Single- and Double-Coated Star Total Ankle Replacements

A clinical and radiographic follow-up study of 109 cases

Å. Carlsson

Department of Orthopaedics, Malmö University Hospital, Department of Clinical Sciences, Lund University, SE-205 02 Malmö, Sweden

ake.carlsson@med.lu.se

Abstract

An up to 12-year follow-up of 51 single-coated STAR revealed that 15 ankles had undergone fusion. The time from index surgery to the first revision was median 51 months. In a series of 58 double-coated STAR ankles followed up to 5 years only one ankle had been revised for component loosening. In this series the clinical survival rate was 98% and the radiographic surival rate 94% at 5 years. The radiographic survival rate, with component loosening as endpoint, was significantly better for the last 31 cases in the series of of single coated prostheses. However, the loosening rate did not differ when these latter 31 cases were compared with the cases operated on with a double-coated prosthesis.

One may conclude that improvement of the anchoring surfaces has had a limited influence on the radiographic survival of the STAR ankle.

However, from the clinical survivorship figures it is obvious the learning process continues as the difference in revision rate between the 31 last implanted single-coated and the later on implanted double-coated prostheses approached significance.

Key words

Ankle, Arthroplasty, Radiostereometry, Replacement

Introduction

Medium term results after ankle replacement using the first and single-coated version of the uncemented Scandinavian Total Ankle Replacement (STAR) have been presented in a limited number of recent reports [1, 8, 9]. The number of cases in these reports with a mean follow-up of 4 to 4.5 years varies from 51 to 200.

In 1999, the anchoring surfaces of the STAR components were changed and since then have a double-coating of titanium and hydroxyapatite (HA). No clinical and radiographic results after implantation of this new design have yet been documented in the literature.

The aim of this study was to report on a longer follow-up of the single-coated design comparing the results with those after implantation of the double-coated design.

Material

I. Fifty-one uncemented total ankle replacements using the single-coated STAR design (Valdemar Link, Hamburg Germany) were implanted in 44 patients between April 1993 and 1999. Twenty-five patients with 28 ankles had been operated on due to rheumatoid arthritis (RA) and 20 patients with 23 ankles due to primary or posttraumatic osteoarthritis (OA and PtA, respectively). Thirty-six ankles were implanted in females and 15 in males. Median age at surgery was 57 years (27-76). The results of the 3- to 8-year follow-up of these cases have been presented in detail previously [1]. The clinical and radiographic follow-up has now been extended up to 12 years using the same protocol.

II. Fifty-eight uncemented total ankle replacements using the double-coated STAR design (Valdemar Link, Hamburg Germany) were implanted in 54 patients between 1999 and March 2005,

Twenty-two patients with 24 ankles had been operated on due to RA and 29 patients with 30 ankles had been operated on due to OA and PtA. Three patients with various other diagnoses had had 4 ankles replaced. Thirty-four ankles were implanted in females and 24 in males. The age at surgery was median 56 years (26-83). Six patients had to be excluded from the radiographic evaluation for the following reasons; one sustained a deep infection and five had only been examined radiographically a few days after surgery. For the remaining 52 cases radiograph follow-up was median 43 months. Another 3 ankles not followed up to 1 year and one ankle that had undergone revision, were excluded from the clinical follow-up. The median follow up for these 48 cases was 37 months (11-64).

Survival analysis

In the clinical survival analysis the endpoint was revision for any reason and in the radiographic survival analysis the endpoint was signs of loosening of either component. In both these survival analyses 57 ankles were included. Only the patient that sustained a deep infection was excluded.

Prosthesis and surgical technique

The metallic components of the STAR total ankle arthroplasty are made of a cobalt-chromium alloy. The components in series I had a 100-μm-thick hydroxyapatite layer applied on a smooth metal surface. In the current version (series II) the metal components have been coated with an approximately 300 micron thick layer of titanium (ISO 5832), applied by vacuum plasma spray technology with a pore size of 75-200 microns and a porosity of 25-35%. In addition, an approximately 25-micron thick hydroxyapatite layer (porosity 60%) has been applied using an electrochemical process.

The menisci used in series I, were made of ultra-high molecular weight polyethylene and had been sterilized by gamma irradiation in air. The menisci in series II had been sterilized by gamma-irradiation in nitrogen-vacuum. All operations are performed in a sterile-air enclosure with vertical airflow and almost always with the use of spinal anaesthesia. An antibiotic is administered intravenously about 30 minutes before the application of the tourniquet and again, immediately after the tourniquet has been released, and then after 6 and after 12 hours.

