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Review

Patient reported outcome measures in ankle replacement versus ankle arthrodesis – A systematic review

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ABSTRACT

Objectives: Compare the functional outcomes of comparative studies of ankle arthrodesis (AA) and total ankle replacements (TAR).
Design: Systematic review using PRISMA guidelines.
Data Sources: Medline, Cochrane and EMBASE databases in July 2020.
Eligibility Criteria: Studies that directly compared TAR and AA which reported patient reported outcomes measures (PROMs) of pain, function and quality of life.
Data Extraction and Synthesis: Two authors independently reviewed all papers. PROMs were allocated into pain, function or quality of life domains. Two summary statistics were created to allow for analysis of the PROMs. These statistics were the mean difference in post-operative score and the mean difference in the change of score.
Results: 1323 papers were assessed of which 20 papers were included. 898 ankle arthrodesis and 1638 ankle replacements were evaluated. The mean follow up was 3.3 years (range 0.5–13.0 years). AA patients had a mean age of 55.7 (range 20–82) and TAR 62.5 (range 21–89).
There was major heterogeneity in outcomes used. We were unable to find a significant difference between the reported change in PROMs following TAR and AA. 29.3% of PROMs and their subscores showed TAR had better outcomes, 68.7% showed no significant difference and only 2.0% showed AA to have better outcomes.
Conclusions: The majority of published studies found equality in patient reported outcomes following TAR and AA although the quality of the studies was of low-level evidence. There is an urgent need for randomised controlled studies to definitively answer this important clinical question.

1. Introduction

Ankle arthrodesis (AA) and total ankle replacement (TAR) are two recognised surgical treatments in the management of end-stage ankle osteoarthritis. AA has been traditionally viewed as the gold-standard but concerns regarding adjacent joint arthritis [1–3] have led to a resurgence of interest in TAR [4,5].

The theoretical benefit of TAR is the maintenance of the range of movement of the ankle and which therefore might improve functional outcomes. However, the cumulative annual failure rates for TAR have been estimated at 1.7% (95% CI 1.2–2.2) [6], which is double that of total hip and knee replacements [7]. In the absence of any published randomised controlled trials debate continues as to whether TAR or AA produce superior outcomes [8,9].

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Haddad et al. (2007) carried out a systematic review and meta-analyses of TAR vs AA [10] but did not contain studies directly comparing TAR against AA. The review concluded that both operations had similar outcomes with a 9% revision rate following ankle arthrodesis compared to 7% for ankle replacements, but with a higher amputation rate in AA [10]. Other systematic reviews have concluded that both AA and TAR have similar outcomes [1,11,12]. Since these publications several new comparative studies have been published.

The aim of this systematic review was to specifically compare the patient reported outcome measures (PROMs) between TAR and AA, using only comparative studies, in particular with regard to pain, function and quality of life.

2. Methods

A systematic review of functional outcomes in comparative studies of total ankle replacements and ankle arthrodesis was undertaken.

2.1. Data sources

A literature search of Medline, Cochrane and EMBASE, from January 1981 to July 2020 using the medical subject headings (MeSH) terms 'ankle,' 'arthroplasty,' 'replacement,' 'arthrodesis,' and 'fusion' was performed (Appendix 1).

2.2. Study selection

The inclusion criteria were (1) studies comparing both AA and TAR, (2) studies that quantitatively reported PROMs, (3) patients with ankle arthritis, (4) currently used TAR implants, (5) any arthrodesis technique, (6) all levels of evidence (7) all patient reported outcome measures and (8) a minimum of 10 patients in each treatment arm at follow up. The exclusion criteria were (1) papers not published in English, (2) papers including other treatments for ankle arthritis (3) papers where individual scores could not be calculated. Non comparative studies were excluded that only analysed the functional results of either ankle arthrodesis or total ankle replacement.

2.3. Data extraction

All papers were reviewed by two authors at all stages of the review. When there was any uncertainty at any stage of the review process, the paper was reviewed by a third author to make the final decision. The studies were selected by reviewing the title and abstract and then the full paper against the eligibility criteria. The references of papers which met the selection criteria were reviewed for further papers. The Newcastle-Ottawa Score (NOS) was used to assess the quality of papers [13–15].

2.4. Data synthesis and statistical analysis

All functional PROMs were included. Mean pre-operative and post-operative PROMs were extracted from the data. There was no specified time that these results were collected due to the large heterogeneity in reporting.

