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Outcome After Salvage Arthrodesis For Failed Total Ankle Replacement
- An analysis of all 118 cases in the Swedish Ankle Registry

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Outcome After Salvage Arthrodesis For Failed Total Ankle

Replacement

- An analysis of all 118 cases in the Swedish Ankle Registry

ABSTRACT

Background: In cases with total ankle replacement (TAR) failure a decision between revision TAR and salvage arthrodesis (SA) must be made. In a previous study we analyzed revision TAR and found low functional outcome and satisfaction. The aims of the current study were to analyze SA concerning failure rate and patient related outcome measures (PROMs).

Methods: Until September 2014, 1110 primary TARs were recorded in the Swedish Ankle Registry. Of the 188 failures, 118 were revised with SA (and 70 with revision TAR). Patient and implant specific data for SA cases were analyzed as well as arthrodesis technique. Failure of SA was defined as repeat arthrodesis or amputation. Generic and region specific PROMs of 68 patients alive with a solid unilateral SA performed more than one year before were analyzed.

Results: First attempt solid arthrodesis rate of SA was 90%. 25/53 (47%) patients were very satisfied or satisfied. Mean SEFAS was 22 (95% CI 20-24), EQ-5D 0.57 (0.49-0.65), EQ-VAS 59 (53-64), SF-36 physical 34 (31-37) and mental 50 (46-54).

Conclusion: Salvage arthrodesis after failed TAR had a solid arthrodesis rate of 90% at first attempt, but less than 50% of the patients were satisfied and the functional scores low. The scores and satisfaction were similar to those after revision TAR but the reoperation rate was significantly lower in SA ($p < .05$). Until studies show true benefit of revision TAR over SA we thus favor SA

for failed TAR. More examinations addressing the limitations of this study are however necessary to establish appropriate general clinical guidelines.

LEVEL OF EVIDENCE: Level IV, retrospective case series

KEYWORDS

Salvage Arthrodesis; Revision TAR; Failed Total Ankle Replacement; Failure Rate; Satisfaction; Outcome; PROM; Ankle Arthritis

INTRODUCTION

Total ankle replacement (TAR) plays an important role in the surgical treatment of ankle arthritis and has become an alternative to arthrodesis. However, the increasing popularity of TAR also leads to increasing numbers of revision procedures and the failure rate of TAR has been reported higher than those of hip and knee replacements.^{6,14} Salvage arthrodesis (SA) is the generally accepted surgical treatment for failed TAR^{2-5,7,10} but revision TAR has gained popularity especially as some studies have found similar implant survival as for primary TAR.^{9,12} We previously analyzed survival and outcome of revision TAR in the Swedish Ankle Registry¹¹ and found a 10-year implant survival of 55%, low outcome scores, and only half of the patients were satisfied with their revision TAR.

The aims of the present study were to analyze results of salvage arthrodesis after failed primary TAR, performed in Sweden from January 1993 until September 2014, and specifically describe (i) failure rate, (ii) methods of treatment for failure and (iii) in available patients also patient reported outcome measures (PROMs).

55 MATERIAL AND METHODS

56 The Swedish Ankle Registry (www.swedankle.se) is a National Quality
57 Registry⁶ of all primary TARs and reoperations performed in Sweden since
58 1993 with patient specific data such as age, sex, diagnosis, surgical
59 technique and type of implant, and since 2008 also PROMs including grade
60 of satisfaction, health-related quality of life (EQ5D, SF-36) and a foot and
61 ankle specific score (SEFAS).

62
63 Until September 2014, 1110 primary TARs were recorded in 1026 patients
64 (617 women). 188 failures were registered, whereof 118 salvage arthrodeses
65 were performed in 114 patients (71 women). The 70 patients (44 women) who
66 underwent revision TAR with component exchange have been presented
67 previously.¹¹

68
69 We evaluated the cases with SA concerning mean age at the time of primary
70 and revision surgery, diagnosis, type of primary prosthesis, cause of failure of
71 the TAR, and arthrodesis technique. We identified if additional surgical
72 procedures had been reported to the registry. SA was defined as a solid
73 arthrodesis if no further major revision (repeat arthrodesis or amputation) was
74 registered during the study period.

