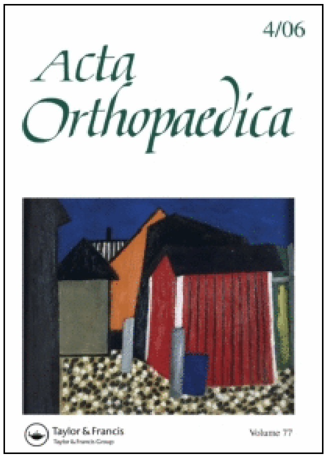

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A New Zealand national joint registry review of 202 total ankle replacements followed for up to 6 years

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A New Zealand national joint registry review of 202 total ankle replacements followed for up to 6 years

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Background and purpose **There have been few reports of large series of ankle replacements. The aim of this study was to document and evaluate the early results of a nationwide series of total ankle replacements (TARs) performed using second- and third-generation implants.**

Methods **Records of total ankle replacements performed between February 2000 and November 2005 were retrieved from the New Zealand National Joint Registry and retrospectively reviewed at a mean of 28 months after the primary procedure. At 6 months post surgery, patient scores were generated from questionnaires. Comparisons between patient scores and categorical variables were made using ANOVA. Regression analyses using Cox proportional-hazards modeling were performed to determine predictors of failure. A Kaplan-Meier survivorship curve was used to describe the rate of prosthetic survival.**

Results **202 total ankle replacements were performed in 183 patients. 14 prostheses (7%) failed. The overall cumulative 5-year failure-free rate was 86%. An unfavorable patient score at 6 months after the initial procedure turned out to be a good predictor of subsequent failure. The cumulative 5-year failure-free rate was 65% at 5 years for patients with an unfavorable score, and 95% for those who had a favorable patient score. Each 1-point increase in the patient score (i.e. poorer outcome) corresponded to a 5% relative increase in the risk of failure ($p < 0.05$). In addition, longer operative time for the primary procedure was found in the group of TARs that subsequently failed ($p < 0.05$).**

Interpretation **The National Joint Registry appears to be a useful tool for monitoring the trends in TAR surgery.** ■

Total ankle replacement (TAR) is rapidly gaining popularity in the treatment of end-stage ankle joint disease. Although complication rates of first-generation, mostly "ball and socket"-shaped prostheses were unacceptably high (Bolton-Maggs et al. 1985, 1986, Kitaoka and Patzer 1996), more encouraging results have been achieved with second-generation, two-component, polyethylene-on-metal prostheses (Conti and Wong 2001, Knecht et al. 2004). A resurgence of interest in TAR developed soon after the publication of the first second-generation implant results (Pyevich et al. 1998). Recent results of third-generation, meniscal-bearing implants (Anderson et al. 2003, Buechel et al. 2003, Valderrabano et al. 2004, Doets et al. 2006) suggest that TAR provides an acceptable benefit-risk ratio (Stengel et al. 2005). Ankle arthrodesis, however, with its predictable pain relief and good initial results which may deteriorate in time (Coester et al. 2001, Muir et al. 2002), is still considered by many to be the gold standard for the treatment of ankle arthritis.

There have been few published results of TAR because of its relatively short history in use. In contrast to the more common joint replacements such as total hip replacement (Furnes et al. 2001) and total knee replacement (Robertsson 2007), the authors have not been able to find any nationwide evaluations of TAR in the literature. Although recent results have been encouraging in several small and a few larger clinical series, there is a need for evaluation of larger numbers (Conti and Wong 2001, Stengel et al. 2005), such as can be obtained from a Joint Registry.

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The aims of this study were: (1) to report on the early results of a nationwide series of TARs performed with different second- and third-generation implant designs, and (2) to evaluate the effect of diverse demographic and clinical variables on failure rate and patient satisfaction after TAR, with regard to patient age, sex, experience of the surgeon, operative time, type of prosthesis, and the indications for the index procedure.

