The Swedish Ankle Register

for total ankle replacements and ankle arthrodeses

Annual report for 2012

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CONTENT: **PAGE:**

1. News since the previous report and summary

In collaboration with Record Centre South (ww.rcsyd.se) an on-line system for feed-back reports to the participating units has been created during 2012. The feed-back reports include number of interventions, whether preoperative questionnaires (PROM´s) were filled in and whether the units reported if complications occurred or not within 3 months. Because few operative procedures are performed at each unit, reporting will take place quarterly. In the future we also plan to report back the 2 and 5 year outcomes in the form generic and ankle-specific scores.

The number of ankle replacements was 84 during 2012, which is about the same as during 2011, and the coverage and completeness of reporting is 100%. Surgery has been performed at 10 units but the great majority (73%) at only 4 units: Falun, Nacka, Spenshult och Malmö.

During 2012, 248 primary ankle fusions have been reported. The willingness to report ankle fusions has increased year by year. Coverage for 2012 has been calculated to 73% and completeness to 78%. Ankle fusions are potentially being performed at 48 units but 15 of these only perform 1-2 fusions annually and certain years none at all. Twentyfour of the units was registred to performe more than 2 fusions during 2012.

A validation of the Self-reported Foot & Ankle Score – based on the register - has been published in Acta Orthpaedica during 2012. The study has also been presented at scientific meetings in Sweden, the Netherlands and USA .

Analyses of PROM-data (Patient Related Outcome Measurements) expressed as generic and ankle-specific scores and degree of patient satisfaction have been initiated during 2012.

2. Background

The first generation of total ankle replacements were cemented, two-component, more or less constrained designs, which in Sweden were abandoned in the mid 1990´s due to inferior results.

Figure 1.

Figure 1. *X-ray of the Rebalance-ankle. Lateral view (left) ap-view (right).*

The second generation total ankle replacements (2-component and uncemented, allowing space for rotation within the mortise) and the third generation (3 - component and uncemented designs with a polyethylene meniscus, avoiding rotational strain) have shown better results in the long term. The second generation prostheses were never introduced in Sweden but the first third generation prosthesis was implanted in 1993.

The concept of reporting all ankle replacements to a national register appeared 1997 and later that year a register was implemented. Since 2008 the register also includes ankle fusions and supramalleolar osteotomies. Questionnaires containing generic and ankle-specific scores (Patient Related Outcome Measurements) are filled in preoperatively at the participating unit and sent to the patient by mail post-operatively by the register – presently after 6 months and 2 years. Analyses of PROM-data, including degree of patient satisfaction, has started during 2012. The database is administered by the Record Centre South located in Lund (www.rcsyd.se). The Swedish and English vesion of the ankle-specific score (SEFAS) can be found under the link questionnaires at our web-page www.swedankle.se

December 31, 2012 the Register contained data of 990 primary ankle prostheses and 1038 primary ankle fusions.

3. Board and secretary

Åke Carlsson, MD,PhD **(Chair)** Dept. of Orthopaedics, Skåne University Hospital, Malmö.
Anders Henricson, MD,PhD, Dept. of Orthopaedics, Falun.
Maria Cöster, MD Dept. of Orthopaedics , Skåne University Hospital, Malmö.
Elisabeth Quensel, BSc, Record Centre South, Lund.
Per-Henrik Ågren, MD, Stockholms Fotkirurgiklinik, Sophiahemmet, Stockholm.
Anna Petersson, Certified Nurse, Dept. of Orthopaedics, Kalmar.
Secretary: **Gunnel Nilsson**, Dept. of Orthopaedics, Skåne University Hospital, Malmö.

4. Web-page (www.swedankle.se)

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

5. Economy

Up to 2010 the finances were based on grants from research funds. From 2011 the Register also has received annual contributions from The Swedish Association of Local uthorities and Regions (SKL). (www.kvalitetsregister.se)

6. Research group

Åke Carlsson, MD, PhD, associate professor

Maria Cöster, MD

Anders Henricson, MD, PhD

Ilka Kamrad, MD

Magnus Karlsson, MD, PhD, Professor

Håkan Magnusson, MD. PhD

Jan-Åke Nilsson, statistician

Björn Rosengren, MD, PhD

7. Research

Maria Cöster's research project deals with Patient Related Outcome Measurements (PROM). Validation of the Self-reported Foot and ankle score (SEFAS) has been concluded and the work has been presented at AAOS in San Fransisco, February 2012 and at EFAS in Holland, also 2012. The project also includes prevalence of primary osteoarthritis and radiographic imaging of the ankle.

