

SwedAnkle

The Swedish Ankle Registry



Annual report for 2018

www.SwedAnkle.se

Participating units

Alingsås	Movement
Borås	Mölnadal
Carlanderska Sportsmedicin	Nacka
Danderyd	Norrköping
Eksjö	Norrtälje
Elisabethsjukhuset	Nyköping
Eskilstuna	Orthocenter Stockholm
Falun	Ortopediska huset Stockholm
Fotcenter Stockholm	Oskarshamn
Gävle	Piteå
Helsingborg	Sophiahemmet
Hudiksvall	Sunderby
Hässleholm	Sundsvall
Jönköping	Södersjukhuset
Kaernan Hbg	Södertälje
Kalmar	Uddevalla
Karlshamn	Umeå
Karlstad	Uppsala
KS Huddinge	Varberg
KS Solna	Visby
Kungälv	Värnamo
Ljungby	Västervik
Lund	Västerås
Malmö	Växjö
Motala	Örebro
	Östersund

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1. Background

The concept of reporting all ankle replacements to a national registry appeared in 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, 16 and 17 on 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.

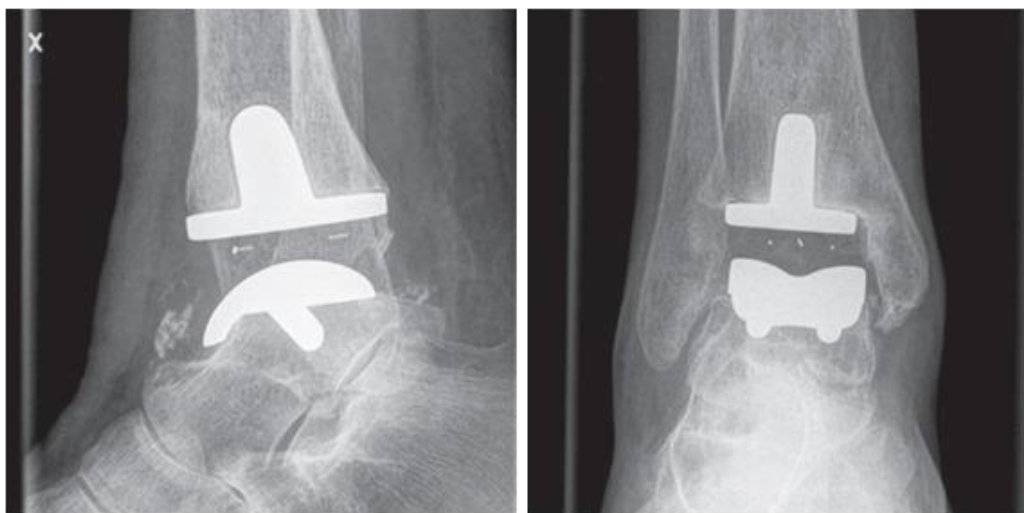


Figure 1. X-ray of the Rebalance ankle. Side view (left) front view (right). This design has been used in Sweden since 2011

2. News since previous report and summary

Decentralized direct reporting to the database was introduced in 2016 and has been utilized in most cases during 2018. That implies that the local surgeons can take part online what has been reported by themselves and their patients. We have started to find ways for patients to report PROM/PREM data electronically without reducing the answering frequency.

Since some years smoking habits in connection with ankle surgery is presented. 224 out of 238 persons undergoing ankle replacement 2015-2018 had reported their smoking habits. 12/224 was smokers but 9 of them had stopped smoking at least 6 weeks before surgery.

There were more smokers among patients undergoing ankle fusion. 1153 out of 1232 persons had reported their habits. 147/1153 (13%) were smokers but 99 of them stopped smoking at least 6 weeks before surgery (Table 5 on page 32).

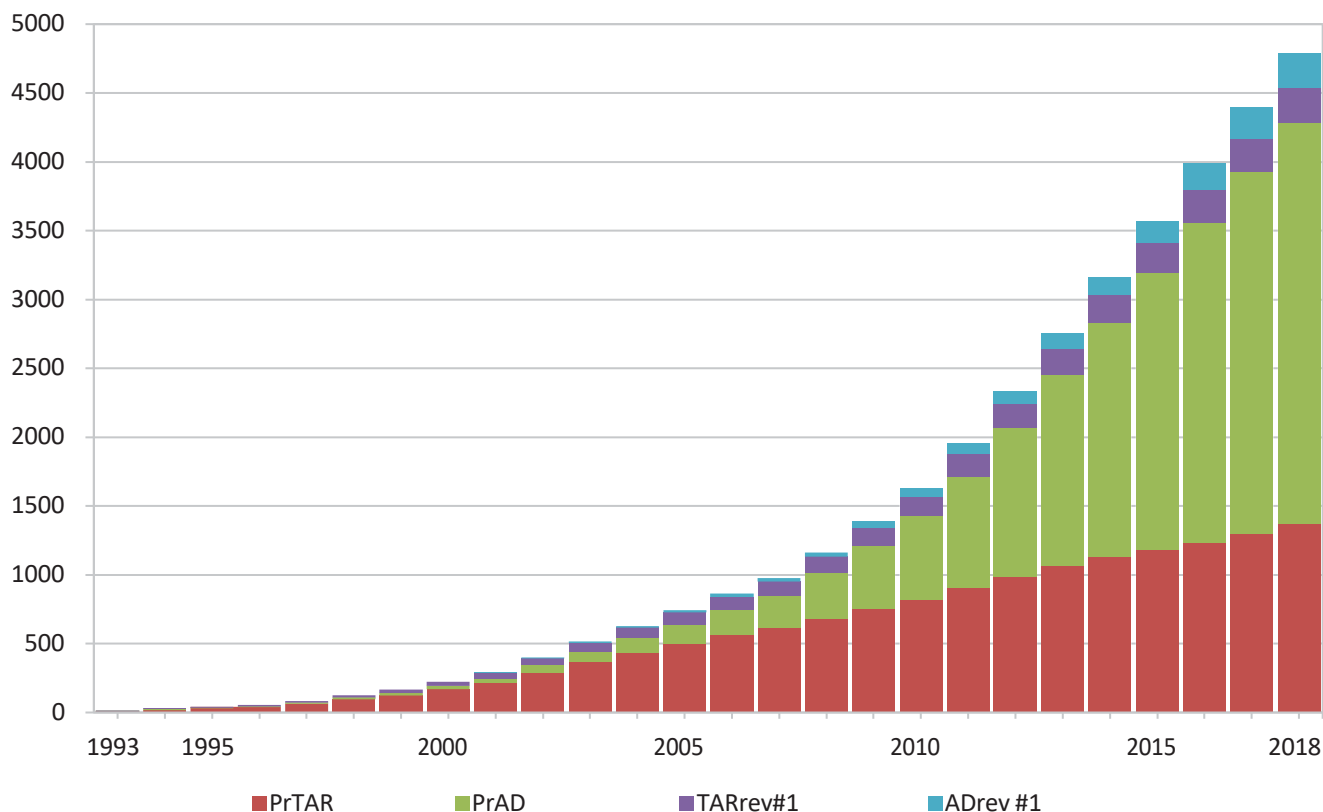


Figure 2. Number of primary ankle replacements (PrTAR), arthrodeses (PrAD), first revisions (TARrev#1) and first re-arthrodeses (ADrev#1) during 1993-2018 in Sweden

We can now for the second time present the outcome of ankle surgery as PROM and PREM data (Table 15, Figure 17a+b and Figure 18a+b), see also chapter 16 in page 35. In summary these data demonstrate that the patients are being helped by surgery and that no obvious differences can be demonstrated

between cases operated on with ankle replacement and arthrodeses – neither before or after surgery. 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 2018, i.e. same number as during 2017. 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 TM-ankle has under 2018 been the dominating prosthetic design. The replacements have been performed at a rather large number of units, but experienced surgeons have in most instances been involved at units with less experience.

