Early Migration of the Tibial Component of the Buechel-Pappas Total Ankle Prosthesis

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Abstract

Interest in mobile-bearing total ankle arthroplasty has increased in recent years. Clinical results show favorable but varying results, with survival rates between 70% and 90% at 10-year follow-up. Design-specific differences in early migration patterns might explain differences in the results and modes of failure. Using radiostereometric analysis (RSA) we prospectively followed 12 RA patients with a cementless mobile-bearing total ankle arthroplasty. The American Orthopaedic Foot and Ankle Society ankle score and radiostereometric radiographs were evaluated immediately postoperatively, 6 weeks postoperatively, 3 months, 6 months, and 12 months postoperatively and yearly thereafter. The postoperative clinical results improved. We observed increased migration of the tibial component during the first 3 months, but this stabilized by the 6-months follow-up. The mean lateral-medial migration was 0.8 mm, distal-proximal migration was 0.9 mm, and posteroanterior migration was -0.5 mm. The latter implies the total resultant migration was in anterior and valgus tilting of this tibial component. We believe the surgical technique (anterior cortical window for placement) and the method of tibial fixation likely explain this migration.

Level of Evidence: Therapeutic study, level IV. See Guidelines for Authors for a complete description of levels of evidence.
5.1 Introduction

The ankle and/or hindfoot is affected in up to 56% of patients with rheumatoid arthritis (RA). In the treatment of debilitated ankle joints, total ankle arthroplasty (TAA) potentially has certain functional advantages compared with ankle arthrodesis in monoarticular and polyarticular disease. Gait is compromised less and adverse effects on the other joints of the lower extremity are not expected with TAA because mobility of the ankle joint is preserved. Because of unsatisfactory results in the past with constrained two-component designs, which had 36 to 90% failure, TAA generally has been considered to be controversial in treating the severely affected ankle joint. Lesser-constrained TAAs using a three-component mobile-bearing prosthesis have distinct mechanical and kinematical advantages compared with two-component designs because there is full congruency of the articulating surfaces without restriction of rotational motion by the prosthesis, thereby reducing the rotational stresses at the bone-prosthesis interface. The latter is reflected in the improved survival rates of a mean of 91% at 5 years in a meta-analysis of this type of design. However, outcomes with these prostheses still lack the excellent long-term results seen consistently with many types of total knee and total hip prostheses. In contrast, the mobile-bearing ankle prosthesis results show some variability (70–95% survival rates).

Clinically symptomatic mechanical loosening is one of the most important modes of failure. Because initial progressive migration relates to long-term prosthesis survival with some implants, the mode of early migration of a prosthesis may predict whether the initial fixation is a factor of concern in a given type of prosthesis. Therefore we began a radiostereometric analysis (RSA) of early migration in mobile-bearing TAA. We focused on the tibial component since in a recently published study from our institution mechanical failure occurred more often with the tibial component than with the talar component.

We sought to ascertain the amount and direction of initial migration of the tibial component after mobile-bearing TAA, and (2) if secondary stabilization occurred within the 1 year interval after surgery.
5.2 Materials and Methods

We prospectively followed fifteen patients (fifteen ankles) having Buechel-Pappas (BP) mobile-bearing TAAs (Endotec, South Orange, NJ) performed from October 2001 to November 2003. This device is our preferred TAA for severely destroyed ankle joints in RA (Larsen Stage 3 and higher\(^{16}\)). Three ankles were classified as Stage 3 (joint space narrowing), nine were classified as Stage 4 (complete loss of joint space), and three were classified as Stage 5 (periarticular bone loss). All patients in this study had RA. There were 12 women and three men with a mean age of 61 years (SD 8.6 years). All ankle prostheses were implanted by an experienced TAA surgeon (RN). No patients were lost to follow-up. The mean follow-up period was 2 years (SD 0.4).

The BP\(^{7,13}\) prosthesis consists of a congruent polyethylene (PE) mobile-bearing matching the curved talar component and the flat tibial and a deep-sulcus talar component, both made of titanium and available in four sizes. The PE insert is available in 3 mm, 5 mm, 7, 9 and 11 mm thicknesses. The tibial component has a central stem, the talar component has two rectangular fins, and the “bone surfaces” of these components are beaded to improve ingrowth (Fig. 1). Initially, one RSA marker was attached with a small dot of bone cement to the tip of the tibial component (7 prostheses). After this initial series the manufacturer provided RSA components with one marker attached to a metal tower at the tip of the central peg of the tibial component in 8 prostheses (Fig. 2).

