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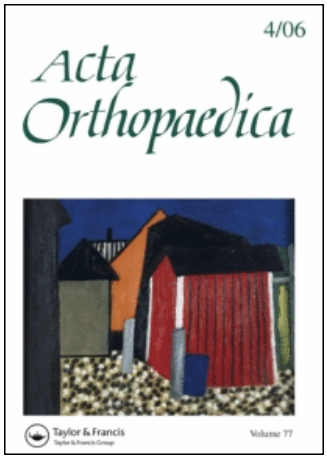

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257 ankle arthroplasties performed in Norway between 1994 and 2005

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257 ankle arthroplasties performed in Norway between 1994 and 2005

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Background and purpose **There have been few reports on the long-term outcome of ankle replacements. The Norwegian Arthroplasty Register has been registering ankle replacements since 1994, but no analysis of these data has been published to date. Here we report data on the use of total ankle replacements and the revision rate in the Norwegian population over a 12-year period.**

Methods **We used the Norwegian Arthroplasty Register to find ankle arthroplasties performed between 1994 and 2005. Patient demographics, diagnoses, brands of prosthesis, revisions, and time trends were investigated.**

Results **There were 257 primary ankle replacements, 32 of which were cemented TPR prostheses and 212 of which were cementless STAR prostheses. The overall 5-year and 10-year survival was 89% and 76%, respectively. Prosthesis survival was the same for the cementless STAR prosthesis and the cemented TPR prosthesis. There was no significant influence of age, sex, type of prosthesis, diagnosis, or year of operation on the risk of revision. The incidence of ankle replacements due to osteoarthritis, but not due to inflammatory arthritis, increased over the years.**

Interpretation **The revision rate was acceptable compared to other studies of ankle arthroplasties, but high compared to total knee and hip arthroplasties. The overall incidence of ankle replacements increased during the study period.**

Most publications on first-generation ankle replacements reported poor results (Bolton-Maggs et al. 1985, Demottaz et al. 1979, Herberts et al. 1982, Kitaoka and Patzer 1996, Takakura et al. 2004). The failures in early studies usually occurred with cemented implants. In general, uncemented prostheses have been associated with better results than cemented ones (Saltzman 1999, Easley et al. 2002), and uncemented types are now predominant.

The use of ankle arthroplasty is still limited compared to hip and knee arthroplasty. There have been few publications, and these have usually included rather small numbers of patients, between 10 and 306 (Kitaoka and Patzer 1996, Anderson et al. 2003, Wood and Deakin 2003, Kofoed 2004, Spirt et al. 2004, Carlsson et al. 2005, Doets et al. 2006,).

The results after ankle replacement in terms of prosthesis survival have generally been poor compared to hip or knee arthroplasty. In two studies in which the STAR prosthesis—a cementless, mobile-bearing implant—was used, the 5-year survival ranged between 70% and 93% (Anderson et al. 2003, Wood and Deakin 2003). Another study involving 306 operations in which the Agility ankle—a cementless, fixed-bearing prosthesis—was used, reported a 5-year prosthesis survival of 80% (Spirt et al. 2004).

In the present study, we attempted to estimate the revision rate and also to find the causes of and risk factors for revision. Patient demographics, the distribution of diagnoses leading to the arthroplasty, and prosthesis types were also investigated, as were time trends in the incidence of ankle arthroplasties

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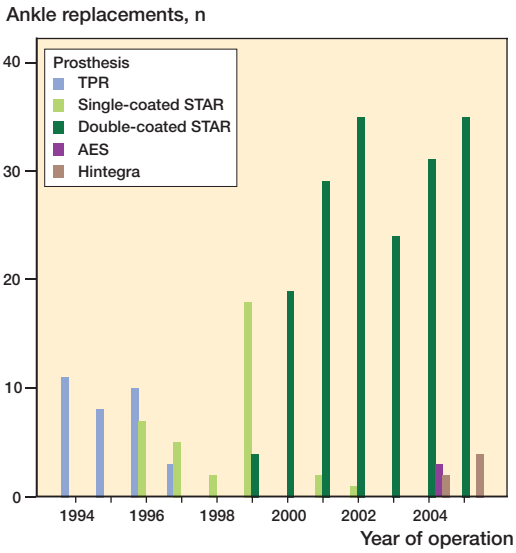