Ika 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 organ-specific instruments.

8. Publications based on the ankle register incl. summary of the result

Carlsson Å.
Single - and double-coated STAR total ankle replacements.
A clinical and radiographical follow-up study of 109 cases.
Orthopäde2006;35:527-532. (Article in German)
Results: All implanted STAR ankles reported to the Ankle Register were identified with the aim to compare prosthetic survival of the early single coated design and the later introduced double coated design. The study demonstrated an obvious learning curve, with inferior survival for the single coated prostheses implanted early, but no difference was observed between the designs implanted later during the study period.

Henricson A, Ågren P-H.
Secondary surgery after total ankle replacement.
The influence of preoperative hindfoot alignment. Foot Ankle Surg 2007; 13:41-44.
Results: 186 ankle prostheses implanted in 3 Swedish Hospitals were identified. Preoperatively the position of the hindfoot was registered. The analysis demonstrated that revision was twice as common in cases with a varus malpositioning preoperatively as in cases with a valgus or normal position.

Henricson A, Skoog. A, Carlsson Å.
The Swedish Ankle Arthroplasty Register. An analysis of 531 arthroplasties between 1993 and 2005. Acta Orthp 2007;78:569-574.
Results: The 5-year protsthetic survival was estimated to 78%. The results, related to the 3 surgeons having performed the majority of the replacement, improved considerably after each of them had performed 30 replacements. Thus, the study demonstrated a long learning curve and also that the risk of a revision operation was higher among younger persons.

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.
Results: Alla AES prostheses implanted in 2 Swedish hospitals (Falun and Lund) were identified from the Ankle Register. The 5-year survival was estimated to 90%. 36 additional surgical procedures were performed in 25 of the 93 (27%) cases simultaneously with the ankle replacement.

Henricson A, Carlsson Å, Rydholm U.
What is a revision of total ankle Replacement Foot Ankle Surg 2011;17:99-102.
Results: Base on a thorough review of the literature it was suggested how a prosthetic revision should be defined**.**

Henricson A, Nilsson J-Å, Carlsson Å.
Titel: ***10-year survival of total ankle arthroplasties. A report on 780 cases from the Swedish Ankle Register. Acta Orthop 2011;82:655- 659.***
Results: The10-year prosthetic survival was estimated to 69%. Excluding the STAR- ankle the corresponding figure was 78%. The latter figure is similar to what has been reported by others.

Cöster M, Karlsson M, Nilsson J-Å, Carlsson, Å.
Validity, reliability, and responsiveness of a self-reported foot and ankle **score (SEFAS).** ***Acta Orthop.2012;83:197-203.***
Results: Patients scheduled for ankle replacement or arthrodesis were asked to fill in questionnaires before and after surgery. The validity, reliability and responsiveness related to the SEFAS-score proved to be excellent. This simple and self-adminstrated instrument is thus suitable for clinical use and in national registers.

9. Abstracts

Henricson A.: The Swedish Ankle Register. Norwegian Orthopaedic Society, Oslo 2010.

Cöster M.: Karlsson M, Nilsson J-Å, Carlsson Å.
Titel: Validering av en fotledsspecifik fotledsscore (SEFAS).
Swedish Orthopaedic Society , Karlskrona 2011.

Cöster M, Karlsson M, Nilsson J-Å, Carlsson Å.
Titel:Validity, reliability, and responsiveness of a self-reported foot and ankle score (SEFAS).
American Academy of Orthopaedic Surgeons (AAOS), San Fransisco 2012.

Cöster M, Karlsson M, Nilsson J-Å, Carlsson Å.
Titel: fotkirurgiska sällskapets Validity, reliability, and responsiveness of a self-reported foot and ankle score (SEFAS). The European Foot & Ankle Society (EFAS), Nordwijk, Holland 2012.

Henricson A.
Titel: What can we learn from the Swedish ankle register?
Nordic Orthopaedic Society, Tallinn 2012.

Henricson A.
Titel: What´s the stack of evidence of total ankle replacement?
The European Foot & Ankle Society (EFAS), Nordwijk, Holland 2012

10. Coverage and Completeness

B) ”Coverage” = number of units that may perform the procedure.
Primary ankle prostheses 2012: **100%**
Primary ankle fusions 2012: **73 %**
Ankle fusions are potentially being performed at 48 units but 15 of these only perform1-2 annually and certain years none at all. The latter have been excluded in our calculation of coverage. Of the 33 units that may perform more than two fusions annually, 24 reported during 2012. It is likely that more than 15 units perform less than two fusion annually and therefore, we consider 73% being a minimum figure.

