Early Clinical Results of the BOX Ankle Replacement Are Satisfactory: A Multicenter Feasibility Study of 158 Ankles

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A B S T R A C T

A new design for a 3-part ankle replacement was developed in an effort to achieve compatibility with the naturally occurring ligaments of the ankle by allowing certain fibers to remain isometric during passive motion. In order to test the design concept clinically, 158 prostheses were implanted in 156 patients within a 9-center trial and were followed up for a mean of 17 (range 6 to 48) months. The mean age at the time of surgery was 60.5 (range 29.7 to 82.5) years. Outcome measures included the American Orthopaedic Foot & Ankle Surgery hindfoot-ankle score and range of motion measured on lateral radiographs of the ankle. The preoperative American Orthopaedic Foot & Ankle Surgery score of 36.3 rose to 74.6, 78.6, 76.4, and 79.0, respectively, at 12, 24, 36, and 48 months. A significant correlation between meniscal bearing movement on the tibial component (mean 3.3 mm; range 2 to 11 mm) and range of flexion at the replaced ankle (mean 26.5°; range 14° to 53°) was observed in radiograms at extreme flexions. Two (1.3%) revisions in the second and third postoperative years necessitated component removal (neither were for implant failure), and 7 (4.4%) further secondary operations were required. The results of this investigation demonstrated that non-anatomic-shaped talar and tibial components, with a fully conforming interposed meniscal bearing, can provide safety and efficacy in the short term, although a longer follow-up period is required to more thoroughly evaluate this ankle implant.

In the early to mid-1970s, total ankle arthroplasty (TAA) was introduced (1,2) as a possible alternative to arthrodesis for the treatment of severe erosions of the articular surfaces of the human ankle, but long-term results of the pioneering designs were disappointing (3–5). More modern designs have produced better results, contributing to a renewed interest in TAA over the past decade (6–17). Although recent reviews (22–26) recommend arthroplasty instead of arthrodesis, they point out that the clinical results of current ankle implant designs are still not fully satisfactory. An inadequate understanding of ankle function and the structures guiding ankle motion in the natural state, namely the ligaments and...
articular surfaces, as well as insufficient restoration of these functions in the prosthetic joint may be responsible for the limited range of postoperative joint mobility that is commonly observed after TAA (9).

Recently, a newly designed TAA was developed, in which the shape of the articular surfaces in the sagittal plane were intended to naturally interact with the preserved ankle ligaments (27–29). The ankle implant was designed based on clinical experience as well as findings derived from a number of investigations, including studies that analyzed ankle function in cadaver specimens, in virtually unloaded conditions, and in mathematical models (30–34). The results of these investigations showed that the articular surfaces and ligaments of the ankle interact together in a complementary and mutually compatible manner. A key feature of the surface and ligament interaction of the new ankle implant is that it allows fibers within the calcaneofibular and tibiocalcaneal ligaments, namely the central superficial fibers of the deltoid ligament complex, to remain isometric over the range of passive motion while the remaining ligamentous fibers tighten only at the limits of plantarflexion or dorsiflexion.

Previous approaches to the design of TAA implants focused almost exclusively on the geometry of the prosthetic components in relation to the morphological features of the intact articular surface of the talus (1,12,35,36). Moreover, mathematical analyses showed that either fixed articular surfaces should have anatomic shapes, or both should be nonanatomic (27–29). Currently available 3-part ankle prostheses approximate the natural convexity of the talus, whereas the tibial component of these devices takes on a nonanatomic flat configuration (6,14,15,17,37–40). This combination of anatomic and nonanatomic surfaces cannot be compatible with the retained ligaments (27,28).

With the aforementioned information in mind, we hypothesized that a ligament-compatible TAA design could achieve satisfactory clinical results on par with or better than results achieved with more conventional ankle prostheses. Having established the feasibility of the operation in a number of cases, the designers invited surgeons from 8 other hospitals to participate in a prospective, multicenter cohort study, the results of which we present in this report.