Patients and methods

The New Zealand National Joint Registry (Rothwell 1999), established in 1999, stores information on primary and revision joint replacements. In January 2000, the registration was extended to include TARs. Our study population consisted of all primary registered TARs performed between February 2000 and November 2005.

At 6 months post surgery, all patients are requested to fill in a questionnaire regarding pain, activity, and function. The questionnaire is modeled on the Oxford 12 for total hip replacement (Dawson et al. 1996), but has not been validated (see Appendix). It contains 12 multiple-choice questions, each scored as 1 to 5 points. The minimum total score of 12 points represents normal function and the maximum score of 60 points represents the most severe disability. In addition, the questionnaire contains questions regarding postoperative complications and TAR-related hospital re-admission.

We extracted the number of recorded revisions (i.e. failures) defined in the Joint Registry as replacement of components, conversion to ankle arthrodesis, or below-the-knee amputation. Patient scores, generated from the questionnaires, represented subjective outcome at 6 months after the index procedure. We analyzed the effect of the following factors on failure rate and patient scores: patient age, sex, surgeon experience, operative time, type of prosthesis (i.e. the second-generation, two-component Agility or the third-generation Ramses, STAR, or Mobility prostheses) and the indications for the index procedure (i.e. primary osteoarthritis, rheumatoid arthritis, or posttraumatic osteoarthritis). In addition, the relationship of the patient scores to subsequent failure was analyzed.

Surgeon experience was evaluated by comparing two categories of surgeons. Group I covered surgeons who had individually performed more than 25 TARs and group II covered surgeons who had individually performed 25 TARs or less over the study period. Experience dating from before January 2000 was not registered, but very few of the surgeons had had any significant experience in TAR surgery before January 2000.

Statistics

Comparisons between patient scores and categorical variables were made using ANOVA. Regression analyses using Cox proportional-hazards modeling were performed to determine the effect of patient age, sex, surgeon experience, operative time, type of prosthesis, preoperative diagnosis, and patient scores on the risk of failure. A Kaplan-Meier survivorship curve was used to describe the failure-free survival rate.

Results

According to the records, between February 2000 and November 2005, 202 TARs had been performed in 183 patients by 18 surgeons in 18 institutions throughout New Zealand. 60% of the patients were male. The average age of patients was 65 (32–83) years. The diagnosis was primary osteoarthritis for 144 (71%), posttraumatic osteoarthritis for 34 (17%), and rheumatoid arthritis for 24 (12%). In the primary osteoarthritis group, 2 patients had hemochromatosis and 1 had hemophiliac arthropathy (Table 1).

Review of the registry data took place at a mean of 28 (7–75) months after the primary procedure. 22% of the patients had had a previous operation on the index joint including: internal fixation for juxtarticular fracture for 21 patients (10%), arthroscopic debridement for 8 (4%), attempted arthrodesis for 6 (3%), realignment osteotomy for 5 (2%), ligament reconstructions for 2, and a tarsal tunnel decompression for 1 patient.

The 4 prostheses recorded were: the Agility Total Ankle System (DePuy, Warsaw, IN) in 117 ankles; the Scandinavian Total Ankle Replacement (STAR) (LINK Orthopaedics, Hamburg, Germany) in 45 ankles; the Mobility (DePuy International,

Table 1. Demographic and clinical data

	All patients	Patients with failed TAR	Patients with non-failed TAR
Number of ankles	202 [a]	14	188
Age, mean (range)	64 (32–83)	66 (59–75)	64 (32–83)
Male (n)	122 (60%)	10	112
Indication for TAR:			
osteoarthritis (n)	144 (71%)	13	131
post trauma (n)	34 (17%)	1	33
rheumatoid arthritis (n)	24 (12%)	0	24
Prosthesis			
Agility (n)	117 (58%)	9	108
Mobility (n)	29 (14%)	0	29
Ramses (n)	11 (5%)	2	9
STAR (n)	45 (22%)	3	42
Previous operations (n)	43 (21%)	3	40
Operative time (in min), mean (range)	140 (50–255)	162 (108–250) [b]	139 (50–255)
Patient scores			
Compliance (n)	148 (74%)	11	137
Scores (of 148 patients), mean (range)	27 (12–58)	34 (19–48) [b]	27 (12–58)

[a] 19 patients had bilateral total ankle arthroplasty, for a total of 202 prostheses.
[b] Significant difference from the patients who did not have a failed TAR.