75
76 We asked all patients who had undergone a solid first attempt SA with a
77 minimum follow-up time of 12 months to reply to the following PROMs: the
78 validated Self-reported Foot & Ankle Score (SEFAS), the Euro Qol 5
79 Dimension (EQ-5D) scale and EQ- Visual Analogue Scale (EQ-VAS) for
80 health, the Short Form-36 Questions (SF-36) scale, and a separate question
81 regarding satisfaction. SEFAS provides values between 0 and 48 where a
82 value of 48 represents normal foot and ankle function.¹ EQ-5D index provides

values between -0,594 and 1 (full health). EQ-VAS ranks the self-estimated health on a visual analogue scale from 0 to 100 with full health at 100. The generic SF-36 score assesses health related quality of life (HRQoL) by values between 0 and 100, interpreting 100 as full health. The patients were also specifically asked if they were very satisfied, satisfied, neither satisfied nor dissatisfied, dissatisfied or very dissatisfied with the revised ankle.¹⁵ The four patients who underwent bilateral SA were excluded from the PROM evaluation. Of the 80 patients alive and with solid unilateral SA, 68 (85%) answered the PROMs at median two (range, 1-17) years after their salvage arthrodesis. Not all of the 68 patients responded to all questions in all questionnaires. In cases of incomplete questionnaires in the SEFAS, we used the following approach¹: (1) questionnaires were disregarded with missing answers to 2 or more questions; (2) in cases with 1 missing question, the mean result of the remaining 11 questions was used; (3) in cases with double answers for 1 question, the worse outcome was recorded; and (4) the worse outcome was recorded in cases when the patients chose to set their mark between 2 answers.

Statistics

Data are reported as numbers and proportions (%), medians or means with standard deviations (SD), ranges or 95% confidence intervals (95% CI). For statistical analysis of group differences, independent t-tests were performed to compare means and Chi-Square tests for categorical variables. Changes within groups were tested by Wilcoxon Rank Sum tests due to the small numbers in each group. To estimate the success rate of SA, a Kaplan-Meier analysis with repeat arthrodesis or amputation as endpoints was utilized. All statistical analyses were performed with statistical package of social sciences (SPSS)® version 22.

111

112 **Ethics**

113 All patients undergoing TAR surgery in Sweden are informed about the
114 Swedish Ankle Registry and participate after verbal agreement. As yet no
115 patients have declined participation or changed their mind later on. The study
116 has been approved by the Relevant Ethical Review Board and was performed
117 according to the declaration of Helsinki.

118

119 **RESULTS**

120 Of the 1026 patients with 1110 primary TARs, 114 patients underwent 118
121 first attempt salvage arthrodeses due to TAR failure. These 114 patients were
122 at mean 55 (range, 21-83) years old at the time of primary TAR surgery and
123 61 (range, 27-90) at the time of SA. Rheumatoid arthritis (RA) was the
124 primary diagnosis in forty-seven (40%) of the 118 cases, posttraumatic
125 arthritis (PTA) in 40 (34%), osteoarthritis (OA) in 26 (22%) and other
126 diagnoses in 5 (4%). In 68 (58%) of the 118 cases aseptic loosening was the
127 cause of failure of the TAR, in 14 (12%) infection and in 36 (30%) pain,
128 technical failure, malalignment or instability. Twelve patients had died before
129 September 2014, all without any further ankle revisions recorded.

130

131 The most common type of primary TAR converted into arthrodesis was the
132 STAR as shown in Table 1. Retrograde nailing was the most frequently used
133 technique for SA (58/118, 49%), followed by plate fixation (15/118, 13%),
134 metal spacer with plate or nail fixation (9/118, 8%), external fixation (7/118,
135 6%) and screw fixation (6/118, 5%). In 23 (19%) cases the arthrodesis
136 technique was not recorded.