**Patients and Methods**

The BOX (Bologna and Oxford Universities) Total Ankle Arthroplasty Design

The Bologna and Oxford Universities (BOX) (BOX Ankle, Finsbury Orthopaedics Ltd, Leatheread, UK) (29) is a 3-part TAA implant, with cast cobalt-chrome-molybdenum alloy components fixed to the body of the talus and the distal portion of the tibia, along with an interposed meniscal bearing (Fig. 1). This implant has previously been discussed in other published reviews (24,26,41,42). The distal tibial component of the BOX implant has a convex spherical surface that corresponds to a proximal, concave sulcus that limits medial to lateral in the frontal plane, displays a concave sulcus that limits anterior to posterior at anterior and posterior fixation, the nonarticulating metal surfaces are covered with small cast-in balls and also coated by plasma spray with a 50-μm-thick layer of hydroxyapatite. The tibial component has 2 parallel cylindrical bars running anteroposteriorly (AP) on its proximal flat surface. On its undersurface, the talar component has a flat, central, horizontal surface, as well as flat anterior and posterior chamfers to match the prepared talar dome. In addition, 2 pegs are used, 1 on the anterior chamfer and the other on the central surface. The pegs are oriented posteriorly to facilitate component implantation.

The meniscal bearing is machined from super-pressed sheets of PUR 1020 (Finsbury Orthopaedics Ltd), a low-calcium medical-grade ultra-high molecular-weight polyethylene. The bearing is placed in gas-impermeable film packaging, evacuated and back filled with nitrogen before sterilization by gamma irradiation with a Co60 source to 25–35 kGy, giving a sterility assurance level of 10–6. The bi-convex meniscal bearing fully conforms to the corresponding highly polished tibial and talar surfaces, irrespective of joint position. Fully conforming meniscal bearings minimize polyethylene wear in knee flexion (43,44) and are likely to do so in ankle replacement. The proximal surface of the bearing is slightly longer posteriorly so that contact area is maximized, and double concavity ensures entrapment of the meniscus. In essence, the difference between maximum and minimum thicknesses, which is similar to the design of currently available 3-part implants, remains aligned despite the larger radius of curvature of the talar arc in the sagittal plane. The minimum thickness of the central component (meniscal bearing) varies in 1-mm increments from 5 to 8 mm, and the most appropriate thickness is chosen to adjust ligament tension after implantation of the tibial and talar metallic components. The same components are used for left and right ankles and are currently available in 3 different sizes. It is recommended that the tibial and talar components be matched within 1 size up or down, and that the meniscal component corresponds with the size of the talar component. To allow radiologic detection, the meniscal bearing contains 3 tantalum spheres (0.8-mm diameter), 2 anterior and 1 posterior, attached to polyethylene pegs.

**Surgical Technique**

For the prosthesis to work properly, the fixed components must be implanted correctly with respect to the preserved ligamentous attachments (29). To satisfy this condition in practice and, in particular, for the meniscal bearing to slide smoothly on both metallic components, it is necessary that a constant gap be maintained between the articular surfaces of the tibia and talar components throughout the arc of rotation. This is, in fact, a critical goal of the surgical implantation procedure. To this end, a longitudinal incision is made, and this is situated either anteromedially or anterolaterally, the latter being preferred, in our opinion, for easier access to the more critical lateral malleolus. Using a talar cutting block mounted on a tibial alignment jig (Fig. 2) to guide the saw blade, a horizontal surface, oriented perpendicular to the long axis of the shaft of the tibia with the ankle in neutral position, is then made across the superior aspect of the body of the talus by removing a section of the talar dome ≤ 4 mm in thickness.

Thereafter, the subsequent amount of tibial bone resection is determined by considering the necessary minimum overall thickness of the prosthesis, taking into consideration the desired amount of final tension on the preserved ankle ligaments, which have to be balanced (Fig. 2). With the use of a joint distraction ratchet and 4 different metal tensioners, each corresponding to the thickness of a specific meniscal bearing component, the final size of the meniscal bearing is determined, as are the anticipated final stability of the TAA and the planned level and orientation of the tibial osteotomy in the transverse plane; all these variables being determined before any sawing of the tibia is performed. The surfaces of the tibia and the malleoli are then prepared with a tibial cutting block attached to the alignment jig (Fig. 2), and holes for the 2 parallel bars of the tibial component are also drilled.
In our experience, the most appropriate AP position for the talar component is determined by means of a step-by-step procedure using a talar template and a series of plastic gap gauges. In every tentative AP position, the gap between the tibial surface and the top (superior surface) of the talar template is measured in both maximal plantar and dorsiexion and dorsiflexion. This procedure is repeated after removal of bone from the tibial cutting block, and tension is applied to the joint through the ratchet knob. This would represent the final tension in the replaced joint, providing the meniscal implant has the same labeled thickness of the tibial tensioner.

