

# TOTAL ANKLE ARTHROPLASTY IN INFLAMMATORY JOINT DISEASE WITH USE OF TWO MOBILE-BEARING DESIGNS

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**Background:** Interest in mobile-bearing total ankle arthroplasty has increased in recent years. However, to our knowledge, no study has focused exclusively on patients with the diagnosis of inflammatory joint disease or has provided a detailed analysis of the risk factors for failure.

**Methods:** A prospective observational study of the results of cementless mobile-bearing total ankle arthroplasty in patients with inflammatory joint disease (mainly rheumatoid arthritis) was conducted at two centers. Ninety-three total ankle arthroplasties were performed. The LCS (low contact stress) prosthesis was used initially, in nineteen ankles, between 1988 and 1992, and a modification of the LCS prosthesis, the Buechel-Pappas design, was used in seventy-four ankles between 1993 and 1999. Clinical and radiographic follow-up was performed at yearly intervals. Three clinical scoring systems were used, and any complication was recorded throughout follow-up. Actuarial survival (with revision as the end point), multivariate analysis, and a competing risk approach were used to describe the long-term outcome.

**Results:** The clinical result at one year after surgery showed a significant improvement in the scores on all three scoring systems ( $p < 0.05$ ). Ankle dorsiflexion (mean,  $7^\circ$ ) also improved significantly ( $p < 0.05$ ) compared with the preoperative state. The most frequent complication was a malleolar fracture, which occurred in twenty ankles. Only when it occurred in combination with a deformity in the frontal plane did this complication have an adverse effect on the end result. At a mean follow-up of eight years, seventeen patients (twenty-one ankles) had died and fifteen ankles had been revised because of aseptic loosening (six ankles), primary or secondary axial deformity with edge-loading (six ankles), deep infection (two ankles), and a severe wound-healing problem (one ankle), leaving fifty-seven ankles (61%) that were evaluated. The mean overall survival rate at eight years was 84%. An increased failure rate was encountered in ankles with a preoperative deformity in the frontal plane of  $>10^\circ$  ( $p = 0.03$ ) and in ankles in which an undersized tibial component had been implanted ( $p = 0.02$ ).

**Conclusions:** Mobile-bearing total ankle arthroplasty is a valid treatment option for the rheumatoid ankle if proper indications are used. Aseptic loosening and persistent deformity are the most important modes of failure.

**Level of Evidence:** Therapeutic Level IV. See Instructions to Authors for a complete description of levels of evidence.

Arthrodesis is considered to be the standard treatment for a severely arthritic ankle joint, although this procedure is known to have certain disadvantages. Short-term potential problems are the risk of nonunion, which has been reported to occur in 4% to 36% of such ankles<sup>1-3</sup>; malunion; and infection. Furthermore, there is always a disturbed gait pattern following ankle arthrodesis<sup>4,5</sup>. In the long-

term, there is both a significant ( $p < 0.0001$ ) risk of deterioration of the joints of the ipsilateral foot and overall functional impairment, as described by Takakura et al.<sup>6</sup> in 1999, by Coester et al.<sup>7</sup> in 2001, and by Fuchs et al.<sup>8</sup> in 2003, in the treatment of both posttraumatic and primary osteoarthritis.

Total ankle arthroplasty has certain theoretical advantages over ankle arthrodesis, both in monoarticular and, more specifically, in polyarticular disease: the gait is less compromised and adverse effects on the other joints of the lower extremity are not expected to occur<sup>9</sup>. High failure rates, however, have been reported with several two-component fully constrained total ankle arthroplasty designs<sup>10-14</sup>, and total ankle



A video supplement to this article will be available from the *Video Journal of Orthopaedics*. A video clip will be available at the JBJS web site, [www.jbjs.org](http://www.jbjs.org). The *Video Journal of Orthopaedics* can be contacted at (805) 962-3410, web site: [www.vjortho.com](http://www.vjortho.com).

TABLE I Demographic Data on the Patients

Diagnosis	No. of Ankles (No. of Patients)	Age* (yr)	Sex (M/F)
Rheumatoid arthritis†			
RF positive	70 (58)	59.4 (28.8-81.0)	59/11
RF negative	14 (12)	55.3 (33.5-78.8)	10/4
Juvenile idiopathic arthritis	4 (3)	38.4 (26.7-65.8)	4/0
Miscellaneous‡	5 (3)	55.7 (43.7-66.9)	3/2
All diagnoses	93 (76)	57.6 (26.7-81.0)	76/17

\*The values are given as the average, with the range in parentheses. †RF = rheumatoid factor. ‡Two patients had ankylosing spondylitis, two had adult-onset Still disease, and one had psoriatic arthritis.

arthroplasty generally has not been considered an acceptable alternative to arthrodesis. The intrinsic constraints of such implants create high shear and tensile forces at the bone-prosthesis interface, leading to mechanical failure of these designs. In a study with the semiconstrained two-component Agility ankle prosthesis, Pyevich et al., in 1998, reported better results<sup>15</sup>.

Unconstrained total ankle arthroplasty with use of a three-component mobile-bearing prosthesis has distinct mechanical and kinematical advantages over two-component designs, as there is full congruency of the articulating surfaces without restriction of rotational motion by the prosthesis. The New Jersey low contact stress (LCS) total ankle prosthesis was the first design applying this mobile-bearing principle to the ankle joint<sup>16</sup>. In 1989, the LCS prosthesis was modified to the current Buechel-Pappas prosthesis<sup>17</sup>. Both designs were developed for application without cement. Buechel et al., the designers of this prosthesis, reported good long-term results in 2003<sup>18</sup>. Kofoed and Lundberg-Jensen<sup>19</sup> and Wood and Deakin<sup>20</sup> reported good medium-term results with the mobile-bearing version of the Scandinavian total ankle replacement (STAR). Anderson et al.<sup>21</sup> reported less favorable medium-term results with this design but still recommended the procedure, especially in patients with rheumatoid arthritis. None of these studies compared diagnostic groups, and no study has been carried out exclusively for the diagnosis of inflammatory joint disease. In recent years, other designs applying the same principle of a mobile-bearing prosthesis have been introduced, but they lack long-term follow-up.