Table 2. Data on the 14 ankles that had a failed TAR

Case	Sex	Age	Prosthesis	Time to failure (months)	Patient score	Reason for failure	Final surgery
1	M	60	S	1		Loosening talar comp.	Change of talar comp.
2	M	66	A	17	45	Varus malalignment	Change of tibial comp.
3	F	64	A	24	30	Loosening talar comp.	Revision of all components
4	F	66	R	7	40	Infection	Ankle arthrodesis
5	M	71	A	1		Infection	Below-the-knee amputation
6	M	67	A	65	24	Loosening talar comp.	Change of talar comp.
7	F	75	A	41	19	Loosening talar comp.	Change of talar comp.
8	M	67	A	24	48	Loosening talar comp.	Change of talar comp.
9	M	63	A	46	37	Loosening talar comp.	Revision to Mobility
10	M	63	S	11	32	Pain	Change of tibial polyethylene
11	M	60	R	20		Loosening tibial comp.	Mobility baseplate with Ramses bearing
12	F	68	A	13	39	Loosening tibial comp.	Ankle arthrodesis
13	M	59	A	27	35	Loosening talar comp.	Ankle arthrodesis
14	M	66	S	17	46	Loosening tibial comp.	Revision bearing

Prosthesis: A – Agility; R – Ramses; S – STAR.

Leeds, UK) in 29 ankles, and the Ramses Total Ankle Arthroplasty (Laboratoire Fournitures Hospitalieres, Heimsbrunn, France) in 11 ankles.

14 revision procedures (10 in males) had been recorded (7% of total). The average age of these patients at the time of the primary procedure was 66 (59–75) years. Loosening of components was the main reason for failure. Loosening of the talar component occurred in 7 ankles, loosening of the tibial component in 3, varus malalignment in 1, and pain from unknown cause in 1. 2 failures were due to a deep infection. Subsequent revision procedures were replacement of components in 10 ankles and arthrodesis in 3 (Table 2). 1 patient had had ini-

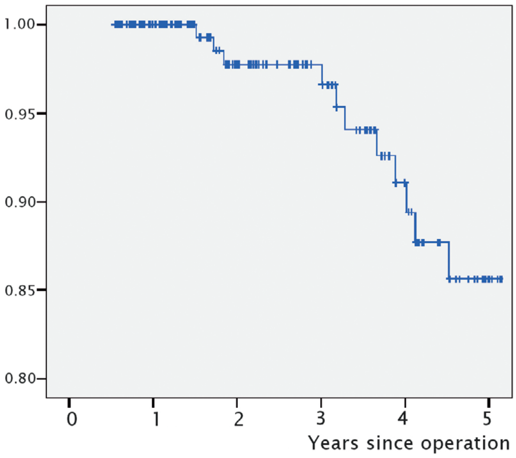

Figure 1. Kaplan-Meier survivorship curve with failure (replacement of components, ankle arthrodesis, or below-the-knee amputation) as the endpoint.

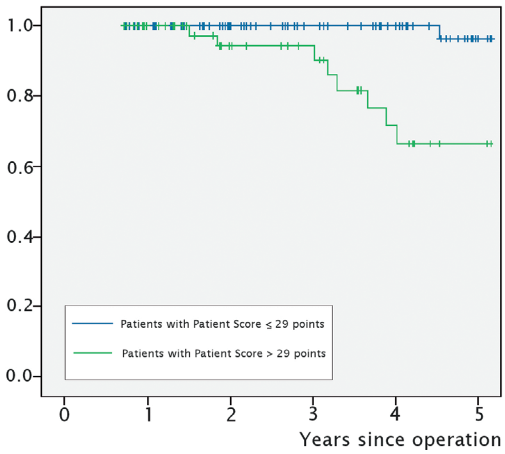

Figure 2. Kaplan-Meier patient score-dependent survivorship curve, with failure (replacement of components, ankle arthrodesis, or below-the-knee amputation) as the endpoint. The failure-free rate was 65% at 5 years for patients with a patient score higher than 29 points, and 95% for those who had a patient score less than or equal to 29 points ($p < 0.001$, log-rank test).

