CLINICAL ORTHOPAEDICS AND RELATED RESEARCH
Number 424, pp. 19–26

Twenty-Year Evaluation of Cementless Mobile-Bearing Total Ankle Replacements

Frederick F. Buechel, Sr., MD; Frederick F. Buechel, Jr., MD†; and Michael J. Pappas, PhD‡*

Two consecutive series of patients who had cementless, porous-coated, congruent-contact, mobile-bearing total ankle replacements were evaluated during a 20-year interval using the New Jersey Orthopaedic Hospital ankle scoring scale to determine clinical outcome and overall implant survivorship with revision as an end point. The initial series of 38 patients (40 ankle replacements) using a shallow-sulcus design had diagnoses of: osteoarthritis, seven (17.5%); rheumatoid arthritis, nine (22.5%); posttraumatic arthritis, 21 (52.5%); and failed fusion, three (7.5%). Clinical results after 2–20 years, (mean, 12 years) were 28 (70%) good to excellent, two (5%) fair, and 10 (25%) poor. Postoperative ankle motion ranged from 10°–47° total arc (mean, 25° total arc). The 20-year overall survivorship for the shallow-sulcus design was 74.2%. A second series of 74 patients (75 ankle replacements) using a deep-sulcus design had diagnoses of: osteoarthritis, eight (11%); rheumatoid arthritis, nine (12%); osteonecrosis, three (4%); and posttraumatic arthritis, 55 (73%). Clinical results after 2–12 years, (mean 5 years) were 66 (88%) good to excellent, four (5%) fair, and five (7%) poor. Postoperative ankle motion ranged from 10°–50° total arc (mean, 29° total arc). The 12-year overall survivorship for the deep-sulcus design was 92%.

Improved total ankle replacement results using mobile bearings have been reported.[3,4,7,16,24] It is postulated that these results have been produced by allowing normal kinematic function of the bones and ligaments as seen in gait analysis[20] and load-bearing cineradiographic studies.[17] Allowing distal fibular rotation to optimize lateral ligamentous function during dorsiflexion and planter flexion motion is an ideal goal. Such rotation can average 2.2° (range, 1.4°–4.8°).[13] Fixed-bearing devices that attempt to eliminate or minimize this fibular motion or restrict axial rotation can be subjected to torsional loads that can loosen tibial component fixation[1,10,11,15,21,25,26] or result in nonunion of the syndesmosis.[12,23]

The current study involves the use of rotationally unconstrained mobile bearings that articulate with a flat tibial plate superiorly and a biconcave trochlear talar component surface inferiorly (Fig 1). The surface geometry remains fully congruent, even during inversion and eversion motions to reduce contact stresses below the medical load limit for UHMWPE of 5 MPa.[8]

Inversion and eversion congruity is essential to prevent edge-loading wear and deformation, which has been reported with flat-on-flat knee replacement designs.[19] Deepening the trochlear sulcus angle tends to center the meniscal bearing and prevent bearing subluxation under normal load-bearing conditions.[7] The improved stability of the deep-sulcus geometry over the shallow-sulcus geometry has been reported in the short term.[7] Our study reflects longer-term use of both designs with more detailed analysis.

MATERIALS AND METHODS

Two consecutive series of patients with cementless, porous-coated, congruent-contact, mobile-bearing total ankle replacements implanted through an anterior surgical approach were evaluated prospectively using the New Jersey Orthopaedic Hospital (NJOH) ankle scoring scale.[3] This validated scoring scale[18] is most heavily weighted for pain (40 points) and function (40 points), with ROM (15 points) and deformity (5 points) also recorded. Evaluations were done at 3 months, 6 months, 1 year, and yearly thereafter.

Differences between the implants mainly involved the talar component geometry, which had a shallow sulcus and central fin, (New Jersey LCS® Total Ankle, DePuy, Warsaw, IN) in the initial group of 40 cases, in which the implants were CoCr alloy with UHMWPE bearings sterilized by gamma radiation in air; and a deeper sulcus with two fixation fins (Buechel-Pappas™ Total Ankle, Endotec, Orange, NJ) in the latter group of 75 cases

From the *Department of Orthopaedic Surgery, UMDNJ-New Jersey Medical School, Newark, NJ; †Pennsylvania Hospital, University of Pennsylvania, Philadelphia, PA; and the ‡Department of Mechanical Engineering, New Jersey Institute of Technology, Newark, NJ.
Correspondence to: Frederick F. Buechel, MD, South Mountain Orthopedic Associates, 61 First Street, South Orange, NJ 07079. Phone: 973-762-8344; Fax: 973-762-1664.
DOI: 10.1097/01.blo.0000132243.41419.59

