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Buechel-Pappas Total Ankle Replacement: Use of Highly Cross-Linked Polyethylene Meniscal Bearings over a 13 - 15 Year Interval

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Abstract

Background: The Buechel-Pappas (BP) meniscal bearing total ankle replacement was initially developed as a "shallow-sulcus" talar component device using cobalt-chromium-molybdenum alloy, in 1978, and later, modified to a "deep-sulcus" talar component device using titanium nitride (TiN) ceramic and porous coating in 1989. Wear related osteolytic cysts were noted in the tibia and talus surrounding these devices that compromised long term fixation and stability when using standard ultra-high molecular weight polyethylene (UHMWPe) as a bearing material. This study explores the use of highly cross-linked UHMWPe (HXLPe) to minimize osteolysis by replacing standard UHMWPe with this more wear-resistant material. **Methods:** There were 12 primary and 8 revision total ankle replacements followed for 13 to 15 years. HXLPe was used in all meniscal bearings, either as primary or revision implants. All stable metallic tibial and talar components were retained in revision cases. Osteolytic cysts greater than 10 mm in diameter were bone grafted with homologous morselized banked bone through cortical windows in the tibia or talus. No adjuvant screw fixation was used to stabilize any metallic implant. **Results:** No HXLPe bearings failed in this study, and no re-revisions were performed. No primary total ankle replacement failed in this study, and there were no substantial osteolytic cysts (>2 mm) observed in primary total ankle replacements on plain X-rays. All bone grafted osteolytic cysts in revision ankle replacements remained stable, even though partial resorption of the grafted material was identified in most of the ankles. No loosening of porous coated and TiN coated tibial and talar components were seen; the longest surviving metal components in the revision group was 24 years with the revised bearing at 15 years. **Conclusions:** HXLPe has greatly improved wear resistance in meniscal-bearing BP total ankle replacements in

both primary and revision arthroplasties. Osteolytic cysts can be successfully bone grafted during bearing exchange revisions. Primary and revision, cementless BP metallic total ankle components have remained well-fixed to bone in the long term (greater than 20 years), without the use of adjuvant screw fixation.

Keywords

Cementless Total Ankle Replacement, Meniscal Ankle Replacement, Osteolysis, Bone Graft of Cysts

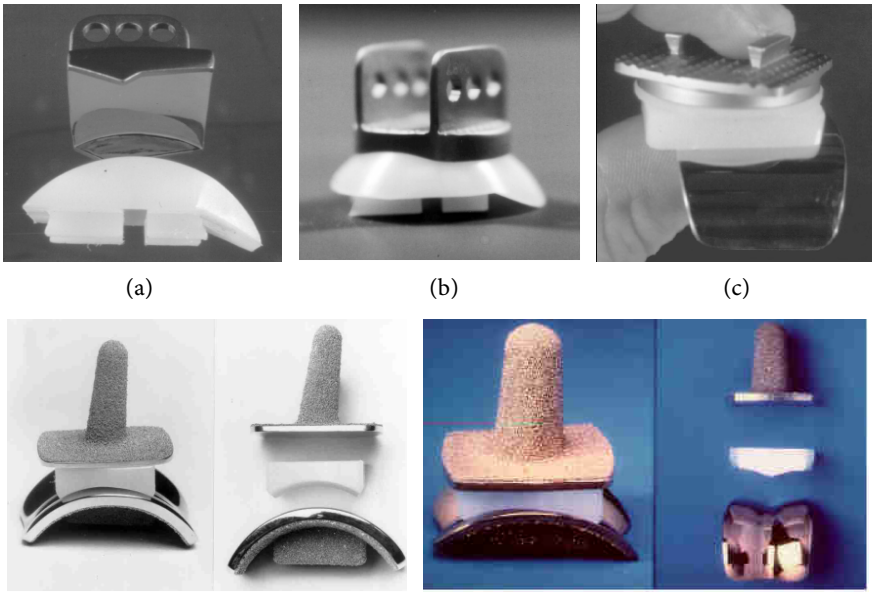
1. Introduction

Total ankle replacement has evolved significantly from the early constrained cylindrical devices [1] and unconstrained spherical devices, [2] to the trunion-cylindrical [3] and sliding-cylindrical devices [4] currently available in various embodiments [5] [6] [7] [8]. The sliding cylindrical (3-piece) devices have the best opportunity to reproduce normal ankle kinematics [9] (see **Figure 1(d)** and **Figure 1(e)**), but have failed in the coronal plane when varus-valgus stresses are not considered, such as seen in the STAR total ankle [10] (see **Figure 2(a)**).

