

Survival Analysis of the Single- and Double-Coated STAR Ankle up to 20 Years: Long-Term Follow-up of 324 Cases From the Swedish Ankle Registry

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Anders Henricson, MD, PhD¹, and Åke Carlsson, MD, PhD^{2,3}

Abstract

Background: The Scandinavian Total Ankle Replacement (STAR) has been used widely in Europe and more recently in the United States. We studied the results of the single-coated and the double-coated STAR with long-term follow-up.

Methods: All STARs (n = 324) used in Sweden (first implanted in 1993) were included. Prosthetic survival was estimated according to Kaplan-Meier.

Results: The 14-year survival of the single-coated STAR was 0.47 (95% confidence interval [CI], 0.38-0.66), and the 12-year survival of the double-coated STAR was 0.64 (95% CI, 0.57-0.71). Women younger than 60 years with osteoarthritis had a statistically significantly higher risk of revision than men and than patients with other diagnoses.

Conclusion: The long-term results of the STAR prosthesis are not encouraging. The results seem to deteriorate by time.

Level of Evidence: Level IV, retrospective case series.

Keywords: total ankle replacement, STAR prosthesis, ankle registry

The Scandinavian Total Ankle Replacement (STAR), a prosthesis with a mobile bearing, was initially used with bone cement but was redesigned in 1990 for cementless use.⁸ The components were single-coated with a hydroxyapatite coating sprayed on a smooth metallic surface but from 1999 double-coated with a titanium porous plasma spray and a calcium-phosphate layer. The prosthesis has been used extensively in Europe and is presently the only Food and Drug Administration (FDA)-approved mobile bearing prosthesis in the United States.

Several long-term studies of the STAR design have been published.^{2,9-11,13} Two of these reports involve the single-coated design^{2,9} and the others a mixture of both coating concepts.^{10,11,13} Kofoed,⁹ being the inventor of the STAR, presented 1 revision out of 25 cases with a follow-up of 12 years. The 10-year survival of 90% in 84 cases was found by Mann et al.¹⁰ Nunley et al¹¹ evaluated 82 ankles and showed 88.5% survival at 9 years. In a consecutive series of 200 STARs, Wood et al¹³ had a ten-year survival of 80%. Brunner et al² found that 29 of 77 ankles were revised with a 14-year survival of 45.6% (Table 1). The aim of this study was to report the long-term prosthetic survival and the number and type of complications following implantation of single- and double-coated STAR prostheses reported to the Swedish Ankle Registry.

Methods

All total ankle replacements in Sweden are reported to the Swedish Ankle Registry. The indication for performing a total ankle replacement was for the surgeon to decide.

From 1993 to October 1999, 118 single-coated STAR ankles (STAR I) (Waldemar Link, Hamburg, Germany) were implanted, and from October 1999 to 2007, 206 double-coated STARs (STAR II) were used. The STAR design has not been used in Sweden since 2007. Four surgeons performed 265 STARs (mean 66) and 6 surgeons performed 59 (mean 10). Sex and diagnoses of the patients are listed in Table 2. The miscellaneous group consists of psoriatic arthritis and hemochromatosis. Sixty-eight patients with STAR I and 107 with STAR II were younger than 60 years.

¹Department of Orthopedic Surgery, Falun General Hospital, Falun, Sweden

²Department of Orthopaedics and Clinical Sciences, Lund University, Malmö, Sweden

³Department of Orthopaedic Surgery, Skåne University Hospital, Malmö, Sweden

Corresponding Author:

Anders Henricson, MD, PhD, Department of Orthopedic Surgery, Falun General Hospital, Falun, 791 82, Sweden.

Email: anders.henricson@ltdalarna.se

Table 1. Numbers and Prosthetic Survival of the Single- and Double-Coated STAR Prosthesis as Reported by Different Authors.

Author	Year	Number	FU Years	Survival, %	95% Confidence Interval
STAR I					
Kofoed ⁹	2004	25	12	95	91-100
Carlsson ³	2006	31 ^a	10	65	47-83
Brunner et al ²	2013	77	14	46	32-65
Present study		118	10	61	51-70
Present study		118	14	47	38-66
STAR II					
Carlsson ³	2006	52	5	98	69-100
Present study		206	10	70	63-76
Present study		206	12	64	57-71
Mixed STAR I and II					
Wood et al ¹³	2008	200	10	80	71-90
Zhao et al ¹⁴	2011	2008 ^b	10	71	61-81
Mann et al ¹⁰	2011	84	10	90	80-95
Nunley et al ¹¹	2012	82	9	89	NR

Abbreviations: FU, follow-up; NR, not reported.

^aSeries 1B.

^bReview.

Table 2. Sex and Diagnoses in Patients With Ankles Replaced by a Single- and/or Double-Coated STAR Prosthesis.

	Women/Men	OA	PtA	RA	Miscellaneous.
STAR I	81/36	25	36	57	
STAR II	125/81	50	80	66	10
Total	206/117	75	116	123	10

Abbreviations: OA, primary osteoarthritis; PtA, posttraumatic arthritis; RA, rheumatoid arthritis.

