

## The Box Ankle Replacement: Results at a Minimum Follow-up of 5 Years

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### Abstract

A new design of 3-part ankle replacement was developed to achieve compatibility with the natural ligaments by allowing certain fibres to remain isometric during passive motion. From July 2003 to April 2008 we have implanted 70 ankle prostheses. The mean age at surgery was 61.5 years (range 29.7-82.5). Mean follow-up is 6.4 years (5-9 years). Radiographs showed good alignment, no loosening and little signs of progressive radiolucency. The pre-operative AOFAS score was 38.4 and at last follow-up increased to 77.9. Function and Range-of-motion scored better than previous total ankles. Two revisions necessitated component removal, neither for implant failure. These results demonstrate that non-anatomically shaped talar and tibial components, with a fully conforming interposed meniscal bearing, can provide satisfactory clinical results in the short term.

**Keywords:** Radiolucency; Ankle ligaments; Calcaneal osteotomy

### Introduction

In the early to mid 1970's, 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 joint but long-term results of the pioneering designs have been 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 is still not as successful as total hip and total knee arthroplasty. Recent publications from the Swedish [18], Norwegian [19] and New Zealand [20] Registries have revealed a steady annual revision rate of 2 to 3% while a similar population study from California showed a 4.6% annual revision rate [21]. Most recent review papers [22-26], while encouraging arthroplasty against arthrodesis, point out that the clinical results of current designs are not fully satisfactory. Poor understanding of the functions of the structures guiding ankle motion in the natural joint, i.e. ligaments as well as articular surfaces, and poor restoration of these functions in the prosthetic joint may be responsible for the limited range of post-operative joint mobility [9].

A new design of TAA was developed recently in which the shapes of the articular surfaces in the sagittal plane were chosen to allow a natural interaction with the retained ankle ligaments [27-29]. A feature of the surface/ligament interaction which the new design attempts to reproduce is to allow fibres within the calcaneofibular (CaFi) and tibiocalcaneal (TiCa, i.e. the central superficial fibres of the deltoid ligament complex) ligaments to remain isometric over the range of passive motion while all other ligament fibres are tight only at the limits of plantar or dorsi flexion [30-34].

Previous designs of TAA focused 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]. Current three-part prostheses [6,14,15,17,37-40] use a more or less natural-like convex surface for the talar component and a non-anatomical flat surface for the tibial component. This combination of anatomical and non-anatomical surfaces cannot be compatible with the retained ligaments [27,28]. In the BOX prosthesis the tibial arch is deduced from the imposed talar arch thus resulting in isometry of the ligaments. This paper provides the results of Box ankle replacement (Figure 1) (Box Ankle, Finsbury Orthopaedics Limited, Leathread, UK) performed by a single surgeon at a minimum follow-up of 5 years in order to compare the achieved results with highest methodological studies available in the literature (Figure 2a and 2b).

### Material and Methods

Between July 2003 and April 2008 70 ankle prostheses were implanted into 68 patients. The mean follow-up was 6.4 years (5-9 years). The mean age of the patients was 61.5 years (range 29.7 to 82.5).

The diagnosis was post-traumatic osteoarthritis (80.4%), primary osteoarthritis (10%), rheumatoid arthritis (6.3%). The remaining ankles were one ochronotic arthritis, one psoriatic arthritis, one osteoarthritis due to club foot sequelae and one post-traumatic osteoarthritis combined with rheumatoid arthritis (Figure 3a and 3b). All patients have been treated by antero-lateral approach to the ankle. Post-operative treatment consisted of a plaster cast without weight bearing for two weeks, followed by active and passive movements and partial weight bearing using a boot. Complete weight bearing with a boot started after 1 month and free weight bearing after 2 months.

