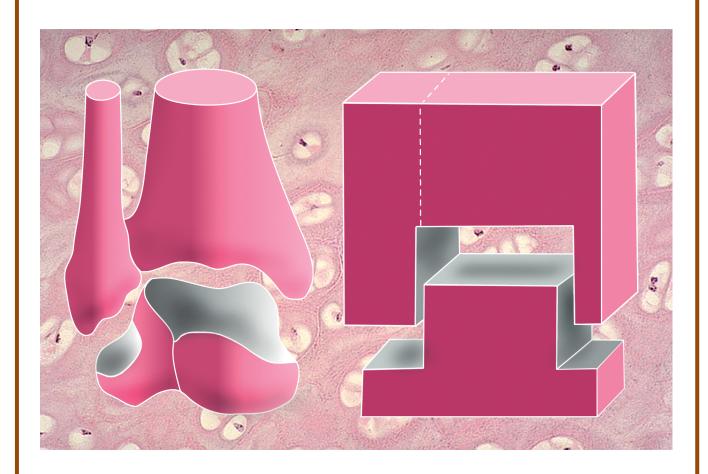
SwedAnkle The Swedish Ankle Registry



Annual Report 2017 Summary in English

Participating units 2017

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Borås Nacka

Carlanderska Sportsmedicin
Carlanderska Ortopedi

Norrköping
Norrtälje
Nyköping

Danderyd Orthocenter Stockholm

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KS Huddinge Värnamo
Kungälv Västervik
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Malmö Örebro Motala Östersund

Movement

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The Swedish Ankle Registry Annual Report 2017

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1. Background

The concept of reporting all ankle replacements to a national registry appeared 1997, and later that year a registry was initiated. Since 2008 the registry also includes ankle fusions and supramalleolar osteotomies. Since 2008 questionnaires containing generic (SF-36 and EQ-5D) and ankle- specific scores SEFAS (Self-Reported Foot and Score) are filled out by the patient preoperatively at participating units. Post-operatively the same questionnaires are sent to the patients after 6 months, 1 and 2 years. The patients are then also asked to report their degree of satisfaction with the performed ankle surgery. See publications no 7, 9, 10 and 17 at page 11-12. The Swedish and English versions of the ankle-specific score (SEFAS) can be found under the link *questionnaires* at www.swedankle.se and the English version as Appendix 1. Our database is administered by the Registry Centre South (RC-Syd) in Lund www.rcsyd.se.



Figure 1. X-ray of the Rebalance ankle. Side view (left) front view (right). This design have been used in Sweden since 2011

2. News since previous report and summary

Decentralized direct reporting in to the database was introduced in 2016 and has been utilized increasingly during 2017. That implies that the local surgeons can take part online what has been reported by themselves and their patients.

Since some years smoking habits in connection with ankle surgery is presented. 160 out of 172 persons undergoing ankle replacement 2015-2017 had reported their smoking habits. 9/160 was smokers but 6 of them had stopped smoking at least 6 weeks before surgery.

There were more smokers among patients undergoing ankle fusion. 850 out of 922 persons had reported their habits. 119/850 (14%) were smokers but 41 of them stopped smoking at least 6 weeks before surgery (Table 5 in page 24)

ASA-class presented for the third time, For 163 out of 173 patients undergoing ankle replacement 2015-2017 there was information on ASA-class. 63/163 (54%) had ASA-class 2 or 3 but none class 4. For 874 out of 911 patients undergoing ankle fusion 2015-2017, 630 (72%) had ASA-class 2-3. Somewhat surprising 9 had ASA-class 4 – i.e. a life-threatening condition (Table 6).

WE can now present the outcome of ankle surgery as PROM and PREM data (Table 15, Figure 16a+b and Figure 17a+b), see also chapter 15 in page 25. In summary these data demonstrates that the patients are being helped by the operation. That is true both with reference to the generic PROM EQ 5D -3L-representing general health- and the foot and ankle specific PROM SEFAS.-

65 ankles were replaced during 2017, somewhat more than the previous two years. That fewer cases were reported 2015-2016 was a consequence of the permanent closing of one major center during the summer 2014. Another reason was that the production of the Mobility ankle prosthesis stopped mid-2014 and some units have not yet decided how to proceed. The procedure based coverage for replacements was 100%. Surgery has been performed at 11 units by surgeons based at 8 hospitals

During 2017, 295 primary ankle fusions were reported, about the same number as in 2014 - 2016. Procedure based coverage for ankle fusions has been estimated to 95%. Ankle fusions are potentially performed at 50 units, but 31 of these performed less than 5 cases during 2017. Eight units performed 10 or more fusions, but only two units 20 or more fusion (Table 4). All but 2 Swedish hospitals have reported there ankle fusions during 2016.

