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The Bologna-Oxford ankle replacement: a case series of clinical and radiological outcomes

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Abstract

Purpose The Bologna-Oxford (BOX®) total ankle arthroplasty (TAA) is a three-component mobile-bearing implant gaining popularity in Europe. We aimed to analyse the outcomes of this TAA.

Methods We retrospectively analysed data on 34 consecutive BOX® TAAs performed at a single centre with a mean follow-up of 58 months. Radiographic outcomes, such as periprosthetic lucency and alignment, were measured and recorded. Prospectively captured clinical scores and range of movement (ROM) were also recorded.

Results There were significant improvements in patient-reported outcome scores recorded in the Manchester-Oxford Foot Questionnaire (MOxFQ) for pain (43.8 ± 20.2, $p < 0.001$), standing and walking (55.6 ± 19.8, $p < 0.001$), social activities (45.0 ± 26.9, $p < 0.02$) and visual analogue score (VAS) (3.1 ± 2.5, $p < 0.001$). Mean improvement in ROM postoperatively was 18.7° ($p < 0.001$), with post-operative dorsiflexion 8.8° (10°–25°) and plantar flexion 32.6° (20°–40°). There was evidence of asymptomatic lucency on five radiographs (15%), which was present in 10% at three years. Nine patients had complications (26%): six (18%) requiring secondary surgery and one requiring revision (3%) for infection.

Conclusions We have demonstrated 97% survivorship at a mean of 58 months. There are maintained improvements in clinical and radiological outcomes and reoperation that are consistent with the literature.

Keywords Mobile bearing · Loosening · Range of movement · Alignment

Introduction

Ankle osteoarthritis (OA) causes pain and disability with an incidence of 47.7 per 100,000 in the UK [1]. Ankle arthrodesis and total ankle arthroplasty (TAA) are both accepted treatments for end-stage OA of the ankle [2–4]. Successful TAA leads to many socioeconomic benefits, including earlier return to work, pain relief and better function of the ankle joint [5, 6]. Longer-term data suggests that the midterm outcome of TAA appears to be similar to that of ankle arthrodesis [7]. However, even with the new generation of TAAs, revision rates continue to be twice as high as those seen in total hip and knee replacements [8].

The BOX® Ankle is a three part TAA implant with an interposed mobile meniscal bearing. It is placed with extramedullary reference guides. According to the UK National Joint Registry, the popularity of the Bologna-Oxford (BOX® Ankle, MatOrtho, Ltd., Leatherhead, UK) implant is increasing; in 2011, the BOX® implant was used in 5.6% of cases in the UK, but in 2016, it was used in 18% of cases [9]. It is the second most commonly used TAA in the UK.

Our aim was to report the short- to medium-term clinical and radiological outcomes of the BOX® TAA from a single independent centre.

Level of Evidence: case series (level 4)

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Patients and methods

Following our local Institutional Review Board approval, this study was performed as a retrospective analysis. Thirty-four consecutive BOX® ankle replacements were performed at a

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single centre by two surgeons experienced in TAA. Patient demographics, body mass index (BMI) and medical comorbidities were recorded. The aetiology of arthritis was classified into post-traumatic OA (postinstability or fracture); inflammatory (rheumatoid arthritis or other inflammatory OA) and where no cause was found, primary OA. All patients had a minimum two year follow-up. Our key primary outcome measures included clinical outcome scores, radiological lucency and complications. Secondary outcome measures included range of movement and radiological alignment.

Clinical outcomes

The pre-operative range of movement was assessed during the clinic appointment before surgery and post-operatively using a validated technique [10]. Surgical time was also recorded for each patient as well as any adjunct surgical procedures. Pre- and post-operative clinical scores included the EQ5D-5L (EuroQol 5-Dimensions, 5-Likert), the Manchester-Oxford Foot Questionnaire for pain, social function and walking (MOxFQ) [11, 12] and visual analogue score for pain (VAS). Scores were captured pre-operatively and at three, six and 12 months post-operatively followed by annually thereafter.

A standard operative technique was used as previously described [13]. All patients were placed in nonweight-bearing plaster for two weeks, followed by a full-weight-bearing plaster for four weeks. All patients received chemical and mechanical thromboprophylaxis for the duration of time in plaster. The plaster was removed at the six week mark and physiotherapy initiated.