Patients

The surgeons involved at the different hospitals shared the following general indications: primary or posttraumatic osteoarthritic patients with a relatively low functional demand, tentatively in patients > 50 years of age; all patients with rheumatoid arthritis; all patients rejecting arthrodesis, but compatible with the exclusion criteria. The general contraindications adopted from the beginning of the trial were morphological defects of the ankle, significant osteoporosis or osteonecrosis affecting the talus, previous or current infections of the foot, vascular pathologies or severe neurological disorders, previous arthrodesis of the homolateral hip or knee or severe deformities of these joints. The following contraindications were resolved before or during total ankle replacement: capsuloligamentous instability, and hindfoot or forefoot deformities affecting a correct posture.

Between July 2003 and October 2007 (approximately 4 years and 4 months), 192 BOX ankle prostheses were implanted in 190 patients, in 9 hospitals in northern Italy, each with a single surgeon involved. Staff from the inventors’ (S.G., A.L., F.C., and J.J.O.) team participated at the very first intervention in each center. The outcomes of 158 ankles in 156 patients (82.3% of the 192 ankles, and 82.1% of the 190 ankles) who had undergone BOX TAA at least 6 months before October 2007, thereby assuring a follow-up duration of at least 6 months, were selected for inclusion in the cohort described in this report. The distribution of TAA over the 9 centers was as follows: 75 (47.5%) (primary data collecting center), 7 (4.4%), 13 (8.2%), 32 (20.3%), 4 (2.5%), 9 (5.7%), 4 (2.5%), 10 (6.3%), and 4 (2.5%). The mean follow-up duration was 17.7 (range 6 to 48) months. The mean age of the patients was 60.5 (range 29.7 to 82.5) years. The distribution of the cause of the ankle arthrosis, for each ankle replaced, was as follows: 127 (80.4%) postrheumatoid arthrosis, 18 (11.4%) primary osteoarthrosis, 10 (6.3%) rheumatoid arthritis, 1 (0.63%) chronic rotator arthritis, 1 (0.63%) psoriatic arthritis, and 1 (0.63%) postrheumatoid osteoarthrosis combined with rheumatoid arthritis. Two patients who underwent bilateral TAA had postrheumatoid osteoarthrosis in both ankles, and these patients had the second ankle implanted at 14 and 11 months, respectively, after the first operation.

Postoperative Management

The operated leg was held in a plaster cast without weight-bearing for 2 weeks, followed by active and passive movements and partial weight-bearing with a rigid, below-the-knee boot. Complete weight-bearing with the boot started 1 month after the operation and free weight-bearing was resumed 2 months postoperatively.

Surgical, Clinical, and Radiological Assessments

Intraoperatively, the final motion of the meniscal bearing component was assessed in regard to smoothness of the excision, and alignment of the implant components throughout the range of ankle motion. The American Orthopaedic Foot & Ankle Surgery (AOFAS) hindfoot-ankle score (45,46) was obtained in each of the centers preoperatively and, when possible, at the following follow-ups: 1, 3, 6, 12, 18, 24, 36, and 48 months. In 31 ankles from 1 center, those patients who agreed to undergo additional radiography, radiographs were also taken with the implanted ankle in maximum plantarflexion and dorsiflexion (Fig. 3), with a minimum of 12 months of follow-up, and the movement of the meniscal bearing relative to the tibia was also measured. Prosthesis component alignment over time and progressive radiolucency were analyzed radiographically. The radiographs were specifically examined at 5 areas inferior to the talar component and in 5 areas superior to the tibial component, both in the lateral and frontal views. All 156 patients in the study were seen at least once at a minimum of 6 months postoperatively, and 1 (0.63% of ankles, 0.64% of patients) of the patients (unilateral TAA) died for reasons unrelated to the operation 12 months after the operation. Postoperative complications associated with the ankle implant were also recorded.

