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

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

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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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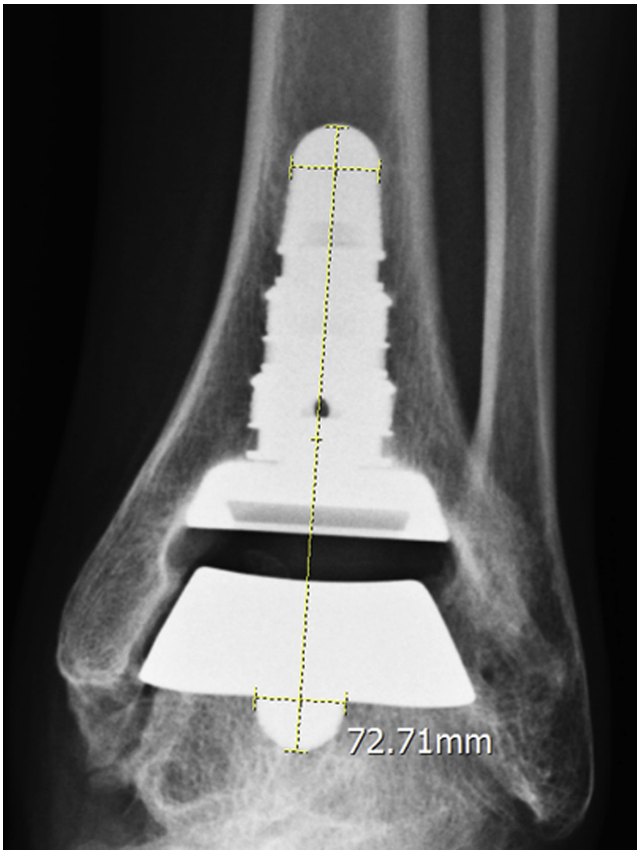

Fig. 1. Implant migration measurements for the stemmed component. Using anteroposterior radiographs, measurements were taken from the apex of the tibial component to the most distal aspect of the talar stem.

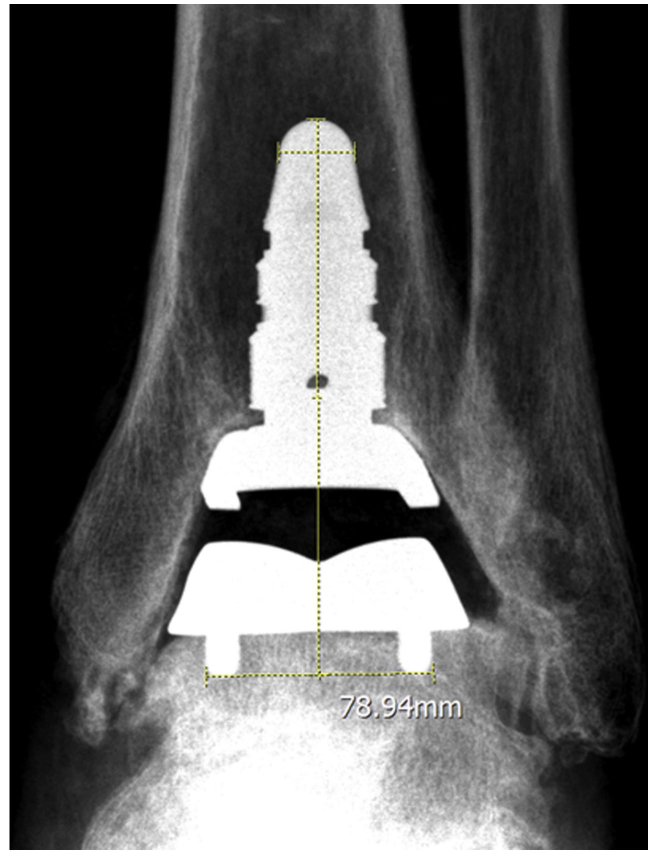

Fig. 2. Implant migration measurements for the nonstemmed component. Using anteroposterior radiographs, measurements were taken from the apex of the tibial component to the mid-saddle of the nonstemmed talar component.

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 $>5^\circ$ 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

Table 1
Patient demographic data

Demographic	All Ankles (N = 35)	INBONE® I (n = 20)	INBONE® II (n = 15)
Age (y)	58.2 ± 12.1	59.3 ± 12.2	56.7 ± 12.1
BMI (kg/m^2)	31.6 ± 6.7	31.1 ± 7.3	32.8 ± 5.8
Gender			
Female	12 (34.3)	6 (30.0)	6 (40.0)
Male	23 (65.7)	14 (70.0)	9 (60.0)
Operative side			
Left	16 (45.7)	10 (50.0)	6 (40.0)
Right	19 (54.3)	10 (50.0)	9 (60.0)

Abbreviation: BMI, body mass index.
Data presented as mean ± standard deviation or n (%).

number of comorbidities between the 2 implant groups. Fisher's exact test was used to compare the number of misalignments between the 2 implant groups. To test our primary hypothesis, a stepwise, linear regression analysis was conducted to examine the contribution of each independent variable to the dependent variable (implant migration). The independent variables initially entered into the regression model included implant group (INBONE® I, INBONE® II), age, arthritis type (post-traumatic, primary, rheumatoid), BMI, gender, hypertension, hypercholesterolemia, diabetes mellitus, aDTA, lDTA, and the deviation from neutral for the aDTA and lDTA. Coronary artery disease, gout, hypothyroidism, and smoking status were excluded as independent variables because of the small sample size within each category (n ≤ 3). The performance of the predictor variable is reported as the squared multiple-correlation coefficient (R^2). Pearson's product moment correlation was conducted to measure the strength and direction of the association between implant migration and the distal tibial angle (aDTA and lDTA).

