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Total ankle replacement

THE RESULTS IN 200 ANKLES

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Between 1993 and 2000 we implanted 200 cementless, mobile-bearing STAR total ankle replacements. None was lost to follow-up for reasons other than the death of a patient. The mean follow-up was for 46 months (24 to 101).

A complication requiring further surgery developed in eight ankles and 14 were revised or fused. The cumulative survival rate at five years was 92.7% (95% CI 86.6 to 98.8) with time to decision to revision or fusion as an endpoint.

The most frequent complications were delayed wound healing and fracture of a malleolus. These became less common with experience of the operation. The radiological appearance of the interface of the tibial implant was significantly related to its operative fit and to the type of bioactive coating.

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Ankle replacements with the mobile-bearing design, such as the Scandinavian Total Ankle Replacement (STAR) and Buechel Pappas (BP), have been in use for more than ten years. Long-term studies have been published by the original designers of these prostheses and reports from other centres have involved small series, with a short follow-up.[1-4] We describe the results of 200 ankle replacements, of which 52 were followed up for more than five years.

The STAR prosthesis (Fig. 1) was used in all cases. The manufacturer (W. Link GmbH & Co., Hamburg, Germany) made one change in design during the period of study. Initially, the coating on the non-articular surface of the talar and tibial implants was a single layer of plasma-sprayed hydroxyapatite, 150 μm in thickness (Osprovit),[5] which was applied directly to the cobalt chrome. In 1998 it was changed to a dual-coating consisting of vacuum plasma-sprayed commercially pure titanium, approximately 200 μm in thickness, and electrochemically-deposited calcium phosphate, approximately 20 μm in thickness (TiCaP). Before May 1999 all implants in this study had the hydroxyapatite coating (Osprovit) and between May and November 1999, both coatings were used depending on availability. After November 1999, all implants had the dual-coating of titanium and calcium phosphate.

Table I. Details of 200 patients with total ankle replacement

Diagnosis	Gender	Number of ankles	Mean age (yrs; range)
IJD	F	89	58 (18 to 83)
IJD	M	30	57 (38 to 75)
OA	F	26	61 (31 to 79)
OA	M	55	63 (48 to 82)

Patients and Methods

Between November 1993 and February 2000, the senior author (PLRW) performed 200 total ankle replacements, using the STAR prosthesis, in patients with painful arthritic ankles which severely limited their mobility. All were prospectively entered into this study (Table I). The underlying diagnosis was inflammatory joint disease (IJD) in 119 patients, 112 of whom had seropositive rheumatoid arthritis, and osteoarthritis in 81 (OA) (25 after a fracture). These patients often also had arthritic changes in the hip or knee and 69 had had one or more of these joints replaced. In 13 patients, triple fusion of the ipsilateral hind foot had been previously performed.

As the study progressed, the number of replacements performed each year increased and this was proportionately greater for OA than for IJD. Patients were entered into the study over a six-year period and the ratio of IJD:OA for the initial three years was 35:10 and for the latter three years 84:71.

Clinical assessment of outcome. Functional activity was assessed by specific questioning on the following activities: how well the patient could climb stairs, how far they could walk, and whether or not they used walking aids (stick, crutches or wheelchair). We considered ankles to have a

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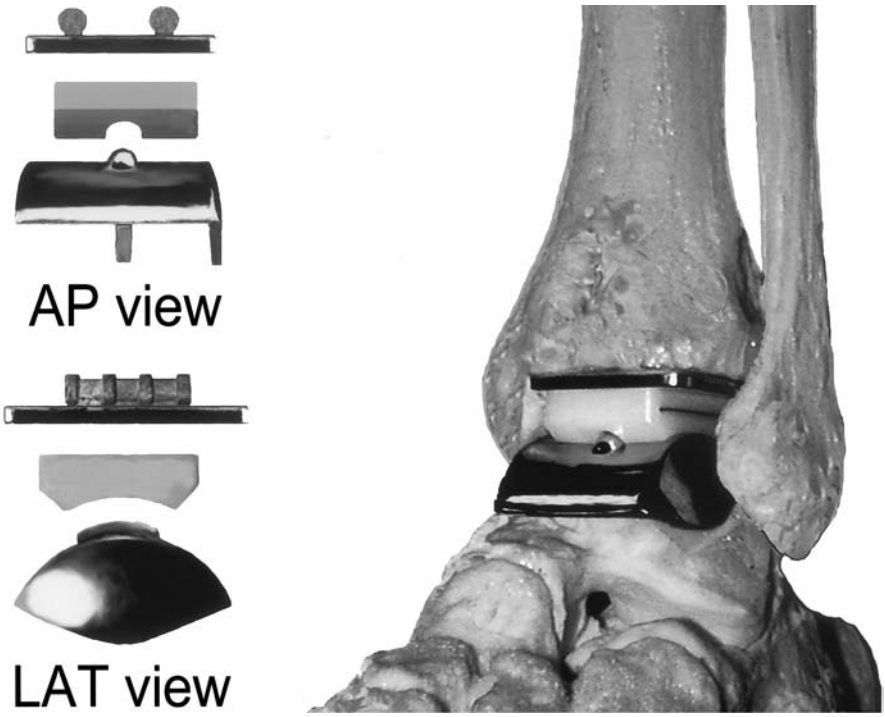