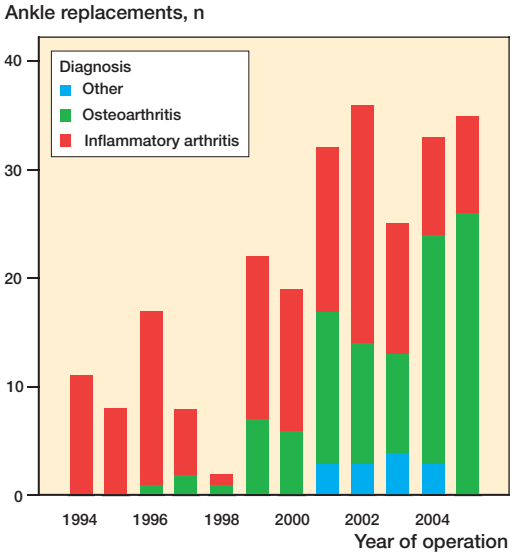

Figure 1. A. Distribution of prosthesis types per year. B. Distribution of diagnoses per year.

in the Norwegian population during the period 1994–2005.

Patients and methods

The Norwegian Arthroplasty Register was established in 1987, first as a hip prosthesis register; but from January 1994 it was extended to include all artificial joints (Havelin 1999). Individual reports of joint replacements are received from all 14 hospitals performing the procedures in Norway (population 4.6 million). Data concerning the identity of the patient, the diagnosis, date of surgery, whether the operation was primary or a revision, type of prosthesis, whether cement was used and type of cement, the use of thrombosis prophylaxis, and antibiotics are taken from the form filled in by the operating surgeon (Furnes et al. 2002).

From 1994 through 2005, 257 primary ankle replacements were performed in 245 patients. 82 were performed in men and 175 in women, and the mean age at primary surgery was 58 (18–85) years for women and 60 (31–89) years for men. The median follow-up time for all patients was 4 years (5 days–12 years).

4 types of ankle prostheses were used: Norwegian TPR (32), STAR (216), AES (3), and Hintegra (6). In 1994 and 1995, the Thompson Parkridge Richards (TPR) ankle prosthesis (Richards International, Memphis, TN) was used in all cases (Figure 1A). This prosthesis was inserted using the Norwegian tibial alignment instruments and technique, as suggested by Dr. Jan Pahle. This prosthesis is thus referred to as the Norwegian TPR. It is a 2-component (fixed-bearing) prosthesis with a high-molecular-weight polyethylene tibial component, and a talar component in cobalt-chromium alloy. In all cases, it was inserted using cement for both components.

In 1996, the STAR prosthesis (Scandinavian Total Ankle Replacement; Waldemar Link, Hamburg, Germany) was introduced and soon became the predominant prosthesis (Figure 1A). This is a 3-component (mobile-bearing) prosthesis consisting of a tibial component of cobalt-chromium alloy, a talar component of cobalt-chromium alloy, and a polyethylene sliding core. The STAR prosthesis was inserted without cement in all but 4 cases. The single-coated version was used until 1999, and from 2000 the double-coated version was used in all cases except 3 (in whom the single-coated version was used).

The AES (Ankle Evolution System; Biomet Merck, France) and Hintegra prostheses (HINTEGRA; Newdeal SA, Lyon, France) were introduced in 2004, but so far they have been used in very few patients. The AES and the Hintegra are 3-component, cementless prostheses. The AES was inserted at one hospital in 3 ankles, and the Hin-

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tegra at another hospital in 6 ankles. Because of the low numbers, these prostheses were not included in the analyses in Tables 3, 4, and 5.

12 patients had replacements bilaterally. In these patients, each ankle replacement procedure was considered as a separate case. In some analyses, rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis were grouped together and called inflammatory arthritis (IA), while primary osteoarthritis was grouped together with sequelae after fractures and ligament damage, and designated osteoarthritis (OA). Included in the subgroup of diagnoses called "other" (n = 13) were patients with hemocromatosis (4), hemophilia (2 patients where one had ankle replacements in both ankles), arthritis urica (2), systemic lupus erythematosus (1), and others (3).

Several causes of revision may be given for one particular ankle replacement (Table 5). However, for the purpose of this study, pain was only registered as the cause of revision in cases where this was the only cause registered.