Results

Surgical Implantation

Overall, the instrumentation worked smoothly and enabled reliable implantation of the 3 components in the target location, even for the initial implantation at each center. After implantation of the final components and before layered wound closure, the meniscal bearing was observed to move anteriorly during dorsiflexion and posteriorly during plantarflexion over both the tibial and talar components in all operated patients. The motion was smooth and continuous, and complete congruence among the 3 components was maintained in all joint positions for 155 (98.1%) of the 158 ankles. In 9 (5.7%) of the ankles, slight misalignment in the AP direction of the 2 metal components was observed, and this was associated with a partial anterior subluxation of the talus that was noted in the preoperative period in these patients.

A number of adjunct procedures were performed at the time that the BOX ankle prosthesis was implanted, including distal first metatarsal osteotomy (47) in 11 (7.0%) ankles, reduction of previous tibiofibular mortise diastasis with a syndesmotic screw in 2 (1.3%) ankles, lateral ligament reconstruction in 5 (3.2%) ankles, calcaneal osteotomy in 2 (1.3%) ankles, and percutaneous Achilles tendon lengthening in 109 (69.0%) ankles-to achieve satisfactory dorsiflexion after component implantation.

Clinical and Radiological Assessment

Follow-up radiographs (Fig. 3) showed no variation in the positions of the implanted components. Radiolucencies > 1 mm were observed in 12 (7.6%) ankles, although not progressive (i.e., observed at the first follow-up but maintained stable at the subsequent follow-up). Radiographs at maximal dorsiflexion and maximal plantarflexion, as viewed fluoroscopically, confirmed that the meniscal bearing component moved in the direction predicted by the computer-based models (27,28) in all cases. Excursion of the meniscal bearing on the tibial component, measured radiographically at the limits of dorsiflexion and plantarflexion (mean 3.3 mm; range 2 to 11 mm), correlated with the corresponding range of joint flexion (mean 26.5°; range 14° to 53°) in the 31 ankles analyzed (Fig. 4).

The mean AOFAS scores recorded preoperatively and then at 12, 24, 36, and 48 months’ follow-up were, respectively, 36.3 (range 0 to 64.1), 35.3 (range 0 to 64.1), 46.3 (range 0 to 64.1), and 48.3 (range 0 to 64.1). The mean postoperative AOFAS hindfoot-ankle score for the 190 ankles was 49.5 (range 0 to 64.1), and the mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 49.9 (range 0 to 64.1). The mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1), and the mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1). The mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1), and the mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1). The mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1), and the mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1). The mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1), and the mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1). The mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1), and the mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1). The mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1), and the mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1). The mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1), and the mean postoperative AOFAS hindfoot-ankle score for the 158 ankles was 55.5 (range 0 to 64.1).
74), 74.6 (range 12 to 100), 78.6 (range 43 to 99), 76.4 (range 24 to 92), and 79.0 (range 76 to 82) (Fig. 5). Using Student’s paired sample t tests, changes at every single follow-up with respect to the preoperative were found to be statistically significant (p < .001), whereas the changes in scores after 6 months postoperative were not (p > .05). These AOFAS scores were, respectively, 35.7, 73.7, 79.9, 76.2, and 79.0 where only posttraumatic osteoarthritic patients were considered, and 29.7, 79.0, 78.0, and 81.5 (none at 48 months) where only rheumatoid arthritic patients were considered; the differences between the 2 groups were not statistically significant (p > .05).

“Function” domain within the overall AOFAS score (maximum value 50 points) improved from 20.6 preoperative to 37.8 at 36 months postoperative, and the “pain relief” domain score (maximum value 40 points) changed from 10.1 preoperatively to 30.0 at 36 months, and this difference was not statistically significant. The “alignment” domain score (maximum value 10 points) changed from 5.5 preoperatively to 8.8 at 36 months, and this difference was not statistically significant. Ankle dorsiflexion increased from 0.1° preoperatively to 7.8°, 7.7°, and 6.1° at 12, 24, and 36 months, respectively, whereas plantarflexion increased from 16.0° preoperatively to 20.3°, 20.4°, and 18.5° at 12, 24, and 36 months, respectively. All these 3 improvements were statistically significant (p < .0001).

The percentage of poor (total score ≤50), fair (51 to 75) and good-plus-excellent scores rose from 73, 27, and 0 preoperative, to 3, 44, and 53 at 12 months, to 2, 26, and 72 at 24 months, and to 4, 29, and 67 at 36 months (Fig. 5).

