Nationella FOTLEDSregistret

www.swedankle.se

Annual report for 2013

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Content

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Tables

1. News since the previous report and summary

The work improving the feed-back reports to the participating units has continued. These reports include number of ankle replacement and arthrodes, whether preoperative questionnaires (PROMs) 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. Within the next few years we also plan to report back the 6 month and 2 year outcomes in the form the ankle-specific SEFAS score.

The number of ankle replacements has during 2013 been essentially the same as the previous year- e.g. about 80, and the procedure based coverage was 100%. Surgery has been performed at 10 units but the great majority (72 %) at only 4 units: Falun, Nacka, Spenshult and Malmö.

During 2013, 297 primary ankle fusions have been reported. The willingness to report ankle fusions has increased year by year. Procedure based coverage for ankle fusions has been calculated to 95.8%. 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.

Analyses of PROM-data (Patient Related Outcome Measurements) expressed as generic and ankle-specific scores and degree of patient satisfaction have continued and three abstract have been accepted for presentation at AAOS i New Orleans, March 2014.

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.
The second generation total ankle replacements (2-component and uncemented, allowing space for rotation within the mortise) and the third generation (3 - component and unce-

mented 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 registry appeared 1997 and later that year a registry was implemented. Since 2008 the registry 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 units and sent to the patient by mail post-operatively by the registry – presently after 6 months, 2 years and 5 years. Analyses of PROM-data, including degree of patient satisfaction started during 2012. The database is administered by the Registry Centre South located in Lund (www.rcsyd.se). The Swedish and English version of the ankle-specific score (SEFAS) can be found under the link questionnaires at our web-page www.swedankle.se.

December 31, 2013 the Registry contained data of 1026 primary ankle prostheses and 1345 primary ankle fusions.

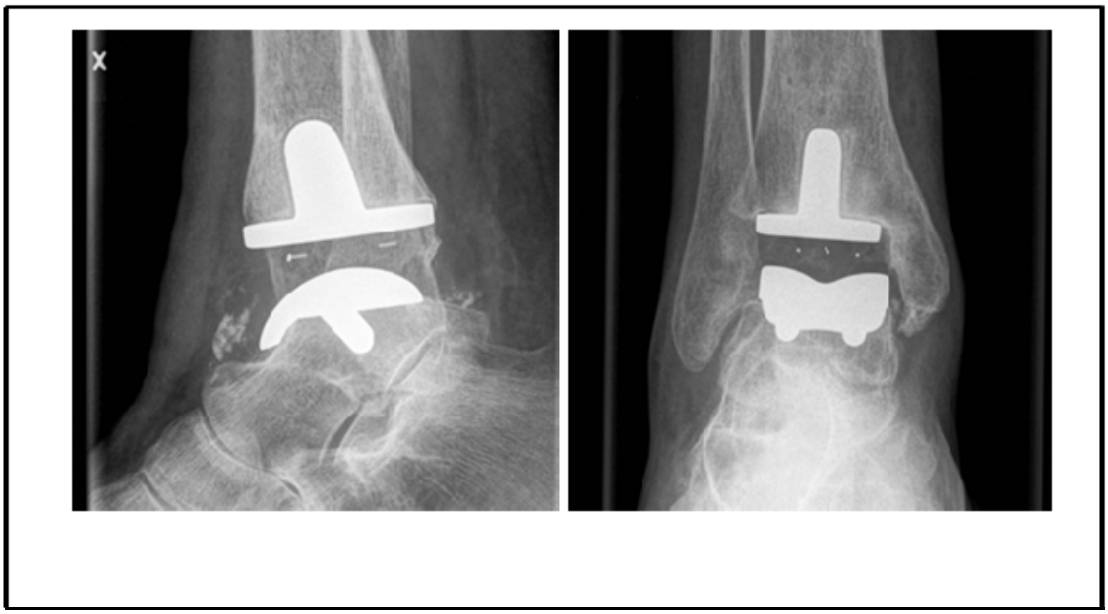

Figure 1. *X-ray of the Rebalance-ankle. Lateral view (left), ap-view (right).*

3. Board and secretary

Åke Carlsson, MD, PhD **(Chair)**, Dept. of Orthopaedics, Skåne University Hospital, Malmö.
Anders Henricson, MD, PhD, Dept. of Orthopaedics, Falu Central Hospital
Maria Cöster, MD, Dept. of Orthopaedics, Skåne University Hospital, Malmö.
Elisabeth Quensel, BSc, Registry 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. 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

Up to 2010 the finances were based on grants from research funds. From 2011 the Registry also has received annual contributions from The Swedish Association of Local Authorities and Regions (SKL). (www.kvalitetsregistry.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 Franscisco, 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 region-specific instruments.

