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Perioperative Complications of a Modular Stem Fixed-bearing Total Ankle Replacement with Intramedullary Guidance

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ABSTRACT

Despite improved total ankle replacement outcomes, investigators have demonstrated that the incidence of complications after total ankle replacement is a function of the surgeon's experience with the technique. We hypothesized that the use of an intramedullary guide during a modular stem fixed-bearing total ankle replacement would decrease the incidence of perioperative complications and produce a similar incidence of complications across time. Because all patients were mobilized early, we also evaluated the influence of early mobilization on wound development. The medical records were reviewed to identify complications, and the radiographs were evaluated to determine the component alignment of the initial 58 consecutive ankles. Major wound complications were defined as complications requiring soft tissue coverage by a plastic surgeon. Minor wound complications were defined as those that could be treated without a return to the operating room. The procedures were separated into 2 groups: the initial 29 procedures (group A) and latter 29 procedures (group B). Eight ankles (14%) had wound complications. The incidence of complications was similar across time [r_s (56) = −0.06, p = .64]. The incidence of complications and component misalignment was similar for groups A and B ($p \geq .19$). All wounds were diagnosed within 15 days of surgery. None of the ankles developed wounds after physical therapy began. These results have demonstrated that the modular stem fixed-bearing total ankle replacement with intramedullary guidance can produce a similar incidence of complications over time, regardless of surgeon experience. Additionally, early mobilization did not appear to influence the incidence of wound complications and should be advocated, when appropriate.

The evolution of implant design has improved the mid- to long-term success of total ankle replacements (TARs) (1). However, it has been consistently shown that the incidence of complications is greater while surgeons are mastering the techniques (2,3). Purportedly, the perioperative complications are a consequence of the technical demands of TAR that, once practiced, can be significantly reduced (4). Although newer prosthetic designs have shown promise, it is well recognized that surgical innovations capable of reducing the high rate of complications during initial arthroplasties are required.

The INBONE® Total Ankle Replacement (Wright Medical Technology, Inc., Arlington, TN; Fig. 1) uses an intramedullary guide to assist with consistent implant placement. This is the first modular stem fixed-bearing TAR with intramedullary alignment instrumentation. It is unclear whether the INBONE® Total Ankle Replacement with intramedullary guidance will reduce the incidence of complications shown to occur when surgeons are performing their initial TARs. To our knowledge, this has not been previously described.

The purpose of the present study was to review the clinical outcomes and report the perioperative complications of the initial 58 consecutive ankles that underwent modular stem fixed-bearing TAR with intramedullary guidance. Given the proven accuracy of intramedullary guides (5), we hypothesized that TAR with intramedullary alignment would decrease the incidence of perioperative complications, including intraoperative fractures, tendon lacerations, and implant misalignment. The present study also evaluated whether the use of an intramedullary guide would produce an equivalent rate of complications across time, which would refute the current idea that TARs are associated with a notable learning curve (2,3).

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Conflict of Interest: Dr. Brigido is a consultant for Wright Medical Technology; in the present study, Dr. Brigido performed the operative procedures and assisted with data collection. For the remaining authors: none reported.

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Fig. 1. View of prosthesis on anteroposterior postoperative radiographic image depicting modular stem fixed-bearing ankle implant (INBONE®).

Patients and Methods

Aims

The primary aim of the present study was to report the overall incidence of perioperative complications and then determine whether the use of a modular stem fixed-bearing ankle implant with intramedullary guidance produced an equivalent rate of complications across time, refuting the current idea of a notable learning curve (4). A secondary aim was to compare our results with those previously published to determine whether the modular stem fixed-bearing ankle implant with intramedullary guidance reduced the incidence of complications. Because all patients were mobilized early, we subsequently evaluated the influence of early mobilization on wound development.

The data were retrospectively collected by 2 investigators (S.A.B., S.T.B.). Statistical analyses were performed by the research associate (N.M.P.) at our institution. The Western Institutional Review Board approved the study protocol and waived the requirement for informed consent. According to the Western Institutional Review Board Regulatory Affairs Department, this research project met the conditions for exemption under 45 CFR 46.101(bX4).