The aims of this study were to report the long-term results of mobile-bearing total ankle arthroplasty for the treatment of inflammatory joint disease and to evaluate the factors influencing outcome.

## Materials and Methods

### Patient Demographics

A prospective observational study was carried out at two centers on all patients receiving a mobile-bearing ankle prosthesis design for the treatment of inflammatory joint disease. Two designs were used because of design changes over time by the manufacturer. From September 1988 to November 1992, nineteen total ankle arthroplasties were performed with the LCS mobile-bearing prosthesis (DePuy,

Warsaw, Indiana) in one center, and, from March 1993 to December 1999, seventy-four total ankle arthroplasties were done with the Buechel-Pappas mobile-bearing prosthesis (Endotec, South Orange, New Jersey) in the two centers participating in this study. The institutional review boards of both centers approved the prospective character of this study. The first two arthroplasties were performed by the surgeon who designed the LCS total ankle prosthesis, seventy-nine arthroplasties were then performed by three experienced ankle-foot surgeons, and the remaining twelve were performed by two orthopaedic surgeons experienced in the field of arthritis surgery. However, none of these five surgeons had any experience with total ankle arthroplasty before the start of this study. Therefore, a learning curve effect has to be taken into account. Within a few years in both centers, total ankle arthroplasty became the procedure of choice for the severely affected ankle joint with inflammatory disease. Ankle arthrodesis was carried out mainly when there were contraindications for prosthetic replacement, such as spontaneous ankylosis of the ankle joint, severe deformity, substantial bone loss at the ankle-hindfoot level, neurological or vascular disease, or infection either locally or at a distance and in heavy smokers. All patients in this study had inflammatory joint disease, and the majority had rheumatoid arthritis. During the study period, total ankle arthroplasty was carried out for osteoarthritis in only six patients. Furthermore, in six more patients, other implants had been used. Therefore, it was thought that performing a comparative study between diagnostic groups or the different implants would not be useful.

The demographic data on the patients at the time of surgery are summarized in Table I. The radiographic degree of ankle joint destruction was assessed with use of the method described by Larsen et al.<sup>22</sup>. Fourteen ankles were classified as stage 3 (joint space narrowing); seventy-two, as stage 4 (complete loss of joint space); and seven, as stage 5 (periarticular bone loss). At the time of surgery, twenty-eight ankles (30%) had an ankylosed subtalar joint, which had developed spontaneously in seventeen ankles (18%) or was the result of prior surgical intervention in eleven ankles (12%). Twenty-four patients (32%) were taking corticosteroids. On the basis of radiographic findings and the gross appearance at the time of surgery, the tibial bone demonstrated mild osteopenia in

forty-nine ankles and severe osteopenia in eleven ankles. The remaining thirty-three ankles were considered to have a normal bone quality.

#### *Implant Characteristics and Surgical Technique*

The LCS prosthesis consists of a congruent polyethylene mobile bearing between a flat tibial component and a talar component with a shallow sulcus, both made of a cobalt-chromium alloy. For osseointegration, a porous coating is applied to the metal components, which are available in two sizes: standard and large. The design changes that were incorporated into the Buechel-Pappas prosthesis in 1989 were a deepening of the sulcus of the talar component in order to reduce the risk of bearing subluxation, the use of titanium for the metal components in order to improve osseointegration, the addition of two more sizes, and the creation of a somewhat thicker tibial stem.

Surgery is carried out through a straight anterior midline approach with the thigh in a leg holder in order to flex the knee to approximately  $60^\circ$  and to rotate the leg to a neutral position. After the incision of the skin and the extensor retinaculum, the interval between the anterior tibial and the extensor hallucis longus tendons is used to reach the anterior capsule, which is then opened medially and reflected laterally as a sleeve together with the dorsalis pedis artery and veins. In general, the tourniquet is inflated after the arthrotomy and before the preparation of the osseous surfaces is begun.

The preparation of the osseous surfaces is started with a flat resection of the lower surface of the distal aspect of the tibia, which is carried out with the aid of a resection guide. The aim is for a horizontal resection of the distal aspect of the tibia in the frontal plane and an anterior slope of  $7^\circ$  in the sagittal plane. For the stem of the tibial component, a window is created in the anterior aspect of the distal end of the tibia with use of a special box chisel. The talar dome is prepared by first making a groove for the central sulcus and then preparing the slots for the fixation fins. After the preparation of the talus is finished, an uncemented talar component and then an uncemented tibial component are implanted. The thickest possible polyethylene liner is then introduced between these components with use of manual distraction of the joint. After bone graft (from locally resected bone) is placed around the tibial stem, the removed tibial cortical window is then replaced and impacted. Routine wound closure with careful suturing of the extensor retinaculum completes the procedure. Lengthening of the Achilles tendon is not carried out. Postoperatively, the ankle is immobilized in a below-the-knee walking cast for six weeks, with weight-bearing to tolerance allowed. The objective of the treatment with a cast is mainly to protect the sutured extensor retinaculum and to promote soft-tissue healing.

#### *Clinical Evaluation*

All patients were evaluated preoperatively and were followed prospectively after the operation at six weeks, three months, one year, and at one to two-year intervals thereafter. Clinical evaluation included the recording of any complications and assessment with use of the three ankle-scoring systems that are

most frequently used in the literature: the LCS ankle score<sup>16</sup>, the AOFAS (American Orthopaedic Foot and Ankle Society) ankle and hindfoot score<sup>23</sup>, and the Kofoed ankle score<sup>24</sup>. All three scoring systems use somewhat similar items for pain, function, range of motion, and deformity, and all have a maximum of 100 points. Although at the start of this study both the AOFAS and the Kofoed ankle score were not yet published, these scores could be calculated retrospectively, as the items that differed from the LCS ankle score (e.g., the use of orthopaedic footwear and walking on uneven surfaces) had been fully recorded since the beginning of the study. The range of motion of the ankle-hindfoot complex was measured manually with use of a goniometer; dorsiflexion, while the patient was standing; and plantar flexion as well as pronation and supination, while the patient was sitting.