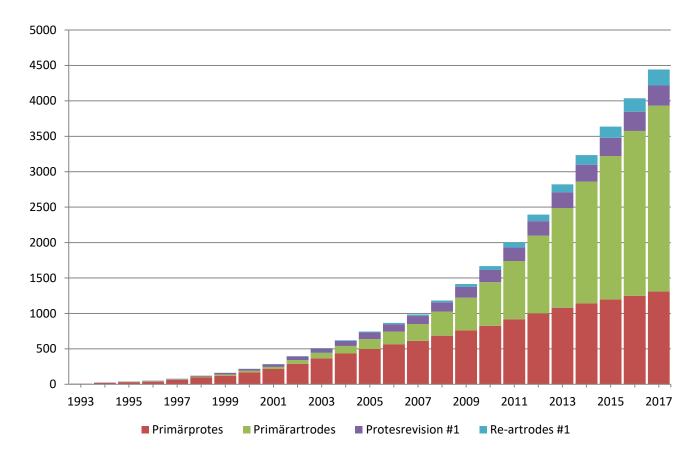


Figure 2. Number of primary replacements, arthrodeses, first revisions and first re-arthrodeses during 1993-2017.

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3. Board and secretary

Board

Chair

Åke Carlsson, MD, PhD, Dept. of Orthopedics, Skåne University Hospital, Malmö *Members*

Maria Cöster, MD, Dept.of Orthopaedics, Skåne University Hospital, Malmö

Per-Anders Hamrén, Patient representative, Stockholm

Anders Henricson, MD, PhD, Dept. of Orthopaedics, Falu Central Hospital

Anna Petersson, Certified Nurse, Dept. of Orthopaedics, Kalmar

Björn Rosengren, MD, PhD Associate Professor, Skåne University Hospital, Malmö

Per-Henrik Ågren, MD, Stockholms fotkirurgiklinik, Sophiahemmet, Stockholm

Secretary

Carina Malm, Dept. of Orthopaedics, Skåne University Hospital, Malmö

4. Webpage: www.swedankle.se

The webpage contains material for both the profession and for patients. For patients in the form of general and specific information on ankle surgery and for the profession report forms, questionnaires, recent results and annual reports are available.

5. Economy

Until to 2010 incomes were based on grants from various research funds. From 2011 the Registry has also received annual contributions from The Swedish Association of Local Authorities and Regions (SKL) (www.kvalitetsregister.se).

6. Research group

Åke Carlsson, Ass. Professor Magnus Karlsson, Professor

Björn Rosengren, Ass. Professor Anders Henricson, PhD

Maria Cöster, PhD Jan-Åke Nilsson, Statistician

Ilka Kamrad, PhD Håkan Magnusson, PhD

Alexandra Undén, MD Lars Jehpsson, Statistician

7. Summary of studies based on the ankle registry

Two studies analyzing the results the result after ankle replacement have been published (3-6). In a study from 2007 the survival rate of 531 primary ankle replacements was estimated to 78% (3). A long learning curve was demonstrated in that the 5-year prosthetic survival regarding the procedures performed by 3 surgeons was 70% for their first 30 cases compared to 86% for those performed thereafter. The risk of revision was higher in younger patients than older (3).

In the second study from 2011 (6) on 780 ankles the 10-year survival of 780 ankles was estimated to 69% Excluding the STAR prosthesis, that no longer is used in Sweden, the 10-year survival was estimated to 78%. It was also demonstrated that women with osteoarthritis and below the age of 60 had a higher risk of revision.

A separate study on the STAR ankle (1) demonstrated that the 5-year survival of the double-coated STAR design was 98% and better than the corresponding value for the earlier and single-coated design.

Malposition of the hind-foot influences the outcome of ankle replacement. An analysis of 182 cases found that patients with a varus position of the ankle preoperatively were revised twice as often as patients with a normal or valgus position (2).

In a study on 93 AES-ankles the 5-year prosthetic survival was 90% (4). In 27% of the cases a total of 36 surgical procedures had been performed simultaneously.

Reviewing existing definitions of "revision" resulted in a recommendation that has been adopted by the Swedish and British registries and is used in several publications (5).

Patient-Related Outcome Measures (PROM) are increasingly used for evaluation of outcome of various interventions. The Self-reported Foot and Ankle specific Score (SEFAS) has been found to have good validity, reliability and sensitivity to within-patient changes (7). It is used routinely in the Swedish Ankle Registry (8).

Ankle prostheses implanted as a revision procedure after failure of a primary prosthesis were found to have an estimated 10-year survival of 55%. Only half of the patients were however satisfied with the operation (9). A corresponding study in which the failed ankle prostheses were treated by fusion has been published (14)

A long-term study of the hitherto largest number of STAR-ankles demonstrated a 14-year survival of 47% for the single-coated STAR-design and a 12-year survival of 64% for the double-coated

design. Women below 60 years of age had a higher risk of revision (12).

SEFAS score did not differ between sides in patients who had had one ankle replaced and the contralateral fused. Most patients were satisfied with both ankles (13).

The 10-year survival of prosthesis implanted after the first replaced ankle had failed was 55%. Half of the patients with the re-replaced ankle were satisfied. (11) The satisfaction rate was about the same in patient who instead had their ankle fused after failure. (14) The PROM- scores were about the same in both studies (11, 14). However, the reoperation rate was higher in the re-replaced group than in the group that had been fused.

