



This article appeared in a journal published by Elsevier. The attached copy is furnished to the author for internal non-commercial research and education use, including for instruction at the authors institution and sharing with colleagues.

Other uses, including reproduction and distribution, or selling or licensing copies, or posting to personal, institutional or third party websites are prohibited.

In most cases authors are permitted to post their version of the article (e.g. in Word or Tex form) to their personal website or institutional repository. Authors requiring further information regarding Elsevier's archiving and manuscript policies are encouraged to visit:

<http://www.elsevier.com/authorsrights>



Originalarbeit zum Themenschwerpunkt

The Swedish National Ankle Registry

Das Nationale Schwedische Sprunggelenkregister

Anders Henricson^{1,*}, Maria Cöster², Åke Carlsson²

¹ Falu General Hospital, Falun, Sweden

² Department of Orthopaedic and Clinical Sciences, Lund University, Skåne University Hospital, Malmö, Sweden

Received 31 January 2014; accepted 5 February 2014

Available online 21 February 2014

KEYWORDS

Ankle;
arthroplasty;
registry;
questionnaire

SCHLÜSSELWÖRTER

Sprunggelenk;
Endoprothese;
Register;
Scorefragebögen

Summary

The Swedish National Ankle Registry in January 2014 contains data on total ankle arthroplasties (TARs) up to 20 years and with a coverage of 100%. Since 2008 also ankle arthrodeses are reported and the coverage is today around 75% and increasing. Besides data related to surgery patients are asked to answer three self-reported questionnaires before and at regular intervals after surgery. The 10-year survival rate for TAR's excluding the STAR-prosthesis and based on registry data was 78%. There was no difference of revision rates between diagnoses.

Zusammenfassung

Im Januar 2014 enthielt das Nationale Schwedische Sprunggelenkregister Daten mit einem Follow up von 20 Jahren und einer 100%igen Erfassung zu Sprunggelenk-endoprothesen. Seit 2008 werden auch Sprunggelenkarthrodesen erfasst und die landesweite Abdeckung dieser Daten beträgt aktuell 75% und steigt stetig an. Neben den klinischen Daten zur Operation werden von den Patienten drei Scorefragebögen präoperativ sowie in regelmäßigen Intervallen auch postoperativ erhoben. In den Registerdaten beträgt die 10-Jahres-Überlebensrate 78% für alle Endoprothesen mit Ausnahme der S.T.A.R.-Prothese. Bezogen auf die Implantationsdiagnose fanden sich dabei keine Unterschiede.

The registry contains all third generation total ankle replacements (TAR) implanted in Sweden since 1993 and since 2008 an increasing number of ankle arthrodeses. Supramalleolar tibial osteotomies are also reported since 2009. The Swedish Registry

is to our knowledge the only national registry that includes the two latter procedures. Six major centers have done 80% of all TARs, and during the last five years four centers have performed 75% of the TARs, implying a concentration to specialized units

* Corresponding address: Department of Orthopaedics and Center for Clinical Research, Falu General Hospital ("Falu lasarett"), S-791 82 Falun, Sweden.

E-Mail: anders.henricson@tdalarna.se (A. Henricson).

<http://dx.doi.org/10.1016/j.fuspru.2014.02.009>

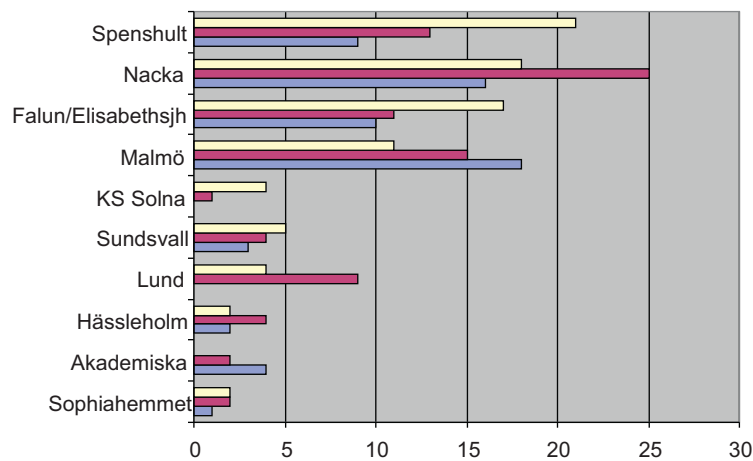


Figure 1. Number of primary ankle replacements per operating unit 2010-2012.