Radiographic measurements (Fig. 1)

Each patient had an intraoperative radiograph and a further radiograph within six months following the surgery. After this, a radiograph was taken annually. All radiographs were assessed pre-operatively to look for any tibial deformity. Standardised weight-bearing antero-posterior (AP), mortise and lateral radiographs were used and captured on a digital picture archiving and communication system (PACS, McKesson, UK). All measurements were performed independently by two authors (AN and KM), blinded to each other's measurements.

Serial radiographs were assessed to identify the presence of aseptic loosening. This was defined as the presence of a periprosthetic lucency of more than 2 mm in width, cavitation at the margin of a component or hardware subsidence of at least 4 mm compared with previous radiographs [14, 15].

The most recent radiograph of the individual patient was used for assessment of alignment. The alignment of components in the coronal plane was measured according to previously published techniques (Fig. 1) [16–19]. Alignment was measured on ankle radiographs at a distance of 10 cm proximal to the tibial plafond, in line with the anatomical axis of the tibia. Coronal ankle alignment (varus/valgus) was determined on AP radiographs by measuring the angle between the vertical axes of the tibial shaft and the tibial plafond (before surgery) or the tibial component (after surgery) (lateral distal tibial angle, LDTA). All measurements were calculated relative to the anatomical axis.

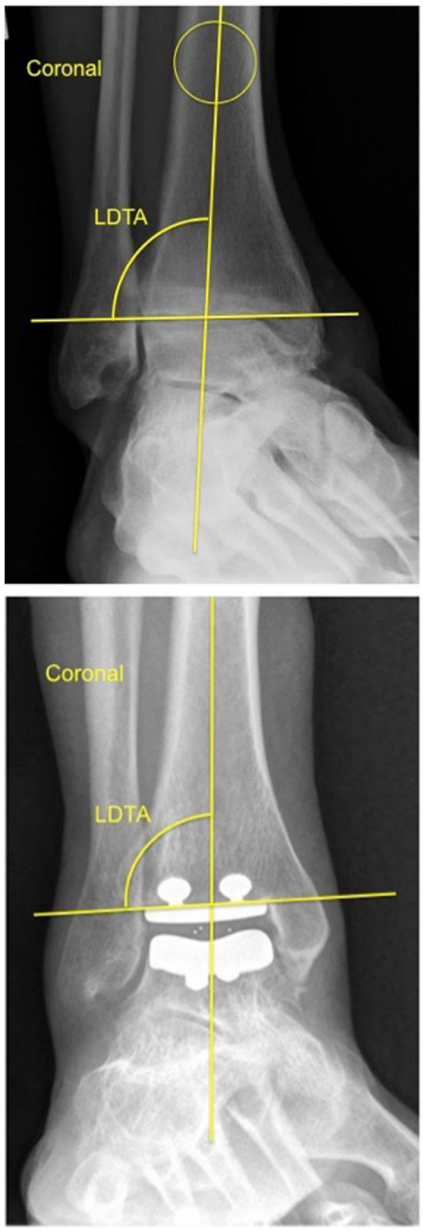

Fig. 1 Method to calculate the LDTA on the pre-operative (top image) and post-operative (bottom image) coronal radiographs

Differences between groups were evaluated using paired *t* tests and repeated-measures analysis of variance (ANOVA) (SPSS version 22.0, Chicago, IL). All data was normally distributed (Kolmogorov-Smirnov test). Significance was set at $p < 0.05$. Interobserver reliability was assessed using kappa coefficients.

Complications

All complications were recorded. Major complications included wound infection, deep infection, aseptic loosening, malalignment, nerve or tendon injury, venous thromboembolism and periprosthetic fracture. Minor complications such as stiffness, loose bodies and heterotopic ossification were noted.

Our definition of revision is that proposed by Henricson et al. which is 'any operation leading to exchange or removal of any of the prosthetic components with the exception of incidental exchange of the polyethylene insert in a mobile bearing (three-component) ankle replacement' [20]. All other secondary procedures on the ipsilateral ankle or foot are recorded as re-operations other than revision.