During 2018, 295 primary ankle fusions were reported, about the same number as in 2014 -2016. Procedure based coverage for ankle fusions has been estimated to 97%. Ankle fusions are potentially performed at 53 units, but 36 of these performed less than 5 cases during 2018. Nine units performed 10 or more fusions, but only two units 20 or more fusion (Table 3).

3. Board and secretary 2018

Board

Chair

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

Members

Maria Cöster, MD, PhD, 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. Web page: www.swedankle.se

The webpage contains information directed to patients concerning ankle surgery and report forms, questionnaires, recent results and annual reports for the profession. During 2018 there were 30 565 visits to the web page (mean 83 per day).

5. Economy

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

(www.kvalitetsregister.se)

6. Research group

Åke Carlsson, Assoc. Professor

Maria Cöster, PhD

Anders Henricson, PhD

Ilka Kamrad, PhD

Alexandra Undén, MD

Magnus Karlsson, Professor

Håkan Magnusson, PhD

Jan-Åke Nilsson, Statistician

Björn Rosengren, Assoc. professor

Lars Jehpsson, Statistician

7. Summary of studies based on the ankle registry

Several studies analyzing the results after ankle replacement have been published (1-4, 6). In a study from 2007 the survival rate of 531 primary ankle replacements was estimated to 78% (3). A long learning curve also found 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 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 the existing definition of "revision" regarded ankle replacements 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 procedure (9). A corresponding study in which the failed ankle prostheses were treated by fusion has also 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. We however found that that most patients are reasonably satisfied and have a fair function after bilateral ankle fusion **(15)**.

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 between two values – e.g. the pre-and postoperative score –should be more than five units to be clinically relevant **(17)**.

In a study performed in cooperation with Statistics Sweden we included 396 population-based men and 383 women (43% of the invited individuals), age 20-89 years, who had completed the SEFAS questionnaire and questions regarding anthropometrics and health. We concluded that in the general population, older age was associated with lower SEFAS value, and that men had higher values than women study. The results may facilitate quantification of disability related to foot and ankle with and without surgery in the foot and ankle **(18)**.

Among 1716 primary ankle arthrodeses in the same number of patients, 8% of cases performed by open technique and screw fixation underwent at least one re-arthrodesis. Fusions performed by arthroscopic technique and screw fixation were in 15% followed by a re-arthrodesis. We believe that inadequate experience of arthroscopic technique may contribute to the found discrepancy **(19)**.

8. Publications based on ankle registry data

1. Carlsson Å. Single - and double-coated STAR total ankle replacements. A clinical and radiographical follow-up study of 109 cases. *Orthopäde* 2006;35:527-532. (*in German*)
2. Henricson A, Ågren P-H. Secondary surgery after total ankle replacement. The influence of preoperative hindfoot alignment. *Foot Ankle Surg* 2007; 13:41-44.
3. Henricson A, Skoog. A, Carlsson Å. The Swedish Ankle 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. The AES total ankle replacement. mid-term analysis of 93 cases. *Foot Ankle Surg* 2010;16:61-64.
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6. Henricson A, Nilsson J-Å, Carlsson Å. 10-year survival of total ankle arthroplasties. A report on 780 cases from the Swedish Ankle Register. *Acta Orthop* 2011;82:655- 659.
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8. Henricson A, Cöster M, Carlsson Å. The Swedish National Ankle Registry. *Fuss Sprungelänk* 2014;12; 65-6.
9. Cöster M. Bremander A, Rosengren B et al. Patientutvärdering skall mäta vad man vill mäta. *Ortopediskt Magasin* 2014:3
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12. Henricson A, Carlsson Å. 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. 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. 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, Nilsson 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
18. Cöster MC, Rosengren BE, Karlsson MK, Carlsson Å. Age- and gender-specific normative values for the Self-reported Foot and Ankle Score (SEFAS) *Foot & Ankle International* 2018; 88:675-680
19. Henricson A, Jehpsson L, Carlsson Å, Rosengren BE Re-arthrodesis after primary ankle fusion 134/1,716 cases from the Swedish Ankle registry. *Acta Orthopaedica* 2018; 89:560- 564

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
2. Cöster MC. SEFAS – The Self-Reported Foot and Ankle Score. Supervisor Karlsson M, Co-supervisors 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 1993-2007.

9. Procedure-based coverage (completeness)

Primary ankle prostheses: 100%

Primary ankle fusions: 97%

All Swedish units performing ankle replacement reported all their cases.

51/53 units potentially performing ankle fusion reported their cases during 2018 (96%)

During 2018, 19/21 Swedish regions (counties) reported all their cases to the registry while reporting from two region was incomplete.



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

10. Ankle replacements

Volumes

During 2018, 65 primary replacements were performed. This is in line with the numbers from 2017 but also implies an increase since 2015 when the numbers were lower.

Table 1. Primary replacements 2013-2017. For 2017 also distributed according to diagnosis, gender and prosthetic design.

Unit	Number of procedures					Distribution year 2018							
	2014	2015	2016	2017	2018	Diagnosis			Gender		Prostesis design		
						OA	RA	Other	Women	Men	ReB	TM	Hintegra
ALL SWEDEN	61	54	52	65	65	44	15	7	35	30	5	48	12
Mölnadal	0	3	5	16	23	15	7	1	12	11	0	12	11
Falu lasarett	20	11	13	15	10	5	3	2	8	2	0	10	0
Movement	1	8	8	14	12	9	3	0	7	5	0	12	0
SUS Malmö	9	12	3	4	1	1	0	0	1	0	1	0	0
Elisabeth-sjukhuset*	3	1	2	4	3	2	0	1	3	0	3	0	0
Hässleholm	0	4	4	2	6	6	0	0	0	6	0	6	0
Fotcenter Sthlm	0	0	0	2	0	0	0	0	0	0	0	0	0
Motala*	0	0	3	2	0	0	0	0	0	0	0	0	0
Danderyd*	0	0	0	2	1	1	0	0	1	0	0	1	0
SUS Lund	5	2	3	1	1	0	1	0	1	0	1	0	0
Sophiahemmet	1	2	4	1	1	0	0	1	0	1	0	0	1
Uppsala*	1	1	1	1	3	1	1	1	1	2	0	3	0
Örebro*	0	0	0	1	0	0	0	0	0	0	0	0	0
Sollefteå*	0	2	0	0	0	0	0	0	0	0	0	0	0
Ortopediska huset	0	0	0	0	4	4	0	0	1	3	0	4	0
Nacka närsjukhus	16	8	6	0	0	0	0	0	0	0	0	0	0
Spenshult	5	Closedt	-	-	-	-	-	-	-	-	-	-	-