tial ankle debridement because of deep infection 6 months after TAR, but subsequently underwent a below-the-knee amputation. Kaplan-Meier analysis as a function of time since the primary TAR revealed that the cumulative 5-year failure-free rate was 86% (95% CI: 78–94) (Figure 1).

74% of the patients (148 TARs) had returned the 6-month questionnaire. There were no significant characteristics in this patient group compared to the group that did not return the questionnaire ($p > 0.05$). Cox proportional-hazards regression indicated that higher patient scores (i.e. poorer outcome) were associated with TARs that subsequently failed ($p = 0.027$). Each 1-point increase in the patient score, from the minimum of 12, corresponded to a 5% relative increase in the risk of failure ($p < 0.05$). An RoC curve analysis revealed that a cutpoint of 29 on the patient score optimized sensitivity and specificity for the prediction of failures. Kaplan-Meier analysis as a function of time since the primary TAR revealed that the cumulative 5-year failure-free rate was 65% at 5 years for patients with an unfavorable score (higher than 29 points) and 95% for those who had a favorable score (less than or equal to 29 points) ($p < 0.001$, log-rank test) (Figure 2). Further analyses revealed that operative time for the primary procedure was longer in the group of TARs that subsequently failed ($p = 0.046$).

Data on postoperative complications that occurred within the first 6 months from the initial procedure were derived from the complication section of 148 questionnaires. Infection in 6 ankles and dislocation in 4 was reported. The infection information obtained from the patient questionnaires did not, however, distinguish between superficial and deep infection. It has been assumed that most patient-reported infections would have been superficial, as only 1 of the 6 had subsequently been recorded as revised because of deep infection. The 4 dislocations reported by patients turned out to be misinterpreted cases of loosening, and they had all been recorded subsequently as revisions. On the other hand, 1 patient reported an unrecorded amputation after an infection in a primary registered joint. This amputation has been included as a failure in our study.

ANOVA indicated a significant effect of prosthesis type on patient score ($p = 0.005$). Further analysis showed that patients with a Ramses prosthesis had higher scores (i.e. poorer outcome) than patients with the Agility ($p = 0.001$), the STAR ($p = 0.001$), and the Mobility ($p = 0.002$) (Table 3).

There was no statistically significant evidence of any influence of other variables (i.e. patient

Table 3. Data on the 4 types of prosthesis

Prosthesis	Number of patients	Mean follow-up (in months)	Number of failures	Number of returned questionnaires	Patient score
Agility	117	32 (7–75)	9 (8%)	87	26 (12–53)
Mobility	29	10 (7–17)	0	19	27 (12–53)
Ramses	11	18 (7–23)	2	6	41 (26–58) [a]
STAR	45	43 (12–74)	3	36	26 (14–46)

[a] Significant difference from other prostheses.

age, sex, diagnosis, previous operations, or surgeon experience) on failure rate or patient score ($p > 0.05$).

Discussion

To our knowledge, this is the first TAR study based on national registry data. The New Zealand National Joint Registry has the advantage of keeping patient-based data from questionnaires in addition to the recorded joint-specific data.

The overall failure rate of 7% for 202 TARs with a mean follow-up of 28 months is difficult to compare with the current literature, as there are no comparable patient groups with regard to the use of 4 different implants. The rates for individual prostheses are comparable, however. With the Agility prosthesis, the failure rate of 9/117 ankles (8%) with a mean follow-up of 33 months compares favorably with the 11% (with a mean follow up of 33 months) previously reported for a series of 306 consecutive TARs (Spirt et al. 2004) and is similar to that for an Agility series reported by the designer of the prosthesis (Alvine and Conti 2006, Knecht et al. 2004).