All PROMs that were reported in the studies were reviewed and then grouped into domains which were pain, function, or quality of life (QoL).

Two summary statistics were created to allow for analysis of the PROMs. The mean difference in the post-operative score (MDPOS) between the two operations was calculated by subtracting the post-operative scores in AA and TAR from each other.

The mean difference in the change of score (MDCS) was calculated by subtracting the difference between the AA pre- and post-operative scores from the difference between the TAR pre- and post-operative scores. Calculations were performed so that positive results equate to TAR demonstrating improved functional outcomes and negative score showed the AA were superior. Stata (version 15) was used to calculate the summary statistics for the two papers which provided raw results. In one paper, the results for open and arthroscopic approaches to AA were presented separately. These results were combined before being used in subsequent calculations. Means, standard errors and standard deviations were calculated when sufficient data was included. These were used to calculate confidence intervals or p values to determine significance. A p value of <0.05 was taken as significant.

A meta-analysis was not performed due to the considerable heterogeneity in study design and outcome measures. The data required to perform a meta-analysis was not present in the majority of studies. Furthermore, the studies were not plausibly measuring the same underlying outcome with respect to design and PROM used [16]. Therefore, it was not possible to conduct a meta-analysis of the available evidence.

2.5. Patient and public involvement

No formal patient involvement.

3. Results

A total of 1323 papers were identified through the search strategy once duplicates were removed with 20 papers satisfying the eligibility criteria. Fig. 1 contains the PRISMA flow chart of the selection process. Tables 1 and 2 contains the study and patient characteristics. A total of 898 patients underwent ankle arthrodesis and 1638 total ankle replacement.

The mean follow up was 3.3 years (range 0.5–13.0 years). AA patients had a mean age of 55.7 (range 20–82) and TAR 62.5 (range 21–89). The mean NOS score was 6.9 (SD 0.9). Nine different TAR were included.

There was variation in how the papers reported the 20 PROMs with some papers only reporting the total score for a PROM while other papers reported PROM subscores. Therefore, there were 66 different PROM subscores reported.

The function domain (Table 3) was the most numerous with 42 different outcome scores reported. The mean difference in post-operative score (MDPOS) was calculated in 52 data sets. Six (11.5%) showed that TAR had significantly better outcomes, 17 (32.7%) demonstrated no significant difference and 29 (55.8%) had insufficient data to draw statistical conclusions. For mean difference in change of score (MDCS), 33 data sets were calculated. There was no significant difference in 21 (63.6%) of the PROMs subsets, 9 (27.3%) data sets showed significantly better outcomes with TAR, and it was not possible to calculate the statistical significance in 3 (9.1%) of the data sets. Zero studies showed AA to be superior in either the MDPOS or the MDCS within the function domain.

In the pain domain (Table 4), there were 11 PROMs analysed. The MDPOS was calculated in 24 data sets. Five MDPOS (20.8%) showed significantly better results with TAR and 25.0% demonstrated no significant difference. One score (4.2%) demonstrated significantly better outcomes with AA. 18 data sets were calculated for the MDCS. There was no significant difference in 61.1% of the data sets for MDCS, 16.7% showed significantly better outcomes with TAR. One (5.6%) of the MDCS data sets demonstrated significantly different change in pain scores with arthrodesis in comparison with TAR.

There were 13 different PROMs within the QoL domain (Table 5). 19 data sets for MDPOS were calculated. 3 (15.8%) MDPOS data sets demonstrated significantly better outcomes with TAR, 8 (42.1%) demonstrated no difference, and in 8 (42.1%) significance could not be determined. The MDCS was calculated for 9 data sets. TAR was superior in three (33.3%) instances and 5 (55.6%) data sets showed no significant difference. No score favoured ankle arthrodesis.