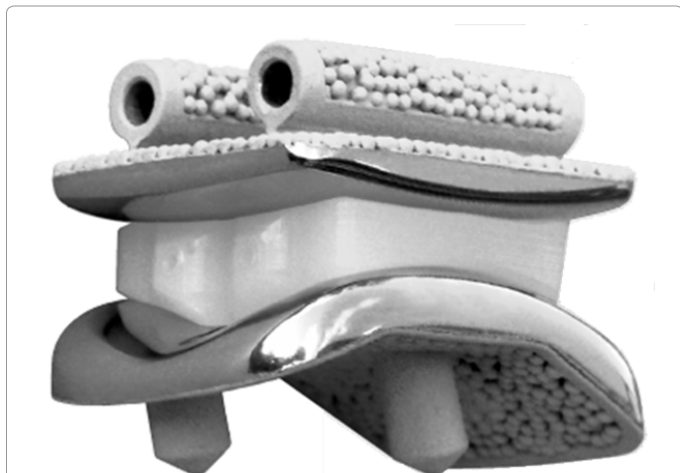
The AOFAS score was produced pre-operatively and at last follow-up. X-ray pictures were also taken at last follow-up at maximum plantar- and dorsi-flexion. The AOFAS score is a validated clinical score composed by three subscales (pain, function, alignment) [41]. Prosthesis component alignment over time and progressive radiolucency were analysed by the senior author. The alignment of the tibial component was evaluated in both projections. The alignment of the tibial component was measured using the angle between the tibial mechanical axis and component axis. The alignment of the talar component was deduced from the lateral projection measuring the angle between component axis and the perpendicular to the line tangential to the inferior border of the calcaneus. For the evaluation of radiolucency the radiographs were examined at five areas under the talar component and in five over the tibial component, both in the lateral and frontal view.

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**Figure 1.** The three components of the Box ankle prosthesis, in the neutral position, i.e. aligned in all three anatomical planes: tibial component (above), meniscal component (in between), talar component (below).



**Figure 2a.** 62 years old man with ankle arthritis.

## Results

During the implantation other procedures were performed in order to achieve a correct foot stance, including distal first metatarsal osteotomy [42], reduction of previous tibiofibular mortise enlargement with a syndesmotomic screw, lateral ligament reconstruction, calcaneal osteotomy, but mainly percutaneous Achilles tendon lengthening in about 70% of the cases to achieve satisfactory dorsiflexion following component implantation. Two intra-operative complications occurred, including one lateral and one medial malleolar fractures treated with K-wires.

The mean AOFAS scores achieved at pre-op and at last follow-up were respectively 38,4 and 77,9. Using paired sample t-tests, changes at last follow-up with respect to the pre-op were found to be significant ( $p < 0.001$ ). These AOFAS scores where post-traumatic osteoarthritic and rheumatoid patients were considered have not significant differences. Clinical range of motion of the ankle pre op was  $2,3^\circ$  of dorsiflexion and  $13,4^\circ$  of plantarflexion. At last follow-up range of motion increased to  $6,6^\circ$  in dorsiflexion and  $19,9^\circ$  in plantarflexion.

Follow-up radiographs showed no variation in the positions of the components. Radiolucencies greater than 1 mm were observed in 12 patients, though not progressive.

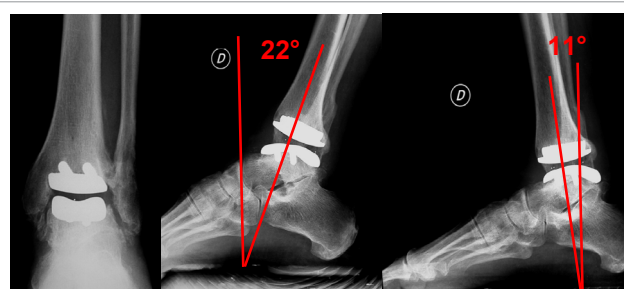
Radiographs at maximal dorsiflexion and maximal plantar flexion and fluoroscanning confirmed that the meniscal bearing component moves in the direction predicted by the computer-based models [27,28].

Complications post-operatively included three problems with wound healing resolved with no need of re-operation. Three patients complained of severe pain on the medial side, proved to be associated with arthrofibrosis and osteophytes at the medial tibio-talar articulation and treated successfully by reoperations for tissue and bone removal (in one of these three operations calcaneal osteotomy was also performed). One isolated calcaneal osteotomy and one subtalar fusion were performed.

Component removal was necessary in two cases. A medial impingement due to ankle varus deformity at 36 months was treated with successful arthrodesis with a retrograde locking nail. The other case of component removal was due to an infected periprosthetic fracture following an high velocity trauma at 2 years follow-up.

