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Prospective Study of Patient Outcomes Following Scandinavian Total Ankle Replacement (STAR) Implantation

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Abstract

Background: *The complexity of the ankle joint has resulted in total ankle replacement procedures only recently showing comparable outcomes to ankle arthrodesis and therefore increasing in popularity. Initial first-generation prostheses had poor outcomes and high failure rates. The two component, semi-constrained, cementless design of second generation prostheses resulted in minimal bone resection and improved outcomes and even further improvements are now being seen with the 3rd generation 3 component designs.*

Methods: *Between 2004 and 2016, 75 consecutive Scandanavian Total Ankle Replacement (STAR) procedures were carried out at Sunderland Royal Hospital by a single surgeon. Patients were assessed using The American Orthopaedic Foot and Ankle Society Score (AOFAS) and scored pre-operatively, post operatively, at 3 months, at 6 months then yearly.*

Results: *A total of 75 ankle replacements were carried out; 63 males, 12 females. Mean follow up was 63 months. 72 (95.9%) of procedures were successful. 3 (4.1%) failed; 2 (2.7%) required revision to arthrodesis and 1 (1.4%) required tibial component revision and PE (polyethylene) liner replacement. The overall failure rate at 5 year follow up was 5.12%. The commonest complications were PE liner replacement in 9 patients (12.2%), symptomatic foot deformity in 5 (6.7%) and chronic pain in 4 (5.4%). The mean increase in AOFAS scores from baseline to final statistically significant follow up was 22.6 for total scores, 25.6 for pain, 14.6 for function and 3.5 for alignment.*

Conclusions: *STAR Ankle Replacement is associated with significant improvements in pain and function. The senior authors function and pain outcomes are comparable to other publications.*

Keywords: *Ankle replacement, Total ankle replacement, STAR system, outcomes, complications*

Introduction

Ankle arthritis can be a debilitating condition for patients and can significantly affect quality of life. Approximately 15% of the world's population has pain or disability from osteoarthritis (OA) and although ankle arthritis remains far less common than hip and knee arthritis, it still has an incidence of around 29 000 cases per year in the United Kingdom. (1) Ankle arthritis can be caused by multiple aetiologies. The primary cause of arthritis of the ankle is Osteoarthritis. Other Causes of arthritis of the ankle include Rheumatoid Arthritis, neuropathy, osteonecrosis, infection, post fracture and haemophilia.

The complexity of the ankle joint has resulted in total ankle replacement (TAR) procedures only recently showing comparable outcomes to joint fusion and therefore increasing in popularity.(2) (3) Initial first generation prostheses in the 1970's had poor outcomes and high failure rates. These were highly constrained, or semi-constrained two component prostheses, used cement fixation on both the talar and tibial sides, high incidence of loosening, wide osteolysis, subsidence, and mechanical failure of prosthesis components. In the early 1980's second generation designs were introduced such as the Buechel-Pappas Total Ankle Replacement. The two

component, semi-constrained, cementless design of these systems resulted in minimal bone resection and improved outcomes. The third generation designs started coming out in the late 1990's and feature more advanced 3 component prostheses, placing a greater importance on the use of ligaments to retain stability, the need for anatomic balancing following component insertion, and minimal bone resection. Initial results are promising however longer term follow has not yet been studied.

Published literature comparative outcomes vary, however Saltzman et al. found that TAR's in general have better functional & pain outcomes than arthrodesis with comparable complication rates. (2) Another paper by Lawton et al. even reported an overall higher complication rate for ankle arthrodesis compared to TAR, although the TAR cohort had higher revision surgery rates. (4) (5)

Study Design

The purpose of the study was to quantify and evaluate the outcomes of patients who have undergone STAR procedures at Sunderland Royal Hospital and compare this to published literature. This was a single surgeon, single site prospective study and data was collected on all patients undergoing consecutive STAR procedures from 2004 – 2016 at Sunderland Royal Hospital. No exclusion criteria were applied. A standard anterior approach to the ankle joint was used with standard gowning, Preparation (social scrub and then alcoholic betadine), draping, Tourniquet, Intravenous Antibiotics in all patients. The standard surgical technique was used for implantation, as described by Stryker, the company that produces the STAR Ankle.(11) Post-operative management included a minimum of two weeks non weight bearing (with a wound check at the same time), partial weight-bearing at 2-3-weeks post-operative and gradually increase until the patient is fully weight-bearing at 4 to 6-weeks post-operatively.

