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Cover letter / Title page

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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

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

30

31 **LEVEL OF EVIDENCE:** Level IV, retrospective case series

32

33 **KEYWORDS**

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

36

37 **INTRODUCTION**

38 Total ankle replacement (TAR) plays an important role in the surgical
39 treatment of ankle arthritis and has become an alternative to arthrodesis.

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

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

54

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

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

100

101 **Statistics**

102 Data are reported as numbers and proportions (%), medians or means with
103 standard deviations (SD), ranges or 95% confidence intervals (95% CI). For
104 statistical analysis of group differences, independent t-tests were performed
105 to compare means and Chi-Square tests for categorical variables. Changes
106 within groups were tested by Wilcoxon Rank Sum tests due to the small
107 numbers in each group. To estimate the success rate of SA, a Kaplan-Meier
108 analysis with repeat arthrodesis or amputation as endpoints was utilized. All
109 statistical analyses were performed with statistical package of social sciences
110 (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

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

144

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

151

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

154

155 The PROMs of at most 68 patients are shown in Table 2a. For comparison,
156 the results of revision TAR are shown in Table 2b. Twenty-five (47%) of 53
157 patients were very satisfied or satisfied with their salvage arthrodesis, 15
158 (28%) neither satisfied nor dissatisfied and 13 (25%) dissatisfied or very
159 dissatisfied. Both pre- and postrevision scores were recorded only in 10
160 patients and are shown in Table 3a. For comparison, Table 3b contains the
161 results of pre- and postoperative scores of 7 revision TAR patients. We found
162 no obvious association between SA technique and functional outcome or
163 satisfaction.

164

165 **DISCUSSION**

166 In this study salvage arthrodesis for failed primary TAR had a first attempt
167 solid arthrodesis rate of 90%. However, subjective outcomes showed that
168 only half of the patients were satisfied with their ankle, and three patients of
169 114 (3%) underwent below knee amputation as a consequence of a failed
170 salvage procedure.

171

172 The presented rate of solid salvage arthrodesis is comparable to those seen
173 in literature. Gross et al. (2015) found in a recently published systematic
174 review of SA an overall first attempt union rate of SA of 84%. Results
175 depended on arthrodesis technique with highest union rates after blade plate
176 use. Furthermore, isolated tibiotalar arthrodesis resulted in higher union rate
177 than tibiotalocalcaneal arthrodesis.⁵ Deleu et al (2014) reported a first attempt
178 success rate in 13 of 17 SA.³ Doets and Zuercher (2009) had nonunion in
179 seven of 18 ankles, all failed cases performed with other techniques than
180 blade plates.⁴ In the study of Culpan et al (2007), 15 of 16 patients united at
181 first attempt and the authors assumed potentially higher nonunion rates of SA
182 in patients with RA.² The same conclusion was reported by Hopgood et al.
183 2006.¹⁰ We did not distinguish between different SA procedures in this study
184 (tibio-talar arthrodesis vs tibio-talo-calcaneal (TTC) arthrodesis). This may
185 however be interesting, as TTC arthrodesis includes an additional joint in
186 addition to the originally failed one. In secondary analyses (data not shown)
187 we did not find any association between arthrodesis technique and outcome
188 (SEFAS or satisfaction). This was however not a primary outcome of our
189 study and future studies aimed at this question may provide further
190 information regarding this matter.

191

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

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

198

199 The evaluation of PROMs in our study showed that all post SA scores
200 including satisfaction were comparatively low. The SF-36 physical function
201 subscale mean score of 40 points was in our study as low as in a recently
202 published study of Rahm et al.¹⁶ A systematic review of SA has found
203 significant increase of the scores from pre- to postoperatively.⁵ We could
204 identify only 10 patients with both pre- and postoperative scores and were
205 unable to find any significant changes, possible due to a type II error (Table
206 3a).

207

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

214

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

222 sometimes be seen as consequences of the former ones. Despite the
223 possibility to record arthrodesis technique this information was lacking in
224 some cases. It would have been interesting to see if operation technique
225 influenced failure rate, patient satisfaction and PROM outcome, as described
226 in other studies, but even in our complete nationwide dataset this was not
227 possible. Another weakness is that failed cases are only captured through
228 recorded revisions. Hence, cases with clinically asymptomatic nonunion are
229 not included in our failure rate. Anyhow, our failure rate of 10% is similar to
230 other studies, and nonunion without any further revision is rare.⁵ A further
231 limitation is the absence of preoperative PROM data in all cases, as this
232 would have given more strength in the evaluation of scores, both concerning
233 patient selection, improvement by surgery and potential differences between
234 salvage arthrodesis and revision TAR (Table 3a+b). Many of the subgroups
235 contained only small numbers, limiting statistical testing and inferences.
236 Patients undergoing SA are diverse and the registry currently does not
237 provide enough background information to enable adjustment. This should be
238 considered when setting up new registries but also in current registries not
239 collecting these data. Finally, comparison of the outcome of SA with primary
240 arthrodesis (PA) would have given valuable additional information on
241 potential differences between primary and secondary procedures. Rahm et al.
242 (2015) found inferior clinical outcome of 23 patients with SA compared to PA
243 in 23 matched pair patients. After a follow-up time of 38 (SA) and 56 (PA)
244 months respectively, patients with SA had significantly more pain and worse
245 function compared to PA.¹⁶ Further comparative studies will have to be done
246 to potentially confirm these results.

247

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

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

253

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

272

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

278 statistically significant better follow-up results in revision TAR patients ($p =$
279 .02).

280

281 First attempt solid arthrodesis rate of SA was 90%. After the 118 first attempt
282 SA, 15 additional surgical procedures were performed in 12 patients. All
283 interventions were major revisions such as repeat arthrodeses or
284 amputations. An interesting observation was that repeat arthrodesis was
285 performed up to eight years after first attempt SA. Our previously published
286 follow up study of revision TARs showed a 10-year survival of revision TAR of
287 55%.¹¹ A total of 47 additional surgical procedures were registered in 28
288 patients after first attempt revision TAR whereof 34 were major revisions such
289 as repeat component exchange, arthrodesis or repeat arthrodesis. Compared
290 to these results, SA was in the current study associated with a statistically
291 significant lower reoperation rate than revision TAR ($p < .05$).

292

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

300

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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
<i>Total</i>	118	63

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

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

PROM	SA	n	Mean (95% CI)	Revision TAR
				Mean (95% CI)
				(n = 29)
SEFAS		68	22 (20-24)	22 (19-26)
EQ-5D index		66	0.57 (0.49-0.65)	0.6 (0.5-0.7)
EQ VAS		64	59 (53-64)	64 (58-74)
SF-36 physical function		64	40 (34-46)	52 (43-61)
SF-36 bodily pain		62	48 (41-54)	50 (40-61)
SF-36 physical		60	34 (31-37)	37 (33-41)
SF-36 mental		60	50 (46-54)	49 (43-55)

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370

371 **Table 3a** Pre- and postoperative
 372 PROMs in salvage arthrodesis^a; p for
 373 differences pre to post^b
 374
 375

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)

376 ^amean age of the 10 patients preop 51 and postop 59, mean time to revision
 377 98 mths

378 ^bWilcoxon rank sum test

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

380
 381
 382

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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389

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

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

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396 **Figure 2** Kaplan-Meier analysis of salvage arthrodesis

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400 **Figure 3** Flowchart reoperations

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