■ FOOT AND ANKLE

The outcome of total ankle replacement

A SYSTEMATIC REVIEW AND META-ANALYSIS

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We performed a systematic review and meta-analysis of modern total ankle replacements (TARs) to determine the survivorship, outcome, complications, radiological findings and range of movement, in patients with end-stage osteoarthritis (OA) of the ankle who undergo this procedure. We used the methodology of the Cochrane Collaboration, which uses risk of bias profiling to assess the quality of papers in favour of a domain-based approach. Continuous outcome scores were pooled across studies using the generic inverse variance method and the random-effects model was used to incorporate clinical and methodological heterogeneity. We included 58 papers (7942 TARs) with an interobserver reliability (Kappa) for selection, performance, attrition, detection and reporting bias of between 0.83 and 0.98. The overall survivorship was 89% at ten years with an annual failure rate of 1.2% (95% confidence interval (CI) 0.7 to 1.6). The mean American Orthopaedic Foot and Ankle Society score changed from 40 (95% CI 36 to 43) pre-operatively to 80 (95% CI 76 to 84) at a mean follow-up of 8.2 years (7 to 10) (p < 0.01). Radiolucencies were identified in up to 23% of TARs after a mean of 4.4 years (2.3 to 9.6). The mean total range of movement improved from 23° (95% CI 19 to 26) to 34° (95% CI 26 to 41) (p = 0.01).

Our study demonstrates that TAR has a positive impact on patients' lives, with benefits lasting ten years, as judged by improvement in pain and function, as well as improved gait and increased range of movement However the quality of evidence is weak and fraught with biases and high quality randomised controlled trials are required to compare TAR with other forms of treatment such as fusion.

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Osteoarthritis (OA) of the ankle is a disabling condition that affects a patient's quality of life as much as arthritis of the hip[1] and congestive heart failure.[2] The most common aetiological factor in the development of OA of the ankle is post-traumatic, often following fractures[3] and severe sprains of the ankle.[4] The incidence of both of these is rising[5-7] and hence post-traumatic OA of the ankle is likely to become an increasing health burden. The demand incidence of symptomatic ankle OA has recently been estimated to be 47.7 per 100 000 in the United Kingdom.[8]

Although fusion is the main form of treatment for end-stage OA of the ankle, total ankle replacement (TAR) is increasingly being recognised as an effective alternative,[9] especially with the introduction of a third generation of three-component mobile-bearing implants.[2,10,11] There are five national joint registries that capture details on the outcomes of TAR: in Finland (since 1980),[12] Norway (1994),[13] Sweden (1997),[14] New Zealand (2000),[15] and the United Kingdom (2010).[16] These registries provide an important contribution to our understanding of the performance of these replacements. However, all have limitations, including that data submission is voluntary, and only hard end points, such as revision, are reported which does not take into account failed or failing implants that are not revised.

Patients, surgeons, and healthcare funders, are increasingly seeking more details about outcomes of this technology and consequently we have carried out an up to date, systematic review and meta-analysis of the literature to look at the outcome of TAR

Materials and Methods

We searched MEDLINE, Cochrane, EMBASE, CINAHL and the Science Citation Index databases until December 2012 using the medical subject headings (MeSH) terms 'ankle', 'replacement', 'arthroplasty' and 'prosthesis' (Fig. 1). We included non-English papers and each study had to contain at least one end-point of clinical relevance. A Google search was also conducted and the contents of the

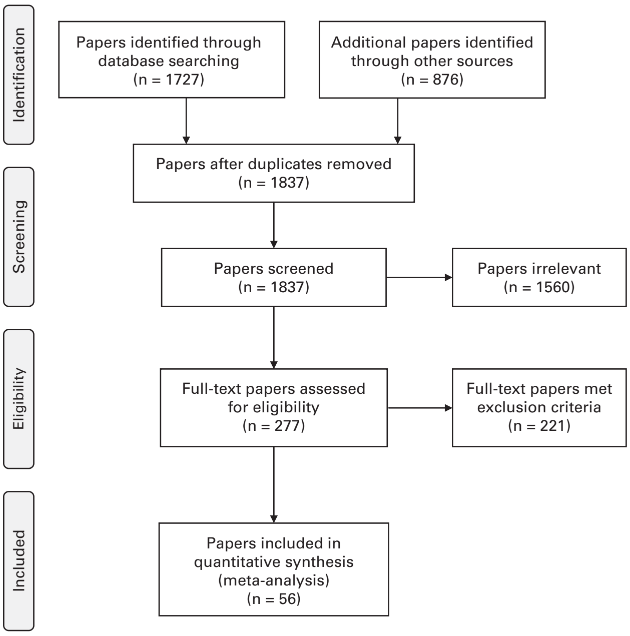

Fig. 1

PRISMA flow chart of the literature search.

