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# 1. News since the previous report and summary

The work improving the feed-back reports to the participating units has continued. Now for the first time we report smoking habits before surgery. Among patients undergoing ankle replacement all but one did not smoke and she stopped smoking 6 weeks before surgery. Among patients undergoing ankle fusion 10% were smokers but more than half of them stopped smoking some time before the operation.

The number of ankle replacements has during 2014 has been somewhat lower than 2013. One reason is that a major center closed permanently during the summer 2014. Another reason is that the production of the Mobility ankle stopped mid-2014. The procedure based coverage was 100%. Surgery has been performed at 9 units but the great majority (74 %) at only 3 units: Falun, Nacka, and Malmö.

During 2014, 308 primary ankle fusions have been reported. Procedure based coverage for ankle fusions has been calculated to 96%. Ankle fusions are potentially being performed at 50 units but more than half of them annually perform less than 5 cases and certain years none at all.

The research group has during the year presented three papers at AAOS in New Orleans, March 2014. Three manuscripts have been accepted for publication and one has been submitted.

# 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 re- sults. The second generation total ankle replacements (2-component and un-cemented, allowing space for rotation within the mortise) and the third generation (3 - component and 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 <u>www.swedankle.se</u>.

December 31, 2013 the Registry contained data of 1135 primary ankle prostheses and 1667 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.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), notably validation of the self-reported Foot and Ankle Score (SEFAS). Her work has been has been presented at various international and Swedish meetings – e.g. at AAOS in New Orleans, March 2014 and at EFAS in Holland in 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. One paper was presented at AAOS in New Orleans, March 2014

# 8. 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.

In the second study from 2011 (6) on 780 ankles the 10-year survival of 780 ankles was estimated to 69% Excluding the STAR, 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 led a higher risk of being revised.

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

Ankle prostheses implanted as a revision procedure after that the primary prosthesis had failed had an estimated 10-year survival of 55%. Half of the patients were satisfied with the operation (9). A corresponding study in which the failed ankle prostheses were treated by fusion has been submitted.

The of the SEFAS score, did not differ between sides in patients who had had one ankle replaced and the contralateral ankle fused. Most patients were satisfied with both ankles (10).

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 led a higher risk of being revised.

# 9. Publications based on the registry

#### Author: Carlsson Å. (1)

Foot Ankle Surg 2007; 13:41-44.

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.)

Authors: Henricson A, Ågren P-H. (2) Title: Secondary surgery after total ankle replacement. The influence of preoperative hindfoot alignment.

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

#### Authors: Henricson A, Knutson K, Lindahl J, Rydholm U. (4)

Title:The AES total ankle replacement. mid-term analysis of 93 cases. Foot Ankle Surg 2010;16:61-64.

### Authors: Henricson A, Carlsson Å, RydholmU.(5)

Title: What is a revision of total ankle Replacement Foot Ankle Surg 2011;17:99-

#### Authors: Henricson A, Nilsson J-Å, Carlsson Å. (6)

Title: 10-year survival of total ankle arthroplasties. A report on 780 cases from the Swedish Ankle Registry. Acta Orthop 2011;82:655- 659.

#### Authors: Cöster M, Karlsson M, Nilsson J-Å, Carlsson, Å. (7)

Title: Å. Validity, reliability, and responsiveness of a self-reported foot and ankle score (SEFAS). Acta Orthop.2012;83:197-203.

#### Authors: Henricson A, Cöster M, Carlsson Å (8)

Title: The Swedish National Ankle Registry Fuss und Sprunggelenk 2014:12; 65-6

#### Authors: Kamrad I, Henricsson A, Karlsson MK, Magnusson H, Nilsson J-Å, Carlsson Å, Rosengren BE (9)

Title: 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(4):407-11.

# Authors: Henricson A, Fredriksson M, Carlsson Å. (10)

Title: Total ankle replacement and contralateral ankle arthrodesis in 16 patients from the Swedish Ankle Registry. Self-reported function and satisfaction. Foot Ankle Surg. In press

# 10. Procedure- based coverage

Primary ankle prostheses: 100%

Primary ankle fusions: 95.8%

Ankle fusions are potentially being performed at 50 units but more than half of these annually perform less than 5 cases and certain years none at all. All but 4 units and all but one of the 21 Swedish regions reported their ankle fusion during 2013. According to statistics from the Swedish health authorities 320 primary ankle fusions are have been performed annually in Sweden during later years. 308 out of an estimated 320 ankle fusions makes a procedure-based coverage of 96.3 %

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

# 11. Ankle replacements

# Number of reported procedures

Number of primary ankle replacements was 61. (Table1). The reason for this figure which is lower compared to previous years is explained in chapter 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.

**Table 1**.Number of primary ankle replacements per unit during 2012–2014. Distribution ofd diagnosis, gender and prosthetic designs during 2014.