Results

Patient Population

A total of 35 patients (age 58.2 ± 12.1 years) met the inclusion and exclusion criteria and were included in the present study (Table 1). Of the 35 patients, 20 (57.1%) were in the INBONE® I group and 15 (42.9%) in the INBONE® II group. The 2 implant groups did not differ by age [t(33) = 0.632, p = .532], BMI [−t(33) = −0.448, p = .657], gender (chi-square = 0.066, p = .797), or operative side (chi-square = 0.060, p = .807). Furthermore, the number of patients with each type of arthritis (primary, post-traumatic, rheumatoid) was similar between the 2 groups (chi-square = 2.288, p = .319; Table 2), and the total number of comorbid conditions was similar between the 2 groups (chi-square = 0.542, p = .461; Table 3). The procedures performed concomitantly with the TAR included Achilles tendon lengthening (16 [45.7%]), removal of painful retained hardware (4 [11.4%]), endoscopic gastrocnemius recession (3 [8.6%]), posterior capsule release (2 [5.7%]), and deltoid peel (1 [2.9%]).

Implant Migration

A stepwise linear regression analysis was conducted to predict implant migration. The significant predictor of implant migration (R^2 = 0.11, p = .049) was gender (r = 0.34; Fig. 3). The positive part correlation between implant migration and gender indicated that implant migration was greater in males (1.0 ± 1.2 mm) than in females

Table 2
Arthritis type

Arthritis type	All Ankles (N = 35)	INBONE® I (n = 20)	INBONE® II (n = 15)
Post-traumatic	18 (51.4)	11 (55.0)	7 (46.7)
Primary	15 (42.9)	7 (35.0)	8 (53.3)
Rheumatoid	2 (5.7)	2 (10.0)	

Data presented as n (%).

Table 3
Patient comorbidities

Comorbidities	All Ankles (N = 35)	INBONE® I (n = 20)	INBONE® II (n = 15)
Coronary artery disease	3 (8.6)	2 (10.0)	1 (6.7)
Diabetes mellitus	4 (11.4)	2 (10.0)	2 (13.3)
Gout	1 (2.9)	1 (5.0)	
Hypercholesterolemia	10 (28.6)	5 (25.0)	5 (33.3)
Hypertension	15 (42.9)	9 (45.0)	6 (40.0)
Hypothyroidism	2 (5.7)	1 (5.0)	1 (6.7)
Esophageal reflux disease	2 (5.7)	1 (5.0)	1 (6.7)
Obesity (BMI ≥30 kg/m^2)	18 (51.4)	9 (45.0)	9 (60.0)
Skin cancer	1 (2.9)		1 (6.7)
Smoker	3 (8.6)	2 (10.0)	1 (6.7)
Total	59 (100.0)	32 (54.2)	27 (45.8)

Abbreviation: BMI, body mass index.
Data presented as n (%).

(0.1 ± 1.2 mm). Controlling for the other variables, implant type (INBONE® I, INBONE® II) did not emerge as a significant predictor of implant migration, indicating that no significant difference was present in implant migration between the INBONE® I (0.7 ± 1.2 mm) and INBONE® II (0.6 ± 1.3 mm) groups (p = .981).

Component Alignment

Implant placement was also evaluated in terms of the aDTA and lDTA (Table 4). The aDTA was significantly greater for the INBONE® I group (90.3° ± 2.1°) than for the INBONE® II group (87.7°± 3.3°, p = .008). However, the lDTA was similar for the 2 groups (p = .076). The deviation from 90° for the aDTA and lDTA was also similar for the 2 groups (p = .167 and p = .483, respectively). However, significantly more misalignments were found in the INBONE® II group (4 [26.7%]) than in the INBONE® I group (0; p = .026). Neither the aDTA (p = .879) nor the lDTA (p = .829) correlated significantly with implant migration.

