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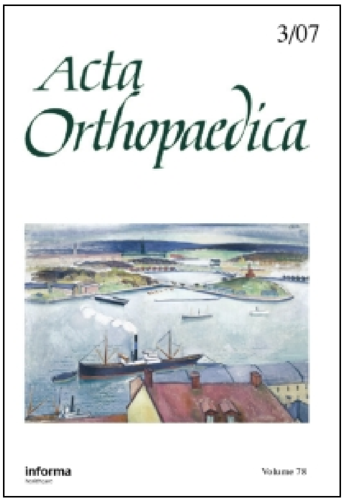

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The Swedish Ankle Arthroplasty Register

An analysis of 531 arthroplasties between 1993 and 2005

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Background Whether or not ankles can be replaced with reasonable safety has been the subject of debate. We present the results of a nationwide series of total ankle arthroplasties.

Patients and methods All Swedish hospitals that implant or have implanted modern three-component ankle prostheses reported demographic data and date of index and revision surgery to a central register. After the data had been introduced into a database, prosthetic survival rates with exchange or permanent extraction of components as endpoint were calculated.

Results Of the 531 prostheses implanted, 101 had been revised by June 15, 2006. The overall survival rate at 5 years was 0.78 (95%CI: 0.74–0.82). For the three surgeons who had inserted the majority of the STAR ankles, the survival rates became significantly higher after the first 30 cases had been performed and was estimated to be 0.86 (0.80–0.93) at 5 years. Lower age at index surgery implied increased risk of revision whereas diagnosis or gender did not.

Interpretation Ankle replacement is a valuable alternative to arthrodesis. However, replacing an ankle is a demanding procedure and the survival is not comparable to that after hip or knee replacement. It is obvious that with increasing experience, the results—including prosthetic survival—will improve.

■

The first generation of total ankle replacements (TARs) were cemented, two-component, more or less constrained designs, which were abandoned several years ago due to inferior results (Kitaoka and Patzer 1996, Wood et al. 2000, Carlsson et al. 2001). The second-generation TARs (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 (Buechel et al. 2004, Kofoed 2004, Knecht et al. 2004), medium term (Pyevich et al. 1998, Wood and Deakin 2003, Valderrabano et al. 2004, Bonnin et al. 2004, Su et al. 2004, Doets et al. 2006) and short term (Hintermann et al. 2004).

Performance of TAR is considered to be a challenging and technically demanding procedure with a long learning curve (Anderson et al. 2003, Wood and Deakin 2003, Hinterman et al. 2004). Furthermore, the number of total ankle replacements performed annually by a single surgeon is most often much lower than those of knee and hip replacements. Consequently, it is difficult for an individual surgeon to evaluate various designs and techniques.

These considerations were the major reasons for our decision to introduce a national ankle replacement register of third-generation ankle replacements in Sweden. We have used this register to assess the revision rate of replacements between 1993 and 2005.

Patients and methods

The first third-generation TAR in Sweden was per-

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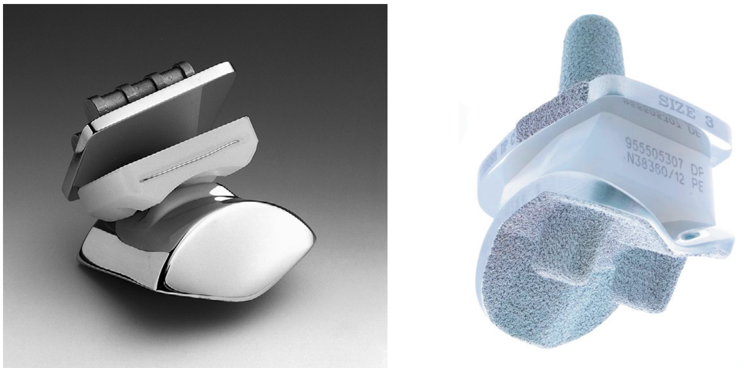

Figure 1. The STAR ankle (left) and the Mobility ankle (right).

formed in 1993. All total ankle replacements after that date have been reported to a national register by each surgeon using a paper form. Hospital, demographic data, date of index and revision surgery, operated side, diagnosis (primary or reason for revision), type of prosthesis, and (in case of revision) type of procedure are registered, and all data are collected in a database. The authors are personally acquainted with every surgeon in Sweden performing TAR, which makes the reporting to the register complete.

Between April 16, 1993 and June 15, 2006, 531 primary total ankle replacements were reported to the register: 318 STAR prostheses (Waldemar Link, Hamburg, Germany), 92 Buechel-Pappas (BP) prostheses (Wright Cremasoli, Toulon, France and Endotec, South Orange, NJ), 69 AES prostheses (Biomet, Nimes, France), 29 HINTEGRA prostheses (Newdeal, Lyon, France), and 23 Mobility prostheses (DePuy International, Leeds, UK) (Figure 1). The STAR prosthesis has been used in Sweden since 1993; the first BP prosthesis was implanted 2000, the AES and HINTEGRA prostheses have been in use since 2002, and the Mobility prosthesis has been used since 2005 (Figure 2).