The surgical technique used in all cases in series II is described in detail elsewhere [2].

Clinical evaluation

All patients in both series were evaluated postoperatively using the AOFAS (American Orthopaedic Foot and Ankle Society) ankle-hindfoot scale [6]. The patients were also asked to report whether they were satisfied, somewhat satisfied or dissatisfied with the result of the operation as proposed by Makwana et al [7].

Radiograph evaluation

All postoperative radiographic examinations were performed with the aid of fluoroscopy in order to obtain standardized and true anteroposterior and lateral views of both components. The angles and distances used in the films to evaluate tilt or migration of the components have been described previously [1]. The criterion for loosening of the tibial component was a change of position of >2° of the flat base of the component in relation to the long axis of the tibia.

Loosening of the talar component as seen on the lateral view was defined as subsidence into the talar bone of > 5 mm or a change of in position of > 3° relative to a line drawn from the tuberosity of the calcaneus to the top of the talonavicular joint. In series II radiolucencies between the tibial component and the bone were searched for. In the anteroposterior films such phenomena seen at the flat surface were separated from those seen around the bars.

Statistical methods

Survival curves were drawn according to the method of Kaplan and Meier [5] and were compared with the use of the log-Rank test. For descriptive statistics we used Statistica 7.0.

Results

Revisions

Series I. At the previous report on the single-coated STAR ankle [1] 5 of the 51 ankles had been fused. Since then another 10 ankles have been fused, 4 of which previously had undergone exchange of at least one component and 5 of which had been reported as pending failures. The time from index surgery to the first secondary surgery occurred at median 51 months (1-124). To summarise, 15 ankles finally underwent arthrodesis 12 of which resulted in a stable fusion. Two ankles with a radiographically not fused ankle are painless.

The cases revised, the reason for revision and the final outcome are presented in Table 1.

Series II. Only one ankle had to be fused 8 months after index surgery due to loosening of the tibial component. Another two cases have radiographic signs of component loosening but have only minor symptoms and are therefore not scheduled for revision.

Survival analysis

The ankles replaced with a single-coated prosthesis (series I) were divided in two groups. Group I A comprises the first 20 cases and group I B the following 31 cases. Group II comprises the 57 ankles replaced with a double-coated prosthesis. The clinical and radiographic survival rates including confidence intervals (CI 95) for the three groups are presented in Table 2 and Figures 1 and 2. Life tables with respect to radiographic loosening in series I and II are presented in Table 3 and 4.

The estimated rate of radiographically intact ankles in the whole series I was 64% at 5 years and the corresponding value in series II 94%

The difference between the proportion of cases *not revised* in group I A and I B is not significant ($p= 0.445$). The difference between group I B and II approaches significance ($p=0.059$).

The difference between the proportion *radiographically intact* cases in group I A and I B is significant ($p<0.003$). The difference between group I B and II is not significant ($p=0.238$)

Neither the clinical nor the radiographic survival rates differed for patients operated on due to RA and OA or PtA.

Radiographic findings group II

There were two cases with signs of component loosening and in another case there was a slight clearance between bone and the medial bar of the tibial component. In all other cases the contact between the tibial component and underlying bone was very good, i.e. without the slightest clearance.

Function (group II)

The total range of motion at the last follow-up was median 33°.

The AOFAS pain score was median 40 (20-40) and the AOFAS total score 81 (63-100).

In 42 of the 48 cases the patients reported that they were satisfied with their ankle, five that that they were somewhat satisfied and one was dissatisfied.

Discussion

The significantly improved radiographic survival rate between the 20 first cases and the 31 thereafter-implanted single-coated STAR ankles has previously been reported [1]. This finding is confirmed in the present study and represents the learning curve. Even if we only observed three cases with radiographic signs of loosening among the 52 double-coated STAR ankles the radiographic survival rate did not differ from the 31 last cases in the series of single-coated STAR ankles, i.e. series I B.

Thus, further experience and improvement of the anchoring surfaces has had a lesser influence on the radiographic survival rate. However, from the clinical survivorship figures it is obvious that the learning process continues as the difference in revision rates between the 31 last implanted single-coated and the 52 double-coated STAR ankles approaches significance. In this material a 98% clinical survival and a 94% radiographic survival at 5 years must be considered as satisfactory. The process of patient selection plays, in my view, an important role for this improvement.