Results

Patient demographics

Thirty-four consecutive patients were included. No patients were excluded. The mean age was 58 years (range 30–78), with a BMI of 27.8 kg/m^2 (range 21.8–41.3). Sixteen were males (47%) and 18 were females (53%). Twenty-two patients suffered from post-traumatic osteoarthritis (65%), 10 patients had inflammatory arthritis (29%) and two patients had primary osteoarthritis (6%).

Three of the patients had previously undergone a triple fusion, and two had a previous talonavicular joint fusion. In these patients, they all had a pain-free ankle at their latest follow-up, with none of them showing radiological lucency on their latest radiographs. At the time of their ankle replacement, 16 patients had additional surgical procedures (47%). Fifteen patients had a Hoke Achilles tendon lengthening procedure (44%), and one patient had a lateral ligament reconstruction (3%). The mean tourniquet time was 112 minutes (range 90–173). The mean follow-up was 58 months (range 24–90 months).

Clinical outcome

Mean improvement in ROM post-operatively was 18.7° ($p < 0.001$). There was a mean improvement in plantar flexion of 13.8° and a mean increase in dorsiflexion of 7.4° ($p < 0.001$). Post-operative dorsiflexion was 8.8° (10°–25°), and plantar flexion was 32.6° (20°–40°) (Table 1).

There were significant improvements in patient-reported outcome scores recorded with mean improvements in MOxFQ for pain (43.8 ± 20.2, $p < 0.001$), standing and walking (55.6 ± 19.8, $p < 0.001$) and social activities (45.0 ± 26.9, $p < 0.02$) and VAS (3.1 ± 2.5, $p < 0.001$) (Table 1). There are clinical improvements which are not significant in EQ5D-5L and EQ-VAS scores.

There was no significant difference in the range of movement, radiographic measurements and clinical scores between the inflammatory arthritis patients and post-traumatic osteoarthritis patients.

Radiographic outcomes

The pre- and post-operative coronal alignments of the TAA are outlined in Table 1. The LDTA in the coronal plane was maintained. An example of a patient with no pain in her ankle at seven years of follow-up is shown in Fig. 2. She had maintained alignment on the AP and lateral radiographs and had no evidence of lucency or cyst formation.

Four patients had previous tibial fractures with malunion. There was an angular deformity in all four patients. In this group, the post-operative coronal alignment was 88.8° (range 85°–92°). There was no significant difference in alignment between those with or without tibial deformity ($p = 0.36$).

There was evidence of asymptomatic radiological lucency or migration on five radiographs (15%). Mean time to

Table 1 Comparison of pre- and post-operative ankle range of movement, radiographic results and clinical scores (mean (range) degrees)

		Pre-operative (range)	Post-operative (range)	*p* value
Ankle range of movement (degrees)	Plantar flexion	18.8 (10–25)	32.6 (20–40)	**< 0.001**
	Dorsiflexion	1.4 (−15–10)	8.8 (0–20)	**< 0.001**
Alignment (degrees)	Coronal (lateral distal tibia angle, LDTA)	88.4 (81–97)	88.4 (81–93)	0.43
Clinical scores	EQ-5D-5L	0.51 (0.018–0.691)	0.65 (0.318–1.0)	0.09
	EQ-VAS	67 (40–99)	69 (15–96)	0.47
	MOxFQ (pain)	69.6 (30–100)	43.8 (5–85)	**< 0.001**
	MOxFQ (walking)	83.49 (38–100)	55.6 (21–100)	**< 0.001**
	MOx(FQ) (social)	60.0 (25–100)	45.0 (0–100)	**0.02**
	VAS (pain)	7.2 (5–10)	3.1 (0–7)	**< 0.001**

The bold *p* values highlight whether the differences observed were statistically significant

EQ5D-5L EuroQol 5-Dimensions, 5-Likert, *MOxFQ* Manchester-Oxford Foot Questionnaire, *VAS* visual analogue score

