Does the IOFIX improve compression in ankle fusion?

Lee Parker BM, FRCS (Tr. & Orth.)a,*, Pinak Ray MS, MCh (Orth), FRCS (Orth)b, Stephan Grechenig MDc, Wolfgang Grechenig MDd

a SpR Trauma and Orthopaedic Surgery, The Royal National Orthopaedic Hospital, Brockley Hill, Stanmore, Middlesex HA74LP, United Kingdom
b Barnet Hospital, Wellhouse Lane, Barnet, Hertfordshire EN5 3DJ, United Kingdom
c University Hospital Regensburg, Department of Traumatology, Franz-Josef-Strauss Allee, Regensburg, Germany
d AUVA Trauma Hospital, Graz, Gostingerstrasse 24, 8020 Graz, Austria

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Background: The new IOFIX is an intra-osseous fixation device comprising an “X-post” through which a lag screw passes to apparently improve force distribution across an arthrodesis.

We conducted a novel human cadaveric study. Our null hypothesis was no difference in force exists in an ankle arthrodesis model stabilized with the IOFIX or a conventional single lag screw.

Method: In ten cadaver ankles a pressure transducer was compressed as an IOFIX and standard single lag screws were alternately compared.

Results: The median average force created by the IOFIX was 3.95 kg and 2.4 kg for the single conventional lag screw (p ≤ 0.01). The IOFIX improved contact area across the arthrodesis with a median average of 3.41 cm² compared with 2.42 cm² in the lag screw group (p ≤ 0.03).

Conclusion: Our results suggest an IOFIX improves force distribution across an ankle arthrodesis compared with a single conventional lag screw.

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1. Introduction

Under optimal conditions arthrodesis occurs between perfectly co-apted cancellous bone surfaces with intact circulation making it comparable to healing of an undisplaced fracture [1]. The ideal arthrodesis should have moderate uniform compression across perfectly co-apted surfaces in order to neutralize shear and bending forces. By avoiding uneven compression across imperfectly co-apted surfaces, areas of high peak contact stress are minimized, reducing the risk of bone resorption by osteolysis, failure of fixation and non-union [2].

During screw insertion, tightening of the screw is limited to a maximal torque and beyond this, either the screw or the bone fails. Provided the screw remains intact, the relationship between insertion torque and axial compression is linear while the trabeculae are intact. Beyond a critical torque of approximately 89% micro-fracturing of the trabeculae occurs leading to loss of screw thread purchase and compression [3]. If thread purchase in the far fragment is maintained, a fracture of the near fragment cortical bone bridge can occur when the arthrodesis is lagged-together. Both of these problems are of particular concern when there is osteoporosis [4,5].

The IOFIX (Extremity Medical, New Jersey, USA) comprises an “X-post” which is a pedicle-like cancellous screw positioned parallel to the fusion surface to act biomechanically like an internal washer. Through the head of the X-post a lag screw is passed across the fusion site into the opposite boney fragment. As the lag screw is tightened it engages the X-post’s morse taper and locks into place thereby reinforcing the cortical bone bridge (Fig. 1).

There are numerous studies focusing on screw design characteristics that optimize pull-out strength and compressive force [6-8] however to our knowledge the performance of the IOFIX has not previously been examined. Like many fixation devices new to the orthopaedic market the principles are often developed using computer modelling software and so we sought to establish the IOFIX’s reliability in a human cadaveric biomechanical experiment. Our null hypothesis was that there is no difference in the magnitude and distribution of force created across an ankle arthrodesis when the IOFIX is compared with traditional cancellous partially-threaded bone screws.

2. Method

The study was conducted at the Anatomical Institute, University of Graz, Austria. The experimental groups were designed to compare arthrodesis site compressions achieved
using the IOFIX couple – Group A (9.5 mm X-post and 6.5 mm tapered lag-screw)-with Group B the stand-alone 6.5 mm AO (Arbeitsgemeinschaft fur Osteosynthesefragen) cannulated lag-screw with a washer. By using the AO 6.5 mm lag-screw for Group B the experiments effectively examined the influence of the critical design component of the IOFIX, the X-post on arthrodesis site compression and force distribution but we do realize it is common practice to stabilize an ankle fusion with more than a single lag screw.

The experiments were performed on 10 randomized, separated adult ankles selected from a pool of cadavers preserved with the method of Thiel [9]. This unique embalming procedure was developed over a period of 30 years in the Department of Anatomy at the University of Graz, Austria. The embalming method preserves tissue colour and consistency as well as allowing an almost full range of movement at articular joints. None of the limbs used in this study had signs of previous injury, abnormality, or disease. The mean age of the donors was seventy-one years (range, 44–84 years) at the time of death and previous bone densitometry on similar ankles from this institute have yielded a mean bone density of 0.558 g/cm² (0.231–0.789 g/cm²) [10].