The 7% failure rate for 45 STAR prostheses with a mean follow up of 43 months is somewhat lower than the 14% for 67 ankles found by Valderrabano et al. (2004) and is more in line with the 8% for 200 ankles reported by Wood and Deakin (2003). Furthermore, we found that the Ramses prosthesis had significantly worse patient scores than the STAR, Agility, and Mobility types (Table 3), which—although the numbers are small—should cause some concern. None of the Mobility prostheses had been revised, but the mean follow-up period of 10 months is very short. Overall, the 5-year survival rate of 86% for TARs is lower than the corresponding figures for total hip replacement (97%) and for total knee replacement (97%) derived from the New Zealand National Joint Registry.

An intriguing finding in this study is that higher, i.e. unfavorable, patient scores at 6 months after the initial procedure indicate an increased likelihood of failure. Although we acknowledge the greater value of using a validated health assessment tool like the SF-36 or FFI (Stengel et al. 2005), we have found that the use of our unvalidated questionnaire has proven to be a useful audit tool, particularly regarding its failure prediction. The finding that there is a 35% risk of failure at 5 years for patients with a patient score higher than 29 points clearly indicates that these patients should be monitored regularly. As part of the registry protocol, further questionnaires are to be sent out at 5 years after the index TAR procedure. Evaluation of these future results with respect to prosthesis failure will be very interesting.

Operative time for the primary procedure was longer in the group of TARs that subsequently failed. Reasons for longer operative time include the condition of the ankle preoperatively, inexperience of the surgeon, and the difficulty of the surgical procedure. A longer duration of surgery is associated with a higher failure rate, as it increases the risk of infection (Scott 1982). However, as only 2 of 14 ankles were revised for infection, there must be other explanations for the association in this study.

Some studies have suggested that there is a steep learning curve for TAR surgery (Conti and Wong 2001, Myerson and Mroczek 2003, Haskell and Mann 2004, Carlsson 2006), while Spirt et al.

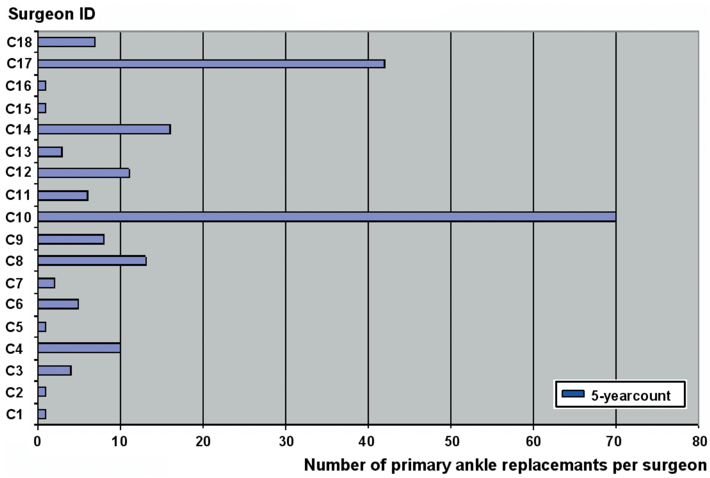

Figure 3. Total ankle replacements performed by 18 surgeons. Two surgeons performed more then 25 TARs within the study period.

(2004) found no evidence of a learning curve in a series of 306 consecutive ankles performed by the same surgeon. For most surgical procedures, it has been established that experience has a favorable effect on outcome (Obertop 2004). With regard to total hip replacement, it has been demonstrated that increased surgical volume is associated with lower dislocation rates (Battaglia et al. 2006). However, this current study showed no influence of surgeon experience on failure rate and patient scores, probably because there were insufficient registered procedures per surgeon for valid statistical analysis, as only 2 surgeons had performed more then 25 TARs (Figure 3).