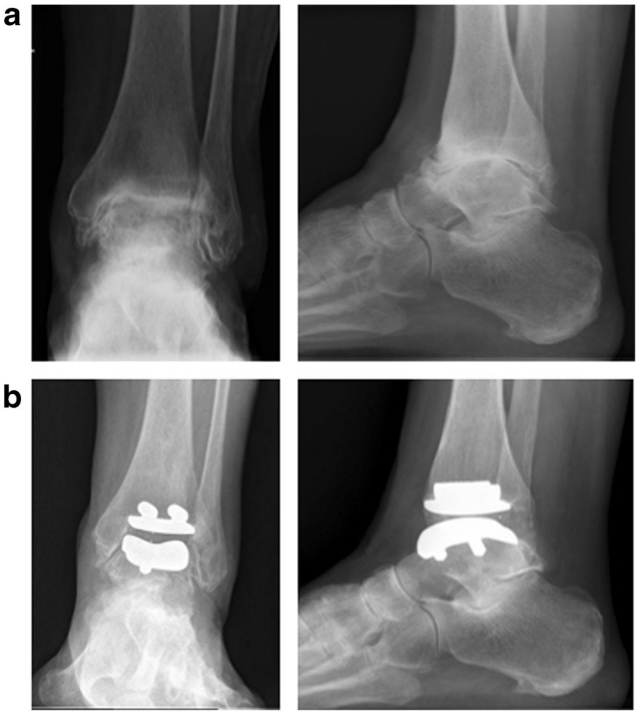

Fig. 2 Pre-operative (**a**) and post-operative (**b**) coronal and sagittal radiographs of a patient with excellent outcome at 7 years postsurgery. The patient had an excellent range of motion, no pain and no radiological evidence of lysis

radiological lucency was 30 months. It was present in 7% of patients at two years and 10% at three years. There was no significant difference in outcome scores between those with asymptomatic radiological lucency and those with normal radiographs.

Radiographic measurements were performed twice in separate sessions. There was excellent interobserver reliability (kappa coefficient 0.81).

Complications

One patient required revision (3%) in the time frame of follow-up. Nine patients had some form of complication (26%) (Table 2). Six patients (18%) required secondary surgery known as 're-operation other than revision', since it did not involve removal of any of the components. The complication rate was 6% at one year, 15% at two years and 26% at eight years. In 3% of patients, the complications were intra-operative, in 3% they were early (within 28 days) and in 20% they were late. Re-operation rate (other than revision) was 3% at 12 months, 9% at 24 months and 18% at eight years.

Two patients (6%) had a deep infection. One patient presented with an acute haematogenous septic arthritis, 16 months after uncomplicated TAA surgery. He underwent a DAIR (debridement, antibiotics, irrigation and retention of implants) with exchange of liner and six weeks of intravenous antibiotics and six weeks of oral antibiotics. He was asymptomatic after three years of follow-up and has required no further intervention. The other patient underwent a two-stage revision procedure 37 months after the initial procedure for a polymicrobial infection (Fig. 3). She was revised to a tibiotalocalcaneal (TTC) fusion with an intramedullary device alongside a free flap for wound coverage following wound breakdown and superficial peroneal nerve symptoms. After 12 months, the construct had clinically united, and the patient had returned to work. She had ongoing superficial peroneal

Table 2 Outline of complications

Complication	Frequency	Percentage	Time of secondary procedure after AA surgery (mean months (range))	Further information
Deep infection; revision surgery	1	3	37	2-stage revision procedure to fusion
Wound breakdown	1	3	1	Required free flap 1 month after TAA surgery. Healed well with no further problems
Deep infection; DAIR	1	3	27	Asymptomatic at 3 years of follow-up
Periprosthetic fracture	1	3	0	Medial malleolus plated at the time of TAA surgery—no further complications
Tibialis posterior (TP) tendon injury	1	3	13	TP repaired. No further complications
Malalignment	1	3	20	Supramalleolar osteotomy for persistent pain 20 months after the first procedure. This patient had no further complications
Loose bodies requiring gutter debridement	1	3	26	He recovered well with no further complications
Heterotopic ossification	2	6	N/A	No surgery performed

N/A not applicable

nerve symptoms at four years of follow-up. The Kaplan-Meier survival curve is shown in Fig. 4.

Two patients were found to have posterior heterotopic ossification: one was asymptomatic, and the other had stiffness. They presented at 24 and 36 months, respectively. Neither patient required surgery. There were no venous thromboembolic or neurological complications.