#### *Radiographic Evaluation*

Radiographic evaluation was done with use of standardized anteroposterior and lateral radiographs of the ankle. Weight-bearing radiographs were made preoperatively, and non-



Fig. 1

The preoperative alignment of the ankle in the frontal plane was defined as the angle (a) formed between a line drawn on the long axis of the tibia and a line drawn perpendicular to the talar dome on the preoperative weight-bearing anteroposterior radiograph.

weight-bearing radiographs were made at the time of follow-up. The preoperative alignment of the ankle joint in the frontal plane was defined as the angle between the long axis of the tibia and the line perpendicular to the talar surface on the weight-bearing anteroposterior radiograph of the ankle (Fig. 1). Postoperatively, both radiographs were aimed so that they were parallel to the base plate of the tibial component and, if necessary, fluoroscopy was used to obtain optimal radiographs. The serial radiographs were evaluated by the two clinical physicians (H.C.D. and R.G.H.H.N.) and by an orthopaedic surgeon who was not involved in the care of these patients. The tibial component was considered to be undersized if there was  $>2$  mm of uncovered bone of the tibial plafond on the anteroposterior radiograph made shortly after surgery. The angular position of the tibial component was defined as the angle between the base plate of the tibial component and the long axis of the tibia on both radiographs. The angular position of the talar component on the lateral radiograph was defined as the angle created by a line parallel

to the fins of the talar component and a line drawn from the most dorsal part to the center of the anterior part of the talus (Figs. 2-A and 2-B). This talar reference line was chosen as it could be drawn reliably even with a fused subtalar joint.

The occurrence of radiolucent lines next to the prosthetic components was measured on the anteroposterior and lateral radiographs for the tibial component and on the lateral radiograph for the talar component. Our criterion to determine loosening of a component was an angular change in position of  $>3^\circ$ , a subsidence of  $>3$  mm in one of the radiographs, or a complete radiolucent line of  $>1$  mm in both radiographs for the tibial component and on the lateral radiograph for the talar component. The polyethylene bearing (which had two small metallic markers) was assessed for subluxation in the sagittal and frontal planes and for other abnormalities (gross wear or fracture).

#### Statistical Methods

All data were recorded in a specially developed ankle module



Fig. 2-A

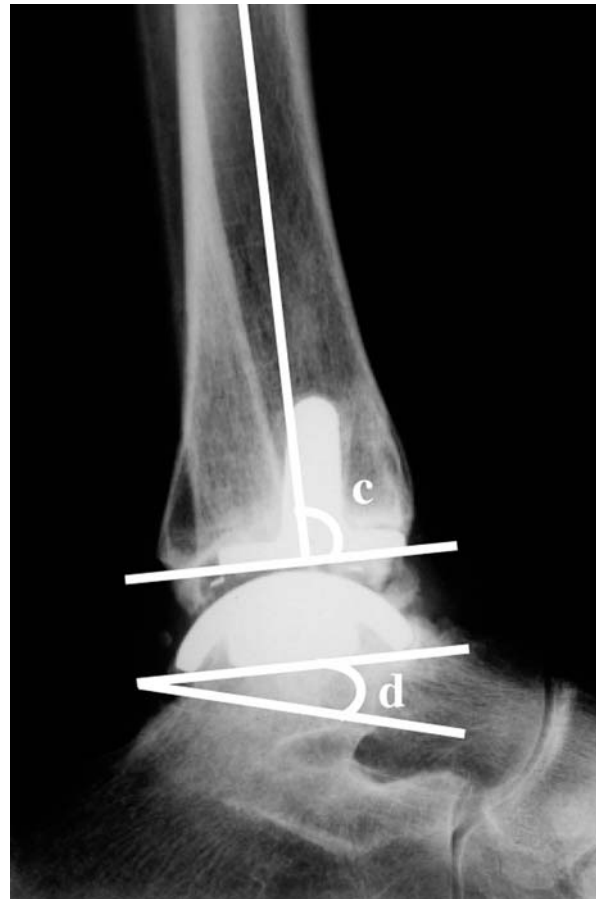


Fig. 2-B

**Figs. 2-A and 2-B** Postoperative alignment of the components. **Fig. 2-A** Anteroposterior radiograph showing the frontal angular position of the tibial component in relation to the long axis of the tibia (angle b). **Fig. 2-B** Lateral radiograph showing the sagittal angular position of the tibial component in relation to the long axis of the tibia (angle c) and the sagittal angular position of the talar component (angle d), which is created by a line drawn parallel to the fins of the talar component and a line drawn from the most dorsal part to the center of the anterior part of the talus on the postoperative lateral radiograph.



of the Project Manager program for data management (IMSOR, Leiden, The Netherlands). Statistical evaluation was done with SPSS software (version 11.5; SPSS, Chicago, Illinois). For the competing risk estimation, NCSS software (version 2001; NCSS, Kaysville, Utah) was used.

Survival analysis techniques were used to estimate the probability of the occurrence of certain outcome events as a function of the time elapsed since the operation. For non-composite end points, curves were estimated with use of the Kaplan-Meier approach. When subgroups (the LCS and the Buechel-Pappas prosthesis) were compared, a log-rank test was used and the separate survival curves were estimated. Revision surgery with removal of the prosthesis was used as a noncomposite end point. Furthermore, revision of the ankle prosthesis for aseptic loosening, revision for other indications, and aseptic loosening without revision were used as the composite end points.