8. Studies based on the ankle registry incl. references

In a study on 531 primary ankle replacements published in 2007 the 5-year survival 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.

In the second study on 780 ankles the 10-year survival was estimated 69%. Excluding the STAR ankle the 10-year survival was estimated to 78%[6]. It was also demonstrated that women with osteoarthritis and below the age of 60 led a higher risk of being revised. A separate study on the STAR ankle[1] demonstrated that the 5-year survival of the double-coated STAR design was 98% and better of the corresponding value for the earlier and single-coated design.

Malposition of the hind-foot influences the outcome of ankle replacement. In an analysis of 182 cases it was found that patients with varus position of the ankle preoperatively was revised twice as often as patient 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 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 used in several publications[5].

Patient-Related Outcome Measures (PROM) is increasingly used when evaluating the outcome of various interventions. The Self-reported Foot and Ankle specific Score (SEFAS) has been shown to have good validity, reliability and sensitivity to changes[7]. It is used routinely in the Swedish Ankle Registry[8].

1. **Author: Carlsson Å.**
   Title: Single - and double-coated STAR total ankle replacements.
   A clinical and radiographical follow-up study of 109 cases.
   Orthopäde2006;35:527-532. (Artikel på tyska.)

2. **Authors: Henricson A, Ågren P-H.**
   Title: Secondary surgery after total ankle replacement.
   The influence of preoperative hindfoot alignment.
   Foot Ankle Surg 2007; 13:41-44.

3. **Authors: Henricson A, Skoog. A, Carlsson Å.**
   Title: The Swedish Ankle Arthroplasty Registry. An analysis of 531 arthroplasties between 1993 and 2005.
   Acta Orthp 2007;78:569-574.

4. **Authors: Henricson A, Knutson K, Lindahl J, Rydholm U.**
   Title:The AES total ankle replacement. mid-term analysis of 93 cases.
   Foot Ankle Surg 2010;16:61-64.

5. **Authors: Henricson A, Carlsson Å, Rydholm U.**
   Title: What is a revision of total ankle Replacement
   Foot Ankle Surg 2011;17:99-

6. **Authors: Henricson A, Nilsson J-Å, Carlsson Å.**
   Title: 10-year survival of total ankle arthroplasties. A report on 780 cases from the Swedish Ankle Registry.
   Acta Orthop 2011;82:655- 659.

7. **Authors: Cöster M, Karlsson M, Nilsson J-Å, Carlsson, Å.**
   Title: Å. Validity, reliability, and responsiveness of a self-reported foot and ankle score (SEFAS).
   Acta Orthop.2012;83:197-203.

8. **Authors: Henricson A, Cöster M, Carlsson Å**
   Title: The Swedish National Ankle Registry
   Fuss und Sprunggelenk 2014:12; 65-6

9. Procedure- based coverage

Primary ankle prostheses: **100%**

Primary ankle fusions: **95.8%**

Ankle fusions are potentially being performed at 48 units but 15 of these only perform1-2 cases annually and certain years none at all. The latter units have been excluded in our calculation of coverage. Of the 33 units that may perform more than two fusions annually, all but 4 units and all but one of the 21 Swedish regions reported their ankle fusion during 2013. 297 out of an estimated 311 ankle fusions makes a procedure-based coverage of 95.8 %

Procedure-based over-coverage regarding primary ankle fusions is estimated to < 1 %.

10. Ankle replacements

Number of reported procedures

Number of primary ankle replacements was 78 – a bout the same number as previous years (Table 1). The procedure-based coverage is 100%. . The majority of the procedures have been performed at 4 units (Figure 2). The annual distribution of prosthetic designs is presented in Figure 3.