Table 1. Diagnosis leading to ankle replacement

Diagnosis [a]	No. of patients	No. of women (%)	Age mean (SD)
Primary osteoarthritis	53	30 (57)	63 (14)
RA	129	100 (78)	58 (14)
Fracture sequelae	57	37 (65)	59 (13)
Ankylosing spondylitis	4	1	43 (13)
Psoriatic arthritis	5	3	54 (17)
Sequelae of ligament damage	5	2	61 (9.0)
Other [b]	13	7	52 (15)
P-value [c]		0.02	0.02

[a] More than one diagnosis was allowed.
[b] Includes hemophilia, hemocromatosis, Crohn's disease, arthritis urica, and others.
[c] Calculated using chi-square test (sex) or ANOVA (age).

Statistics

We used the Student t-test and analysis of variance (ANOVA) to compare continuous variables. For comparison of proportions, the Chi-squared test was used. All p-values were two-tailed, and the significance level was set to 5%. The observation time was the time from primary replacement until revision or until the end of study, or death. The date of death of patients was obtained from Statistics Norway (www.ssb.no/english/). Median follow-up (observation) time was calculated using the reverse Kaplan-Meier method.

A revision was defined as the removal or exchange of a part of an implant, or the whole implant. In failure curves, calculated by the Kaplan-Meier method, the endpoint was revision for any reason. The failure curves were discontinued when the number of patients at risk was less than 10. Differences in revision rates between groups were tested using the log-rank test. Cox multiple regression analysis was used to study relative risk (RR) of revision according to prosthesis brand, diagnosis, age, sex, and year of primary operation (2000–2005 vs. 1994–1999). All relative risks have been adjusted for the other variables.

Poisson regression analysis was used to analyze trends in the incidence of ankle replacement procedures. These analyses were performed based on yearly population rates for the Norwegian population, obtained from Statistics Norway. The p-values given in the text describing Figure 1B were derived from these Poisson analyses. All analyses were done using SPSS version 13.0.

Results

One-half of the prostheses were inserted in patients with rheumatoid arthritis, while the other major causes of surgery were primary osteoarthritis and sequelae after ankle fracture (Table 1).

Diagnosis and time trends

An increase in the total incidence of ankle replacements took place from 1994 to 2005 ($p < 0.001$) (Figure 1B). No statistically significant change in the number of arthroplasties due to IA was found ($p = 0.4$), but a significant increase in operations due to OA took place during the study period ($p < 0.001$).

Type of prosthesis

The TPR was almost exclusively inserted in patients with inflammatory arthritis (Table 2). The median follow-up time was longer for the TPR

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Table 2. Comparison of the Norwegian TPR and the STAR prostheses according to age, gender, diagnosis, number of hospitals using (or having used) the prosthesis, and year of surgery

	Norwegian TPR (n = 32)	STAR (n = 216)
Age, mean (SD)	61 (15)	58 (13)
No. of women (%)	24 (75)	146 (68)
Diagnosis, n (%)		
IA [a]	31 (97)	106 (49)
OA [b]	1 (3)	97 (45)
Other	0	13 (6)
No. of hospitals	7	10
Year of surgery		
1994–1999	32	36
2000–2005	0	180
Observation time, mean years (SD)	7.7 (3.2)	3.1 (2.3)

[a] IA: Inflammatory arthritis, including rheumatoid arthritis, psoriatic arthritis, and ankylosing spondylitis.
[b] OA: Osteoarthritis, including primary osteoarthritis, fracture sequelae and sequelae after ligament damage.

prosthesis (9.2 years) than for the STAR (3.3 years) ($p < 0.001$).

Survival of prostheses

Revision was performed in 27 (11%) of 257 cases, and the mean time until revision was 2.3 (0.1–8) years. The overall 5-year and 10-year survival was 89% and 76%, respectively (Figure 2A). 6 revisions were registered in patients with the Norwegian TPR prosthesis and 21 in those with STAR prostheses. No revisions were registered for the AES or Hintegra prostheses.

For the Norwegian TPR prosthesis, the only cause of revision was aseptic loosening of prosthetic parts or the whole prosthesis (Table 3). Several different causes of revision were registered for the STAR prosthesis, among which the most common were aseptic loosening, incorrect axis, and pain. Only aseptic loosening of the proximal component was seen in the STAR ankles. There were more cases of aseptic loosening with the single-coated version than with the double-coated version (RR = 12, $p = 0.01$, log rank test) (Table 4).

In the 27 patients who underwent revision, the procedures performed were: exchange of the distal component in 1 ankle, exchange of the proximal part in 8, and exchange of the whole prosthesis in 6 cases. The polyethylene insert of the STAR prosthesis was exchanged in 14 ankles; this was the only procedure performed at revision in 6 cases. Removal of prosthetic parts without replacement was registered in 6 cases and other revision procedures were done in 3 ankles.