Fig. 1

Photograph of the STAR prosthesis.

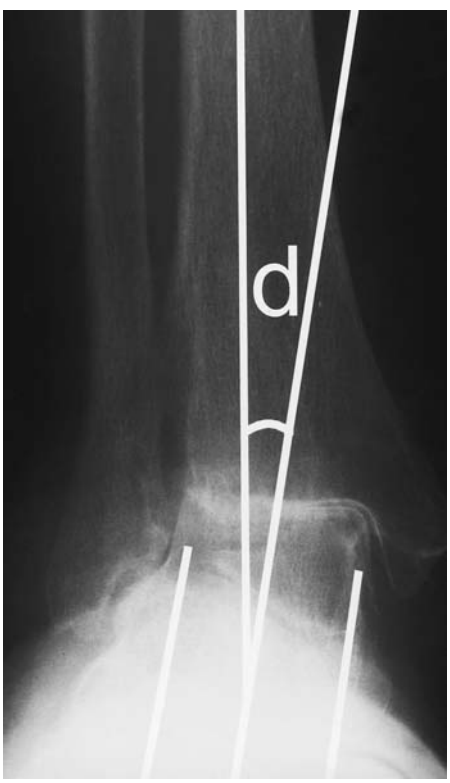

Fig. 2

AP radiograph showing angular measurement of the preoperative deformity. 'd' is the angle between the anatomical axis of the tibia and a line perpendicular to the articular surface. When this has been eroded by the arthritic process an estimate is made by reference to the sides of the talus.

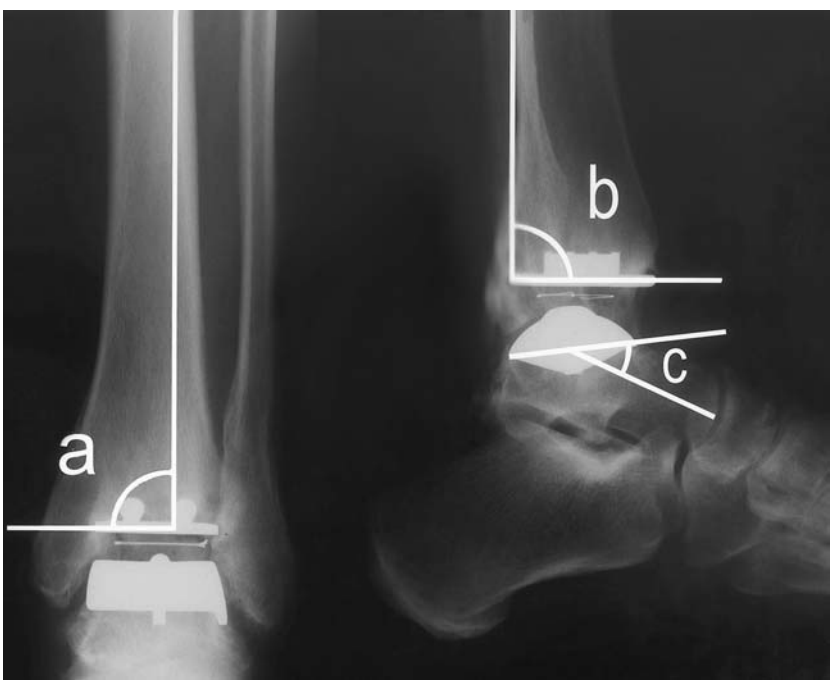

Fig. 3

Radiographs showing angular measurement of the position of implants. 'a' is the angle between the anatomical axis of the tibia and the articular surface of the tibial implant, 'b' is the angle between the anatomical axis of the tibia and the articular surface of the tibial implant on a lateral radiograph, and 'c' is the angle between a line joining the posterior and anterior margins of the articular surface of the talar implant and a line drawn along the centre of the talar neck. The latter is imprecise especially when there is deformity in the hindfoot.

