Total ankle replacement

MEDIUM-TERM RESULTS IN 200 SCANDINAVIAN TOTAL ANKLE REPLACEMENTS

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We describe the medium-term results of a prospective study of 200 total ankle replacements at a single-centre using the Scandinavian Total Ankle Replacement. A total of 24 ankles (12%) have been revised, 20 by fusion and four by further replacement and 27 patients (33 ankles) have died. All the surviving patients were seen at a minimum of five years after operation. The five-year survival was 93.3% (95% confidence interval (CI) 89.8 to 96.8) and the ten-year survival 80.3% (95% CI 71.0 to 89.6).

Anterior subluxation of the talus, often seen on the lateral radiograph in osteoarthritic ankles, was corrected and, in most instances, the anatomical alignment was restored by total ankle replacement. The orientation of the tibial component, as seen on the lateral radiograph, also affects the position of the talus and if not correct can hold the talus in an abnormal anterior position. Subtalar arthritis may continue to progress after total ankle replacement. Our results are similar to those published previously.

Total ankle replacement (TAR) is being offered more often as an alternative to ankle fusion. In Europe, approximately 10 different designs of implant are in use, most being mobile-bearing. In the United States, the Federal Food and Drug Administration approved the Scandinavian Total Ankle Replacement (STAR; W. Link GmbH, Hamburg, Germany) for general use in April 2007,¹ making it the only mobile-bearing design available there.

Our aim was to determine whether TAR in certain patients is reliable enough in the medium term to allow recommendation as an alternative to ankle fusion and whether the normal anatomical relationship of the talus and tibia is restored. We also wished to ascertain if it protects the subtalar joint from progressive arthritis.

We now report the medium-term results, at a minimum of five years after operation, of the largest single-centre prospective study of a mobile-bearing ankle replacement to date. This follows an earlier report on the same series of patients.²

Patients and Methods

A consecutive series of 200 TARs in 184 patients were entered into the study. The STAR prosthesis was used in all cases. Of the 200 ankles there were 119 with inflammatory

arthritis and 81 with osteoarthritis (OA). In 25 patients there had been a previous fracture.

All the surviving patients had an annual clinical and radiological review. Most were seen as outpatients. Six were unable to attend and were followed-up by a telephone interview and radiographs taken near their home.

The ankles were considered to have a good clinical outcome if pain had been abolished or was much decreased, disability from the ankle had been reduced and any complications had resolved, with or without supplementary surgery.

Pain and function were assessed using the American Orthopaedic Foot and Ankle Society (AOFAS) ankle and hindfoot score.³ Failure was defined as the need for revision by exchange of either component or conversion to an arthrodesis.

The radiological outcome was determined by the following criteria:

1) Assessment of osseous integration. Aseptic loosening was defined as radiolucency greater than 2 mm in width, cavitation or migration of components;

2) Measurement of pre-operative varus or valgus deformity of the talus within the ankle mortise;

3) Grading of arthritis of the subtalar joint before and five years after TAR, using the scale of Kellgren and Lawrence;⁴

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Fig. 1a

Fig. 1b

Lateral radiographs taken a) pre- and b) post-operatively showing an increase in the tibiotalar ratio ($AX/AB\%$) from 31% pre-operatively to 36% after total ankle replacement showing that there has been relocation of an anteriorly subluxed talus.

Fig. 2a

Fig. 2b

Fig. 2c

Lateral radiographs showing measurement of the inclination of the tibial component to the long axis of the tibia (angle b): a) forward-facing, b) correct, and c) backward-facing.

4) Measurement of the relocation of the talus within the mortise in those osteoarthritic ankles which showed anterior subluxation of the talus on the lateral radiograph. The tibiotalar ratio⁵ was measured on pre- and post-operative radiographs. This is the ratio of the length of the posterior part of the talus to its full length, expressed as a percentage. The smaller the tibiotalar ratio the more anteriorly subluxated is the talus. On the lateral radiograph (Fig. 1) the mid-

line of the tibia, a distal tibial axis,⁶ is extended to divide the talus into anterior and posterior parts. In a control group of 32 normal ankles seen in our clinic, the mean tibiotalar ratio was 40% (SD 3);

5) Measurement of the inclination of the tibial component to the long axis of the tibia (Fig. 2). This angle was defined in our earlier paper.² We thought that it was likely that the anteroposterior position of the talus within the mortise might

Fig. 3

Anteroposterior radiograph showing measurement of varus or valgus of the prosthesis (angle a).

be affected by the inclination of the tibial component with respect to the long axis of the tibia. One group was defined as 'correct' because the inclination of the tibial component was within the intended limits, namely 83° and 90° . A second group had 'backward-facing' malposition of the tibial component with an angle of inclination $> 90^\circ$, and a third group was defined as 'forward-facing' with an angle of inclination $< 83^\circ$;

6) Measurement of varus or valgus of the prosthesis (Fig. 3). This angle was also defined in our previous paper.²

Statistical analysis. Survival of the implants was estimated using Kaplan-Meier methods. Asymmetric 95% confidence intervals (CI) were constructed using Greenwood's method.⁷ Pair-wise comparisons of movement of the talus between groups as defined by the inclination of the tibial component (i.e. 'forward-facing', 'backward-facing' and 'correct') were made using a Mann-Whitney test. A Bonferroni correction to account for multiple comparisons was applied to the p-values. A p-value < 0.05 was deemed statistically significant.

