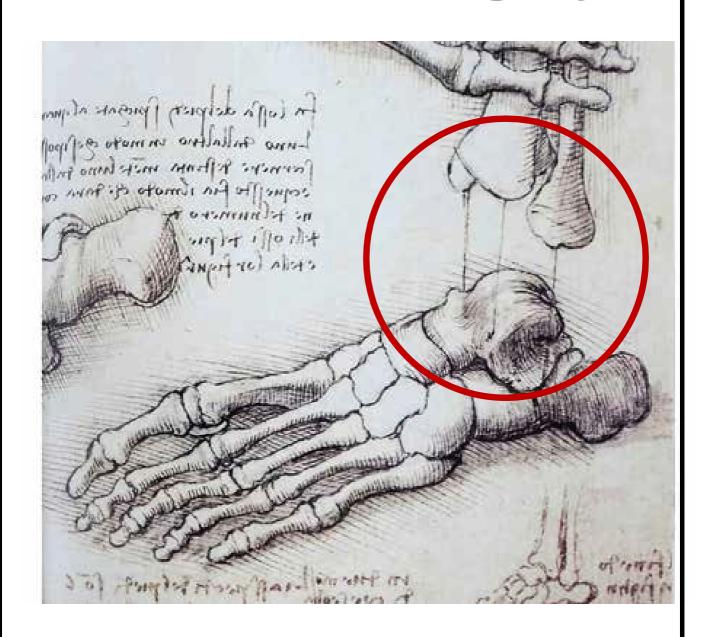
SwedAnkle The Swedish Ankle Registry



Annual Report

2016 Summary in English

[Skriv här]

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Legally responsible for the publication

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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. 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 year, 2 years and 5 years. The patients are then also asked to report their degree of satisfaction with the performed ankle surgery. The Swedish and English versions of the ankle-specific score (SEFAS) can 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-rays of the ankle prosthesis Rebalance

2. News since the previous report and summary

Fifty-two ankles were replaced during 2016 which is fewer than during each of the years 2010-2013. One reason is that one major center closed permanently during the summer 2014. Another reason is 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 was 100%. Surgery has been performed at 11 units by surgeons based at 9 hospitals

During 2016, 3014 primary ankle fusions were reported, about the same number as in 2014 and 2015. Procedure based coverage for ankle fusions has been estimated to 96%. Ankle fusions are potentially performed at 48 units but 20 of these performed less than 5 cases during 2016. (Table 2) All but 2 Swedish hospitals have reported there ankle fusions during 2016. The registry introduced decentralized reporting and feed-back online during spring 2016.

For the third time we report smoking habits immediately before surgery. Among patients 106 patients scheduled for ankle replacement 2015-2016 information was available for 96 patients. Of these 7 were smokers but 5 of these stopped smoking 6 weeks before surgery. Among the 624 patients undergoing ankle fusion information was available for 563 patients. 75 of these were smokers but54 stopped smoking at least 6 weeks before surgery. (Table 4)

For the second time we report ASA-classification (American Society of Anesthesiologists Physical Status) for patients scheduled for replacement and fusion of the ankle 2015-2016. 62 % of the 102 patients undergoing, and in whom information was available, were classified as ASA 2-3 but non as ASA 4.

Information was available for 590 of the patients undergoing ankle fusion during 2015-2016 and 70% of these were classified as ASA 2-3. ASA 4, i.e. with a life-threatening disease, was reported in 4 cases. ASA >1 was more common in women than in men. (Table 5 a and b)

In May 2015 Maria C öster presented her thesis "SEFAS – The Self-Reported Foot and Ankle Score". Concurrently analyzes of generic and ankle-specific scores (PROM/PREM) have continued. In 2015 two papers were published and another two have been accepted for publication.

This annual report includes outcome of surgery in the form of PROM and PREM data (Table 3).