Hospital	2012	2013	2014	Dia	gnosis	2014	Gender	2014	Prost	hetic de	esigns 2	2014
ricopital	n	n	n	OA	RA	Other	Women	Men	Mob	CCI	Reb	ТМ
Falun	12	17	20	14	4	2	11	9	0	0	15	5
Nacka	18	13	16	12	2	2	11	5	5	0	11	0
Malmö	11	12	9	7	1	1	2	7	9	0	0	0
Lund	4	5	5	2	2	1	5	0	0	0	5	0
Spenshult	21	14	5	2	3	0	4	1	0	0	5	0
Elisabeth sjukhuset	5	4	3	2	0	1	0	3	0	3	0	0
Akademiska sjukhuset	0	5	1	1	0	0	1	0	1	0	0	0
Sophiahemmet	2	2	1	1	0	0	0	1	0	1	0	0
Movement	0	0	1	1	0	0	1	0	0	0	1	0
Sundsvall	5	4	0	0	0	0	0	0	0	0	0	0
Karolinska Solna	4	2	0	0	0	0	0	0	0	0	0	0
Hässleholm-	2	0	0	0	0	0	0	0	0	0	0	0
TOTAL	86	78	61	42	12	7	35	26	15	4	37	5



The Swedish Ankle Registry annual report for 2014

Figure 2. Number of primary ankle replacements per unit during 2011-2014.



Figure 3: Number and types of prostheses implanted 1993-2014

# 12. Revisions, prosthetic survival and risk factors

Since 1993, i.e. during a period of 21 years, 218 (19%) ankle replacements have been revised. Numbers and reasons for first time revisions – defined as exchange of components or fusion – are presented in Table 2. In addition, about 121 re-operations in 86 ankles, 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.

Prosthetic design	Single- coated STAR	Double- coated STAR	BP	AES	HINTEGR A	Mobility	CCI	Rebalan ce	All
Years in use	1993- 1998	1999- 2007	2000- 2008	2002- 2008	2002- 2006	2005- 2014	2008-	2011-	
Total number	118	206	108	114	36	269	149	130	1130
Number regised	58	67	19	25	7	21	18	3	218
Percent revised	49%	33%	18%	22%	19%	8%	12%		
Loosening	34	28	8	8	4	7	12	1	102
Percent loosening	29%	14%	7%	7%	11%	3%	8%		
Technical error	6	8	2		2	2		1	21
Instability		1	2	2	1	3	1		9
Infection	4	10	1	3		2	1		21
Unexplained pain	4	6	1			3	3		17
PE-wear or fracture	10	9	1	2		1	1		24
Painful valgus			1	3		2			6
Painful varus		3	1	2			1		7
Fracture		2	2	1					5
Other				4		1		1	6

Table 2. Reason for revision 1993–2014

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 fsion as endpoint.



Figure 5a and b The STAR prosthesis



Figure 6: Survival-curve for the single-coated (blue) and double coated (green) STAR ankle

# 13. 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.



Figure 7: Distribution of diagnoses in patients operated on with ankle arthrodesis.



Figure 8. Screw-fixated ankle arthrodes

	Numbers 2014		Diagnosis 2	014	Gender	2014
		OA	RA	Other	Women	Men
All Sweden	308	211	34	53	145	163
01 Stockholm	56	43	5	8	32	24
Danderyds sjukhus	0	0	0	0	0	0
Karolinska sjukhuset Solna	6	2	3	1	6	0
Karolinska sjukhuset Huddinge	5	5	0	0	2	3
Nacka sjukhus	26	21	2	3	13	13
Norrtälje sjukhus	3	3	0	0	2	1
S:t Görans sjukhus	3	3	0	0	3	0
Sophiahemmet	3	1	0	2	0	3
Södersjukhuset	2	1	0	1	1	1
Södertälje sjukhus	8	7	0	1	5	3
03 Uppsala	25	17	1	7	17	8
Akademiska sjukhuset	19	11	1	7	13	6
Elisabethsjukhuset	6	6	0		4	2
04 Södermanland	7	7	0	0	3	4
Eskilstuna	5	5	0	0	2	3
Nyköping	2	2	0	0	1	1
05 Östergötland	13	11	1	1	5	8
Linköping	1	1	0	0	1	0
Motala lasarett	8	7	0	1	3	5
Norrköping	4	3	1	0	1	3
06 Jönköping	13	11	0	2	5	8
Eksjö	5	5	0	0	2	3
Jönköping	3	1	0	2	2	1
Värnamo sjukhus	5	5			1	4
07 Kronoberg	8	4	1	3	4	4
Ljungby/ Växjö lasarett	8	4	1	3	4	4
08 Kalmar	5	5	0	0	2	3
Kalmar	3	3	0	0	1	2
Oskarshamn	2	2	0	0	1	1
09 Gotland	4	3	1	0	3	1
Visby lasarett	4	3	1	0	3	1
10 Blekinge	6	4	2	0	5	1
Blekingesjukhuset	6	4	2	0	5	1
12 Skåne	48	36	2	10	23	25
Helsingborg	1	1	0	0	0	1
Hässleholm-Kristianstad	13	11	0	2	10	3
Lund	3	1	1	1	1	2
Malmö	31	23	1	7	12	19

