The effect of accuracy of implantation on range of movement of the Scandinavian Total Ankle Replacement

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When performing the Scandinavian Total Ankle Replacement (STAR), the positioning of the talar component and the selection of mobile-bearing thickness are critical. A biomechanical experiment was undertaken to establish the effects of these variables on the range of movement (ROM) of the ankle.

Six cadaver ankles containing a specially-modified STAR prosthesis were subjected to ROM determination, under weight-bearing conditions, while monitoring the strain in the peri-ankle ligaments. Each specimen was tested with the talar component positions in neutral, as well as 3 and 6 mm of anterior and posterior displacement. The sequence was repeated with an anatomical bearing thickness, as well as at 2 mm reduced and increased thicknesses. The movement limits were defined as 10% strain in any ligament, bearing lift-off from the talar component or limitations of the hardware.

Both anterior talar component displacement and bearing thickness reduction caused a decrease in plantar flexion, which was associated with bearing lift-off. With increased bearing thickness, posterior displacement of the talar component decreased plantar flexion, whereas anterior displacement decreased dorsiflexion.

The STAR (LINK Scandinavian Total Ankle Replacement; Waldemar Link GmbH & Co, Hamburg, Germany) prosthesis was designed in order to provide high congruity between implant surfaces while allowing some freedom in the transverse plane. In this three-component system, a floating polyethylene bearing insert lies between two metal components. Owing to its unique shape, the mobile bearing is rotationally constrained by the talar but not the tibial component. Theoretically, this mobile-bearing design reduces stress at the implant-bone interfaces, thus decreasing the risk of loosening. The STAR system has demonstrated encouraging medium-term results in limited clinical series.1-5

The selection of the thickness of the polyethylene bearing and the anteroposterior placement of the talar component are critical variables in the operative technique. We hypothesised that both factors affected the functional range of ankle movement. The purpose of this study was to establish the effects of these two factors on the range of movement under weight-bearing conditions.

Materials and Methods

Six fresh-frozen ankle specimens (mean age 64 years (57 to 74)) were obtained post-mortem from three male donors. Each specimen was thawed at room temperature before testing and dissected free of soft tissue, keeping all major supporting ligaments intact. No deformities, contractures, ligament injuries, or areas of articular degeneration were found on visual or manual inspection. To enable mounting in the testing machine, the mid-shaft of the tibia/fibula, the calcaneum and the distal phalanges were secured in three separate blocks of polymethylmethacrylate.

A size 4 STAR prosthesis which had a modified talar component (Fig. 1) was implanted into each ankle. This component, which was mounted on a separate platform cemented to the talus, could be translated in the anteroposterior plane by increments of 3 mm on the platform. The modified prosthesis allowed placement of the talar component in five possible positions: anatomical, 3 and 6 mm anterior, and 3 and 6 mm posterior. As opposed to a normal STAR implantation, the modified talar component required a flat talar osteotomy to cement the platform. All experiments were conducted using the position of the native talar dome in both craniocaudal and anteroposterior directions as the reference position. We refer to this as the anatomical position. The platform was aligned with the longitudinal
axis of the talar dome and placed so that the talar component was in the anatomical position when it was indexed in the central position of the platform. The interface of the talar component and the mobile bearing was considered as the joint, since this is the interface where the major direction of movement (dorsal and plantar flexion) occurs.

The thickness of the tibial osteotomy was controlled so that the anatomical vertical distance between the tibia and talus would be reproduced when an 8-mm thick mobile polyethylene bearing was used. The total height of the implant, with an 8-mm bearing, was 22 mm. Therefore, the combined thickness of the tibial and talar osteotomies was carefully set at 23 mm, in order to allow an additional 0.5 mm for cement fixation on each side. Insertion of a 6- or 10-mm bearing resulted in 2-mm reduction or expansion of the joint space, respectively.

To monitor peri-ankle ligament strain, miniature differential variable reluctance transducers (DVRT; Microstrain Inc, Williston, Vermont, New England) were attached directly onto the ligaments. A DVRT can continuously measure the separation between the two points at which it is sutured by means of an output voltage, which is then converted to a length using a predetermined calibration. DVRTs were sutured to the mid-substance of the following six ligaments: the anterior talofibular ligament, the calcaneofibular ligament, the posterior talofibular ligament, and the anterior, middle and posterior bundles of the superficial deltoid ligament complex. The deep deltoid ligaments were not included because their fibres were too short and too deep to attach a DVRT.

After placing the DVRTs, each specimen was subjected to a ligament zero-strain determination procedure. The ankle was manually manipulated while observing a particular ligament, to ascertain the point at which the ligament became taut. The DVRT output at this point, defined as the zero-strain output, was recorded and the procedure repeated for the remaining ligaments. Ligament strain was defined as percent elongation of the transducer mounted on each ligament, relative to this zero-strain length. As a result, positive values of strain indicated that the ligament was lengthened, while negative values indicated that it was shortened.