## Discussion

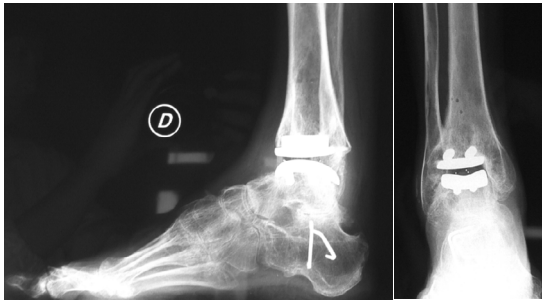
The disappointing results reported in the literature about the use of ankle prostheses have prompted many surgeons to abandon this type of implant in favor of ankle fusion. These results refer to series of patients with a rather wide indication and the use of prosthetic designs that do not completely restore the joint physiology and biomechanics of the ankle and lower limb [7,8]. A review of the literature and our experience suggest that indications for this type of operation are limited to patients with arthritis over 50 years of age, or under 50 if functional requirements are low, patients with rheumatoid arthritis with reduced functional compensation due to the involvement of other joints, patients with arthritis with less than  $20^\circ$  flexion-extension in other foot joints, and patients that refuse arthrodesis. These main indications suggest that for the success of total ankle arthroplasty the patient's level of activity must be moderate and therefore the mechanical stress on the prosthesis must also be low. For that reason it is important to assess and correct any deformities in the hip or knee beforehand, as they



**Figure 2b.** X-rays at 6 years follow-up following total ankle replacement with BOX implant.



**Figure 3a.** 39 years old female with less than  $20^\circ$  in other footjoints in club foot sequelae.



**Figure 3b.** X-Rays at 7 years follow-up following total ankle replacement with BOX implant.

may be a cause of overloading. Other contraindications to this type of surgery are varus or valgus deviation of the hindfoot and instability due to capsulo-ligamentous imbalance. These contraindications can be overcome by treatment before or during the total ankle arthroplasty procedure. Absolute contraindications are marked osteoporosis, especially in the talus, because it may cause subsidence in the talar component, severe neurological disorders, severe vascular disorders, and infective processes in progress.

The main objectives of total ankle arthroplasty are to resolve the pain, achieve joint range of movement in terms of joint excursion and kinetics and kinematics, and restore the original stability of the joint. Besides these main objectives, there is the desire to have a prosthesis that will survive as long as those of the hip and knee. The clinical results of this new device have demonstrated safety and efficacy. The present survival rate at 6,4 years (97.1%) compares very well with multi-centre 5-year rates published by the Swedish [18] (531 cases, survival 78%), Norwegian [19] (257, 89%) and New Zealand [20] (202, 86%) registries. In addition, type and number of complications, range of motion, and X-ray analyses are 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 caused at several different joint levels.

The extensive meta-analysis by Stengel et al. [43] provides a convenient basis for comparison of the clinical results. The overall AOFAS score improvement in the present trial patient population is similar to that of the meta-analysis. However, the most encouraging figure is the absence of device-related revisions at short term, which compares very well with the typical long list of failures [44]. It has been reported [37] that revisions can occur at 2, 5, 8, 9, 10, 11, 12, and 21 months even in a series of 122 patients with 1 to 3 year follow-up. A recent study [45] reports a 8.2% revision rate in a population of 49 TAA at a mean followup time of 28 months (12 to 67). A most recent study [46] reports 8% revisions in a population of 200 TAA at a mean followup time of 54 (36 to 85) months. Range of motion and AOFAS here reported compare well also with Haddad et al. [47]. Finally the very little signs of progressive radiolucency reinforce further the claim of a robust overall implant.

We are aware that a recent literature stated that AOFAS score may be inappropriate and this represents a limitation of our study. On the other hand most of the International case series form national registry used this score imposing us to adopt it in the evaluation of our patients [48].

In conclusion, a new TAA was designed to restore physiological function at the replaced ankle joint. Surgical results are encouraging,

demonstrating intra-operatively the suitability of the prosthetic components, the operative technique and the surgical instruments. While reproducing physiologic ankle mobility, the new design maintains complete congruence of the articulating surfaces over the entire motion arc, with the prospect of minimizing wear. Clinical outcomes at 6,4 years are encouraging but a longer follow-up is required.