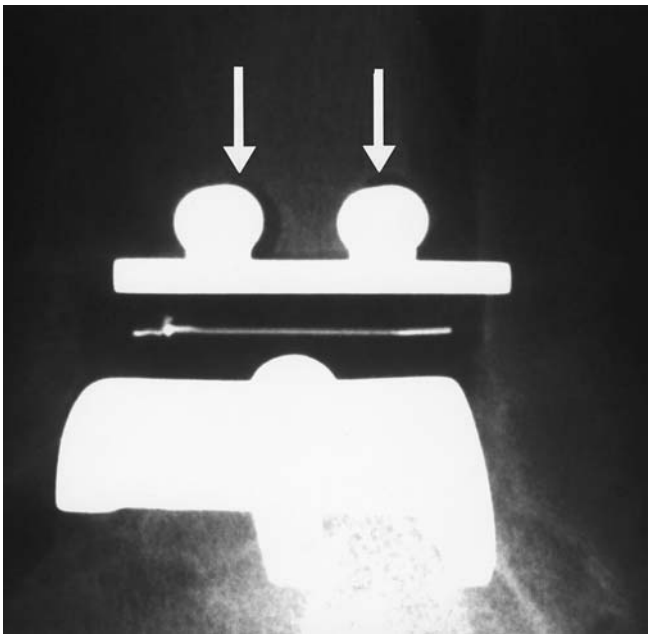

Fig. 4

Radiograph showing gaps between the implant and bone present immediately after operation (arrows).

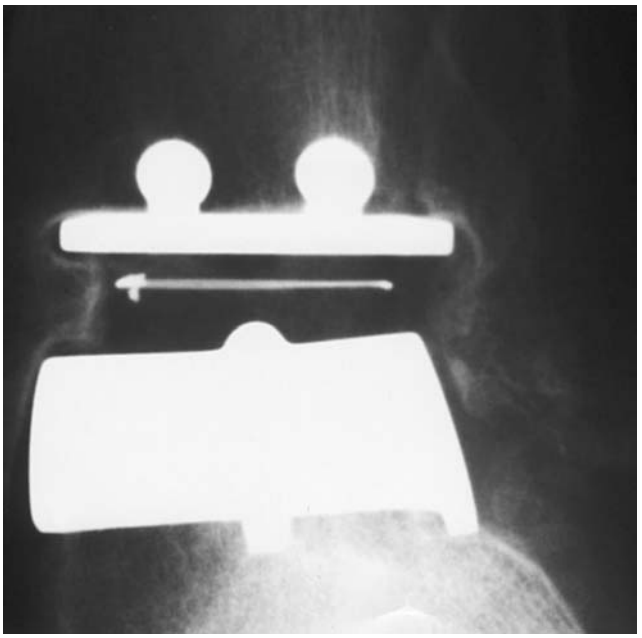

Fig. 5

Radiograph showing edge loading of the UHMWPE bearing.