There was a theoretical maximum of 208 scores if sufficient data was included within the studies to calculate the scores. The papers found

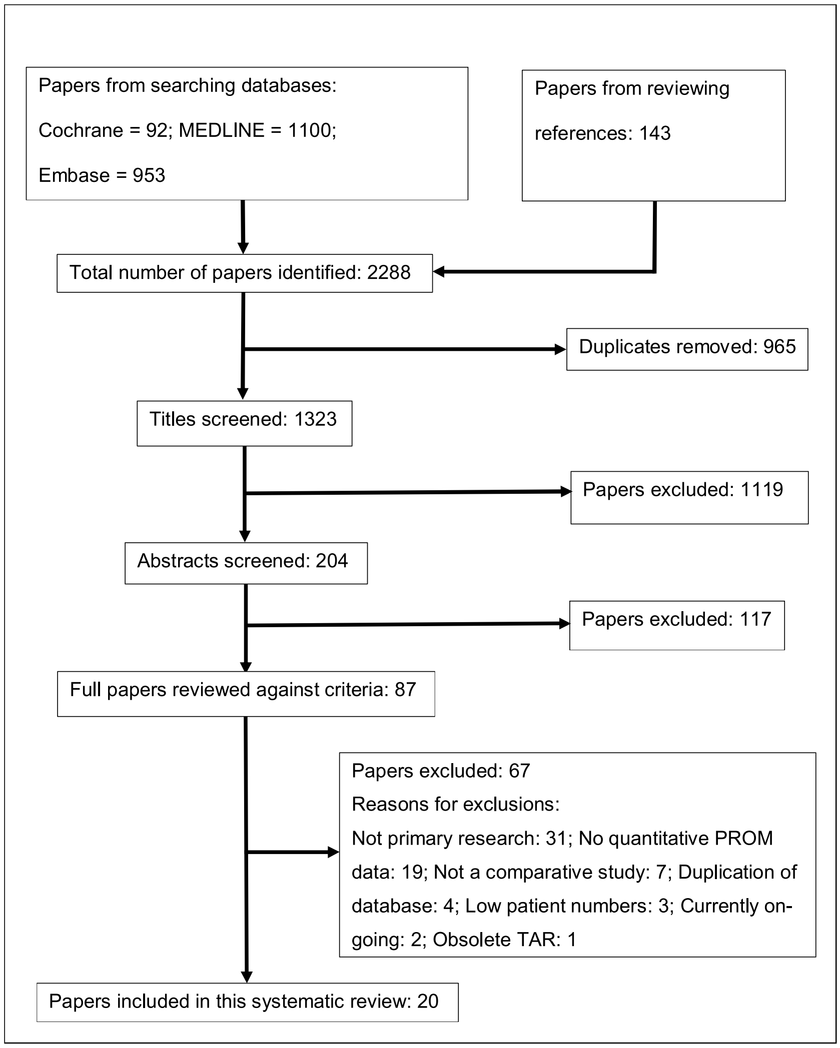

Fig. 1. PRISMA flow chart.

allowed for 155 (74.5%) of the theoretical maximum number of scores to be calculated.

Of the scores calculated (155) across all the domains, there was no significant difference in 43.9% of data sets. It was not possible to calculate significance in 36.1% of data sets, and TAR was superior in 18.7% of results. There was only one score in both MDCS and MDPOS in a single paper (1.3%) where AA was shown to have statistically significant outcomes than TAR.

Overall, of the scores where significance could be calculated across all the domains (99), TAR was shown to be superior in 29.3% (29) of data sets (MDPOS 14 (30.4%), MDCS 15 (28.3%)), AA was superior in 2 (2.0%) data sets (MDPOS 1 (2.2%), MDCS 1 (1.9%) and there was no significant difference in 68 (68.7%) of data sets (MDPOS 31 (67.4%), MDCS 37 (69.8%).

4. Discussion

To our knowledge, this is the first study to compare PROMs grouped by domains and directly compare the different PROMs between ankle replacement and arthrodesis. This allowed for a greater body of evidence to be reviewed and analysed than in previous reviews. All the studies included within this review were either level 2 or 3 evidence and there was considerable heterogeneity within study designs [36].

TAR was found to give significantly improved outcomes compared to ankle arthrodesis in 30.4% of MDPOS and 28.3% of MDCS where significance was calculated. Only one study with regards to the pain scores, both MDPOS and MDCS, demonstrated AA to be superior than TAR.

The studies within this systematic review used a wide range of different PROMs without any consistency of reporting or statistical analysis. Many of the PROMs used have not been validated as outcome measures [37,38], and incomplete data resulted in being unable to reliably calculate the statistical significance in 36.1% of scores. This heterogeneity in PROMs makes interpretation and comparison of results from individual studies next to impossible.

Nine different TAR were included in this review and each prosthesis has different reported longitudinal data, and differing surgical techniques. In addition, reporting bias could have impacted on the relevance of the clinical results. The STAR (Stryker, Michigan, USA) prosthesis for example, has high rates of reported patient satisfaction [39–41].

