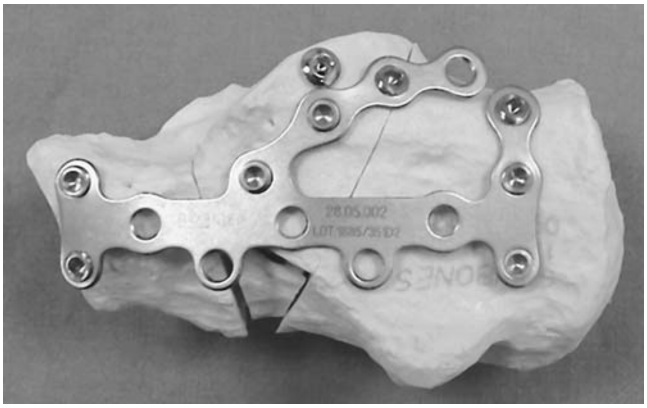

Fig. 1b

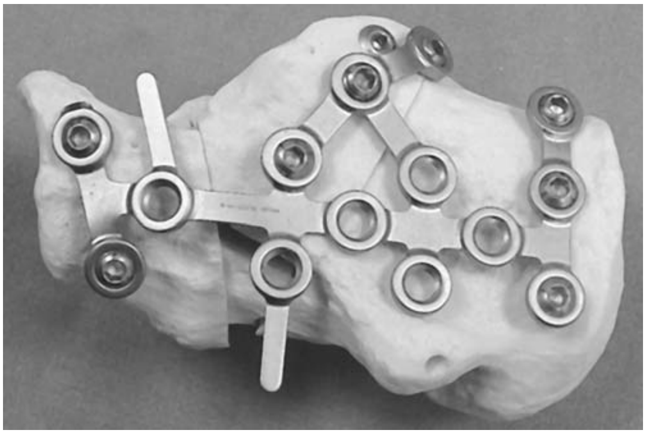

Fig. 1c

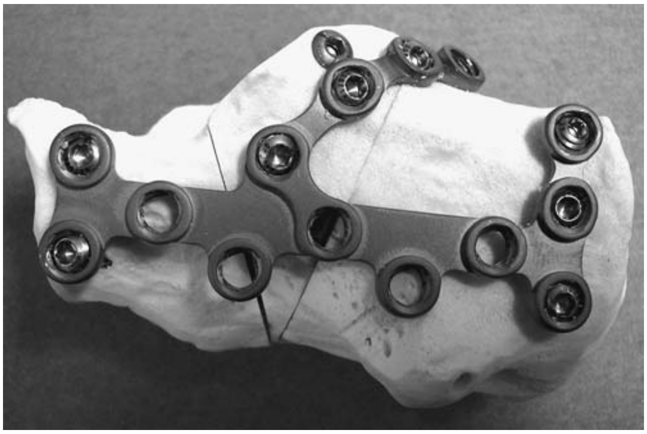

Fig. 1d

Calcaneal plates – a) Newdeal Calcaneus Plate (Newdeal Inc., Vienne, France) a plate with one anterior and two posterior uniaxial locking screws (circled); b) Darco Calcaneus Plate (Darco Inc., Diessen, Germany); c) Titanium Calcaneus Locking Plate (Clinical House (Synthes) Inc., Bochum, Germany) and d) a plate with polyaxial locking screws; Rimbus (Intercus Inc., Rudolstadt, Germany).

the screw head at the end of insertion to lock the screw to the plate. All plates and screws are made of titanium and are self-tapping.

The implants were positioned and fixed in a standard manner as described by Zwipp[1] and Sanders and Gregory.[14] This involved the reduction and stabilisation of the posterior facet fragments using one standard 3.5 mm titanium cortical lag screw (Titanium Cortical Screw, Clinical House (Synthes) Inc.). This was separate from the plate and was directed from the lateral side beneath the posterior facet to the suscentaculum tali (Fig. 2). The anterior and posterior processes were then reduced and the plates applied. The plates were securely fixed using three screws beneath the posterior facet, three in the posterior process and two in the anterior process. All screws were inserted in a bicortical manner. The middle screw under the posterior facet was aimed to hit the sustentaculum for increased stability in all cases (Fig. 2).[5] Seven bony specimens were configured for each plate. A power analysis was performed to determine the sample size.