(Fig. 1). The registry is web based but reporting currently takes place via paper forms and central registration. The registry is handled by Registry Center South (www.rcsyd.se). A future direct web registration procedure is currently developing.

What is registered?

We register demographic data (social security number and gender), diagnosis, side, date of operation, type of prosthesis and per-operative complications. We also register the name of the operating and assisting surgeon, the length and weight of the patient, the ASA (American Society of Anesthesiologists) classification, the Charnley classification of arthropathy and comorbidity, smoking habits, whether oxygen was given postoperatively, simultaneous operations and earlier performed operations in the same foot and ankle. In case of revision we also register the reason for revision, type of revision according to Henricson et al. [5] and the kind of procedure performed. The data base for arthrodeses in addition includes preoperative alignment, type of arthrodesis, and type of bone transplant if used. In the case of SMO preoperative alignment, the type of wedge, type of fixation and type of possible bone transplant are registered.

Annual number of replacements in Sweden and other countries

Up to 2013 there are 1061 primary ankle prostheses and 277 revisions [5] reported to the registry. The coverage concerning TARs is 100%. This is due to the fact that we are acquainted with everyone per-

forming TARs in Sweden and furthermore the data base is compared with the data base of the Swedish National Health Board. The number of primary ankle arthrodeses reported is 1258 and in addition there are 110 re-arthrodeses. The coverage is slowly increasing and is to date around 75%. Twenty-six SMOs are so far reported to the registry. The annual number of TARs in Sweden with a population of 10 million is around 80 or 1.0 per 100 000 inhabitants below the age of 15. The corresponding figure for Norway, England and Wales and Scotland is about the same. Twice as many replacements per 100 000 inhabitants below the age of 15 years are performed annually in Finland and three times as many in Denmark and New Zealand.

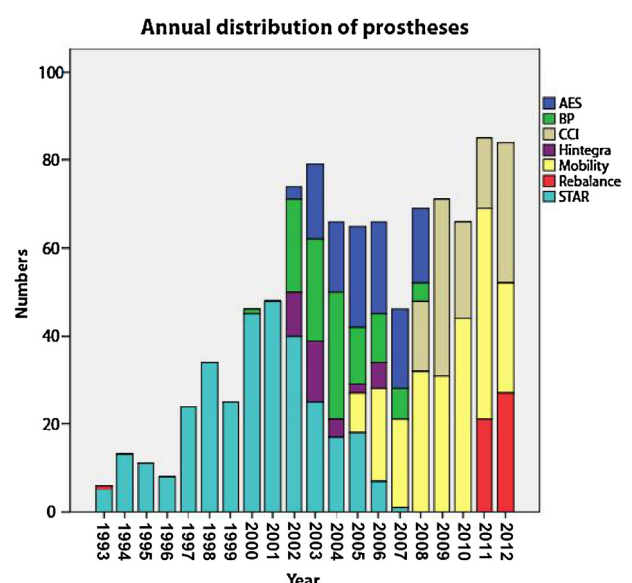


Figure 2. Number and type of prostheses per year.

SELF-REPORTED FOOT & ANKLE QUESTIONNAIRE (SEFAS)

We would like you to answer the 12 questions below. Each question is graded from 0- 4
4 = the mildest or least troublesome and 0 = the most severe or most troublesome.