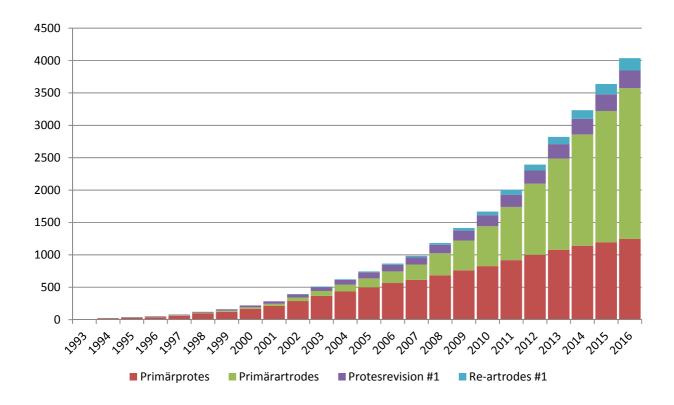


Figure 2. Number of primary ankle replacements and arthrodeses, first ankle revisions and first time rearthrodeses.

3. Board and secretary

Board

Chair

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

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

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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 information directed to patients concerning ankle surgery. For the profession it contains report forms, questionnaires, recent results and annual reports.

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, MD, PhD, Associate Professor Magnus Karlsson, MD, PhD, Professor Björn

Rosengren, MD, PhD Associate Professor Håkan Magnusson, MD, PhD

Anders Henricson, MD, PhD Jan-Åke Nilsson, statistician

Maria Cöster, MD, PhD Ilka Kamrad,

7. Research

Maria Cöster's research project deals with various aspects of Patient-Related Outcome Measurements (PROM) – notably the self-reported Foot and Ankle Score (SEFAS).

Ilka Kamrad's research project deals with self-evaluated function after primary ankle prosthesis and ankle fusion, but also following various revision procedures using validated generic and region-specific instruments.

8. 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, demonstrating that replacement surgery often is demanding.

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 submitted.

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.



Figure 3. The CCI ankle (left) and the Mobility ankle (right)

9. Publications based on the ankle registry

1. Carlsson Å.

Titel: Single - and double-coated STAR total ankle replacements. A clinical and radiographical follow-up study of 109 cases.
Orthopäde 2006;35:527-532. (Artikel på tyska)

2. Henricson A, Ågren P-H.

Titel: Secondary surgery after total ankle replacement. The influence of preoperative hindfoot alignment.

Foot Anlde Surg 2007; 13:41-44.

3. Henricson A, Skoog. A, Carlsson Å.

Titel: The Swedish Ande Arthroplasty Register. An analysis of 531 arthroplasties between 1993 and 2005.

Acta Orthop 2007;78:569-574.

4. Henricson A, Knutson K, Lindahl J, Rydholm U.

Titel: The AES total ankle replacement. mid-term analysis of 93 cases.

Foot Anlde Surg 2010;16:61-64.

5. Henricson A, Carlsson Å, Rydholm U. Titel:

What is a revision of total ankle Replacement.

Foot Anlde Surg 2011;17:99-

6. Henricson A, Nilsson J-Å, Carlsson Å.

Titel: 10-year survival of total ankle arthroplasties. A report on 780 cases from the Swedish Anlde Register.

Acta Orthop 2011;82:655-659.

7. Cöster M, Karlsson M, Nilsson J-Å, Carlsson, Å.

Titel: Validity, reliability, and responsiveness of a self-reported foot and ankle score (SEFAS).

Acta Orthop 2012;83:197-203.

8. Henricson A, Cöster M, Carlsson Å Titel:

The Swedish National Ankle Registry Fuss

Sprungelänk.2014:12; 65-6.

9. Cöster M. Bremander A, Rosengren B et al. Titel:

Patientutvärdering skall mäta vad man vill mäta.

Ortopediskt Magasin 2014:3

10. Cöster M, Rosegren B, Carlsson Å, Montgomery F, Karlsson M. Titel:

Frågeformulär bra utvärderingsmetod vid fot- och fotledsbesvär.

Läkartidningen. 2015; 112:C9LS

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11. Kamrad I, Henricsson A, Karlsson M, Magnusson H, Nilsson J-Å, Carlsson Å, Rosengren B

Titel: Poor prosthetic survival and function after component exchange of total ankle prosthesis. An analysis of 69 cases in the Swedish Ankle Register. Acta Orthop 2015;86:407-1 1.

12. Henricson A, Carlsson Å.

Titel: 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. Foot Ankle Int 2015; 36: 1156-1160.