*Implies replacements performed by surgeons from Falun or Nacka
ReB=ReBalance

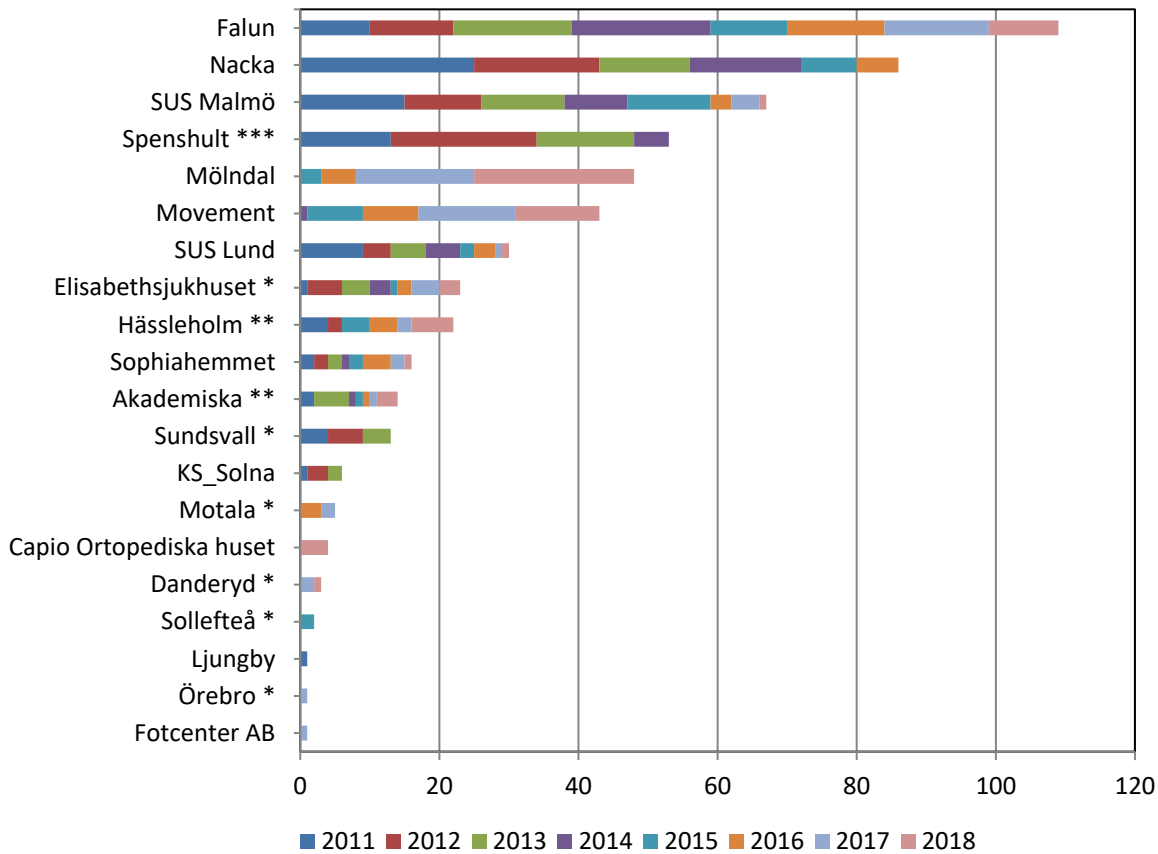


Figure 5. Number of primary replacements per unit 2011-2017.
 *All replacements performed by a surgeon based at another department
 **Some replacements performed by a surgeon based at another department
 ***Unit closed 2014



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

11. Revisions, prosthetic survival and risk factors

Since 1993, i.e. during a period of 25 years, 286 (21 %) ankle replacements have been revised.

In addition, 134 extra-articular secondary interventions have been undertaken in 115 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 ($p < 0.05$) while not statement was possible regarding differences between other designs. Future survival analyses may give more answers in the matter.

Table 2. Reasons for revision 1993–2018 according to prosthetic design. Colored columns indicate presently used prosthesis designs.

	Prosthesis design									TOOTAL
	STAR		BP	AES	Hintegra	Mobility	CCI	ReBalance	TM	
	Single-coated	Double-coated								
Period of use	1993-1999	1999-2007	2000-2008	2002-2008	2002-2006 2015-	2005-2015	2008-2015	2011-	2015-	
Implanted (n)	118	205	109	115	83	269	152	210	123	1383
Revisions (n)	62	77	21	41	10	27	24	22	2	286
Revisions (%)	53%	38%	19%	36%	12%	10%	20%	10%	2%	21%
Reason for revision										
Loosening	36	31	8	18	4	9	30	10		146
Technical error	7	10	1	1	2			1		22
Instability		1	3	5	1	2	1	2	1	16
Infection	4	12		5	1	1	1			24
Intractable pain	5	5	1	1	1	7	4	4		28
PE failure	10	12	2	2		1	1	4		32
Painful valgus			1	4		4				9
Painful varus		2	2	2			2			8
Fracture		3	3	3				1	1	11
Other		1			1	3	1			4

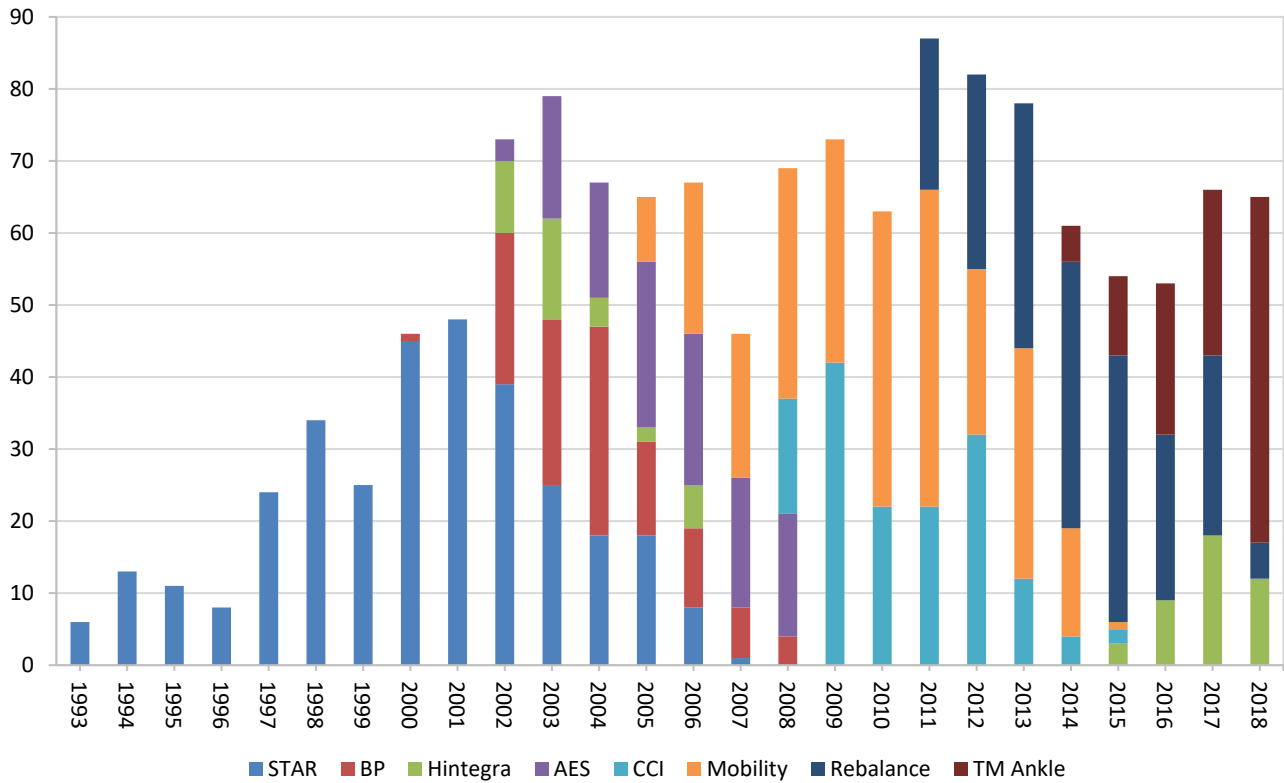


Figure 7. Number of primary ankle replacements per year 1993- 2018 with distribution according to prosthetic design.