A hydraulic testing machine (Zwick 1445, Zwick Inc., Ulm, Germany) was used for loading, force and movement analysis (Fig. 3). The specimens were embedded with their posterior process fixed to standard veterinary bone cement (Demotec 95, Demotec Inc., Nidderau, Germany; Figs 3 and 4), which has the same ingredients and properties as that used for humans (Palacos, Biomet Merck Inc., Berlin, Germany). A calcaneal angle of inclination of 20° and a hindfoot angle of 0° was achieved in all experiments, simulating normal anatomy. The angles (calcaneal inclination, hindfoot angle) were controlled with a digital goniometer (Winkelmesser-DIGIT, Gottlieb Nestlé Inc., Dornstetten, Germany; accuracy ± 0.1°). The load was applied and transmitted through artificial tali which were incorporated into the testing machine. These were made of a metal-like material (Magic Bond Epoxydkitt, ITW Devcon Industrial Products Inc., Kiel, Germany). The talus was shaped by an impression from the standard talus from the artificial bone specimen manufacturer (Sawbones, Pacific Research Laboratories). Physiological alignment between the talus and

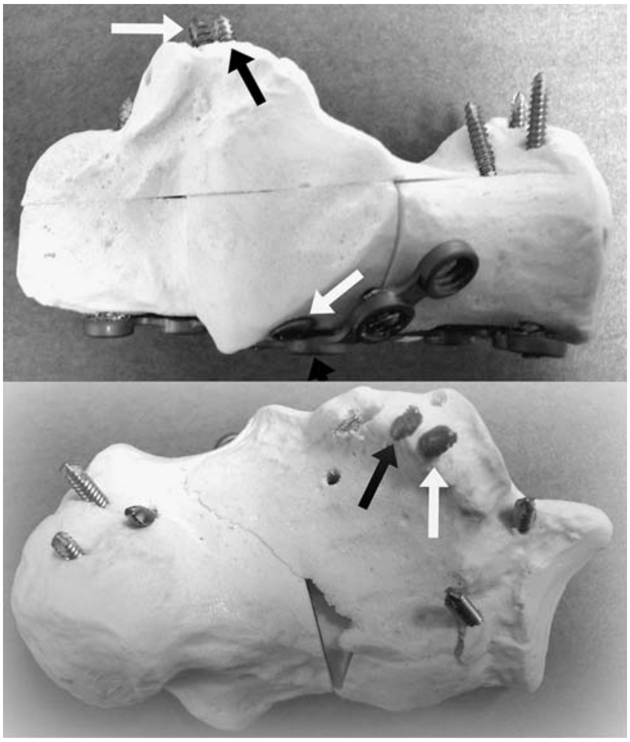

Fig. 2

The sustentaculum plate screw (black arrow) and the lag screw that is placed beneath the posterior facet and above the plate (white arrow). Owing to a shortage of short screw sizes, longer screws were used than were needed for tight bicortical fitting.

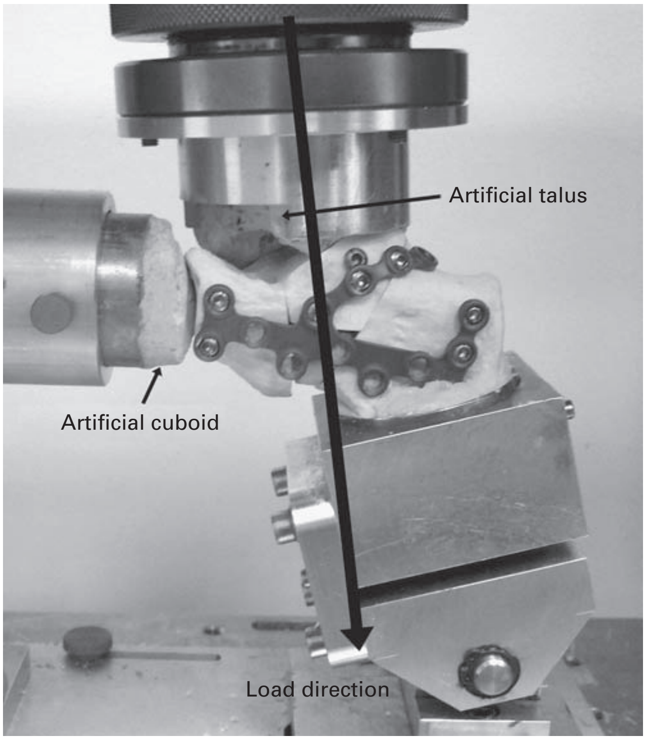

Fig. 3

A hydraulic testing and measuring machine (Zwick 1445, test-expert-Software, Zwick GmbH & Co KG, Ulm, Germany) with fixed calcaneus/plate specimen. The specimen's process is fixed to the holding device with cement. The lower portion of the process-holding device is able to rotate freely around the coronal axis. The anterior process is in contact with a metal support having an artificial joint surface. The load is applied from the top on to the posterior and anterior joint facets of the subtalar joint. The contact between the cross-head of the testing machine and the specimen is provided by a metal artificial talus with two joint facets.