We acknowledge that this registry-based study has certain weaknesses. The first weakness is that the Joint Registry is limited in the collection of information on soft tissue complications and radiographic changes. This may be offset to some extent by extra data derived from the "complications" section of the questionnaires. The complication data from the questionnaires adds value to the registry database, as well as being a useful audit tool.

The second weakness of this study is that the registry data did not represent all the TARs performed in New Zealand during our study period. Following contact with the individual surgeons, 45 unregistered TARs were discovered. As the focus of the paper was to determine the effect of different variables on patient scores, we had to exclude those cases from our analyses. All omissions occurred in the period at the beginning of the National Joint Registry, before strict compliance audits were implemented. It has since been compulsory for every New Zealand surgeon to comply with data collection, as it is a requirement for re-certification. In addition, suspected shortfalls in compliance are now rigorously investigated.

In conclusion, the National Joint Registry appears to be a useful tool for monitoring the trends in TAR surgery. Longer operative time and an unfavorable patient score turned out to have an adverse effect on prosthesis survival. The ankle questionnaire modeled on Oxford 12 would appear to be a very useful tool for prediction of failure, and will continue to be used.

Contributions of authors

AH and AR: designed the study. AH: conducted literature searches, analyzed all data, and drafted the manuscript. TH: contributed to the analysis. RM: contributed to the analysis and collected additional data. All authors read and approved the final manuscript.

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TOTAL ANKLE REPLACEMENT – QUESTIONNAIRE

Patient name:
Patient address:

Date of birth:
Operating surgeon:
Date of surgery:

We would llike you to score yourself on the following 12 questions. Each question is scored from 1 to 5, from least to most difficultu or severity: 1 beinng the least difficult/severe and 5 being the most difficult/severe. Please circle the number which best describes yourself OVER THE LAST 4 WEEKS

Please circle the SIDE on which yo had suregry performed Left Right

1. How would you describe the pain you usually have from your operated on ankle?
   1 None
   2 Very mild
   3 Mild
   4 Moderate
   5 Severe

2. For how long have you been able to walk before the pain from your operated on ankle becomes severe?
   1 No pain up to 30 minutes
   2 16 to 30 minutes
   3 5 to 10 minutes
   4 Around the house only
   5 Unable to walk at all because of severe pain

3. Have you been able to walk on uneven ground?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 Extreme difficulty
   5 No, impossible

4. Have you had to use an orthotic (shoe insert), heel lift, or special shoes?
   1 Never
   2 Occasionally
   3 Often
   4 Most of the time
   5 Always

5. How much has pain from your ankle interfered with your usual work (including housework and hobbies)?
   1 Not at all
   2 A little bit
   3 Moderately
   4 Greatly
   5 Totally

6. Have you been limping when walking because of your operated on ankle?
   1 No days
   2 Only one or two days
   3 Some days
   4 Most days
   5 Every day

5. Have you been able to climb a flight of stairs?
   1 Yes, easily
   2 With little difficulty
   3 With moderate difficulty
   4 with extreme difficulty
   5 Impossible

8. Have you been troubled by pain from your operated on ankle in bed at night?
   1 No nights
   2 Only one or two nights
   3 Some nights
   4 Most nights
   5 Every nights

9. How much has pain from your operated on ankle interfered with your usual recreational activities?
   1 Not at all
   2 A little bit
   3 Moderately
   4 Greatly
   5 Totally

10. Have you had swelling of your foot?
   1 None at all
   2 Occasionally
   3 Often
   4 Most of the time
   5 All the time

11. After a meal (sat at a table) how painful has it been for you to stand up from a chair because of your operated on ankle?
   1 Not at all painful
   2 Slightly painful
   3 Moderately painful
   4 Very painful
   5 Unbearable

12. Have you had any sudden severe pain – shooting, stabbing or spasms from your operated on ankle?
   1 No days
   2 Only one or two days
   3 Some days
   4 Most days
   5 Every day

Additional information

Have you at any time been hospitalised because:

	Yes	No	Approx date
The artificial joint dislocated?			
The joint became infected?			
or for any other reason related to the artificial joint:			

Hospital admitted to: