Acta Orthop. Belg., 2020, **86**, 109-114

ORIGINAL STUDY

Total ankle replacement : comparison of the outcomes of STAR and Mobility

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Total Ankle Replacement is a recognised treatment for end-stage ankle arthritis and an alternative to arthrodesis. This study reviews a single centre series of prospectively collected outcome measures to determine whether the Mobility performs better than the Scandinavian ankle replacement. The primary outcome measure was the survivorship. Secondary outcome measures consisted of complications and international scoring systems.

147 Scandinavian and 162 Mobility ankle replacements were reviewed at a mean follow up of 12.4 and 7.7 years respectively. The revision rate, which included liner exchange, component exchange or removal of implant was at 7 years 12.3% (18) for Scandinavian and 5.2% (8) for Mobility. The complication rate was 16.5% (22) for Scandinavian compared to 9.9 % (15) for Mobility.

The results of our unit compare favourably with previous published studies. In this study the Mobility has been shown to have more favourable results at 7 years compared to the Scandinavian.

Keywords : ankle ; replacement ; arthroplasty ; prosthesis ; arthritis.

INTRODUCTION

Surgical options for end stage ankle arthritis include ankle fusion or total ankle replacement (TAR). The benefits of joint replacement include pain relief as well as maintaining ankle joint movement, which is lost in joint fusion *(4)*.

TARs have undergone several changes since their rather unsuccessful introduction in the 1960s. The design has evolved from the initial early models, which had both high complication and failure rates *(1,4,6,12,18)*. The development of unconstrained, uncemented mobile bearings prosthesis such as the STAR (STAR, Link Orthopaedics, Rockaway NJ,USA) in the mid 1980s, resulted in improved results with better survivorship *(2,3,7)*. Our unit has regularly carried out TARs over the last 15 years. From 1996 to 2003 predominately the STAR prosthesis was used. The unit published a retrospective review of 52 STAR's in 2010, which showed an 84 % survival at 8 years *(5)*.

The Mobility TAR (Depuy International, Leeds, UK) was introduced in 2003 as an unconstrained, uncemented, mobile bearing three component implant, with perceived advantages of less bone resection, improved instrumentation and possibly less polyethylene insert wear *(10,14-16)*. Due to

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No benefits or funds were received in support of this study.
The authors report no conflict of interests.

the perceived advantages of the Mobility the unit switched over in 2004.

The aim of this study was to review the prospectively collected outcomes of the STAR and Mobility TAR to determine whether there was an advantage of using one replacement over the other. The primary outcome measure was the revision rate. The secondary outcome measures consisted of intra and postoperative complications and patient scoring systems : the American Orthopaedic Foot and Ankle Score (AOFAS), Foot Function Index (FFI), European five dimension quality of life scores (EQ-D5), range of movement, Visual Analogue Pain Scale (VAS).

PATIENTS AND METHODS

Our Unit is a tertiary referral centre for complex foot and ankle problems. Patients with end stage arthritis who are deemed suitable for ankle arthroplasty are referred to the unit where they are assessed against the selection criteria shown in Table I.

The pathway was similar for both implants and the only difference was the change in implant. Patients were educated and assessed pre-operatively. Surgery is performed in accordance to the standard practice and techniques as described by Wood et al. *(16)*. Post-operatively patients are put into a below knee plaster cast and can weight bear as tolerated. Patients stay on average between 2-5 days. The standard post-operative regime includes follow up at 2 weeks, 6 weeks, 3 months, 6 months and then annually. Follow up is carried out by an independent physiotherapist who reviews and records the patient's outcomes : radiographs of the prosthesis, functional questionnaires and range of movements.

Table I. — Selection criteria for TAR

Inclusion	Exclusion
Failure of non-operative measures	Patients < 35 years old
End stage disabling ankle pain	Heavy manual occupation
Patients > 35 years	Severe hindfoot deformity*
Active lifestyle and ambulatory	Severe ankle instability
Compliance with treatment	
No active infections	

* Severe deformity was defined as more than 20° deformity in the coronal plane.