Fig. 4

Bone-plate specimen after testing sequence with failed fixation at the posterior facet (Synthes plate, lateral view). The arrow shows the remaining joint depression, i.e. joint depression of the lateral posterior facet fragment in relation to the process fragment. The circle shows plastic deformation of the posterior portion of the plate.

the calcaneus was ensured. The testing machine was controlled by a standard IBM-compatible personal computer, with control software installed (test-expert-Software, Zwick Inc., Ulm, Germany) and measured the displacement of the testing machine head. This was considered to be equivalent to the displacement of the surface of the specimens posterior facet. All data were exported and stored for further statistical analysis.

Following the construction of the specimens, the mechanical testing machine was started and the following testing sequences performed:

1. 1000 cycles (0.75 mm/sec) of 20 N preload and 800 N cyclic loads.
2. Load to failure at 0.75 mm/s.

Failure (end-point) was defined as a further deformation of the specimen plus a decrease of the load at the same time, i.e. a rapid decrease of the load/deformation graph, resulting in the specimen being unable to take any further loading. Failure (end-point) was also defined for a displacement of more than 3 cm in the primary loading direction. The measurements during cyclic loading and the load-to-failure sequences were considered to be a parameter for the sum of elastic and plastic deformation. After the entire testing sequence the specimens were removed from the machine. The constructs were examined independently by two senior orthopaedic trauma surgeons (SZ and TG) and observa-

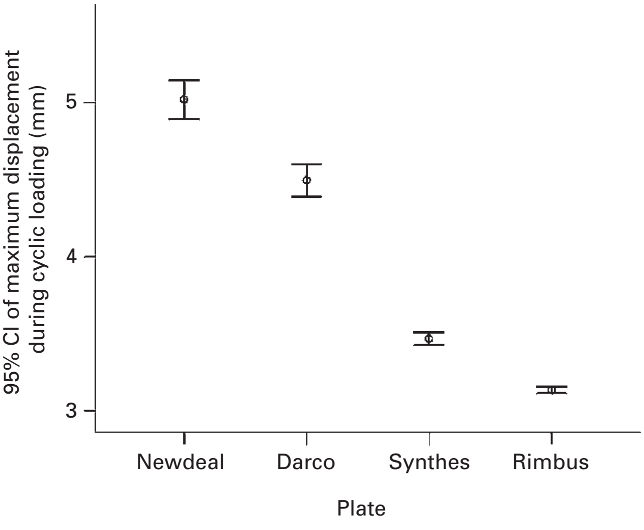

Fig. 5

Error bars with 95% confidence interval (CI) of the displacements in the primary loading direction during load in all cyclic loadings of the plate/specimens.

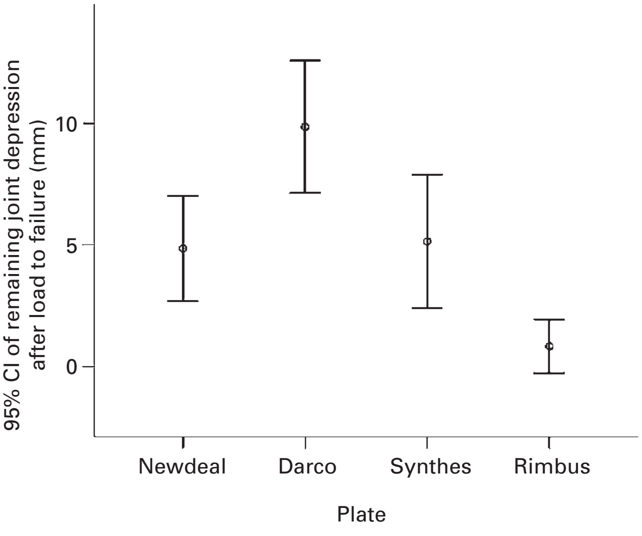

Fig. 6

Error bars with 95% confidence interval (CI) of the remaining depression of the posterior facet fragment after load to failure of the plates/specimens.

