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Evaluating Component Migration: Comparing Two Generations of the INBONE® Total Ankle Replacement

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A R T I C L E I N F O

Level of Clinical Evidence: 3

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A B S T R A C T

Although total ankle replacement (TAR) designs have radically evolved, the compressive forces at the ankle can cause aseptic loosening, talar subsidence, and implant failure. The purpose of the present report was to compare the implant migration associated with the INBONE® I, a TAR system with a stemmed talar component, and the newer generation INBONE® II, a TAR system without a stemmed talar component (Wright Medical Technology, Inc., Arlington, TN). Because core decompression could weaken the integrity of the talus, we hypothesized that the stemmed component would result in greater implant migration. A total of 35 consecutive patients (age 58.2 ± 12.1 years; 23 men) were included. Of these 35 patients, 20 (57.1%) had been treated with the INBONE® I and 15 (42.9%) with the INBONE® II. To assess implant migration, using anteroposterior radiographs, the distance from the apex of the tibial component to the most distal aspect of the talar stem or to the mid-saddle of the nonstemmed component was measured. The measurements were recorded from the immediate postoperative radiographs and the 12-month postoperative radiographs. Implant migration was quantified as the difference between the 12-month and the immediate postoperative measurements. Despite our hypothesis, no significant difference was found in implant migration between the INBONE® I (0.7 ± 1.2 mm) and INBONE® II (0.6 ± 1.3 mm, $p = .981$). However, previously published data have suggested that implant migration can continue for ≥2 years after surgery. Therefore, additional investigations with larger sample sizes and longer follow-up periods are needed to draw definitive conclusions.

In the 1970s, total ankle replacements (TARs) were introduced as an alternative to arthrodesis. Although the short-term results were encouraging, subsequent reviews revealed unacceptable failure rates, and the use of TARs was largely abandoned (1–5). Learning from the areas of faulty implant design, TARs underwent continual modification and, over time, the mid- to long-term survivorship improved (6).

As TARs become more widely accepted, the implant designs must be continually evaluated and improved. To best accomplish this goal, the factors contributing to premature implant failure must be identified, quantified, and compared across TAR systems.

Through the evolution and investigation of TAR systems, implant migration has emerged as a primary indicator of premature implant failure (7–10). Kärrholm et al (10) defined implant migration as "the longitudinal movement of an implant with respect to the bone in which it is imbedded over time." Although investigators have recognized the need to better understand and quantify implant migration at the ankle, only preliminary reports have surfaced (11–15). It remains unclear whether specific implant designs are more prone to implant migration than other implant designs.

Investigating the implant migration associated with various ankle implant designs could assist in filtering out inferior designs. Therefore, the purpose of the present study was to compare implant migration between the INBONE® I, a modular stemmed fixed-bearing TAR with a stemmed talar component, and the INBONE® II, a modular stemmed fixed-bearing TAR without a stemmed talar component (Wright Medical Technology, Inc., Arlington, TN). We theorized that

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Conflict of Interest: Stephen A. Brigido serves on the surgery advisory board for Alliqua and Bacterin International, and serves as a consultant for Stryker. Alliqua, Bacterin International, and Stryker had no knowledge of or influence on the study design, protocol, or data collection.

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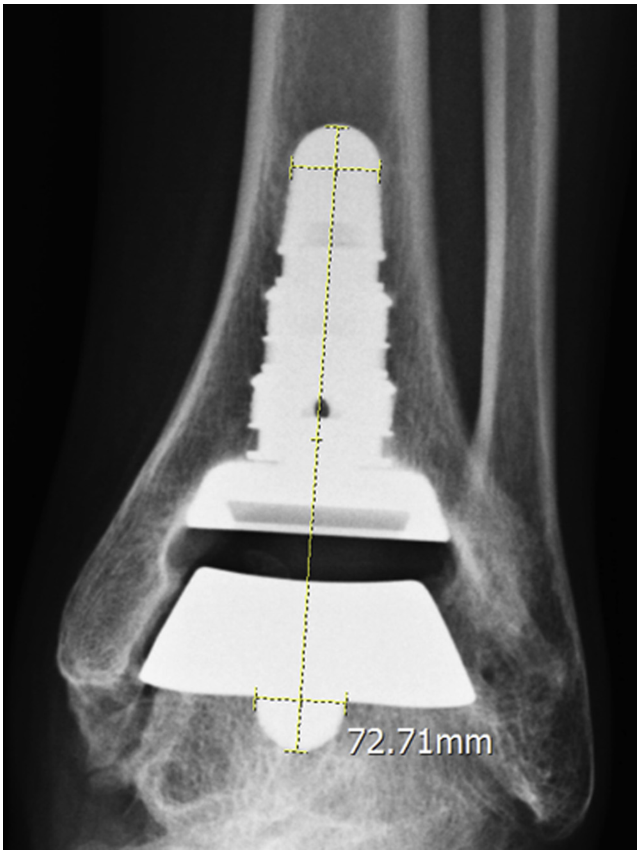

Fig. 1. Implant migration measurements for the stemmed component. Using anteroposterior radiographs, measurements were taken from the apex of the tibial component to the most distal aspect of the talar stem.