## References

1. Kempson GE, Freeman MA, Tuke MA (1975) Engineering considerations in the design of an ankle joint. *Biomed Eng* 10: 166-171.
2. Freeman MA (1976) Current state of total joint replacement. *Br Med J* 2: 1301-1304.
3. Lachiewicz PF (1994) Total ankle arthroplasty. Indications, techniques, and results. *Orthop Rev* 23: 315-320.
4. Rush J (1996) Management of the rheumatoid ankle and hindfoot. *Current Orthopaedics* 10: 174-178.
5. Conti SF, Wong YS (2001) Complications of total ankle replacement. *Clin Orthop Relat Res* : 105-114.
6. Kofoed H, Sørensen TS (1998) Ankle arthroplasty for rheumatoid arthritis and osteoarthritis: prospective long-term study of cemented replacements. *J Bone Joint Surg Br* 80: 328-332.
7. Pyevich MT, Saltzman CL, Callaghan JJ, Alvine FG (1998) Total ankle arthroplasty: a unique design. Two to twelve-year follow-up. *J Bone Joint Surg Am* 80: 1410-1420.
8. Neufeld SK, Lee TH (2000) Total ankle arthroplasty: indications, results, and biomechanical rationale. *Am J Orthop (Belle Mead NJ)* 29: 593-602.
9. Saltzman CL, McIlff TE, Buckwalter JA, Brown TD (2000) Total ankle replacement revisited. *J Orthop Sports Phys Ther* 30: 56-67.
10. Gould JS, Alvine FG, Mann RA, Sanders RW, Walling AK (2000) Total ankle replacement: a surgical discussion. Part I. Replacement systems, indications, and contraindications. *Am J Orthop (Belle Mead NJ)* 29: 604-609.
11. Gould JS, Alvine FG, Mann RA, Sanders RW, Walling AK (2000) Total ankle replacement: a surgical discussion: Part II: The clinical and surgical experience. *Am J Orthop* 29: 675-682.
12. Giannini S, Leardini A, O'Connor JJ (2000) Total ankle replacement: review of the designs and of the current status. *Foot Ankle Surg* 6: 77-88.
13. Easley ME, Vertullo CJ, Urban WC, Nunley JA (2002) Total ankle arthroplasty. *J Am Acad Orthop Surg* 10: 157-167.
14. Anderson T, Montgomery F, Carlsson A (2003) Uncemented STAR total ankle prostheses. Three to eight-year follow-up of fifty-one consecutive ankles. *J Bone Joint Surg Am* 85-85A: 1321-9.
15. Buechel FF Sr, Buechel FF Jr, Pappas MJ (2003) Ten-year evaluation of cementless Buechel-Pappas meniscal bearing total ankle replacement. *Foot Ankle Int* 24: 462-472.
16. Natens P, Dereymaeker G, Abbara M, Matricali G (2003) Early results after four years experience with the S.T.A.R. uncemented total ankle prosthesis. *Acta Orthop Belg* 69: 49-58.
17. Wood PL, Deakin S (2003) Total ankle replacement. The results in 200 ankles. *J Bone Joint Surg Br* 85: 334-341.
18. Henricson A, Skoog A, Carlsson A (2007) The Swedish Ankle Arthroplasty Register: An analysis of 531 arthroplasties between 1993 and 2005. *Acta Orthop* 78: 569-574.
19. Fevang BT, Lie SA, Havelin LI, Brun JG, Skredderstuen A, et al. (2007) 257 ankle arthroplasties performed in Norway between 1994 and 2005. *Acta Orthop* 78: 575-583.
20. Hosman AH, Mason RB, Hobbs T, Rothwell AG (2007) A New Zealand national joint registry review of 202 total ankle replacements followed for up to 6 years. *Acta Orthop* 78: 584-591.
21. SooHoo NF, Zingmond DS, Ko CY (2007) Comparison of reoperation rates following ankle arthrodesis and total ankle arthroplasty. *J Bone Joint Surg Am* 89: 2143-2149.