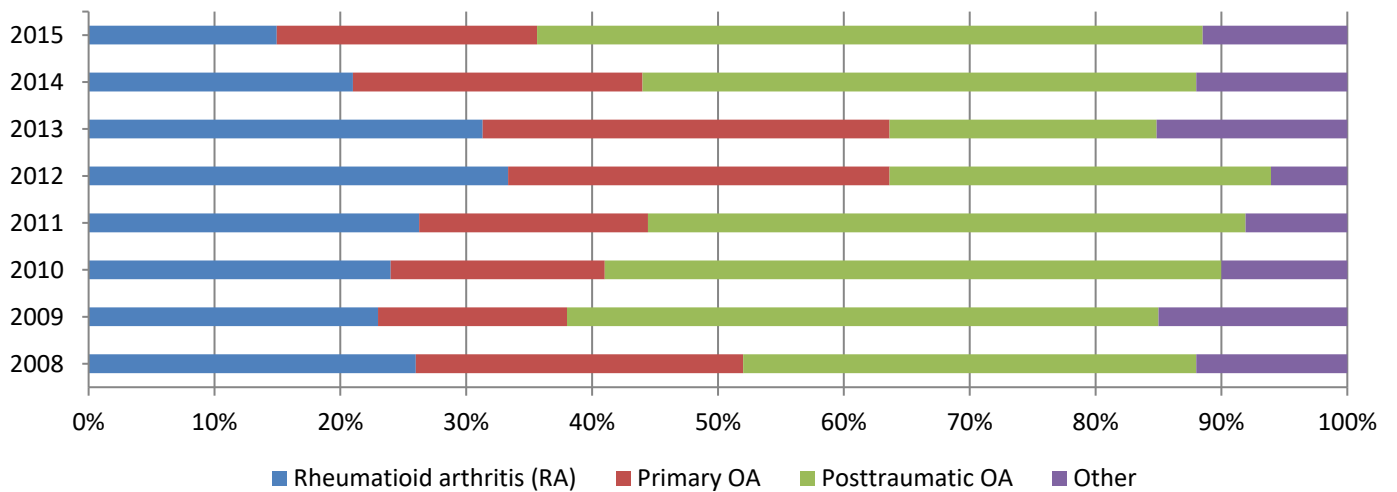


Figure 8. Distribution of diagnoses regarding ankle replacements during 2008-2018.

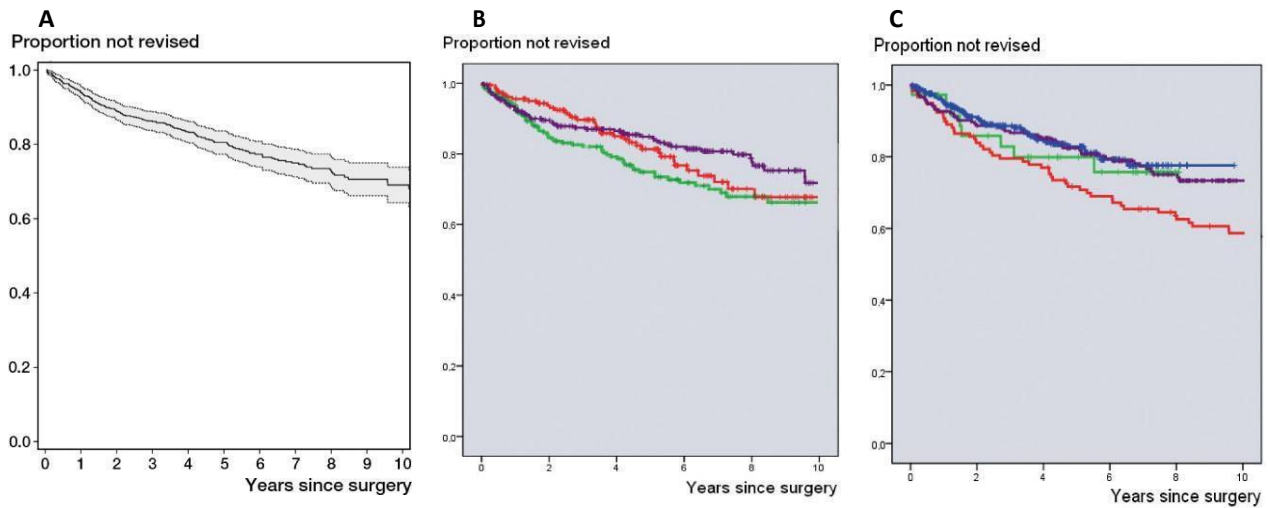


Figure 9. Estimated cumulative prosthetic survival with 95 % CI for (A) all ankle replacement in Sweden up to 2010 (B) Per diagnosis (rheumatoid arthritis (purple), primary osteoarthritis (red) posttraumatic osteoarthritis (green)) (C) per prosthetic design (BP-type (blue), Hitegra (green), double-coated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

12. Primary ankle arthrodeses

The Swedish Ankle Registry is considered the most accurate source regarding number of procedures, surgical methods and diagnoses regarding ankle fusions.

Only 10 of the 51 reporting units performed 10 or more primary fusions in 2018 and only 2 performed 20 or more fusions (Table 3).

Table 3: Number of ankles arthrodeses per type of hospital 2018

Type of unit (n)	Number of annual procedures				
	≥ 20	10-19	5- 9	1-4	0
University hospital (8)*	1	3	1	2	1
Other hospitals/units	1	5	8	21	8

*Karolinska sjukhuset Solna - Huddinge and Malmö - 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 –a reduction by about 50% - while fixation by plate and screws has gradually increased. Arthroscopic exploration with screw fixation has during later years been reported in about 16 % of cases (Table 4 and Figure 10). During 2018 only 2 primary cases using external fixation were performed.

Table 4. Number of primary ankle fusions 2008-2018 distributed according to surgical method

Year	Type of surgery								TOTAL	
	Screw			IM nail	External fixation	Plate	Stapler	Other		Unknown method
	Per-cutaneous	Arthroscopic	Open							
2008	4	6	40	44	3	0	0	0	0	97
2009	5	2	64	47	1	0	0	1	0	120
2010	0	16	72	45	8	9	1	0	0	151
2011	8	14	101	59	5	15	0	0	2	204
2012	1	30	132	80	15	12	0	0	1	271
2013	0	35	168	81	8	16	0	0	0	308
2014	4	22	177	92	4	13	0	0	1	313
2015	1	59	162	59	6	23	0	0	0	310
2016	0	54	152	54	9	44	0	4	0	317
2017	1	48	142	49	4	55	1	1	0	301
2018	1	46	129	49	2	64	0	3	1	295
TOTALT	25	332	1339	659	65	251	2	9	5	2687