In series II patient satisfaction was high. 29 of 48 ankles were completely painless and 18 only caused occasionally discomfort (pain score 30) In 42 cases (88%) the patients were satisfied with the result.

Although as many as 15 ankles of the 51 that received a single-coated prosthesis (Series I A and B) had to be fused, 12 of the fusion healed and even if three did not heal radiographically, two of them were painless. This is in accordance with previous reports [3, 4], showing that arthrodesis in most cases is a successful salvage procedure if an ankle replacement fails.

References

1. Anderson T, Montgomery F, Carlsson Å (2003) Uncemented STAR total ankle prostehses. J Bone Joint Surg Am 85:1321-1329
2. Anderson T, Montgomery F, Carlsson Å (2004) Uncemented STAR total ankle prostheses. Surgical technique. J Bone Joint Surg Am 86:Suppl 1:103-111
3. Anderson T, Linder L, Rydholm U, Montgomery F, Besjakov J, Carlsson Å (2005) Tibio-talocalcaneal arthrodesis as a primary procedure using a retrograde intramedullary nail. Acta Orthop 76:580-587
4. Carlsson ÅS, Montgomery F, Besjakov J (1998) Arthrodesis of the ankle secondary to replacement. Foot Ankle Int 19:240-245
5. Kaplan EL, Meier P (1958) Non-parametric estimation from incomplete observations. J Am Statist Assoc 53:457-481
6. Kitaoka HB, Alexander IJ, Adelaar RS, Nunley JA, Myerson MS, Sanders M (1994) Clinical rating systems for the ankle-hindfoot, midfoot, hallux, and lesser toes. Foot Ankle Int 15:349-353
7. Makwana NK, Morrison P, Jones CB, Kirkup J (1995) Salvage operations after failed total ankle replacement. The Foot 5:180-184
8. Valderrabano V, Hintermann B, Dick W (2004) Scandinavian total ankle replacement: a 3.7-year average follow-up of 65 patients. Clin Orthop 424:47-56
9. Wood PL, Deakin S (2003) Total ankle replacement. The results in 200 ankles. J Bone Joint Surg Br 85:334-341

Acknowledgement

Jan-Åke Nilsson, statistician at the Departments of Orthopaedic, Malmö University Hospital, supervised the statistical analyses and Jack Besjakov, Department of Diagnostic Radiology, Malmö University Hospital, scrutinized the radiographs.

Figure legends

Figure 1.

Survival with revision for any reason as endpoint.

Figure 2.

Survival with radiographic loosening of at least one component as endpoint.

Table 1. The revision undertaken in series of single-coated STAR ankles (series I)

Case no	**Gender and age**	**Year of surgery**	**Diag-nosis**	**Months to first rev.**	**Reason for first revision**	**First revision**	**Final surgery**	**Function**
1	M 71	-93	OA	40	Loose tibial component	Stemmed tibial component	**Arthrodesis**	Not healed arthrodesis
3	M 69	-93	OA	5	Loose tibial component	Stemmed tibial component		Deceased
7	F 68	-94	RA	1	Technical mistake	Cemented tibia	**Arthrodesis**	Healed arthrodesis
9	F 60	-94	RA	49	Rupture of the syndesmosis	Insertion of lag screw	**Arthrodesis**	Healed arthrodesis
10	F 52	-94	OA	124	Loose talar component	**Arthrodesis**		Healed arthrodesis
12	F 66	-94	OA	23	Malposition of tibial comp	Stemmed tibial component		Good function
14	M 51	-94	RA	100	Loose talar component	**Arthrodesis**		Healed arthrodesis
15	F 57	-94	OA	57	Loose talar component	Exchange of talar component		Excellent function until death
18	F 41	-94	RA	51	Loose talar component	**Arthrodesis**		Healed arthrodesis
21	M 54	-95	PTA	50	Equinus position	Stemmed tibial component		Good function
23	F 55	-95	RA	89	Loose talar component	**Arthrodesis**		Healed arthrodesis
25	F 50	-95	RA	47	Loosening of	**Arthrodesis**		Healed arthrodesis