C) *”Completeness”* = number of surgeons of those who may perform the procerdure.
Primary ankle prostheses 2012: **100%**
Primary ankle fusions 2012: **76 %**

11. Ankle Replacements

Results:

The number of ankle replacements during 2012 was 84, wich is about the same as during 2011 (Table 1). The coverage and completeness of reporting is 100%. Surgery has been performed 10 units but the great majority (73%) at only 4 units: Falun, Nacka, Spenshult och Malmö (Figure 2).

Table 1.

Hospital	2010 n	2011 n	2012 n	2012 Diagnosis: OA- RA- Other	2012 Gender: Women- Men	2012 Design: Mob–CCI - Reb
Falu lasarett	9	10	12	7 - 5- 0	9 - 3	0 - 0- 12
Hässleholm-Kristanstad	2	4	2	2 - 0 - 0	0 - 2	2 - 0 - 0
Karolinska sjh Solna	0	1	4	0 - 3 - 1	2 - 2	1 - 3 - 0
Nacka närsjukhus	17	24	18	17 - 1 -0	7 - 11	11 - 7 - 0
Sophiahemmet	1	2	2	2 - 0 - 0	0 - 2	0 - 2 - 0
Spenshult	9	13	21	11 - 8 - 2	12 - 9	0 -10 -11
Sundsvalls sjukhus	3	4	5	3 - 1 - 1	2 - 3	0 - 5 - 0
SUS Lund*	0	9	4	0- 4 - 0	4 - 0	0 - 0 - 4
SUS Malmö	18	15	11	5 - 5 - 1	10 - 1	11 - 0 - 0
Uppsala Akademiska	4	2	0	0 – 0 - 0	0 - 0	0 - 0 - 0
Uppsala Elisabeth sjh**	1	1	5	4 - 1 - 0	2 - 3	0 - 5- 0
TOTAL:	**64**	**85**	**84**	**51- 28 - 5**	**48 - 36**	**25 - 32 - 27**

* same surgeon as in Spenshult , ** same surgeon as in Falun

Table 1.
Primary ankle replacements per unit during

Figure 2.