Table I. Exclusion criteria for search (TAR, total ankle replacement)

	Exclusion criteria
1	Papers that reported on TARs that are no longer on the market
2	Papers relating only to revision
3	Papers that reported a series of < 20 TARs
4	Papers reporting on TARs with < two years follow-up
5	Studies published in non-peer-reviewed journals
6	Reviews, case reports, and basic science articles

Journal of Bone & Joint Surgery (American and British volumes), *Clinical Orthopaedics and Related Research*, *Foot and Ankle International*, and the *Journal of Foot and Ankle Surgery* were included. The reference lists of identified papers were also searched. Exclusion criteria were applied (Table I), based on previous systematic reviews.[17,18] The unit of analysis was the patient. Where studies had reported on the same cohort of patients at different follow-ups (kin studies), we ensured that every patient appeared only once and included data once from a kin study in analyses where both kin studies reported the same outcome at the same time-point.

Two reviewers (RZ, NS) assessed the paper for level of evidence,[19] and risk of bias using a tool that was adapted from the Cochrane handbook (Table II).[20] Bias is defined as systematic error, or deviation from the truth and is assessed in five different domains.[21] The data extracted from each study included patient demographics, numbers of TARs, clinical scores, survivorship, radiological outcomes, range of movement (ROM), gait, and intra- and post-operative complications.

Statistical analysis. Continuous outcome scores were pooled across studies using the generic inverse variance method. This method combines individual study outcomes using a weighted mean where the weight given to each study is chosen to be the inverse of the variance of the outcome estimate. Thus, larger studies which have smaller variances are given more weight than smaller studies which have larger variances. Variation in the study outcomes (statistical heterogeneity) was measured using Higgin's I^2 statistic.[20] A p-value of the chi-squared test of < 0.1 was considered to indicate significant statistical heterogeneity. In order to incorporate the observed heterogeneity the random-effects model was used.[22] Where there was no evidence of statistical heterogeneity the fixed-effects model was used. In order to examine overall survivorship we extracted data on the total number of failures and total exposure time (sum of the exposure time of the failures and non-failures). We were able to extract the exposure times of all the failures.

Where a study presented a life table of survivorship or a Kaplan–Meier curve, we were also able to extract detailed exposure time of the non-failures. In the absence of a life table or Kaplan–Meier graph we assumed that non-failures survived for the mean follow-up time of the study. We used the mean as this was readily available. Annual rates of revision were calculated for each study by dividing the total number of failures by the total patient exposure time (in years).[23] Revisions were assumed to be Poisson-distributed counts and confidence intervals were calculated. Revision rates were pooled for each study, weighted using the generic inverse variance method. Survival proportions were calculated from the relationship between the event rate and survival, assuming constant rates. The statistical formula used to calculate survival from the yearly failure rate is: Survival at time $T = (\mathrm{EXP}(-T \times Y))$ (where T is the timeframe, and Y is the annual failure rate (AFR).[23] Meta-analysis of proportions was applied to the complications and radiological data.

All statistical analysis was performed using Stata/IC version 12.0 (StataCorp, College Station, Texas) and StatsDirect statistical software (StatsDirect Ltd, Altrincham, United Kingdom).

Results

The abstracts of 1837 studies were reviewed and 1560 papers were excluded for not being relevant to the topic, leaving 277 that were studied in detail. Of these, 219 met the exclusion criteria, leaving 58[11-15,24-76] for analysis (Fig. 1). The analysis included a total of 7942 TARs. For the various types of bias the interobserver reliability was excellent (kappa values of 0.83, 0.97, 0.9, 0.98, 0.98, respectively) between the two reviewers (RZ, NS) ($p < 0.01$). For level of evidence the interobserver reliability was also excellent (kappa 0.87, $p < 0.01$).