Outcome Measures

Patients were assessed using The American Orthopaedic Foot and Ankle Society Score (AOFAS) which is a self-reported, ankle specific functional outcome measure *(Figure 1).* They were scored pre-operatively, post operatively, at 3 months, at 6 months then yearly. The primary outcome measure was total AOFAS score. Secondary outcomes included AOFAS scores for pain, function and alignment subscales. Complications were recorded from follow up documentation, operation notes & clinic letters.

Failure was defined as the need for removal or revision of either the tibial or the talar metallic components.

Ankle-Hindfoot Scale (100 Points Total)

Pain (40 points)	
None	40
Mild, occasional	30
Moderate, daily	20
Severe, almost always present	0
Function (50 points)	
Activity limitations, support requirement	
No limitations, no support	10
No limitation of daily activities, limitation of recreational activities, no support	7
Limited daily and recreational activities, cane	4
Severe limitation of daily and recreational activities, walker, crutches, wheelchair, brace	0
Maximum walking distance, blocks	
Greater than 6	5
4-6	4
1-3	2
Less than 1	0
Walking surfaces	
No difficulty on any surface	5
Some difficulty on uneven terrain, stairs, inclines, ladders	3
Severe difficulty on uneven terrain, tairs,inclines,ladders	0
Gait abnormality	
None, slight	8
Obvious	4
Marked	0
Sagittal motion (flexion plus extension)	
Normal or mild restriction (30° or more)	8
Moderate restriction (15°-29°)	4
Severe restriction (less than 150)	0
Hindfoot motion (inversion plus eversion)	
Normal or mild restriction (75%-100% normal)	6
Moderate restriction (25%-74% normal)	3
Marked restriction (less than 25% normal)	0
Ankle-hindfoot stability (anteroposterior,varus-valgus)	
Stable	8
Definitely unstable	0
Alignment (10 points)	
Good, plantigrade foot, midfoot well aligned	15
Fair, plantigrade foot, some degree of midfoot malalignment observed, no symptoms	8
Poor, nonplantigrade foot, severe malalignment, symptoms	0
Total=	100

American Orthopaedic Foot and Ankle Society
From: http://www.aofas.org/i4a/pages/index.cfm?pageid=3494

Fig1. *AOFAS Scoring System*

Statistical Analysis

The IBM SPSS Statistics Software was used for the statistical analysis. Analysis of variance analysis (ANOVA) was used to test pre-operative vs. post-operative mean significance in outcome. For the total AOFAS this showed significant differences on repeated measures ANOVA between pre-op total scores and post-op scores out to 9 years. For the pain AOFAS this showed significant differences on repeated measures ANOVA between pre-op scores for pain and post-op scores out to 9 years (p=0.05). For function AOFAS this showed significant differences on repeated measures ANOVA between pre-op scores for function and post-op scores out to 6 years. For alignment AOFAS this showed significant differences on repeated measures ANOVA between pre-op scores for alignment and post-op scores out to 7 years. In latter years, statistical significance is difficult to achieve due to reduced follow up rates.

Results

A total of 75 Scandinavian total ankle replacements were carried out; 63 males, 12 females. Mean follow up was 63 months (range 3 months- 120 months). Pre-operative scoring was available in 35 patients *(Table 1)*. Unfortunately, available scores in latter years are low which made it impossible to perform statistical analysis.

Table1. *Number of completed AOFAS score sheets*

Time point	Number of available scores
Pre-op	35
3 months	31
6 months	32
1 year	34
2 years	28
3 years	11
4 years	12
5 years	6
6 years	8
7 years	8
8 years	5
9 years	2
10 years	1

72/75 (95.9%) procedures were successful. 3 (4.1%) failed; 2 (2.7%) required revision to arthrodesis and 1 (1.4%) required tibial component revision and PE (polyethylene) liner replacement. The indications for arthrodesis were avascular necrosis, subluxation of the bearing due to an increased varus deformity causing edge loading of the polyethylene(PE) bearing and a failed PE liner revision. The arthrodesis procedures were performed at a mean time of 46 month's post STAR implantation. The patient that required tibial component revision had tibial component malposition in varus (25 degrees) at 4 months leading to failure (loosening, ligament elongation and increased contact pressures on the PE bearing leading to subluxation). *(Table 2)* 39 patients have had over 5 years follow up since replacement and the overall failure rate at 5 years was 5.12%. The commonest complications were PE liner replacement in 9 patients (12.2%), symptomatic foot deformity in 5 (6.7%) and chronic pain in 4 (5.4%). Superficial joint infection and intra-articular joint infections occurred in 3 (4.1%) patients respectively. *(Table 3)* The mean increase in AOFAS scores from baseline to final statistically significant follow up were; 22.6 for total scores, 25.6 for pain, 14.6 for function (FXTN) and 3.5 for alignment (ALGT). *(Figure 2)*