# Table 3. Number of arthrodeses per operating unit. Distribution of diagnoses and gender

#### Cont. Table 3

	Numbers 2014	Diagnoses 2014			Gende	<sup>.</sup> 2014
		OA	RA	Other	Women	Men
13 Halland	27	23	3	1	10	17
Halmstad	Ej rapporterat		Ej rapporte	rat	Ej rappo	orterat
Varberg	2	2	0	0	2	0
Movement	11	10	1	0	3	8
Spenshult	14	11	2	1	5	9
14 Västra Götaland	43	27	8	8	14	29
Alingsås	4	4	0	0	1	3
Borås	2	1	0	1	0	2
Carlanderska Sport	1	1	0	0	0	1
Kungälv	4	4	0	0	0	4
Mölndal	10	3	2	5	7	3
Perago ortopedi	5	5	0	0	0	5
Skövde	Ej rapporterat		Ej rapporter	rat	Ej rappo	orterat
Uddevalla	17	9	6	2	6	11
17 Värmland		3	0	0	0	3
Karlstad		3	0	0	0	3
18 Örebro	3	0	1	2	2	1
Örebro	3	0	1	2	2	1
19. Västmanland	3	3	0	0	0	3
Västerås	3	3	0	0	0	3
20 Dalarna	7	4	1	2	4	4
Falu lasarett	7	4	1	2	3	4
21 Gävleborg	5	3	2	0	3	2
Bollnäs sjukhus	0	0	0	0	0	0
Gävle sjukhus	3	1	2	0	2	1
Hudiksvalls sjukhus	2	2	0	0	1	1
22 Västernorrland	12	7	1	4	6	6
Sundsvalls sjukhus	10	5	1	4	6	4
Sollefteå sjukhus	2	2	0	0	0	2
23 Jämtland	Ej rapporterat		Ej rapporter	rat	Ej rappo	orterat
Östersunds sjukhus	Ej rapporterat		Ej rapporte	rat	Ej rappo	orterat
24 Västerbotten	6	5	1	0	2	4
Umeå	4	3	1	0	1	3
Skellefteå	2	2	0	0	1	1
25 Norrbotten	14	10	1	3	6	8
Gällivare	0	0	0	0	0	0
Piteå	14	10	1	3	6	8
Sunderbyns sjukhus	0	0	0	0	0	0



*Figure 9.* Number of reported primary arthrodeses per region 2012 and 2014. White= reports missing; Grey= none performed; Yellow= reporting incomplete; Red= reporting complete.



Table 4. Surgical methods during 2014

	Percutaneous screwa	Artroscopy+ screw	Open surgery + screws	Plate and screws	Intra- medullary nail	External fixation	Total number
All Sweden	2	18	185	10	90	3	308

		n	Mean age	Lowest age	Highest age
Women		220	60	17	87
	Primary osteoarthritis	35	68	44	87
	Posttraumatic OA	78	62	41	84
	Rheumatoid arhtritis	93	57	17	79
	Other	14	55	34	73
Men		151	63	81	29
	Primary osteoarthritis	48	67	47	81
	Posttraumatic OA	71	60	29	81
	Rheumatoid arhtritis	10	59	46	71
	Other	21	61	42	73
Total		371	61	17	87

**Table 5a.** Age distribution and reason for surgery in patients who had their ankle replaced duringthe 5 -year period 2010--2014 .

*Table 5b.* Age distribution and reason for surgery in patients who had their ankle fused during the 5 -year period 2010--2014.

		n	Mean age	Lowest age	Highest age
Women		590	61	15	91
	Primary osteoarthritis	123	67	43	87
	Posttraumatic OA	245	59	19	91
	Rheumatoid arhtritis	124	63	16	84
	Diabetic osteopathy	11	59	47	71
	Pes equinovarus adductus	9	42	19	69
	Septic arthritis	3	61	45	71
	Other	75	58	15	80
Men		705	61	14	86
	Primary osteoarthritis	232	66	30	86
	Posttraumatic OA	302	59	16	86
	Rheumatoid arhtritis	39	64	33	82
	Diabetic osteopathy	20	63	43	79
	Pes equinovarus adductus	8	44	25	67
	Septic arthritis	9	65	52	80
	Other	95	56	14	79
Total		1295	61	14	91

		Stopped smoking		
	Non-smoker	> 6 weeks before	Smokers	Unknown
		surgey		
Replacement	53	1		7
Men	18			4
Women	35	1		3
Arthrodesis	219	18	10	61
Men	118	9	5	21
Women	101	9	5	31

Tabell 6.	Smoking	habits	at the	time	of surger	v during 2014.
						/ 0

## 14. 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 2007 to 2014, 4 units have together reported only 31 cases - 3 during 2014. 18 ankles were corrected by an "opening wedge" and 11 by a "closing wedge" and two by a different technique. Median age was 51 years (20–70).

# 15. 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 score SEFAS-score, which is used in our follow up and outcome study, 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" is excellent and without any floor- or ceiling-effect. (See publication no 7 and 8 in chapter 11publicatio) The SEFAS-score is based on the oxford-12 for hips and because it contains only 12 simple questions it is user friendly. Since a couple of years ours questionnaires also include a satisfactions scale in five steps from very satisfied to very dissatisfied.

# APPENDIX 1. The SEFAS score

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