The determination of range of movement (ROM) was performed using a custom loading fixture mounted in a material testing machine (Model 858.20; MTS Inc, Eden Prairie, Minnesota) (Fig. 2). Each specimen was mounted
Initially, at zero flexion, and 300 N of axial load was applied to the tibia. This load, which is approximately one-half body weight, was chosen so as to approach physiological conditions while avoiding ligamentous rupture or bony fracture. To allow normal ankle movement, anteroposterior translation and internal/external rotation of the tibia were unconstrained. The inversion/eversion position was fixed after the 300 N axial load was applied. During testing, the flexion angle under load was recorded by a potentiometer. Each ankle was plantar flexed and dorsiflexed manually by a single investigator (YT) in order to determine the limit of ROM.

Limits in plantar or dorsiflexion were defined as the angle at which any one of the following four conditions first occurred: 10% strain in any ligament; lift-off of the mobile bearing from the talar component; the limit of implant movement as demonstrated by mobile bearing impingement on the platform of the modified talar component; or the limit of flexion of the loading device (approximately ± 30°). The first condition was imposed to avoid potentially irreversible ligament elongation. The second condition was to prevent unstable behaviour of the bearing such as complete ejection from the joint. By necessity, lift-off was determined visually, as it was not accompanied by any increase in flexion torque. In fact, it was because of the need to avoid bearing lift-off that flexion was controlled manually, rather than under test machine control. In a few cases, a marked increase of flexion torque was felt before any of these four conditions occurred and in those cases, movement was assumed to be restricted by an unmonitored structure.

Each specimen was tested first with an 8-mm (anatomical thickness) bearing, followed by 6- and 10-mm bearings. The 10-mm tests were performed last because of concern about possible stretching of the ligaments. At each bearing thickness, the talar component was first placed in the anatomical position; for further tests, at that bearing thickness, the remaining four talar positions (3 and 6 mm anterior and posterior) were randomised. After the full set of tests was completed on each specimen, several individual tests were chosen at random and repeated. In all cases, the maximum flexion angles obtained were within ± 1°.

Total ROM was defined as the sum of the limit angles in plantar and dorsiflexion. Total ROM was used in order to evaluate the effect of bearing thickness and/or talar component positioning, while each limit angle was also used to explore the details of the effect. The data were statistically analysed with a linear mixed model analysis in repeated measures, using SAS Version 8.2 (SAS Institute Inc, Cary, North Carolina). Values for \( p < 0.05 \) were regarded as significant.

**Results**

**Anatomical bearing thickness (8 mm).** Total ROM was maximal with 8-mm bearing thickness when the position of the talar component was either in neutral or 3 mm posteriorly (Fig. 3 and Table I). The ROM decreased progressively as the talar component was displaced anteriorly; the decrease was primarily in plantar flexion. The plantar flexion limit angle decreased significantly with anterior displacement (\( p = 0.0003 \)). For all specimens, when an anterior displacement from neutral resulted in a decrease in plantar flexion of more than 5°, the decrease was the result of anterior lift-off of the polyethylene mobile bearing (Fig. 4). Lift-off was observed in five of the six specimens.

**Reduced bearing thickness (6 mm).** Reduction of bearing thickness caused a decrease in ROM, which was primarily

| Table I. The mean (˚) ± SD for both flexion limit angles and the sum of the two as a total of range of movement (ROM) |
|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Bearing thickness (mm) | Measure         | 6 mm anterior | 3 mm anterior | Neutral | 3 mm posterior | 6 mm posterior |
| 6               | Plantar flexion | 11.8 ± 7.0    | 15.6 ± 6.6    | 20.8 ± 7.1    | 25.3 ± 6.2    | 29.7 ± 2.2    |
|                 | Dorsiflexion    | 29.8 ± 2.1    | 30.8 ± 0.3    | 30.7 ± 0.6    | 30.3 ± 1.0    | 30.7 ± 0.6    |
|                 | ROM             | 41.7 ± 5.8    | 46.4 ± 6.5    | 51.5 ± 7.6    | 55.7 ± 6.8    | 60.4 ± 2.3    |
| 8               | Plantar flexion | 18.6 ± 5.8    | 23.7 ± 6.6    | 29.6 ± 2.4    | 29.3 ± 1.9    | 26.0 ± 2.2    |
|                 | Dorsiflexion    | 27.3 ± 5.1    | 29.3 ± 3.7    | 30.3 ± 0.8    | 31.0 ± 0.0    | 31.0 ± 0.1    |
|                 | ROM             | 46.0 ± 6.4    | 53.0 ± 6.5    | 59.9 ± 2.7    | 60.3 ± 1.9    | 57.0 ± 4.1    |
| 10              | Plantar flexion | 23.0 ± 4.6    | 26.3 ± 4.4    | 26.7 ± 3.4    | 22.2 ± 5.2    | 17.8 ± 7.6    |
|                 | Dorsiflexion    | 16.9 ± 3.2    | 22.4 ± 4.2    | 27.9 ± 5.5    | 28.8 ± 3.2    | 30.1 ± 1.5    |
|                 | ROM             | 39.9 ± 4.3    | 48.7 ± 6.5    | 54.4 ± 6.5    | 51.0 ± 4.5    | 48.0 ± 7.6    |
The superficial deltoid ligament is seen on the lower left (black arrow). In this view, the DVRT monitoring strain in the anterior part of the superficial deltoid ligament is seen on the lower left (black arrow). Lift-off of the polyethylene mobile bearing from the talar component (white arrow). In this view, the DVRT monitoring strain in the anterior part of the superficial deltoid ligament is seen on the lower left (black arrow).