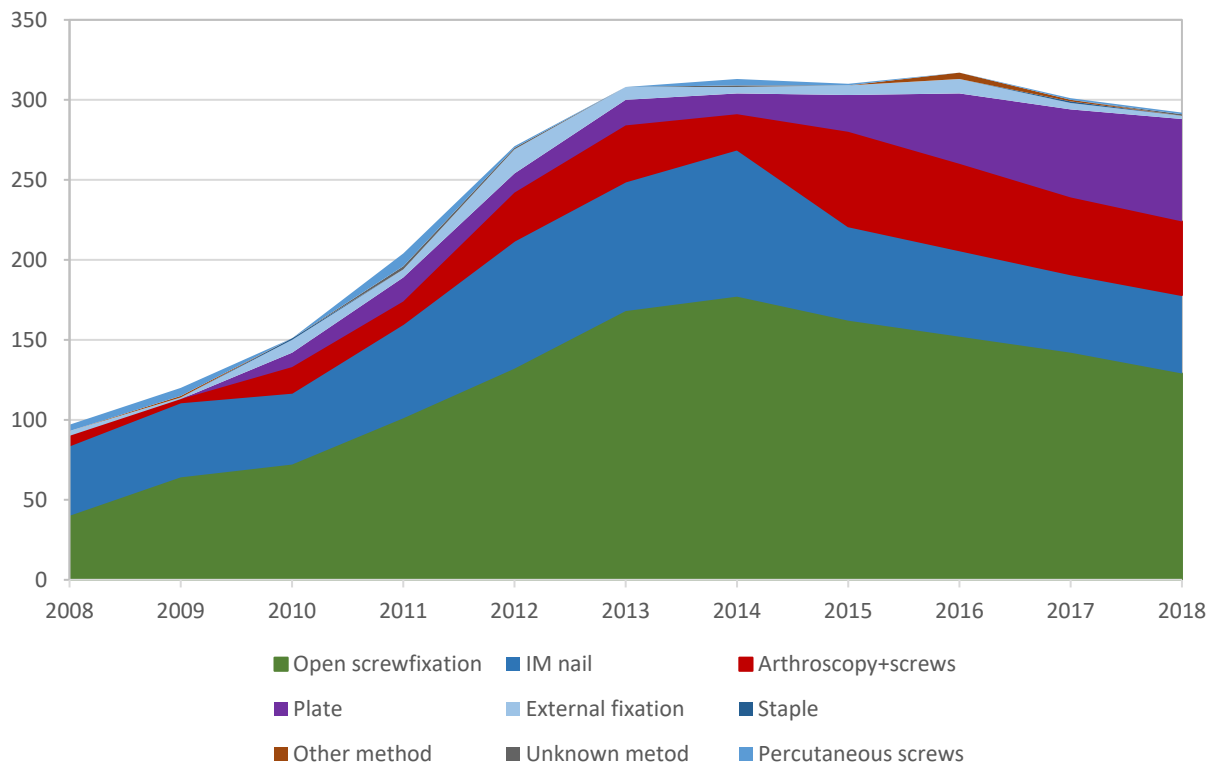


Figure 10. Number of primary ankle fusions 2008 – 2018 distributed according to surgical method

The number of primary ankle fusions has successively increased from 182 in 2011 to about 300 each year – in 295 cases in 2018. The procedure-based coverage has during later years exceeded 95%. Osteoarthritis (OA) is the most common diagnosis (75 %) - posttraumatic OA being somewhat more common than primary OA. The distribution by diagnosis and gender can be found in Table 7 and the distribution of surgical method in Table 8.

13. Re-arthrodeses

Out of 1716 primary arthrodeses reported to the registry until December 31 2016, 134 (7.8%) had undergone at least one re-arthrodesis – most of them within 2.5 years. 15/134 (11%) underwent one or more re-arthrodeses. (Publication no 19).

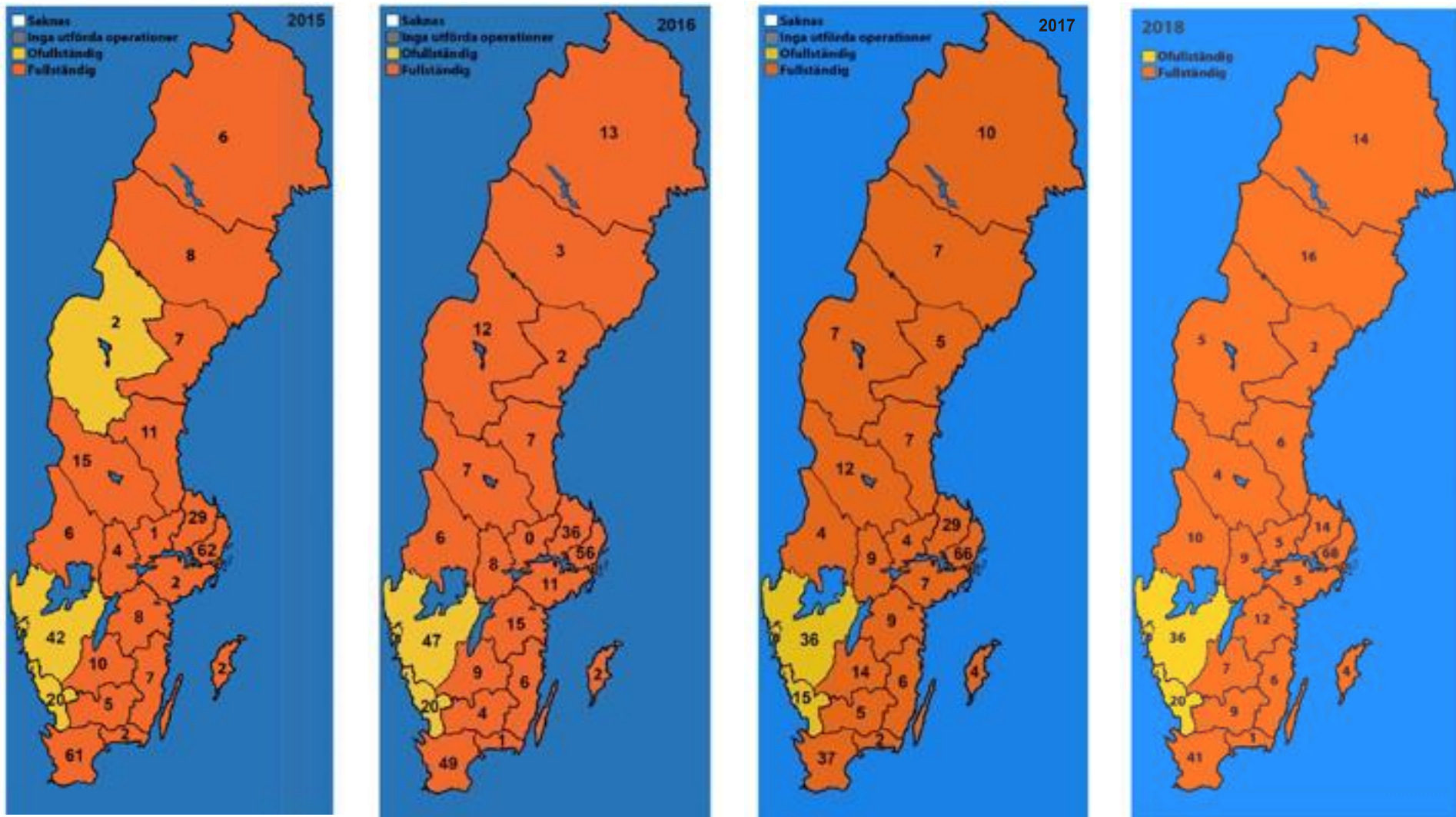


Figure 11. Number of primary ankle fusion 2015-2018 per Swedish region/county.