In the multivariate approach, we used the Cox proportional hazards model to analyze whether gender, age at the time of surgery, the year of surgery (as a factor indicating the learning curve), the type of prosthesis, ankylosis of

the subtalar joint at the time of surgery, a varus position of the tibial component, or undersizing of the tibial component influenced the survival rate. The Cox proportional hazards model estimates the “probability of survival” of the prosthesis during follow-up time as a function of several risk factors<sup>25</sup>.

When the event-of-interest was actually a composite outcome (for example, “failure” as a noncomposite end point compared with “failure due to infection, failure due to malalignment, etc.,” as a composite outcome), we used a competing risk approach in order to obtain valid estimates for the cumulative incidence of the various subcategories of the overall outcome measure. By applying the competing risk estimation rather than the Kaplan-Meier estimation, the sum of the cumulative incidence of the various components added up to the usual Kaplan-Meier estimate on the non-composite outcome.

One should note that the estimated hazard ratios within the Cox model framework are still valid estimates for the comparison of the LCS and the Buechel-Pappas prostheses even in the presence of competing risks. Only the survival curves



Fig. 3-A



Fig. 3-B

**Figs. 3-A through 3-D** Radiographs of a sixty-seven-year-old woman (Case 6, Appendix) who had rheumatoid arthritis for thirty-six years and a stiff hindfoot with a valgus deformity. **Fig. 3-A** The preoperative anteroposterior radiograph shows almost complete loss of the joint space. **Fig. 3-B** Two months after implantation of the LCS prosthesis. The patient had sustained an intraoperative fracture of the medial malleolus, which was treated with osteosynthesis.

themselves are, in that case, not estimated correctly by the Kaplan-Meier method and should be calculated with use of the competing risk approach.

The results were considered significant if  $p < 0.05$ .

### Results

Follow-up was completed as of January 2005, and no patient was lost to follow-up. Fifteen ankles were revised with either an arthrodesis (thirteen ankles) or an implant exchange (two ankles), which are described in detail below. Seventeen patients (twenty-one ankles) had died at an average interval of sixty-three months (range, five to 171 months) after the surgery. There was no apparent relationship between the cause of death and the total ankle arthroplasty. The median duration of follow-up for the sixty-two patients (seventy-eight ankles) who had not reached the end point under study (that is, the patients who had died and those who had not had a revision) was 7.2 years (range, 0.4 to 16.3 years), and the average duration of follow-up was 7.6 years. These measures, therefore, reflect the distribution of the follow-up times of the study itself.

### Clinical and Radiographic Outcome

The clinical outcome at one year after surgery for eighty-seven ankles is listed in Table II. The one-year result was not available for six ankles: two ankles were in two patients who had died, two ankles had been revised for early deep infection, one ankle had been revised for severe wound dehiscence, and one ankle was in a patient who remained severely disabled following a cerebrovascular accident nine months after surgery.

For the fifty-seven ankles seen at a follow-up evaluation in 2005, the mean survival of the total ankle replacement was eight years (range, five to 16.3 years), the mean LCS ankle score was 83.3 (95% confidence interval, 80.0 to 86.6), the mean AOFAS score was 77.0 (95% confidence interval, 73.2 to 80.8), and the mean Kofoed score was 75.7 (95% confidence interval, 72.1 to 97.3).

At the time of the final follow-up, nine of the fifty-seven ankles showed no radiolucency around the tibial component; thirty-nine ankles had partial radiolucent lines, especially around the tibial stem; six had a complete radiolucent line of  $\leq 1$  mm; and three tibial components showed subsidence.



Fig. 3-C



Fig. 3-D

**Fig. 3-C** Despite repeat fixation with tension-band wiring and Kirschner wires, a nonunion of the medial malleolus developed, resulting in lateral edge-loading and subluxation of the bearing. The radiograph shows the ankle after some of the hardware had been removed. **Fig. 3-D** Twenty-six months after the index operation, a successful arthrodesis was carried out.

TABLE II Clinical Outcome for All Ankles at One Year

	Ankle Scoring Systems <sup>15,22,23</sup>			Range of Motion	
	LCS*	AOFAS†	Kofoed‡	Dorsiflexion (deg)	Plantar Flexion (deg)
Preop.# (n = 93)	36.1 (33.6-38.7)	26.5 (24.1-28.8)	26.9 (24.1-29.7)	3.9 (2.9-5.0)	22.4 (20.2-24.6)
One year# (n = 87)	81.5 (78.4-83.9)	77.7 (74.7-80.6)	74.0 (70.9-77.2)	7.1 (5.8-8.4)	24.8 (22.6-27.2)
Gain	45.4**	51.2**	47.1**	3.2**	2.4

\*At one year, fifteen ankles had a score of <70, forty had a score of 70 to 85, and thirty-two had a score of >85. LCS = low contact stress.  
†At one year, seventeen ankles had a score of <70, forty-four had a score of 70 to 85, and twenty-six had a score of >85. AOFAS = American Orthopaedic Foot and Ankle Surgeons. ‡Thirty-two ankles had a score of <70, thirty-three had a score of 70 to 85, and twenty-two had a score of >85. §At one year, eighteen ankles had <5° of dorsiflexion, forty-eight had 5° to 9°, and twenty-one had ≥10°. #The values are given as the mean, with the 95% confidence interval in parentheses. \*\*Student paired t test; p < 0.05.

Complete osseointegration of the talar component was seen in fifty ankles, and partial radiolucent lines were seen around the component in seven ankles, with subsidence in four of them. The seven ankles with subsidence of the implants had no important symptoms.

Fracture or substantial wear of the polyethylene bearing

did not occur in this series, despite the fact that the thinnest bearing (3 mm) had been implanted in forty-eight ankles (52%).