Study Population

The charts were reviewed for first 58 consecutive ankles that underwent modular stem fixed-bearing TAR with an intramedullary alignment system from April 2008 to December 2011 (3 years, 9 months; Table 1) at the clinic of the senior author (S.A.B.). Using database analytics, our electronic medical records were reviewed to extract the data of patients of the senior author (S.A.B.) who had the Common Procedural Terminology procedure code 27702, indicating they had undergone primary TAR (6). Two investigators (S.A.B., S.T.B.) were responsible for manually reviewing medical records to determine which of these patients met the inclusion and exclusion criteria (Table 2). Because the patient data were extracted using the procedure code, no patients (0%) with a history of revision arthroplasty were identified. The operative procedure was performed by the principle investigator (S.A.B.). The same technique was used for all patients. After patient identification, the data were abstracted and recorded in a password-protected, secure database. None of the 57 patients (58 ankles) were lost to follow-up.

Table 1
Patient demographics

Demographic	All Ankles (April 2008 to December 2011)	Group A (April 2008 to February 2010)	Group B (March 2010 to December 2011)
Patients (n)	58	29	29
Age (y)	59.5 ± 10.9	61.4 ± 10.2	57.6 ± 11.5
Gender (n)			
Male	39 (67)	21 (72)	18 (62)
Female	19 (33)	8 (28)	11 (38)
BMI (kg/m^2)	31.7 ± 5.9	30.5 ± 4.9	31.9 ± 6.5
Indications (n)			
Post-traumatic osteoarthritis	28 (48)	16 (55)	12 (41)
Primary osteoarthritis	25 (43)	9 (31)	16 (55)*
Rheumatoid arthritis	5 (9)	4 (14)	1 (3)

Abbreviation: BMI, body mass index.
Data presented as mean ± standard deviation or n (%).
* $p < .05$ compared between groups A and B.

The indication for TAR was painful ankle arthritis refractory to conservative management. Conservative treatment included physical therapy, oral anti-inflammatory medications, direct viscous supplementation, and bracing. The patients who required periarticular joint fusion underwent arthrodesis before TAR in a staged surgical procedure. This was performed to limit the amount of postoperative non-weightbearing in a cast with no range of motion.

Intervention

The surgery was performed using an anterior approach under a thigh tourniquet. An incision was made in the interval between the tibialis anterior tendon and extensor hallucis longus tendon. The extensor retinaculum was incised lateral to the extensor hallucis longus tendon. Blunt dissection was performed to protect the dorsalis pedis artery and the deep peroneal nerve. Along with the extensor tendons, these structures were retracted laterally, and the tibialis anterior tendon was retracted medially. After the ankle joint capsule was adequately exposed, a linear incision was made in the capsule to expose the tibiotalar joint. Excess synovial tissue and osteophytes within the joint capsule were thoroughly debrided. The leg was placed in the accompanying jig, which provided adequate padding. With the ankle joint in a mortise view under large c-arm fluoroscopy, the tibial tray was inserted. The appropriate bone cuts were made using a sagittal saw. The bone fragments were removed, copious irrigation was performed, and the prosthesis was implanted according to the surgical technique for INBONE® Total Ankle Replacement. Closure was performed in layers. The adjunctive procedures performed included gastrocnemius recession in 3 patients and Achilles tendon lengthening in 14 patients. A posterior splint was applied. A prophylactic antibiotic (Ancef, 2 g) was given intravenously at induction, followed by 3 doses postoperatively within 24 hours.

All patients were admitted for pain control and a physical therapy assessment. Discharge was dependent on pain and the requirement for rehabilitation placement. Patients were discharged on postoperative day 2 or 3. The patients were non-weightbearing for 2 weeks, during which time the limb was in a posterior splint. The staples were removed 2 to 3 weeks postoperatively, and the patient was transitioned into a sneaker. At that point, physical therapy for range of motion was initiated.

The incision was evaluated during the postoperative visits. All ankles with wound development were referred to the plastic surgery department for evaluation and possible grafting. Range of motion and weightbearing were not begun in the patients with wound development until complete skin healing was observed. When the charts were reviewed, the wound complications were followed up until resolution was noted.

Endpoints

Perioperative complications were recorded for the 58 consecutive ankles that underwent modular stem fixed-bearing TAR with intramedullary guidance. The patients

Table 2
Inclusion and exclusion criteria for patient selection

Inclusion criteria
Underwent TAR with a modular stem fixed bearing ankle implant
Procedure performed by principle investigator (S.A.B.)
Same technique used
Exclusion criteria
Previous anterior ankle incision
History of revisional ankle arthroplasty
Received nonmodular stem fixed-bearing implant

Abbreviation: TAR, total ankle replacement.