Hospital	2011	2012	2013	Diagnosis 2013			Gender 2013		Design 2013		
	n	n	n	OA	RA	Other	Women	Men	Mob	CCI	Reb
Falu hosp	10	12	17	9	4	4	5	12	0	0	17
Hässleholm-Kristianstad	4	2	0								
Karolinska hosp Solna	1	4	2	0	2	0	2	0	0	2	0
Nacka närsjukhus	24	18	13	11	2	0	8	5	12	1	0
Sophiahemmet	2	2	2	1	0	1	0	2	0	2	0
Spenshult	13	21	14	7	5	2	7	7	0	1	13
Sundsvalls hosp.	4	5	4	3	0	1	0	4	1	0	3
SUS Lund	9	4	5	1	2	2	5	0	1	0	4
SUS Malmö	15	11	12	5	5	2	8	4	12	0	0
Uppsala Akademiska	2	0	5	2	3	0	3	2	5	0	0
Uppsala Elisabeth hosp.	1	5	4	3	1	0	2	2	2	2	0
TOTAL	**85**	**86**	**78**	**42**	**24**	**12**	**40**	**38**	**32**	**12**	**34**

Table 1. *Primary ankle replacements 2011–2013. Diagnosis, gender and designs specified only for 2013.*

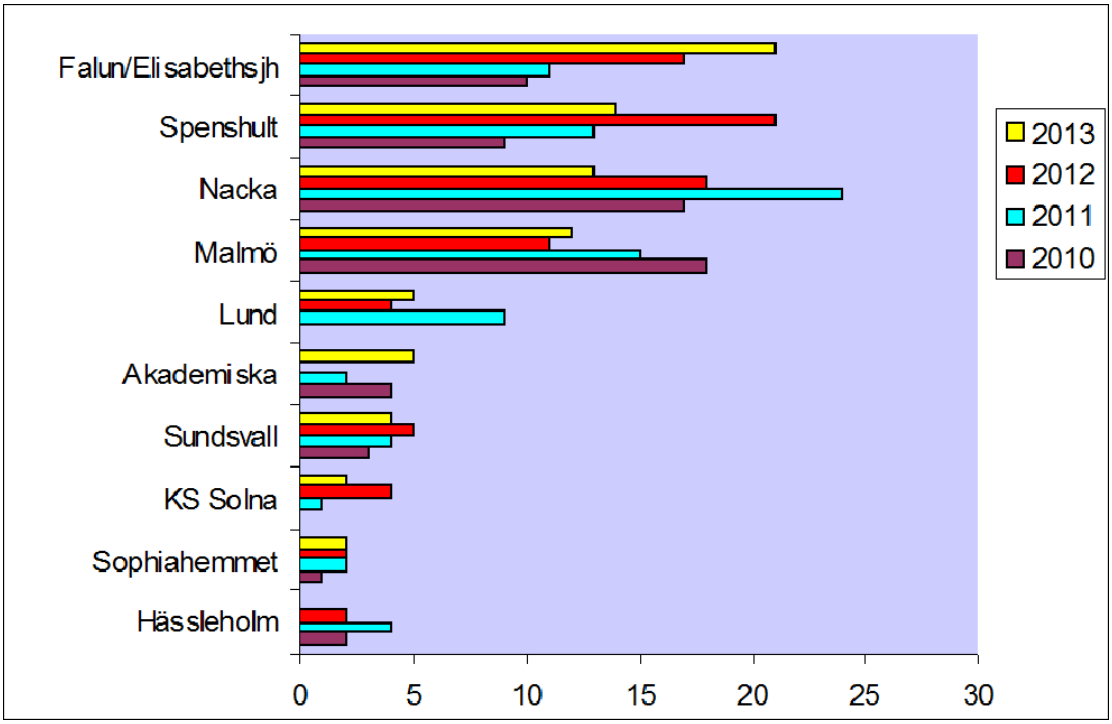

***Figure 2**. Number of primary ankle replacements per unit during 2010-2013.*

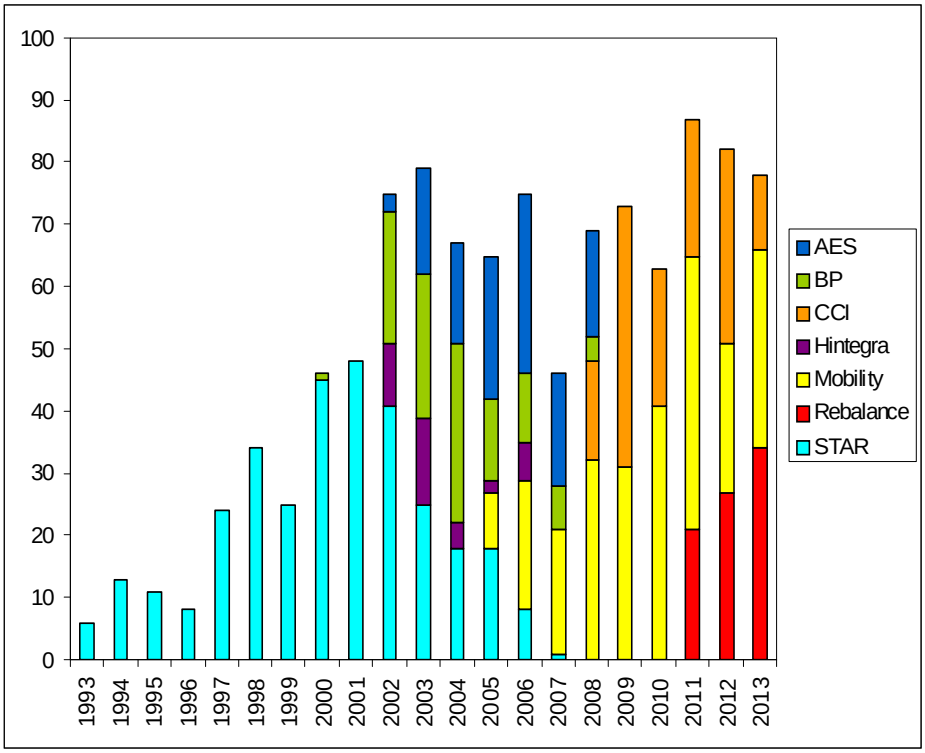

***Figure 3.** Annual distribution of prosthetics designs during 1993- 2013.*

11. Revisions, prosthetic survival and risk factors

Since 1993, i.e. during a period of 19 years, 208 (21%) ankle replacements have been revised. Numbers and reasons for revision – 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.

Design	STAR single	STAR double	BP	AES	HIN-TEGRA	Mobility	CCI	Reba-lance	All
Year in use	1993-1998	1999-2007	2000-2008	2002-2008	2002-2006	2005-	2008-	2011-	
Total number	**118**	**207**	**108**	**114**	**36**	**254**	**145**	**82**	**1064**
Number of revisions	**47**	**76**	**19**	**27**	**7**	**14**	**15**	**1**	**206**
Reason for revision									
Loosening	28	32	5	8	3	5	9	1	91
Technical error	5	10			2				17
Instability	1	1	3	4	1	2	1		13
Infection	4	11	1	4		1			21
Unexpected pain	2	7	1	2		3	3		18
Plastic wear or fracture meniscus	7	10	3	2		1			23
Painful valgus			1	3	1	2			7
Painful varus		2	2	2			2		8
Bone fracture		3	3	2					8

Table 2. *Reason for revision and prosthetic design, 1993–2013.*

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. 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 analyzed 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.