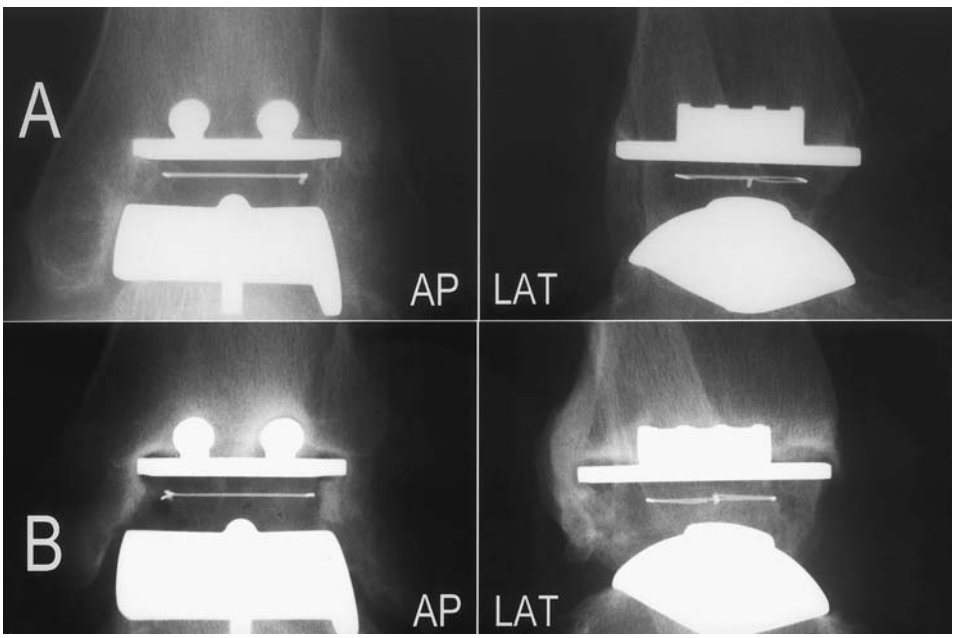

Fig. 6

Radiographs at two years of patients with a good outcome showing the appearances A and B.

good clinical outcome if the following three criteria were satisfied: a) the pain had been eased so that there was minimal or no pain; b) the disability caused by the ankle had been reduced; and c) any complications had resolved without the need for further surgery. Any ankle which did not fulfil these criteria was classified as unsatisfactory. If revision was needed it was classified as a failure. Revision was defined as exchange of the implant or fusion of the ankle.

The American Orthopaedic Foot and Ankle Surgeons (AOFAS) ankle and hindfoot score[6] was determined before operation and again after two years.

Radiological assessment of outcome. The alignment of the talus in the ankle mortise was measured before operation by the angle 'd' (Fig. 2) and the alignment of the implants was assessed from the angles 'a', 'b', and 'c' (Fig. 3). The precision with which the bony bed matched the contours of the

Table II. Overall outcome including complications and reasons for further surgery

	No further surgery	Surgery for complication	Revision or fusion
Good clinical and radiological outcome without major complication (n = 146)	146	0	0
Major delay of wound healing (n = 5)	3	1	1
Fractured malleolus at the time of surgery (n = 9)	8	1	0
Fractured malleolus at later date (n = 10)	7*	1	2
Established or threatened aseptic loosening (n = 14)	5*	1	8
Edge loading of the bearing (n = 9)	3	3	3
Pain and stiffness (n = 7)	6	1	0
Totals (n = 200)	178	8	14

*one ankle also had early subsidence of the talar implant which had not progressed. It is only included in the group 'fractured malleolus at later date'

tibial implant was judged from the presence or absence of gaps between the fixation bars and the bone on the first radiograph after operation (Fig. 4). The interface of the tibial implant was assessed for osseous integration, cavitation, and migration. The shape of the talar implant hides the interface from view and only migration can be assessed. The foot was positioned using image intensification to give standard views as shown on Figure 3. This enabled sequential radiographs to be compared and the migration was assessed as described by Carlsson et al.[7] This method notes changes in angles 'a', 'b' or 'c' and/or movement of implants with respect to bony landmarks. The radiological outcome was considered to be good if there was no migration of the implant, no evidence of progressive lucency and full contact between the articulating surfaces without any tendency for the ultra-high-molecular-weight polyethylene (UHMWPE) bearing to tip causing edge loading as shown in Figure 5. The appearance of the bony interface of the tibial implant for those with a good radiological outcome was categorised as A or B (Fig. 6). Appearance A showed bone of constant density in close apposition to the implant over its whole visible extent. Appearance B showed a line of sclerosis just proximal to the implant, running onto and sometimes over the fixation bars. There was a line of relative lucency less than 2 mm wide between all or part of the sclerotic area and the tibial implant.

Results

All replacements were reviewed annually until the time of revision or fusion or the patient's death. Fourteen ankles failed and required either an exchange of implant or a fusion. None of the 186 surviving ankle replacements had been lost to follow-up except when a patient died. There were 163 surviving replacements. The mean follow-up was 46 months (24 to 101). Twenty-three replacements were in 19 patients who had died with a mean follow-up of 37 months (4 to 87). Eight patients had undergone further surgery without removal of the implant. The results are summarised in Table II and are described below.

Good clinical and radiological outcome and uncomplicated recovery (146 ankles)**.** At their last review, these patients had a good clinical and radiological outcome. In 71, the ankle did not restrict activity but demands were modest because of other factors such as generalised arthritis. In the remaining 75 normally active patients, 33 climbed stairs normally, the mean walking distance increased from 198 m to 2000 m and 59 used neither sticks nor other walking aids. Eighteen ankles were in patients who had died and their outcome is reported to the last review (range: four to 87 months).