Please cross the box that best describes your condition during the last 4 weeks

<p>1. How would you describe the pain you usually have from the foot/ankle in question?</p> <p>4 <input type="checkbox"/> None 3 <input type="checkbox"/> Very mild 2 <input type="checkbox"/> Mild 1 <input type="checkbox"/> Moderate 0 <input type="checkbox"/> 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 <input type="checkbox"/> Not at all 3 <input type="checkbox"/> A bit 2 <input type="checkbox"/> Moderately 1 <input type="checkbox"/> Greatly 0 <input type="checkbox"/> 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 <input type="checkbox"/> No pain up 30 min. 3 <input type="checkbox"/> 16-30 minutes 2 <input type="checkbox"/> 5-10 minutes 1 <input type="checkbox"/> Around the house only 0 <input type="checkbox"/> 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 <input type="checkbox"/> No days 3 <input type="checkbox"/> Only one or two days 2 <input type="checkbox"/> Some days 1 <input type="checkbox"/> Most days 0 <input type="checkbox"/> Every day</p>
<p>3. Have you been able to walk on uneven ground?</p> <p>4 <input type="checkbox"/> Yes, easily 3 <input type="checkbox"/> With little difficulty 2 <input type="checkbox"/> With moderate difficulty 1 <input type="checkbox"/> With extreme difficulty 0 <input type="checkbox"/> No impossible</p>	<p>7. Have you been able to climb a flight of stairs?</p> <p>4 <input type="checkbox"/> Yes, easily 3 <input type="checkbox"/> With little difficulty 2 <input type="checkbox"/> With moderate difficulty 1 <input type="checkbox"/> With extreme trouble 0 <input type="checkbox"/> Impossible</p>
<p>4. Have you had to use an orthotic (shoe insert), heel lift or special shoes?</p> <p>4 <input type="checkbox"/> Never 3 <input type="checkbox"/> Occasionally 2 <input type="checkbox"/> Often 1 <input type="checkbox"/> Most of the time 0 <input type="checkbox"/> Always</p>	<p>8. Have you been troubled by pain from the foot/ ankle in question in bed at night?</p> <p>4 <input type="checkbox"/> No night) 3 <input type="checkbox"/> Only one or two nights 2 <input type="checkbox"/> Some nights 1 <input type="checkbox"/> Most nights 0 <input type="checkbox"/> Every night</p>
<p>9. How much has pain from the foot/ankle in question affected your usual recreational activities?</p> <p>4 <input type="checkbox"/> Not at all 3 <input type="checkbox"/> A bit 2 <input type="checkbox"/> Moderately 1 <input type="checkbox"/> Greatly 0 <input type="checkbox"/> 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 <input type="checkbox"/> Not at all painful 3 <input type="checkbox"/> Slightly painful 2 <input type="checkbox"/> Moderately painful 1 <input type="checkbox"/> Very painful 0 <input type="checkbox"/> Unbearable</p>
<p>10. Have you had swelling of your foot?</p> <p>4 <input type="checkbox"/> None at all 3 <input type="checkbox"/> Occasionally 2 <input type="checkbox"/> Often 1 <input type="checkbox"/> Most of the time 0 <input type="checkbox"/> 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 <input type="checkbox"/> No days 3 <input type="checkbox"/> Only one or two days 2 <input type="checkbox"/> Some day 1 <input type="checkbox"/> Most days 0 <input type="checkbox"/> Every day</p>

Figure 3. The English version of the SEFAS questionnaire.

Results

In 2011 we presented a 10-year survival analysis on 780 TARs and found a prosthetic survival rate of 69% [6]. The Swedish experience with the STAR prosthesis was not successful (58% 10-year survival of the single coasted STAR) and a separate analysis of 458 cases excluding the STAR showed a 10-year survival of 78%. This figure corresponds rather well with other 10-year reports [1,10,11]. The STAR prosthesis has not been used in Sweden since 2006 (fig. 2). There is only one further national registry that has reported 10-year survival rates, namely the New Zealand Joint Registry with 82% [9]. No difference between the different designs, except for the STAR was found in the Swedish registry [6]. Moreover were there any difference of revision rates between the different diagnoses. Age had some influence on the revision rate and women below 60 years with osteoarthritis had a higher revision rate. Septic complication occurred in 4% and of these 50% had to be revised.

Patient related outcome measurements (PROMs)

A registry should not only report the number of cases but also outcome and adverse events. We found it unrealistic to use a score including medical recorded joint-specific data and searched for a validated score in which the questions mirrored the patients own opinion, but during the registry's early years we could not find such a score suiting our aims. However, in 2007 Hosman et al. [7] published a self-administered ankle questionnaire based on the validated Oxford-12 questionnaire for total hip replacement. It was constructed by the New Zealand National Joint Registry but had never been validated. It is a simple tool in which each of the 12 multiple-choice questions are scored from 0 to 4 and where 0 total points represent the most severe disability and 48 points represent normal function [8]. When the Swedish version of this questionnaire was created, it was translated according to a standardized cross-cultural adaption procedure [4]. A slight modification without changing the original content was undertaken, so that the questionnaire could be used not only postoperatively but also before an intervention. The score was named SEFAS (Self-reported Foot and Ankle Score) and is found at www.swedankle.se. An English translation is found at the English version of the web page (fig. 3). In 2009 we started the validation process where we compared SEFAS against two validated

generic scores (EQ-5D and SF-36) and one ankle specific score (FAOS). The results have been presented at EFAS and AOFAS meetings and have thereafter been published [2]. In summary we found good psychometric properties in terms of validity, reliability and responsiveness and there were no floor or ceilings effects. The analysis of results up to two years after primary ankle replacement and ankle fusion will start during the coming year. The results after various secondary procedures are presently being analyzed.

