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CLINICAL RESEARCH

Total Ankle Replacement Compatible with Ligament Function Produces Mobility, Good Clinical Scores, and Low Complication Rates

An Early Clinical Assessment

Sandro Giannini MD, Matteo Romagnoli MD, John J. O'Connor PhD, Francesco Malerba MD, Alberto Leardini DPhil

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Abstract

Background A three-part ankle replacement was developed to achieve compatibility with the natural ligaments by allowing fibers on the medial and lateral sides to remain isometric during passive motion. Unlike all current prostheses, the new design uses nonanatomically shaped components on the tibia and talus and a fully conforming interposed meniscal bearing.

Questions/purposes Does this new design restore ankle mobility, improve clinical score, and result in low complication and early revision rates?

Patients and Methods We reviewed 51 patients in whom 51 prostheses were implanted in a seven-center trial from July 2003 to July 2006. The mean age of the patients at surgery was 61.5 years (range, 35.1–82.5 years). We used the AOFAS score to assess clinical outcome. We used lateral radiographs to assess function. The minimum followup was 24 months (mean, 30 months; range, 24–48 months).

Results The mean preoperative AOFAS score of 38.5 increased to 76.9, 79.1, 76.4, and 79.0 at 12, 24, 36, and 48 months, respectively. We observed a correlation between meniscal bearing movement on the tibial component (mean, 3.4 mm; range, 2–12 mm) and range of flexion at the replaced ankle (mean, 27.4°; range, 16°–53°). We revised one arthroplasty in the second postoperative year for lateral impingement, providing a 3-year cumulative survival rate of 97% and performed one other secondary operation for hindfoot pain.

Conclusions These data suggest the new prosthesis can provide short-term restoration of ankle mobility, a good clinical score, and low complication and failure rates. Longer followup with larger numbers is required.

Level of Evidence Level IV, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

The Istituto Ortopedico Rizzoli and one of the authors (JJO) have a licensing arrangement with the company producing the prosthesis, under which they receive royalties.

Each clinician in the list of authors certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

The design and development work were performed at Istituto Ortopedico Rizzoli, Bologna, Italy, at Oxford Orthopaedic Engineering Centre, Oxford, UK, and Finsbury Orthopaedic Ltd, Leatherhead, UK. The surgery and clinical examinations took place at Bologna and at the six other hospitals listed in the Acknowledgments. Data analysis was performed at Bologna.

S. Giannini, M. Romagnoli
Department of Orthopaedic Surgery, Istituto Ortopedico Rizzoli, Bologna, Italy

S. Giannini, A. Leardini (✉)
Movement Analysis Laboratory, Istituto Ortopedico Rizzoli, Via di Barbiano 1/10, 40136 Bologna, Italy
e-mail: leardini@ior.it

J. J. O'Connor
Department of Engineering Science, University of Oxford, Oxford, UK

F. Malerba
Istituto Ortopedico Galeazzi, Milano, Italy

Introduction

Although total ankle arthroplasty (TAA) was introduced in the early 1970s [16, 28], most studies do not report high

functional scores or high long-term survival [3, 7, 9, 10, 14, 17, 19–23, 31, 32, 40–42, 44, 52]. Recent publications from the Swedish [24], Norwegian [15], and New Zealand [26] registries have revealed a steady annual revision rate of TAA (with removal of components) of 2% to 3%, whereas a similar population study from California reported a 4.6% annual revision rate [46]. One meta-analysis with more than 1000 cases showed limited improvement in range of flexion, pain, function, and alignment, and a high rate of other complications [48]. Poor understanding of the functions of the structures guiding ankle motion in the natural joint, ie, ligaments and articular surfaces, and poor restoration of these functions in the prosthetic joint may be responsible for the high complication and revision rates [45].