					both components			
29	F 75	-96	RA	72	Loose talar comp	**Arthrodesis**		Healed arthrodesis
31	F 27	-96	RA	6	Loosening of both components	**Arthrodesis**		Not healed arthrodesis Painless
33	F 73	-96	OA	64	Rupture of the meniscus	Exchange of meniscus		Scheduled for arthrodesis
35	M 48	-96	OA	87	Loose talar component	**Arthrodesis**		Healed arthrodesis
36	F 61	-97	RA	12	Pain&stiffness	**Arthrodesis**		Healed arthrodesis
40	M 46	-96	OA	71	Rupture of the meniscus	Excange of meniscus		Painless
44	F 29	-98	RA	65	Loosening tibal comp	**Arthrodesis**		Not healed arthrodesis Painless
53	F 45	-98	OA	51	Instability	Exchange of meniscus	**Arthrodesis**	Healed arthrodesis
57	M 57	-99	RA	61	Talus loose at revision	**Arthrodesis**		Healed arthrodesis

Table 2. Life table: Radiographic survival for series I.

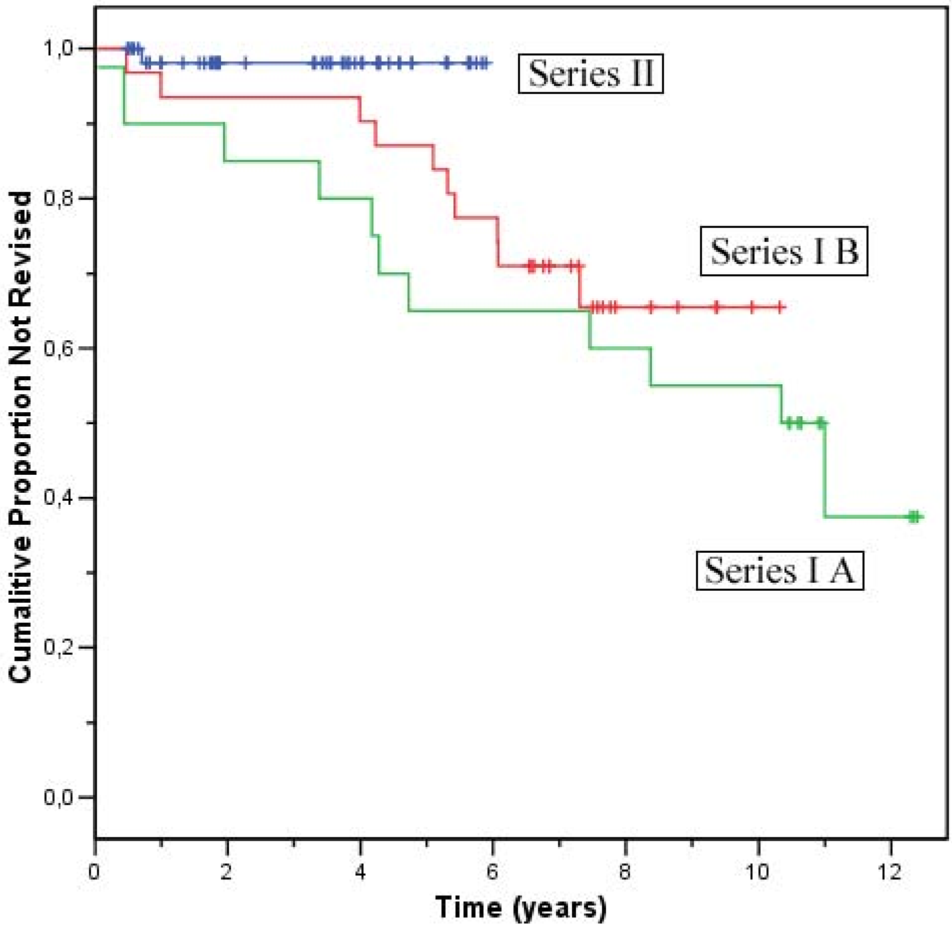
Year	Number entering	Number censored	Events	Cumulative proportion Not loose	SE
0	51	1	8	0.8416	0.0514
1	42	0	3	0.7815	0.0583
2	39	2	3	0.7198	0.0636
3	34	1	0	0.7198	0.0636
4	33	6	2	0.6718	0.0678
5	25	4	1	0.6426	0.0709
6	20	7	1	0.6036	0.0765
7	12	5	0	0.6036	0.0765
8	7	2	0	0.6036	0.0765
9	5	1	0	0.6036	0.0765
10	4	3	0	0.6036	0.0765

