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Six year results of the Rebalance mobile bearing total ankle replacement

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ABSTRACT

Background: We report the outcomes of a prospective consecutive series of 267 total ankle replacements (TARs) using a new mobile bearing Rebalance® prosthesis.
Methods: Between April 2011 and December 2018, 267 consecutive Rebalance® prostheses were implanted in 255 patients at 3 different centers. Estimated survival curves with 95% confidence intervals were produced with the Kaplan–Meier method. 110 ankles were followed for at least 5 years and clinical and radiological outcomes were assessed in 92 of these ankles.
Results: Twenty-one ankles were revised at a mean of 34 (7–60) months. The estimated survival was 90% (95% CI 86–95) at 5 years and 88.3% (95% CI 83.–94 at 6 years. The ankles followed for at least 5 years demonstrated a median Likert score of 1 (1–4). Radiolucent zones were detected in 14% and osteolytic cysts in 3%.
Conclusion: The survival rate of the Rebalance prosthesis conforms with other reports of similar designs. The satisfaction rate was high. Radiological zones and osteolytic cysts were found at a lower rate than usually reported for mobile bearing TARs. These results favour further use of this implant.

1. Introduction

Total ankle replacement (TAR) is a well established treatment of disabling ankle arthritis. The third generation design with uncemented tibial and talar components a and mobile bearing was introduced by Buechel et al. as the LCS prosthesis (DePuy, Warsaw, Indiana, USA) in 1981 and as the Buechel-Pappas (BP) prosthesis (Endotec, Orange New Jersey, USA) in 1991 [1]. Kofoed developed the Scandinavian Total Ankle Replacement (STAR) (Stryker, Mahwah, New Jersey, USA) as an uncemented design in 1990 [2]. These inventors have reported survival rates of 92% and 95% respectively at 12 years [1,2]. Independent researchers have reported 4–5 years survival for the STAR prosthesis of 90–96% [3–5], and of 64–90% at 10 years or more [4–8]. For the Mobility prosthesis (DePuy International, Leeds, United Kingdom) survival rates at 4–5 years of 78–95% have been reported [9–12]. Non-inventor analysis of the Hintegra design (NewDeal, Lyon, France) showed 90% survival at 4–5 years [9]. The Salto mobile bearing prosthesis (Tornier SA, Saint Ismier, France) achieved 4–5 year survival of 94–95% in independent reports [13–15].

This study presents the design, clinical, and radiological outcome of a new mobile bearing total ankle replacement, the Rebalance prosthesis (Zimmer-Biomet, Warsaw, Indiana, USA). We asked whether the changed design and coating will results in less problems with osteolysis and improved implant.

2. Patients and methods

This study is prospective with two hundred and sixty-seven total ankle replacements with the Rebalance prosthesis performed in 255 patients between April 2011 and December 2018. All procedures were performed at 3 centers by the authors, either by themselves or with them as assistants to another experienced foot and ankle surgeon. There were 145 women and 110 men with a mean age of 61 (20–83) years. The diagnoses were posttraumatic arthritis in 124, primary osteoarthritis in 47, rheumatoid arthritis in 90, psoriatic arthritis in 4, and pigmented villonodular synovitis in 2 ankles. Mean follow-up time was 4.2 years (0.1–7.7). 246 ankles (92%) have been followed for 1 year or more and 110 ankles for at least 5 years.

Clinical and radiological follow-ups were done at 6 months, 1, 2, 3, 5, and 7 years and are also scheduled at 10 years. For 112

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consecutive patients from one center and the first 50 consecutive patients from another center the AOFAS score was registered. One center did not use this score and another stopped at 50 patients because the AOFAS score was considered inadequate in rheumatoid arthritis patients, many of them treated with hip and/or knee arthroplasty or changing medication during the follow-up period. All patients with follow-up of 5 years or more were asked to grade their satisfaction according to the Likert scale – very satisfied (1), satisfied (2), neither satisfied or dissatisfied (3), dissatisfied (4) or very dissatisfied (5). They were also asked if they would recommend the procedure to a friend. The radiographs were plain radiographs and were assessed by the authors. Any radiolucent zones and osteolytic lesions were detected.