A new design of TAA was developed [38] in which the shapes of the articular surfaces in the sagittal plane were chosen to be compatible with the function of the retained ankle ligaments. The design was based on investigations that included measurements on cadaver specimens in unloaded conditions [11, 37, 47] and simulations with mathematical models [35, 36]. These studies suggested that during passive dorsiflexion/plantar flexion, the shapes of the articular surfaces maintain isometric fibers in the calcaneofibular and tibiocalcaneal (the central superior fibers of the deltoid) ligaments, and these fibers maintain the articular surfaces just in contact. The articulating surfaces of the new prosthesis were designed to reproduce this phenomenon, or, in other words, to be compatible with the ligaments [33, 34].

Previous designs of TAA focused exclusively on the geometry of the prosthetic components in relation to the morphologic features of the intact articular surface of the talus [5, 8, 17, 28]. A mathematical analysis (Fig. 1) showed that to achieve ligament compatibility, either both fixed articular surfaces should have anatomic shapes or both should be nonanatomic [33, 34]. Current three-part prostheses [3, 6, 7, 25, 30, 31, 50–54] use a more or less natural-like convex surface for the talar component and a nonanatomic flat surface for the tibial component. We have shown this combination of anatomic and nonanatomic surfaces cannot reproduce isometricity of ligaments and therefore cannot be compatible with normal ligament function [33, 34]. The new design uses nonanatomic shapes for both fixed metal components and an interposed fully conforming meniscal bearing [33, 34].

We therefore asked whether (1) the implanted prosthesis would reproduce a large range of flexion, and movements of the meniscal bearing as predicted mathematically and observed preliminarily in vitro; (2) the American Orthopaedic Foot and Ankle Society (AOFAS) scores for pain, function, and alignment would improve from those in previous multicenter studies; (3) early complication rates

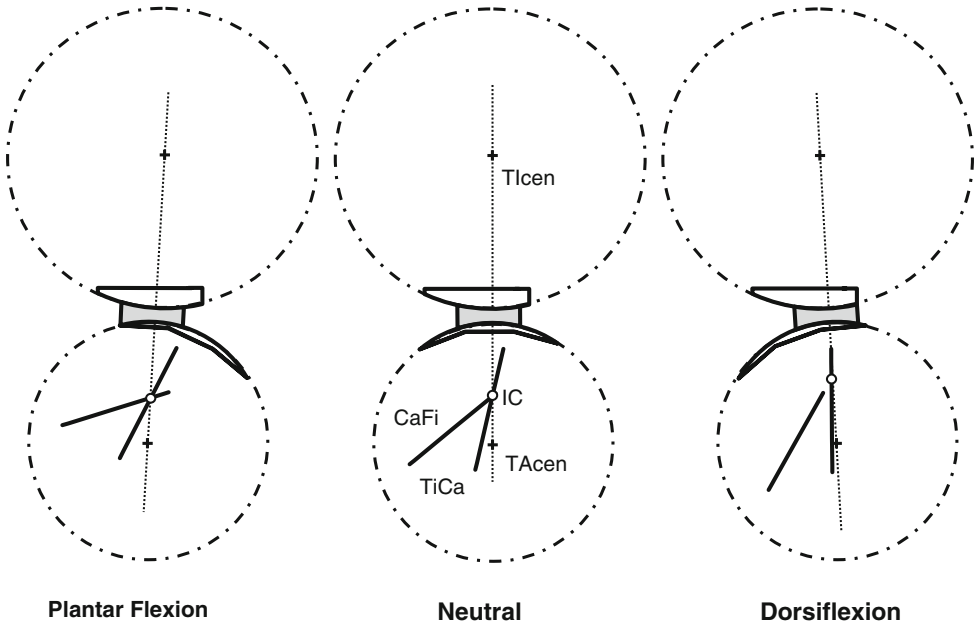

Fig. 1 A diagram of the mathematical sagittal model of the ankle replaced by the BOX ankle prosthesis is shown. The circular arcs of the tibial and talar components fixed to the bones (dash-dot circles, centered at TIcen and TAcen, respectively) are shown at three joint positions. In each of these, the line joining their centers passes through the instantaneous center of rotation (IC), at the intersection of the isometric fibers in the calcaneofibular (CaFi) and tibiocalcaneal (TiCa) ligaments. The biconcave meniscal bearing (gray, between) is required to slide forward on both components during dorsiflexion and backward during plantar flexion while maintaining full congruity. The IC moves forward and proximally during dorsiflexion and backward and distally during plantar flexion.

would be lower than those of previous studies; and (4) early rates of revision, requiring removal of components, would be lower than those of previous studies.