Table II. Bias is defined as systematic error or deviation from the truth and is assessed in five different domains, adapted from Cochrane handbook[20]

Type of bias	Description	Relevant domains in the collaboration's 'Risk of bias' tool
Selection bias	Systematic differences between baseline characteristics of the groups that are compared	Sequence generation. Allocation concealment
Performance bias	Systematic differences between groups in the care that is provided, or in exposure to factors other than the interventions of interest	Blinding of participants, personnel and outcome assessors. Other potential threats to validity
Attrition bias	Systematic differences between groups in withdrawals from a study	Incomplete outcome data. Blinding of participants, personnel and outcome assessors
Detection bias	Systematic differences between groups in how outcomes are determined	Blinding of participants, personnel and outcome assessors. Other potential threats to validity
Reporting bias	Systematic differences between reported and unreported findings	Selective outcome reporting

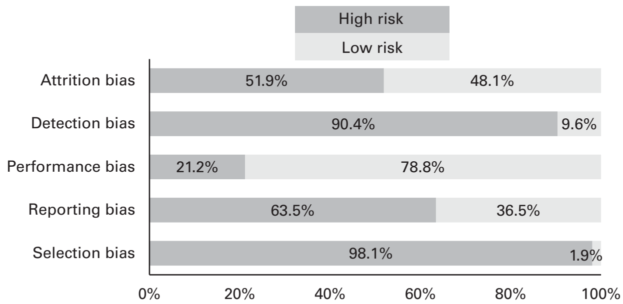

Fig. 2

Risk of bias profile of the total ankle replacement in the literature.

Most studies were level IV (n = 39, 70%). Level V studies were excluded by design and there were no level I studies. Only one randomised controlled trial comparing two different TARs has been published,[66] and this was classified as level II. Level II and III studies formed 7% (n = 4) and 23% (n = 13), respectively. There were intrinsic biases in all the papers (Fig. 2). We planned to perform sensitivity analyses to determine the validity of our findings by study quality, however, as there was a high risk of bias in all the studies we did not proceed with this.

Table III details the distribution of reported data from the 58 papers. A total of 41 papers (comprising 5292 patients) gave breakdown of gender, of which 52% were female and 48% male. The mean age across all the studies was 60 years (17 to 95). Body mass index (BMI) was reported by only 11 papers (1370 patients), giving a mean BMI of 28 kg/m^2 (SD 1.8; 19 to 44) (Table III). The indication for surgery was given in 36 papers (5529 patients). The most common indication was post-traumatic OA (46%, 2543 patients), followed by primary OA (27%, n = 1493) and rheumatoid arthritis (19%, n = 1051) (Table III, Table IV).

Implants. The STAR prosthesis (Small Bone Innovations Inc., Morrisville, Pennsylvania) was used in the highest number of publications and the Hintegra (Integra Life Sciences, New Jersey,) had the greatest numbers of TARs in the literature (Table V).

Complications. Details of intra-operative complications were found in 24 studies (2706 patients) (Table III). These included a rate of medial malleolar fracture of 6% (95% CI 3.5 to 9), a rate of intra-operative nerve injury of 1.3% (95% CI 0.5 to 2.3) and a rate of lateral malleolar fracture of 1% (95% CI 0.05 to 1.8). Post-operative complications were reported in 41 papers (5579 patients), with an overall rate of incidence of 13.5% (95% CI 9.7 to 17.7) (Table III). These included re-operation other than revision in 2.7% (95% CI 1.0 to 4.9), superficial infection in 2.4% (95% CI 1.3 to 3.8), deep infection in 1.1% (95% CI 0.7 to 1.7) and thromboembolic events in 0.3% (95% CI 0.1 to 0.5).

Clinical outcomes. Although 44 papers reported the use of clinical scores, we only included those reporting pre- and post-operative values. The most frequently reported measure was the American Orthopaedic Foot & Ankle Society (AOFAS) score[77] in 27 papers, followed by a visual analogue scale (VAS; from 0 to 10, with 10 denoting the worst pain) for pain in seven papers (Table III). Only two studies included a quality-of-life score, the Short-Form 36.[77] The mean pooled summary estimate AOFAS score improved from 40 (95% CI 36 to 43) pre-operatively to 80 (95% CI 76 to 84) between seven and ten years post-operatively ($p < 0.01$) (Table VI). The mean pooled summary VAS scores went from 7.4 (95% CI 6.8 to 7.9) pre-operatively to 1.6 (95% CI 1.4 to 1.8) at four to five years post-operatively ($p < 0.01$).

Range of movement (ROM). ROM data was available in 11 papers, of which nine presented pre-operative total ROM data (Table III). The mean pooled pre- and post-operative total ROM changed from 23° (95% CI 19 to 26) to 34° (95% CI 26 to 41) (p = 0.01). The mean pooled pre- and post-operative dorsiflexion was 4.6° (95% CI 2.3 to 6.9) and 8.0° (95% CI 7.5 to 8.5) (p = 0.01). The mean pooled pre- post-operative plantar flexion improved from 17° (95% CI 12 to 21) to 19° (95% CI 13 to 26) (p = 0.53).