Results

Clinical. The mean follow-up was 88 months (60 to 156) for the 143 ankles in 137 patients who were alive at the end of the period of follow-up, and 43 months (4 to 111) for 33 ankles in 27 patients who died during the period of follow-up. Of these patients, 21 (27 ankles) had inflammatory arthritis. A total of 24 ankles in 24 patients were

revised (four of these patients had successful replacement on the opposite side).

Of the 200 ankles in the study, 135 (67.5%) (127 patients) had good relief from pain with no complications and satisfactory radiographs. The mean AOFAS score for pain and function showed no deterioration at the last review compared with the scores at two years after operation. The mean score for pain was 35 (0 to 40) and for function was 40 (20 to 54), which was higher than that reported in 2003.² This is because some of the patients with the lowest scores at two years after operation had died by the time of this review.

Radiological. Aseptic loosening was defined either as migration of components or in two other distinct ways. The first of these was failure along the whole of the bony interface which was seen as a linear lucency more than 2 mm wide. However, since the implant conceals the interface on the talar side, some cases of talar loosening may have gone undetected. The second was the development of an osteolytic cavity causing the implant to be bare of bone in one area but fixed firmly elsewhere. Such cavities were seen on both sides of the joint. On the tibial side they were generally between the central fixation bars. Those under the talar component only became visible when large enough to extend distally to the prosthesis. Overall, 25 ankles (12.5%) showed aseptic loosening, ten of which had minimal symptoms that were not progressing and further surgery was not just justified, one had a bone graft to a lytic cavity, four were revised and ten fused.

Other complications. Nine ankles (4.5%) (nine patients) showed edge loading; two had a bony realignment procedure and five were fused. One ankle had a fractured insert and this was revised. Six ankles (3%) (six patients) were persistently painful without apparent cause, and debridement was undertaken in one. Three ankles (three patients) which eventually required fusion at 50, 76 and 110 months after TAR, respectively had previously had a lesser surgical procedure without lasting benefit. Overall, 24 ankles (12%) failed and were revised at a mean of 48 months (1 to 108) after operation, 20 by fusion and four by revision. One ankle which had a revision of the talar component at 11 months, failed after a further five years and arthrodesis was then performed (Table I).

Five ankles (five patients) had delayed wound healing and for one this led to revision by fusion at one month. Nine ankles (4.5%) (nine patients) sustained an intra-operative malleolar fracture. This displaced subsequently in one ankle and required open reduction and internal fixation. In another it led to migration of components necessitating revision by fusion. Ten ankles (5%) (ten patients) sustained a post-operative fracture and this always occurred within 12 months of TAR. One of these required open reduction and fixation and two required revision to fusion.

There were 39 ankles with a pre-operative varus or valgus deformity greater than 15° . Six developed aseptic loos-

Table I. Overall outcome of the patients including complications and reasons for further surgery

	No further surgery	Corrective surgery*	Revised by fusion (20) or exchange (4)
Good clinically and radiologically	135		
Major delay to wound healing	3	1	1
Intra-operative fracture	8		1
Post-operative fracture	7	1	2
Aseptic loosening	10	1 [†]	14
Edge loading and recurrent deformity	2	2	5
Broken polyethylene insert			1
Pain and stiffness	5	1	

*three patients who had corrective surgery and were revised later appear in the revision column only

[†]the patient had a well-fixed tibial component but there was a large osteolytic cavity that was packed with autologous bone graft with a good outcome

Table II. Kaplan-Meier life-table survival of 200 total ankle replacements with the decision to revise as the endpoint

Years since operation	Number at start	Number revised	Withdrawn	Number at risk	Survival rate (%)	95% confidence interval
0 to 1	200	6	2	199	97.0	94.6 to 99.4
1 to 2	192	4	4	190	94.9	91.9 to 98.0
2 to 3	184	1	8	180	94.4	91.2 to 97.6
3 to 4	175	0	5	172.5	94.4	91.2 to 97.6
4 to 5	170	2	2	169	93.3	89.8 to 96.8
5 to 6	166	4	33	149.5	90.8	86.6 to 95.0
6 to 7	129	2	34	112	89.2	84.5 to 93.9
7 to 8	93	3	36	75	85.6	79.6 to 91.6
8 to 9	54	1	20	44	83.7	76.7 to 90.6
9 to 10	33	1	16	25	80.3	71.0 to 89.6
10 to 11	16	0	16*	8	80.3	71.0 to 89.6

* six patients had a follow-up of 11 to 14 years and no ankle has so far failed after ten years

Fig. 4

Kaplan-Meier survival curve for total ankle replacement with 95% confidence interval.

ening and three of these have been revised. Two sustained a late fracture of the medial malleolus and one has been revised. Seven developed edge-loading of which four have been revised.