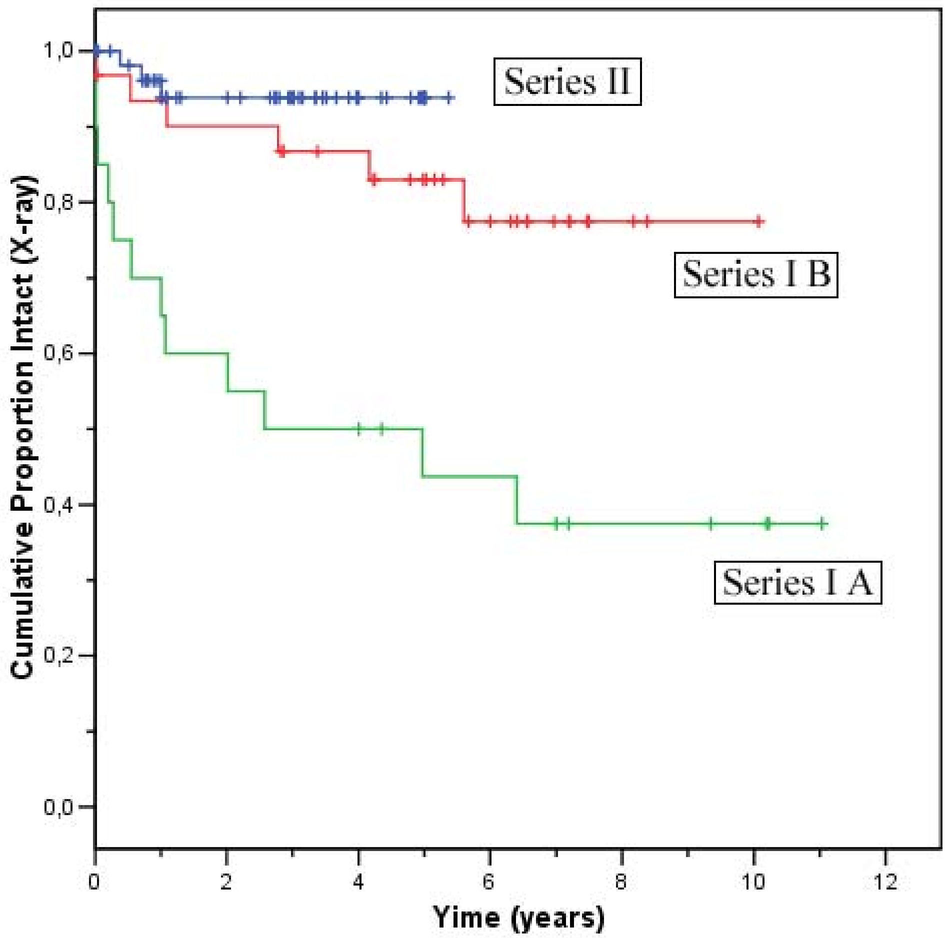
Table 3. Life table: Radiographic survival for series II.

Year	Number entering	Number censored	Events	Cumulative proportion Not loose	SE
0	57	11	2	0.9612	0.0269
1	44	7	1	0.9374	0.0352
2	36	9	0	0.9374	0.0352
3	27	14	0	0.9374	0.0352
4	13	8	0	0.9374	0.0352
5	5	5	0	0.9374	0.0352

Table 4. Clinical and radiographic survival rates for the single-coated (series I A-B) and double-coated (series II) STAR ankle.

Group	Proportion not revised at 5 years	95% CI	Proportion not revised at 10 years	95% CI	Proportion intact (X-ray) at 5 years	95% CI	Proportion intact (X-ray) at 10 years	95% CI
I A n=20	0.65	0.44-0.86	0.37	0.11-0.64	0.44	0.22-0.66	0.38	0.15-0.60
I B n=31	0.88	0.75-0.99	0.65	0.47-0.83	0.83	0.69-0.97	0.77	0.61-0.94
II n=52	0.98	0.96-1.0	-	-	0.94	0.87-1.0	-	-


Series II
Series I B
Series I A
1,0
0,8
0,6
0,4
0,2
0,0
Cumalitive Proportion Not Revised
0
2
4
6
8
10
12
Time (years)


Series II
Series I B
Series I A
Cumulative Proportion Intact (X-ray)
1,0
0,8
0,6
0,4
0,2
0,0
0
2
4
6
8
10
12
Yime (years)