tions concerning failures were recorded (Fig. 4). In two cases the observations concerning failures differed. Both surgeons then repeated their evaluation together. This second evaluation did not differ from the first. The remaining joint depression was measured with an electronic caliper (Absolute Digimatic, Mitutoyo Inc., Neuss, Germany; accuracy ± 0.001 mm) and the plastic plate deformation was measured with an electronic goniometer (Winkelmesser-DIGIT, Gottlieb Nestle Inc.; accuracy ± 0.1°). These measurements were considered to be a parameter for plastic deformation.

One-way analysis of variance (ANOVA) was used for the measurement of force analysis. When significant differences occurred during the ANOVA test, a *post hoc* Scheffé test was used to locate the differences between the different specimen/plate constructs. The null hypothesis at the level $p < 0.05$ was that there was no difference between the different plates.

## Results

The sustentaculum plate screws were correctly placed in all cases with the Newdeal and the Rimbus systems (Table I). No failure of fixation was observed after the testing sequence.

The maximum displacement in the primary loading direction during cyclic loading differed for each of the plates (one-way ANOVA, $p < 0.001$; Fig. 5). The Rimbus system showed the lowest displacement (*post hoc* Scheffé test $p < 0.001$ *versus* all other plates).

The remaining joint depression after load to failure was lowest for the Rimbus plate (one-way ANOVA, $p < 0.001$; *post-hoc* Scheffé test $p < 0.05$ *versus* all other plates; Fig. 6). Failure loads, displacement during load to failure and plastic plate deformation after load to failure all failed to reach statistical significance.

There was no significant correlation between the results of load-to-failure sequence (maximum load, motion amplitude during load to failure, plastic plate deformation), and those obtained from the cyclic loading sequence (Pearson correlation coefficient $p > 0.05$), except for the remaining depression of the posterior facet (Pearson correlation coefficient $p = 0.04$, $r = 0.8$).

The joint depression fracture type according to the Essex-Lopresti[15] classification was similar for all the plates (Table I, Fig. 4). A rotation or translation of the anterior process occurred in four of 21 specimens (1, 6, 16 and 21). This feature was observed in all plates except for the Darco and the Rimbus. No loss of fixation at the locking mechanism was observed in any implants. The constructs failed because of plate bending, screw bending and loss of screw fixation.

The null hypothesis was rejected for the cyclic loading and remaining joint depression measurements.

## Discussion

The aim of this study was to test the relative strength of different calcaneal plates, in an experimental fracture fixation model using cyclic loading and load to failure. The fracture model and the load were designed to mimic the forces transmitted through the calcaneus during standing.[11] However, this design had several shortcomings.

Artificial bones were used and these do not accurately reproduce the internal architecture and mechanical properties of the real calcaneus.[16] However, they were identical,