All the data is prospectively collected and entered into the unit's database. Patients are informed that follow up will continue for the life of the prosthesis and are seen annually. At each follow up visit questionnaires as well as clinical and radiological assessments are carried out by the physiotherapists as part of routine follow up.

The unit's prospectively collected database was interrogated from March 1999 until September 2013. From 1999 to 2005 STARs were implanted and from 2005 until 2013 Mobility TARs were implanted all by the same surgeon. All replacements with less than one year follow up were excluded. Any missing records from the database were obtained from collection of patient notes, electronic records or telephone follow up by the authors. Patients were only considered lost to follow up when they did not re-attend outpatient clinic and could not be reached via telephone.

The primary outcome measure was the survivorship of the TARs. The date of primary operation was used as the starting point for the time to revision outcome. Estimates of revision rates were derived by the Kaplan-Meier method using Stata/IC version 13.1, (StataCorp, College Station, TX, USA). A revision included any operation on a TAR where the component was changed for example liner change is a revision or removal of components to a fusion. Time to revision was defined as the time between the primary operation and revision procedure. Re-operations or additional operations were performed to aid the TAR for example osteotomy or ligament reconstruction or clearance of excess bone, but in these cases the TAR remains unchanged or unaltered.

Secondary outcome measures consisted of the intra and post-operative complications such as infection, loosening, fracture, nerve damage, wound breakdown and component failure. The AOFAS, FFI, EQ-D5, range of movement, VAS and patient satisfaction was independently assessed at each follow up visit.

RESULTS

There were 147 STAR and 162 Mobility TAR performed. The Demographics of the patients are

Table II. — Patient Demographics

TAR	STAR	Mobility
Mean Age (yrs)	71	68
(range)	39-87	37-98
Male : Female	100:47	109:53

Table III. — Intra-operative and Post-operative Complications of TAR

TAR	STAR	Mobility
Infection - Superficial	5	8
- Deep	2	0
Fracture - Intra-operative	11	4
- Post-operative	4	3

Table IV. — Additional surgery for TAR

Additional Surgery	STAR	Mobility
Subtalar fusion	5	3
Lateral ligament reconstruction	3	6
Tendo-achilles Lengthening	5	4
Excision of heterotopic ossification or scar	1	1
Arthroscopy	3	0
Bone grafting of cyst	1	0
Osteotomy	2	1

shown in Table II. The maximum follow up time was 14 years for STAR with a mean of 12.4 years, during which 27 (18.4%) patients were revised, 19 (12.9%) died and 14 (9.5%) were lost to follow up. The maximum follow up time was 8 years for Mobility, with a mean of 7.7 years, during which 8 (4.9%) patients were revised, 7 (4.3%) died and 10 (6.2%) were lost to follow up. Reviewing those lost to follow up ; from their final clinic outpatient visit there had been no recorded problems with their ankle replacements and no documented post-operative complications or revision surgery. Of those that died, none died as a result of the ankle replacement. From the last clinic letter and data review none of these ankle replacements were revised or had any active ankle symptoms.

There were 22 post-operative complications (16.5%) for the STAR and 15 (9.9%) for the Mobility. These consisted of infections and fractures and are demonstrated in Table III. Superficial infection was defined as any ankle replacement with a sloughy or wet looking wound and surrounding erythema. This was treated with topical antibiotics. Deep infection

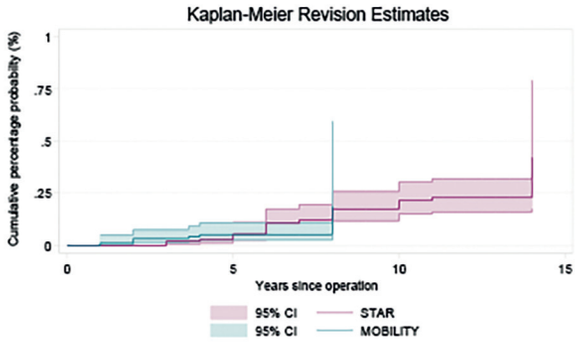

Fig. 1. — Kaplan Meier estimates of the cumulative percentage probability of revision (95% CI) by implant. N.B. Only 7 Mobility patients remained at risk at 8 years. Only 5 STAR patients remained at risk at 14 years.

involved the ankle replacement and resulted in revision surgery. Intra-operative fractures if undisplaced were treated non-operatively in a below knee plaster. Post-operative fractures were treated with open reduction and internal fixation. There was no recorded deep vein thrombosis.