The diagnoses were reumatoid arthritis in 216 patients, primary or idiopathic osteoarthritis in 119, posttraumatic arthritis in 175, and various diagnoses including hemophilia, hemochromatosis, and psoriatic arthritis in 21 cases (Table 1). 25 patients with RA and 14 patients with other diagnoses had both ankles replaced. 13 hospitals have reported to the register, but at the time of writing TAR is performed in 10 hospitals in Sweden. 73% of all TARs have been done in 4 hospitals by 3 surgeons.

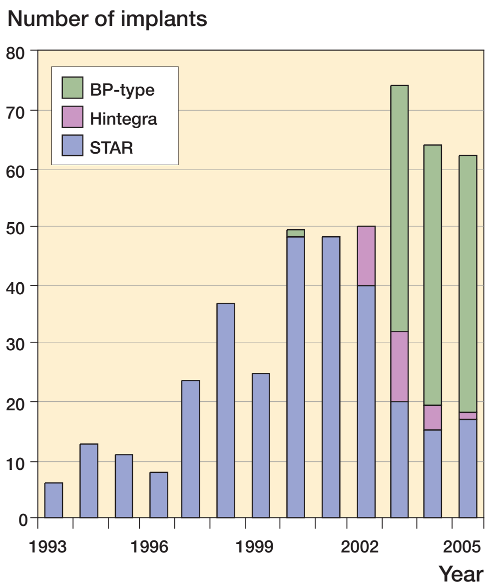

Figure 2. Number of ankle prostheses implanted in Sweden per year. BP-type includes the AES and Mobility ankles.

Table 1. Demographic data

	n	% females	Mean age (SD)
RA	216	78	57 (13)
OA	119	50	61 (11)
PtA [a]	175	54	56 (12)
Other	21	52	58 (13)
All diagnoses	531	63	58 (12)

[a] post trauma.

Statistics

Survival curves were constructed according to Kaplan-Meier and for comparisons we used log-

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Table 2. Reasons for revision

	Uncemented			Cemented			
	STAR	BP	AES	STAR [a]	HINTEGRA	Mobility	Total
Year first implanted:	1993	2000	2002	1998	2002	2005	
	n = 303	n = 92	n = 69	n = 15	n = 29	n = 23	n = 531
Aseptic loosening	27	1		1	2		31
Technical error	15	1			1		17
Instability	3	8	4		1		16
Infection	10	1	2				13
Intractable pain	8	3					11
PE breakdown	5	1	1	1			8
Painful varus	1	1	1				3
Fracture	2						
Total	71	16	8	2	4	0	101

[a] Stemmed tibial component.

rank test. Chi-square was used for comparison of proportions between groups. Cox regression analysis was use to evaluate the influence of age on the revision rate. As endpoint, we used revision leading to exchange or extraction of one or more prosthetic components.

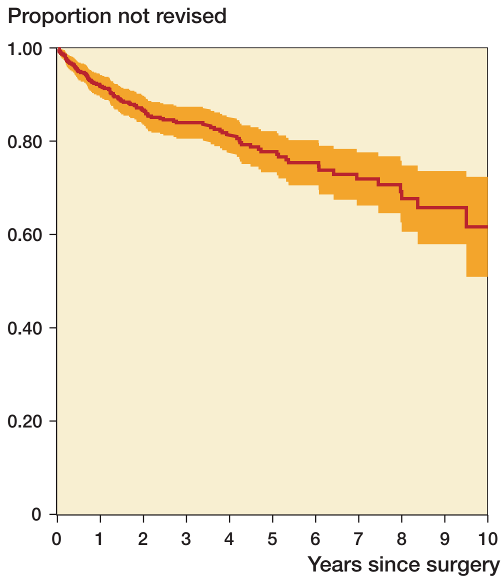

Figure 3. Estimated cumulative survival and 95% CI for all 531 ankle arthroplasties.

Results

101 ankles (19%) were revised (Table 2), 31 because of loosening of the tibial and/or the talar component and 16 because of instability with or without dislocation of the polyethylene (PE) meniscus. 13 ankles developed early or late infection necessitating permanent removal of the prosthesis. 17 ankles were considered to be technical failures with malpositioning of the tibial component (either too lateral or too medial or at an incorrect angle) or from using a tibial component that was too short from front to back. Severe pain for no obvious reason in 11 ankles eventually resulted in revision. Furthermore, 8 ankles were revised because of severe wear or fracture of the PE component. Painful varus malalignment in 3 patients and malleolar fracture postoperatively in 2 patients also ended in revision.