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



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

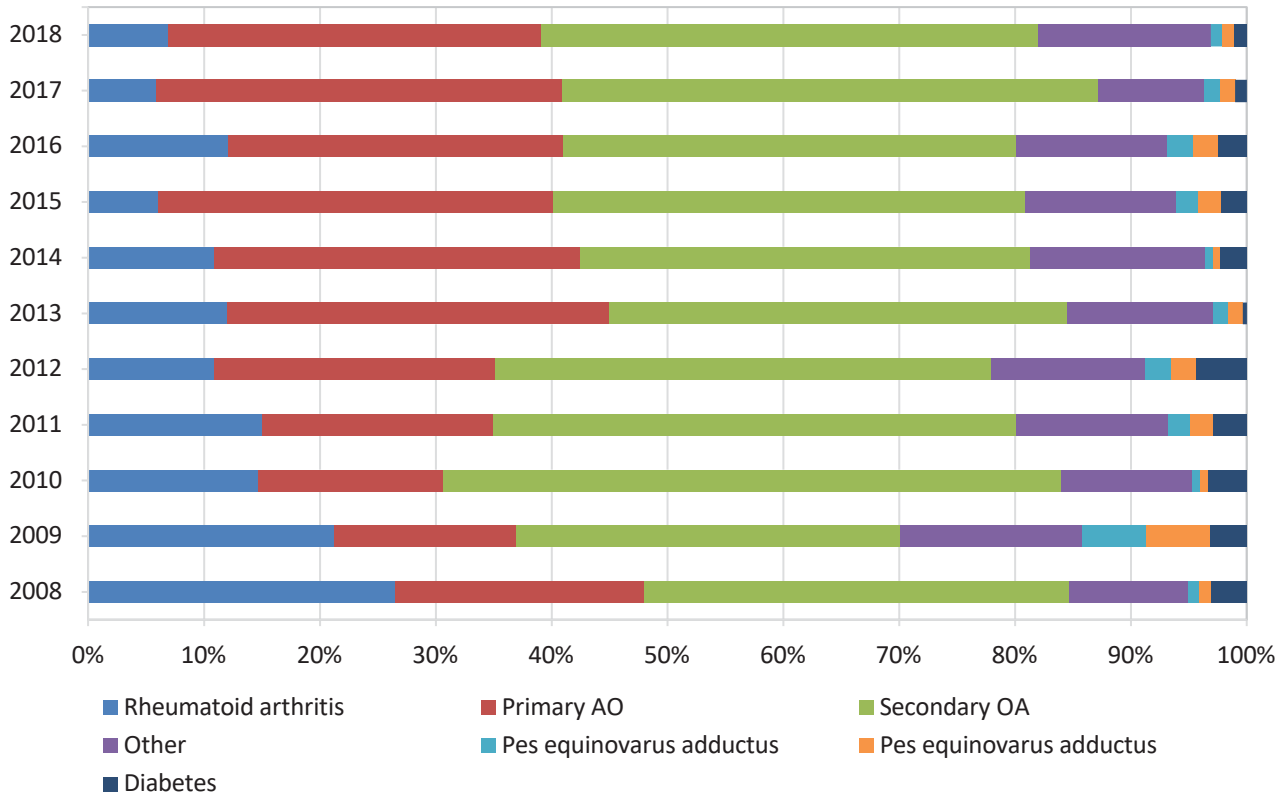


Figure 14. Distribution of diagnoses in cases that underwent primary ankle fusion 2008-2018



Figure 15. Ankle fusion fixated with cannulated screws

14. Smoking habits and ASA classification

Data on smoking habits of patients undergoing ankle arthrodesis or replacement surgery are presented in Table 5.

Table 5. Smoking habits in patients that underwent ankle arthrodesis or replacement during 2015-2018 according to type of surgery and gender.

	Total (n)	Non smoker	Quit smoking >6 weeks ago	Smoker	Unknown smoking habit
Total	1460	1208 (83%)	108 (7%)	51 (3%)	93 (6%)
Arthrodesis	1232	1006 (82%)	99 (8%)	48 (4%)	79 (6%)
Women	531	434 (82%)	42 (8%)	23 (4%)	32 (6%)
Men	701	572 (82%)	57 (8%)	25 (4%)	47 (7%)
Replacement	238	212 (89%)	9 (4%)	3 (1%)	14 (6%)
Women	123	107 (87%)	7 (6%)	2 (2%)	7 (6%)
Men	115	105 (91%)	2 (2%)	1 (1%)	7 (6%)

Data on pre-operative ASA-class (American Society of Anesthesiologists (ASA) Physical Status) for patients that underwent primary ankle replacement and primary arthrodesis during the years 2015-2018 are found in Table 6a and 6b. For 232 of the 238 patients who underwent surgery with ankle replacement information was available. 156 (67%) were ASA 2 or 3 and 1 was ASA 4. For 1177 of the 1222 patients who underwent ankle fusion procedure during 2015–2018 information was available. Of these 846 (69%) were ASA 2–3 and 12 were reported ASA 4 – i.e. with severe systemic disease that is a constant threat to life.

Age distribution and distribution of BMI are presented for patients who underwent primary ankle replacement or arthrodesis in Table 7.

Table 6a. ASA-class (American Society of Anesthesiologists (ASA) Physical Status) in cases that underwent primary ankle replacement 2015-2018.

Diagnosis	ASA 1	ASA 2	ASA 3	ASA 4	Unknown
All	75	116	40	1	6
Other	8	12	5	0	1
Posttraumatic OA	42	41	7	1	0
Primary OA	23	33	7	0	2
Rheumatoid arthritis	2	30	21	0	3
Women	29	63	26	1	4
Other	1	5	2	0	0
Posttraumatic OA	21	18	3	1	0
Primary OA	5	15	1	0	1
Rheumatoid arthritis	2	25	20	0	3
Men	46	53	14	0	2
Other	7	7	3	0	1
Posttraumatic OA	21	23	4	0	0
Primary OA	18	18	6	0	1
Rheumatoid arthritis	0	5	1	0	0

Table 6b. ASA-class (American Society of Anesthesiologists (ASA) Physical Status) in cases that underwent primary ankle fusion 2015-2018

Diagnosis	ASA 1	ASA 2	ASA 3	ASA 4	Unknown
Alla	319	553	293	12	45
Other	37	82	76	2	8
Posttraumatic OA	174	236	88	6	16
Primary OA	107	196	76	2	20
Rheumatoid arthritis	1	39	53	2	1
Kvinna	112	238	153	4	14
Other	11	41	40	1	4
Posttraumatic OA	68	91	45	0	3
Primary OA	32	75	25	1	6
Rheumatoid arthritis	1	31	43	2	1
Män	207	315	140	8	31
Other	26	41	36	1	4
Posttraumatic OA	106	145	43	6	13
Primary OA	75	121	51	1	14
Rheumatoid arthritis	0	8	10	0	0

Table 7. Age distribution and BMI among patients operated on with ankle replacement or arthrodesis during 2016-2018

Age	Number (%)		BMI	Number (%)	
	Arthrodesis	Replacement		Arthrodesis	Replacement
<20	3 (0.3%)	1 (0.5%)	<18	3 (0.4%)	1 (0.7%)
20-29	22 (2%)	3 (2%)	18-24	177 (24%)	45 (31%)
30-49	39 (4%)	3 (2%)	25-29	300 (41%)	69 (48%)
40-49	79 (9%)	13 (7%)	30-35	189 (26%)	28 (19%)
50-59	198 (22%)	38 (21%)	>35	65 (9%)	2 (1%)
60-69	236 (26%)	49 (27%)			
70-79	285 (31%)	66 (36%)			
80-89	44 (5%)	10 (5%)			
>90	2 (0.2%)	1 (0.5%)			

15. Supramalleolar osteotomies

Supramalleolar osteotomies have been unusual procedures in Sweden. The indication has been malposition combined with early signs of osteoarthritis. Between 2007 and 2018, 14 units have reported a total of 89 such procedures- 13 during 2018.- 31 ankles with "opening wedge", 47 with "closing wedge" and 6 with other techniques. The median patient age for the procedures was 55 years. (range 16–75).