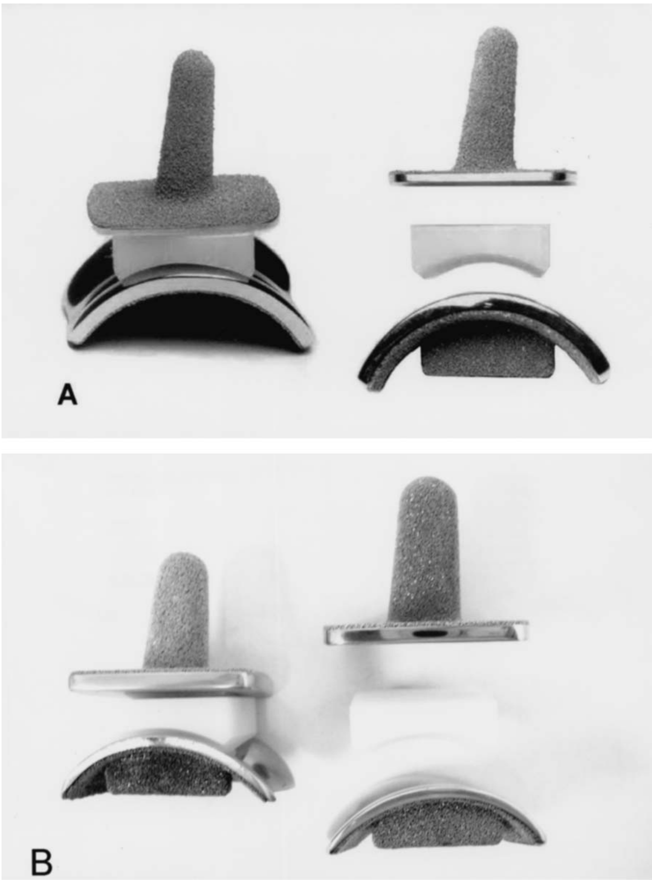

Fig 1A–B. (A) The photographs show shallow sulcus and (B) deep sulcus total ankle replacements.

in which the implants were titanium nitride-coated and the UHMWPE bearings were EO sterilized[22] (Fig 1). The shallow sulcus group of patients was part of an FDA clinical trial. The Institutional Review Board (IRB) of our institution (NJOH) approved the protocol. In the deep sulcus group a clinical trial had not been initiated and was done under the FDA regulations 21CFR, Part 807.85, exemption from premarket notification.

The initial series of 40 ankle replacements using the shallow-sulcus design in 38 patients were implanted from December 1981 to December 1988. The diagnoses were OA (seven patients, 17.5%), RA (nine patients, 22.5%), post fusion (three patients, 7.5%) and posttraumatic (21 patients, 52.5%). The patients' ages ranged from 21–89 years (mean, 55 years). Their heights ranged from 132–193 cm (mean, 163 cm) and their weights ranged from 45–123 kg (mean, 73 kg). Preoperative ankle motion ranged from 0°–45° total arc (mean, 26° total arc).

The second series of 75 ankle replacements using the deep-sulcus design in 74 patients with ligamentous stability were implanted from January 1991 to December 2000. The diagnoses were OA (eight patients, 11%), RA (nine patients, 12%), ON (three patients, 4%), and posttraumatic (55 patients, 73%). The patients' ages ranged from 25–78 years (mean, 49 years). Their heights ranged from 152–193 cm (mean, 170 cm) and their weights ranged from 44–130 kg (mean, 85 kg). Preoperative ankle motion ranged from 0°–50° total arc (mean, 24° total arc).

Kaplan-Meier[14] survivorship analysis was done to compare the long-term survivorship of both groups. Radiographic analysis using coordinate axes of orientation were done on available radiographs in the immediate postoperative period (0–6 months) and compared with the radiographs taken at the last followup to determine component migration, wear, osteolysis, or bearing subluxation or dislocation.

Postoperative Care

As a consequence of significant wound healing problems seen when using the anterior approach and early mobilization that was used in the 1970s, a more conservative immobilization approach has been adopted and combined with recent improvements for wound care. Specifically, nasal oxygen (3–5 L/minute) should be applied for the initial 48 hours after surgery to improve initial wound healing. If extensive swelling occurs during the first 48 hours, the short leg cast should be bivalved laterally and medially. No drain is used. Weightbearing to tolerance begins on the first postoperative day with intermittent elevation when the patient is nonambulatory. The initially applied, well-padded, plaster cast is removed and replaced with a well-padded fiberglass cast at 2 weeks postoperatively. Final cast removal usually is done at 6 weeks postoperatively, after which an ankle air-stirrup is applied for 6 additional weeks to allow a return of dorsiflexion and plantar flexion motion. Additional immobilization may be needed for delayed wound healing or malleolar fracture complications. A high top hiking-type shoe and support stockings then should be worn for 6–12 months until swelling has subsided and ankle strength has returned. Thereafter, comfortable footwear should be worn during activities of daily living, which should include routine isometric and resistive dorsiflexion and plantar flexion and inversion and eversion exercises to tolerance.

RESULTS

The overall clinical results of the shallow-sulcus design with a followup of 2–20 years (mean, 12 years) were 28 (70%) good to excellent, two (5%) fair, and 10 (25%) poor using a strict ankle scoring scale.[3] The overall results of the deep-sulcus design with a followup of 2–12 years (mean, 5 years) were 66 (88%) good to excellent, four (5%) fair, and five (7%) poor. Postoperative ankle motion ranged from 10°–47° total arc (mean, 25° total arc) in the shallow-sulcus group, and 10°–50° total arc (mean, 29° total arc) in the deep-sulcus group. The complications of both groups, including but not limited to those requiring revision or fusion, are summarized in Table 1.