137

Twelve (10%) of the 118 salvage arthrodeses did not unite at first attempt, resulting in two amputations and 10 repeat arthrodeses (Figure 1). Of the 10 repeat arthrodeses seven united whereas three did not. One of the latter cases led to amputation and two to repeat repeat arthrodesis. The Kaplan-Meier analysis estimated 91% of the patients without further major revisions after five years and 83% after 10 years (Figure 2).

Failure of SA was recorded in two (8%) of the 26 cases with OA, in six (13%) of the 47 with RA, and in four (10%) of the 40 with PTA. Concerning arthrodesis technique, six (10%) of the 58 retrograde nailing SA cases failed, one of the 15 plate fixations, three of the seven external fixations, one of the nine with metal spacer and one of the 23 without registered technique. Due to small subgroup sizes statistical testing was not reasonable.

Figure 3 shows reoperations registered for the failed ankles. Once SA was solid no further reoperations could be found in the registry.

The PROMs of at most 68 patients are shown in Table 2a. For comparison, the results of revision TAR are shown in Table 2b. Twenty-five (47%) of 53 patients were very satisfied or satisfied with their salvage arthrodesis, 15 (28%) neither satisfied nor dissatisfied and 13 (25%) dissatisfied or very dissatisfied. Both pre- and postrevision scores were recorded only in 10 patients and are shown in Table 3a. For comparison, Table 3b contains the results of pre- and postoperative scores of 7 revision TAR patients. We found no obvious association between SA technique and functional outcome or satisfaction.

DISCUSSION

In this study salvage arthrodesis for failed primary TAR had a first attempt solid arthrodesis rate of 90%. However, subjective outcomes showed that only half of the patients were satisfied with their ankle, and three patients of 114 (3%) underwent below knee amputation as a consequence of a failed salvage procedure.

The presented rate of solid salvage arthrodesis is comparable to those seen in literature. Gross et al. (2015) found in a recently published systematic review of SA an overall first attempt union rate of SA of 84%. Results depended on arthrodesis technique with highest union rates after blade plate use. Furthermore, isolated tibiotalar arthrodesis resulted in higher union rate than tibiotalocalcaneal arthrodesis.⁵ Deleu et al (2014) reported a first attempt success rate in 13 of 17 SA.³ Doets and Zuercher (2009) had nonunion in seven of 18 ankles, all failed cases performed with other techniques than blade plates.⁴ In the study of Culpan et al (2007), 15 of 16 patients united at first attempt and the authors assumed potentially higher nonunion rates of SA in patients with RA.² The same conclusion was reported by Hopgood et al. 2006.¹⁰ We did not distinguish between different SA procedures in this study (tibio-talar arthrodesis vs tibio-talo-calcaneal (TTC) arthrodesis). This may however be interesting, as TTC arthrodesis includes an additional joint in addition to the originally failed one. In secondary analyses (data not shown) we did not find any association between arthrodesis technique and outcome (SEFAS or satisfaction). This was however not a primary outcome of our study and future studies aimed at this question may provide further information regarding this matter.

In cases with nonunion of SA, repeat arthrodesis is most often utilized but in isolated cases below knee amputation may have to be considered. In our

study, three of the 12 failed SA cases resulted in amputation. Other studies seldom report amputations as a final consequence of failed TAR, though it is often mentioned as a possible treatment, especially in severe cases with large bone loss or infection.^{5,10,13,17}

The evaluation of PROMs in our study showed that all post SA scores including satisfaction were comparatively low. The SF-36 physical function subscale mean score of 40 points was in our study as low as in a recently published study of Rahm et al.¹⁶ A systematic review of SA has found significant increase of the scores from pre- to postoperatively.⁵ We could identify only 10 patients with both pre- and postoperative scores and were unable to find any significant changes, possible due to a type II error (Table 3a).

The strengths of the current study include large data regarding SA after failed primary TAR. The unselected, nationwide patient cohort includes all or almost all cases and the results reflect the everyday life practice with the inclusion of different hospitals and different surgeons. The evaluation of validated PROMs allows comparison with other alternative surgical procedures such as revision TAR and with other studies.