Seventeen of the twenty-one ankles in the patients who had died had functioned well both clinically and radiographically. A sixty-one-year-old man who had a Buechel-Pappas



Fig. 4-A



Fig. 4-B

**Figs. 4-A through 4-D** Radiographs of a forty-two-year-old woman who had rheumatoid arthritis for seventeen years and had undergone a prior hindfoot arthrodesis. The early postoperative anteroposterior (Fig. 4-A) and lateral (Fig. 4-B) radiographs show a well-aligned Buechel-Pappas prosthesis and fixation of an intraoperative medial malleolar fracture with a screw and Kirschner wire.

TABLE III Intraoperative and Early Postoperative Complications

	Medial Malleolar Fracture	Lateral Malleolar Fracture	Anterolateral Distal Tibial Fracture	Postoperative Distal Tibial Fracture	Wound-Healing Disturbance	Infection
No. of ankles	15	5	7	4	8	3
No. of failures*	2	–	–	–	1	1

\*See text and Appendix for details.

ankle arthroplasty bilaterally for the treatment of severe ankle joint destruction due to longstanding rheumatoid arthritis had early aseptic loosening of both tibial components. As the ankles were not symptomatic, no revision surgery was carried out. He died fifty months and thirty-eight months, respectively, after the two operations. A seventy-year-old woman who had a Buechel-Pappas ankle arthroplasty bilaterally for the treatment of severe ankle joint destruction due to longstanding rheumatoid arthritis also had early aseptic loosening of both tibial and both talar components. The ankles had remained asymptomatic, and no revision surgery was carried

out. She died 119 and seventy-one months, respectively, after the two operations.

#### Early Complications

At the time of surgery, osseous complications were seen in twenty-seven ankles: fifteen had a fracture of the medial malleolus; seven, an anterolateral distal tibial fracture (four were incomplete); and five, a fracture of the lateral malleolus (Table III). Screw fixation was used to treat one ankle with an anterior tibial fracture, six ankles with a fracture of the medial malleolus, and two ankles with a fracture of the lat-



Fig. 4-C



Fig. 4-D

**Figs. 4-C and 4-D** Radiographs made at ten years show excellent osseointegration of the tibial and talar components. The hardware in the medial malleolus was removed one year after implantation for the treatment of local symptoms. The ankle had 20° of motion, and the patient was satisfied with the result. She was able to walk a few hundred meters and was limited by symptomatic arthritis of the contralateral hip.



eral malleolus. The other fractures were treated with routine immobilization of the ankle in a plaster cast and without osteosynthesis of the fracture. In only four ankles, these complications led to a change in postoperative management, which involved a non-weight-bearing period of four to six weeks. In two ankles with a preexisting valgus deformity, the medial malleolar fracture went on to nonunion. Both ankles also had development of a stress fracture of the lateral malleolus, eventually leading to valgus instability and edge-loading, which required an arthrodesis (Figs. 3-A through 3-D). None of the other twenty-five fractures influenced the end result (Figs. 4-A through 4-D). Intraoperative fractures occurred both early and late in this series, but there were no injuries to nerves or vessels.

Postoperative complications included delayed wound-healing in seven ankles, with additional surgery required in only two of them (one had a local flap and one had excision of a necrotic anterior tibial tendon), and one major wound dehiscence with an open ankle joint that required conversion to an arthrodesis after two months (Table III). Three ankles had an early deep infection. Open lavage combined with culture-specific systemic intravenous antibiotics for two weeks, followed by oral antibiotics for four and ten weeks, respectively, resulted in resolution of the two infections. The third ankle had to be converted to an arthrodesis after four months.

Four ankles had an early spontaneous postoperative fracture of the distal aspect of the tibia, which occurred four to six months after surgery at the level of the tip of the stem of the tibial component. All four patients had severe osteopenia assessed intraoperatively. These fractures healed after treatment with cast immobilization, and they did not influence the end result. The distal tibial fractures (both intraoperative and early postoperative) were seen only with the Buechel-Pappas prosthesis.

#### **Subsequent Surgery without Implant Exchange**

Besides the above-mentioned complications, subsequent surgery included arthroscopic débridement for arthritis between the talus and malleolus in three ankles and valgus osteotomy of the calcaneus in one ankle in a patient who had a residual symptomatic varus deformity of the hindfoot. The results of these procedures were good in all four ankles.

#### **Late Complications and Revisions**

Two ankles had a secondary deep infection. In one of them, the infection developed after arthroscopic débridement for arthritis of the talus and malleolus (described above). It was treated effectively with open lavage and culture-specific intravenous antibiotics for four weeks, followed by ten weeks of oral antibiotics. At eleven years, the ankle showed no signs of active infection. In the second ankle, the late infection developed after a subsequent hindfoot fusion that became infected. After a two-stage revision was performed, the infection resolved. The ankle eventually required conversion to an arthrodesis as a result of aseptic loosening of the cemented tibial component.

Six ankles were revised because of aseptic loosening. One ankle in a woman with juvenile idiopathic arthritis who was managed with the LCS prosthesis had subsidence of the talar component after ten years. The ankle was successfully treated with an exchange of both the bearing and the talar component with use of Buechel-Pappas implants. Another five ankles (two with LCS components and three with Buechel-Pappas prostheses) had aseptic loosening of the tibial components. Four of them also had loosening of the talar component. The six ankles were converted to an arthrodesis 2.5 to thirteen years after implantation.

Another eight ankle replacements were converted to an arthrodesis because of an early deep infection (one ankle), major delay of wound-healing with an open ankle joint (one ankle, which was described in the section on early complications), persistent varus deformity with edge-loading (two ankles treated early in this series), valgus deformity with edge-loading due to nonunion of an intraoperative medial malleolar fracture (two ankles described in the section on early complications), secondary edge-loading due to a late lateral malleolar fracture (one ankle), and secondary valgus instability with edge-loading (one ankle).

In summary, a total of fifteen ankles (fourteen patients) were revised with an implant exchange (two ankles) or conversion to an arthrodesis (thirteen ankles). These data are listed in the Appendix.