Radiographic lucencies of 2 mm or greater persisted around three tibial components between 10 and 14 years postoperatively in the shallow-sulcus group. Twenty-six patients with unilateral ankle replacements had radiographs of satisfactory quality to evaluate radiolucencies around tibial and talar components. One tibial component developed a fracture of the loading plate and required

TABLE 1. Complications of Mobile-Bearing Total Ankle Replacement

Complications	Shallow-Sulcus 40 Ankles		Deep-Sulcus 75 Ankles	
	Number of Ankles	*%*	*Number of Ankles*	*%*
Delayed wound healing	9	22.5	11	14.7
Talar component subsidence	6	15.0	3	4.0
Bearing subluxation	4	10.0	0	0.0
Severe bearing wear	5	12.5	3	4.0
Malleolar fracture	3	7.5	6	8.0
Infection	2	5.0	2	2.7
Reflex sympathetic dystrophy	2	5.0	3	4.0
Tibial component loosening	0	0	0	0.0
Osteolysis tibia	2	5.0	6	8.0
Osteolysis fibula	1	2.5	2	2.7
Osteolysis talus	1	2.5	2	2.7

revision; the other two tibial components were revised because of excessive wear. No tibial component was clinically loose; all three revised tibial components were stable at the time of revision.

Talar component lucencies of 2 mm or greater were seen to persist around four talar components between 8 and 19 years postoperative. Only one of these four talar components required revision because of severe wear. Stable fixation was encountered at surgery during this talar revision. Despite the absence of radiolucencies, six additional talar components subsided; five of these were revised because of associated bearing wear in three components and bearing subluxation in two components.

Typical radiographs of a successful shallow-sulcus device are shown in Figure 2. Typical radiographs of the deep-sulcus device in patients diagnosed with OA and RA are shown in Figure 3 and Figure 4, respectively.

Radiographic lucencies of 2 mm or greater were seen to persist around four tibial components between 2 and 8 years postoperatively in the deep-sulcus group. Forty-one patients with 42 ankle replacements had radiographs of satisfactory quality to evaluate radiolucencies around tibial and talar components. One tibial component was malpositioned anteriorly and was revised because of excessive bearing wear leading to osteolytic tibial cysts.

Talar component lucencies of 2 mm or greater were seen to persist around four talar components between 7 and 12 years postoperative. One of these four talar components also subsided in the bone approximately 3 mm but no talar component revisions or bearing subluxations were encountered in this group. A typical successful deep-sulcus device is shown in Figure 5.

Survivorship analysis using an end point of implant revision for each series and the annual confidence intervals are shown in Figure 6 A and 6 B respectively. The 20-year overall survivorship for the initial shallow-sulcus design was 74.2%; the 12-year overall survival for the deep-sulcus design was 92%.

DISCUSSION

As with comparative studies in mobile-bearing knee replacement,[5,6] some important observations made in this study are likely to influence the design of mobile-bearing ankle replacements. Bearing subluxation problems developed in four patients (10%) with the shallow-sulcus design, which were eliminated in the deep-sulcus design, by developing a sufficient sulcus angle to resist talar tilting and lateral displacement forces on the bearing. Such forces when applied in shallow-sulcus or flat articulations can cause medial or lateral bearing displacement, which destabilizes the replacement and leads to accelerated wear. Additionally, the volume of bearing thickness increases with a deeper-sulcus engagement, thereby improving the tensile strength of the bearing to resist fracture. Five (12.5%) shallow-sulcus meniscal bearings developed wear-related fractures; whereas only three (4%) deep-sulcus bearings developed significant wear with no fractures. Radiographic measurements to assess component wear or subsidence were not explored statistically but rather were used to correlate with clinical conditions.

A related design issue involves the fixation difference between one central talar fixation fin and two off-center talar fixation fins. In the single-fin group (shallow-sulcus) six (15%) talar components subsided, whereas in the double-fin group (deep-sulcus) only three (4%) talar components have subsided. This improvement in talar component fixation and bearing stability strongly favors the deep-sulcus talar component design with two fixation fins.