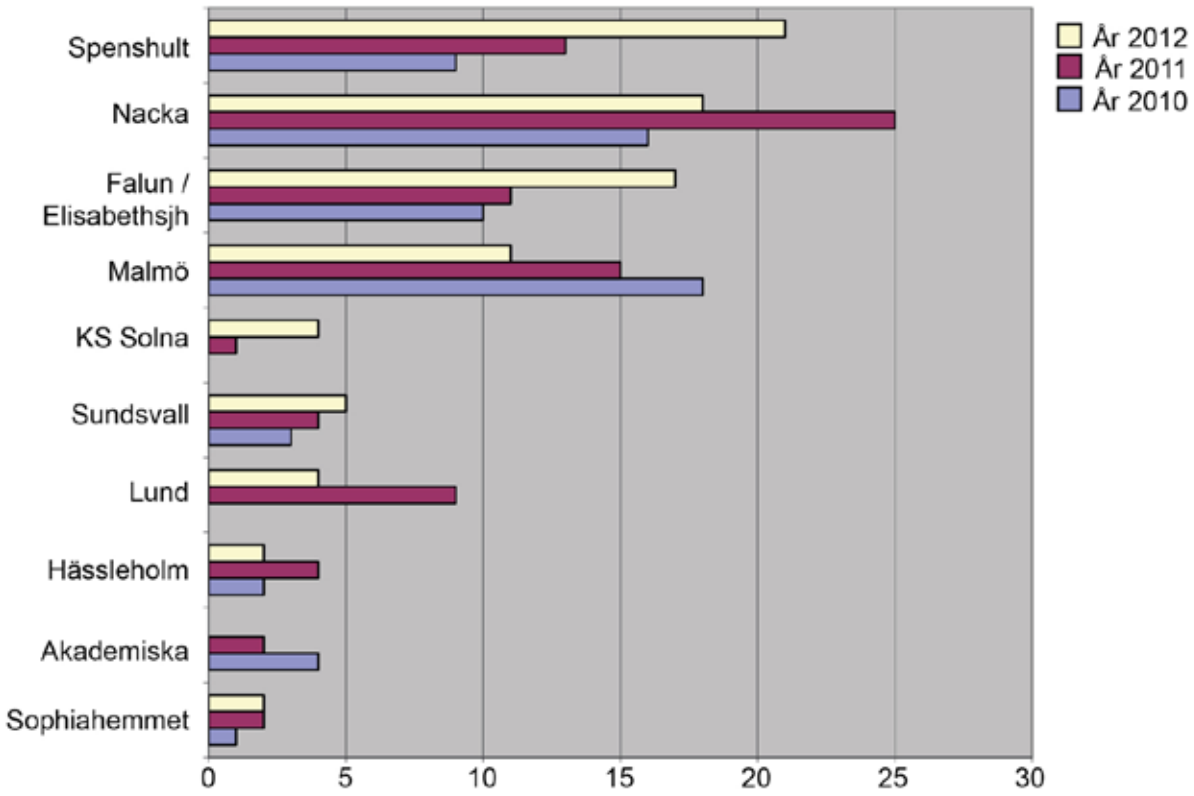

Figure 2. *Number of primary ankle replacements per unit during 2010-2012 incl. diagnosis, gender and prosthetic design.*

Figure 3.

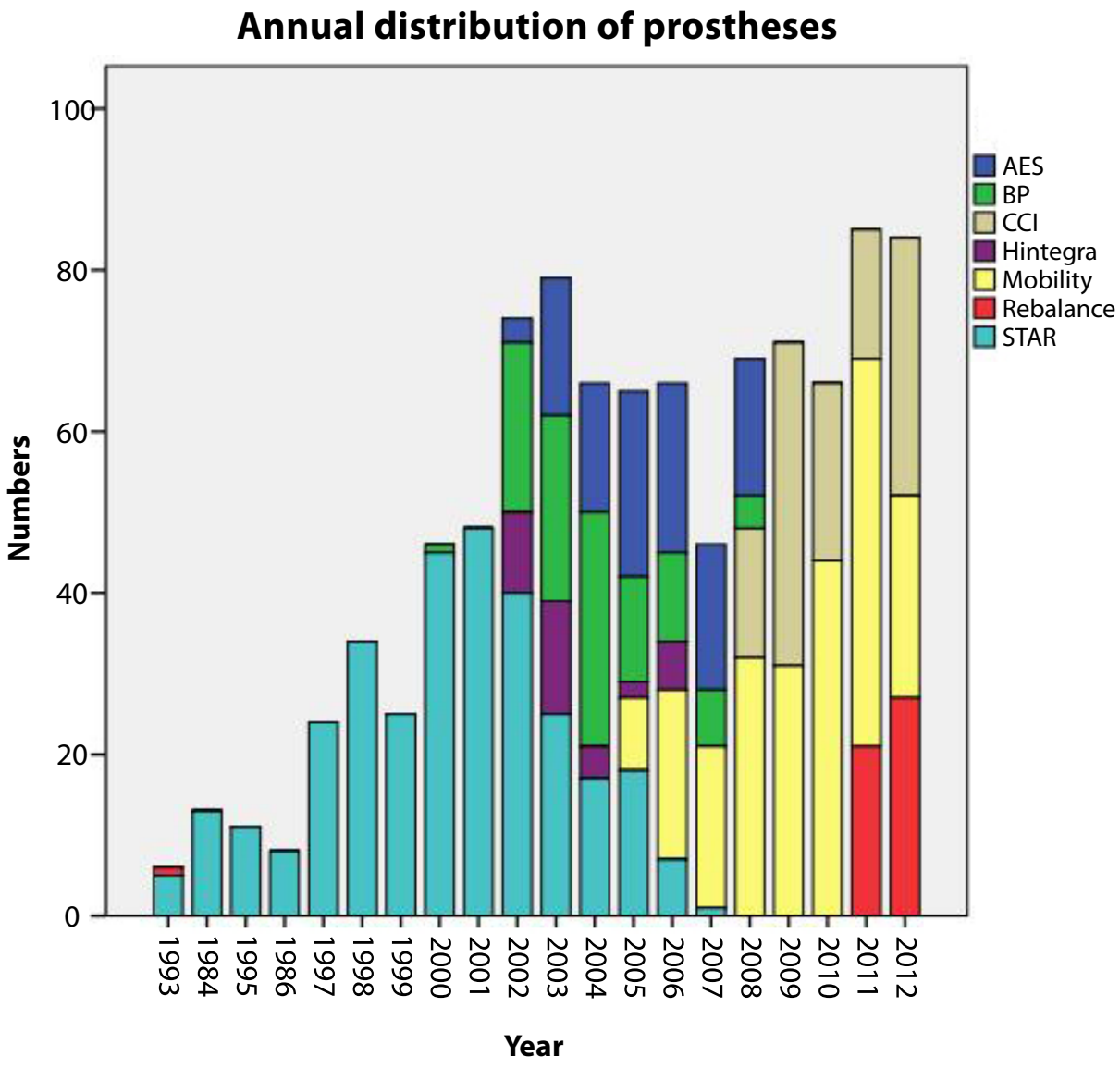

Figure 3. *Annual distribution of prostheses.*

12. Revisions, Prosthetic Survival and Risk Factors

Since 1993, i.e. during a period of 19 years, 208 (21%) replacements have been revised. Numbers and reasons for revsion – defined as exchange of components or fusion – are presented in Table 2 .
In addition, about 100 re-operations, defined as secondary surgery not including the ankle itself, were undertaken. Examples are lengthening of the achilles tendon, osteotomies of the calcaneus and subtalar fusions.