In the National Joint Registry for England, Wales and Northern Ireland the most commonly used ankle replacement implants have drastically changed over the last 5 years. In 2018, the most commonly used implant was the Infinity (Wright Medical, TN, USA) with the STAR and Box (MatOrtho, Leatherhead, UK) implants the second and third most popular [4]. Only the Infinity implant was not used in any of the published studies we reviewed. Therefore, the interpretation of the results of this study does not reflect the current most commonly used ankle replacement. Although this implant is currently subject to a prospective industry funded post market surveillance non-comparative study. Early

Table 1
Study characteristics.

Primary Author	Year	Study Design	Study Timing	Evidence Level [18] (all therapeutic)	Single or Multicentre	Implant Used	Arthrodesis Technique
Benich [17]	2017	Non-randomised trial	Prospective	2	Multicentre	Agility, Inbone, Salto	Rigid internal fixation
Braito [18]	2014	Cohort	Retrospective	3	–	Hintegra	–
Dalat [19]	2014	Case-control	Retrospective	3	–	Ankle evolutive system (AES)	Anterolateral approach with screw fixation or titanium staple
Daniels [20]	2014	Cohort	Prospective	2	Multicentre	Agility, Hintegra, Mobility, STAR	Open or arthroscopic
Esparragoza [21]	2011	Non-randomised trial	Prospective	2	Single-centre	AES	Open anterior approach with retrograde transalcaneum nail, transarticular screw or Charnley compressor
Henricson [22]	2016	Cohort	Retrospective	3	Multicentre	AES, Ceramic coated implant, Mobility, STAR	Retrograde intramedullary nail or screw fixation
Jastifer [23]	2015	Cohort	Prospective	2	–	STAR	Open anterior or open lateral approach with plate fixation
Kofoed [24]	1994	Case-control	Prospective	3	Single-centre	Hintegra, STAR	Charnley compression frame
Krause [25]	2011	Cohort	Retrospective	3	–	Agility, Hintegra, Mobility, STAR	Open or arthroscopic
Mehdi [26]	2019	Cohort	Retrospective	3	Single-centre	Salto	Open by cross screws or anterior locking plate
Norvell [27]	2019	Cohort	Prospective	3	Multicentre	–	–
Pedowitz [8]	2016	Cohort	Retrospective	3	Single-centre	Salto	Anterior approach
Rajapakshe [28]	2019	Cohort	Prospective	3	Single-centre	–	–
$Saltzman_1$ [29]	2009	Non-randomised trial	Prospective	2	Multicentre	STAR	Lateral approach
$Saltzman_2$ [30]	2010	Cohort	Retrospective	3	Single-centre	STAR	Cannulated screws, screws and plate or external fixator
Schuh [31]	2012	Cohort	Retrospective	3	–	Hintegra	Self-cannulated screws under fluoroscopic visualisation
Segal [32]	2018	Non-randomised trial	Prospective	2	Single-centre	Agility, Salto	Open internal screw fixation
Singer [33]	2013	Non-randomised trial	Prospective	2	Single-centre	Hintegra, STAR	–
Veljkovic [34]	2019	Cohort	Retrospective	3	Multicentre	Hintegra	Rigid internal fixation with compression with cancellous screws
Wasik [35]	2019	Cohort	Retrospective	3	Single-centre	Salto Tolaris, AES, J&J	Open surgery by Campbell or Adams technique

Table 2
Patient characteristics.