The issue of component subsidence and loosening may be more complicated than initially was considered.[4] For

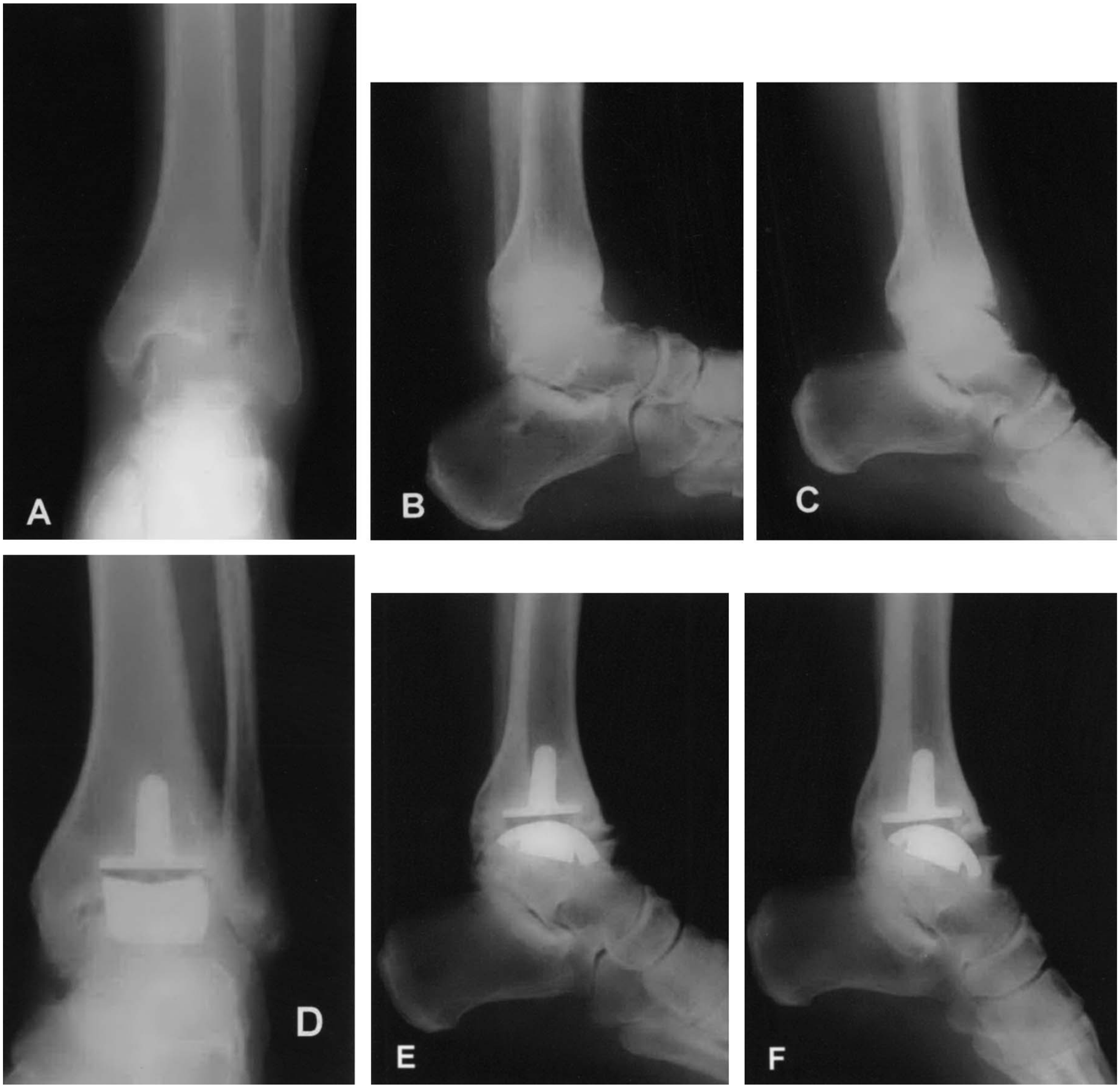

Fig 2A–F. (A) An AP radiograph shows the left ankle of a 32-year-old, 180-lb (82 kg), 72-inch (183 cm) tall active man with severe posttraumatic arthritis. (B) Lateral radiographs of the same patient show the ankle in dorsiflexion and (C) plantar flexion. (D) An AP lateral radiograph of the same patient was obtained 19 years after shallow-sulcus total ankle replacement. (E) Lateral radiographs show the ankle in dorsiflexion and (F) plantar flexion.

instance, the PE bearings used in the 1980s contained significant fusion defects and were gamma sterilized in air, whereas the PE used in the deep-sulcus design were fusion defect-free and sterilized by EO. The higher wear rate seen in the shallow-sulcus design may be related to both of these issues and may have induced osteolysis and subsequent subsidence of the talar component.

The fully porous-coated tibial component loading stem and platform worked equally well in both designs with no gross migration or loosening observed. One shallow-sulcus tibial component loading plate fractured after complete bearing wear-through, most likely because of excessive point contact loading. A longer stem does not seem to be necessary unless severe bony defects