Lift-off was observed in four of the six specimens. When the talar component was in the neutral position, 3 mm anterior, or 6 mm anterior, the plantar flexion limit angle was significantly less than for the corresponding position with 8 mm thickness (p < 0.01). The plantar flexion limit angle was maximal in the 6 mm posterior position, and significantly decreased with anterior displacements from this position (p < 0.0001). For individual specimens, in every case when a reduction in bearing thickness resulted in decrease in plantar flexion of more than 5°, this decrease was associated with bearing lift-off. Lift-off was observed in four of the six specimens.

**Increased bearing thickness** (10 mm). With 10 mm bearing thickness, the talar component displacements in both anterior and posterior directions caused a decrease of the total ROM (Fig. 3 and Table I). The decrease in total ROM with anterior talar component displacement was primarily in plantar flexion, whereas the decrease with posterior displacement was primarily in plantar flexion.

The plantar flexion limit angle was maximal with the talar component in the neutral position, and decreased significantly with posterior displacements from this position (p = 0.008). For both 3 and 6 mm posterior talar component displacements, the limit angle was less than for each corresponding position with an 8 mm bearing thickness (p = 0.005 and p = 0.001, respectively). For individual specimens, the decrease in plantar flexion was specifically associated with increased middle deltoid ligament strain in two specimens and increased anterior deltoid ligament strain in a third. In four specimens, bearing lift-off occurred when the talar component displacement was 6 mm anterior. The resulting mean decrease in plantar flexion was 8 ± 5°.

The dorsiflexion limit angle decreased significantly with anterior displacements of the talar component from the neutral position (p < 0.0001). For both the 3 and 6 mm anterior talar component positions, the limit angle was less than for each corresponding position with 8 mm bearing thickness (p = 0.002 and p = 0.0004, respectively). For individual specimens, anterior talar component displacement caused a decrease in dorsiflexion without occurrence of lift-off or an increase in ligament strain.

**Discussion**

This study involved determination of the ROM to explore the effects of talar implant malpositioning and improper mobile bearing thickness on the functional ROM with a STAR prosthesis. Ankle movement was primarily limited by excessive ligament strain or lift-off of the mobile bearing from the talar component. The former was chosen because increased ligament strain causes restriction of ankle movement which often disturbs smooth gait. The latter indicated the limit of stable implant motion.

The results demonstrated that both anterior displacement of the talar component and reduction of bearing thickness led to premature polyethylene bearing lift-off and that the individual effects augmented each other. The bearing lift-off that occurred presumably resulted from axial forces becoming concentrated on the posterior edge of the bearing. Anterior translation of the talar component probably moved the centre of pressure on the bearing in a posterior direction, leading to anterior edge lift-off. Another plausible cause of the lift-off is subfibular impingement on the lateral talar process. Decrease of the joint space owing to reduced bearing thickness might involve subfibular impingement, thus shielding the axial force and reducing the contact pressure at the implant interface, especially at the anterior edge. There was no occurrence of posterior lift-off which tends to support this notion. A selection of bearing thickness that reduces the joint space, and anterior malplacement of the talar component, should be avoided.

With increased bearing thickness, posterior displacement of the talar component reduced the ROM in plantar flexion, while anterior displacement reduced the ROM in dorsiflexion. Those reductions were likely to be secondary to excessive stretch of the peri-ankle ligaments owing to joint distraction. The reduction in plantar flexion was often because of increased strain in either the middle or anterior deltoid ligament. However, dorsiflexion was restricted without causing increased ligament strain or lift-off. This suggests that a plausible source of the restriction is tautness of the deep layer of the deltoid ligament, which, for technical reasons, we were unable to monitor. The deep layer, connecting the lateral talus and the medial malleolus, is formed by weak anterior and very strong posterior bundles. Thick and short fibres of the posterior bundle run mostly posterior to the ankle axis and are stretched with dorsiflexion; this increase can be amplified by anteriorly positioning the talar displacement. A selection of bearing thickness that expands the joint space with anterior-posterior malpositioning of the talar component should be avoided.

For the STAR implant to have maximal range of stable movement, the talar component should be placed in the
anatomical position. Slightly posterior placement may be acceptable if the joint height remains anatomical. However, anterior placement should be avoided. Slight expansion of the joint space may be acceptable with anatomical anteroposterior talar component positioning. However, any reduction in joint height should be avoided.

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References