Primary Author	Patient Numbers		Follow Up in Years (Range)		Age (Range)		Gender (Male%/Female%)		NOS Score
	AA	TAR	AA	TAR	AA	TAR	AA	TAR	
Benich [17]	103	170	3.0 (–)		57.4 (27–82)	64.4 (35–89)	59.2%/40.8%	52.3%/47.7%	7
Braito [18]	16	62	No mean (Minimum value is 0.5)		Not documented		Not documented		5
Dalat [19]	22	32	4.8 (1.0–12.2)	4.4 (2.5–12.2)	51.4 (22–37)	50.4 (24–72)	68.2%/31.2%	59.4%/40.6%	8
Daniels [20]	107	281	5.2 (4.0–8.0)	5.6 (4.0–9.8)	53.5 (SD = 12.3)	63.6 (SD = 10.7)	60.0%/40.0%	54.0%/46.0%	8
Esparragoza [21]	16	14	2.1 (1.5–2.2)		61.0 (42–73)	64.0 (48–77)	62.5%/37.5%	57.1%/42.9%	6
Henricson [22]	16	16	5.5 (1.0–13.0)	6.1 (1.0–12,1)	55.3 (34–75)	55.3 (34–75)	Not documented		5
Jastifer [23]	19	76	1 (–)		60.2 (33–73)	65.2 (34–83)	Not documented		7
Kofoed [24]	14	14	7.4 (4.8–10.0)	7.3 (5.0–9.7)	45.3 (21–71)	52.1 (22–71)	Not documented		6
Krause [25]	47	114	3.0 (2.3–9.1)	3.2 (2.1–5.7)	58.5 (28–82)	64.2 (36–88)	68.1%/31.9%	55.3%/44.7%	7
Mehdi [26]	25	25	5.6 (3.3–8.8)		62 (52–81)	60 (27–82)	68%/32%	60%/40%	7
Norvell [27]	93	386	2 (–)		54.2 (SD = 12.7)	63.2 (SD = 9.7)	59%/41%	57%/43%	8
Pedowitz [8]	27	41	3.4 (2.1–5.0)	2.8 (2.0–4.1)	55.0 (24–78)	65.0 (43–79)	51.8%/48.2%	41.5%/58.5%	7
Rajapakshe [28]	61	28	Not documented		Not documented		Not documented		7
$Saltzman_1$ [29]	66	158	2 (–)		57.1 (SD = 12.3)	63.2 (SD = 12.6)	45.5%/54.5%	49.4%/50.6%	8
$Saltzman_2$ [30]	29	42	4.8 (2.2–5.9)	3.8 (2.2–4.3)	56.2 (–)	64.0 (–)	65.2%/34.8%	54.1%/45.9%	7
Schuh [31]	21	20	2.5 (–)	3.3 (–)	63.8 (SD = 11.1)	56.2 (SD = 10.5)	40.0%/60.0%	52.4%/47.6%	6
Segal [32]	20	27	3.1 (–)		53.4 (37–71)	59.9 (46–81)	76.9%/23.1%	40.0%/60.0%	8
Singer [33]	17	17	1.6 (–)	1.3 (–)	48.9 (20–71)	61.3 (39–78)	70.6%/29.4%	47.1%/52.9%	7
Veljkovic [34]	150	88	3.6 (2–9)		55.9 (SD = 11.6)	58.6 (SD = 11.6)	62.7%/37.3%	45%/55%	7
Wasik [35]	29	27	4.6 (0.5–12.5)		51 (20–64)	51 (21–72)	67%/33%	93%/7%	7

published data on the most commonly used TAR demonstrates improved outcomes. Therefore, it could be extrapolated that the functional results of TAR in this review are a worst case scenario.

With regards AA, there were a heterogeneity of techniques used to perform the arthrodesis including arthroscopic and open techniques [2,3,5,20,45–48] yet there are insufficient studies to determine differences

Table 3
Function PROMs.