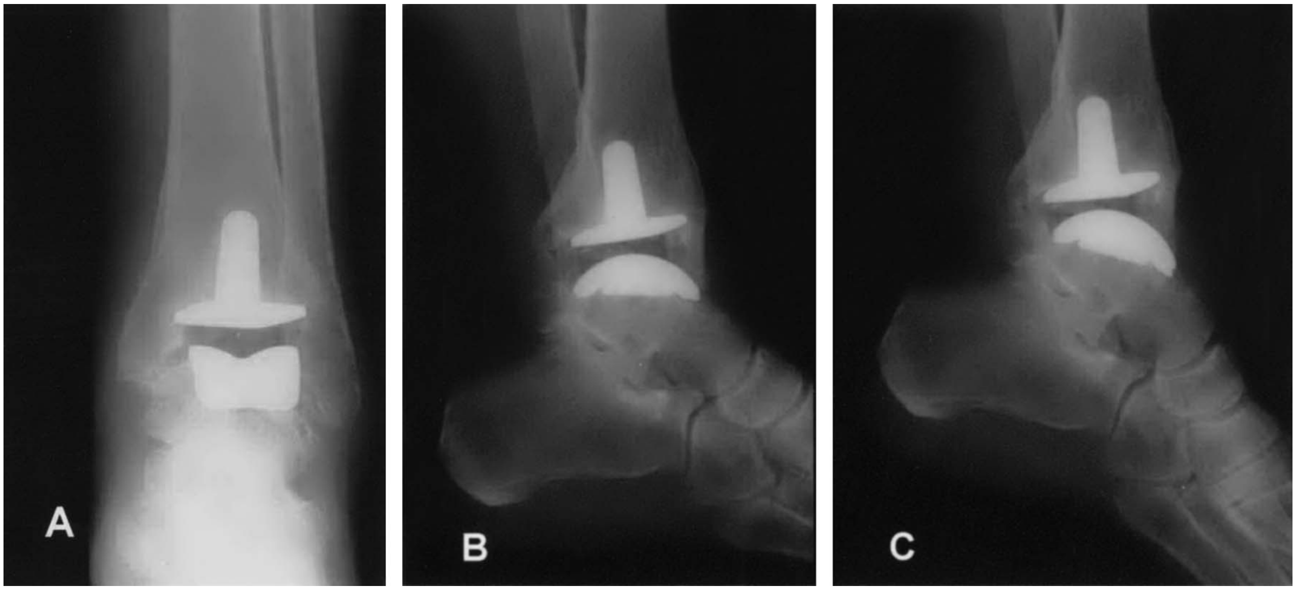

Fig 3A-C. (A) An AP radiograph shows the left ankle of a 72-year-old, 185-lb (84 kg), 66-inch (168 cm) active man 4 years after deep-sulcus total ankle replacement for osteoarthritis. Lateral radiographs of the same patient show the ankle in (B) dorsiflexion and (C) plantar flexion.

are encountered; a shorter stem or no stem may allow loosening.

The absence of talar component side flanges on the shallow-sulcus and deep-sulcus components did not seem to affect the quality of the clinical outcome with time with the exception of increased talar component subsidence seen in the shallow-sulcus group. Although a theoretical concern over intermalleolar bone bridging was entertained, this phenomenon rarely was encountered. More of a concern is the possibility of stress shielding of the talus

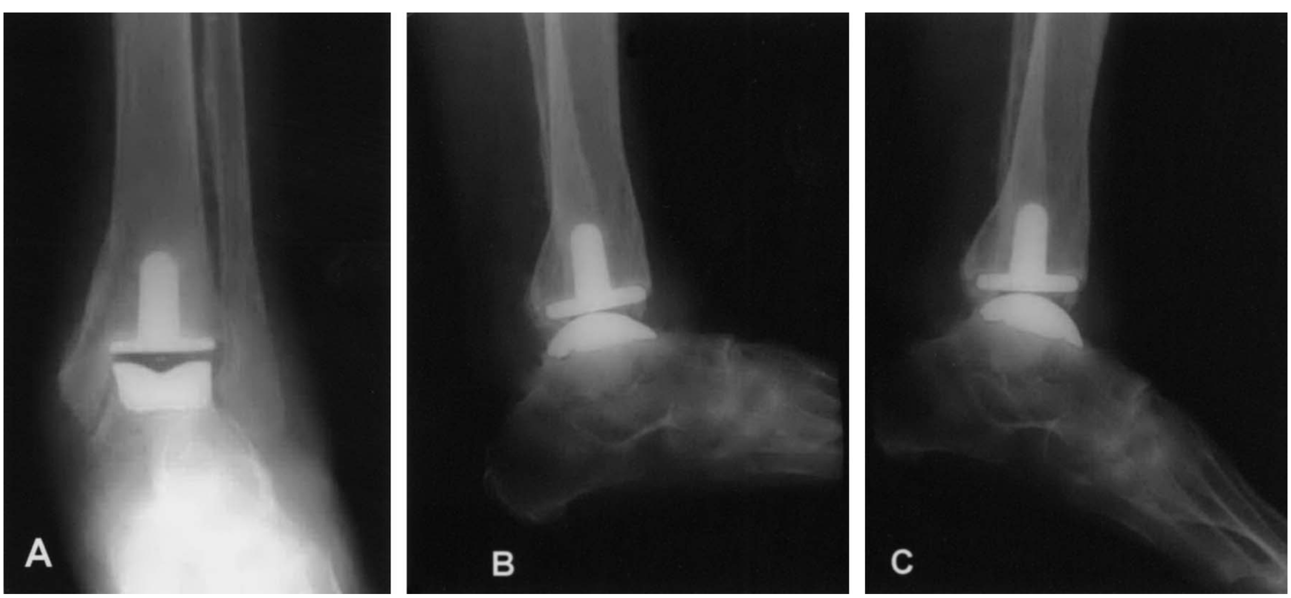

Fig 4A–C. (A) An AP radiograph shows the left ankle of a 67-year-old, 141-lb (64 kg), 63.5-inch (161 cm) active woman with RA. Lateral radiographs of the same patient taken 3 years after deep-sulcus total ankle replacement show the ankle in (B) dorsiflexion and (C) plantar flexion.