#### **Survival Analysis**

Kaplan-Meier survival analysis and the cumulative rate of survival in a competing risk scenario were used for the analysis of the risks for failure.

Separate end points for failure were defined as (1) a revision (or conversion to an arthrodesis) for any reason, (2) a revision for aseptic loosening, and (3) radiographic evidence of loosening without a revision.

The eight-year overall survival rate for both prostheses, with revision or conversion to an arthrodesis for any reason as the end point, was 84% (95% confidence interval, 73% to 93%).

Log-rank analysis revealed no significant difference, with the numbers available, in the mean overall survival rate between the LCS prosthesis and the Buechel-Pappas prosthesis during the observation period ( $p = 0.33$ ) (Figs. 5-A and 5-B). However, a significant difference was demonstrated in the overall survival rate between the ankles with or without a preoperative deformity in the frontal plane. Seventeen ankles had a preoperative varus or valgus deformity of  $>10^\circ$ , and the overall survival rate for these ankles at eight years was 48% (95% confidence interval, 6% to 90%). Ankles with a neutral alignment preoperatively ( $<10^\circ$  of varus or valgus) had an eight-year mean overall survival rate of 90% (95% confidence interval, 82% to 98%). Log-rank analysis demonstrated that the difference was significant ( $p = 0.03$ ) (Figs. 6-A and 6-B).

The mean eight-year overall survival rate was 91% (95% confidence interval, 81% to 100%) for the sixty-six ankles that had a tibial component of the correct size and 66% (95% confidence interval, 45% to 88%) for the twenty-seven ankles

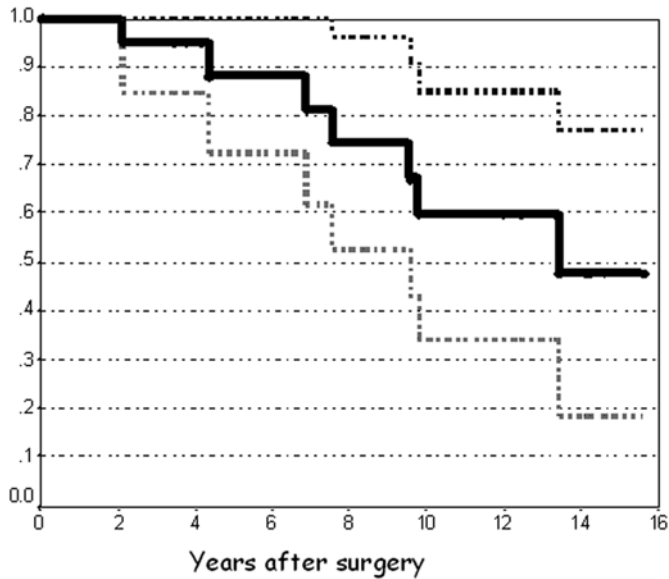


Fig. 5-A

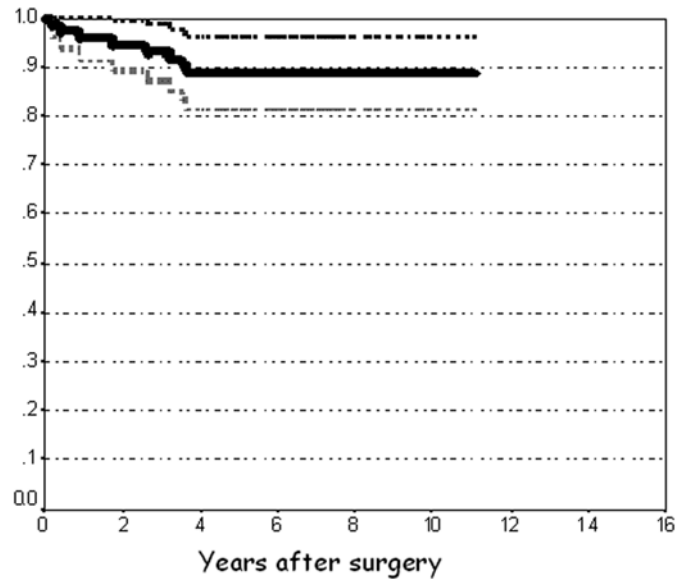


Fig. 5-B

**Figs. 5-A and 5-B** The Kaplan-Meier survival curves (solid black lines), with the 95% confidence intervals (dotted lines), for the LCS (Fig. 5-A) and the Buechel-Pappas (Fig. 5-B) total ankle replacements. With the numbers available, log-rank analysis showed no significant difference during the period of observation ( $p = 0.33$ ).

with an undersized tibial component. The difference was significant ( $p = 0.02$ ).

The eight-year cumulative incidence of failure was calculated for the composite end points. At eight years, twenty-four ankles were in the follow-up. The incidence of failure was 13% (95% confidence interval, 7% to 25%) with revision for other reasons (infection, edge-loading, etc.) as the end point,

3% (95% confidence interval, 1% to 10%) with revision because of aseptic loosening as the end point, and 16% (95% confidence interval, 9% to 30%) for aseptic loosening without revision as the end point (Fig. 7).