Discussion

The ankle remains one of the most challenging total joint arthroplasties. Intraoperatively, the technical demands are extensive, and after implantation, the compressive forces are extreme and the surface area for prosthetic support is small. Therefore, the tremendous stress on the underlying cancellous bone can result in settling of the prosthesis (7–10). To simplify implantation, replicate normal ankle anatomy and kinematics, and reduce complications, TAR systems are

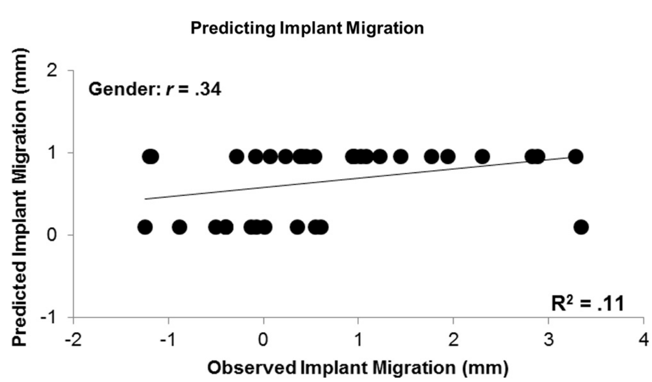

Fig. 3. Predicting implant migration. In our patient population (N = 35), implant migration was best predicted by gender. Males were coded as 1 and females as 0. The equation that best predicted implant migration was 0.102 + (0.853 × gender).

Table 4
Component misalignment

Variable	All Ankles (N = 35)	INBONE® I (n = 20)	INBONE® II (n = 15)
Anterior distal tibial angle (°)	89.2 ± 2.9	90.3 ± 2.1	87.7 ± 3.3*
Deviation from neutral (°)	2.1 ± 2.1	1.7 ± 1.2	2.8 ± 2.9
Misalignment	2 (5.7)		2 (13.3)
Lateral distal tibial angle (°)	90.5 ± 2.9	89.8 ± 2.2	91.6 ± 3.5
Deviation from neutral (°)	2.0 ± 2.2	1.8 ± 1.3	2.4 ± 3.0
Misalignment	2 (5.7)		2 (13.3)
Misalignment total	4 (11.4)		4 (26.7)*

Data presented as mean ± standard deviation or n (%).
Four patients in the nonstemmed group were classified as misaligned; misalignment was defined as a deviation >5° from normal (90°).
* $p \leq .05$, compared across the INBONE® I and INBONE® II groups.

continually being revised. Recently, design changes were made to the INBONE® I TAR system, producing the newer generation, INBONE® II TAR system.

In a comparison of the INBONE® I and INBONE® II, Scott et al (20) highlighted the key design features of the 2 implants. As noted in the present report, a primary differentiating characteristic is the talar stem. The newer INBONE® II system includes 2 pegs with an optional central stem, in contrast to the single stem of the INBONE® I system. The 2 points of fixation are presumed to increase axial stability (20). Additionally, the initial talar saddle design was exchanged for a sulcus design to increase coronal plane stability (20). Finally, the tibial base plate was elongated to increase coverage in the anteroposterior plane without requiring additional mediolateral resection (20). With the increased surface area, the load will be more evenly distributed throughout the tibial plafond (20). Although the implant has evolved, several characteristics of the INBONE® I were preserved. For example, both systems use modular tibial stem components. This modularity allows for a larger tibial stem to be built within the existing osseous framework without the associated bony resection. The longer stem also distributes the forces throughout the tibial shaft and decreases the shear forces at the bone–implant interface. Both implants are equipped with an intramedullary guide, which has been shown to aid in accurate implantation with reproducible results (21). Finally, the 2 systems allow for the preservation of the medial and lateral malleolus, which provides additional stability for the tibial base plate.

Given the recent changes in prosthetic design, the purpose of the present report was to compare implant migration between the INBONE® I and INBONE® II in the short term. Despite our hypothesis, at 12 months postoperatively, the stemmed and nonstemmed implant groups demonstrated similar implant migration. However, research indicates that ankle implant migration can continue for ≥2 years after surgery (11,12). Therefore, we plan to undertake additional studies to determine whether the INBONE® I and INBONE® II TAR systems continue to demonstrate similar implant migration at longer follow-up intervals.

Adhering to previous findings (11), the present study also found that implant migration was greater in males than in females. This discrepancy between genders has been theorized to arise from the greater compressive forces at the ankle and larger anatomy in males, resulting in greater implant migration (11). Given these findings and presumptions, future research is needed to determine whether implant migration thresholds should differ for males and females to best predict later implant failure.

Just as with any retrospective study, the present study had a number of limitations that could threaten the validity of our conclusions. For example, we were responsible for the data collection and measurements, increasing the potential for bias. Additionally, our patient population was restricted to a small sample size (N = 35). Also, non-weightbearing films were used, although the reliability of these measurement techniques has been previously validated with excellent results (11). Despite these limitations, we believe the results of the present investigation are a valuable addition to the published data.

This is the first study of its kind to compare implant migration between 2 generations of an implant. Although the INBONE® I and INBONE® II TAR systems demonstrated similar implant migration at 12 months after implantation, a longer follow-up period is needed to determine whether the design alterations will deter additional implant migration. Presumably, more appreciable differences will be present in implant migration across the TAR systems with marked differences in design instead of generational modifications. We hope the present report will encourage future implant migration comparison studies to filter out the inferior TAR designs and reduce implant failure.

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