Fig. 1 A mobile-bearing BP ankle prosthesis (rough beaded bone surface, polished articular surface).
After administration of prophylactic antibiotics, a tourniquet was applied. This was used during the procedure until skin closure (all procedures were finished within 2 hours). Surgery was performed through a straight anterior midline approach with the leg slightly internally rotated on the surgical table. After incision through the skin and the extensor retinaculum, the interval between the anterior tibial and the extensor hallucis tendons was used to reach the anterior capsule, which then was opened medially and reflected laterally as a sleeve together with the dorsal artery to the foot. The preparation of the osseous surfaces was started by a flat resection of the lower surface of the distal tibia with the aid of a resection guide. Our goal was to achieve a horizontal resection of the distal tibia in the frontal plane and an anterior slope of 7° in the sagittal plane, as recommended by the manufacturer. For the stem of the tibial component a window was created in the anterior part of the distal tibia using a special box chisel.

Preparation of the talar dome was performed by making a central groove antero-posteriorly using a round burr, and subsequently reaming of two slots for the fins of the talar component. After finishing the preparation of the talus, a nonce-
mented talar and a noncemented tibial component were implanted. The thickest possible PE liner was then introduced between these components by distracting the joint. After bone grafting around the tibial stem, the removed tibial cortical window was replaced and impacted. During the surgery six 1-mm tantalum markers (MEDIS Medical Imaging Systems, Leiden, The Netherlands) were inserted into the distal tibia. Routine wound closure with careful suturing of the extensor retinaculum was used. We did not lengthen the Achilles tendon in any of the cases. Postoperatively, the ankle was immobilized in a below-knee walking cast for 6 weeks, with weight-bearing allowed as tolerated. The cast was used mainly to protect the sutured extensor retinaculum and promote soft-tissue healing.

Due to logistical problems, replicate examinations for exact accuracy assessment were not made for this study. Therefore, the accuracy of the RSA measurements was extrapolated form an RSA study of a similar sized elbow prosthesis performed at our institution\textsuperscript{17}. As the allowed volume for positioning markers in the distal tibia and distal humerus are comparable, we presumed this is a valid assumption. The accuracy for translations along the transverse, longitudinal, and sagittal axes in the earlier study was 0.13 mm, 0.14 mm and 0.34 mm respectively.

All patients were observed at regular intervals. The patients were evaluated preoperatively, then at 1 week, 6 weeks, 3 months, 6 months and 1 year postoperatively, and at yearly intervals thereafter. We recorded complications and evaluated patients with the American Orthopaedic Foot and Ankle Society (AOFAS) score\textsuperscript{18}. This scoring system allows for evaluation of pain, function, ROM, and deformity based on a 100-point scale. ROM of the ankle-hindfoot complex was measured using a goniometer. Alignment and dorsiflexion were measured while the patient was standing, and plantar flexion, pronation and supination were measured while the patient was sitting.

Conventional anteroposterior (AP) and lateral radiographs were taken immediately after surgery. The angle between the long axis of the tibia and the line perpendicular to the talar surface on the weightbearing AP view of the ankle was defined as the preoperative alignment of the ankle joint. 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 views. The angular position of the talar component on the lateral radiograph was defined as the angle 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. A prosthesis aligned more than 3° off neutral was considered a malaligned prosthesis. The PE bearing was assessed for subluxation and other abnormalities.

The radiostereometric setup consisted of two synchronized roentgen tubes and a uniplanar calibration box (Carbon Box, MEDIS medical imaging systems) (Fig\textsuperscript{[8]}...
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2). The roentgen tubes were at an angle with the vertical of 20°, thus the angle between the tubes was 40°.

The RSA radiographs, with the patients in a supine position, were taken before weightbearing at the fifth postoperative day and thereafter at 6 weeks, 3 months, 12 months and 24 months. The first RSA examination served as the baseline reference. All subsequent evaluations of micromotion were related to the relative position of the prosthesis with respect to the bone markers at that time. Migration of the tibial component was expressed as translatory movements of the marker attached to the proximal tip of the tibial component along the three orthogonal axes: lateral-medial, posterior-anterior, and distal-proximal. Because only one marker was attached to the tibial component, only translatory migration along the three orthogonal axes could be measured. Rotation could not be measured. Because some of the markers in the bone were obscured, only 12 ankle prostheses could be studied using RSA.