**Table I.** Testing protocol and results of mechanical testing

| Number | Plate | Sustentaculum plate screw | Load to failure (N) | Failure (joint depression type fracture due to Essex-Lopresti[15] in all specimens) | Remaining joint depression (mm) | Plate deformation (°) | Problems |
|---|---|---|---|---|---|---|---|
| 1 | NewDeal | Correct | 1014 | Eversion of anterior process, no plate deformation | 7.5 | 5 | Artificial talus reached artificial cuboid |
| 2 | | Correct | 3640 | No rotation, no plate deformation | 6 | 2 | None |
| 3 | | Correct | 3674 | No rotation, no plate deformation | 5 | 3 | Artificial talus reached artificial cuboid |
| 4 | | Correct | 3035 | No rotation, no plate deformation | 4.5 | 0 | Artificial talus reached artificial cuboid, complete lateral displacement |
| 5 | | Correct | 2717 | No rotation, no plate deformation | 5.5 | 5 | None |
| 6 | | Correct | 2390 | Abduction of anterior process, no plate deformaton | 5.5 | 3 | None |
| 7 | | Correct | 1940 | No rotation, no plate deformation | 0 | 6 | Artificial talus reached artificial cuboid, complete lateral displacement |
| 8 | Darco | Incorrect | 2000 | No rotation, plate deformation posterior | 10 | 8 | None |
| 9 | | Incorrect | 2014 | No rotation, plate deformation posterior | 12.5 | 12 | Lateral displacement at 2000 N, maximum load 3800 N |
| 10 | | Incorrect | 2382 | No rotation, no plate deformation | 5.5 | 5 | None |
| 11 | | Correct | 3175 | No rotation, plate deformation posterior | 9.5 | 15 | None |
| 12 | | Incorrect | 2918 | No rotation, plate deformation posterior | 12 | 9 | None |
| 13 | | Incorrect | 3122 | No rotation, plate deformation posterior | 13 | 7 | None |
| 14 | | Incorrect | 2129 | No rotation, plate deformation posterior | 6.5 | 5 | Artificial talus reached artificial cuboid |
| 15 | Synthes | Incorrect | 2886 | No rotation, no plate deformation | 8 | 5 | Stop at 1500 N, restart of system |
| 16 | | Incorrect | 1683 | Inversion anterior process, no plate deformation | 5 | 7 | None |
| 17 | | Incorrect | 2912 | No rotation, plate deformation posterior | 9 | 15 | None |
| 18 | | Incorrect | 3296 | No rotation, no plate deformation | 4 | 3 | Artificial talus reached artificial cuboid |
| 19 | | Incorrect | 2807 | No rotation, no plate deformation | 4 | 2 | Artificial talus reached artificial cuboid |
| 20 | | Incorrect | 2806 | No rotation, no plate deformation | 0 | 7 | None |
| 21 | | Incorrect | 1929 | Abduction of anterior process, no plate deformation | 6 | 4 | None |
| 22 | Rimbus | Correct | 2818 | No rotation, minimal plate deformation posterior | 0.6 | 3 | None |
| 23 | | Correct | 2560 | No rotation, minimal plate deformation posterior | 2 | 4 | None |
| 24 | | Correct | 3007 | No rotation, minimal plate deformation posterior | 0 | 4 | None |
| 25 | | Correct | 1819 | Abduction anterior process, plate deformation posterior | 3 | 12 | Artificial talus reached artificial cuboid |
| 26 | | Correct | 3014 | No rotation, minimal plate deformation posterior | 0 | 3 | None |
| 27 | | Correct | 2930 | Fracture upper anterior process, no rotation, plate deformation posterior | 0.2 | 6 | None |
| 28 | | Correct | 2785 | No rotation, minimal plate deformation posterior | 0 | 3 | None |

allowing the different plate systems to be compared.[17,18] Cadaver bone could have been used but there would have been variability between the specimens.[6] Most cadaver specimens are harvested from individuals with a mean age of 80 years; in contrast, the mean age of patients with calcaneal fractures is 35 years.[1,19] We have previously investigated tissue tolerance and adaptation over time of different calcaneal specimens without implants, and observed no significant differences between the specimens (Sawbones; Synbone Inc., Davos, Switzerland; fresh-frozen cadaver; embalmed cadaver).[20] However, we were unable to define soft-tissue tolerance to the mechanical deviations of the specimen/plate constructs in this or the earlier tests.[11,20] We did not measure the torque forces that may be produced *in vivo* by muscular contraction and ligamentotaxis. Consideration of soft-tissue tolerance is only possible if cadaver specimens are used, with all muscles and tendons left intact and equipped with a system for artificial muscle activity. The soft tissues may influence calcaneal fracture patterns, for example the tendo Achillis in tongue-type fractures.[15] Our loading regimen with 1000 cycles at 800 N was designed to represent 1000 steps with full weight-bearing *in vivo*. The load-to-failure sequence should assess the maximum stability of the constructs. Lin et al[6] used fracture models similar to the ones in our study. However, they only measured single load to failure as opposed to cyclic loading. Furthermore, cadaver specimens were used in their study, which have potential disadvantages as described above.[6] Carr et al[7] used fresh-frozen cadaver specimens. In their study, different fracture configurations were created through direct impact on the specimens and not through precisely defined osteotomies.[7] Despite the use of cyclic loading, the data recorded from their study were of questionable value as the loading was only 100 N.[7]