The Rebalance prosthesis has a three component meniscal bearing design. It is mainly an expansion of the AES total ankle replacement (Biomet, Nimes, France) which was withdrawn from the market due to high incidence of osteolytic lesions. The hydroxy-apatite coating of this prosthesis was considered to be the one of main causes of the osteolytic lesions due to delamination [16]. The coating technique has therefore changed. The tibial and talar components are chrome-cobalt alloy coated with Porous Plasma Spray Titanium alloy (PPS) and then coated with hydroxyapatite with an electro-chemical method (Bonemaster®). Furthermore is the talar component equipped with two pegs instead of rails in order to enhance the stability of the component. The length of the tibial stem is decreased from 30 mm to 20 mm implying smaller cortical window when inserting the component. The polyethylene meniscal component is vitamin-E treated. The tibial component has a flat polished bearing surface. The stem has a triangular shape with rounded edges. The talar component is sulcus shaped with the pegs angled in a posterior direction. The polyethylene bearing is flat proximally and sulcus-shaped distally. The tibial and talar components are available in 5 different sizes and the polyethylene bearing comes in heights of 3, 5, 7, 9, and 11 mm. The procedure uses the standard anterior access between the tendons of tibialis anterior and extensor hallucis longus. The tibial cut is flat with 5 degrees posterior slope, and the tibial component is inserted through an anterior cortical window for the stem. The talar cut is flat and determined by a special spring-charged instrument, the Rebalancer, which acts both as a spacer and as an alignment guide. Postoperatively the ankle is kept in a plaster and allowed partial weight-bearing with crutches for three weeks. Thereafter a stiff orthosis is applied for another three weeks with weight-bearing as tolerated. After six weeks the patients are free to mobilise with full weight-bearing without any support. The Rebalance total ankle replacement is in limited use as a multicenter pilot study.

Estimated survival curves was calculated with the Kaplan–Meier method (the SAS system). Revision was defined according to Henricson et al. meaning removal or exchange of one or more of the components with the exception of incidental exchange of the polyethylene insert [17].

3. Results

Simultaneous procedures were performed in 55 ankles (21%), subtalar fusion being the most common (Table 1).

Intraoperatively there were 8 (3.1%) complications, 2 fractures of the medial malleolus and 6 fractures of the lateral malleolus. All healed after perioperative screws or pins intramedullary.

Postoperative complications occurred in 13 (4.9%) ankles. Fractures of the medial malleolus in 3 patients and one fracture of the lateral malleolus after trauma were treated conservatively with plaster and all healed. One stress fracture of the distal tibia was treated with plaster as was a stress fracture through the talar neck, and one stress fracture of the medial malleolus was treated with screws. These fractures were all in patients who showed no radiolucency or osteolytic cysts Four superficial wound infections all healed with antibiotics and wound care. There was one deep early infection, which was treated with debridement, antibiotics and implant retention (DAIR) including incidental exchange of the polyethylene insert. One pulmonary embolism was treated with Dalteparin.

Table 1
Simultaneous procedures.

Subtalar arthrodesis	15
Release deltoid ligament	12
Extraction plates/screws	12
Achilles tendon lengthening	6
Talo-navicular arthrodesis	3
Navicular-cuneiform arthrodesis	2
Calcaneal osteotomy	2
Osteotomy medial malleoluos	2
Release gastrocnemius muscle	1
Total	55

Thirty-three secondary non-revisional procedures was performed in 31 patients (Table 2).

There were 21 revisions at a mean of 34 months (range 7–60 months), 3 within the first year, and 8 within the first 2 years. Ten revisions were due to component loosening, 6 of the tibial component, 3 of the talar component and 1 of both components which were treated with exchange of components in 5 cases and a talocrural arthrodesis in 5 cases. No osteolytic cysts were found in these loosenings. Polyethylene breakage was seen in 3 patients, in one patient after ankle fracture, and all were treated with exchange of the insert. Five patients had recurrent varus deformity and instability, 3 of those were fused, the other 2 were treated with ligamentoplasty and calcaneal osteotomy. One recurrent valgus deformity was treated with fusion. Intractable antero-medial pain in one patient was treated with percutaneous augmenting screws in the medial malleolus and further on with changing the insert to a higher one. Another patient was revised with exchange of the tibial component due to technical error with misplaced component.

Estimated survival was 90.% (95% CI 86–95) after 5 years (Fig. 1).

3.1. Ankles with follow-up of 5 years or more

Satisfaction rates were acquired from 92 of the 110 ankles followed 5 years or more, mean 6.4 (5–7.8) years. Twelve ankles were revised, 4 patients were deceased, one patient was too ill to attend, and one patient could not be reached. Eighty-three (90%) patients were satisfied or very satisfied, 7 (8%) were neither satisfied nor unsatisfied, and 2 (2%) were unsatisfied. The median

Table 2
Secondary non-revisional surgery.