Figure 16 X-rays demonstrating planning for supramalleolar wedges

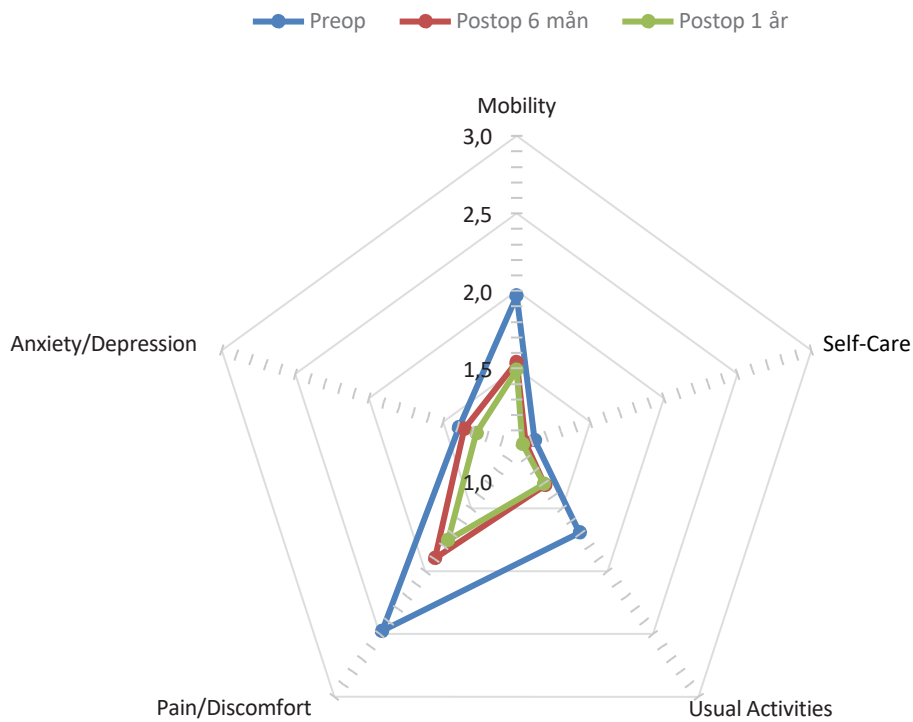
16. Patient-reported outcomes

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 generic EQ 5D (Figure 17a-b) demonstrates that the patients' general health situation is cumbersome before surgery but that their situation improves after replacement or fusion.

The foot and ankles specific SEFAS-score also demonstrates (Figure 18a-b) that the patients' situation is cumbersome before surgery concerning all evaluated issues. A considerable improvement occurs both after replacement and fusion of the ankle. The difference between outcome at 6 and 12 months is small.

20a EQ5D-3L Ankle replacement



20b EQ5D-3L Ankle arthrodesis

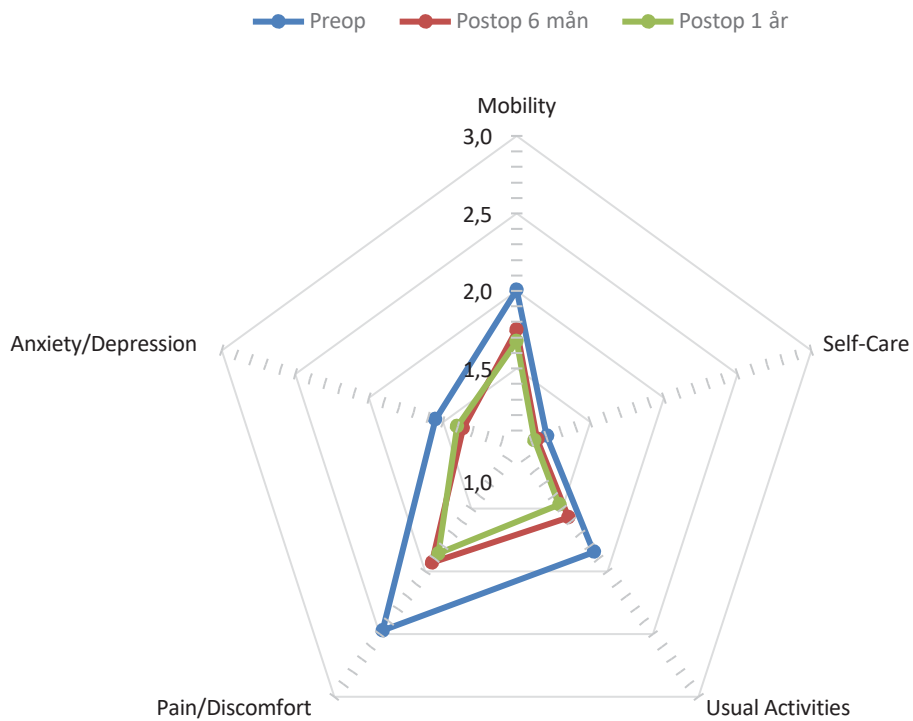


Figure 17 a and b. The spider-diagram shows the mean outcome for the 5 questions in EQ5D -3 L preoperatively and 6 and 12 months postoperatively for patients that had undergone (a) ankle replacement and (b) ankle fusion during 2017. Value 3 implies the worst possible situation and value 1 the best possible situation concerning each specific question.

SEFAS Ankle replacement

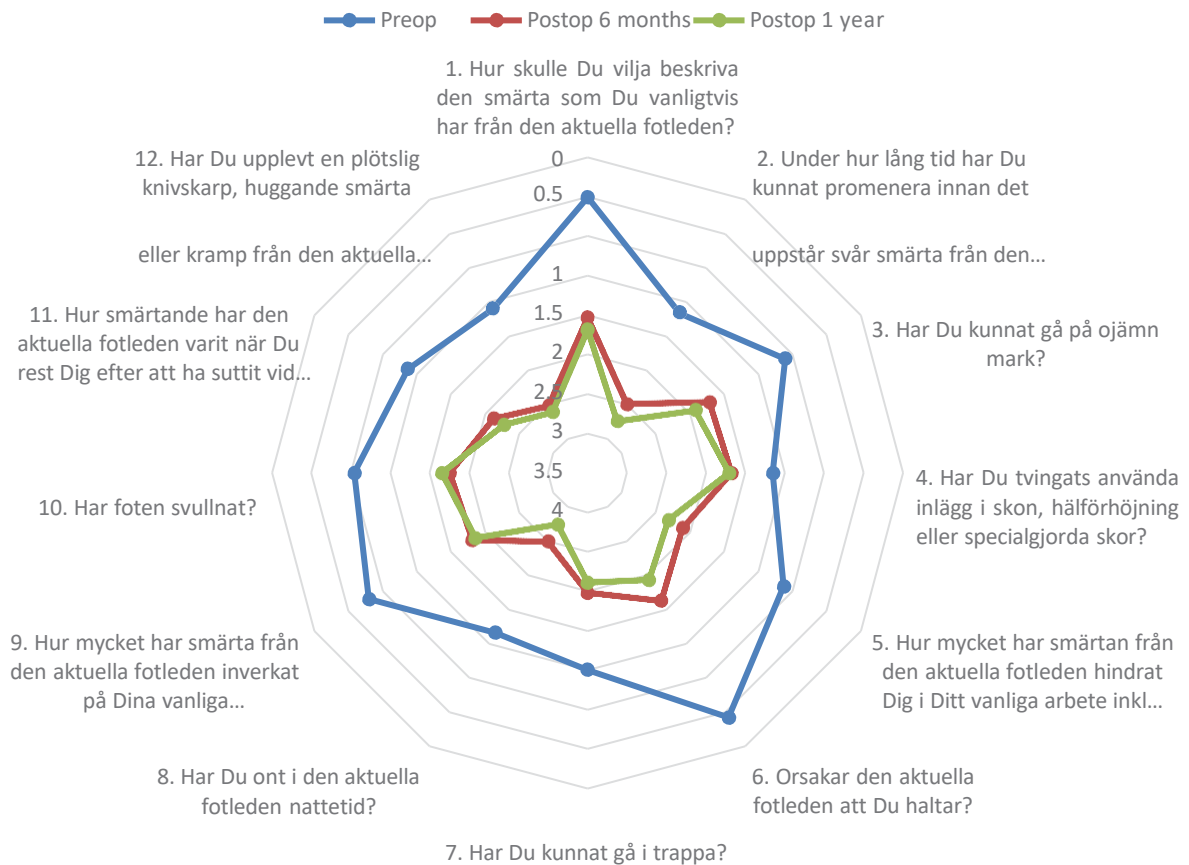


Figure 18 a. The spider-diagram shows the mean outcome for the 12 questions in SEFAS preoperatively and 6 and 12 months postoperatively for patients that had undergone ankle replacement during 2017 – Value 0 implies the worst possible situation and value 4 the best possible situation. Please see appendix 1 for SEFAS questions in English.