Patients and Methods

We designed a prospective multicenter trial to enroll sufficient numbers of patients in a reasonable time and to determine the answers to these four questions from the work of a group of surgeons of varied experience. The first two implantations took place in July 2003. By July 2006, seven surgeons had contributed 21, 11, six, five, four, three, and one, a total of 51 ankles in 51 patients. The diagnosis was posttraumatic osteoarthritis in 38 ankles (75%), primary osteoarthritis in eight (16%), and rheumatoid arthritis in four (8%) with a similar distribution in each center. The remaining ankle had ochronotic arthritis. The mean age of the patients at surgery was 62 years (range, 35–83 years); 32 of the 51 patients (63%) were female. The minimum followup was 2 years (mean, 29.7 months; maximum, 48 months). No patients were lost to followup. The study was approved by ethics committees at each center. The patients were instructed about the new prosthesis and signed an informed consent.

The indications for the operation were (1) patients with primary or posttraumatic osteoarthritis with relatively low functional demand (light work, no strenuous activities, no sport); (2) initially patients were older than 50 years, a criterion that was relaxed with experience later in the trial; (3) patients with severe ankle rheumatoid arthritis but not severe osteoporosis of the ankle; and (4) patients suitable for arthrodesis but rejecting it. The general contraindications for the procedure were (1) varus or valgus deformity greater than 15°, severe bony erosion, severe talus subluxation; (2) substantial osteoporosis or osteonecrosis particularly affecting the talus; (3) previous or current infections of the foot; (4) vascular disease or severe neurologic disorders; and (5) previous arthrodesis of the ipsilateral hip or knee or severe deformities of these joints. Other potential contraindications such as capsuloligamentous instability and hindfoot or forefoot deformities affecting correct posture, were not considered relevant if resolved before or during surgery.

The BOX Ankle (Finsbury Orthopaedics Limited, Leatherhead, UK) is a three-part implant with metal components fixed to the proximal talus and the distal tibia and an interposed ultrahigh-molecular-weight polyethylene meniscal bearing (Fig. 2). Descriptions of the design rationale and of the prosthesis have been published [38] and discussed in recent reviews [12, 13, 22, 39, 49].

At surgery, spinal or peripheral nerve block anesthesia was administered. The patient was positioned supine on the operating table. A tourniquet was applied around the upper third of the thigh. The leg was sterilized up to the knee. An 8- to 10-cm anterolateral skin incision one-third distal and two-thirds proximal to the joint line, respectively, was performed. After capsulotomy, osteophytes were removed. Using a talar cutting block mounted on a tibial alignment jig (Fig. 3) to guide the saw blade, a horizontal surface was prepared on the top of the talus, perpendicular to the longitudinal axis of the tibia in ankle neutral position, by removing a bone slice 4 mm thick. A tibial cutting block then was attached to this jig via a ratchet to distract the joint and to apply tension to the ligaments; metal tensioners were used with thicknesses corresponding to those of the final meniscal bearings and the amount of tension applied represented the tension in the replaced joint (Fig. 3). If the selected position of the horizontal cut on the tibia after tensioning was considered too distal, ie, removing too little tibial bone, the ratchet was repositioned, a thicker tensioner introduced, and tension applied again, until the desired tension and level of tibial cut were reached. This allowed correct tensioning of the ligaments and, at the same time, precisely the right amount of bone was resected to suit the combined thickness of implant components, including the thinnest possible meniscal bearing. The surfaces of the tibial mortise then were prepared using a slotted guide (Fig. 3). The most appropriate AP position for the talar component was determined by removing bone on the talar neck to move the talar template backward until the gap between the tibial surface and the top of the talar template, measured with a series of plastic gap gauges, was the same in maximal plantar flexion and dorsiflexion. After tests with trial components, the final talar and tibial components were implanted and the most appropriate meniscal bearing was inserted between them. Percutaneous Achilles tendon