Augmenting screws medial malleolous	7
Calcaneal osteotomy	6
Cleaning medial gutter	4
Cleaning gutter bilaterally	3
Achilles tendon lengthening	3
Subtalar arthrodesis	3
Tarsal tunnel release	1
Lengthening tibialis posterior tendon	1
Excision bony overgrowth	1
DAIR	1
Debriding, bone transplantation osteolytic cyst	2
Lateral ligament reconstruction	1
Total	33

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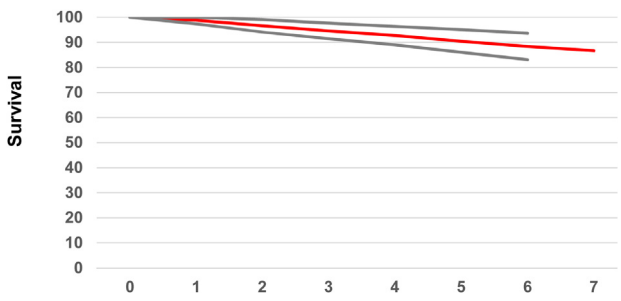

Fig. 1. Kaplan–Meier survival curve with 95% confidence intervals (dotted curves).

Likert score was 1 (1–4). Eighty-four (91%) declared that they would recommend the procedure to friend.

The AOFAS score was obtained in 58 consecutive non-revised patients followed for 5 years. The preoperative score was 49 (19–78) and at 1 year 80 (35–100). This score was retained at 5 years (80 (32–100)).

After 5 years there were no radiolucent zones in 78 patients. In 16 of these there were tiny radiolucent zones during the initial follow-ups, but these were absent at the 3 or 5 year follow-ups. Small, less than 1 mm, non-progressive radiolucent zones was found at 5 years in 13 patients, 11 at the tibial and 2 beneath the talar component. In another patient there were progressive 2–3 mm zones at both components indicating loosening. However this patient refused revision due to other medical issues. Subsidence of the talar component of 1–2 mm appeared in 7 ankles without any radiolucent zones or clinical symptoms. Three osteolytic cysts (defined as being larger than 2 mm) have been cleaned out and filled with bone transplant, all 3 healed with no further cyst formation. Tiny osteolytic areas (less than 2 mm) were seen in 8 cases, all around the tibial component. In 30 patients a double cortical contour at the medial malleolous was noted (Fig. 2).

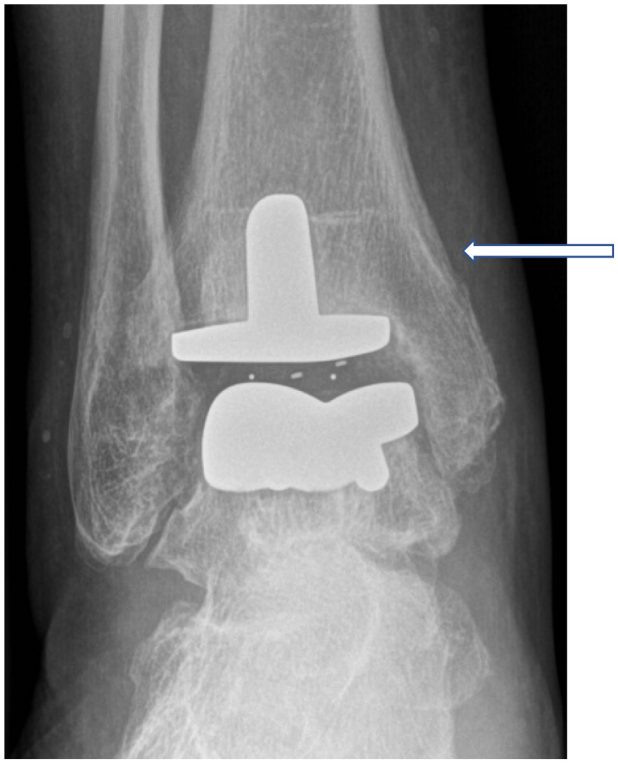

Fig. 2. Double cortical contours at the medial malleolous.

4. Discussion

This study, being one of the largest of mobile bearing TARs, has shown a survival rate of 88% at 6 years for the Rebalance prosthesis. Other studies of comparable designs have found survival rates of 78–98% after 4–5 years [3–5,9–11,13]. However, comparing survival rates from different studies is a troublesome task since different authors use different definitions for revision. The definition used in this study is used by many authors and also by the Swedish Ankle Registry and the National Joint Registry of the UK [7,13,15,17,18]. This definition emphasizes that in a three-component design a procedure for failure of any component is regarded as a revision. Koivu et al. [4] and Palanca et al. [5] did not include polyethylene exchange due to breakage as a revision in their survival analyses implicating that they actually had a lower survival rate than reported in their articles. An appropriate and elegant way of avoiding misunderstandings regarding this issue is the work of Frigg et al. which reports survival analyses using three different definitions of revision, namely 1) exchange of the whole prosthesis or conversion to arthrodesis, 2) exchange of at least one metallic component, or 3) exchange of any component including the inlay (due to breakage or wear) [8].