Function PROM	Primary Author	Results					
		MDPOS			MDCS		
		Score	95% CI	Significance	Score	95% CI	Significance
Ankle Activity Score	Schuh [31]	0.2	−1.2 to 1.6	Not significant (NS)	0.0	−2.2 to 2.2	NS
Ankle Evaluation Chart (AEC) Function	Kofoed [24]	11.82	6.5−17.1	Significant (Sig)	–		
AOFAS Function Subscore	Braito [18]	6.8		–	–		
	Mehdi [26]	0.7		–	−1.5		–
	Schuh [31]	2.8	−2.1 to 7.7	NS	–		
AOFAS Limitation of Activities	Dalat [19]	1.1		–	–		
AOFAS Terrain	Dalat [19]	0.93		–	–		
AOFAS Walking Distance	Dalat [19]	0.2		–	–		
AOS Disability	Daniels [20]	5.8	−0.4 to 12.0	NS	5.3	−1.3 to 11.9	NS
	Krause [25]	2.6		–	3.0		–
	Saltzman$_2$ [30]	11.3	−2.2 to 24.8	NS	–		
	Singer [33]	2.9		–	1.0	−11.9 to 13.9	NS
	Veljkovic [34]	–			5.9	3.8−8.0	Sig
Buechall-Pappas Function	Saltzman$_1$ [29]	1.2		–	3.7	1.2−6.2	Sig
Buechall-Pappas Limp	Saltzman$_1$ [29]	–			0.7	−0.7 to 0.5	NS
Buechall-Pappas ROM	Saltzman$_1$ [29]	9		–	7.3	3.0−11.6	Sig
Buechall-Pappas Stairs	Saltzman$_1$ [29]	–			0.7	0.04−1.4	Sig
Buechall-Pappas Standing	Saltzman$_1$ [29]	–			1.7	0.7−2.7	Sig
Buechall-Pappas Support	Saltzman$_1$ [29]	–			0.9	−0.2 to 1.6	NS
Buechall-Pappas Walking	Saltzman$_1$ [29]	–			−0.1	−0.7 to 0.5	NS
Foot and Ankle Ability Measure (FAAM) Activities of Daily Living (ADL)	Dalat [19]	14.2		–	–		
	Norvell [27]	6.8	6.5−7.2	Sig	8.7	2.8−14.5	Sig
FAAM ADL Subjective	Dalat [19]	11.5		–	–		
FAAM Sport	Dalat [19]	19.7		–	–		
	Norvell [27]	6.0	5.6−6.4	Sig	8.1	−0.6 to 16.8	NS
FAAM Sport Subjective	Dalat [19]	17.1		–	–		
Foot and Ankle Outcome Score (FAOS) ADL	Braito [18]	2.1	−9.5 to 13.7	NS	1.5	−6.4 to 9.4	NS
	Pedowitz [8]	10.5	2.7−18.3	Sig	–		
FAOS Sport	Braito [18]	6.6	−6.7 to 19.9	NS	10.0	−5.9 to 25.9	NS
	Pedowitz [8]	5.8	2.6−25.2	Sig	–		
FFI Difficulties	Dalat [18]	3.3		–	–		
FFI Limitation of Activities	Dalat [18]	13.3		–	–		
Musculoskeletal Function Assessment	Benich [17]	5.2		–	2.5	0.3−4.7	Sig
	Segal [32]	3.0		–	−1.0	−15.7 to 13.7	NS
Overall Subjective Ankle Function (OSAF)- Abnormal	Dalat [19]	0.3		–	–		
OSAF - Nearly Normal	Dalat [19]	0.3		–	–		
OSAF - Normal	Dalat [19]	0.02		–	–		
OSAF - Very Abnormal	Dalat [19]	0.05		–	–		
SF-12 Physical Component Score (PCS)	Pedowitz [8]	2.2	−3.3 to 7.7	NS	–		
	Wasik [35]	−1.2	−3.9 to 6.3	NS	−2.2	−3.0 to 7.4	NS
SF-36 Limitations Due to Physical Condition	Dalat [19]	15.1		–	–		
SF-36 Mean Physical Health Score	Dalat [19]	7.6		–	–		
SF-36 Physical Activity	Dalat [19]	8.8		–	–		
SF-36 PCS	Daniels [20]	−1.1	−1.5 to 3.8	NS	−1.2	−4.0 to 1.6	NS
	Norvell [27]	2.4	2.3−2.5	Sig	4.1	1.3−6.9	Sig
	Saltzman$_2$ [30]	1.0	−0.3 to 2.3	NS	–		
	Singer [33]	−0.1		–	0.1	−7.2 to 7.9	NS
	Veljkovic [34]	–			0.1	−0.7 to 0.9	NS
SF-36 Physical Function	Benich [17]	7.6		–	6.4	2.0−10.8	Sig
	Segal [32]	7.1		–	8.5	−19.7 to 36.7	NS
SF-36 Social Functioning	Dalat [19]	10.8		–	–		
Sports Participation	Schuh [31]	0.0		–	0.1		–
University of California at Los Angeles Activity Scale (UCLA)	Schuh [31]	−0.2	−1.3 to 0.9	NS	–		
Visual Analogue Scale (VAS) Uneven Surfaces	Jastifer [23]	1.0	−0.3 to 2.3	NS	0.8	−3.4 to 5.0	NS
VAS Walk Downhill	Jastifer [23]	0.9	−1.8 to 3.6	NS	0.6	−3.5 to 4.7	NS
VAS Walk Downstairs	Jastifer [23]	1.5	−0.4 to 3.4	NS	0.7	−3.2 to 4.6	NS
VAS Walk Flat Surface	Jastifer [23]	0.7	−0.1 to 1.5	NS	0.3	−2.3 to 2.9	NS
VAS Walk Uphill	Jastifer [23]	1.2	−0.5 to 2.8	NS	0.5	−3.5 to 4.5	NS
VAS Walk Upstairs	Jastifer [23]	1.5	−0.4 to 3.4	NS	3.5	−3.1 to 10.1	NS

in PROMs between these techniques. It has been demonstrated that the results of arthroscopic ankle arthrodesis are superior to those of open arthrodesis [49].