Survival. The time of failure was taken as the point at which the decision either to exchange the implant or to fuse the ankle was made. Life-table analysis (Table II) shows the survival at five years as 93.3% (95% CI 89.8 to 96.8) and survival at ten years

as 80.3% (95% CI 71.0 to 89.6). The Kaplan-Meier survival curve is shown in Figure 4.

Arthritis. Arthritic change was often present in the subtalar joint before TAR. Of the 200 ankles in the study, 91 (45.5%) had grade-4 changes present pre-operatively (10 with OA and 81 with rheumatoid arthritis). We assessed radiographs in 156 patients (167 ankles) surviving a nominal five years after TAR whose ankles had not been revised. There were 72 ankles (43%) with grade-4 changes pre-operatively in the subtalar joint. The remaining 95 showed no change in 70 (42%) and deterioration in 25 (15%) (14 OA and 11 rheumatoid arthritis).

With regard to relocation of the talus within the ankle mortise in patients with anterior subluxation due to OA, we were able to measure the tibiotalar ratio before and after surgery in 144 ankles. This was not possible in 56 ankles because the arthritis had destroyed the talus to the extent that its boundary could not be seen. In some cases the radiographs did not include an adequate length of the distal tibia to allow its axis to be drawn accurately. The remaining radiographs were adequate for measurement although some were not weight-bearing views. In these cases the talar reference line was drawn parallel to the plantar surface of the foot, always ensuring that the ankle was in a similar position on the two radiographs being compared. The mean tibiotalar ratio was 36% (17% to 57%) pre-operatively and 39% (19% to 63%) post-operatively.

We measured the pre-operative lateral radiographs of those patients with OA who had anterior displacement of the talus within the mortise, excluding those who had a previous fracture. The mean value of the tibiotalar ratio in normal ankles in our hospital is 40% (SD 3). Of the 34 ankles in which the ratio was < 34%, i.e. outside 2 SDs, it increased in all but two. The mean increase was 9% (-4% to +19%) and for 20 ankles the post-operative tibiotalar ratio lay within 2 SDs of normal. This effect was independent of the effect of the inclination of the tibial implant.

With regard to the effect of the inclination of the tibial implant (Fig. 2) on the position of the talus and tibia as determined by the tibiotalar ratio, in 86 ankles the angle was between 83° and 90° i.e. in the correct group. A total of 19 ankles were 'forward-facing' and 39 'backward-facing'. The tibiotalar ratio indicated that in 61 cases the talus moved posteriorly after TAR when the inclination of the tibial component was 'correct' (mean 88° (83° to 90°)). However, it moved anteriorly if the tibial implant was 'forward-facing' (mean 80° (72° to 82°)). The difference was highly significant ($p = 0.0005$). It moved posteriorly to a greater degree in the 'backward-facing' group (mean 95° (92° to 105°)) than in the 'correct' group, but this was not significant ($p = 0.06$).

The valgus or varus orientation of the implant in relation to the long axis of the tibia (Fig. 3) had no statistically measurable effect on the need for revision. The mean angle in the 24 ankles which had been revised was 85° (75° to 90°) and in the remaining 176 it was also 85° (75° to 100°).

Discussion

Most patients in our series undergoing TAR had no complications, good relief from pain and improved function. The survival rates of 93.3% at five years and 80.3% at ten years are similar to those of TAR generally⁸⁻¹⁴ and of the STAR prosthesis in particular.^{15,16}

Since our previous paper² ten more ankles have failed, two because of recurrent deformity and edge-loading. One was in severe varus and the other in severe valgus pre-operatively, and such deformities greater than 15° are described as being associated with early failure.^{8,11,17} Therefore, TAR is not generally recommended for these patients.

We have been unable to assess correction of pre-operative varus or valgus because the STAR implant hides the body of the talus on radiographs. All that can be seen is the position of the metal implant which is controlled by the surgeon and consequently it does not necessarily correspond to that of the talus. It would have been of benefit if we had taken accurate clinical photographs to show the alignment of the foot to the lower leg before and after the TAR.

Measurement of the tibiotalar ratio before and after operation has shown that TAR frequently restores an anteriorly subluxed talus to an anatomical position. We believe that this indicates that ligaments have re-aligned and it is reasonable to infer that this will help to restore the normal axis of rotation of the joint.

We have not shown that TAR prevents progression of subtalar arthritis, possibly because most of the patients in our study had pre-operative arthritic changes. However, we believe that if these ankles had been fused, the extra strain on the arthritic subtalar joints might have made them symptomatic.

Our survivorship figures are similar to those of early reports of total knee replacement when techniques and designs were being developed.¹⁸⁻²⁰ The survival for knee replacement is now much improved²¹⁻²³ and we anticipate that over the next few years, as indications and techniques are refined, TAR will also become as reliable as knee replacement. If so, it will become a standard option for those patients with severe symptoms in an arthritic ankle provided that there is no major valgus or varus deformity.

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