Table 2.

Design	STAR single	STAR double	BP	AES	HINTE-GRA	Mobility	CCI	Rebal-ance	All
Year in use	1993-1998	1999-2007	2000-2008	2002-2008	2002-2006	2005-	2008-	2011-	
Total number	n=118	n=207	n=108	n=114	n=36	n=223	n=134	n=48	n=990
Reason for revision									
Loosening	36	22	5	8	3	6	9	1	90
Technical mistake	5	11			2				18
Instability		1	3	4	1	2	1		12
Infection	3	11	1	4		3			22
Uexplained pain	4	7	1	2		3	3		20
Plastic wear or fracture meniscus	7	10	3	2					23
Painful valgus			1	3	1	1			6
Painful varus		2	2	2			2		8
Bone frakture		4	3	2					9
Total	46	77	19	27	7	15	15	1	208

Table 2. *Reason for revision and prosthetic design 1993–2012.*

13. Prosthetic Survival

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 a inferior survival compared to the other designs. The survival of the latter did not differ.

Prosthetic survival improved significantly during the 5-year period 2004-2008 compared to the previous 5-year period. The next 5-year period will be analysed during 2014, (Figure 4).
The 10-year survival was not influenced by diagnosis. However, women below 60 at the time of surgery and operated on due to osteoarthritis led a higher risk than those above the age of 60. No such risk was observed for men irrespective of age and diagnosis.

Figure 4.

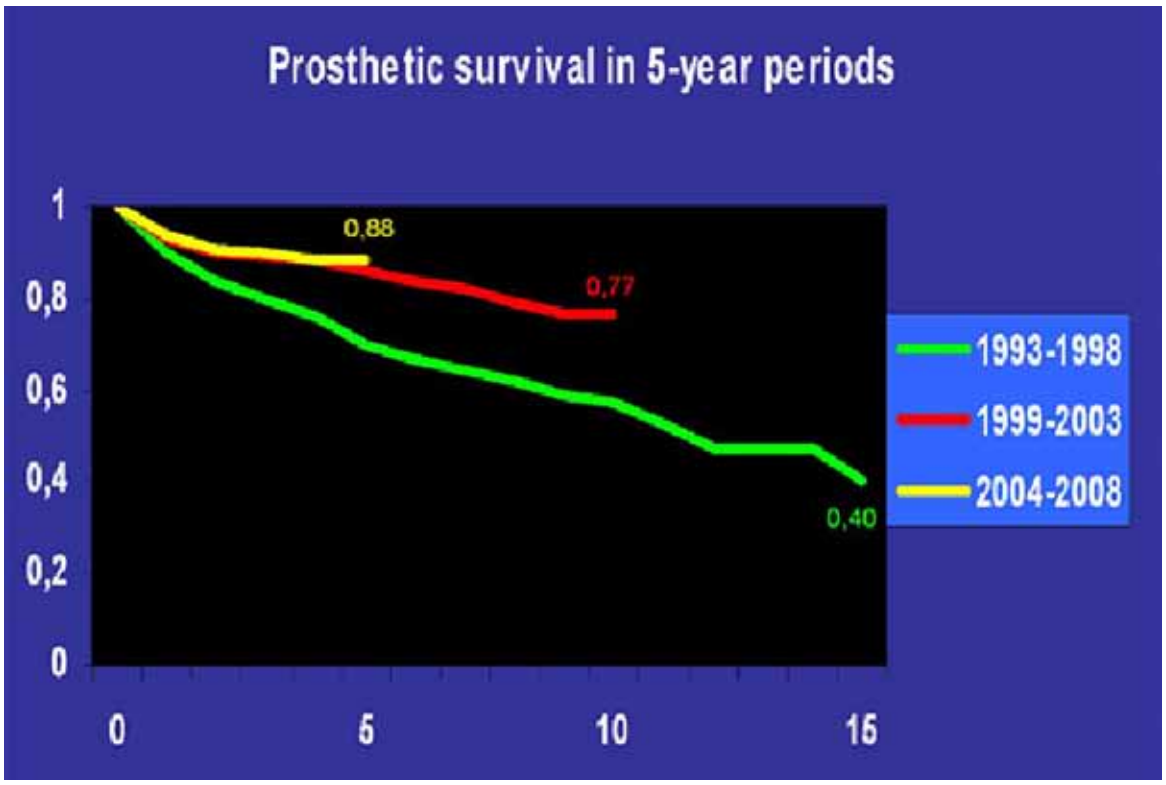

Figure 4.
Prosthetic survival in 5-year periods with exchange.