A limitation of this review was that neither complication nor re-operation/revision rates were reported. There is disagreement within the literature regards to the complication and re-operation rates following TAR and AA [1,12]. One recent systematic review found a significantly higher re-operation rate and complication rate after TAR, but other studies have found similar complication rates [10,12]. Some studies have concluded that there is insufficient high quality evidence to draw any meaningful conclusions [11], which our data would support.

A further limitation of this study is that due to the heterogeneity of the studies and outcome measures it is impossible to analyse confounding factors that may affect outcomes. There are also factors that may affect the decision to treat patients with either ankle arthrodesis of ankle replacement that are not reported in the studies. These include patient factors such as age, obesity, medical co-morbidities, smoking status, as well as surgical factors such as deformity, instability and

Table 4
Pain PROMs.

Pain PROM	Primary Author	Results MDPOS Score	95% CI	Significance	MDCS Score	95% CI	Significance
AEC Pain	Kofoed [24]	12.0	3.0–21.1	Sig	–		
AOFAS Pain Subscore	Braito [18]	−5.3		–	–		
	Dalat [19]	3.6		–	–		
	Mehdi [26]	−7.7		–	−8.4		–
	Schuh [31]	−4	−8.9 to 0.9	NS	–		
AOS Pain	Daniels [20]	7.6	2.0–13.2	Sig	6.8	0.9–12.7	Sig
	Krause [25]	−4.2		–	−2.7		–
	Saltzman$_2$ [30]	25.2	10.9–39.5	Sig	–		
	Singer [33]	5.2		–	−2.8	−16.0 to 10.4	NS
	Veljkovic [34]	–			3.1	1.3–4.9	Sig
Buechall-Pappas Pain	Saltzman$_1$ [29]	0.9		–	2.3	−0.7 to 5.3	NS
FAOS Pain	Braito [18]	21	10.9–31.1	Sig	30.9	17.0–44.8	Sig
FAOS Symptoms	Braito [18]	−7.6	−20.2 to 5.0	NS	−9.5	−26.6 to 7.6	NS
FFI Pain	Dalat [19]	7.7		–	–		
Pain Score	Benich [17]	0.8		–	0.3	−0.2 to 0.8	NS
	Segal [32]	−0.3		–	0.5	−9.1 to 10.1	NS
SF-36 Body Pain	Benich [17]	0.7		–	−0.5	−5.4 to 4.6	NS
	Segal [32]	−2.6		–	−8.3	−39.4 to 22.8	NS
SF-36 Physical Pain	Dalat [19]	9		–	–		
VAS	Braito [18]	−0.7	−2.0 to 0.6	NS	−0.4	−1.9 to 1.1	NS
	Jastifer [23]	0.7	−2.0 to 3.4	NS	−0.7	−5.8 to 4.4	NS
	Mehdi [26]	−1.6	−2.5 to −0.7	Sig	−1.2	−1.9 to −0.53	Sig
	Pedowitz [8]	12.8	3.3–22.3	Sig	19.22		–
	Saltzman$_1$ [29]	−1.6	−7.7 to 4.5	NS	7.2	−1.1 to 15.5	NS
	Wasik [35]	0.74	−0.4 to 1.9	NS	0.8	−0.59 to 2.19	NS

Table 5
QoL PROMs.