The estimated overall 5-year survival rate was 0.78 (95%CI: 0.74–0.82) and the 10-year survival rate was 0.62 (0.52–0.72) (Figure 3) (Table 3). For rheumatoid arthritis, the 5-year survival rate was 0.82 (0.76–0.88), for osteoarthritis it was 0.80 (0.76–0.88), and for posttraumatic arthritis it was 0.70 (0.61–0.79) (Figure 4). The differences in survival rate are not statistically significant ($p = 0.1$). Lower age at the index surgery implied an increased risk of later having to undergo a revision ($p = 0.002$, RR 0.98, CI: 0.96–0.99). There was no influence of gender on risk ($p = 0.4$).

In order to evaluate whether experience of the surgeon had an influence on the prosthetic survival, uncemented and uninfected STAR prostheses implanted by the 3 surgeons who had performed more than 40 cases were selected. Separate survival curves for their 30 first cases and the cases

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Table 3. Life table

Interval (years)	No. entering	No. of events	Cumulative proportion surviving at end of interval	95% CI
0–1	531	41	0.92	0.90–0.94
1–2	428	22	0.87	0.85–0.89
2–3	348	10	0.84	0.82–0.86
3–4	274	7	0.82	0.80–0.84
4–5	213	8	0.78	0.76–0.80
5–6	146	4	0.76	0.74–0.78
6–7	100	4	0.72	0.69–0.75
7–8	73	2	0.70	0.67–0.73
8–9	46	2	0.66	0.61–0.71
9–10	24	1	0.62	0.55–0.69

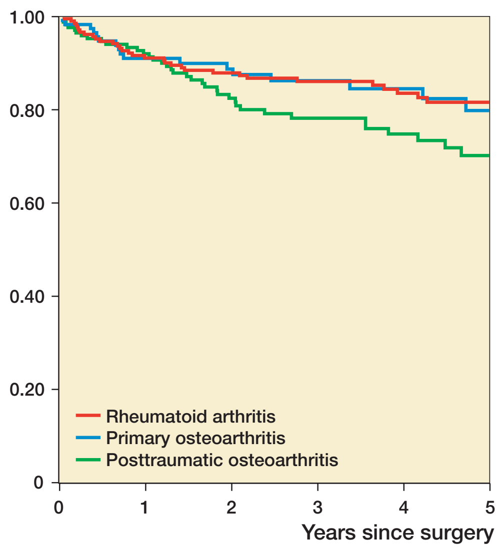

Figure 4. Estimated cumulative survival for ankles replaced due to rheumatoid arthritis and osteoarthritis (the two upper curves). The lower curve represents the survival rate for ankles replaced due to posttraumatic osteoarthritis.

performed thereafter were constructed. The 5-year survival increased from 0.70 (0.57–0.77) for their first 90 cases to 0.86 (0.80–0.93) for the following 132 cases (p = 0.01) (Figure 5).

Discussion

Studies on long-term prosthetic survival rates of total ankle arthroplasty, i.e. those with an obser-

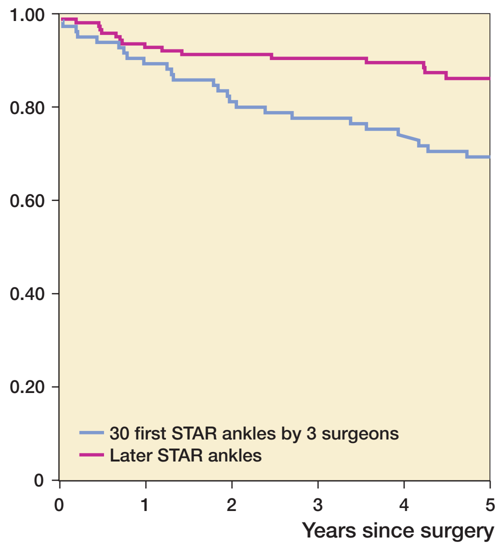

Figure 5. The lower curve represents the estimated cumulative survival for the 30 first STAR ankles implanted by each of 3 surgeons. The upper curve represents the survival of STAR ankles replaced thereafter by the same surgeons.

vation time exceeding 10 years, have mainly been done by inventors of different prostheses. Thus, Buechel et al. (2004) reported a 12-year survival of 92% for 75 BP prostheses and Kofoed (2004) reported an 8- and 12-year survival of 95% for 25 uncemented STAR prostheses. Knecht et al. (2004) found a 10-year survival of 85% with 132 Agility prostheses.