14. Primary Ankle Arthrodeses

Results

The number of reported primary ankle fusions has increased since previous years (Table 3). The distribution according to diagnosis and gender is presented in Table 4 and the surgical methods in Table 5. Coverage och completeness are presented elsewhere in this report.

Table 3.

Hospital	2010	2011	2012	Reporting 2012
All Sweden	147	182	248	
01 Stockholm	25	34	42	Incomplete
Danderyds sjukhus	Missing	Missing	Missing	
Karolinska sjukhuset Solna	11	6	8	
Nacka sjukhus	6	20	15	
Norrtälje sjukhus	Missing	Missing	Missing	
S:t Görans sjukhus	Missing	Missing	7	
Sophiahemmet	8	8	3	
Södersjukhuset	Missing	Missing	1	
Södertälje sjukhus	None perf.	None perf.	8	
03 Uppsala	9	21	23	Complete
Akademiska sjukhuset	Missing	16	13	
Elisabethkliniken	9	5	10	
04 Södermanland	0	0	0	Missing
Mälarsjukhuset	Missing	Missing	Missing	
05 Östergötland	0	0	10	Complete
Motala lasarett	Missing	Missing	6	
Vrinnevisjukhuset Norrköping	None perf.	None perf.	4	
06 Jönköping	1	1	2	Incomplete
Höglandssjukhuset Eksjö	Missing	Missing	Missing	
Ryhov, länssjukhus Jönköping	Missing	Missing	1	
Värnamo sjukhus	1	1	1	

Table 3.
Cont.

Table 3.

Hospital	2010	2011	2012	Reporting 2012
07 Kronoberg	0	0	11	Complete
Ljungby/ Växjö lasarett	Missing	Missing	11	
08 Kalmar	5	8	6	Incomplete
Länssjukhuset Kalmar	5	8	6	
Oskarshamns sjukhus	Missing	Missing	Missing	
09 Gotland			1	Complete
Visby lasarett	Missing	Missing	1	
10 Blekinge			5	Complete
Blekingesjukhuset	Missing	Missing	5	
12 Skåne	39	43	53	Complete
Helsingborgs lasarett	1	4	2	
Hässleholm-Kristianstad	5	5	11	
Universitetssjukhuset Lund	10	7	5	
Universitetssjukhuset MAS	23	27	35	
13 Halland	25	35	45	Complete
Hallands sjukhus Halmstad	Missing	3	1	
Hallands sjukhus Varberg	Missing	Missing	1	
Movement	Missing	Missing	13	
Spenshults reumatikersjukhus	25	32	30	
14 Västra Götaland	19	13	32	Incomplete
Carlanderska Sport	Missing	Missing	1	
NU-sjukvården Uddevalla	Missing	Missing	9	
Mölndal	18	13	16	
Skaraborgs sjukhus Skövde	Missing	Missing	Missing	
Södra Älvsborgs sjukhus Borås	1	Missing	6	
17 Värmland	0	0.	0	Missing
Karlstads sjukhus	Missing	Missing	Missing	
18 Örebro	4	6	0	Complete

Table 3.
Cont.

Table 3.

Hospital	2010	2011	2012	Reporting 2012
Universitetssjukhuset Örebro	4	6	0	
19 Västmanland	Missing	Missing	3	Complete
Västerås	Missing	Missing	3	
20 Dalarna	10	12	6	Complete
Falu lasarett	10	12	6	
21 Gävleborg	0	0	0	Missing
Bollnäs sjukhus	Missing	Missing	Missing	
Gävle sjukhus	Missing	Missing	Missing	
Hudiksvalls sjukhus	Missing	Missing	Missing	
22 Västernorrland	4	3	6	Complete
Sundsvalls sjukhus	4	3	4	
Sollefteå	Missing	Missing	2	
23 Jämtland	0	0	0	Missing
Östersunds sjukhus	Missing	Missing	Missing	
24 Västerbotten	6	7	3	Incomplete
Universitetssjukhuset Umeå	6	7	3	
Skellefteå lasarett	Missing	Missing	Missing	
25 Norrbotten	0	0	0	Missing
Gällivare lasarett	Missing	Missing	Missing	
Piteå Älvdals sjukhus	Missing	Missing	Missing	
Sunderbyns sjukhus	Missing	Missing	Missing	

Table 3. Number of primary ankle fusions per year and hospital.