Table 3. Causes of revision by type of prosthesis

Cause [a]	Norwegian TPR n = 32	STAR n = 216
Aseptic loosening of either or both components	6	7
Instability	0	3
Incorrect axis (malalignement)	0	7
Deep infection	0	2
Fracture	0	1
Pain	0	5
Defect/wear of polyethylene insert	0	2
Other	0	2
Total number of revisions	6	21

[a] More than one cause may be given for each ankle, but pain was included only when it was the sole cause of revision.

Table 4. Causes of revision for single- and double-coated STAR prostheses

Cause [a]	Single-coated n = 35	Double-coated n = 177
Aseptic loosening	5	1
Instability	1	1
Incorrect axis (malalignement)	3	3
Deep infection	0	2
Fracture	1	0
Pain	0	5
Defect/wear of polyethylene insert	2	0
Other	0	2
Total number of revisions	8	13

[a] More than one cause may be given for each ankle, but pain was included only when it was the sole cause of revision.

Risk factors for revision

Neither age nor sex had a significant influence on prosthesis survival. No statistically significant difference in survival was found for patients with the different diagnoses ($p = 0.3$). Furthermore, no difference in survival was found between the STAR and the Norwegian TPR prostheses (Figure 2).

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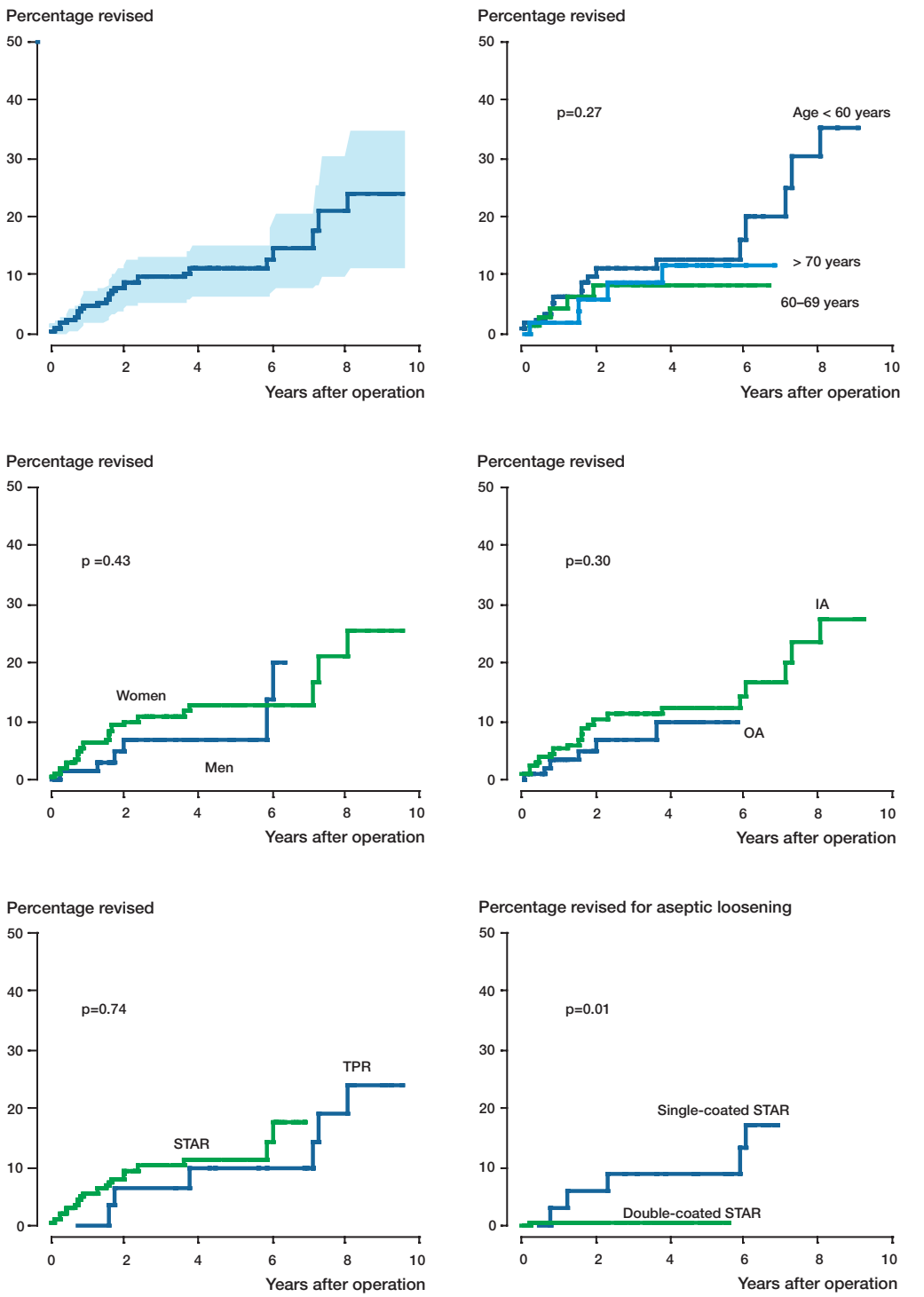