Data concerning revisions and other complications was extracted from the Swedish Ankle Registry.⁷ All patients operated on for ankle arthritis had to give their consent to be registered in the Swedish Ankle Registry. Revision was defined as removal or exchange of 1 or more of the prosthetic components with the exception of incidental exchange of the polyethylene insert.⁵

Proportion survival was estimated according to the Kaplan-Meier method, and 95% confidence interval was calculated. Log-rank test was used to test difference between groups.

Results

Fifty-eight (49%) revisions were recorded in the single-coated group and 67 (32%) in the double-coated group. The reasons for revision are presented in Table 3. The main reason for revision was classified by the revising surgeon. Detailed information on the technical mistakes or

Table 3. Reasons for Revision of the Single- and Double-Coated Scandinavian Total Ankle Replacement Prosthesis.

	Single-Coated (n = 11)	Double-Coated (n = 206)
Aseptic loosening	34	28
PE breakage or wear	10	9
Infection	4	10
Technical error	6	8
Intractable pain	4	6
Painful varus		3
Fracture		2
Instability		1
Total	58	67

Abbreviation: PE, polyethylene.

bacteriology was in many cases not reported to the registry. The revision rate was 40% for the high-volume surgeons and 46% for the low-volume surgeons.

The 5-year survival was 0.75 (95% confidence interval [CI], 0.67-0.82) for STAR I and 0.82 (95% CI, 0.76-0.87) for STAR II. The corresponding figures at 10 years were 0.61 (95% CI, 0.51-0.70) and 0.70 (95% CI, 0.63-0.76). The estimated 14-year survival for STAR I was 0.47 (95% CI, 0.38-0.66), and the 12-year survival for STAR II was 0.64 (95% CI, 0.57-0.71) (Figure 1).

With the numbers available, no statistically significantly difference between STAR I and STAR II ($P = .068$ by log-rank test) could be detected.

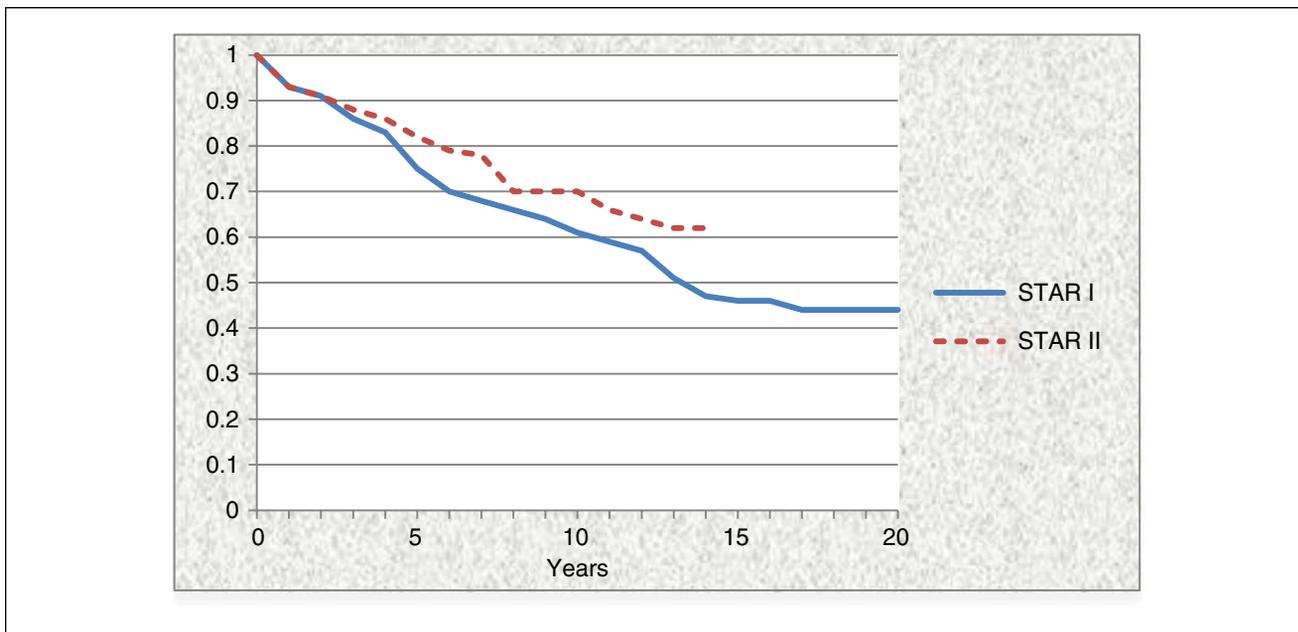


Figure 1. Cumulative prosthetic survival curves of the single- (STAR I) and double-coated (STAR II) STAR prosthesis. Abbreviation: STAR, Scandinavian Total Ankle Replacement Prosthesis.