The 10 ankles received both treatments in a randomized fashion in order to allow direct comparisons between repeated measurements and also rationalize the use of cadaveric material. The soft tissues from the ankles were removed to facilitate the experiment and the articular surfaces of the distal tibia and talus were prepared with a 2.5 cm wide saw to create uniformly flat arthrodesis cuts. The tibia and talus were aligned and supported in a bench jig and the IOFIX was inserted as follows: a 1.6 mm guide-wire was inserted through the anterior distal tibia across the arthrodesis into the posterior talar body after which an alignment guide was passed over the guide-wire to allow targeting of the X-post placement approximately 15 mm above the tibial joint-line. The 1st guidewire was then removed and over the X-post guide-wire the X-post depth-gauge was passed. In normal practice the siting of the X-post and lag screw and their respective lengths are determined using a C-arm but we used a constant X-post length of 35 mm. Over the X-post guide-wire a 4.5 mm pilot drill was used to pre-drill the tibia and following this a hand-reamer used to allow sufficient counter-sinking of the X-post. The 9.5 mm diameter × 35 mm long X-post was then inserted with a screw-driver until the X-post lag-screw hole was positioned just below the anterior cortex of the tibia. Arthrodesis site compression was measured using a Tekscan/Iscan (Tekscan Inc. South Boston MA, USA) pressure transducer calibrated to display force in kilogram (kg) and contact area in cm² and inserted into the arthrodesis. The pressure cells in the paper-thin transducer produce a force value over the entire area of the sensor within the arthrodesis allowing for the screw and the area of the sensor outside the arthrodesis. Therefore in order to maximize the measured area, only one lag-screw at a time was used to hold the arthrodesis in each case. With the transducer inserted into the arthrodesis fractionally away from the lag-screw trajectory, a lag-screw guide-wire was inserted through the head of the X-post at an angle of 60° determined by seating the guide-wire guide in the morse taper of the X-post. The wire was advanced into the talus and in normal practice this guide-wire depth and position is verified with a C-arm however we used a constant 6.5 mm lag-screw length of 60 mm with a thread length of 16 mm. A 4.5 mm pilot drill was used to pre-drill the lag-screw hole and then the lag screw was inserted until its head had engaged with the morse-taper of the X-post. After final tightening, the pressure transducer was initiated and so mean average force in kg plus those pixels within the sensor being within the arthrodesis and therefore active to determine average contact area in cm² was recorded over 25 s (Fig. 2). This was done to remove manual pressure exerted by the experimenter as a source of error. Group B measurements were performed in a similar manner except the AO 6.5 mm × 65 mm lag-screw with 16 mm thread length was inserted with a washer over the guide-wire and pre-drilled with a 4.5 mm drill and no X-post was used. In investigating the force exerted by the single AO lag screw, we replicated the proximal to distal direction of the IOFIX lag screw insertion beginning approximately 15 mm above the anterior distal tibial joint line aiming posteriorly in the talus (Fig. 3).

Fig. 1. The IO Fix™ is shown implanted in the configuration used in our ankle arthrodesis model. We utilized flat arthrodesis cuts to permit the use of the flat Tekscan pressure transducer (Image courtesy of Extremity Medical).

Fig. 2. In our experimental set-up, the Tekscan pressure transducer has been inserted into the arthrodesis and the lag-screw is about to be fully tightened to load the pressure transducer.

Fig. 3. Line graphic of the ankle arthrodesis model. The AO lag screw is positioned with a washer in a similar trajectory to the IOFIX lag-screw beginning anteriorly in the tibia, heading posteriorly in the talus. The blue arrow indicates the positioning of the pressure transducer between flat arthrodesis cuts.
Data was analyzed using Stata/IC version 12.1 (StataCorp, College Station, TX, USA) and throughout a p value <0.05 was considered statistically significant. The Shapiro–Wilk test for normality confirmed that the average force measurements (in kg over 25 s) and average sensor contact area (in cm$^2$ over 25 s) was not normally distributed. The non-parametric Wilcoxon Signed rank test was therefore used for the comparisons of paired measurements.

3. Results

The median average force in the arthrodesis achieved with the IOFIX was 3.95 kg (IQR 2.9–4.2) compared with 2.35 kg (IQR 1.8–2.9) in the AO lag-screw group ($p = 0.01$) (Table 1). The IOFIX was seen to create a more uniform contact area across the entire arthrodesis. The sensor loading area within the arthrodesis was averaged over 25 s and in the IOFIX group the median average of these values was 3.41 cm$^2$ (IQR 2.61–4.36) compared with 2.42 cm$^2$ (IQR 1.4–2.98) in the single AO lag-screw group ($p = 0.03$) (Table 2).

An example (Ankle 5) of the graphs produced by the Tekscan software demonstrates the higher mean force (Fig. 4) produced within the arthrodesis for the IOFIX (4.9 kg) compared with the AO lag-screw (2.8 kg). What is also apparent is how the IOFIX exerts this higher mean force over a greater proportion of the arthrodesis (4.14 cm$^2$) compared with the AO lag-screw (2.98 cm$^2$) (Figs. 5 and 6).