13. Henricson A, Fredriksson M, Carlsson Å.

Titel: Total ankle replacement and contralateral ankle arthrodesis in 16 patients from the Swedish Ankle Registry. Self-reported function and satisfaction. Foot and Ankle Surgery 2016;22:32-34

14. Kamrad I, Henricson A, Magnusson H, Carlsson Å, Rosengren B. Titel: Outcome After Salvage Arthrodesis for Failed Total ankle Replacement. Foot and Ankle International 2016;37: 255-261

15. Författare; Henricson A, Kamrad I, Rosengren B, Carlsson Å

Titel: 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





Figure 4 The STAR ankle

10 .Procedure- based coverage

Primary ankle prostheses: 100%

Primary ankle fusions: 96.3%

Ankle fusions are potentially performed at 50 units in Sweden but more than half of these perform less than 5 cases annually and certain years none at all. All but 2 Swedish units reported data on their ankle fusion during 2016. According to statistics from the Swedish health authorities 325 primary ankle fusions were been performed in Sweden during 2015. The 314 cases reported to the registry out of an estimated total of 325 ankle fusions results in a procedure-based coverage of 96.3 %.

9. Ankle replacements

The number of primary ankle replacements performed in 2016 was 52, i.e. somewhat than 2014 and 2015 (Table1). That one major center closed down permanently during 2014 and that the company producing the well-functioning Mobility prostheses withdrew it, has contributed to fewer ankle have replaced during later years. The procedure-based coverage is 100%. The annual distribution of prosthetic designs since 1993 is presented in Figure 6.



Figure 5. The TM-ankle was introduced in Sweden during 2014.

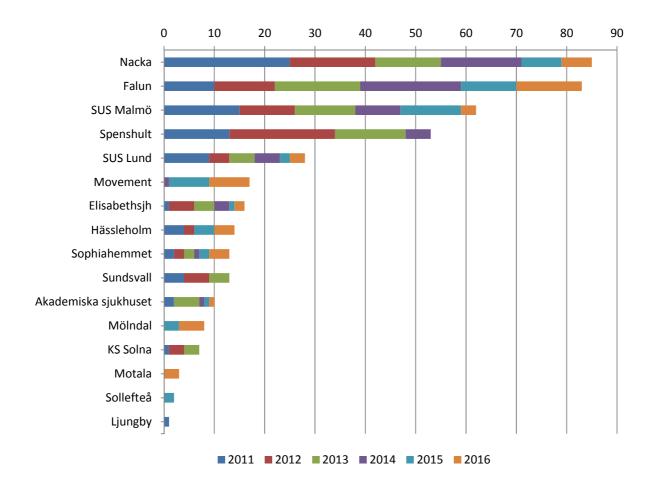


Figure 6 Number of ankle replacements per unit during 2011-2016.

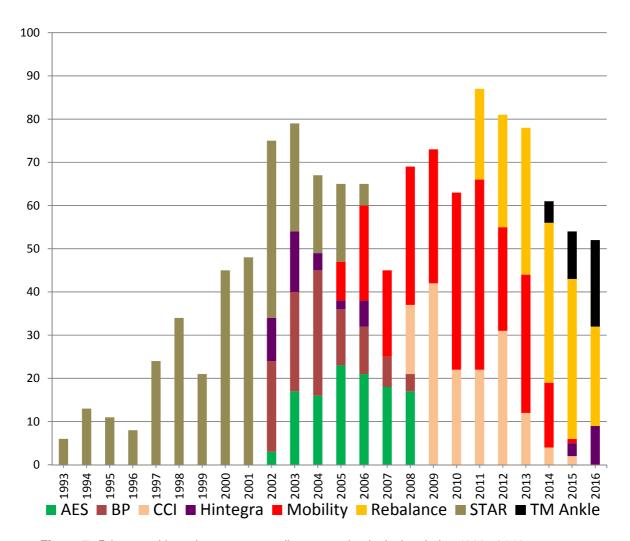


Figure 7. Primary ankle replacement according to prosthesis design during 1993 - 2016.

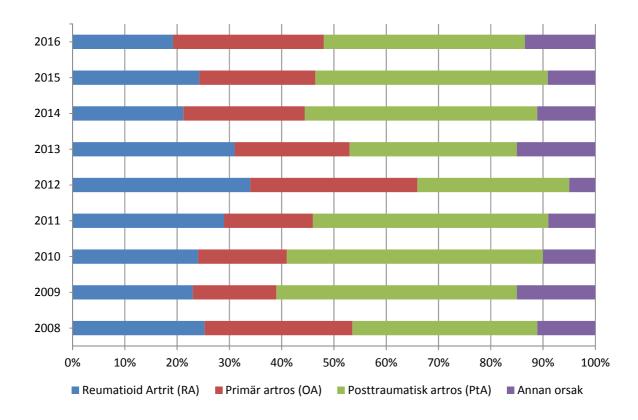


Figure 8. Primary ankle replacements according to diagnosis 2008-2015.