Survivorship. Long-term registry revision data was presented in four papers (n = 2239) (Table III). The mean pooled ten-year survival rate was 73% (95% CI 64 to 82) with a mean AFR of 3.2% (95% CI 2.0 to 4.4) and 11 non-registry studies (n = 855) with long-term data were also

Table III. Distribution of reported data in the 56 studies

Data reported*	Papers (reference numbers)
Body mass index	11, 24, 29, 30, 39, 42, 47, 49, 50, 61, 73
Aetiology of osteoarthritis	11, 12, 14, 15, 24, 28, 32, 34, 37, 38, 40-47, 49-53, 55-60, 62, 63, 65-69, 75
Complications	
Intra-operative	11, 26, 29, 32, 34-37, 40, 42, 44-46, 48, 53, 55-59, 64, 65, 68, 69
Post-operative	11-15, 24-26, 29, 32, 34-42, 44-47, 49, 51, 53-60, 62, 64, 65, 68, 69, 74-76
AOFAS	24, 26, 28-30, 33-37, 39, 41, 42, 44, 49, 50, 52, 55, 57, 58, 61-63, 65-67, 69
VAS for pain	28, 29, 50, 55, 58, 65, 69
Short-Form 36	52, 76
Range of movement	
Pre-operative	27, 28, 31, 32, 41, 42, 55, 57, 68
Post-operative	26-28, 31, 32, 37, 41, 42, 55, 57, 68
Long-term revision data	
Registry-based	12-14, 73
Non-registry-based	24, 29, 30, 32, 43, 49, 57, 67, 71, 74, 75
Radiological results	11, 26, 28, 30, 32, 33, 35, 37, 38, 40-44, 49, 50, 53, 55, 57, 59, 62, 63, 65, 67-69

* AOFAS, American Orthopaedic Foot & Ankle Society; VAS, visual analogue scale

Table IV. Aetiology of ankle osteoarthritis

Aetiology of osteoarthritis	%
Post-traumatic	46
Primary	27
Rheumatoid	19
Inflammatory	1.0
Systemic	1.0
Post-infection	4.0
Secondary to instability/malalignment	0.05
Haemophilia	0.02
Psoriatic	0.02
Haemochromatosis	0.01
Other	3.0

Table V. Number of papers and size of the study related to each type of total ankle replacement

Prosthesis	Manufacturer (address)	Papers (n)	Prostheses (n)
BOX	MatOrtho Ltd (Leatherhead, United Kingdom)	3	230
BP	Endotec (Orange, New Jersey)	6	324
STAR	Small Bone Innovations, Inc. (Morrisville, Pennsylvania)	14	1283
HINTEGRA	Integra LifeSciences Services (Saint Priest, France)	7	1652
SALTO	Tornier N.V. (Amsterdam, the Netherlands)	2	316
AGILITY	DePuy (Warsaw, Indiana)	9	969
MOBILITY	DePuy (Warsaw, Indiana)	3	370
TNK	KYOCERA Medical Corp. (Osaka, Japan)	1	21
Mixed cohort		11	2777
Total		56	7942

pooled to report survivorship (Table III). This showed an overall ten-year survival rate of 89% (95% CI 85 to 93) with a mean AFR of 1.2% (95% CI 0.7 to 1.6) (Table VII). In papers from the surgeon designer of the TAR the mean AFR was 1.1% (95% CI 0.7 to 1.5) compared with those for non-surgeon-designer papers in which the mean AFR was 1.7% (95% CI 1.2 to 2.2).

Radiological findings. Radiological outcomes were reported in 26 papers (3045 ankles) (Table III). At a mean follow-up of 4.4 years, radiolucencies were reported adjacent to a mean of 21% (95% CI 13 to 30) of the tibial and 1.4% (95% CI 0.5 to 2.7) of the talar components. Of these, only 9.4% of the patients underwent further surgery or a revision.

OA in the adjacent joints was reported in four papers,[11,43,49,67] of which only three mentioned the presence of pre-operative OA in the adjacent joints. The progression of OA in the subtalar joint ranged from 19% to 59%, seen at a mean follow-up of seven years (5.0 to 9.6).