Associated operations carried out due to secondary deformity or new diagnosis were 15% *(20)* in the STAR group and 9.9% *(15)* in the mobility group. The most common procedures being : subtalar fusion, lateral ligament reconstruction and tibialis anterior lengthening (Table IV).

The revision rate at 7 years was 12.3% for STAR and 5.2% for Mobility (Fig. 1.). The revision rates did rise to 42.1% STAR at 14 years and 18% Mobility at 8 years. These results should be interpreted cautiously considering the lower numbers of patients who had been followed up for 14 years (5 STAR) and 8 years (7 Mobility) respectively.

At 13 years 27 patients (20.3%) in the STAR group had been revised. In the Mobility group, 8 patients (5.2%) had been revised at 7 years. Revision surgery occurred due to liner problems, instability, loosening and infection. Revision procedures included liner exchange, revision of either tibial, talar or all components, conversion to arthrodesis and change to an Ilizarov frame (Table V). The reasons for conversion to arthrodesis included infection, component misalignment and chronic pain.

Table V. — Revision operations for TAR

Revision Operation	STAR	Mobility
Exchange of insert	15	3
Revision of tibial component	2	0
Revision of talar component	1	0
Revision of all components	2	0
Conversion to fusion	4	4
Ilizarov frame	1	0

Table VI. — Range of movement in degrees for foot and ankle joints in patients with TARs

Mean Post-operative Range of Movement (Range) (°)	STAR	Mobility
Ankle Dorsiflexion	5 (-10-20)	5 (-10-15)
Ankle Plantar Flexion	14 (0-40)	16 (0-50)
Subtalar Eversion	5 (-5-20)	5 (0-15)
Subtalar Inversion	4 (0-20)	3 (0-20)
Mid-foot Eversion	8 (0-30)	9 (0-30)
Mid-foot Inversion	13 (0-45)	16 (0-45)
Mid-foot Dorsiflexion	8 (0-15)	9 (0-20)
Mid-foot Plantar flexion	8 (0-20)	9 (0-20)
Hind-foot Varus	2 (0-15)	1 (0-20)
Hind-foot Valgus	1 (0-10)	1 (0-10)
Forefoot Supination	0 (0-30)	1 (0-30)
Forefoot Pronation	0 (0-10)	1 (0-15)

Table VII. — Post-operative outcome scores for TAR, (Range)

TAR	STAR	Mobility
AOFAS	75 (24-10)	75 (14-100)
FFI	20 (0-73)	20 (0-71)
EQ5D	74 (10-100)	74 (10-100)

Other secondary outcomes showed that both prosthesis provided an acceptable range of movement (Table VI). The mean improvement of the AOFAS score increased to 75 for both TAR from a preoperative mean score of 40 (20-40). There was no significant difference in the outcome scores of AOFAS, FFI and E5QD (Table VII). Indeed there was no significant difference in patient satisfaction rating when comparing STAR to Mobility.

DISCUSSION

Our unit is performing well compared to the outcomes reported in the literature (Table VIII) with one of the largest series of Mobility TARs *(16)*. The unit also has one of the longest follow-ups at an average of 7.7 years (92.4 months) for both implants and up to 14 years for the STAR.

When comparing the use of the STAR prosthesis to the Mobility we found that the Mobility had a better survivorship at 7 years, a lower revision and complication rate.

However we do acknowledge that some published data have shown better results with the STAR than we achieved in this unit *(17)*. The Mobility results in this unit still surpassed that of the published STAR data although it is not yet comparable to hip or knee arthroplasty *(11)*.