4. Discussion

To our knowledge the performance of the IOFIX has not been tested in a biomechanical model or compared against the established standard fixation technique of the 6.5 mm partially-threaded cannulated cancellous lag-screw in ankle arthrodesis. Although the IOFIX is designed to be used in fusing other joints in the foot we chose to evaluate its performance in the ankle as the large surface area made it technically easier to perform. We analyzed the mean average force in kilograms exerted by the IOFIX across the arthrodesis and the area in cm$^2$ over which this force was exerted. These parameters were analyzed using a paper-thin pixelated pressure transducer which permits a frame-by-frame real-time analysis that can be displayed graphically. We elected to commence twenty-five second recordings of the forces generated once the IOFIX and standard AO screws had been fully-tightened so

![Fig. 4. Tekscan graph of force (F) measurement (kg) for ankle 5. The graph reveals minimum, maximum and mean force (kg) and Imp = area under curve in kg-s: IOFIX ankle 5 (green line) (upper). F: min = 4.8, max = 5.0 at 10.8 s, mean = 4.9 kg, Imp: 123.5 kg s. Lag-screw ankle 5 (red line) (lower). F: min = 2.6, max = 2.9 at 13.3 s, mean = 2.8 kg, Imp: 69.8 kg s. (For interpretation of the references to color in this text, the reader is referred to the web version of the article.)](image)

![Fig. 5. Tekscan graph of contact area (A) in ankle 5 determined by the sensor (cm$^2$). The graph reveals minimum, maximum and mean area (cm$^2$): IO FIX$^\text{TM}$ ankle 5 (green line) (upper). A: min = 4.03, max = 4.25 at 1.3 s, mean = 4.14 cm$^2$. Lag-screw ankle 5 (red line) (lower). A: min = 2.69, max = 3.23 at 24.1 s, mean = 2.98 cm$^2$. (For interpretation of the references to color in this text, the reader is referred to the web version of the article.)](image)
the experiment could not be influenced by the pressure exerted on screw-drivers during insertion.

The results (Table 1) showed that the IOFIX was able to create significantly higher median average forces within the arthrodesis compared with the single cancellous lag-screw and washer (3.95 kg (IQR 2.9–4.2) compared with 2.35 kg (IQR 1.8–2.9) (p < 0.01). Where equally high forces were achieved both with the IOFIX and the AO screws we hypothesize this was due to improved bone quality in these ankles, although the bone density of the individual ankles was not analyzed in this study and so remains a confounding factor.

The IOFIX was able to create a more uniform pressure across the arthrodesis and exhibited a higher median average contact area by activating more of the sensor pixels within the arthrodesis (Table 2), whereas the AO lag-screw and washer tended to concentrate stress nearest where it was inserted (3.41 cm² (IQR 2.61–4.36) compared with 2.42 cm² (IQR 1.4–2.98)) in the single AO lag-screw group (p < 0.03). Bone resorption in areas of high peak contact stress within an arthrodesis may lead to progressive loss of bone interdigitation, gapping and non-union at the interface [11] and reassuringly the IOFIX exhibited a more uniform contact area in this study.

Potential limitations of this study are that the cadaveric ankles used in the experiments, although randomized, were from a large age range (44–84 years). We also used each ankle twice for compression measurements by taking readings with the IOFIX and the lag screw. We varied the order in which the IOFIX and AO lag screw were inserted across the arthrodesis so that one fixation method was not given an advantage over another by changing the nature of the cancellous bone, however to further minimize the possibility of the cancellous bone being altered more ankles could have been used. In addition, we varied the side of the ankle each fixation method was used on but this was not formally randomized.

Our experiment focused on compressive forces acting across flat arthrodesis cuts when it is common-place to prepare the ankle joint maintaining the usual domed morphology of the ankle mortise. We did not take into account possible torsional and shear forces that undoubtedly occur across an arthrodesis in vivo. Indeed, the results obtained reflect a measure of immediate stability and of course do not provide a direct validation of the stability imparted to the arthrodesis in vivo during the healing phase. Also it is apparent that normally more than one single lag screw is used to stabilize an ankle fusion, however by comparing the IOFIX construct with the single AO lag screw we were able to assess the influence of the defining design characteristic (The X-post) of the IOFIX on compression at the arthrodesis interface.

Further research should focus on the impact of varying bone density on the performance of the IOFIX, investigating whether there is an influence of the position in which the IOFIX is used in the ankle on compression and confirming the number and configuration of devices that are required to impart maximal stability. The use of the IOFIX in preference to AO cancellous screws will require further justification by patient audit, particularly assessing its claimed advantages of lower non-union rates and hard-ware related soft-tissue impingement.

5. Conclusion

This research supports the theory that the IOFIX improves force generation and distribution across an ankle arthrodesis when compared with a single partially-threaded cancellous lag-screw supplemented by a washer. We recognize that in practice more than a single cancellous lag-screw is used to stabilize an ankle arthrodesis, however, this study aimed to investigate the claimed advantages of the essential defining characteristic of the IOFIX which is the X-post through which the devices lag-screw passes. On-going evaluation of this new device is required and should be a stimulus for further research.

Conflict of interest

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