Complications and Implant Survival

Some intraoperative complications occurred, including 1 (0.63%) lateral and 2 (1.3%) medial malleolar fractures; 2 were treated with Kirschner wires and 1 was treated with an interfragmental compression screw. A single (0.63%) major surgical technical error resulted in incorrect talar component positioning; namely, the talar component was positioned too far posteriorly, and this required surgical revision by means of reimplantation, which was undertaken on postoperative day 3. Complications observed in the postoperative period included 4 (2.5%) problems with wound healing that resolved with local care and did not require a return to the operating room, and 2 (1.3%) malleolar stress fractures, 1 of which was also treated with subtalar distractional realignment arthrodesis. Three (1.9%) patients complained of severe pain on the medial side, which proved to be associated with arthrofibrosis and osteophytes at the medial tibiotalar articulation and responded successfully to reoperations for tissue and bone removal (in 1 of these 3 operations, calcaneal osteotomy was also performed). One (0.63%) isolated calcaneal osteotomy and 1 (0.63%) subtalar fusion were performed, for a total of 11 (7%) secondary operations with no component removal. Osteoarthritis of the talo-navicular joint was observed in 2 (1.3%) patients.
and 36 months was designated as moderate (relief score equal to 20) in 11 (7%) and 4 (2.5%) patients, respectively, and severe (score equal to 0) in 0 and 1 (0.63%) patients. Component removal was necessary in 2 (1.3%) cases, in 2 different centers (Table 1). One of these cases involved lateral impingement due to ankle varus deformity in a patient with Charcot-Marie-Tooth disease who was treated after 24 months with successful arthrodesis with the use of a retrograde locking nail. The other patient complained of severe pain of unknown origin and was treated after 12 months with a triple arthrodesis, although this did not lead to resolution of the pain (Table 1). After more than 4 years of follow-up, 152 (96.1%) of the implanted BOX ankle prostheses remained functional.

Discussion

In total joint replacement design, for the articular surfaces to complement the joint ligaments in order to provide natural rolling and sliding, the shapes of the prosthetic surfaces should be chosen not arbitrarily, but deduced by a mathematical model of joint mobility (48). We applied this analysis in the design of an ankle prosthesis, resulting in the use of nonanatomic surfaces for both talar and tibial components, which, nonetheless, can be compatible with the ligaments of the ankle (29). The results of our investigation show that compatibility between bearing movement on the tibia and range of motion has been achieved. The first implantation took place in July 2003, after extensive biomechanical studies (30–34). The device in itself combines freedom from restraint in the sagittal plane with congruity of the components throughout the 3-dimensional motion arc. This should contribute eventually to physiologic stress in the ligaments as well as minimizing wear of the meniscal bearing. These features should result in longevity and efficacy of the TAA, although this assumption has yet to be borne out in regard to the ankle implant evaluated in this investigation. These assertions have to be proved in clinical trials, and this preliminary study seeks to contribute in this direction.

For the new design to function as claimed, not only must the prosthesis components be designed according to biomechanical principles, they must also be implanted correctly relative to the ligamentous attachments. A strong force was often necessary to insert the meniscal bearing between the fixed tibial and talar components. This did not result in a limited flexion arc, and we believe that it may have guaranteed safe entrapment of the bearing. The results in the cohort described in this report demonstrated that the status of the ligaments in severely arthritic ankles can still allow implantation of ligament-compatible TAA designs. Unlike total knee replacement, which regularly sacrifices 1 if not both of the cruciate ligaments, ankle ligaments can in fact be easily retained with the use of an anterior incision and access. In addition, the mean thickness of the meniscal component used in this clinical trial was 5.5 mm, and there was a trend from thicker to thinner over time for each surgeon, which implied to us that the instrumentation enabled an accurate prediction of this parameter and that, with experience, the minimum required amount of bone could be removed.

Based on our experience with the patients in this report, we believe that the observations at operation and postoperatively confirmed the principles on which the design was based (27). After appropriate component placement and ligament tensioning, the gap between the metal components remained the same throughout the flexion arc, indicative of smooth and congruent AP motion of the meniscal bearing. The fact that, with appropriate positioning of the metal components, a constant gap could be maintained between their surfaces is a demonstration that some ligament fibers remain effectively isometric over the range of motion.

