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

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A R T I C L E I N F O

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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), but TAA still has not been associated with the degree of success observed with total hip and total knee arthroplasty procedures. Recent publications from Swedish (18), Norwegian (19), and New Zealand (20) registries revealed a steady annual revision rate of 2% to 3%, whereas a similar population in California showed a 4.6% annual revision rate (21). 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

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Conflict of Interest: Four of the authors (S.G., J.J.O., F.C., and A.L.) are inventors of the patent for the device here analyzed.

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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 spherical surface of the meniscal bearing with an equal radius. The proximal surface of the talar component has a circular, convex sagittal plane arc, with a radius of curvature that is compatible with the chosen radius of the tibial arc, thereby allowing fibers within the calcaneofibular and tibiocalcaneal ligaments to remain isometric during passive joint motion (27,29). In order to allow the ligaments to remain isometric, a radius of curvature larger than that of the natural talus was required, and this differed from the design of most other 3-part ankle implants. It also required that the meniscal bearing move forward on the tibial and talar components during dorsiflexion, and backward during plantarflexion. The talar component of the BOX ankle implant, when viewed in the frontal plane, displays a concave sulcus that limits medial to lateral dislocation of the meniscal component. Furthermore, the sagittal arcs of the metal components are slightly longer posteriorly, in order to allow for more plantarflexion than dorsiflexion. Still further, the talar component is narrower posteriorly so that it more accurately matches the morphology of the talus.

For cementless component-to-bone 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.

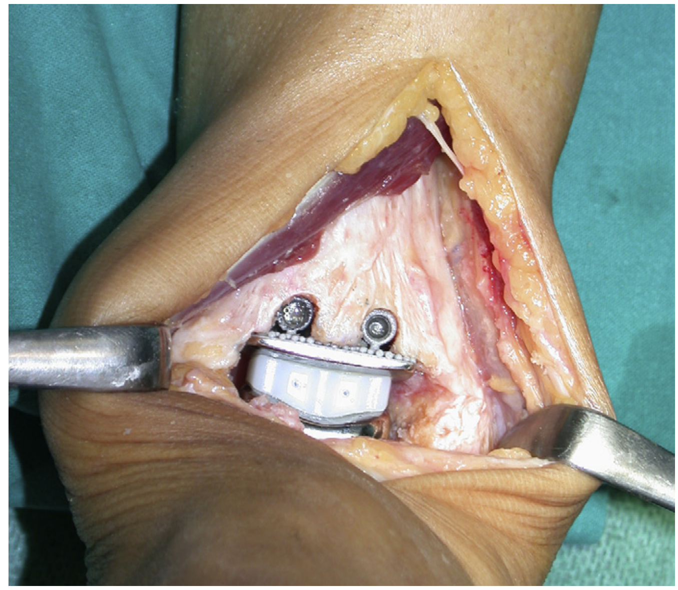

Fig. 1. The 3 components of the BOX ankle prosthesis, immediately after implantation: tibial component (*above*), meniscal component (*in between*), talar component (*below*).

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-concave 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 replacement (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 tibial and the 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 $\leq$ 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.