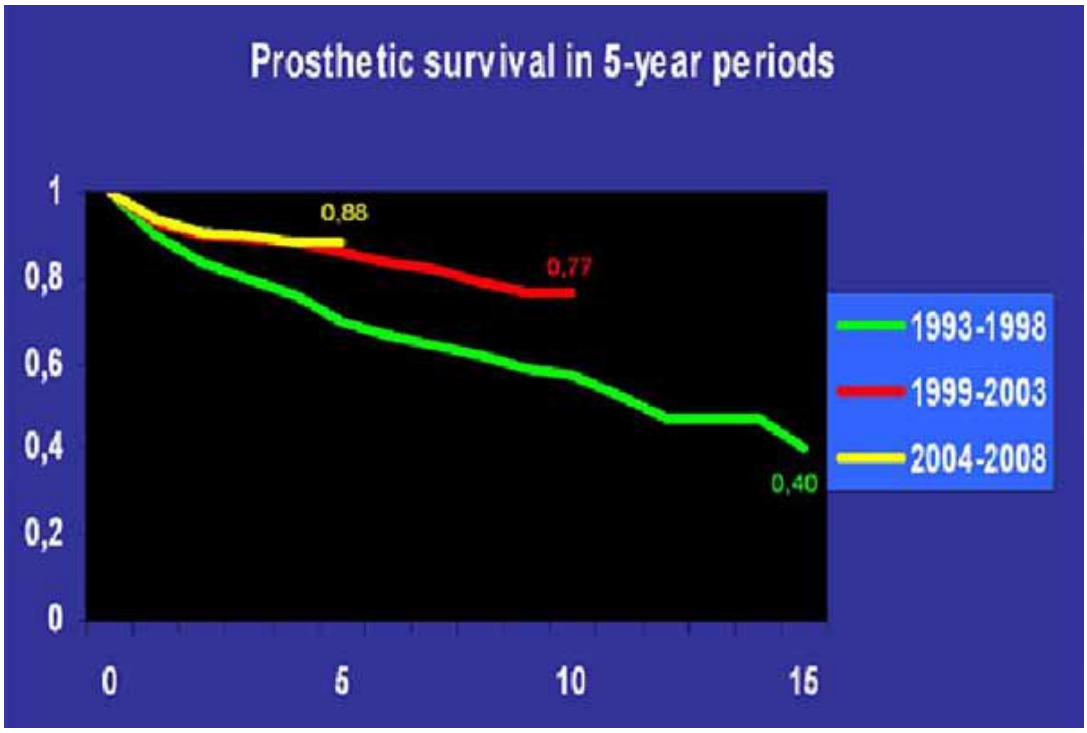

Figure 4. *Prosthetic survival in 5-year periods with exchange of components or fusion as endpoint.*

12. Primary Ankle Arthrodeses

Number of reported procedures

The distribution according to diagnosis and gender is presented in Table 3 and the surgical methods in Table 4. Distribution of age, gender and diagnosis in patients with primary ankle replacement and fusion is presented in Table 5.

	n	Diagnosis 2013			Gender 2013	
		OA	RA	Other	Women	Men
All Sweden	**297**	**220**	**36**	**41**	**138**	**159**
01 Stockholm	**66**	**47**	**4**	**15**	**36**	**30**
Danderyds sjukhus	2	2	0	0	1	1
Karolinska sjukhuset Solna	6	6	0	0	3	0
Nacka sjukhus	31	26	1	4	17	14
Norrtälje sjukhus	4	4	0	0	1	3
S:t Görans sjukhus	5	4	0	1	3	2
Sophiahemmet	1	1	0	0	1	0
Södersjukhuset	2	2	0	0	0	2
Södertälje sjukhus	15	8	1	6	9	6
03 Uppsala	**25**	**17**	**4**	**4**	**10**	**15**
Akademiska sjukhuset	20	13	4	3	9	11
Elisabethsjukhuset	5	4	0	1	1	4
04 Södermanland	**10**	**9**	**1**	**0**	**4**	**6**
Eskilstuna	6	6	0	0	3	3
Nyköping	4	3	1	0	1	3
05 Östergötland	**11**	**8**	**2**	**1**	**7**	**4**
Motala lasarett	5	5	0	0	3	2
Norrköping	6	3	2	1	4	2
06 Jönköping	**5**	**5**	**0**	**0**	**1**	**4**
Eksjö	Missing	Missing			Missing	
Jönköping	2	2	0	0	0	2
Värnamo sjukhus	3	3	0	0	1	2

Table 3. *Number of primary ankle arthrodeses. Diagnosis and gender.*

Cont. Table 3

07 Kronoberg	**5**	**5**	**0**	**0**	**3**	**2**
Ljungby/ Växjö lasarett	5	5	0	0	3	2
08 Kalmar	**9**	**7**	**0**	**2**	**4**	**5**
Kalmar	6	4	0	2	4	2
Oskarshamn	3	3	0	0	0	3
09 Gotland	**0**	**0**	**0**	**0**	**0**	**0**
Visby lasarett	0	0	0	0	0	0
10 Blekinge	**7**	**2**	**5**	**0**	**4**	**3**
Blekingesjukhuset	7	2	5	0	4	3
12 Skåne	**47**	**32**	**5**	**10**	**27**	**20**
Helsingborg	3	3	0	0	1	2
Hässleholm-Kristianstad	14	11	3	0	10	4
Lund	7	0	2	5	3	4
Malmö	23	18	0	5	13	10
13 Halland	**33**	**22**	**5**	**6**	**13**	**20**
Halmstad	0	0	0	0	0	0
Varberg	0	0	0	0	0	0
Movement	10	10	0	0	4	6
Spenshult	23	12	5	6	9	14
14 Västra Götaland	**26**	**16**	**5**	**5**	**12**	**14**
Carlanderska Sport	2	2	0	0	0	2
Uddevalla	12	7	5	0	7	5
Mölndal	10	6	0	4	4	6
Skövde	Missing	Missing			Missing	
Borås	2	1	0	1	1	1
17 Värmland	**8**	**8**	**0**	**0**	**4**	**4**
Karlstad	8	8	0	0	4	4
18 Örebro	**2**	**1**	**0**	**1**	**0**	**2**
Örebro	2	1	0	1	0	2
19. Västmanland	**6**	**6**	**0**	**0**	**2**	**4**
Västerås	6	6	0	0	2	4
20 Dalarna	8	**6**	**1**	**1**	**4**	**4**