#### Cox Regression Analysis

With revision or conversion to an arthrodesis for any reason

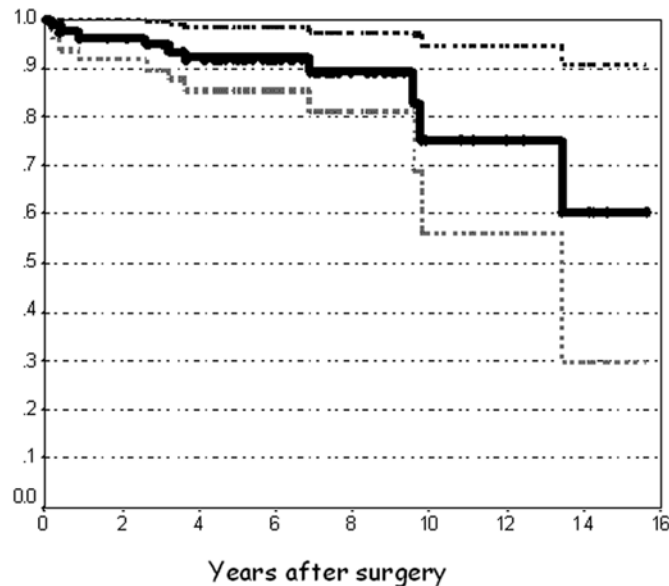


Fig. 6-A

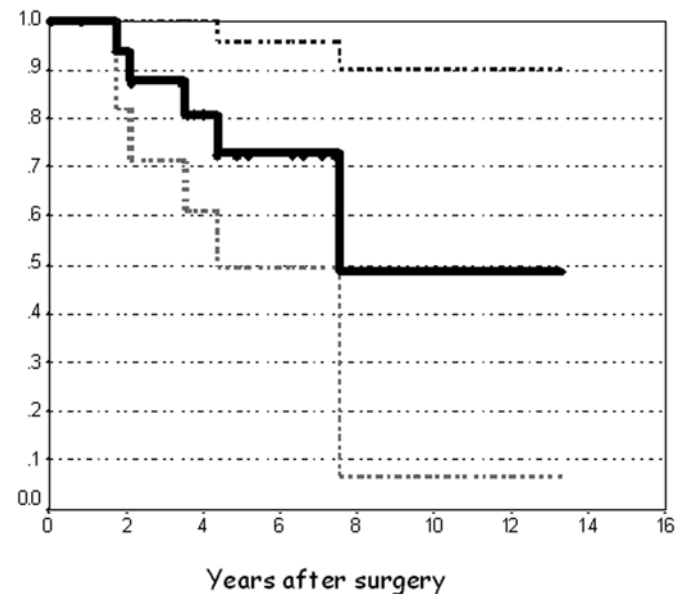


Fig. 6-B

**Figs. 6-A and 6-B** The Kaplan-Meier survival curves (solid black lines), with the 95% confidence intervals (dotted lines), for the ankle replacements in the neutrally aligned ankles (Fig. 6-A) and in the ankles with a preoperative deformity in the frontal plane of  $>10^\circ$  (Fig. 6-B). Log-rank analysis showed a significant difference in favor of the ankles with a neutral alignment ( $p = 0.03$ ).

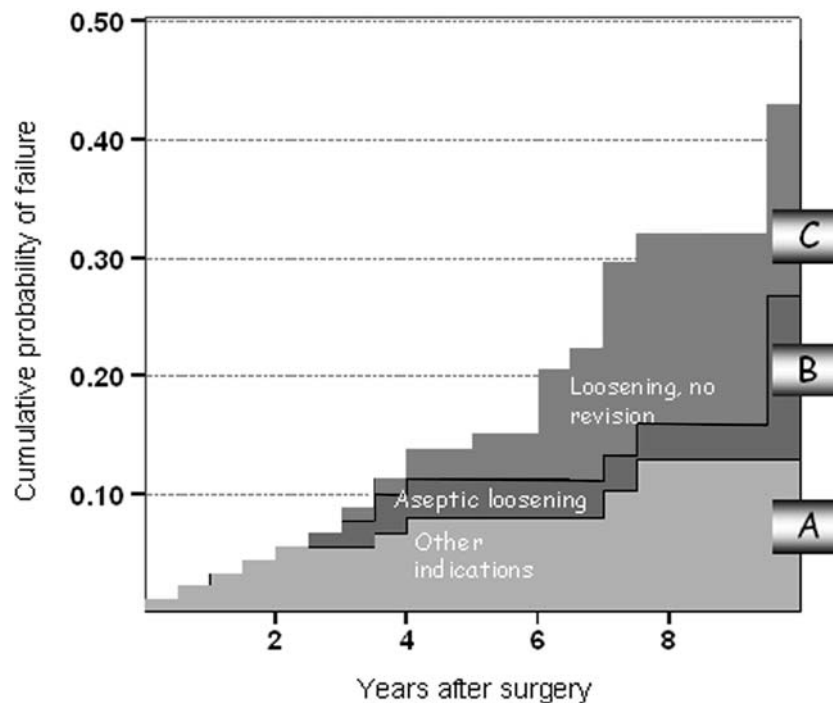


Fig. 7  
Cumulative incidence analysis of the risk of failure with revision for other indications (A), revision for aseptic loosening (B), and aseptic loosening with no revision (C) as the end points.

as the end point, a multivariate analysis was carried out to assess which factors influenced the survival of the replacement. The following items were evaluated: the type of prosthesis (LCS or Buechel-Pappas), year of surgery, sex, age at the time of surgery (forty-eight patients were less than sixty years old, and forty-five were at least sixty years old), ankylosis of the hindfoot at the time of surgery, and the position of the tibial component in the frontal plane (sixty-six ankles had  $\leq 4^\circ$  of varus deformity, and twenty-seven had  $\geq 5^\circ$  of varus deformity).

With the numbers available, no factor was identified as having a significant effect on survival. However, ankylosis of the hindfoot showed a trend toward significance ( $p = 0.07$ ). As there was a high correlation between a varus position and an undersized tibial component, these factors could not be assessed together in one statistical model.

### Discussion

There is considerable controversy with regard to total ankle arthroplasty as a valid option in the treatment of inflammatory arthritis of the ankle. All studies that we know of on the various constrained two-component designs have shown unsatisfactory results<sup>10-14</sup>, and these implants have been abandoned by most authors. Acceptable results have been reported only for the semiconstrained Agility total ankle arthroplasty in two studies in mixed populations of patients with posttraumatic arthritis, primary arthritis, and rheumatoid arthritis<sup>15,26</sup>. Both studies, however, used less strict radiographic criteria

than we used for loosening without revision. With the same prosthesis, Spirt et al. reported a relatively high rate of early failure<sup>27</sup>, especially with respect to a high level of reoperations that occurred after the total ankle arthroplasty. The inferior results in their study may have been the result of the younger age of the patients.