This group of 146 ankles had a mean range of movement of 23° (5 to 60) before operation and 27° (10 to 60) at the last review. The 46 ankles with less than 20° of movement before operation gained the most, increasing from a mean of 11° to a mean of 26°. The main difficulty was restoration of dorsiflexion and only 86 (59%) had 10° or more at the last review.

Complications resolving with or without surgery and failures (54 patients)**.** Five categories of complication are itemised in Table II. These are major delay to wound healing, fracture of a malleolus, established or threatened loosening, edge loading of the UHMWPE bearing (Fig. 5) and persistent pain and stiffness. Moderate delay of wound healing is discussed under the heading 'Effect of primary diagnosis on outcome and complications'.

Major delay to wound healing. Five ankles had delayed wound healing of more than 12 weeks and one of these developed deep infection and failed. The prosthesis was removed and fusion undertaken. One wound healed with a split skin graft and the remaining three resolved in a mean of 11 months with conservative treatment and had a good clinical outcome at the last review.

Fracture of a malleolus. Nine ankles sustained a fracture at the time of surgery and ten subsequently. The medial malleolus was fractured during surgery on eight occasions and the lateral malleolus once. The fractures were undisplaced and internal fixation was not undertaken. One failed to unite and internal fixation was undertaken ten weeks later. In this case it appeared that the talar implant was oversized with respect to the ankle mortise and thus displaced the malleolus and prevented union. Fracture of the medial malleolus occurred between three days and 23 months after operation in ten ankles. In one case, it was associated with a severe varus deformity which had been underestimated and a corrective osteotomy of the distal tibia was performed 46 months later

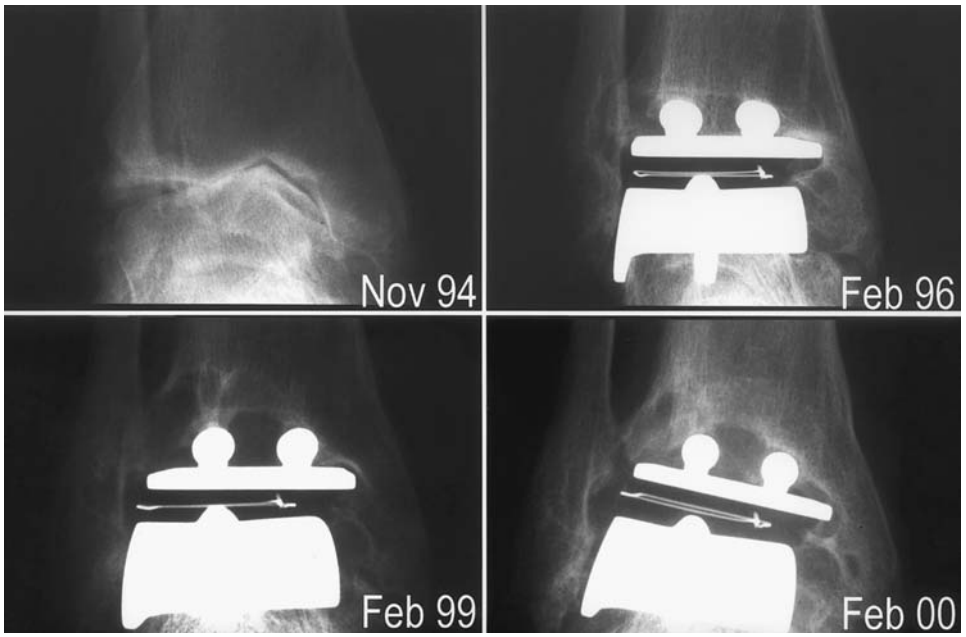

Fig. 7

Radiographs showing the effect of cavitation in one patient.

Table III. Details of patients who underwent further surgery for a complication

Diagnosis	Gender	Age (yrs)	Complication*	Time to further surgery (mths)	Further surgery†	Time from total ankle replacement to last review (mths)
IJD	F	50	Wound	3	Split skin graft	24
OA	M	65	Fx at surgery	3	Internal fixation	62
IJD	F	59	Fx later	46	Tibial osteotomy	50
OA	M	63	Cavitation	36	Autogenous bone graft	60
IJD	M	63	Edge loading	4	Calc Ost Lig	49
OA	M	72	Edge loading	11	Calc Ost	15
OA	M	52	Edge loading	52	Calc Ost Lig	61
OA	M	51	Pain/stiffness	54	Heterotopic bone removal	60

*Fx, fracture of medial malleolus
†Calc Ost, calcaneal osteotomy; Lig, lateral ligament reconstruction

to improve the alignment of the foot and reduce the risk of further stress fracture. Two of the fractures were associated with loosening, and failed. These ankles appear only under the heading 'Late fracture' in Table II because it is considered likely that the fracture was the primary complication. The remaining five fractures united with conservative treatment and had a good clinical outcome at the last review.