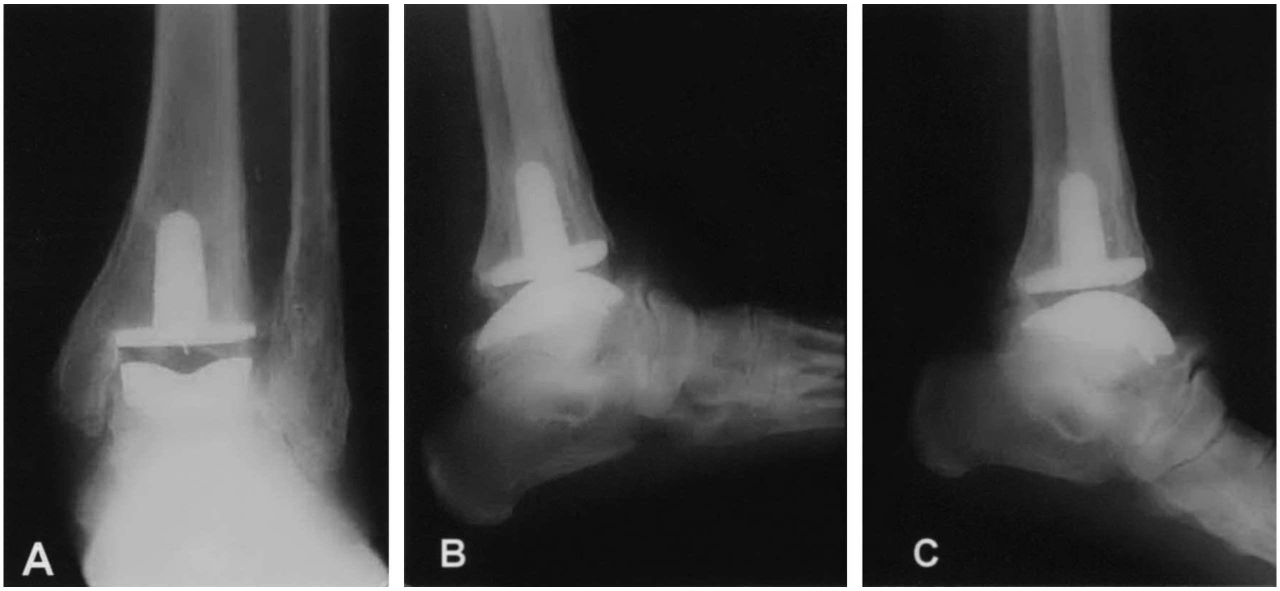

Fig 5A–C. (A) An AP radiograph shows the left ankle of a 61-year-old, 196-lb (89 kg), 60-inch (152 cm) tall active woman 10 years after deep-sulcus total ankle replacement for posttraumatic arthritis. Lateral radiographs of the same patient show the ankle in (B) dorsiflexion and (C) plantar flexion.

by using such covering flanges that eliminate malleolar bony contact, thereby reducing normal malleolar loading patterns and introducing metal-on-bone articulations. Maintaining malleolar contact with the talus and allowing normal fibular rotation is desirable and provides satisfactory long-term function and survivorship of the replaced ankle using mobile-bearing designs.

Of some additional concern is the radiographic observation of tibial bony overgrowth, anteriorly and posteriorly, around the tibial component loading plate, seen in the shallow-sulcus and deep-sulcus designs with time. The AP dimensions of the loading plate, used in this study, fall short of the true AP dimensions of the resected distal tibia, thereby allowing osteogenesis and spur formation to form bony overgrowth, which can limit ROM. Although these spurs can be resected later, it would be useful to prevent their formation. Such could be accomplished by use of indomethicin in the immediate postoperative period or by extending the anterior and posterior dimensions of the loading plate to help prevent the bony overgrowth. Both considerations are reasonable and currently are being implemented to improve ankle motion in the long term.

Delayed wound healing continues to be the most common complication (17.4% overall) and perhaps is inevitable in this region of anatomy. Persistent diligence in minimizing this complication by extending the incisions and avoiding constant retraction pressure is recommended. In ankles that had multiple operations, incision planning to avoid wound compromise remains paramount.

Fracture of the medial malleolus (7.8% overall) can be an annoying but not a catastrophic problem, unless excessive varus of the ankle is involved, which can lead to progressively increasing varus and later stress fracture of the medial malleolus. Such conditions may require realignment osteotomy to allow compressive rather than shearing loads at the ankle. Diligence to avoid varus malalignment of the ankle is recommended.