Fusion of both ankles is unusual but sometimes necessary when no other alternative is possible or suitable. Publication no **15** demonstrates that most patients are reasonably satisfied and have a fair function.

A significant improvement of all scores was demonstrated after 2 years for 241 patients that had undergone ankle replacement. 71% was satisfied or very satisfied irrespective of diagnosis and type of prosthesis. The postoperative SEFAS-score correlated positively with higher age. (16)

The MIC-value (minimally important change) for the SEFAS-score was estimated to five units concerning intervention in fore- and hindfoot as well as in the ankle. That implies that the difference be between two values – e.g. the pre-and postoperative score –should be more than five units to be clinically relevant. (17)

8. Publications based on the ankle registry

Publications

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- 14. Kamrad I, Henricson A, Magnusson H, Carlsson Å, Rosengren B. Outcome After Salvage Arthrodesis for Failed Total ankle Replacement. Foot and Ankle International 2016;37: 255-261.
- 15. Henricson A, Kamrad I, Rosengren B, Carlsson Å. Bilateral Arthrodesis of the Ankle Joint: Self-reported Outcomes in 35 patients from the Swedish Ankle Registry. The Journal of Foot and Ankle Surgery 2016:55:1195-1198.

- 16. Kamrad I, Carlsson Å, Henricson A, Magnusson H, Karlsson MK, Rosengren B. Good outcome scores and high satisfaction rate after primary total ankle replacement. Acta Orthop. 2017;88:675-680.
- 17. Cöster MC, Nilsdotter A, Brudin L, Bremander A. Minimally important change, measurement error, and responsiveness for the Self-Reported Foot and Ankle Score. Acta Orthop. 2017;88:300-304.

Theses

- 1. Anderson T. On arthrodesis and replacement of the human ankle. Lund University, Faculty of Medicine Doctoral Dissertation Series 2005 ISBN 91-628-6411-4
- Cöster MC. SEFAS The Self-Reported Foot and Ankle Score. Supervisor Karlsson M, Cosupervisors Rosengren B, Carlsson Å; Lund University, Faculty of Medicine Doctoral Dissertation Series 2015:54 ISBN 978-91-7619-130-0
 Available at: http://lup.lub.lu.se/record/5276552
- 3. Kamrad I. Outcome of surgery for end-stage ankle arthritis. Lund University, Faculty of Medicine Doctoral Dissertation Series 2017:51 ISBN 978-91-7619-431-7

 Available at: http://lup.lub.lu.se/record/e1718024-f780-4c84-add8-e81825babd15

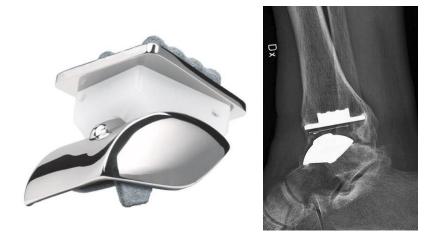


Figure 3. The STAR ankle was used in Sweden 1993-2006.

9. Procedure-based coverage 2017

Primary ankle prostheses: 100%

All Swedish units performing ankle replacement reported all their cases.

Primary ankle fusions: 95.0%

48/50 units performing ankle fusion reported their cases (96%)

During 2017, 19/21 Swedish regions (counties) reported all their cases to the registry while reporting from two region was incomplete. (Figure 11).



Figure 4. The CCI-ankle (left) was used 2008 – 2015. The Mobility-ankle (right) was used 2005 -2015).

10. Ankle replacements

Volumes

During 2017, 65 primary replacements were performed, i.e.14 more than during 2016 and in spite of the fact that only 5 ankles were replaced in the capital-region.

Table 1. Primary replacements 2013-2017. For 2017 also distributed according to diagnosis, sex and prosthetic design. *Implies replacements performed by surgeons from Falun and Nacka.

		Number	of replac	ements		Diag	nosis 2	2017	Sex	2017		Design 2	017
Department	2013	2014	2015	2016	2017	Artros	RA	Annat	F	M	Reb	TM	Hintegra
All Sweden	68	56	54	52	66	42	16	8	36	30	26	23	17
Mölndal	0	0	3	5	17	8	3	5	11	6	0	1	16
Falu lasarett	21	20	11	13	15	11	3	1	7	8	6	9	0
Movement	0	1	8	8	14	9	4	1	5	9	5	9	0
SUS Malmö	12	9	12	3	4	1	2	1	3	1	4	0	0
Elisabeth- sjukhuset*	4	3	1	2	4	3	1	0	4	0	4	0	0
Hässleholm	0	0	4	4	2	2	0	0	0	2	2	0	0
Fotcenter Sthlm	0	0	0	0	2	2	0	0	2	0	2	0	0
Motala*	0	0	0	3	2	2	0	0	0	2	0	2	0
Danderyd*	0	0	0	0	2	2	0	0	2	0	1	1	0
SUS Lund	5	5	2	3	1	0	1	0	1	0	1	0	0
Sophiahemmet	2	1	2	4	1	0	1	0	1	0	0	0	1
Uppsala*	5	1	1	1	1	1	0	0	0	1	0	1	0
Örebro*	0	0	0	0	1	1	0	0	0	1	1	0	0
Sundsvalls sjukhus*	4	0	0	0	0	0	0	0	0	0	0	0	0
Sollefteå*	0	0	2	0	0	0	0	0	0	0	0	0	0
Karolinska sjh Solna	2	0	0	0	0	0	0	0	0	0	0	0	0
Nacka närsjukhus	13	16	8	6	0	0	0	0	0	0	0	0	0
Spenshult	14	5	Closed	-		-	-	-	-	-	-	-	-