With a mean eight-year overall survival rate of 84% in patients with inflammatory joint disease, our study shows that mobile-bearing total ankle arthroplasty is a valid treatment option. Above all, our study reflects the learning curve for this procedure, not only with regard to the surgical technique but also with regard to its application to the proper indications, and that fact should be taken into account. The results were better if only well-aligned ankles (which had a mean survival rate of 90% at eight years) or tibial components of the correct size (which had a mean survival rate of 91% at eight years) were considered. Younger age could not be identified as a risk factor for failure. A positive phenomenon was the absence of substantial wear or fracture of the polyethylene bearing in this series. The most important modes of failure were edge-loading in ankles with a preexisting deformity in the frontal plane, mainly occurring early in this series, and aseptic loosening of either the tibial or the talar component occurring with longer-term follow-up.

In 2003, Buechel et al.<sup>18</sup> reported a mean cumulative survival rate of 93.5% at eight years in a prospective study of the Buechel-Pappas prosthesis. Most of their patients had posttraumatic or primary osteoarthritis. In a prospective se-

ries of 200 ankles with both inflammatory joint disease and osteoarthritis that were managed with the mobile-bearing STAR (Scandinavian total ankle replacement) prosthesis, Wood and Deakin reported a survival rate of 87.9% at eight years<sup>20</sup>. Aseptic loosening and edge-loading as a result of persistent deformity were the most important modes of failure. Radiographic evidence of improved fixation was seen with a new version that had a dual coating of hydroxyapatite on porous titanium. Using the same prosthesis, Anderson et al.<sup>21</sup> reported less favorable results, with a five-year survival rate of 70%. The mode of failure in that study was aseptic loosening in seven ankles and fracture of the polyethylene bearing in two of the twelve ankles that had a revision. They commented that total ankle arthroplasty was a challenging procedure and the instrumentation used was unsatisfactory. Nevertheless, they still recommended this procedure in well-aligned ankles with sufficient bone stock and noted that the instrumentation had been improved after their study had concluded.

In general, the results with mobile-bearing designs are better than those described for two-component designs. This is probably due to the unconstrained biomechanical characteristics of the mobile-bearing prosthesis: the vertical rotational forces occurring at the ankle during walking<sup>28</sup> should be better tolerated with an unconstrained implant. In vitro kinematical studies comparing the normal ankle, the fused ankle, the Agility two-component design, and two mobile-bearing designs (STAR and HINTEGRA) have demonstrated relatively normal kinematics at the ankle after implantation of the mobile-bearing prostheses; these findings are in strong contrast to the situation after ankle arthrodesis and also after arthroplasty with the Agility prosthesis<sup>29-31</sup>. The lower rate of early mechanical failure in the mobile-bearing designs compared with the constrained two-component designs could therefore be explained by their better kinematical characteristics.

The survival rate for mobile-bearing total ankle replacements is somewhat lower than that for replacements of the hip<sup>32-34</sup> and knee<sup>35-37</sup>. However, the long-term results are certainly acceptable, and the complication rate is similar to that for arthrodesis. Applying the threshold of ten-year survival, as identified by SooHoo and Kominski<sup>38</sup>, total ankle arthroplasty with use of a mobile-bearing prosthesis appears to be a cost-effective procedure in the treatment of inflammatory joint disease.


Preoperative deformity in the frontal plane is quite difficult to correct during total ankle arthroplasty and, if it persists after surgery, frequently results in instability and a subluxation of the bearing, eventually leading to failure. This could be avoided by making a varus or valgus deformity of  $>10^\circ$  an absolute contraindication for total ankle arthroplasty.

In our series, there was a relatively high rate of malleolar fractures. This can, at least to some extent, be explained by both the more osteopenic bone in the ankles in patients with rheumatoid arthritis and by the limited experience of the participating surgeons. No long-term adverse effects of malleolar fractures were seen in well-aligned ankles. Furthermore, there was an increased risk of distal tibial fractures both at the time

of surgery and in the early postoperative period. This is most likely related to the window that is created in the distal part of the tibia for the stem of the tibial component and to the sometimes severely osteopenic bone in severely disabled patients with rheumatoid arthritis who take corticosteroids. Although no long-term adverse effects of such fractures were seen, they still carry a potential risk for failure. Finally, durable long-term fixation of the total ankle arthroplasty components might better be achieved with the use of implants with improved coating characteristics<sup>20,39</sup>.

In conclusion, good clinical results can be achieved with the LCS or Buechel-Pappas total ankle prosthesis in the treatment of severe inflammatory joint disease if proper indications are applied. A varus or valgus deformity of the ankle and/or hindfoot of  $>10^\circ$  should be considered a contraindication to this procedure. If such a deformity is present, we believe a procedure to correct it (e.g., triple arthrodesis) should be performed prior to the ankle arthroplasty. Mobile-bearing total ankle arthroplasty can certainly be considered an alternative to ankle arthrodesis in patients with rheumatoid arthritis. Because of the technical difficulties that can be encountered during surgery, and the low frequency of this procedure in the typical orthopaedic practice, total ankle arthroplasty probably should be restricted to the experienced ankle surgeon.

## Appendix

 A table with data on the revision procedures is available with the electronic versions of this article, on our website at [jbjs.org](http://jbjs.org) (go to the article citation and click on "Supplementary Material") and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

NOTE: The authors thank Dr. Mick C. Van Joost, MD, formerly of the Department of Orthopaedics, Academic Medical Center, Amsterdam, The Netherlands, for his assistance in the radiographic evaluation of the patients.

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The authors did not receive grants or outside funding in support of their research for or preparation of this manuscript. They did not receive payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, educational institution, or other charitable or nonprofit organization with which the authors are affiliated or associated.

doi:10.2106/JBJS.E.00414

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