Weaknesses of the study include the risk of incomplete reporting to the registry. Yet, we are confident that the reporting to the Swedish Ankle Registry is complete or almost complete concerning TAR registration and secondary revision procedures.⁸ Unfortunately, additional non-ankle procedures such as subtalar or midfoot arthrodesis after SA were not recorded, as these procedures are not considered true revisions to the primary TAR. Some other studies do include these procedures as they may

sometimes be seen as consequences of the former ones. Despite the possibility to record arthrodesis technique this information was lacking in some cases. It would have been interesting to see if operation technique influenced failure rate, patient satisfaction and PROM outcome, as described in other studies, but even in our complete nationwide dataset this was not possible. Another weakness is that failed cases are only captured through recorded revisions. Hence, cases with clinically asymptomatic nonunion are not included in our failure rate. Anyhow, our failure rate of 10% is similar to other studies, and nonunion without any further revision is rare.⁵ A further limitation is the absence of preoperative PROM data in all cases, as this would have given more strength in the evaluation of scores, both concerning patient selection, improvement by surgery and potential differences between salvage arthrodesis and revision TAR (Table 3a+b). Many of the subgroups contained only small numbers, limiting statistical testing and inferences. Patients undergoing SA are diverse and the registry currently does not provide enough background information to enable adjustment. This should be considered when setting up new registries but also in current registries not collecting these data. Finally, comparison of the outcome of SA with primary arthrodesis (PA) would have given valuable additional information on potential differences between primary and secondary procedures. Rahm et al. (2015) found inferior clinical outcome of 23 patients with SA compared to PA in 23 matched pair patients. After a follow-up time of 38 (SA) and 56 (PA) months respectively, patients with SA had significantly more pain and worse function compared to PA.¹⁶ Further comparative studies will have to be done to potentially confirm these results.

When a TAR fails the situation demands a decision between revision TAR and salvage arthrodesis, but there is no generally accepted algorithm on how

to choose. Literature supports salvage arthrodesis as a valid method for failed TAR with high union rate and few complications, though the results can depend on both primary diagnosis and fusion technique.^{2-5,7,10,13}

Our data covers all or almost all cases with salvage arthrodesis after failed primary TAR in Sweden. By contrasting these results with those from the alternate procedure, component exchange, from the same registry¹¹ we have some opportunity to compare the two procedures. It should be clearly stated that the comparison must be interpreted with caution due to differences in patient selection. Patients in the SA group were older both at the time of primary and secondary surgery whereas the median follow-up time was two years in the SA group compared to eight years in the revision TAR group, leading to similar ages in both groups at the time for evaluation. Table 4 illustrates differences in background factors, which may reflect some aspects of the patient selection. In our data we found revision TAR in younger patients ($p < .005$) with posttraumatic arthritis ($p = .03$), in cases due to unspecified reasons for failure ($p = .04$) and after a time well below the expected survival of primary TARs. On the contrary SA was found in cases with well-defined causes of failure after a significantly longer period after the primary TAR. Yet, obvious factors affecting case selection including bone quality and comorbidities, which may potentially influence the choice of treatment, are not recorded in the registry.

In both SA and revision TAR patients the satisfaction rate was similar in that about half of the patients were satisfied or very satisfied with their ankle at the time of evaluation. Mean functional scores, both generic and specific, were mostly similar (Table 2a+b) (p -values for group differences ranging from .1 to .9). The only exception was the SF-36 physical function subscale with

statistically significant better follow-up results in revision TAR patients ($p = .02$).

First attempt solid arthrodesis rate of SA was 90%. After the 118 first attempt SA, 15 additional surgical procedures were performed in 12 patients. All interventions were major revisions such as repeat arthrodeses or amputations. An interesting observation was that repeat arthrodesis was performed up to eight years after first attempt SA. Our previously published follow up study of revision TARs showed a 10-year survival of revision TAR of 55%.¹¹ A total of 47 additional surgical procedures were registered in 28 patients after first attempt revision TAR whereof 34 were major revisions such as repeat component exchange, arthrodesis or repeat arthrodesis. Compared to these results, SA was in the current study associated with a statistically significant lower reoperation rate than revision TAR ($p < .05$).