Because this was a study on only one type of ankle prosthesis, a t test was used for calculation of 95% confidence limits. We compared the clinical scores from those obtained preoperatively and those obtained 2 years postoperatively. The SPSS software package (version 11.5; SPSS Inc., Chicago, IL) was used for analysis.

### 5.3 Results

Initial tibial component migration was seen mainly during the first 3 months. The mean mode of migration of the tibial component was along the distal-proximal axis after surgery, after which progression decreased between 3 and 6 months postoperatively along all three axes (Table 1 and Fig. 3). The common initial migration mode of this component was into anterior, proximal, and valgus tilting.

The clinical AOFAS score at the last follow-up improved (p = 0.001) from a preoperative mean score of 22 points (SD 9.7) to a mean 80 points at 2 years (SD 8.0). All patients reported they had little or no pain in their ankles at the last follow-up. If pain was present this was markedly reduced as evaluated by the AOFAS score. Nine patients had no pain in the ankle region and six patients had slight pain in the ankle region at follow-up. Comparing the preoperative with the last follow-up values, the ROM of the ankles improved (p = 0.03) from a mean of 2° (SD 5.1°) dorsiflexion to a mean of 7° (SD 4.8°). Plantar flexion did not improve significantly (p = 0.18). According to the subscore of the AOFAS score, the subtalar joint in three patients showed moderate function; in 12 patients this function was severely affected (< 20° pronation or supination).

At the last follow-up, we observed no radiolucencies around the tibial component and no signs of bone resorption around the tibial and talar components. All
but two patients had their prostheses placed within 2° varus or valgus; the mean alignment was 0.8° (SD 3.1°). Fracture of the PE bearing did not occur in any patients, despite the fact that 10 patients (67%) had the thinnest PE bearing (3 mm).

We observed one superficial wound infection in a patient who had immunosuppressive therapy (anti-TNF alpha). The infection resolved with antibiotic therapy and cast immobilization. One year after this infection, no signs of deep (prosthetic) infection were present.

Two patients had spontaneous distal tibia fractures at the proximal part of the cortical window at 2 weeks while in the below-knee plaster. These fractures healed with prolonged immobilization (8 weeks in a cast postoperative instead of 6 weeks). The migration pattern of these two patients was similar to those of the other patients at 3 to 6 months and beyond.

| TABLE 1 Migration of the Tibial Component along Three Orthogonal Axes* |
|--------------------------|------------------|------------------|-----------------|
| Migration (mm)**         | Follow-up        | Lateral-Medial   | Distal-Proximal |
|                         |                  | 0.16 (0.43)      | 0.37 (0.24)     |
|                         | 3 months         | 0.16 (0.52)      | 0.63 (0.43)     |
|                         | 6 months         | 0.53 (0.64)      | 0.69 (0.46)     |
|                         | 1 year           | 0.45 (0.82)      | 0.80 (0.49)     |
|                         | 2 years          | 0.80 (0.58)      | 0.94 (0.26)     |

**Means and standard deviations are shown.

*At the 1-year follow-up n=12; at the 2-year follow-up n=8.

**Fig. 3** Translation of the tibial component of the BP mobile-bearing ankle prosthesis (up to 1 year follow-up n=12; 2-year follow-up n=8). A positive lateral-medial migration indicates valgus tilt, a positive distal-proximal migration indicates upward migration, and a negative posteroanterior migration indicates an anterior tilt of the tibial component.
5.4 Discussion

Although this was a pilot study on a mobile-bearing ankle prosthesis with a central tibial peg fixation, some observations can be made on the migration pattern of this design. The migration of the BP ankle prosthesis showed an initial progressive migration that decreased at 3 months and stabilized at 6 months postoperatively. The main mode of migration of the tibial component was into anterior and valgus tilting during the initial postoperative months, after which the prosthesis stabilized. Failure can be related to prosthetic design factors, position of the prosthesis, and biologic factors. Several studies document a relation of ankle prosthesis design and failure, with revision rates of 30% to 50% for the more constrained and semi-constrained designs. Since the introduction of the nonconstrained mobile-bearing designs, survival rates of total ankle arthroplasty have improved considerably.