In the STAR I group, patients younger than 60 years when their ankles were replaced had a statistically significantly higher risk for revision ($P = .009$ by log-rank test). In the STAR II group, there were no detectable differences between patients who were younger than 60 years or patients who were 60 years or older when their ankles were replaced.

No differences between the diagnoses could be detected. However, women younger than 60 years with osteoarthritis had a statistically significantly higher risk for revision than did men and patients with other diagnoses ($P = .042$ by log-rank test).

In addition to the 125 revisions mentioned above, 11 secondary surgical procedures were performed in each design group, the most common being debridement of the gutters and stabilization of the ankle by ligament augmentation and/or different osteotomies.

Discussion

This study is, to our knowledge, the largest series of STAR prostheses that has been published. The follow-up time is also longer than in previously published studies. The estimated 47% survival at 14 years of the single-coated design is equal to that of Brunner et al,² who found a 14-year survival of 46%. However, Kofod,⁹ the inventor of the STAR, reported 95% survival at 12 years. The figure at 14 years in our study is based on a time point when there are rather few

cases left and indeed very few events, making the figure somewhat uncertain, which is clearly seen in the wide confidence interval. Brunner et al² also had a wide confidence interval, suggesting few cases left and few events.

Concerning the double-coated STAR prosthesis, there have been no other specific long-term studies published. Carlsson³ found 98% survival after 5 years with the double-coated design. The 5-year survival of 82% in our study corresponds well with the findings of other authors. However, the 10-year survival of 70% is somewhat lower than other reports on the STAR ankle, although none deals exclusively with the STAR II. In their review of the STAR ankle (including both STAR designs), Zhao et al¹⁴ found a pooled 5-year survival of 90% and a pooled 10-year survival of 71%. Mann et al,¹⁰ also having a mixture of single- and double-coated prostheses, reported a survival of 90% at 10 years. Wood et al¹³ reported a 10-year survival of 80% in a mixed series of 200 cases. Nunley et al,¹¹ also having a mixture of the 2 coatings, found a survival rate of 93% at 5 years and 86% at 9 years. However, their figures did not include exchange of 3 fractured polyethylene inserts. Neither did Brunner et al² include meniscal breakage in their survival analysis, although they had 11 (14%) insert fractures. This suggests that the proper survival rate of the Nunley et al¹¹ and Brunner et al² series would be somewhat lower than stated. A possible explanation of the 70% ten-year survival in our study is that it showed results from several different units and not from any specialized unit or surgeon.

The polyethylene insert is indeed an important component of the prosthesis and might be one of the weaker components in the long run regarding mobile-bearing total ankle replacements. In our study, wear or fracture of the polyethylene meniscus was the second most common reason for revision.

The differences of coating in the 2 series of the STAR prosthesis are important. The hydroxyapatite will at least partially resorb over time, and then the prerequisite for any bone-implant ingrowth is lacking if no underlying structure allows bony ingrowth or ongrowth. In this study, aseptic loosening was the reason for revision in 34 STAR I cases (59%). Carlsson³ found that 62% of the revisions were due to aseptic loosening, and Brunner et al² stated in their mixed series that the majority of their revisions were due to problems at the bone-implant interface when reporting a 31% aseptic loosening rate. Aseptic loosening was also the most common reason for revision in the review by Zhao et al.¹⁴ The single-coated STAR in our series had considerably more revisions than the double-coated STAR, although no statistically significant difference concerning survival could be detected.

The issue of a learning curve might play an important role when discussing inferior results of the single-coated STAR. This has been emphasized in many studies.^{1,3,4,12} Anderson et al¹ increased the 5-year survival from 0.53 in their first 20 replacements to 0.82 in their subsequent 31 cases. Henricson et al⁴ found, when comparing the 30 first performed STARs of each of 3 surgeons with their subsequent 132 cases, that the 5-year survival increased from 0.70 to 0.86. Carlsson³ also found considerably better results in his later series with STAR II than in his earlier series with STAR I. Schimmel et al¹² found decreased surgery time, fewer perioperative fractures, and improved tibial component orientation when comparing their first 50 STARs (STAR I and STAR II) with their last 50 STARs (STAR II). The revision rates between high-volume surgeons and low-volume surgeons did not differ much, 40% and 46%, respectively. An explanation might be that high-volume surgeons perform more difficult cases and thus have a higher risk of revision.

Demographic differences seem to play a role in the results of total ankle replacement. We found a higher revision risk for the STAR in women younger than 60 years with osteoarthritis, a result also found in the entire Swedish Ankle Registry.⁶ Brunner et al² also reported significantly more revisions of the STAR in younger patients.

An obvious limitation of registry data is uncertainty whether reporting is complete or not. We are quite confident that the reporting of total ankle replacements and revisions to the Swedish National Ankle Registry are complete. Primarily, we compare our registry data with the data from the Swedish National Health Service, and second, we know every surgeon in Sweden performing total ankle

replacements, which ensures a complete procedure-based coverage. An obvious strength with registry data is that it collects data from several different surgeons and units, thus giving a fairer picture of the total ankle replacement results than reports from single surgeons or units.

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