Reflex sympathetic dystrophy (4.3% overall) is a devastating complication after ankle replacement. Despite proper alignment of components and prolonged immobilization, this condition persists for many years and should be considered a lifetime condition with intermittent relapses. Three patients in this study, encouragingly, improved after 2–12 years from poor ankle scores to good ankle scores; the remaining two patients with reflex sympathetic dystrophy continue to have poor scores, despite excellent component alignment and fixation after 3 and 6 years, respectively.

Infections after ankle replacement (3.5% overall) remain worrisome, although debridement and/or antibiotic suppression were successful in three of the four cases of 115 seen in this study. It is likely that the decreased vascularity in the ankle, especially after multiple surgical interventions, is responsible, not only for significant delayed wound healing but also contributes to the overall increased incidence of wound dehiscence that was seen. Patients with multiple surgical incisions or immunocompromised tissues should be alerted to these potential complications

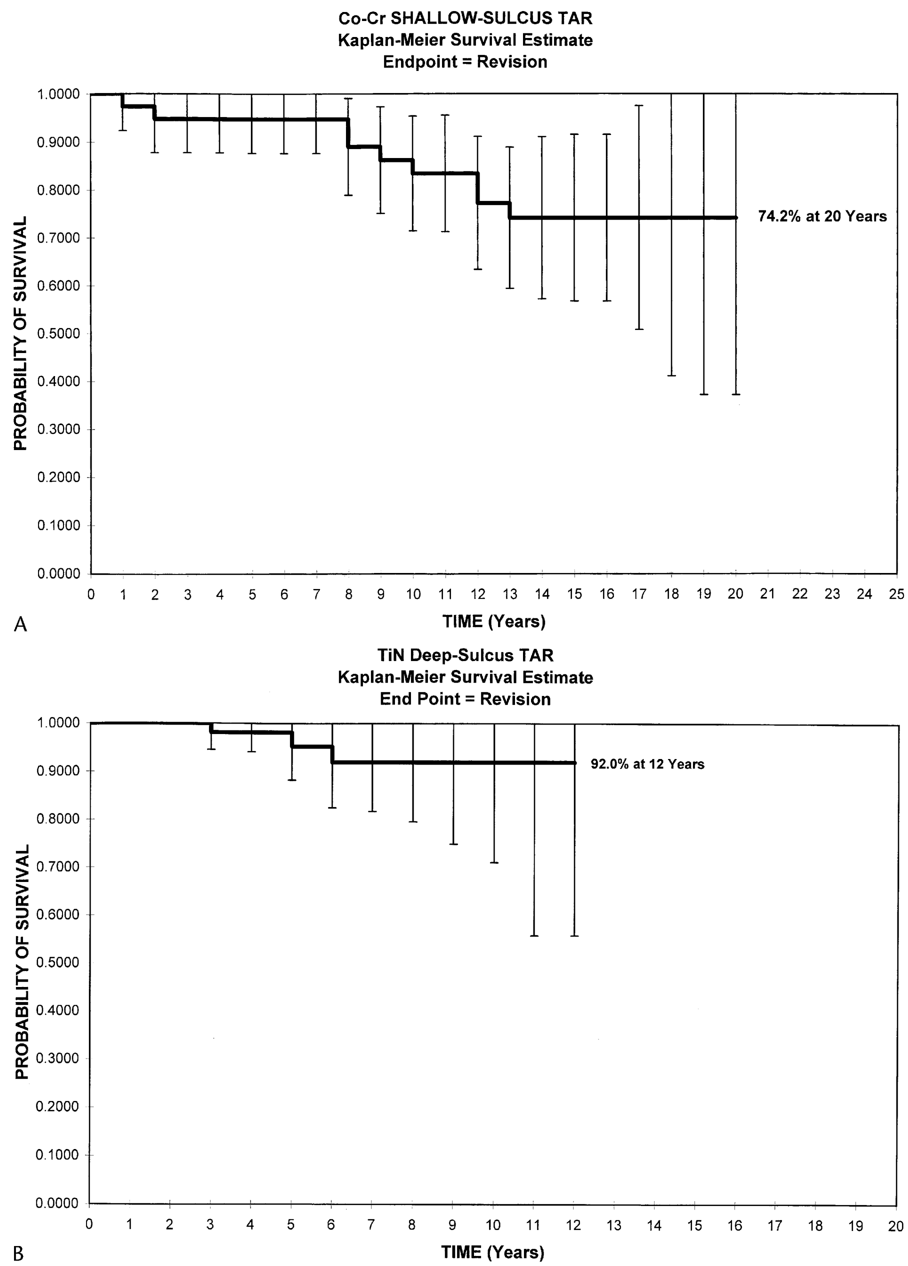

Fig 6A–B. (A) The graphs show the survivorship of the cementless shallow-sulcus meniscal-bearing and (B) the cementless deep-sulcus meniscal-bearing total ankle replacements.

and should be prepared for prolonged wound care and possible plastic surgical intervention if needed.