The unit's post-operative complication rate of 9.9% is better than the published literature for Mobility TAR (Table VIII). However this is still a significant complication rate compared to other joint replacement surgery. This could in part, be due to the significant pre-operative deformity dealt with in our unit which was certainly more than Woods original criteria for excluding patients for an ankle replacement if the coronal deformity of the ankle was more than 20 degrees *(8,16)*. In hip and knee replacements complications such as infection or fracture are quoted as between 1-2% in worse case scenarios *(13)*. The Mobility has double this complication rate in the hands of specialist foot and ankle surgeons who carry out high volumes

Table VIII. — Outcomes of Mobility TAR

Authors	Rippstein et al. *(10)*	Wood et al. *(11)*	Sproule et al. *(13)*	Muir et al. *(14)*
Number	240 Mobility	100 Mobility	88 Mobility	178 Mobility
AOFAS Score	84.1(44-100)	79(44-100)	74.8 (46-100)	-
Post-op Complications	30 (12.8%)	18(19%)	13 (15%)	-
Revision	5 (2.1%)	5 (5%)	10(11%)	10(5.6%)
Follow-up (months)	233 Mobility 12(12-63) months	91 Mobility 43(40-63) months	87 Mobility 40(30-60) months	129 Mobility 48 (24-76) months
Survival	97.7% at 1 year (96.5-98.9)	93.6% at 4 years (84.7-97.4)	88.4% at 4yrs (79.3-93.9)	-

of replacements. It is clear that surgeons need to be rigorous in their selection of patients for ankle replacements and patients need to be educated about the possibility of higher complication rates. It seems obvious, therefore that ankle replacements should remain a procedure for the experienced foot and ankle surgeons carrying out significant numbers of replacements per year ideally in specialized centres.

A small group of patients were dissatisfied with their TARs (5, STAR and 10, Mobility) and yet no objective structural cause was found. These patients complained of chronic pain around their replacement, indeed one Mobility Ankle needed revision surgery to a fusion. At time of revision no osseous integration was found between implant and bone. This could be a reason for underlying pain and it remains the senior authors view that micro-motion due to incomplete bonding in uncemented TAR's is the potential source of constant pain. The other dissatisfied patients are being reviewed, none have requested further surgery and yet none are completely happy with their outcome. A similar group of patients often complaining of persistent medial pain has been found in other studies of the Mobility TAR *(9)*. There is no clear reason yet for this and further study is needed to review this small but troubled group of patients.

We must acknowledge the following limitations when comparing the results of STAR and Mobility prosthesis. Firstly surgeon experience undoubtedly increased over the years and from previous studies of joint registries it is known that there exists a steep learning curve with ankle replacements and a minimum number need to be carried out before competency is reached *(8,9)*. Currently there is greater involvement of the multi-disciplinary team, which consists of a specialist foot and ankle anaesthetist with an interest in ankle blocks, a specialist physio-therapist who follow up all the patients, optimization of patients peri-operatively, close liaison and easy return access post-operatively. This multi-disciplinary support did not exist previously in the unit. All of these confounding factors could suggest a potential improvement over time independent of the change from STAR to Mobility.

The groups of patients have changed over time with different medical comorbidities and different functional demands. There has certainly been a trend for implantation of ankle replacements in younger fitter patients who are more functionally demanding. It is uncertain how this could have affected the comparison between the two ankle replacements.

CONCLUSION

The results of our unit compare favourably with previous published studies. The Mobility had a lower revision rate compared to STAR in this series, but there is significant room for improvement when compared to hip and knee arthroplasty outcomes. It is the opinion of the authors that improvements can be made with further development of the TAR prosthesis, refining indications and improving surgical technique to ensure reproducibility of results. It would seem prudent, given the complication rate, that patient selection should be very rigorous and only surgeons who are experienced with the techniques and carry out a high volume in their practice, perform ankle replacements. The Mobility seemed to perform as well as the STAR in the short to medium term. The longer term will require further study. The Mobility ankle replacement has now been withdrawn from the market. It is evident that the Mobility TAR was not pulled for clinical reasons, but the exact reason for the withdrawal remains unclear. In any case the three component uncemented ankle replacement seems to have favourable results in the medium term.

Acknowledgements

We thank Miss Katie Lee and Mr Haroon Majeed who helped with data collection.

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