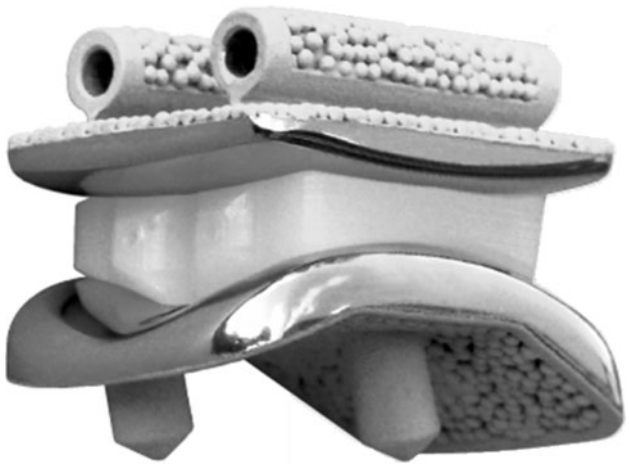

Fig. 2 The three components of the BOX ankle prosthesis, in the neutral position, ie, aligned in all three anatomic planes: tibial component (above), meniscal component (between), talar component (below).

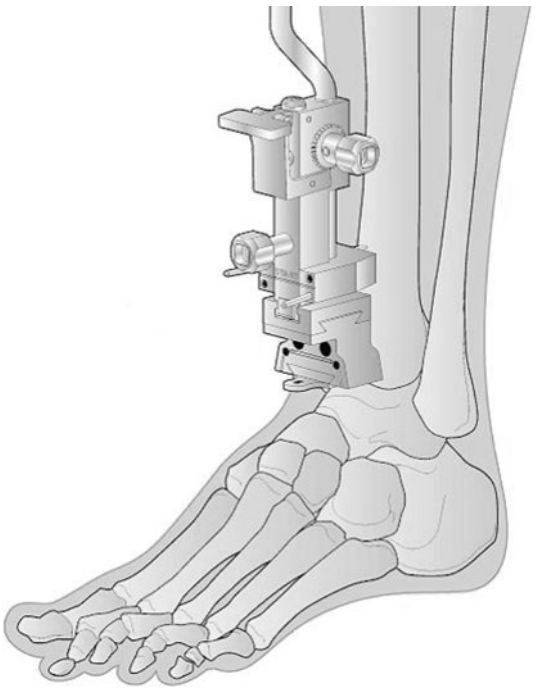

Fig. 3 A diagram of the tibial bone preparation phase from the operative technique is shown; the tibial cutting block is inserted onto the tibial alignment guide, and the tibial tensioner of the appropriate thickness is inserted. Tension to the joint is applied through the ratchet knob until desired; this would represent the final tension in the replaced joint, providing the meniscal implant has the same labeled thickness of the tibial tensioner (Drawing published with the courtesy of Finsbury Orthopaedics Ltd, Leatherhead, UK).

lengthening was performed in 36 of the 51 cases to achieve at least 10° dorsiflexion after component implantation. The other procedures performed at surgery were two distal first metatarsal osteotomies [18], two reductions of previous tibiofibular mortise enlargements with a syndesmotic screw, and one lateral ligament reconstruction. This was a coronal plane malalignment resulting from chronic instability and was treated by medial release and lateral ligament reconstruction with a tendon graft harvested partially from extensor communis digitorum. Continuous smooth movement of the meniscal bearing relative to both fixed components was observed in all cases before wound closure.

The operated leg was held in a plaster cast without weightbearing for 2 weeks. After removal of the plaster cast, active and passive movements (30 minutes three times a day) and partial (30% of body weight) weightbearing using a boot and crutches were recommended. No specific physiotherapy protocols were recommended. Complete weightbearing with a boot started after 1 month and free weightbearing after 2 months.