Established or threatened aseptic loosening. Fourteen ankles, in which there had been no malleolar fracture, were either considered to have aseptic loosening or had radiological evidence of cavitation behind the tibial implant, causing concern for its long-term survival. There was cavitation in seven patients. The cavity was small in four ankles and no active intervention was undertaken. They are being closely monitored. One ankle had a large cavity which was packed with iliac-crest bone graft. At surgery the tibial implant was firmly fixed but there were large cavities centrally and on either side of the fixation bars. At review 24 months later, the patient was walking two miles with minimal discomfort and the cavities had not recurred. Cavitation caused failure in two ankles when the bone gave way (Fig. 7) and in both fusion was undertaken. Seven ankles showed migration of implants. One with migration of the talar component was causing minimal symptoms. Six have failed clinically and radiologically, of which five have been revised and one is awaiting surgery.

Edge loading of the UHMWPE bearing. Nine ankles showed this appearance (Fig. 5). Three patients were asymptomatic and surgical intervention was contraindicated. Three had aching and surgery was carried out to improve the alignment of the ankle with the aim of relieving the symptoms (Table III). It was only partially successful.

Table IV. Life-table survival analysis of total ankle replacements with decision to revise as endpoint

Years since operation	Number at start	Number revised	Withdrawn	Lost to follow-up	Number at risk	Survival rate (%)	Confidence interval (%)
0 to 1	200	6	2	0	199.0	*97.0*	*94.6* to *99.3*
1 to 2	192	4	4	0	190.0	*94.9*	*91.8* to *97.9*
2 to 3	184	1	61	0	153.5	*94.2*	*90.6* to *97.8*
3 to 4	122	0	45	0	99.5	*94.2*	*89.8* to *98.7*
4 to 5	77	1	23	0	65.5	*92.7*	*86.6* to *98.8*
5 to 6	53	2	23	0	41.5	*87.9*	*78.6* to *97.2*
6 to 7	28	0	16	0	20.0	*87.9*	*74.5* to *100*
7 to 8	12	0	9*	0	7.5	*87.9*	*66.0* to *100*

*three ankles have a follow-up of more than eight years

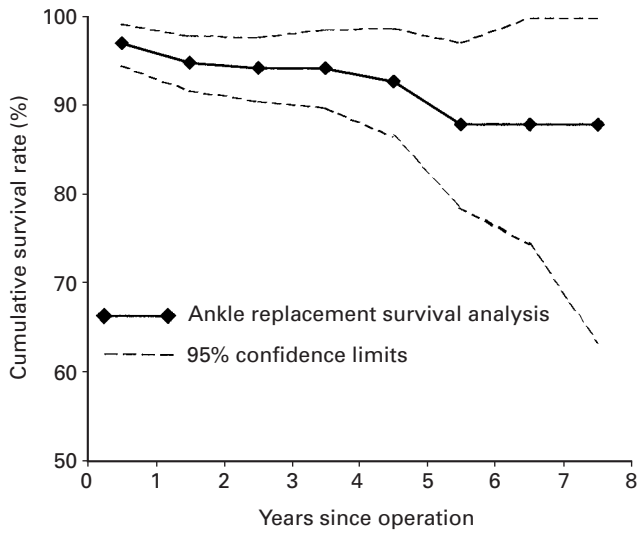

Fig. 8

Survival curve for total ankle replacement.

Three ankles were causing severe pain and were revised to fusion.

Pain and stiffness. Seven ankles continued to be painful with a mean range of movement of 15° (5 to 20). The radiographs remained satisfactory and the functional result was fair. All patients walk as far or further than before the operation. The cause of the symptoms is unclear. One ankle has been explored and heterotopic bone from the medial side of the joint was removed but this produced only minimal improvement in symptoms.

Further surgery for a complication. The details of the eight ankles and the surgery undertaken to treat the complications are given in Table III.