A more limited range of movement was observed in ankles with more limited bearing movement (Fig. 4), as observed in those replacements not fully aligned because of original misalignments such as talus subluxation. Despite the longevity of some current 3-part ankle implant designs, we are not aware of any published data specifically detailing the meniscal bearing movement. The limited range of dorsiflexion and plantarflexion achieved by these previous designs (49) could perhaps be explained by the absence of bearing movement resulting from a ligament-incompatible combination of anatomic and nonanatomic surfaces. With restoration of the physiologic role of the ligaments, natural joint motion could be reproduced (27,28), as well as natural muscle lever arm lengths (33). In other words, because the function of the ligaments in controlling passive joint mobility seems to have been restored with the BOX ankle prosthesis, their physiologic contribution to joint stability appears to have been restored. Interestingly, gait analysis of a group of these patients confirms restoration of function (50).

These early clinical results of the BOX ankle implant have also demonstrated safety and efficacy. We think that the present survival rate at 4 years (96.1%) compares very well with multicenter 5-year rates published by the Swedish (18) (531 cases, survival 78%), Norwegian (19) (257 cases, 89% survival), and New Zealand (20) (202 cases, 86% survival) registries. In addition, the type and number of complications, range of motion, and radiographic analyses that we observed were also encouraging. The only observation consistent with the previous literature is the degree of remaining pain after TAA, which at the ankle can be accounted for by many factors and can be attributed to ailments at several different joint levels in the involved extremity.

There were issues that could have complicated this series. Nine different surgeons were involved, with 7 out of 9 performing less than 15 TAA procedures. It has been shown recently from a large national registry (18) that the survival rate from the initial 30 TAAs from each surgeon are usually worse than the subsequent, and our results appear to be consistent with those from other centers. We also found it interesting that, in terms of mobility and ligament function, rheumatic patients can perform better (best survivability) than one might expect, and this was also observed in the Swedish study (18). In fact, in our cohort, improvement in the AOFAS score from preoperative to 36 months was 40.6 for the 127 patients with posttraumatic osteoarthritis, and 51.8 for the 10 rheumatic patients.

The meta-analysis by Stengel et al (49) provides a convenient basis for comparison of the clinical results. The overall AOFAS score improvement in the present trial patient population (36.3

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<th>No. of Failures</th>
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meta-analysis. The most encouraging analysis, and the approximately 18-point increase in the preoperative to 79.0 at 48 months) was similar to that of the meta-implants (49). In fact, the need for revision after TAA has been however, was the absence of device-related revisions in the short-term patients with 1 to 3 years of follow-up(37). Another study (51) reported at 2, 5, 8, 9, 10, 11, 12, and 21 months in a series of 122 a mean follow-up of 28 (range 12 to 67) months, and another study (52) described an 8% revision rate in a population of 200 TAA at a mean follow-up of 54 (Range 36 to 85) months. Still further, a more recent study (53) reported that only 83% of the cases remained revision-free after 5 years of follow-up. In regard to range of ankle motion, our results also compared favorably with those described by Haddad et al (54). Finally, we also believe that the minimal evidence of observed radiolucency in the present series further reinforces our claim that the BOX prosthesis is a robust form option for TAA.

Like many prospective cohort studies, our investigation was subject to a number of methodological limitations that could have threatened the validity of our results and conclusions. Despite the prospective nature of our investigation, it was still influenced by some biases, including the fact that the surgeons assessed the clinical and radiographic outcomes. The fact that we used the AOFAS hindfoot and ankle score, however, was an advantage, because the subjective component of this has been shown to reliable and valid (46). Furthermore, we are aware of the limitations related to the use of historical controls for comparison of results. However, we felt that the pilot nature of this investigation, as well as the quality of existing reviews, in particular meta-analyses, presented a situation where it made sense to make such comparisons. Just the same, we fully realize that the conclusions that we have made based on our findings in this investigation still must be thoroughly tested in the form of a randomized controlled trial.

In conclusion, a new TAA, namely the BOX ankle prosthesis, was designed to restore physiological function to the replaced ankle joint. Our early surgical results are encouraging, demonstrating intra-operatively the suitability of the prosthesis components, the operative technique, and the surgical instruments. While reproducing physiology ankle mobility, the new design maintains complete congruence of the articulating surfaces over the entire motion arc, with the prospect of minimizing wear. The present preliminary clinical outcomes are encouraging, but a longer follow-up, as well as other prospective cohort and randomized controlled trials are still needed.

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