Figure 2. Unadjusted Kaplan-Meier curves with revision as endpoint: A. All; B. According to age category; C. According to gender; D. According to diagnosis; E. According to type of prosthesis; F. Revisions due to aseptic loosening, according to version of STAR prosthesis.

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Table 5. Survival analysis (Kaplan-Meier and Cox regression) for revision after ankle arthroplasty according to potential explanatory factors

	No. of ankle replacements	No. of revisions	S_5 (%)	95% CI	RR	95% CI
All	235 [a]	26 [b]	89	84–93		
Age					1	1–1
Sex						
Men	71	6	93	86–100	1.2	0.5–3
Women	164	20	87	82–93	1	
Type of prosthesis						
TPR	32	6	90	80–100	1	
STAR	203	20	89	84–94	1.2	0.6–2
Diagnosis						
OA	98	6	90	83–98	1	
IA	137	20	88	82–94	1.5	0.6–4
Year of surgery						
1994–1999	68	12	90	82–97	1	
2000–2005	167	14	89	83–95	1.1	0.4–3

[a] N = 235 because only Norwegian TPR and STAR prostheses were included and only patients with OA (primary and secondary osteoarthritis) or IA (inflammatory arthritis including RA, psoriatic arthritis, and ankylosing spondylitis) were included in the analysis.
[b] Only 26 of 27 revisions were included because the diagnosis was unknown in 1 case.
S_5: Kaplan-Meier 5-year survival probabilities with 95% confidence intervals.

A difference in survival was found between the two versions of the STAR prosthesis (single- and double-coated), the double-coated version having better results regarding prosthetic loosening (p = 0.01) (Figure 2).

The 5-year survival was about 90% for all patients. Neither age, sex, type of prosthesis, diagnosis, or year of operation significantly influenced the risk of revision (Table 5). We did not adjust for the number of ankle arthroplasties performed at each hospital. However, when adjusting for this factor, the results were similar and no difference in the revision rate was observed for hospitals that had performed 1–20 arthroplasties compared to those that had done > 20 ankle arthroplasties (p = 0.9, derived from Cox regression analysis).

Discussion

Our main finding was the rather poor results, with overall 5- and 10-year survival of 89% and 76%, respectively. Thus, the survival after ankle arthroplasty is still much lower than after hip and knee replacements, the 5-year overall survival probability in Norway being 98% for cemented hip prostheses (Espehaug et al. 1995), and 94–96% for knee prostheses (Furnes et al. 2002). However, a 5-year survival of 89% is relatively high compared to other studies on ankle replacements, which have reported 5-year survival rates of 54% to 93% (Anderson et al. 2003, Wood and Deakin 2003, Spirt et al. 2004, Doets et al. 2006).

Advantages and weaknesses of the present study

Randomized studies are considered the best approach for comparing different treatment methods or implants. When properly performed, the effect of confounding factors can be eliminated and conclusions concerning the best implant may be drawn. However, the costs are high, the workload large, and the time to obtain results is long, which is why such studies are rarely performed in orthopedic surgery, and we could find no randomized studies on ankle arhthoplasty. Ankle arthroplasties are rather infrequently performed, and there would be great difficulty in obtaining a large enough patient population for a randomized study.

Using data from the NAR, we were able to evaluate a relatively large number of ankle replacements with results from all centers performing the procedure in the country. The results reflect those of the

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average surgeon at the average hospital, not a specialized center, which is often the case in randomized studies. National registry studies also offer the opportunity to investigate incidences and possible changes in incidence (Fevang et al. 2007). A few studies have been published reporting results from series of at least 200 ankle replacements (Kitaoka and Patzer 1996, Wood and Deakin 2003, Spirt et al. 2004), but otherwise, the number of cases has generally been low.