10. Revisions, prosthetic survival and risk factors

Since 1993, i.e. during a period of 23 years, 252 (29 %) ankle replacements have been revised. Numbers and reasons for first time revisions – defined as exchange of components or fusion – are presented in Table 1. The revision rate of the Mobility prosthesis is lower than that of CCI (p<0.5)-

Table 1. Reasons for revision per type of prosthesis 1993–2016

	Prosthetic design									
	STAR		ВР	AES	Hintegra	Mobility	CCI	ReBalance	TM	TOTAI
	Single- coated	Dubble coated								
Used during:	1993-	1999-	2000-	2002-	2002-	2005-	2008-	2011-	2015-	
	1999	2007	2008	2008	2006	2015				
					2015-					
Implanted(n)	118	205	109	115	48	269	152	178	37	1231
Revisiones (n)	70	88	36	56	11	44	43	9	0	357
Revisiones (%)	59%	43%	33%	49%	23%	16%	28%	5%	0%	29%
Cause of revision										
Loosening	37	32	8	15	4	16	28	4		144
Technicak error	9	12	3		2			1		27
Instability		2	4	6	2	4	3			21
Infection	4	17	2	6	1	3	2	1		36
Unexplained pain	7	7	4	8	1	9	5	1		42
PE-wear/frakture	13	14	6	4		1	1			39
Painful valgus			2	3		2				7
Painful varus		1	4	6		2	3			16
Fracture	Fracture 2 3 1							6		
Other causes		1		7	1	7	1	2		19

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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.

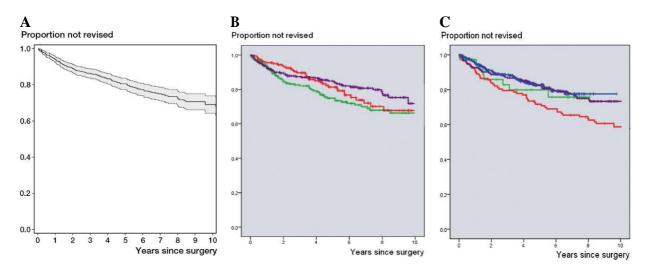


Figure 9 Estimated cumulative prosthetic survival inc. 95 % CI for (A) all ankle replacement in Sweden up to 2010 (B) Per diagnosis (rheumatoi.d arthritis (purple), primary osteoarthritis (red) posttraumatic osteoarthritis (green)) (C) per prosthetic design (BP-type (blue), Hintegra (green), double-coated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

11. Primary ankle arthrodesis

The number of arthrodeses 2016 according to type of hospital is presented in Table 2 and the surgical methods used between 2008 to 2016 in Fig 10. Distribution of age, gender and diagnosis in patients with primary ankle fusion is presented in Table 6 b.

Table 2: Number of primary arthrodeses 2016 according to hospital type.

Hospital		Cases (n)		
Поѕрна	>20	10-19	5-9	<5
University hospital (8)	2	1	3	2
Other hospitals/units (40)	1	5	13	21