Table2. *Failure Rates*

Results: Failure Rates			
	No of Patients	% Total Patients	Mean Time/Outcome
Success Rate	**72**	**95.9%**	
Failure Rate	**3**	**4.1%**	
*Revision to Arthrodesis**	*2*	*2.7%*	*46 months*
Tibial Component Revision + PE Liner Replacement▲	*1*	*1.4%*	*4 months*

* 1) Avascular necrosis 2) Sublux Varus Deformity with failed PE liner revision
▲Tibial Component inclination causing failure

Table3. *Complication Rates*

Results: Complication Rates			
Complication	No of Patients	% Total Patients	Mean Time/Outcome
PE Liner Replacement*	9	12.2%	31 months
Tibia Component Revision + PE Liner Replacement	1	1.4%	4 months
Intra Articular Infection	3	4.1%	1 required washout + liner replacement
Superficial Infection	3	4.1%	Settled PO Abx
Pulmonary Embolism	1	1.4%	Cast left on >6 weeks
Chronic Pain	4	5.4%	
Fracture	2	2.8%	1 intra op, 1 peri op
Symptomatic Foot Deformity	5	6.7%	

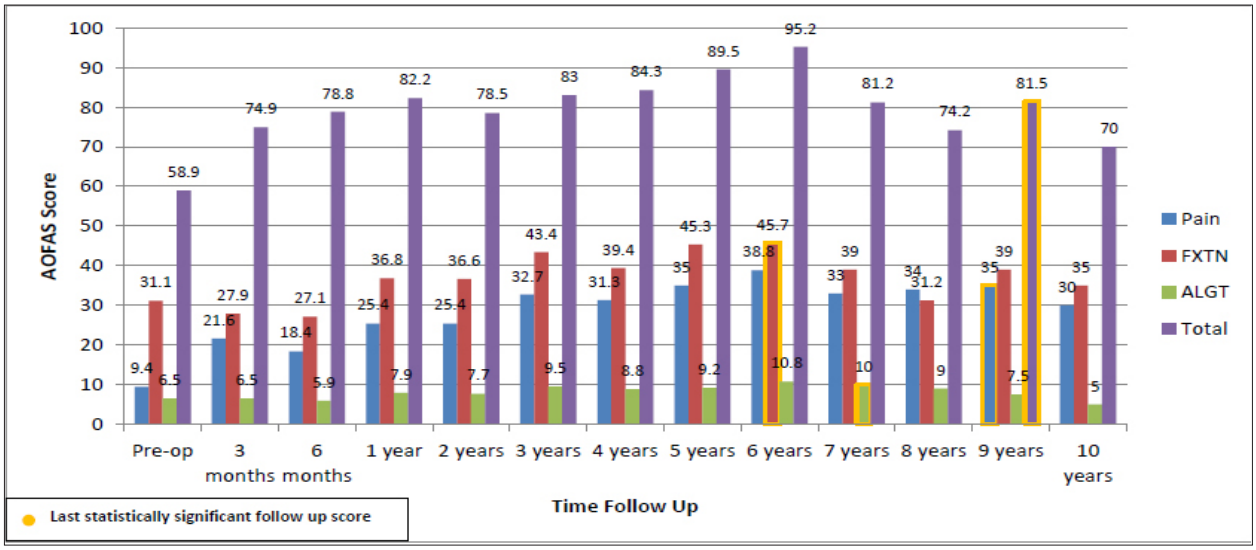

Fig2. *Graph showing AOFAS Scores at follow up appointments*

Discussion

The STAR system was first designed by Dr Kofoed in 1978 and first implanted in 1981. It was initially a metallic talar component with polyethylene tibial component fixed with bone cement. In 1986 two anchorage bars on a tibial component were introduced and in 1990 a cementless bioactive surface was added. It has, until recently, been the most commonly used ankle prosthesis in Europe since 1991(5). In 1999 a double coated bioactive surface was added to the prosthesis and it achieved FDA clearance for use in USA in 2007. Studies have shown that the optimal patient for a TAR is elderly (>50 years) with end stage ankle arthrosis. It was previously thought that younger patients with post-traumatic ankle arthritis did less well following TAR procedures due to excessive wear and increased failure rates; however evidence is now emerging that TAR may also be beneficial in this group of patients. (6) The longevity of the STAR implant still remains the best of all total ankle replacements. A recent study by Clough et al looking at the long term results of the prosthesis report five-, ten-, and 15.8-year survival rates of 90.41%, 82.76%, and 76.16%, respectively. (7)

The results from this prospective study regarding complication and failure rates are in-keeping with published literature findings. A paper by Daniels et al in 2015 looked at 111 STAR patients followed up to 9 years. 12% required metal wear revision and 18% required PE liner revision. They concluded that patient complications reduce with increasing surgeon experience in the procedure. Karantana et al published a study in 2010 which looked at 48 patient's outcomes following STAR procedures.(8) They showed a 90% prosthesis survival rate at 5 years, a 6% arthrodesis rate and 5.4% superficial infection rate. The mean post-operative AOFAS score at final follow up was 78. Zhao et al's article from 2011 reviewed 16 studies assessing patient outcomes following STAR procedures.