Completeness of data

The completeness of registration in the Norwegian Arthroplasty Register was recently evaluated and it was 97% for hip replacements and 99% for knee replacements, while 82% of all primary ankle replacements had been registered (Espehaug et al. 2006).

Time trends

The overall incidence of ankle arthroplasties increased in Norway during the study period. Studies from several countries have shown a similar increase in the use of hip replacement over the last 10–15 years (Havelin et al. 2000, Ingvarsson 2000, Puolakka et al. 2001, Soderman et al. 2001, Ostendorf et al. 2002, Mahomed et al. 2003, Pedersen et al. 2005). The incidence of ankle replacements due to primary or secondary osteoarthritis increased with time, but this was not so for the inflammatory arthritides—as was also found by Wood and Deakin (2003). These findings are consistent with a general trend in recent years of more joint replacements being performed due to osteoarthritis, and less for inflammatory arthritis (da Silva et al. 2003, Pedersen et al. 2005, Weiss et al. 2006, Fevang et al. 2007).

Risk factors for revision

In this study, no factor was found to significantly influence survival. In a study of 306 ankle replacements, the only factor having an influence on prosthesis survival was age, younger age being associated with an increased revision rate (Spirt et al. 2004). We found no difference in survival of the prostheses between patients with different diagnoses, which is in accordance with the results of previous studies (Spirt et al. 2004, Doets et al. 2006). Furthermore, a study comparing migration of the prosthesis in patients with RA and OA found no difference in survival at 4 years (Carlsson et al. 2005). Furnes et al., who analyzed more than 50,000 total hip replacements, found no difference in revision rate between patients with primary osteoarthritis and rheumatoid arthritis (Furnes et al. 2001).

Prosthesis type and survival

Only one study of 14 consecutive patients, comparing the cemented TPR ankle prosthesis with the cementless STAR prosthesis, has been published (Wood et al. 2000). It reported better results with the STAR prosthesis. Kofoed (2004) compared cemented and uncemented STAR prostheses in 58 patients and found more revisions with cemented prostheses. In Norway, the cemented TPR prosthesis was exchanged for the cementless STAR prosthesis in 1996/1997. We found no difference in revision rate between the cemented TPR prosthesis and the uncemented STAR prosthesis. There seems to be a different pattern in the causes of revision for the two prostheses, with aseptic loosening being the main cause of revision for TPR prostheses while several different causes (including aseptic loosening, incorrect axis, and pain) were major reasons for revision with the STAR prostheses. The follow-up time was different for the two prostheses and the number of TPR prostheses was small, making a comparison between the two brands difficult.

In a study of 306 ankle replacements with the Agility prosthesis, the 5-year survival of the implant was 54% (Spirt et al. 2004). This is a fixed-bearing (2-component), cemented prosthesis, in contrast to the STAR prosthesis which is a mobile-bearing (3-component), uncemented prosthesis. The reason for the poor results may have been the prosthesis design. However, the TPR prosthesis in our study, which is more similar in design to the Agility prosthesis, also had a much better 5-year survival (90%) than that reported for the Agility prosthesis. Although the numbers are small (32 TPR prostheses), this argues against the design of the prosthesis causing the inferior survival of the Agility prosthesis, and other factors may have contributed.

In 1990 a cementless single-coated version of the STAR prosthesis was introduced, and this was modified in 1999 when the anchoring surfaces were given a double coating. In our study, significantly more revisions due to aseptic loosening were per-

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formed in patients with single-coated STAR prostheses than with the double-coated counterpart. Thus, it is probable that the change in the coating had the intended effect.

Based on our findings, we cannot conclude that any prosthesis was superior to any other. Thus, larger studies, preferably randomized controlled studies, are needed to evaluate prosthesis types. However, we found an improvement in prosthesis survival compared to older studies using first-generation protheses. The results of ankle arthroplasty are still inferior to knee and hip arthroplasty, and further improvement in prosthesis design, surgical technique, and/or modification of the indications for this procedure are required.

Contributions of authors

All authors contributed to the conception and design of the study and manuscript preparation. In addition, individual authors contributed as follows. BTF: data processing, statistical analysis, and writing of manuscript. SAL: data processing and statistical analysis. LIH, AS, and ONF: Data collection and interpretation.

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No competing interests declared.

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