Gait analysis. The three gait studies[31,39,61] showed significant increases in gait velocity cadence, and stride length

Table VI. Analysis of American Orthopaedic Foot and Ankle Score (AOFAS) and change over time (CI, confidence interval)

		Mean (SD) AOFAS score	
Study	**n**	**Pre-operative**	**Post-operative**
1- to 2-year follow-up			
Hintermann et al[37]	125	40 (10)	85 (17)
Giannini et al[35]	158	36 (19)	75 (22)
Valderrabano et al[61]	15	34 (9.0)	93 (4.5)
Ingrosso et al[39]	10	44 (9.0)	81 (7.0)
Pooled estimate (95% CI)		38* (35 to 42)	84* (75 to 92)
Total		n = 308	n = 308
2- to 3-year follow-up			
Barg et al[27]	92	35 (15)	74 (11)
Giannini et al[35]	158	36 (19)	79 (4.7)
Kim et al[41]	45	54 (12)	81 (11)
Rippstein et al[55]	240	48 (18)	84 (12)
Valderrabano et al[63]	152	36 (16)	84 (18)
Pooled estimate (95% CI)		42* (35 to 49)	80* (77 to 84)
Total		n = 687	n = 687
3- to 4-year follow-up			
Giannini et al[35]	158	36 (19)	76 (5.7)
Hintermann et al[36]	278	40 (12)	85 (14)
Bai et al[26]	67	49 (10)	86 (7.4)
Kim et al[42]	348	43 (17)	72 (18)
Schenk et al[58]	218	51 (17)	82 (14.0)
Wood et al[65]	100		79 (11)
Naal et al[50]	123	46 (17)	84 (13)
Valderrabano et al[62]	74	25 (10)	84 (14)
Kopp et al[44]	43	34 (15)	83 (8.8)
Pooled estimate (95% CI)		40* (35 to 46)	81* (78 to 85)
Total		n = 1409	n = 1409
4- to 6-year follow-up			
Giannini et al[35]	158	36 (19)	79 (1.5)
Barg et al[28]	317	37 (16)	75 (12)
Wood et al[66]	200		80 (7.4)
Claridge et al[34]	28	35 (12)	77 (4.7)
Ali et al[24]	34	35 (9.0)	76 (11)
Barg et al[29]	123	35 (18)	75 (11)
Nunley et al[52]	91	34 (13)	86 (11)
Bianchi et al[69]	62	35 (17)	78 (11)
Pooled estimate (95% CI)		36† (35 to 37)	78* (77 to 80)
Total		n = 813)	n = 1013
7- to 10-year follow-up			
Wood et al[67]	200		75 (10)
Choi et al[33]	90	55 (12)	83 (11)
San Giovanni et al[57]	31		81 (13)
Bonnin et al[30]	98	27 (8.9)	79 (12)
Mann et al[49]	84	43 (15)	82 (15)
Pooled estimate (95% CI)		40* (36 to 43)	80* (76 to 84)
Total		n = 503	n = 503

* based on random-effects, tests for heterogeneity, p < 0.01
† based on fixed-effects, p = 0.64. The pooled mean pre-operative AOFAS over all unique studies with reported AOFAS data, n = 2915, was 40 (95% CI 36 to 43)

after TAR at a mean follow-up of two years, two showed an increase in the power of the ankle. No correlation of gait with clinical scores was reported.

Discussion

We employed broad search terms, including papers in non-English languages, and applying risk of bias profiling to nearly 8000 TARs. The mean age at operation was 60 years (17 to 95), which is lower than that for hip (68 years) or knee (69 years) replacement reported in the Swedish joint registry.[78] The most common indication for surgery was post-traumatic OA (46%), followed by primary OA (27%) and rheumatoid arthritis (19%) (Table IV). This differs markedly from hip and knee replacement where more than