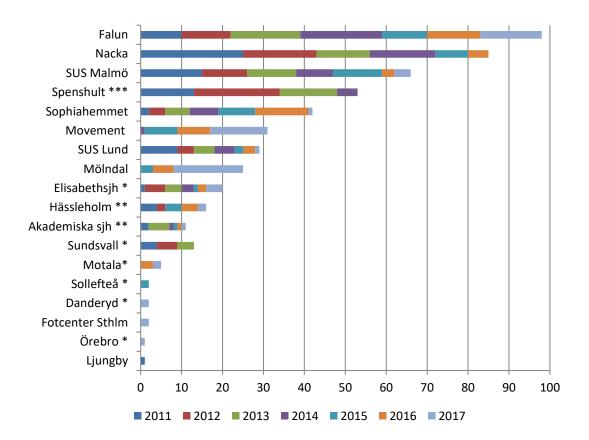


Figure 5. Number of primary replacements per unit 2011-2017. *All replacements performed by a surgeon based at another department **Some of the replacements performed by a surgeon based at another department ***Unit closed 2014



Figure 6. The TM-ankle was introduced in Sweden in 2014.

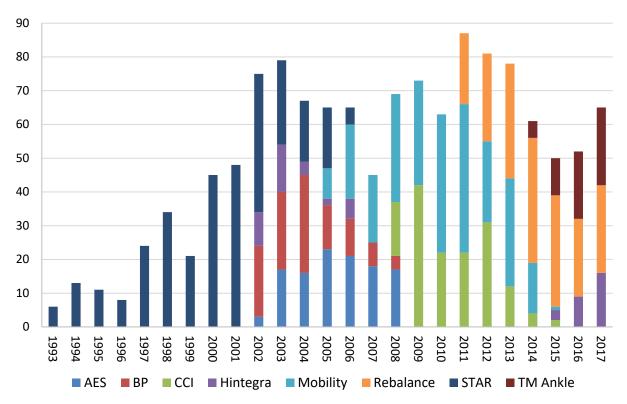


Figure 7. Number of primary ankle replacements per year 1993- 2017 by prosthetic design.

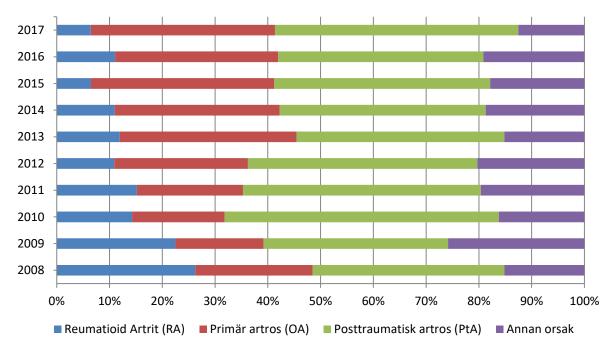


Figure 8. Distribution of diagnoses (percent) 2008-2017 for ankle replacements

11. Revisions, prosthetic survival and risk factors

Since 1993, i.e. during a period of 25 years, 277 (21 %) ankle replacements have been revised (The figures presented in the previous report have been corrected). In addition 102 extra-articular secondary interventions have been undertaken in 91 ankles since 1993 – mostly osteotomies of the calcaneus and subtalar fusions.

Numbers and reasons for first time revisions – defined as exchange of components or fusion – are presented in Table 2. The revision rate of the Mobility prosthesis is lower than that of CCI (p<0.05).

Revisions, prosthetic survival and risk factors Prosthetic survival at 5 years irrespective of reason was estimated to 0.81 (95% CI: 0.79-0.83) and to 0.69 (95% CI: 0.67-0.71) at 10 years when all designs were included. Notably the outdated single-coated STAR-prosthesis tended to have an inferior survival compared to the other designs which were similar in this aspect. The 10-year survival was not influenced by diagnosis. Figure 9

Table 2. Reasons for revision 1993–2017 according to prosthetic design. Presently used designs are bolded.