SEFAS Ankle arthodesis

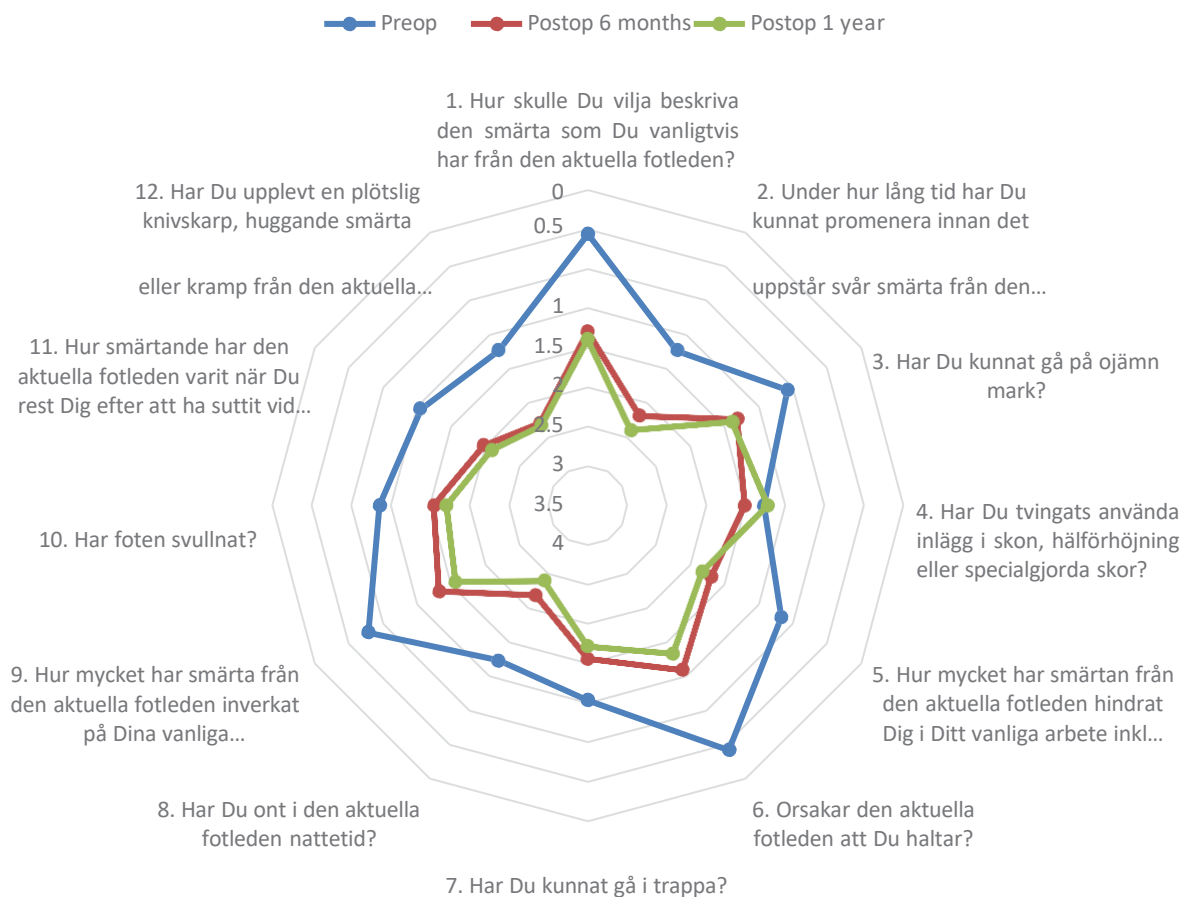


Figure 18b. The spider-diagram shows the mean outcome for the 12 questions in SEFAS preoperatively and 6 and 12 months postoperatively for patients that had undergone ankle arthrodesis during 2017 – Value 0 implies the worst possible situation and value 4 the best possible situation. Please see appendix 1 for SEFAS questions in English.

Table 11. Outcome measures (SEFAS and EQ-5D) after primary ankle replacement (Kamrad I, Outcome of surgery for end-stage ankle arthritis, Lund University, Faculty of Medicine Doctoral Dissertation Series 2017:51)

PROM	Preop mean (SD) n=220-236*	Postop 24 months Mean (SD) n=150-167*	Mean 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

* All patients did not answer all questionnaires.

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 on page 12).

PROM-results after revision of ankle replacement

Both exchange of prosthetic components and secondary arthrodesis resulted in low scores with a mean SEFAS score of 22 (compared to 31 after primary replacement). Less than half of the patients reported that they were satisfied with the result. One third of those who underwent component exchange underwent another revision. Conversion to arthrodesis resulted in another attempt to fuse the ankle in 10% of patients. Thus; according to these results, conversion to an arthrodesis is in most cases to prefer after failure.

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

<p>1. How would you describe the pain you usually have from the foot/ankle in question?</p> <p>4 None 3 Very mild 2 Mild 1 Moderate 0 Severe</p>	<p>5. How much has the pain from the foot/ankle in question interfered with your usual work including housework and hobbies?</p> <p>4 Not at all 3 A bit 2 Moderately 1 Greatly 0 Totally</p>
<p>2. For how long have you been able to walk before severe pain arises from the foot/ ankle in question?</p> <p>4 No pain up 30 min. 3 16-30minutes 2 5-15 minutes 1 Around the house only 0 Unable to walk at all because of severe pain</p>	<p>6. Have you been limping when walking because of the foot/ankle in question?</p> <p>4 No days 3 Only one or two days 2 <i>Some days</i> 1 Most days 0 Every day</p>
<p>3. Have you been able to walk on uneven ground?</p> <p>4 Yes, easily 3 With little difficulty 2 With moderate difficulty 1 With extreme difficulty 0 No impossible</p>	<p>7. Have you been able to climb <i>a flight of stairs</i>?</p> <p>4 Yes, easily 3 With little difficulty 2 With moderate difficulty 1 With extreme trouble 0 Impossible</p>
<p>4. Have you had to use an orthotic (shoe insert), heel lift or special shoes?</p> <p>4 Never 3 Occasionally 2 Often 1 Most of the time 0 Always</p>	<p>8. Have you been troubled by pain from the foot/ ankle in question in bed at night?)</p> <p>4 No night) 3 Only one or two nights 2 Some nights 1 Most nights 0 Every night</p>
<p>9. How much has pain from the foot/ankle in question affected your usual recreational activities?</p> <p>4 Not at all 3 A bit 2 Moderately 1 Greatly 0 Totally</p>	<p>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?</p> <p>4 Not at all painful 3 Slightly painful 2 Moderately painful 1 Very painful 0 Unbearable</p>
<p>10. Have you had swelling of your foot?</p> <p>4 None at all 3 Occasionally 2 Often 1 Most of the time 0 All the time</p>	<p>12. Have you had a severe sudden pain shooting, stabbing or spasms from the foot/ankle in question?</p> <p>4 No days 3 Only one or two days 2 Some day 1 Most days 0 Every day</p>

The Swedish Ankle Registry

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