Limitations of the study include the use of only one marker (attached to the tip of the tibial component). However, translation measurements along the three orthogonal axes could be assessed accurately. Although the study population was small, and follow-up short, the accurate RSA measurements indicated some trends on prosthesis migration. Another limitation was that only RA patients were studied, who are generally considered a low demand population. On the other hand bone quality is in general more osteoporotic in a rheumatoid population and prosthesis migration might reflect a worst case scenario. Carlsson et al. showed similar migration in TAAs between RA and osteoarthritis. In that study, tibial component fixation was different from that in our study. The design effect on migration is also accentuated by the different first 3–6 months migration pattern of the STAR and the BP prosthesis.

Prosthesis alignment contributes to failure. The importance of alignment and stability of the hindfoot in patients with RA is reflected by a failure rate of 24% at 14-year follow-up examinations in patients with malaligned ankles. The postoperative alignment of the ankle prosthesis in this series was moderate (87% within neutral alignment). The initial prosthesis migration in this series largely will be determined by biologic factors. Malaligned ankles are more likely to migrate at long-term follow-up. Because an initial progressive migration existed for the studied ankles but stabilized after a few months, a dynamic biologic process is likely to be the cause. This has also been observed with knee prostheses; if cementless prostheses stabilize, the bony-prosthesis interlock is likely to last longer than a slowly degrading bone-cement interface. In addition to these biological factors, mechanical factors will influence longevity of prosthesis survival as well.

We observed no osteolysis around the tibial component at this short follow-
Importance of the initial biologic factor is not only related to bone ingrowth into the tibial component, but also to the healing of the tibial cortical window made during surgery to insert the pegged tibial component. Although no loosening occurred during this short follow-up, two patients experienced a fracture of the distal tibia at the level of the proximal part of the cortical tibia window during the plaster weight-bearing period. Both patients were housebound preoperatively due to the incapacitating pain, suggesting osteopenia may have contributed to the fractures in addition to the stress riser of the cortical window.

Authors have shown varying mid-term and long-term results for different mobile-bearing ankle prosthesis designs. The pegged tibial components of the BP prosthesis show tibial loosening in 12% of cases. In contrast, the Scandinavian Total Ankle Replacement, Salto, and Integra ankle prostheses have been shown to have lower loosening rates, although with shorter follow-up in the newer designs. The major differences between these designs are mainly focused on the fixation of the tibial side. The BP design needs a cortical window for insertion, whereas the other designs rely on the subchondral tibial bone without making a cortical window. On the tibial side, the cylindrical peg provides good compression of the metal base plate onto the distal tibial cut surface at impaction, eliminating the need for a tibial window. Being located away from the cut tibial surface, there is no risk of bone weakening during drilling. The high variability of migration of the BP design might be partly reflected in future differences in long-term survival rate. Ryd et al. and Kärrholm et al. showed that high initial migration is related to long-term failure, which implies the tibial fixation and insertion techniques used with the BP prosthesis in the current study might have to be changed in order to improve long-term survival.

Because all patients in the current study had RA and patients with RA generally have more osteoporotic bone, initial prosthesis migration might be higher compared with that seen in patients with osteoarthritis. However, in a small study the authors could not confirm this observation with that particular design. Furthermore, survival rates for ankle prostheses implanted in patients with RA are similar to OA, with an 8-year survival of 82% (95% confidence interval 73% to 93%) in RA patients. Other factors to consider when treating patients with RA are hindfoot problems, which are seen in 60% of patients with ankle joint arthritis. This is either caused by tendon disease of the tibialis posterior, which contributes to the valgus shift of the hindfoot, or a valgus shift of the hindfoot resulting from subtalar and midfoot arthritis. These latter processes will cause more stress on the ankle prosthesis, which might be reflected in the lower implant survival rates in patients with RA. In our series all patients had deteriorated subtalar and midtarsal foot function preoperatively. In three patients the function was moderate and in 12 patients this function was
affected severely (< 20° pronation or supination according to the AOFAS score).

We showed initial migration of this mobile-bearing ankle prosthesis into upward anterior and valgus tilting, which stabilized at 6 months. This pattern was observed in other cementless prostheses as well21. The surgical (anterior cortical window for placement) and tibial fixation techniques may explain this early migration pattern although such pattern might differ with a different design20.

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References