In the case of total ankles that have a talar component with a cylindrical lateral shape and a flat upper surface in the antero-posterior plane, varus-valgus loading causes an "edge loading" effect, which increases contact stresses in the polyethylene beyond the acceptable load limit of approximately 20 mega Pascals (MPa) [11]. This overload phenomenon can result in premature wear, cracking and fracture across the bearing surface with subsequent failure of the device [3]. HXLPe bearing material improves abrasive wear properties but is more susceptible to fatigue failure and fracture when used in incongruent contact devices that have point or line contact [3]. This means that congruent surface geometry, such as spherical contact, while eliminating point or line contact is a significant design principle for ensuring longevity of the bearing surface.

In devices that are designed to eliminate point or line contact, the use of HXLPe minimizes abrasive wear over regular UHMWPe [12] [13], which inhibits excessive wear particles from causing osteolytic bone cysts, a significant cause of premature failure of total ankle replacements.

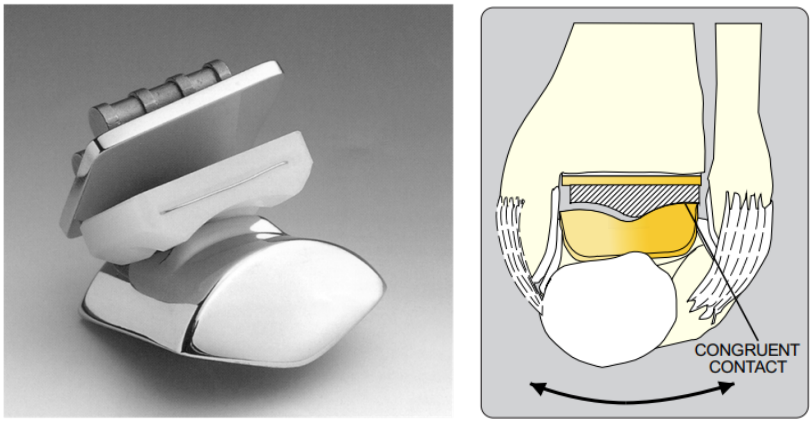
Since 1989, the B-P Total Ankle has fulfilled the kinematic requirements of a successful device [4] [9] and has enjoyed world-wide success [14] [15] [16]. The biomechanical and engineering principles of this device have stood the test of time in the hands of multiple orthopaedic surgeons, but because of a reactionary Food and Drug Administration (FDA) in the United States it has become unavailable since 2009, after an appeal by the FDA overturned a primary judge's favorable trial decision to continue its use [17]. The FDA continues to ignore the overwhelming scientific data on mobile bearing devices and requires multi-million dollar clinical trials on devices that have been successful for many decades.



(a) (b) (c)

(d) (e)

Figure 1. Development history of the B-P Meniscal Bearing Ankle replacement (MBA) [3] [10]. (a) NJ Cylindrical 1974; (b) NJ spherical 1975; (c) Trunion cylindrical 1976; (d) LCS sliding cylindrical MBA 1978, Shallow Sulcus; (e) BP Sliding cylindrical MBA 1989, Deep Sulcus.



(a) (b)

Figure 2. (a) Edge contact during inversion and eversion seen in non-condylar talar components; (b) Spherical Area Contact seen in B-P total ankle during inversion and eversion.

Multiple studies have demonstrated the long term beneficial effects of the BP total ankle in terms of fixation stability and kinematic equivalency for normal ankle function [4] [15] [16] [18] [19] [20] [21]. The major problem in well-designed sliding cylindrical ankle replacements, discovered after 5 to 10 years of active use, has been wear-debris osteolysis of the tibia and talus [10] [22]. The osteolytic lesions would gradually progress over time to threaten the fixation of the tibial and talar components, thus requiring consideration for revision or ankle fusion.

In an attempt to maintain ankle function and avoid a hind-foot fusion, it was postulated that the success seen in total hip replacement bearings made of HXLPe [12] [13] would translate into improved wear resistance in total ankle mobile bearings. This paper presents the earliest work in ankle replacement surgery to document the improvement seen in wear resistance for this type of arthroplasty.

2. Materials and Methods

There were 10 females, age 55 to 69 (mean 60) and 10 males, age 40 to 59 (mean 50) in the study. Diagnoses of patients were post-traumatic arthritis or osteoarthritis, with intractable pain, that was uncontrolled by medications or footwear changes. No inflammatory arthritis patients were involved. All patients had undergone a cementless BP total ankle replacement using a previously published technique [23] that removes an anterior tibial bone window for insertion of a short-stemmed tibial component and a sculpted talus to allow insertion of a deep-sulcus, bicondylar talar component without the use of adjuvant screw fixation.

Osteolytic cysts of greater than 10 mm in diameter, in the tibia and/or talus of 7 revision ankles, were routinely bone grafted with cancellous homologous banked bone, using a bone window approach. All metallic tibial and talar components were physically inspected for loosening during the bone grafting procedure. Routine short leg cast immobilization and wound care was performed allowing weight bearing to tolerance on the first post-operative day for a total of 6 weeks. Delayed wound healing was treated with honey dressings until full healing occurred in all patients. Survivorship analysis [24] was employed, even though the sample population was small.