Table 4.

Table 4.	Number 2012	Diagnoses 2012 OA-RA-Other	Gender 2012 Women-Men
All Sweden	248	168 - 30 - 50	106 - 142

Table 4. Distribution of diagnoses and gender during 2012.

Table 5.

Table 5.	Per-cutaneous screws	Arthroscopy + screws	Open surg. + screws	Plate + screws	Intra-medullary nail	Extern-fixation	Total
All Sweden	1	29	119	11	73	15	248
01 Stockholm							
Danderyds sjukhus							Missing
Karolinska sjukhuset Solna		1	6		1		8
Nacka närsjukhus			13		1	1	15
Norrtälje sjukhus							Missing
S:t Görans sjukhus		2		5			7
Sophiahemmet		2	1				3
Södersjukhuset					1		1
Södertälje sjukhus			4		4		8
03 Uppsala							
Akademiska sjukhuset			5		7	1	13
Elisabethkliniken		7	2		1		10
04 Södermanland							
Mälarsjukhuset							Missing
05 Östergötland							
Motala lasarett			6				6
Norrköping			2		2		4
06 Jönköping							
Eksjö							Missing
Jönköping					1		1
Värnamo sjukhus					1		1
07 Kronoberg							
Ljungby/ Växjö lasarett			7		3	1	11
08 Kalmar							
Länssjukhuset Kalmar			4		2		6
Oskarshamns sjukhus							Missing
09 Gotland							
Visby lasarett			1				1
10 Blekinge							
Blekingesjukhuset			3		2		5
12 Skåne							
Helsingborgs lasarett			2				2
Hässleholm-Kristianstad		11					11
SUS Lund	1		2		2		5
SUS Malmö			16		7	12	35

Table 5.
Cont.

Table 5.

Cont. Table 5.	Per-cutaneous screws	Arthroscopy + screws	Open surg. + screws	Plate + screws	Intra-medullary nail	Extern-fixation	Total
13 Halland							
Halmstad			1				1
Varberg			1				1
Movement		3	5		5		13
Spenshults reumatikersjukhus			20		10		30
14 Västra Götaland							
Carlanderska Sport			1				1
Uddevalla			5		4		9
Mölndal			9		7		16
Skövde							Missing
Borås Sjukhus			1	5			6
17 Värmland							
Karlstads sjukhus							Missing
18 Örebro							
Universitetssjukhuset Örebro							0
19 Västmanland							
Västerås		2			1		3
20 Dalarna							
Falu lasarett				1	5		6
21 Gävleborg							
Bollnäs sjukhus							Missing
Gävle sjukhus							Missing
Hudiksvalls sjukhus							Missing
22 Västernorrland							
Sundsvalls sjukhus			2		2		4
Sollefteå sjukhus		1			1		2
23 Jämtland							
Östersunds sjukhus							Missing
24 Västerbotten							
Universitetssjukhuset Umeå					3		3
Skellefteå lasarett							Missing
25 Norrbotten							
Gällivare lasarett							Missing
Piteå Älvdals sjukhus							Missing
Sunderbyns sjukhus							Missing

Table 5. *Surgical methods for primary ankle fusion during 2012.*

Figure 5.

Figure 5.
X-ray of an ankle arthrodesis fixated by a retrograde intramedullary nail. AP-view to the left and lateral view to the right.

Figure 6.