Outcome of surgery for failure of replacement operation. There were 14 revisions or fusions, seven in patients with IJD and seven in those with OA. Eleven were converted to a fusion, one had a tibial revision which remained satisfactory until the patient died 20 months later, one had a talar revision which was unsuccessful and this patient is awaiting fusion, and one is awaiting surgery for aseptic loosening. Of the 11 fusions, six united with an acceptable final result and five did not unite at the first attempt. Of these five, minimal symptoms were present in three and no further surgery was performed. The other two have had further surgery; in one union has been obtained but in the other there remains a painful mobile nonunion for which surgery will be needed.

Life-table analysis and survival curves. The time of failure is described as the point at which the decision either to exchange the implant or fuse the ankle was taken. Further surgery for a complication (Table III) is not included in the survival analysis. Life-table analysis (Table IV) showed survival at five years of 92.7% (95% confidence interval (CI) 86.6 to 98.8). The Kaplan-Meier survival curve is shown in Figure 8.

Effect of primary diagnosis on outcome and complications. There were 29 ankles with delayed wound healing, five with major delay (Table II) and 24 in which the delay was more than four weeks but healing occurred with conservative treatment by 12 weeks. This was more frequent in the IJD group (19%) than in the OA group (7%) and it is notable that for those with IJD the incidence dropped from 25% of the first 60 ankles to 13% of the second 59 ankles. Operative fractures occurred in both IJD and OA patients. They occurred less frequently with experience and the incidence fell from 7% in the first 100 ankles to 2% in the second 100. Pain and stiffness were more frequent in patients with post-traumatic OA: three of 25 ankles (12%) compared with one of 61 primary OA (1%) and three of 119 with IJD (3%). There was no statistical difference in the rate of failure between the IJD and OA groups.

AOFAS ankle and hindfoot scores. The AOFAS score[6] gives a maximum of 40 points for pain and 60 points for function. The scores were determined before operation and at the time of the two-year review for the 182 ankles in patients who were alive and had not undergone a revision procedure. The mean AOFAS hindfoot score for pain improved from 0 to 35 and the mean functional score improved from 28 to 35.

Effect of preoperative ankle alignment on outcome. The ankle alignment as assessed by angle 'd' (Fig. 2) was >15° in 39 ankles before operation. In 17 ankles, it was varus and in 22 it was valgus. Varus ankles were predominantly in patients with OA (OA:IJD 15:2) and valgus ankles in those

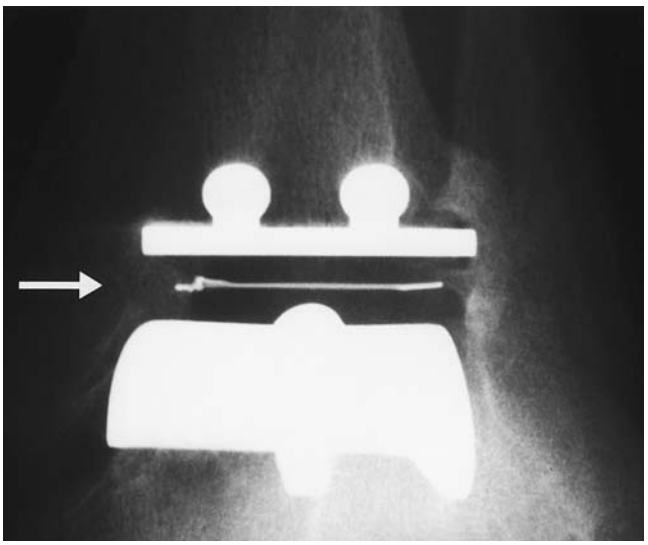

Fig. 9

Radiograph showing heterotopic new bone formation (arrows).

with IJD (OA:IJD 5:17). Seven of these 39 ankles showed edge loading of the UHMWPE bearing on the postoperative anteroposterior (AP) radiograph and this represents most of those in which this complication occurred (Table II).

Positioning of implants. This was measured by angles 'a', 'b' and 'c' on the immediate postoperative radiographs (Fig. 3). An angle 'a' of between 85° and 95° was achieved in 130 of the 200 ankles. The mean was 85° (75 to 100). No correlation was found between late fracture of a malleolus and a low angle 'a'. An angle 'b' of between 80° and 90° was achieved in 149 ankles. The mean was 88° (70 to 100). An angle 'c' of between 20° and 40° was achieved in 172 ankles. The mean was 22° (6 to 40).

Heterotopic bone formation. This appeared radiologically in 47% of the ankles (Fig. 9). There was no association between its presence and the clinical outcome.