(9) 2088 patients were assessed and mean follow up was 54 months. The prosthesis had a 5-year survival rate of 85.9% and 10-year survival rate of 71.1%. The mean AOFAS score was 77.8. Zaidi et al published a meta-analysis of 58 publications in 2013 looking at 7942 total ankle replacement procedures.(10) They pooled outcome scores across studies and used inverse variance method and random effects model to incorporate clinical and methodological heterogeneity. They showed a 10-year success rate of 89% and an annual failure rate of 1.2%. The mean AOFAS score rose from 40 pre-operatively to 80 post operatively. It was concluded however that the randomised studies included in the meta-analysis were low quality and fraught with biases. Below is a table summarising the surrounding literature published failure rates, complication rates and AOFAS scores. *(Table 4)*

Table4. *Literature Summary*

Comparison of Literature Summary Table							
Paper	Year	Sample Size	TAR Type	5 year failure rate	10 year failure rate	Total failure rate	AOFAS Score
Sunderland	**2016**	**75**	**STAR**	**5.12 %**	**-**	**4.10%**	**82.11**
Daniels et al.	2015	111	STAR	-	-	12.00%	-
Gougoulias et al.	2010	1105	Various	10.00%	-	-	-
Zaidi R et al.	2013	7942	Various	-	-	11.00%	80.00
Karantana et al.	2010	48	STAR	10.00%	-	-	-
Wood et al.	2008	200	STAR	7.00%	12.00%	-	-
Nunley et al.	2012	82	STAR	-	-	6.10%	85.90
Mann et al.	2011	80	STAR	4.00%	10.00%	-	83.00
Zhao et. Al	2011	2088	STAR	14.10%	18.90%	-	77.80

Our study largely reflects the outcomes as described in the above papers. Two of the very first STAR implants in our series were the ones that went on to require revision to arthrodesis, with one of these revised due to failure secondary to tibial inclination. This reflects the conclusions reported in the Daniels et al paper, being that the operative surgeons learning curve and increasing surgical technique can be highly influential in reported failure and complication rates.

A strength of our study is that compared to other single centre studies it has a larger cohort size due to the long study period. By having the same surgeon performing all procedures with the same standard setup it may reduce bias in surgical technique, approaches and skills. Possible limitations of the study include a potential source of bias in selection criteria for patients to undergo the STAR procedures initially. Unfortunately, there were not pre-operative AOFAS scores for the majority of patients which may have reduced the reliability of conclusions made. Again as only 39 patients had follow up >5 years post replacement, published complication and success rates may not be as accurate as other studies.

Conclusion

In conclusion STAR Ankle Replacement is associated with significant improvements in pain and function (especially past 1 year once pain and swelling settled). The senior authors function and pain outcomes are comparable to other publications. Complication rates are lower than reported in published data. Ankle replacement outcomes improve with surgeon experience and more pre-operative scores and longer follow up are required for more accurate analysis.

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