Could SEFAS also be used to estimate the function of patients with all kind of foot and ankle disorders? The answer in a recent study is yes! [3] In this validation study 118 patients, scheduled for surgery due to forefoot disorders and 105 patients due to hindfoot or ankle disorders completed the same four patient-reported questionnaires as in the previous study. The analyses were done separately for patients with forefoot and patients with hindfoot or ankle disorders. In summary, there were no floor or ceiling effects in any of the groups. In this population we also found good psychometric properties of the score, comparable with those for the ankle. The SEFAS questionnaire is patient-friendly and it has been proved to take only a few minutes to answer the twelve items. The tool is reliable but also valid and has abilities to detect changes after an intervention. It can be used both in clinical contexts and in national registries.

Conflict of interest

The authors declare that there is no conflict of interest.

References

- [1] A. Barg, L. Zwicky, M. Knupp, H.B. Henninger, B. Hintermann, HINTEGRA total ankle replacement: survivorship analysis in 684 patients, *J Bone Joint Surg (Am)* 95 (2013) 1175–1183.
- [2] M. Cöster, M.K. Karlsson, J.-Å. Nilsson, Å. Carlsson, Validity, reliability, and responsiveness of a self-reported foot and ankle score (SEFAS), *Acta Orthop* 83 (2012) 197–203.
- [3] M.C. Cöster, A. Bremander, B.E. Rodengren, H. Magnusson, Å. Carlsson, M.K. Karlsson, Validity, reliability, and responsiveness of Self-reported Foot and Ankle Score (SEFAS) in forefoot, hindfoot, and ankle disorders, *Acta Orthop* (2014), In press.
- [4] F. Guillemin, C. Bombardier, D. Beaton, Cross-cultural adaption of health-related quality of life measures: literature review and proposed guidelines, *J Clin Epidemiol* 46 (1993) 1417–1432.

- [5] A. Henricson, Å. Carlsson, U. Rydholm, What is a revision of total ankle replacement? *Foot Ankle Surg* 17 (2011) 99–102.
- [6] A. Henricson, J.-Å. Nilsson, Å. Carlsson, 10-year survival of total ankle arthroplasties. A report on 780 cases from the Swedish Ankle Register, *Acta Orthop* 82 (2011) 655–659.
- [7] A.H. Hosman, R.B. Mason, T. Hobbs, A.G. Rothwell, A New Zealand national ankle registry review of 202 total ankle replacements followed for up to 6 years, *Acta Orthop* 78 (2007) 584–591.
- [8] D.W. Murray, R. Fitzpatrick, K. Rogers, H. Pandit, D.J. Beard, A.J. Carr, J. Dawson, The use of Oxford hip and knee scores, *J Bone Joint Surg (Br)* 89 (2007) 1010–1014.
- [9] M. Tomlinson, M. Harrison, The New Zealand Registry. Report of 11-year data for ankle arthroplasty, *Foot Ankle Clin* 17 (2012) 719–723.
- [10] P.L.R. Wood, M.T. Karski, P. Watmough, Total ankle replacement. Medium-term results in 200 Scandinavian total ankle replacements, *J Bone Joint Surg (Br)* 90 (2008) 605–609.
- [11] R. Zaidi, S. Cro, K. Gurusamy, N. Siva, A. MacGregor, A. Henricson, A. Goldberg, The outcome of total ankle replacement: a systematic review and meta-analysis, *J Bone Joint Surg (Br)* 95 (2013) 1500–1507.



Lebens Füße
Im Laufe unseres Lebens
tragen uns unsere Füße
fast dreimal um die Welt.

Damit dies auch in Zukunft so bleibt, bietet axomed innovative winkelstabile Plattensysteme sowie bewährte Schraubensysteme für die Fußchirurgie an.

axomed gmbh • Heinrich-von-Stephan-Str. 5c • D-79100 Freiburg • Tel +49 (0) 761.611 66-0 • www.axomed.de



PipTree™

Implantat für die intramedulläre Osteosynthese der Arthrodese am proximalen Interphalangealgelenk der Kleinzehen



medizintechnik