Each surgeon agreed to see the patients preoperatively, and at 12, 24, 36, and 48 months, and, if possible, at 1, 3, 6, and 18 months postoperatively, to record the range of dorsiflexion and plantar flexion; the AOFAS scores [29] for pain, function, and alignment; any perioperative or postoperative complications; and any revision operations requiring complete removal of components. The complete clinical examination was performed in each center by one physician from the staff of the surgeon. Twenty-one of the 51 patients, the complete cohort from one center and with a minimum of 12 months followup, agreed to undergo additional radiography of the foot on the ground in active maximum plantar flexion and maximum dorsiflexion (Fig. 4) to determine the amplitude of bearing movement on the tibia. These 21 patients had AOFAS scores similar to those of the other patients (mean, 72.3). The results from the seven centers were pooled to form a single cohort. The data were collected and analyzed at the Istituto Ortopedico Rizzoli.

We used paired one-sided t-tests to determine the statistical significance of the increases in range of flexion and AOFAS scores from preoperatively to postoperatively. The Kaplan-Meier method was used to calculate cumulative survival rates and Peto's method to calculate the 95% confidence limits for those rates [4]. The survival rates were compared with those in published series [3, 15, 24, 26, 46, 52], particularly those from national registries [15, 24, 26], and the AOFAS scores, complication rates, and range of flexion results with Stengel's meta-analysis [48]. We used the regression utility in Microsoft Excel 2003 (Microsoft Inc, Redmond, WA, USA) to determine the statistical significance of the relationship between range of ankle flexion and bearing movement.

Results

For the 51 patients, the range of dorsiflexion increased from an average of 0° preoperatively to 9°, 7°, and 6° at 12, 24, and 36 months, respectively. The range of plantar flexion increased from 12° preoperatively to 20°, 21°, and 18°, respectively. Among the 21 patients with additional radiography, the range of bearing movement on the tibial component (Fig. 5) was large (mean, 4 mm, over a mean of dorsiflexion and plantar flexion of 27°). We found a correlation ($r^2 = 0.326$; $p = 0.007$) between bearing movement and range of dorsiflexion and plantar flexion. This movement had the amplitude and direction as predicted mathematically [33, 34].

The mean AOFAS scores increased considerably, from the 38.5 (range, 0–70) preoperatively to 76.9 (range, 12–100), 79.1 (range, 43–99), 76.4 (range, 24–92), and 79.0 (range, 76–82), respectively, at 12-, 24-, 36-, and 48-month followups (Fig. 6). This AOFAS score increased from the preoperative condition at each followup (from $p < 0.001$ to $p = 0.003$ at 48 months); from the comparison of each followup to the previous, only the 3- to 6-month