Radiological appearance of the tibial implant/bone interface and the implant coating. Of the 146 ankles with a good clinical and radiological outcome, five were in patients who had died before the two-year review. The radiographs of the remaining 141 ankles immediately after operation and at two years were examined to determine whether there was a relationship between the implant coating and the radiological appearance. These ankles were chosen to avoid the possibility of the appearance having been affected by a complication. Hydroxyapatite coating had been used on 104 implants and 37 had the dual-coating of titanium and calcium phosphate. Small gaps were seen between the tibial implant and the bone on 47 immediate postoperative radiographs (Fig. 4). These were usually adjacent to the fixation bars.

Of the 141 radiographs, 119 (84%) had appearance A and 22 (16%) appearance B (Fig. 6). Multivariate logistic regression analysis was used to determine whether the type of implant coating and/or gaps seen on the initial radiographs were related to the two-year radiological appearances A or B.

Even after controlling for diagnosis (IJD or OA) it was found that ankle replacements in which the hydroxyapatite had been applied directly onto the cobalt chrome were 7.5 times more likely to show appearance B ($p = 0.014$, 95% CI 1.5 to 37.4) than those with the dual-coating of titanium and calcium phosphate. Those with a gap between the bone and implant were 5.6 times more likely to have appearance B ($p = 0.002$, 95% CI 1.9 to 16.7). It is notable that all those with the dual-coating of titanium and calcium phosphate and no gap, showed appearance A, whereas 40% of those with the single layer of hydroxyapatite applied directly to the cobalt chrome and a gap, showed appearance B.

Discussion

The designers of the STAR and BP total ankle replacements have reported a cumulative survival rate of 75% at 14 years in 52 cases and 95% at ten years in 40 cases, respectively.[1,8] A life-table analysis in our study showed survival at five years of 92.7% and at eight years of 87.9%.

A previous report has commented on the technical difficulties[4] and in this study the authors found that the incidence of complications was initially high but reduced with experience. Outcomes should improve as surgeons and the orthopaedic community become familiar with the indications and techniques of this procedure. The importance of gentle handling of tissues especially with the retraction of the skin edges and the need to gain adequate exposure, especially of the lateral side of the joint, cannot be overemphasised.

Our study and others have shown that dorsiflexion is not easily regained.[9] Lengthening of tendo Achillis was not carried out in this group, but we now recommend this at the time of surgery, if it is necessary to achieve 10° of dorsiflexion. A range of movement sufficient for normal walking is generally achieved and those ankles which are stiff before operation usually gain an increased range of movement.

The complication of edge loading of the UHMWPE bearing was more common in those with varus or valgus angulation of more than 15° before operation. We now recommend that this be considered a relative contraindication to ankle replacement with this design.

Cavitation of the bone behind the tibial implant was seen in our series as distinct from other reports.[10] It is a cause for concern since it did result in failure in two replacements.

There were seven patients in our series who continued to have pain and stiffness without an apparent cause. Heterotopic new bone formation has been implicated as a cause in other reports[2,9] but we found that heterotopic bone (Fig. 9) was frequently seen radiographically on the medial side yet it was not associated with a poor result.

Our study was not designed to investigate the relationship between the type of implant coating and the radiological appearance of the bony interface. The decision to change

the coating was made by the manufacturer during the course of the study. The highly significant effect of the coating and the presence of a gap between the implant and bone were not anticipated. Animal studies have shown that the addition of hydroxyapatite, a bioactive coating, enhances fixation when there are gaps present between the bone and the implant.[11,12] Even so, when the gap is greater than 1 mm, fixation is adversely affected.[13] Hydroxyapatite-augmentation of porous-coated tibial implants reduced the rate of migration measured by radiostereometric analysis.[14] Studies of implants for dental use in vitro and in animals have shown that calcium phosphate deposited electrochemically may be able to replace plasma-sprayed hydroxyapatite for an enhanced bone response.[15] To our knowledge, there have been no histological studies which have compared hydroxyapatite applied directly onto the cobalt chrome with a dual-coating of porous titanium and calcium phosphate. Whether or not the type of coating will affect the outcome for this group of patients in the long term remains to be seen and will be reported in due course.

These results of ankle replacement are encouraging but the follow-up is only midterm. It seems probable that ankle replacement will find a place alongside other joint replacements but it is unlikely that it will displace fusion as has occurred in the knee. We recommend that ankle fusion should remain the treatment of choice for patients in whom heavy and prolonged activity is anticipated and that ankle replacement be recommended for those with more modest requirements.

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