3. Results

No HXLPe bearings failed in this study, and no re-revisions were performed. All bone grafted osteolytic cysts remained stable, even though partial resorption of the grafted material was identified in most of the ankles. No primary total ankle replacements failed in this study and there were no progressive ostolytic cysts (>2 mm) observed on plain X-rays. No loosening of the porous coated and TiN coated tibial and talar components were seen. The longest surviving metal components in the revision group was 24 years, with the revised bearing at 15 years. This patient's ankle score was 100/100 points (excellent) using a modified knee scoring scale [25], and she remained "thrilled" with her ankle arthroplasty, see **Figure 3**.

Survivorship, in this small cohort of patients, was 100% at the 12 to 15 year intervals.

4. Discussion

Long term follow-up in primary total ankle replacement is unusual beyond

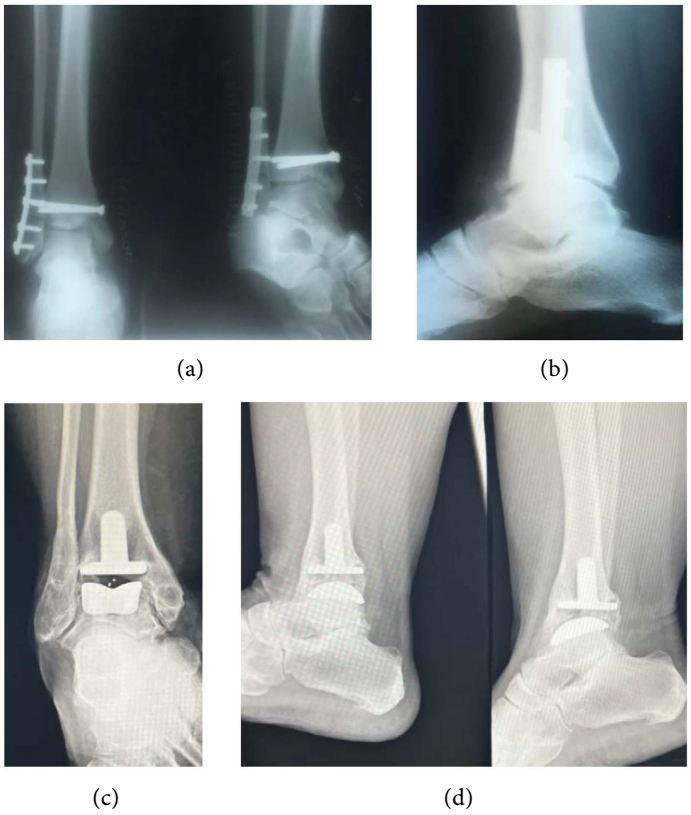


Figure 3. Pre-operative and Post-operative X-rays of a 42 year old female patient with Post-traumatic arthritis of the Right Ankle and Retained Hardware. (a) Pre-Operative, Anterior-posterior (AP) X-rays; (b) Pre-Operative Lateral, X-ray of the same patient; (c) Post Operative, A/P X-ray of the same patient in A & B, Metals: 24 Years, Bearing: 15 Years; (d) Post-Operative Lateral, X-rays of the same patient in A & B, Metals: 24 Years, Bearing: 15 Years.

10 years, let alone revision total ankle replacement. The current study is a culmination of more than 45 years of ankle replacement development, evaluation, modification and reporting on clinical success and failure of this difficult arthroplasty. Several three-piece meniscal bearing devices have been developed since our earliest mobile bearing designs in 1977 [5] [7]. All of them share the important qualities of minimizing constraint, while allowing for reasonable ankle kinematics.

The most important and subtle design principle is to maintain surface congruity throughout the unrestricted range of motion, without allowing point or line contact that could compromise the long term integrity of the bearing surface by exceeding the contact stress limit of the bearing material (~20 MPa) [11].

Failure to observe this principle has led to premature failure in designs such as the STAR ankle, which developed surface fatigue fractures and bearing failure in the short term (less than 10 years) [26]. Conversely, there have been no structural failures, other than mild abrasive wear, in the BP ankle meniscal bearings in either standard UHMWPe, followed for greater than 30 years, or HXLPe followed for over 15 years.

5. Conclusion

HXLPe has greatly improved abrasive wear resistance in meniscal-bearing BP total ankle replacements in both primary and revision arthroplasties with no failures seen in patients followed for 13 to 15 years. Large osteolytic cysts (≥10 mm) seen in the tibia and talus were successfully bone grafted during bearing exchange revisions. Primary ankle replacements did not develop significant osteolytic cysts greater than 2 mm. Primary and revision cementless BP total ankle components remained well-fixed to bone in the long term (greater than 30 years) without the need for screw augmentation.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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