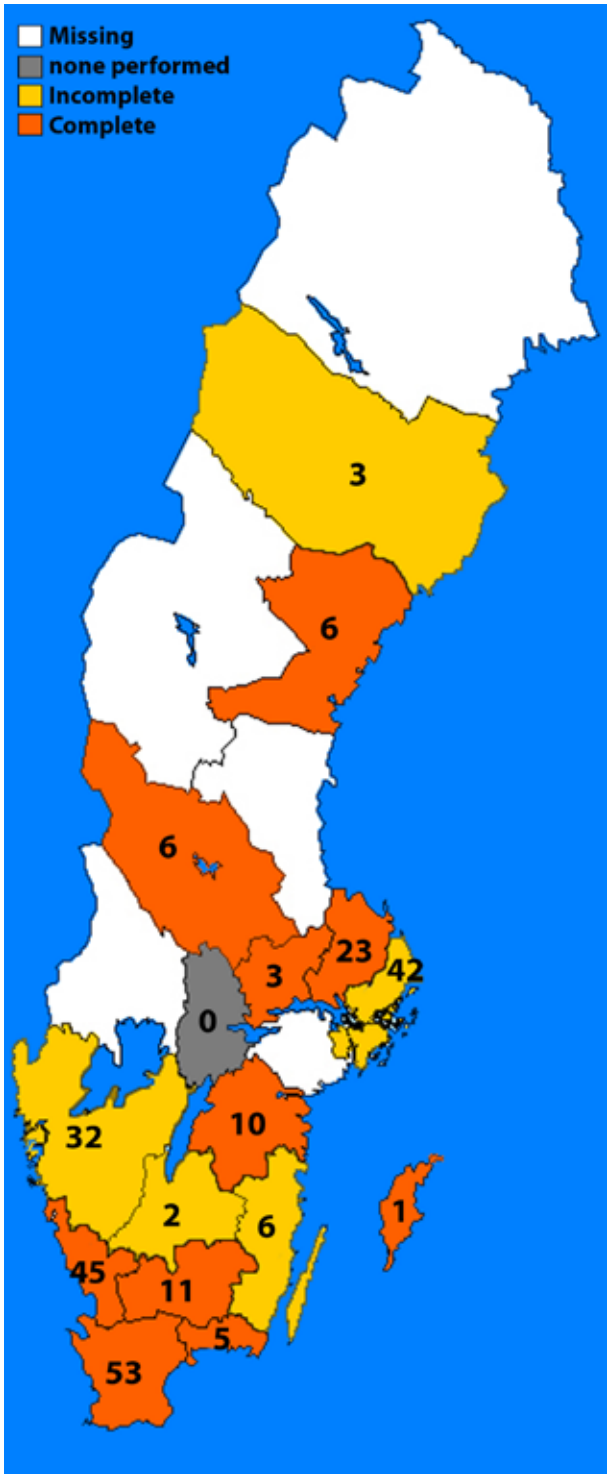

Figure 6.
Number of reported primary arthrodeses per region.

Table 6.

Replacement		n	Mean age	Median	Lowest	Highest
Women	OA	212	61	62	30	85
	RA	175	54	57	17	84
	RA + OA	387	58	60	17	85
Men	OA	201	60	61	29	84
	RA	43	55	55	27	83
	RA + OA	244	59	60	27	84

Arthrodesis		n	Mean age	Median	Lowest	Highest
Women	OA	**179**	**60**	**61**	**19**	**91**
	RA	**118**	**61**	**64**	**17**	**84**
	RA +OA	**297**	**60**	**62**	**17**	**91**
Men	OA	**269**	**60**	**61**	**15**	**85**
	RA	**33**	**64**	**65**	**33**	**81**
	RA + OA	**302**	**60**	**62**	**15**	**85**

Table 6. *Age distribution during 2002 - 2011 among patients with a replaced ankle and primary arthrodesis.*

15. Supramalleolar Osteotomies

RESULTS

Supramalleolar osteotomy has been an unusual procedure in Sweden. The most common indication for surgery has been malposition of the ankle combined with early signs of osteoarthrosis. From 2007 to 2012, 4 units have together reported only 20 cases.14 ankles were corrected by an ”opening wedge” and 6 by a ”closing wedge”. Median age was 51 years (20–70).

16. Patient Related Outcome Measures (PROM)

The SEFAS- score, that is used for follow up and outcome studies, has not previously been validated in any language. It has now been validated with reference to the generic EQ-5D and SF36 scores and the foot-specific FAOS-score. The validity, reliability, and ”responsiveness” were excellent and without any floor- or ceiling-effect. The study was published in 2012 - see the chapter of publications. The SEFAS-score is based on the Oxford-12 for hips and because it contains only 12 simple questions which makes it user friendly.

17. Summary

About 70 - 85 primary total ankle replacements have been performed annually in Sweden during the last 10-year period. The real need is presumably much higher because twice as many patients per 100.000 inhabitants are operated on in Denmark and Finland. We estimate that somewhat more than 300 primary ankle fusions are undertaken in Sweden each year. The Reporting of this procedure started much later than for ankle prostheses. However the willingness to report fusions has increased and the coverage for 2012 was 73%. Several publications from the Register are now available and there are a fair number ongoing research projects. Self-administrated outcome instruments (PROM´s) are an important part of the projects.

The Swedish Ankle Register

www.swedankle.se

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