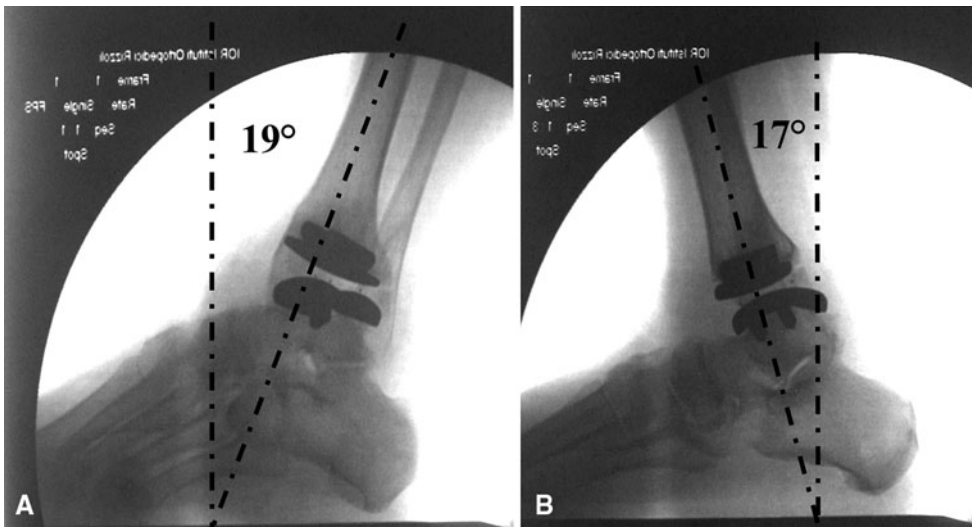

Fig. 4A–B Fluoroscopic radiographs were taken at the 48-month followup with the patient in double-leg stance, with the ankle in maximum (**A**) plantar flexion and (**B**) maximum dorsiflexion, the latter achieved by maintaining the foot in the same plantigrade position on the floor and advancing the contralateral leg as much as possible. Dorsiflexion at the replaced ankle is physiologically coupled with axial rotation. The flexion angle is calculated between the middiaphyseal axis and vertical to the floor. The posterior and the two anterior markers on the meniscal bearing also are visible.

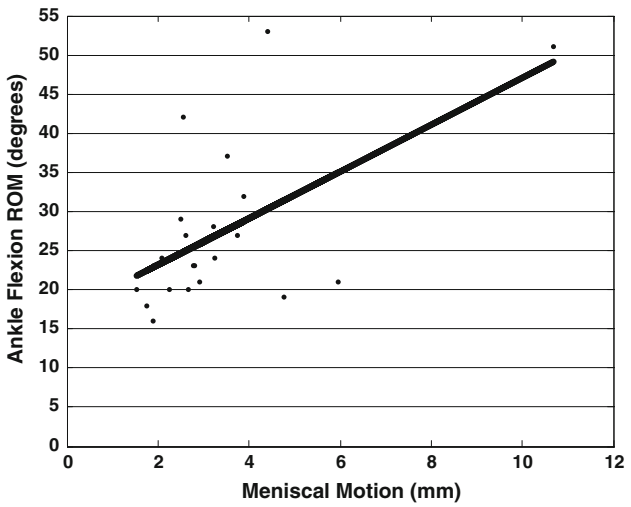

Fig. 5 A correlation plot between the range of ankle dorsiflexion and plantar flexion and meniscal AP displacement from measurements on 21 ankles validates the prosthesis design rationale and appropriate component positioning.

improvement was significant ($p = 0.028$). The largest AOFAS subscore increase was for function (from 20.8 preoperatively to 37.8 at 36 months; maximum value 50), pain relief (from 11.6 to 30.0; maximum, 40) and alignment (from 6.2 to 8.8; maximum, 10) increasing to smaller extents. The percentages of poor (total score equal or less than 50), fair (51–75), and good-plus-excellent scores increased from 69, 31, and 0 preoperatively to 2, 45, and 53 at 12 months to 2, 26, and 72 at 24 months and to 5, 28, and 67 at 36 months, respectively.

One intraoperative complication occurred, a medial malleolar fracture treated with a screw. One postoperative complication early in the trial was the result of incorrect talar component positioning, ie, too far posteriorly, treated after 3 days with repositioning of the component. Four additional postoperative complications occurred for which one secondary operation was necessary without removal of the components: three patients had delayed superficial wound healing which resolved without additional surgery and one patient with hindfoot pain was treated by subtalar fusion.

At the end of the third postoperative year, with 36 at risk, the cumulative survival rate was 97.2% (confidence interval, 92%–100%) (Table 1). One of the 51 patients had revision surgery with complete removal of the three components. The surgeon exceeded the agreed contraindications and performed the replacement in the foot of a patient with Charcot-Marie-Tooth disease; the patient had lateral impingement develop and a successful arthrodesis was performed after 24 months.

Discussion

A novel ankle prosthesis was designed after original experimental observations on intact human rear feet and a relevant mathematical theory of ligament strain. According to this theory, certain fibers in the calcaneofibular and tibiocalcaneal ligaments remain isometric during passive dorsiflexion or plantar flexion; others are recruited throughout the flexion arc and under load in activity. To allow recovery of this normal function and good