				Design						
	ST	AR	ВР	AES	Hintegra	Mobility	CCI	ReBalance	тм	TOTALT
	Enkel-	Dubbel-								
	belagd	belagd								
Years in use	1993-	1999-	2000-	2002-	2002-	2005-	2008-	2011-	2015-	
	1999	2007	2008	2008	2006	2015	2015			
					2015-					
Numbers (n)	118	205	109	115	64	269	152	204	60	1296
Revisiones (n)	62	77	21	41	9	27	31	10	0	277
Revisones (%)	53%	38%	19%	36%	14%	10%	20%	5%	0%	21%
Revisionsorsak										
Lossning	36	31	8	18	3	9	21	5		131
Tekniskt fel	7	10	1	1	3			1		23
Instabilitet		1	3	5	1	5	1	1		17
Infektion	4	12		5	1	1	2			25
Oförklarlig smärta	5	5	1	1		6	4	1		23
Plast-slitage/fraktur	10	12	2	2		2	1			29
Smärtande valgus			1	4	1	1				7
Smärtande varus		2	2	2		1	2	1		10
Fraktur		3	3	3		1				10
Annan		1				1				2

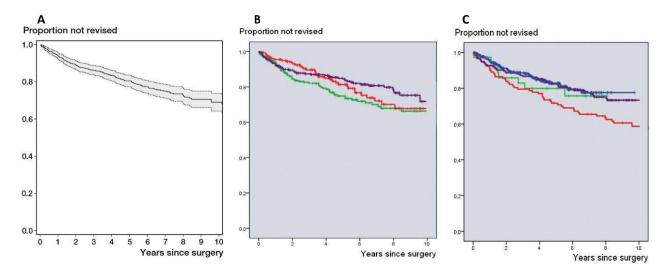


Figure 9. Estimated cumulative prosthetic survival with 95 % CI for (A) all ankle replacement in Sweden up to 2010 (B) Per diagnosis (rheumatoid arthritis (purple), primary osteoarthritis (red) posttraumatic osteoarthritis (green)) (C) per prosthetic design (BP-type (blue), Hintegra (green), double-coated STAR (purple) and single-coated STAR (red))

12. Primary ankle arthrodeses

Only 8 of the 50 units performing ankle fusion reported 10 or more cases during 2017 and only 2/50 units reported more than 20 cases (Table4).

Table 3. Number of ankles arthrodeses per type of hospital 2017.

	Number of	Number of arthrodeses						
Type of hospital(nmber)	≥ 20	10-19	5- 9	1-4	0			
University Hospital (9)*	1	2	4	0	2			
Other hospitals (40)	1	4	9	22	4			

^{*}Karolinska sjukhuset Solna and Huddinge and Malmö and Lund are presented as separate units.

Open surgery and fixation by cannulated screws has since 2008 - the year registration of fusions started – been the dominating surgical method. Retrograde intramedullary nails has since the top year 2014 become less common –ad reduction by about 50%, while fixation by plate and screws has increased. Arthroscopic exploration and screw fixation has later years been reported in about 15 % of the cases (Table 4 and Figure 10). Only 4 primary cases has during 2017 been performed using external fixation.

Table 4. Number of primary ankle fusions 2008-2017 distributed according to surgical method

				Туре о	f surgery					
Year		Screw fixation		Plate	IM- Nail	External fixation	Staple	Other metod	Not known	TOTAL
•	Percut.	Arthroscopic	Open							
2008	4	6	40	0	44	2	0	1	6	103
2009	5	2	64	0	47	1	0	0	1	120
2010	0	16	72	9	45	8	1	0	4	155
2011	8	14	101	15	59	5	0	0	4	206
2012	1	30	132	12	79	15	0	0	6	275
2013	0	34	168	17	81	8	0	0	2	310
2014	4	22	177	13	92	4	0	0	1	313
2015	1	57	163	22	59	6	0	0	0	308
2016	0	54	152	42	53	9	0	4	0	314
2017	1	44	141	55	48	4	1	1	0	295
TOTALT	24	279	1069	185	607	62	2	6	24	2258

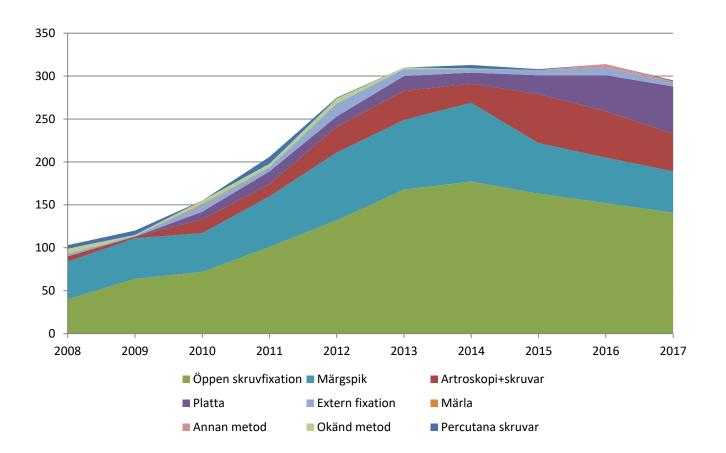


Figure 10. Number of primary ankle fusions 2008 – 2017 distributed according to surgical method

13. Rearthrodeses

Out of 1716, primary ankle arthrodeses performed up to December 31 2016 134 have undergone at least one re-arthrodesis (7.8%) - in most cases within 2.5 years. In 15/134 (11%) cases one or more attempts to fuse the ankle has been undertaken (study accepted for publication in Acta Orthopaedica).