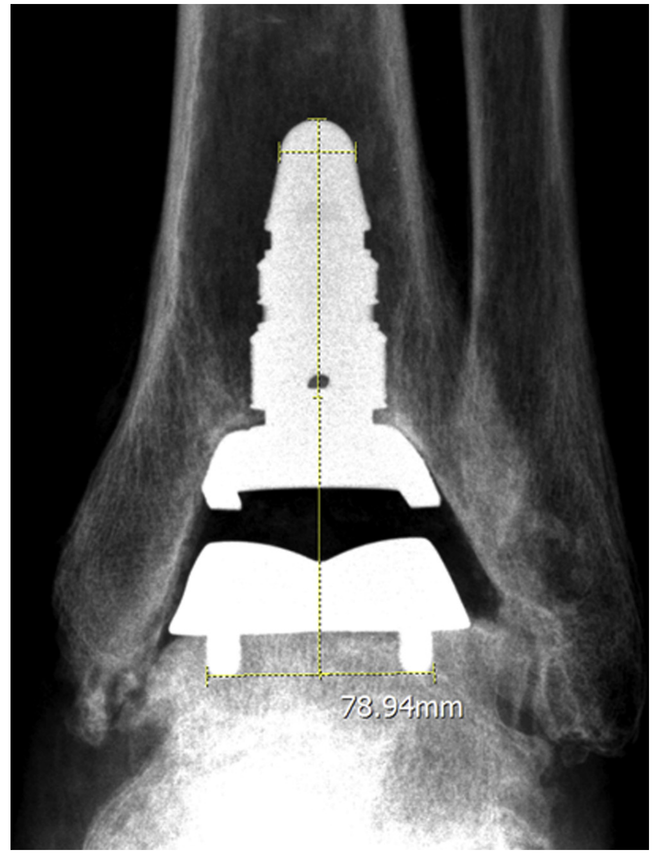

Fig. 2. Implant migration measurements for the nonstemmed component. Using anteroposterior radiographs, measurements were taken from the apex of the tibial component to the mid-saddle of the nonstemmed talar component.

core decompression could weaken the integrity of the talus and hypothesized that the stemmed component would result in greater implant migration.

Patients and Methods

Aims

The primary aim of the present study was to compare implant migration between the INBONE® I TAR system (stemmed) and the INBONE® II TAR system (nonstemmed). We also compared the component alignment between the 2 TAR systems. Our final aim was to assess the relationship between the distal tibial angles and implant migration.

Assessors

The senior author (S.A.B.) performed all TARs. The contributory patient demographic and comorbidity data were recorded by 2 of us (M.M.G., G.M.W.). These consisted of patient age (in years), body mass index (BMI) (kg/m^2), gender (male, female), operative side (left, right), smoking status, and the presence of coronary artery disease, diabetes mellitus, gout, hypercholesterolemia, hypertension, hypothyroidism, esophageal reflux disease, obesity (defined as a BMI of $\geq$ 30 kg/m^2), and skin cancer. The type of arthritis was also recorded from the medical records (post-traumatic, primary, or rheumatoid). The concomitant procedures were recorded from the operative reports. Statistical analyses were performed by 1 of us (N.M.P.), who also serves as a research associate at our institution.

Study Population

The inclusion criteria were age (>18 years), a diagnosis of end-stage ankle arthritis, conservative treatment exhaustion, surgical intervention with either the INBONE® I TAR or INBONE® II TAR, an immediate postoperative radiograph available, and $\geq$12 months of radiographic follow-up. All patients underwent surgery by the senior author (S.A.B.) at 1 of 2 facilities from May 1, 2008 to November 31, 2012. The institutional review board approved the protocol and waived the informed consent requirement. Data were recorded in a password-protected, secure database. The confidentiality and privacy of the patients was ensured and maintained.

Endpoints

The primary outcome was implant migration. It was quantified as the difference between the 12-month and the immediate postoperative measurements. All measurements were made from radiographs with the patient in a supine, unloaded position. The methods were consistent with those previously reported by Wobst et al (11). Using anteroposterior radiographs, the distance from the apex of the tibial component to the most distal aspect at the center of the talar stem (Fig. 1) or to the mid-saddle of the nonstemmed component (Fig. 2) was measured. As previously described, 2 of us (N.M.P., G.M.W.) performed all measurements (11). These measurements were averaged for each patient at each follow-up point (11).

One of us (G.M.W.) evaluated component alignment, according to previously described protocols (16–19). Using the definitions introduced by Paley (18), the anterior distal tibial angle (aDTA) and the lateral distal tibial angle (lDTA) were measured. The aDTA was defined as the angle between the anatomic axis of the tibia and the articular surface of the tibial component. The lDTA was defined as the angle between the anatomic axis of the tibia and the articular surface of the tibial component. Ninety degrees was considered normal. Misalignment was defined as implant deviation $>5°$ from normal (16). Given the fixed-bearing design of these 2 implants, talar positioning was not assessed.

Statistical Analysis

All statistical analyses were conducted using IBM® SPSS® Statistics software, version 20 (IBM Corporation, Armonk, NY). The data were tested for normality, and an approximately normal distribution was confirmed. Statistical analyses were performed to compare implant migration with the INBONE® I TAR system and the INBONE® II TAR system. The significance level for all statistical tests was set at $p = .05$. The data are reported as the mean $\pm$ standard deviation.

Independent samples t tests were conducted to compare the mean age, gender, BMI, aDTA, and lDTA between the 2 implant groups. The chi-square test was used to compare the number of males and females, operative side, arthritis type, and the total