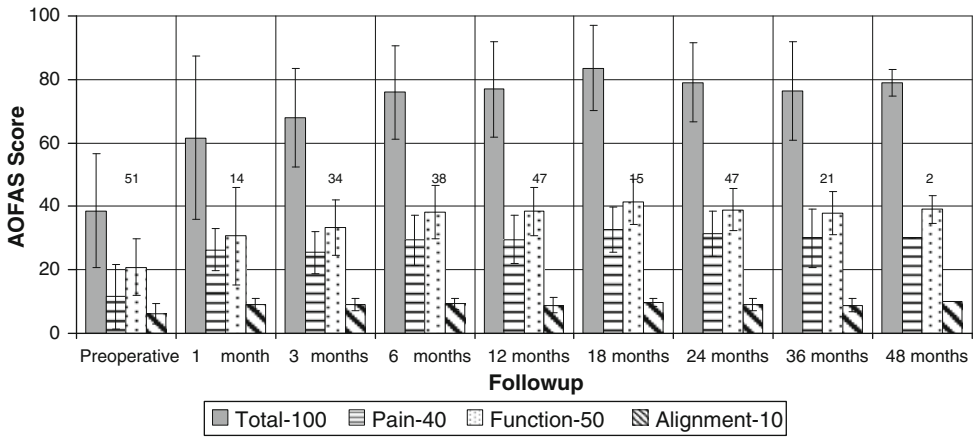

Fig. 6 The bar plot shows the average values of the AOFAS score (with SDs) over the followup, also subdivided for pain, function, and alignment subscores. The numbers of ankles from which data were obtained at each followup also are shown.

Table 1. Survival for the BOX ankle prosthesis

Year	Number of prostheses entering	Number of ankles withdrawn	Number of ankles at risk	Number of failures	Survival rate	Cumulative survival	Lower 95% confidence	Upper 95% confidence
0–1	51	0	51	0	1	1	100.0	100.0
1–2	51	2	50	0	1	1	100.0	100.0
2–3	49	27	35.5	1	0.9718	0.9718	91.7	100.0
3–4	21	19	11.5	0	1	0.9718	91.7	100.0
4–5	2	2	1	0	1	0.9718	91.7	100.0

entrapment of the components, nonanatomically shaped articular surfaces of the fixed components and an interposed fully conforming meniscal bearing were designed. Recent additional computer model-based predictions [43], simulator tests [1], measurements on retrievals [2], and gait analysis [27] have provided some evidence of good performance of this prosthesis. Nevertheless, we organized the current multicenter clinical trial to see if improvements occurred with respect to existing devices in (1) flexion at the replaced joint; (2) AOFAS scores; (3) complication rates; and (4) revision rates. The only relevant meta-analysis, by Stengel et al. [48], summarizing various clinical results from 1107 TAAs, provides a convenient basis for comparison of the current results with published results.

We acknowledge several limitations. First, the followup of the patients is still short with only 11.5 ankles at risk in the fourth and one in the fifth postoperative years (Table 1). Although we can identify the shorter-term complications and describe patient function, we cannot yet predict long-term survival rates. Second, of the seven surgeons, three reported less than five TAAs. This resulted from the minimum 2-year followup constraint; these and other surgeons are still performing TAAs, and data from additional patients are being collected. Third, we had a large number (75%) of posttraumatic osteoarthritic ankles compared with only 28% on average in a recent meta-analysis [48]. Another study suggests patients with posttraumatic osteoarthritis have higher complication and revision rates than patients with rheumatoid or primary osteoarthritis [24], and therefore this bias might reinforce the value of corresponding rates from the current study. Fourth, we report the range of foot-to-shank rather than that of the tibiotalar joint. Fifth, we cannot determine whether the improvements in range of flexion, AOFAS score, and complication and revision rates are attributable to the ligament-compatible nature of the design.