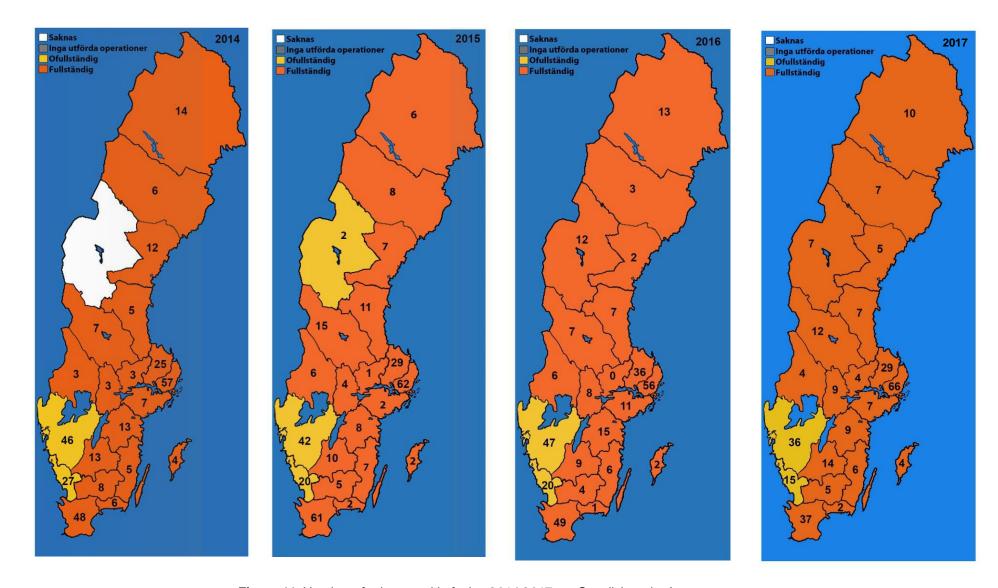


Figure 11. Number of primary ankle fusion 2014-2017 per Swedish region/county.



Figure 12. X-rays of ankle fusion fixated by a retrograde nail. Frontal (left) and side view (right).



Figure 13 X-rays of ankle fusion fixated plates and screws. Frontal (left) and side view (right).

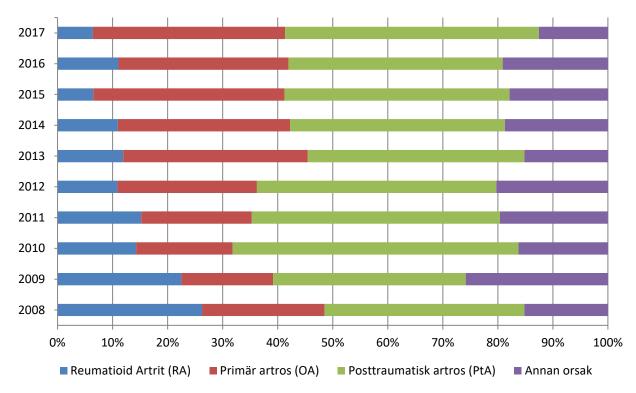


Figure 14. Distribution of diagnoses in cases that underwent primary ankle fusion 2008-2017.



Figure 15. Ankle fusion fixated by cannulated screws

Table 5. Smoking habits 2015-2017 according to type of surgery and sex.

	Non-smoker	Stopped >6 weeks prior to surgery	Smokers	No known
Totalt	577	50	32	71
Replacement	152 (86%)	6 (4%)	3(2%)	12 (6%)
Men (41%)	76	1	1	6
Women (59%)	76	5	2	5
Arthrodesis	731 (79%)	78 (8%)	41 (5%)	72 (8%)
Men (56%)	422	44	22	40
Women (44%)	309	34	19	32

Table 6a. ASA–class (American Society of Anesthesiologists (ASA) Physical Status) in cases that underwent primary ankle replacement 2015-2017.

Diagnoiss	ASA 1	ASA 2	ASA 3	ASA 4	No known
All	57	80	30	0	6
Reumatoid arthritis	2	19	16	0	3
Primary osteoarthritis	16	24	6	0	2
Posttraumatic arthritis	33	28	4	0	0
Other	6	9	4	0	1
Women	23	43	19	0	4
Reumatoid arthritis	2	15	15	0	3
Primary osteoarthritis	4	12	1	0	1
Posttraumatic arthritis	17	13	1	0	0
Other	0	3	2	0	0
Men	34	37	11	0	2
Reumatoid arthritis	0	4	1	0	0
Primary osteoarthritis	12	12	5	0	1
Posttraumatic arthritis	16	15	3	0	0
Other	6	6	2	0	1

Table 6b. ASA–class (American Society of Anesthesiologists (ASA) Physical Status) in cases that underwent primary ankle fusion 2015-2017.