22. Guyer AJ, Richardson G (2008) Current concepts review: total ankle arthroplasty. *Foot Ankle Int* 29: 256-264.
23. Chou LB, Coughlin MT, Hansen S Jr, Haskell A, Lundeen G, et al. (2008) Osteoarthritis of the ankle: the role of arthroplasty. *J Am Acad Orthop Surg* 16: 249-259.
24. Cracchiolo A 3rd, Deorio JK (2008) Design features of current total ankle replacements: implants and instrumentation. *J Am Acad Orthop Surg* 16: 530-540.
25. Younger A, Penner M, Wing K (2008) Mobile-bearing total ankle arthroplasty. *Foot Ankle Clin* 13: 495-508, ix-x.
26. Deorio JK, Easley ME (2008) Total ankle arthroplasty. *Instr Course Lect* 57: 383-413.
27. Leardini A, Catani F, Giannini S, O'Connor JJ (2001) Computer-assisted design of the sagittal shapes of a ligament-compatible total ankle replacement. *Med Biol Eng Comput* 39: 168-175.
28. Leardini A, Moschella D (2002) Dynamic simulation of the natural and replaced human ankle joint. *Med Biol Eng Comput* 40: 193-199.
29. Leardini A, O'Connor JJ, Catani F, Giannini S (2004) Mobility of the human ankle and the design of total ankle replacement. *Clin Orthop Relat Res* : 39-46.
30. Leardini A, O'Connor JJ, Catani F, Giannini S (1999) Kinematics of the human ankle complex in passive flexion; a single degree of freedom system. *J Biomech* 32: 111-118.
31. Leardini A, O'Connor JJ, Catani F, Giannini S (1999) A geometric model of the human ankle joint. *J Biomech* 32: 585-591.
32. Leardini A, O'Connor JJ, Catani F, Giannini S (2000) The role of the passive structures in the mobility and stability of the human ankle joint: a literature review. *Foot Ankle Int* 21: 602-615.
33. Leardini A, O'Connor JJ (2002) A model for lever-arm length calculation of the flexor and extensor muscles at the ankle. *Gait Posture* 15: 220-229.
34. Corazza F, O'Connor JJ, Leardini A, Parenti Castelli V (2003) Ligament fibre recruitment and forces for the anterior drawer test at the human ankle joint. *J Biomech* 36: 363-372.
35. Calderale PM, Garro A, Barbiero R, Fasolio G, Pipino F (1983) Biomechanical design of the total ankle prosthesis. *Eng Med* 12: 69-80.
36. Bauer G, Eberhardt O, Rosenbaum D, Claes L (1996) Total ankle replacement: Review and critical analysis of the current status. *Foot Ankle Surg* 2: 119-126.
37. Hintermann B, Valderrabano V, Dereymaeker G, Dick W (2004) The HINTEGRA ankle: rationale and short-term results of 122 consecutive ankles. *Clin Orthop Relat Res* : 57-68.
38. Bonnin M, Judet T, Colombier JA, Buscayret F, Graveleau N, et al. (2004) Midterm results of the Salto Total Ankle Prosthesis. *Clin Orthop Relat Res* : 6-18.
39. Kofoed H (2004) Scandinavian Total Ankle Replacement (STAR). *Clin Orthop Relat Res* : 73-79.
40. Wood PL, Crawford LA, Suneja R, Kenyon A (2007) Total ankle replacement for rheumatoid ankle arthritis. *Foot Ankle Clin* 12: 497-508, vii.
41. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, et al. (1994) Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. *Foot Ankle Int* 15: 349-353.
42. Giannini S, Vannini F, Faldini C, Bevoni R, Nanni M, et al. (2007) The minimally invasive hallux valgus. *Interact Surg* 2: 17-23.
43. Stengel D, Bauwens K, Ekkernkamp A, Cramer J (2005) Efficacy of total ankle replacement with meniscal-bearing devices: a systematic review and meta-analysis. *Arch Orthop Trauma Surg* 125: 109-119.
44. Ingrosso S, Benedetti MG, Leardini A, Casanelli S, Sforza T, et al. (2009) GAIT analysis in patients operated with a novel total ankle prosthesis. *Gait Posture* 30: 132-137.
45. Schutte BG, Louwerens JW (2008) Short-term results of our first 49 Scandanavian total ankle replacements (STAR). *Foot Ankle Int* 29: 124-127.
46. Wood PL, Sutton C, Mishra V, Suneja R (2009) A randomised, controlled trial of two mobile-bearing total ankle replacements. *J Bone Joint Surg Br* 91: 69-74.
47. Haddad SL, Coetzee JC, Estok R, Fahrbach K, Banel D, et al. (2007) Intermediate and long-term outcomes of total ankle arthroplasty and ankle arthrodesis. A systematic review of the literature. *J Bone Joint Surg Am* 89: 1899-1905.
48. Pinsker E, Daniels TR (2011) AOFAS position statement regarding the future of the AOFAS Clinical Rating Systems. *Foot Ankle Int* 32: 841-842.