Discussion

The purpose of this nondesigner case series was to demonstrate the short- to medium-term outcomes in a TAA which is increasing in popularity. Comparisons of different TAAs can guide surgeons towards using favourable prostheses with less complications such as infection, osteolysis and loosening, which remain a problem after TAA [21]. Our results demonstrate a 97% survivorship at a mean follow-up of 58 months

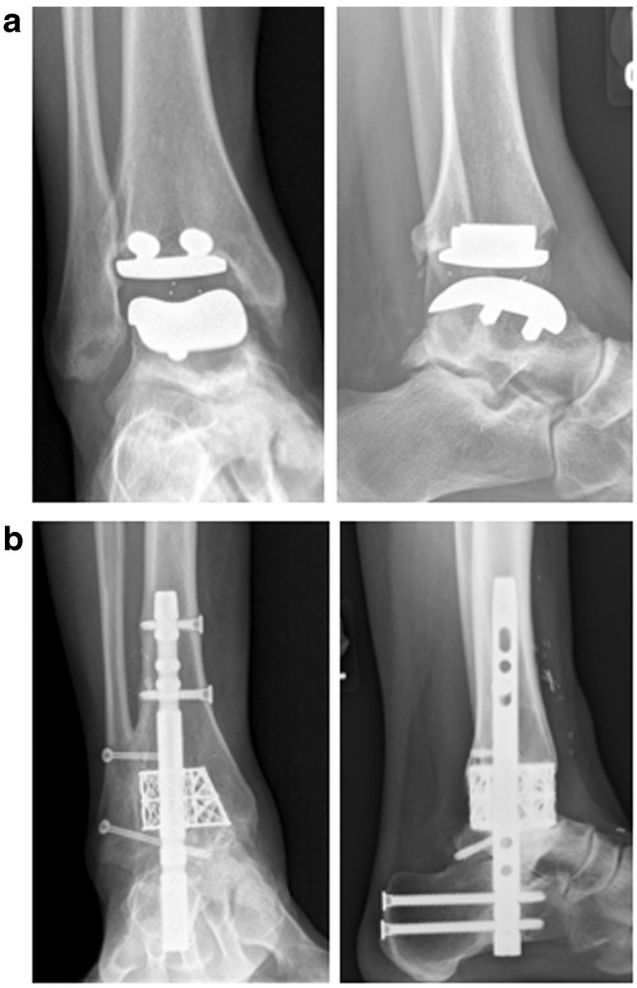

Fig. 3 A deep infection occurred in one patient. Preoperative coronal and sagittal radiographs are shown in **a**. There was extensive lysis beneath the talar component with significant bone loss. The patient underwent revision to a tibiotalocalcaneal (TTC) fusion with a custom cage using patient specific instrumentation (**b**)

for the primary BOX® TAA. Nine patients had some form of complication (26%), only one of which required revision of the primary implant (3%). Other studies looking at the BOX® TAA have shown survivorship of 92–97% at three to four years and improvements in clinical scores form pre- to post-operatively [13, 22, 23], and hence, our results are consistent with the literature. Other implants have demonstrated revision rates of 10–14% at five years [24, 25], and hence, the BOX® implant appears to have comparable outcomes to other modern implant designs [5, 13, 22]. To our knowledge, this is the first nondesigner series describing the results of the BOX® TAA and highlights the equivalent efficacy compared with other TAA designs.

We have demonstrated significant improvements in range of movement and clinical scores post-operatively. A mean dorsiflexion of 8.8° was present at final assessment which compares with other published results [22, 23]. Pedowitz et al. showed that a mean total arc of movement was 34.2° in the TAA cohort (Salto Talaris) with increased functional scores compared with ankle arthrodesis [26]. Better range of movement and walking speed is likely to have a positive impact on clinical scores, as demonstrated by the improvement in function and pain [27]. These outcomes have been shown across mobile- and fixed-bearing implants; the improvements in ROM may be a reflection of the physiological AP translation of the flexion axis and the stability throughout the ROM.

Radiological lucency has been described to be 23% at 4.4 years [5]. Bianchi et al. described the rate of radiological lucency to be 32% at mean 42.5 months of follow-up, although they have included all major complications [22]. Our series seems to demonstrate a lower rate of lucency, although we excluded the two patients with infection from this number, and not all patients were followed up to eight years.