Six patients were revised due to recurrent deformity mostly in varus. Doets et al. [19] and Wood and Deakin [20] describe failures of mobile bearing TARs in ankles with more than 10–15 degrees of deformity and considered such ankles to be a relative contraindication for TAR. Contrary to these statements Reddy et al. found it possible to achieve neutral alignment in ankles with up to 25 degrees of coronal deformity with simultaneous soft tissue procedures [21]. However, considering our experience and the results of our study we believe that some caution should be considered in ankles with varus deformity.

Satisfaction rates are usually high after TAR. The satisfaction rate of 90% (satisfied or very satisfied) in our study conforms with other published reports. Wood et al. [11] found 97% and Rippstein et al. [22] 96% satisfied patients after 4 years with the Mobility design. In a short term study Jung et al. reported 91% satisfaction for the Hintegra system and 88% for the Mobility [23]. However, Kerkhoff et al. found only 76% satisfaction with the Mobility after 5 years [12]. Recommending the procedure to a friend did 91% of the patients followed for 5 years in our study. Koo et al. found that all patients in their study of the Hintegra system also did so [13]. With the Mobility prosthesis Kerkhoff et al. [13] and Rippstein et al. [22] state that 80% and 97% respectively would undergo the same procedure again.

We used the AOFAS score in two centers for the reason that it is used by many other authors and thus a comparison would be useful. The AOFAS score is much debated and its continued use is not recommended, mainly because of poor construct validity and low reliability [24]. There is also a high potential for researcher bias [25]. The score in this study was 80 after 1 year and this figure was maintained at 5 years. This score is in accordance with other studies. Rippstein et al. found a score of 84 after both 1 and 4 years [21]. Short term follow-ups of the Mobility design showed 75–84 [10,11,23]. Studies of the Salto system found a score of 80 after 4 and 7 years respectively [15,18]. Zaidi et al., in meta-analysis of 27 papers, found a mean AOFAS score of 80 after 8 years [26].

The complexity of TAR surgery is well known and is proven by our rate of simultaneous procedures in 21% of the cases. Other authors have reported rates of 13–52% with the Mobility system [11,12,23,27]. Furthermore there were 12% non-revisional secondary surgery in our study. Sixteen and 8% secondary surgery respectively are reported in other studies [7,21]. In their long-term study Frigg et al. found 41% secondary surgery with the STAR design [8].

Radiolucent zones are a common finding following TAR with a mobile bearing design, most often around the tibial component. In

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the current study radiolucent zones were found in 11% at the tibial component, and in 2% at the talar component. Others report rates of radiolucent zones of 14–48% around the tibial component and 2–7% around the talar component after 4–5 years. [7,10,11,13,15,22,27]. These zones are usually tiny, less than 1 mm, and without symptoms, however Kerkhoff et al. found 9% zones of more than 2 mm after 7,5 years [7]. In their meta-analysis Zaidi et al. found zones in 21% of the tibial component and 1% of the talar component [26].

In a review and meta-analysis Arcangelo et al. found 18% peri-prosthetic bone cysts in 2430 TARs, 66% being mobile bearing designs [28]. The 3% osteolytic cysts in this study is in accordance with other reports of similar designs and follow-ups that found 4–9% cysts after 4–7 years [13,18,22]. Van Wijngaarden et al. suggest that the reason for ostoeolysis might be multifactorial including implant design, biochemical factors, and local anatomic-physiological factors [29]. The three cases in this study that were cleaned and bone transplanted all showed firmly fixed components and no malalignment.

Medial pain after TAR is a rather common feature [22,23,27]. In one third of the cases followed for 5 years in this study double cortical contours at the medial malleolous were found. This might be due to a remodelling process eminating from sub-radiological microfractures or a stress reaction of the bone medially. In 7 patients in this study medial augmenting screws were used for medial pain with good pain relief. Lundeen and Dunaway also described good outcome of secondary augmenting screws in the medial mallelolous [30].

Limitation of this study is the short follow-up even if 41% were followed for at least 5 years. Longer follow-up is needed for more definite conclusions. Another limitation is that not all patients had the AOFAS score performed. The strength of the study is that it is a large consecutive series performed by 3 very experienced non-designer foot and ankle surgeons.

In conclusion, the estimated survival rate of the Rebalance prosthesis (88.3%) at 6 years is comparable with similar designs. Satisfaction rates are high. The rate of radiolucent zones and peri-prosthetic cysts are however lower than in most other reports. These results favour further use of this implant.

Conflict of interest

Dr. Henricson reports personal fees from Zimmer-Biomet, during the conduct of the study. All other authors have nothing to disclose.

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