Table VII. Survival analysis of non-registry data at ten years

Study	Total (n)	Mean follow-up (yrs)	Maximum follow-up (yrs)	Revisions (n)	Total exposure (yrs)	Estimated failure rate per year	Estimated survival after ten years
Non-registry studies							
Ali et al[24]	34	5	13	1	168	0.006	0.942
Barg et al[28]	123	5	10	6	622	0.010	0.908
Bonnin et al[30]	96	9	11	12	802	0.015	0.861
Buechel et al[32]	50	5	10	2	282	0.007	0.932
Criswell et al[74]	42	8	11	16	296	0.054	0.582
Knecht et al[43]	96	9	16	14	820	0.017	0.843
Mann et al[49]	84	9	11	9	860	0.010	0.901
San Giovanni et al[57]	30	8	12	2	240	0.008	0.920
Wood et al[67]	200	7	13	24	1144	0.021	0.811
Buechel et al[32]	75	5	12	6	905	0.007	0.936
Kofoed et al[71]	25	9	12	1	238	0.004	0.959
Total	855			Pooled estimate*		0.012 (0.007 to 0.016)	0.887 (0.852 to 0.932)
Registry studies							
Fevang et al[13]	216	3	12	21	692	0.030	0.741
Henricson et al[14]	780	6	10	158	3703	0.043	0.651
Skyttä et al[12]]	515	3	10	59	1664	0.035	0.705
Tomlinson[73]	728	-	11	50	2496	0.020	0.819
Total	2239			Pooled estimate*		0.032 (0.020 to 0.044)	0.726 (0.644 to 0.819)

* based on random-effects, test for heterogeneity, p = 0.01

93% of patients have primary osteoarthritis.[16] Clinical scores including the AOFAS and visual analogue scale for pain showed statistically significant improvements ten years post-operatively. The longest previous reported improvement in AOFAS after TAR was 44 months.[17]

We have shown a hierarchy of survival data, with the best results being obtained by surgeon designers who reported a mean AFR of 1.1%. In contrast, non-surgeon-designers centres reported a mean AFR of 1.7%, and national joint registries reported a mean AFR of 3.2% ($p < 0.01$). The lower AFR reported by surgeon designers is likely to represent a familiarity with the implant and hence the most likely group to get the best results,[18] although this could also represent reporting bias.[78] Registries collect data in a prospective fashion using standardised datasets, and are analysed by a fully independent group.[79] They include a wide range of data from surgeons, including those carrying out small volumes, and surgeons who are within their learning curves, and would be expected to have higher rates of failure.

We have termed this phenomenon of different survivorship data being reported by surgeon designer, independent groups and registries the ‘cascade of generalisability’ since survivorship falls across these groups. In the absence of high quality level I studies, governments and healthcare funders are more likely to use data from registries to estimate cost-effectiveness as these are most likely to represent the real world situation. The higher AFR reported by registries may also be explained by the inclusion of data from implants, which are no longer being used. Such withdrawn implants were not included in our study but are included in the registry data.

Limitations to this work include the inherent poor quality of the evidence. Most papers are level IV evidence, which corroborates the findings of Easley et al[9] and although a meta-analysis should only include RCTs[80,81] this is not possible in areas where there are none. Our use of risk of bias profiling[20,82] allows a larger volume of papers to be included in order to assess their true impact, which in this study has shown that the major weaknesses in the literature were associated with selection, attrition and detection biases (Table II). Because of the high risk of bias in the studies, it is possible that the effect estimates, such as the proportion of TARs which survived, may not reflect the actual proportion which survived. However, it is not possible to quantify the difference between the observed effect estimates and the true value. We appreciate that outcomes might be related to the type of implant or surgical technique, although a lack of sufficient papers relating to certain TARs made meta-analysis by type of implant impossible. Similarly, variability in data reporting prevented us from analysing the mode of failure.

A further limitation includes the variation of outcome measures and the absence of a consistent definition of revision. Henricson et al[83] recommend that revision be defined as removal or exchange of one of the components. All other operations including exchange of polyethylene insert constitute “re-operation, other than revision”.

The most common clinical score which was reported was the AOFAS score, and although there were improvements in this score, this is partly a result of improved range of movement, and does not necessarily indicate that other components of the score have improved. Since the AOFAS score has not been validated its continued use has been discouraged.[84] In the United Kingdom, foot and ankle surgeons are increasingly using the Manchester & Oxford Foot & Ankle Questionnaire,[85] which is a validated patient reported outcome measure. A validated quality of life score such as the SF-36 is also likely to become a requirement in order to assess cost-effectiveness and we recommend this approach to ensure more consistent and better reporting of outcomes.

This study did not set out to directly compare TAR with other forms of treatment such as fusion. A study by Haddad et al[81] has shown that the mid-term outcome of TAR appears to be similar to that of fusion but they also highlighted the poor quality of supporting data.

We have shown that TAR has an overall survivorship of up to 89% at ten years, however, there is a prevalence of lucencies is up to 23% after a mean of 4.4 years. The significance of this finding is unclear and randomised controlled trials are needed which include patient reported outcomes and the cost-effectiveness of TAR compared with fusion in patients with end-stage OA of the ankle.

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