Diagnosis	ASA 1	ASA 2	ASA 3	ASA 4	Not reported
All	244	415	215	9	37
Reumatoid arthritis	1	33	41	2	1
Primary osteoarthritis	81	151	54	1	17
Posttraumatic arthritis	133	173	66	4	12
Other	29	58	54	2	7
Reumatoid arthritist	93	177	108	3	12
Primary osteoarthritis	1	25	33	2	1
Posttraumatic arthritis	27	57	16	0	5
Other	56	69	33	0	3
Reumatoid arthritis	9	26	26	1	3
Men	151	238	107	6	25
Reumatoid arthritis	0	7	8	0	0
Primary osteoarthritis	54	94	38	1	12
Posttraumatic arthritis	77	105	33	4	9
Other	20	32	28	1	4

14. Supramalleolar osteotomies

Supramalleolar osteotomies have been unusual procedures in Sweden. The indication has been malposition combined with early signs of osteoarthrosis. Between 2007 and 2017, 14 units have reported a total of 71 such procedures- 16 during 2017.- 29 ankles with "opening wedge", 36 with "closing wedge" and 6 with other techniques. The median patient age for the procedures was 54 years (range 17–75).

15. Patient- reported outcome

A national registry should include not only number of reported cases but also complications and the patients' opinion about the result. The foot and ankle specific SEFAS-score, which is used in our follow up and outcome studies, was in 2011 validated with reference to the generic EQ-5D and SF-36 scores and the foot-specific FAOS- score. The validity, reliability and responsiveness are excellent and without any floor- or ceiling-effect (See publication no 7 and the summary of registry research in page 9).

Because the SEFAS-score only contains 12 simple questions it is fast and user friendly. Our questionnaires also include a satisfaction scale in five steps from very satisfied to very dissatisfied.

The SEFAS questionnaire has recently been used in 6 scientific publications originating from Norway, Italy and the Netherlands.

The generic EQ 5D (Figure 16a-b) demonstrates that the patients' general health situation is cumbersome before surgery but that their situation improved both after a replacement and a fusion.

The foot and ankles specific SEFAS-score also demonstrates (Figure 17a -b) that the patients' situation is cumbersome before surgery concerning all evaluated issues. A considerable improvement seems to occur within 6 months after both replacement and fusion of the ankle while further improvement between 6 and 12 months seems small.

EQ5D - 3L ANKLE REPLACEMENTS

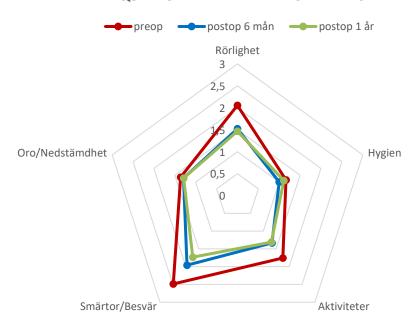


Figure 16a. The spider-chart shows the mean outcome for the 5 questions in EQ5D -3 L 8 preoperatively, 6 and 1 months postoperatively for patients that had undergone ankle replacement during 2016 – Value 3 implies the worst possible situation and value 0 the best possible situation concerning each specific question.

EQ5D-3L FOTLEDSARTRODES

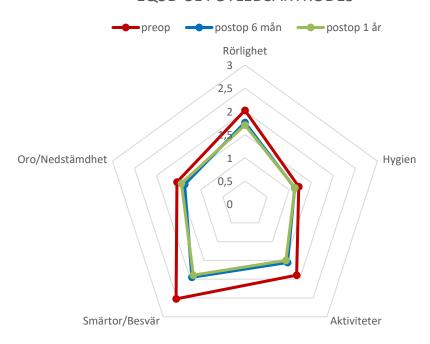


Figure 16b. The spider-chart shows the mean outcome for the 5 questions in EQ5D -3 L 8 preoperatively, 6 and 1 months postoperatively for patients that had undergone ankle arthrodesis during 2016 – Value 3 implies the worst possible situation and value 0 the best possible situation concerning each specific question.

SEFAS Replacement

postop 6 mån postop 1 år **p**reop 1. Hur skulle Du vilja beskriva den smärta som Du vanligtvis har från den aktuella foten/fotleden? 12. Har Du upplevt en plötslig 2. Under hur lång tid har Du 0 knivskarp, huggande smärta eller kunnat pro- menera innan det kramp från den aktuella 0,5 uppstår svår smärta från den fotleden? aktuella foten/fotleden? 11. Hur smärtande har den aktuella foten/ fotleden varit när 3. Har Du kunnat gå på ojämn Du rest Dig efter att ha suttit vid mark? ett bord och ätit? 4. Har Du tvingats använda inlägg 10. Har foten/fotleden svullnat? i skon, hälförhöjning eller specialgjorda skor? 5. Hur mycket har smärtan från 9.Hur mycket har smärta från den den aktuella fo- ten/fotleden aktuella foten/fotleden inverkat hindrat Dig i Ditt vanliga arbete på Dina vanliga fritidsaktiviteter? inkl hushållsarbete och... 8. Har Du ont i den aktuella 6. Orsakar den aktuella foten/fotleden nattetid? foten/fotleden att Du haltar? 7. Har Du kunnat gå i trappa?

Figure 17a. The spider-chart shows the mean outcome for the 12 questions in SEFAS preoperatively, 6 and 12 months postoperatively for patients that had undergone ankle replacement during 2016 – Value 0 implies the worst possible situation and value 4 the best possible situation.

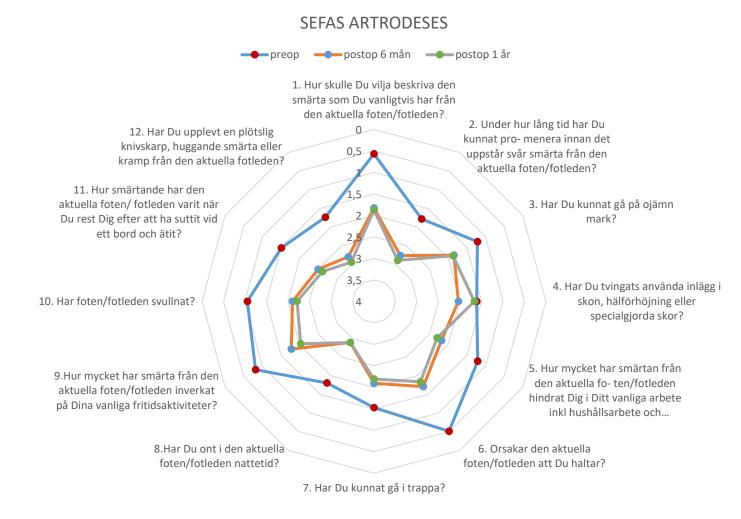


Figure 17b. The spider-chart shows the mean outcome for the 12 questions in SEFAS preoperatively, 6 and 12 months postoperatively for patients that had undergone ankle arthrodesis during 2016 – Value 0 implies the worst possible situation and value 4 the best possible situation.

Table 7 Outcome measures (SEFAS och EQ-5D) after primary ankle replacement.

PROM	Preop mean (SD) n=220-236*	Postop 24 months Mean (SD) n=150-167*	an difference (95% CI)	p
SEFAS	16 (7)	31 (9)	+15 (13.5-16.6)	<0.001
EQ-5D	0.40 (0.32)	0.68 (0.26)	+0.26 (0.20 – 0.32)	<0.001

The improvement is both statistically and clinically significant. SEFAS can reach values between 0 and 48. Minimal important change (MIC) for ankle surgery is 5 units regarding SEFAS and reflects the lowest value patients experience as a real improvement (ref 17 in page 12).

14. PROM-results after revision of ankle replacement

Both exchange of prosthetic components and arthrodesis resulted in low scores. The mean SEFAS score was 22 compared to 31 after primary replacement. Less than half of the patients reported that they were satisfied with the result. On third of those have undergone component exchange underwent another revision. Conversion to arthrodesis resulted in another attempt to fuses the ankle in 10%.

Thus, conversion to an arthrodesis is in most cases to prefer.

Det Svenska Fotledsregistret - Årsrapport 2017

Appendix 1. The foot-and ankle specific SEFAS questionnaire (Self-reported Foot and Ankle Score).

1.	How would you describe the pain you usually have from the foot/ankle in question?	5. How much has the pain from the foot/ankle in question interfered with your usual work including housework and hobbies?
	4 None	4 Not at all
	3 Very mild	3 A bit
	2 Mild	2 Moderately
	1 Moderate	1 Greatly
	O Severe	0 Totally
2.	For how long have you been able to walk before severe pain arises from the foot/ ankle in question?	Have you been limping when walking because of the foot/ankle in question?
	4 No pain up to 30 minutes	4 No days
	3 16-30 minutes	3 Only one or two days
	2 5-15 minutes	2 Some days
	1 Around the house only	1 Most days
	O Unable to walk at all because of severe impairment	0 Every day
3.	Have you been able to walk on unevenground?	7. Have you been able to climb <i>a flight of</i> stairs?
	4 Yes, easily	4 Yes, easily
	3 With little difficulty	3 With little difficulty
	2 With moderate difficulty	2 With moderate difficulty
	1 With extreme difficulty	1 With extreme trouble
	0 No impossible	0 Impossible
4.	Have you had to use an orthotic (shoe insert), heel lift or special shoes?	Have you been troubled by pain from the foot/ ankle in question in bed at night?)
	4 Never	4 No night
	3 Occasionally	3 Only one or two nights
	2 Often	2 Some nights
	1 Most of the time	1 Most nights
	0 Always	0 Every night
9.	How much has pain from the foot/ankle in question affected your usual recreational activities?	11. After a meal (sat at a table) how painful has it been for you to stand up from a chair because of the foot/ankle in question?
	4 Not at all	4 Not at all painful
	3 A bit	3 Slightly painful
	2 Moderately	2 Moderately painful
	1 Greatly	1 Verypainful
	0 Totally	0 Unbearable
10.	Have you had swelling of your foot?	12. Have you had a severe sudden pain shooting, stabbing or spasms from the foot/ankle in question?
	4 None at all	4 No days
	3 Occasionally	3 Only one or two days
	2 Often	2 Some day
	1 Most of the time	1 Most days 0 Every day
	0 All the time	

The Swedish Ankle Registry

www.swedankle.se

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