We observed a mean gain in the range of flexion of 17°, 16°, and 13° at 12, 24, and 36 months, respectively, which compares with the mean 7° at various followups in the meta-analysis [48]. This trend toward smaller flexion with longer followup can be attributed to the reduced number of subjects over the followups. The correlation between joint flexion and bearing movement (Fig. 5) showed that compatibility with the ligaments was achieved by the design and implantation of the novel prosthesis. Bearing movement on the tibia indicates that the rolling element of the natural movement of the talus on the tibia [11, 33, 34] is reproduced. We found no mention of bearing movement in any of the reports of the current three-component devices with anatomic talar and flat tibial components [3, 6, 7, 25, 30, 31, 50–54]. The overall AOFAS score improved by a mean of 40.5 points (38.5 preoperatively to 79.0 at 48 months) and was similar to the 45-point increase of the meta-analysis [48]. However, the 18-point increase in the

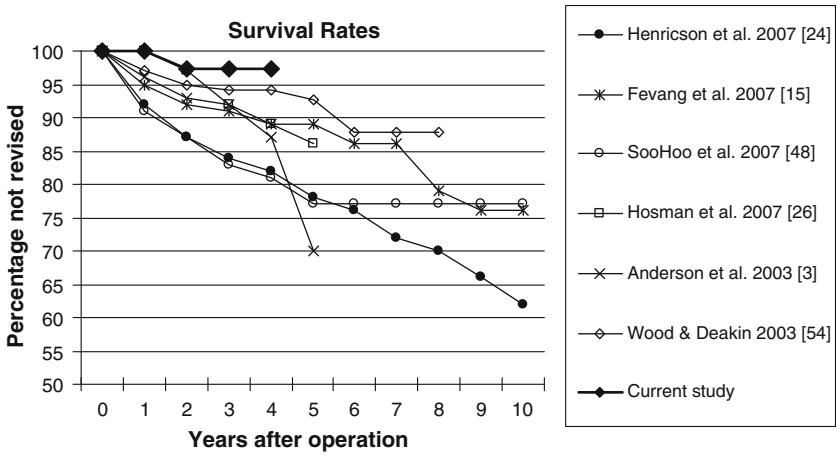

Fig. 7 The graph shows a trend of cumulative survival rates from similar studies; the current series shows the best results in the period analyzed.

function score, achieved by Month 12 and maintained at followup, appears to be better than the mean 12.5 of the meta-analysis. The increase in the pain relief score (in the current study, between 18.1 and 19.7 points during the 12- to 36-month followup) is worse than the value of 28 in the meta-analysis, although in our patients, pain was reported as occurring mainly at other joints of the hindfoot.

Two of our 51 patients required revision surgery on the ankle (one repositioning and one arthrodesis), fewer than the corresponding 12.5% of the meta-analysis, and although we had one patient who underwent arthrodesis, the meta-analysis reported a rate of 6.3%. Wound healing problems occurred in 5.9% of our patients, fewer than the 10.8% superficial infections in the meta-analysis. The current 2.0% intraoperative malleolar fractures also were fewer than the 13.4% fractures reported in the meta-analysis. The other complications reported in the meta-analysis, ie, 1.6% deep infection, 5.4% loosening, 3.2% dislocation, 14.7% impingement, have no equivalents in our series. The current 2.0% of subtalar fusion attributable to residual pain has no explicit correspondence in the meta-analysis.

Our data with 51 ankles at risk during the first year and a 4-year survival rate of 97.2% suggest few postoperative complications requiring component removal in contrast to reports from the registries [15, 24, 26] or from experienced surgeons [3, 6, 7, 25, 30, 40, 42, 51–53] (Fig. 7). In one series of 122 cases with 1 to 3 years followup [25], revisions have occurred at 2, 5, 8, 9, 10, 11, 12, and 21 months. Our current trial has not reproduced the experience of the Swedish TAA registry of a higher failure rate among the first 30 cases contributed by individual surgeons [24].

The new TAA designed to restore physiologic function at the replaced ankle was analyzed in a multicenter trial with seven learning curves. The design and implantation together (1) produced large flexion arcs and movements of the meniscal bearing as predicted; (2) produced improvements in AOFAS scores; and had (3) intraoperative and postoperative complication rates and (4) revision rates with component removal smaller than reported for previous studies. The correlation between bearing movement on the tibia and range of flexion, not previously seen, argues for our claim of a ligament-compatible design. We believe expansion of the clinical trial is justified, but longer followup with larger numbers of patients is required to assess the new TAA in the longer term.

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