To our knowledge, there have been no long-term follow-up reports by independent researchers. However, medium-term results with 5-year survival rates of 94% were reported by Carlsson (2006), of 93% by Wood and Deakin (2003), and of 70% by Anderson et al. (2003) for the STAR prosthesis. A five-year survival rate of 80% has been reported by Spirt et al. (2004) for the Agility prostheses. Doets et al. (2006) found an 8-year survival of 84% for the LCS and BP prostheses. In a recent meta-analysis, 10 papers with 497 three-component ankle prostheses in total qualified for being included. 6 of these papers provided survival rates, but complete life tables were available in only 3 of them. The weighted 5-year survival averaged 91% (95% CI: 84–97) (Stengel et al. 2005).

In this report from the Swedish National Register, the survival rates are in the same range as in

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other medium-term reports (Andersson et.al. 2003, Spirt et al. 2004), but considerably lower than in the series from Carlsson (2006) and Wood and Deakin (2003). The 70% survival rate for the posttraumatic group is somewhat (but not statistically significantly) lower than for the other diagnoses, which could reflect that in posttraumatic osteoarthritis the ankles are more traumatized, stiff, and more often malaligned in varus than ankles with other diagnoses. Ankles in varus are a greater challenge than ankles in valgus or neutral position (Haskell and Mann 2004, Henricson and Ågren 2007). In our study, 11 of the 16 revisions due to instability were ankles malaligned in varus.

Our 19% revision rate is higher than most reported revision rates, which range from 1% to 24% (Andersson et al. 2003, Wood and Deakin 2003, Buechel et al. 2004, Knecht et al. 2004, Spirt et al. 2004, Carlsson 2006). The revision rate for the STAR prosthesis in our study is much higher than for other prostheses. One obvious explanation is that the STAR prosthesis was introduced earlier, and at a time when most surgeons were in the early learning phase. Another explanation is that implantation of the STAR prosthesis is technically demanding and that the instrumentation during the first years was unsatisfactory. Thus, 15 of the 17 revisions undertaken due to technical mistakes occurred with the STAR prosthesis. In fact, the number of STAR prostheses implanted in Sweden has decreased considerably during recent years (Figure 2). Our revision rates for the BP and AES prostheses, though with smaller numbers and shorter follow-up, are similar to those in other reports (Wood and Deakin 2003, Hintermann et al. 2004, Kofoed 2004, Spirt et al. 2004, Valderrabano et al. 2004). It is remarkable that only one of 161 replacements of the latter two designs was revised due to aseptic loosening, and one due to technical error.

The surgical challenge of performing a TAR and the long learning curve are well known (Andersson et al. 2003, Wood and Deakin 2003, Hintermann et al. 2004, Henricson and Ågren 2006) and were also found in this series. Anderson et al. (2003) had a significantly higher survival rate in their late cases than in their early cases, and Carlsson (2006) made the same observation in his series. Henricson and Ågren (2007) had more than twice as many revisions during the first 4 years than during the last 4 years.

Total ankle replacement surgery is undoubtedly a task for well-trained and experienced surgeons. Knowing how and when to perform additional pre-, peri- or postoperative surgery is crucial in order to achieve stability and alignment. Examples of such procedures are calcaneal osteotomy, subtalar and/or talo-navicular fusion, medial ligament release, lateral ligament reconstruction, and tendon transfers.

The alternative procedure to TAR is fusion of the ankle. The longest follow-up studies of ankle fusion have shown development of ipsilateral hindfoot degenerative disease in approximately half (Ahlberg and Henricson 1981) or almost all (Coester et al. 2001) ankle fusions. Fuchs et al. (2003) reported that hindfoot arthritis was seen in all 18 of their cases with a fused ankle, but it was predominantly located in the subtalar joint and had only a limited effect on the clinical outcome. In a prospective study, Kofoed and Stürup (1994) found subtalar arthritis in one-third of 14 fused ankles after 7 years, but none in 14 ankles with arthroplasty. Furthermore, patients with ankle fusion have substantial functional limitations, such as difficulty in walking on uneven ground and in climbing stairs, aching around the ankle with prolonged standing, walking or working, and difficulty in getting out of a bath (Muir et al. 2002).

For these reasons, Salzman (2004) stated that joint replacement in ankle arthritis with the right indications may be considered the standard of care. If a TAR fails for any reason, it is possible to perform an ankle arthrodesis with good results using various techniques (Carlsson et al.1998). In many cases, the use of an intramedullary nail is preferable (Anderson et al. 2005).

In conclusion, the somewhat low overall survival rate and high revision rate in this material reflects the demanding surgical procedure and the long learning curve. Experience, strict indications, improved designs, and especially improved instrumentation will probably lead to better results in the future.

Contributions of authors

AH: introduction and maintenance of the register, writing of manuscript. AS: maintenance of the register. ÅC: data analysis and writing of manuscript.

No competing interests declared.

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