Considering the current status of ankle fusion and the progressive hindfoot arthritis known to follow,[2,9] cementless, mobile-bearing ankle replacement, with the ability to exchange worn bearings if needed, offers a reasonable alternative in properly selected patients.

Acknowledgments

We thank Mark Buechel, Jerry D'Alessio, and Jared Pappas for technical assistance in the preparation of this paper.

References

1. Bolton-Maggs BG, Sudlow RA, Freeman MAR: Total ankle arthroplasty: A long-term review of the London Hospital experience. J Bone Joint Surg 67B:785–790, 1985.
2. Buchner M, Sabo D: Ankle fusion attributable to posttraumatic arthrosis: A long-term followup of 48 patients. Clin Orthop 406:155–164, 2003.
3. Buechel FF, Buechel Jr FF, Pappas MJ: Eighteen year evaluation of cementless meniscal bearing total ankle replacement. Instr Course Lect 51:143–151, 2002.
4. Buechel FF, Buechel Jr FF, Pappas MJ: Ten year evaluation of cementless Buechel-Pappas meniscal bearing total ankle replacement. Foot Ankle Int 24:462–472, 2003.
5. Buechel FF, Buechel Jr FF, Pappas MJ, D'Alessio J: Twenty-year

evaluation of meniscal and rotating platform knee replacements. Clin Orthop 388:41–50, 2001.
6. Buechel FF, Pappas MJ: New Jersey Low Contact Stress knee replacement system: Ten-year evaluation of meniscal bearings. Orthop Clin North Am 20:147–177, 1989.
7. Buechel FF, Pappas MJ: Survivorship and clinical evaluation of cementless meniscal-bearing total ankle replacements. Semin Arthroplasty 3:43–50, 1992.
8. Buechel FF, Pappas MJ, Makris G: Evaluation of contact stress in metal-backed patellar replacements: A predictor of survivorship. Clin Orthop 273:190–197, 1991.
9. Coester LM, Saltzman CL, Leupold J, Pontarelli W: Long-term results following ankle arthrodesis for post-traumatic arthritis. J Bone Joint Surg 83A:219–228, 2001.
10. Groth HE, Fitch HF: Salvage procedures for complications of total ankle arthroplasty. Clin Orthop 224:245–249, 1987.
11. Hay SM, Smith TW: Total ankle arthroplasty: A long-term review. Foot Ankle 4:1–5, 1994.
12. Hansen ST: Cementless Ankle Arthroplasty in the United States of America: The Alvine Agility Total Ankle Arthroplasty. In Kofoed H (ed). Current Status of Ankle Arthroplasty. New York, Springer 37-40, 1998.
13. Helweg J, Kofoed H: The Fibula Rotates During Motion in the Ankle Joint. In Kofoed H (ed). Current Status of Ankle Arthroplasty. New York, Springer 59-63, 1998.
14. Kaplan E, Meier P: Non-parametric estimation from incomplete observations. J Am Stat Assoc 53:457–481, 1958.
15. Kofoed H: Cylindrical cemented ankle arthroplasty: A prospective series with long-term follow-up. Foot Ankle 16:474–478, 1995.
16. Kofoed H, Sorensen T: Ankle arthroplasty for rheumatoid arthritis and osteoarthritis: Prospective long-term study of cemented replacements. J Bone Joint Surg 80B:328–332, 1998.
17. Komistek RD, Buechel FF, Stiehl JB, et al: A determination of ankle kinematics using fluoroscopy. Foot Ankle Int 21:343–350, 2000.
18. Levi N, Kofoed H: Comparison of Five Different Scoring Systems of Ankle Arthroplasty. In Kofoed H (ed). Current Status of Ankle Arthroplasty. New York, Springer 135–137, 1998.
19. Moran CG, Pinder IM, Lees TA, et al: Survivorship analysis of the uncemented porous coated anatomic knee replacement. J Bone Joint Surg 73A:848–857, 1991.
20. Nelissen RG, Doets HC, Meskers C: The Value of Ankle Prostheses: A Gait Analysis Approach. In Kofoed H (ed). Current Status of Ankle Arthroplasty. New York, Springer 72–77, 1998.
21. Pappas MJ, Buechel FF, DePalma AF: Cylindrical ankle joint replacement. Clin Orthop 118:82–92, 1976.
22. Pappas MJ, Makris GM, Buechel FF: Titanium nitride ceramic film against polyethylene: A 48 million cycle wear test. Clin Orthop 317:64–70, 1995.
23. Pyevich MT, Saltzman CL, Callaghan JJ: Total ankle arthroplasty: A unique design. J Bone Joint Surg 80A:1410–1420, 1998.
24. Rippstein PF: Clinical experiences with three different designs of ankle prostheses. Foot Ankle Clin 7:817–831, 2002.
25. Unger AS, Inglis AE, Mow CS, et al: Total ankle arthroplasty in rheumatoid arthritis: A long-term follow-up study. Foot Ankle 8:173–179, 1988.
26. Wynn AH, Wilde AH: Long-term follow-up of Conaxial (Bech-Stefee) total ankle arthroplasty. Foot Ankle 13:303–306, 1992.