Table 3 *Number of primary ankle arthrodeses. Diagnosis and gender.*

	Percutaneous screws	Arthroscopy+ screws	Open surg+ screws	Plate+ screws	Intramedullary nail	External fixation	Total
All Sweden	**1**	**30**	**165**	**16**	**78**	**7**	**297**
01 Stockholm		**5**	**40**	**9**	**11**	**1**	**66**
Danderyds sjukhus			2				2
Karolinska sjukhuset Solna			3		3		6
Nacka närsjukhus			25	3	3		31
Norrtälje sjukhus				4			4
S:t Görans sjukhus		4		1			5
Sophiahemmet		1					1
Södersjukhuset			1	1			2
Södertälje sjukhus			9		5	1	12
03 Uppsala		**4**	**14**	**3**	**4**		**25**
Akademiska sjukhuset			13	3	4		16
Elisabethkliniken		4	1				5
04 Södermanland			**7**		**3**		**10**
Eskilstuna			3		3		6
Nyköping			4				4
05 Östergötland			**6**	**1**	**4**		**11**
Motala lasarett			5				5
Norrköping			1	1	4		6
06 Jönköping			**4**		**2**		**6**
Eksjö							Missing
Jönköping			2		1		3
Värnamo sjukhus			2		1		3
07 Kronoberg			**5**				**5**
Ljungby/ Växjö lasarett			5				5
08 Kalmar			**6**		**3**		**9**
Kalmar			5		1		6
Oskarshamns			1		2		3
09 Gotland							**0**
Visby lasarett							0
10 Blekinge			**3**		**4**		**7**
Blekingesjukhuset			3		4		7
12 Skåne		**12**	**27**		**4**	**4**	**47**
Helsingborgs lasarett			3				3
Hässleholm-Kristianstad		12	1		1		14
SUS Lund			5		2		7
SUS Malmö			18		1	4	23

Table 4. *Surgical methods for primary ankle fusion during 2013.*

Cont. Table 4

	Percutaneous screws	Arthroscopy+ screws	Open surg+ screws	Plate+ screws	Intramedullary nail	External fixation	Total
13 Halland		**2**	**24**		**7**		**33**
Halmstad							Missing
Varberg			0				0
Movement		2	5		3		10
Spenshults reumatikersjukhus			19		4		23
14 Västra Götaland			**11**	**2**	**10**		**23**
Carlanderska Sport			2				1
Uddevalla			5		4		12
Mölndal			4		6		10
Skövde							Missing
Borås Sjukhus				2			2
17 Värmland			**8**				**8**
Karlstads sjukhus			8				8
18 Örebro			**1**		**1**		**2**
Örebro			1		1		2
19 Västmanland	**1**	**1**	**3**		**1**		**6**
Västerås	1	1	3		1		6
20 Dalarna				**1**	**7**		**8**
Falun				1	7		8
21 Gävleborg			**1**		**2**		**6**
Bollnäs sjukhus		1					1
Gävle sjukhus		2	1		1		4
Hudiksvall sjukhus					1		1
22 Västernorrland			**2**		**2**		**4**
Sundsvalls sjukhus			2		1		3
Sollefteå sjukhus		1			1		1
23 Jämtland							**Missing**
Östersunds sjukhus							Missing
24 Västerbotten			**1**		**3**		**4**
Umeå					3		3
Skellefteå lasarett			1				1
25 Norrbotten			**9**		**4**		**13**
Gällivare lasarett							0
Piteå			9		3		12
Sunderbyns sjukhus					1		1