A systematic review of the literature showed that the overall rate of complications following primary TAA was 13.5% based on a systematic review of the literature. This includes a re-operation (other than revision) rate of 2.7% after 12 months, as well as deep infection in 1.1% and medial malleolar fracture in 6% [5]. Younger et al. found a re-operation rate of 25.2% in patients with a minimum two year follow-up [28] which is consistent with our findings. In this study, we used the definition of revision proposed by Henricson et al., whereas other surgery such as joint debridement, washout or adjacent joint surgery would constitute a re-operation other than revision [20, 29]. Our re-operation rate at 12 months following the primary procedure was 6% which is slightly lower than that described by Zaidi et al., who reviewed the UK National Joint Registry data and showed a rate of re-operation other than revision within 12 months of the primary procedure of 6.6% [5]. Giannini et al. reported a 4.4% rate for secondary procedures [13]. Bianchi et al. reported 11% of patients with a BOX® TAA required secondary surgery [22]. Odum et al. [30] found that major early complications occurred in 5.3%,

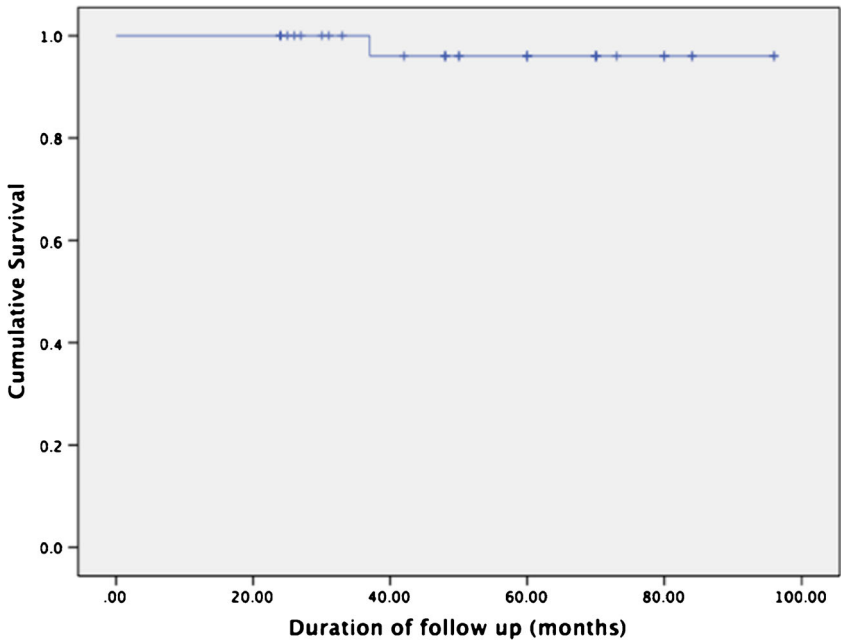

Fig. 4 Kaplan-Meier curve for survival analysis of BOX TAA

whereas a minor early complications were found in 5.9% of patients. This study shows a higher rate of complications, but this is because our reporting is over a longer period of time and includes all minor complications. It is also possible that other papers might be under reporting complications. No patients sustained a venous thromboembolism, although all patients were on chemical and mechanical thromboprophylaxis whilst in plaster. This topic remains controversial [31, 32].

The small sample size and short follow-up are clearly a limitation of this study. We were unable to draw conclusions about subgroups, such as BMI, tibial deformity or inflammatory arthritis, due to small numbers. The large ranges in the outcome scores reflect the small number of patients in the study and the type 2 error; a larger study would have demonstrated post-operative improvements more accurately. Longer-term follow-up is ongoing. Strengths include our status as a nondesigner centre, where other TAA designs were also being used, which reduces designer or selection bias. Recall bias was also not an issue due to electronic records and contemporary patient-reported outcome measures.

Conclusion

The BOX® TAA has demonstrated 97% survivorship at a mean 58 months with improvements in clinical and radiological outcomes. It preserves motion and provides improved function and pain relief. Secondary surgery rates and complication rates seem to be consistent with other modern implant designs. We recommend standardised reporting of ankle replacement complications to obtain a true reflection of the outcomes of this technology.

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