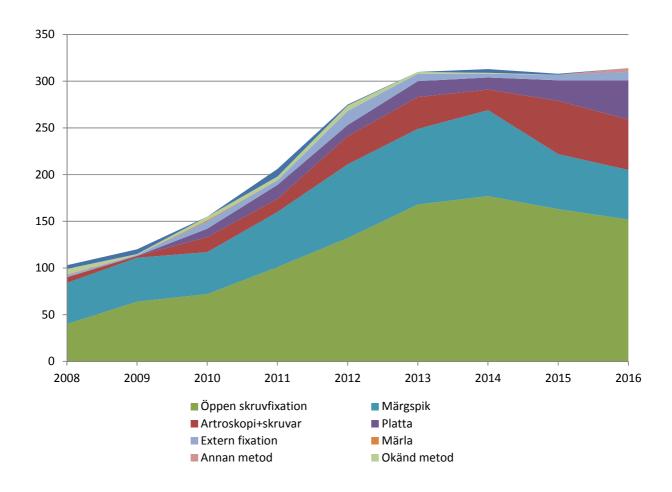


Figure 10: Surgical methods used between 2008 and 2016

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It is natural that the greatest number of ankle fusions is performed at hospitals with experts in ankle surgery. Thus, only 9 of about 50 orthopaedic units performed 10 or more ankles fusions during 2016. Two out of 8 university hospitals performed more than 20 primary ankle fusions-(Table 2). Open surgery and fixation with cannulated screws has been the dominating method during later years whereas the use of retrograde intramedullary nailing has become less common. Instead, arthroscopic exploration and fixation by screws has become somewhat more common during later years. The same can be shown for open surgery and fixation by plates and screws. Only 9 cases treated with external fixation have been performed, all but one at a single in Malmö University Hospital.

Out of 1773 primary fusions reported to the registry from 2008 until December 31st 2015, 146 have undergone at least one re-arthrodesis (8.2 w%). Of these 10 % has undergone one re-re-arthrodesis.

The annual number of ankle fusions has been about 300 during later years or about 3 per 100.000 inhabitants.. Osteoarthritis is the most common diagnosis - posttraumatic osteoarthritis being somewhat more common than primary osteoarthritis. Table 6 b and Fig 14



Figure 11. Ankle arthrodesis fixated by retrograde intramedullary nail. X-ray frontal (left) and lateral view (right).



Figure 12. Ankle arthrodesis fixated with plates and screws. X-ray frontal (left) and lateral projection (right)

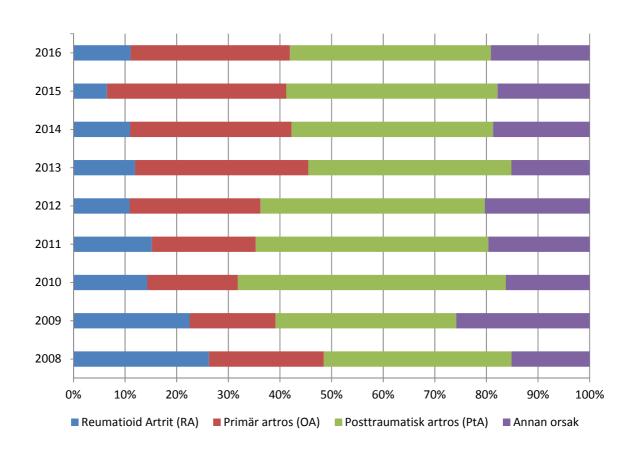


Figure 13. Distribution of diagnoses in patients that underwent arthrodesis 2008-2016

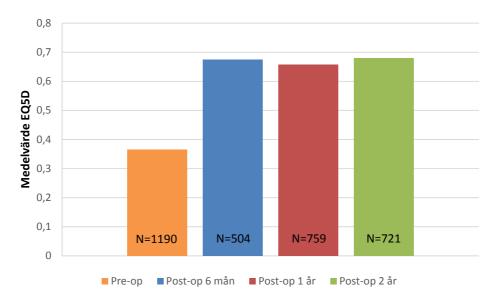
12. Supramalleolar osteotomies

Supramalleolar osteotomies have been unusual procedures in Sweden. The indication has been malposition combined with early signs of osteoarthrosis. Between 2007 and 2015 only 4 units have reported a total of 40 such procedures- 22 ankles with "opening wedge", 16 with "closing wedge" and 2 with other techniques, the median patient age for the procedures was 51 years range 20–70).

13. Patient-reported Outcome Measures (PROMs)

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" is excellent and without any floor- or ceiling-effect. (See publication no 7 and the summary of registry research in page 9.)

The SEFAS-score is based on the oxford-12 for hips and is because it contains only 12 simple questions fast and user friendly. Our questionnaires also include a satisfactions scale in five steps from very satisfied to very dissatisfied.



Figur 14. Mean EQ-5D preop and after surgery in Sweden for ankle arthrodesis and ankle replacement during 2009-2016.

PROM and PREM after primary ankle replacements

Patients with a replaced ankles report a significant improvement after 2 years and 70% were satisfied or very satisfied with the result. Most of the improvement had occurred at 1 year.

 Table 3 Outcome measures (SEFAS och EQ-5D) after primary ankle replacment..