Table 4. *Surgical methods for primary ankle fusion during 2013.*

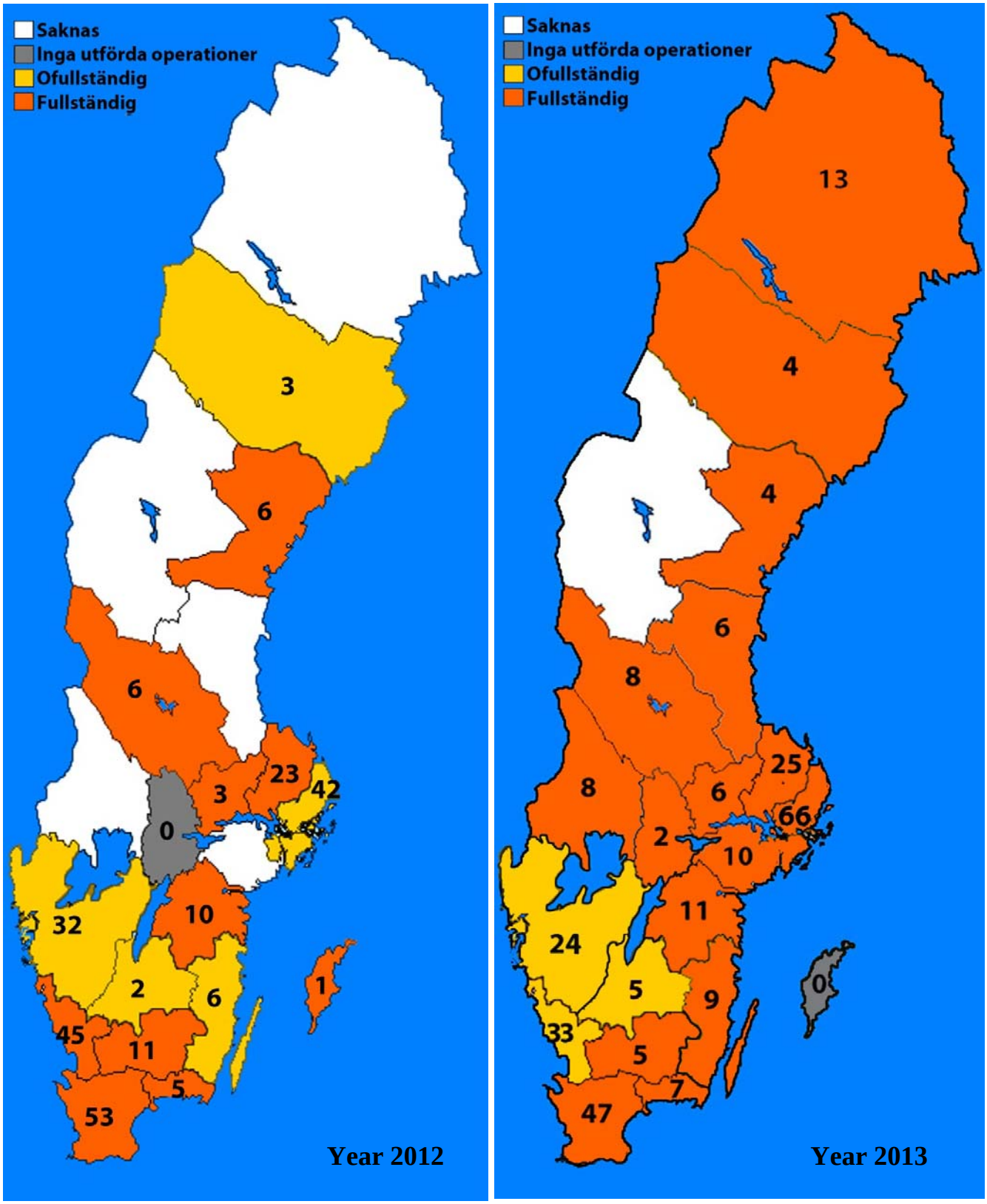

Figure 5. *Number of reported primary arthrodeses per region 2012 and 2013. White= reports missing; Grey= none performed; Yellow= reporting incomplete; Red= reporting complete.*

Figure 6. *X-ray of an ankle arthrodesis fixated by a retrograde intramedullary nail. AP-view to the left ant lateral view to the right*

Table 5 a

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

Table 5 b

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 5. *Age , gender and diagnosis during 2002-2011 among patients with a replaced ankle and primary arthrodesis.*

13 Supramalleolar Osteotomies

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 2008 to 2013, 4 units have together reported only 29 cases - 5 during 2013. 16 ankles were corrected by an ”opening wedge” and 11 by a ”closing wedge” and to by a different technique. Median age was 51 years (20–70).

14. Patient-reported Outcome Measures (PROMs)

The SEFAS-score, which 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 SF-36 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 on publications. The SEFAS-score is based on the oxford-12 for hips and because it contains only 12 simple questions it is user friendly.