In our study, movement was measured only by the mechanical testing machine. In an earlier study we also performed a movement analysis using ultrasound.[11] Data extracted from the mechanical testing machine were considered to be analogous to data from the movement analysis system. We achieved a reproducible fracture pattern by using standardised osteotomies, which differed from clinical situations in certain respects.[6,21-25] In our model the most unstable part was the central articular fragment. This would be expected to displace vertically under axial loads in line with the tibia, such as during physiological weight-bearing. Thus, the displacement of the posterior facet after preloading was considered to be the most important parameter for biomechanical behaviour during cyclic loading and load to failure. Remaining joint depression, plastic plate deformation and failure loads were additionally considered as parameters for biomechanical behaviour during and after load to failure. The results of this study suggest that the plate with polyaxially-locked screws provides higher stability regarding this parameter than plates with uniaxially-locked screws. The Rimbus plate showed the lowest displacement during cyclic loading, and the lowest remaining joint depression after load to failure. The fixed angle between plate and locked screw, which is 90° (± 0°) for the implants with uniaxially-locked screws (Synthes, New Deal, Darco), was problematic in our tests. Theoretically, the screws might be placed in a different angle if the drilling sleeve was not used or not used correctly. However, all manufacturers of plates with uniaxially-locked screws strongly recommend an exact rectangular placement.[5,9-12] The Rimbus plate allows a polyaxial screw position of 90° (± 15°) with locking stability within this range guaranteed by the manufacturer. The screws were all placed according to the manufacturer's recommendations and we did not observe any loss of fixation of the locking mechanisms in any implant. Thus, the stability of the locking mechanism was not relevant to the stability of the constructs. Another problem may be caused by the locking process itself which prevents the plate being tightened to the bone for the implants with locked screws except for the Rimbus (Intercus) plate.[5,9-12] Plate fixation for calcaneal fractures using plates without locked screws is characterised by the 'force-connection' principle, which is based on the generation of friction between plate and bone by compressive contact between the two surfaces.[5,21-26] Plates with locked screws in general, and the Darco and Synthes plates in this study, are based on the 'form-connection' principle, which is characterised by interlocking of the connection partners (screw and bone) without effecting forces.[12] The Newdeal plate with locked screws (one locked screw at the anterior process and two at the posterior process) and non-locked screws (beneath posterior facet, anterior and posterior processes) combined both principles at different screw sites. The Rimbus plate with the special screwdriver combines the form-connection and force-connection principles at all screw sites. Another possibility for pressing the plate to the bone to enable force-connection would be to use a clamp. We observed two significant problems with this technique during the clinical use of a conventional plate with uniaxially-locked screws. First, the clamp needs to be placed through the stab incisions at the medial side, which increases the morbidity of the approach. Secondly, the clamp needs to be placed at all or almost all screw sites to press the plate to the bone before the screw locks. The force-connection screwdriver presses the plate to the bone at all screw sites without increasing the morbidity of the approach. As the use of a clamp seems possible but disadvantageous compared with the screwdriver, we did not feel that a clamp was a real alternative which should be tested in the laboratory. When using plates without locked screws, and plates with locked screws, and the force-connection screwdriver, the blood supply might be affected when the plate is pressed to the bone. However, we are not aware of problems caused by decreased blood supply in the treatment of calcaneal fractures. The calcaneus differs in this respect from the long bones, in which the internal fixation principle as provided by locked plates has been shown to be advantageous.[1]

In our setting, hitting the sustentaculum with the middle plate screw under the posterior facet was only achieved in all cases with the Rimbus system among the plates with all screws locked. This issue might be responsible for the higher stability of the Rimbus system compared with the other plates tested. In the other plates, either the sustentaculum plate screw was exactly placed but not locked (Newdeal), or was locked but not accurately placed (Synthes and Darco). A separate lag screw at the posterior facet that was hitting the sustentaculum was used in all constructs (Fig. 2). By placing this screw before fixing the plate, we followed our principles and the recommendations of other specialists.[1,14] Because we used this separate screw in all constructs it was not a relevant factor for stability in our setting. However, we could not determine whether the sustentaculum plate screw or the combination of the form-connection and force-connection at all screw sites was responsible for the higher stability of the Rimbus plate. We did not analyse the stability with different screw angles for the plate with polyaxially-locked screws. Consequently, we are unable to state whether angulation alone makes a difference.

In conclusion, our results show that the tested plate with polyaxially-locked screws (Rimbus) provides higher stability during cyclic loading, and a lower remaining depression of the posterior facet fragment after load to failure than do the plates with uniaxially-locked screws (Synthes, Newdeal, Darco) in an experimental setting. The increased stability of plates with polyaxially-locked screws might be beneficial for clinical use.

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No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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