PROM	Preop PROM Mean (SD) n=220-236*		Mean diffrence (95% CI)	р
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

^{*} Samtliga patienter besvarade inte samtliga enkäter.

The improvment is both statistivally 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. (*Cöster M, Nilsdotter A, Brudin L and Bremander Acta Orthopaedica* Acta Orthop. 2017;88:300-304.

11. Smoking habits and ASA-classification

Table 4. Smoking habits at the time of ankle replacement and arthrodesis

	Icke rökare	Rökstopp >6 veckor	Rökare	Uppgift saknas
Totalt	577	50	32	71
Fotledsprotes	89 (83%)	5 (5%)	2 (2%)	10 (9%)
Män (41%)	46	1	0	6
Kvinnor (59%)	43	4	2	4
Artrodes	488 (78%)	45 (7%)	30 (5%)	61 (9%)
Män (56%)	280	24	17	32
Kvinnor (44%)	208	21	13	29

Tabell 5a. ASA-classification (American Society of Anesthesiologists (ASA) Physical Status) at the time of ankle replacement 2015-2016.

Diagnos	ASA 1	ASA 2	ASA 3	ASA 4	Ej Rapporterat
Alla	39	46	17	0	4
Reumatoid artrit	2	11	9	0	1
Primär artros	8	14	3	0	2
Posttraumatisk artros	24	16	4	0	0
Annan	5	5	1	0	1
Kvinnor	16	24	11	0	2
Reumatoid artrit	2	9	9	0	1
Primär artros	2	7	1	0	1
Posttraumatisk artros	12	7	1	0	0
Annan	0	1	0	0	0
Män	23	22	6	0	2
Reumatoid artrit	0	2	0	0	0
Primär artros	6	7	2	0	1
Posttraumatisk artros	12	9	3	0	0
Annan	5	4	1	0	1

Tabell 5. B ASA–classification (American Society of Anesthesiologists (ASA) Physical Status) at the time of ankle arthrodesis during 2015-2016.

Diagnos	ASA 1	ASA 2	ASA 3	ASA 4	Ej rapporterat
Alla	172	272	141	6	33
Reumatoid artrit	1	24	31	1	1
Primär artros	56	97	34	0	14
Posttraumatisk artros	90	109	39	3	11
Annan	25	42	37	2	7
Kvinnor	66	115	76	2	11
Reumatoid artrit	1	18	25	1	1
Primär artros	17	33	11	0	4
Posttraumatisk artros	40	42	22	0	3
Annan	8	22	18	1	3
Män	106	156	65	4	22
Reumatoid artrit	0	5	6	0	0
Primär artros	39	64	23	0	10
Posttraumatisk artros	50	67	17	3	8
Annan	17	20	19	1	4

Appendix 1. The SEFAS questionnaire

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 3 Very mild 2 Mild 1 Moderate 0 Severe		4 Not at all 3 A bit 2 Moderately 1 Greatly 0 Totally
2.	For how long have you been able to walk before severe pain arises from the foot/ ankle in question? 4 No pain up 30 min. 3 16-30 minutes 2 5-15 minutes 1 Around the house only 0 Unable to walk at all because of severe pain	6.	Have you been limping when walking because of the foot/ankle in question? 4 No days Only one or two days Some days Most days Devery day
3.	Have you been able to walk on uneven ground?	7.	Have you been able to climb a flight of stairs?
	 4 Yes, easily 3 With little difficulty 2 With moderate difficulty 1 With extreme difficulty 0 No impossible 		4 Yes, easily 3 With little difficulty 2 With moderate difficulty 1 With extreme trouble 0 Impossible
4.	Have you had to use an orthotic (shoe insert), heel lift or special shoes?	8.	Have you been troubled by pain from the foot/ ankle in question in bed at night?)
	4 Never 3 Occasionally 2 Often 1 Most of the time 0 Always		4 No night) 3 Only one or two nights 2 Some nights 1 Most nights 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 3 A bit 2 Moderately 1 Greatly 0 Totally		4 Not at all painful 3 Slightly painful 2 Moderately painful 1 Very painful 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 3 Occasionally 2 Often 1 Most of the time 0 All the time		4 No days 3 Only one or two days 2 Some day 1 Most days 0 Every day

The Swedish Ankle Registry

www.swedankle.se

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