In summary, based on our results we see the advantage of salvage arthrodesis over revision TAR when primary TAR fails. Despite an assumed patient selection, functional outcome and satisfaction were similar in both groups but the reoperation rate was significantly lower in the SA group. Until studies show true benefit of revision TAR over SA we thus favor SA for failed TAR. More examinations addressing the limitations of this study are however necessary to establish appropriate general clinical guidelines.

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- 357

358 **Table 1** Type of prosthesis and mean time
359 from primary TAR to salvage arthrodesis (SA)

Type of Prosthesis	n (%)	Mean time to SA in months
STAR	72 (61)	79
AES	14 (12)	44
Mobility	13 (11)	35
BP	10 (8)	42
CCI	6 (5)	27
Hintegra	3 (3)	47
Total	118	63

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Table 2a Mean functional scores of patients with salvage arthrodesis (SA)

PROM	SA	n	Mean (95% CI)
SEFAS		68	22 (20-24)
EQ-5D index		66	0.57 (0.49-0.65)
EQ VAS		64	59 (53-64)
SF-36 physical function		64	40 (34-46)
SF-36 bodily pain		62	48 (41-54)
SF-36 physical		60	34 (31-37)
SF-36 mental		60	50 (46-54)

Table 2b Mean scores of patients with revision TAR (from Kamrad et al.¹¹)

Revision TAR
Mean (95% CI)
(n = 29)
22 (19-26)
0.6 (0.5-0.7)
64 (58-74)
52 (43-61)
50 (40-61)
37 (33-41)
49 (43-55)

Table 3a Pre- and postoperative PROMs in salvage arthrodesis^a; p for differences pre to post^b

Table 3b Pre- and postoperative PROMs in revision TAR^c; p for differences pre to post (from Kamrad et al.¹¹)

Salvage arthrodesis			Revision TAR		
PROM	Pre (n=10)	Post (n=10)	PROM	Pre (n=7)	Post (n=7)
SEFAS	13	17 (p = .3)	SEFAS	19	22 (p = .2)
EQ-5D	0.4	0.5 (p = .6)	EQ-5D	0.5	0.6 (p = .4)
EQ-VAS	43	52 (p = .2)	EQ-VAS	51	56 (p = .6)
SF-36 pf	35	32 (p = .4)	SF-36 pf	46	48 (p = .9)
SF-36 bp	33	37 (p = 1.0)	SF-36 bp	34	47 (p=.04)
SF-36 phys	33	29 (p = .4)	SF-36 phys	31	35 (p = .2)
SF-36 ment	45	47 (p = .7)	SF-36 ment	48	49 (p = .8)

^amean age of the 10 patients preop 51 and postop 59, mean time to revision 98 mths

^bWilcoxon rank sum test

^cmean age of the 7 patients preop 48 and postop 52, PTA in 5/7 cases

383 **Table 4** Basic differences between salvage arthrodesis (SA) patients and
 384 revision TAR patients

	SA n=118	Revision TAR n=69	p
Mean (SD) age in yrs at time of primary TAR	55 (12)	53 (12)	.2
Mean (SD) age in yrs at time of revision	61 (13)	55 (11)	<.005
Diagnosis:			.03
OA (total prim TAR 24%)	22%	20%	
RA (total prim TAR 34%)	40%	23%	
PTA (total prim TAR 35%)	34%	55%	
Other (total pim TAR 7%)	4%	2%	
Cause of failure:			.04
Aseptic loosening	58%	54%	
Infection	12%	3%	
Other	30%	43%	

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Figure 1 Flowchart cases with salvage arthrodesis (SA) after failed primary TAR.

^asolid: no further major revision (repeat arthrodesis or amputation) recorded

Figure 2 Kaplan-Meier analysis of salvage arthrodesis

Figure 3 Flowchart reoperations