QoL PROM	Primary Author	Results MDPOS Score	95% CI	Significance	MDCS Score	95% CI	Significance
EQ-5D VAS	Rajapakshe [28]	1.0	−6.4 to 8.4	NS	1.8		–
FAOS QoL	Braito [18]	−1.7	−15.3 to 11.9	NS	2.6	−12.4 to 17.6	NS
HAQ Scale	Wasik [35]	0.03	−0.2 to 0.3	NS	0.4	0.2–0.6	Sig
Satisfaction	Henricson [22]	2.9	−3.5 to 9.2	NS	–		
	Jastifer [23]	0.1	−0.3 to 0.5	NS	–		
SF-12 Mental Component Score (MCS)	Pedowitz [8]	−0.33	−0.9 to 0.2	NS	–		
	Saltzman$_2$ [30]	5.5	1.4–9.6	Sig	–		
	Wasik [35]	4.5	−1.2 to 10.2	NS	−3.13	−1.21 to 7.47	NS
SF-36	Dalat [19]	7.3		–	–		
	Esparragoza [21]	13.6	7.4–19.8	Sig	12.9	5.4–20.5	Sig
SF-36 General Health	Dalat [19]	3.6		–	–		
SF-36 General Health Perceptions	Dalat [19]	−1.1		–	–		
SF-36 Limitations Due to Mental Condition	Dalat [19]	16.7		–	–		
SF-36 MCS	Daniels [20]	−2.3	−4.7 to 0.2	NS	−2.4	−5.0 to 0.2	NS
	Norvell [27]	0.4	0.3–0.5	Sig	−1.2	−4.1 to 1.7	NS
	Singer [33]	3.5		–	−1.8	−8.3 to 4.7	NS
	Veljkovic [34]	–			4.1	3.2–5.1	Sig
SF-36 Mean Mental Health Score	Dalat [19]	5.4		–	–		
SF-36 Physical Health	Dalat [19]	3.1		–	–		
SF-36 Vitality	Dalat [19]	1.5		–	–		

adjacent joint arthritis. As there are no randomised studies, there may have been bias in the selection of patients based on potential confounders.

Despite the limitations of this study, this is the largest and most up to date review of studies which directly compared AA to TAR and which reported the patient reported outcomes. Further work needs to be undertaken to obtain level 1 data and to draw a consensus of the validity of different PROMs which should then be used in future papers to enable valid conclusions to be made when comparing studies [37]. This systematic review demonstrates that the functional outcomes of ankle replacement are at least equivalent to ankle arthrodesis and in many cases significantly improved. Further studies with validated outcomes measures are required to confirm this finding, which has implications to potentially increase the use of ankle replacements.

5. Conclusion

The majority of studies found equality in patient reported outcomes between AA and TAR. Several studies found TAR to be superior in PROMs outcome compared to AA, only one study demonstrated AA to be superior to TAR in any outcome measure. There is an urgent need for randomised controlled studies to definitively answer this important clinical question.

Brief summary

What is already known:

- Ankle arthrodesis and ankle replacement are both recognised treatments for end stage ankle osteoarthritis.
- Ankle arthrodesis invariably leads to adjacent joint osteoarthritis, whereas the failure rates of ankle replacement are higher than in hip and knee replacements.
- Previous systematic reviews and meta-analyses showed no difference between ankle arthrodesis and total ankle replacement but did not include studies which directly compared the two operative methods.

What this study adds:

- This is the most comprehensive study to date directly comparing patient reported outcome measures (PROMs) of patients that took part in comparative studies between ankle arthrodesis and total ankle replacement.
- 68.7% of PROMs and their subscores showed no difference between groups. Total ankle replacement was shown to lead to superior PROMs in 29.3%.
- There is no level 1 data to inform clinical practice and hence there is an urgent need for randomised controlled studies.

Declarations of interest

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Data statement

All data included in the paper. No repository available.

Author statements

All authors have approved the final article.
S Gajebasia involved with data collection, writing and analysis.
T Jennison involved in data collection, writing and analysis.
J Blackstone involved in writing and analysis.
R Zaidi involved with data collection, writing and analysis.
P Muller involved in writing and analysis.
A Goldberg involved in concept, analysis and writing.
All authors were fully involved in the study and in the preparation of the manuscript and that the material within will not be submitted for publication elsewhere if successful.

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Appendix 1 MEDLINE search strategy

The search strategy below was used by the authors of this systematic review on MEDLINE through the web platform Ovid:

	Searches
1	exp ANKLE/
2	exp Ankle Joint/
3	1 or 2
4	exp ARTHROPLASTY, REPLACEMENT/ or exp ARTHROPLASTY/ or exp ARTHROPLASTY, REPLACEMENT, ANKLE/
5	exp “Prostheses and Implants”/
6	4 or 5
7	ARTHRODESIS/
8	6 and 7
9	3 and 8
10	exp Arthritis/
11	9 and 10
12	(ankle* or tibiotalar*).mp
13	(replace* or arthroplast* or prothe* or TAR or TAA).mp
14	(arthrodes* or fusion* or AA).mp
15	13 and 14
16	12 and 15
17	(arthrit* or arthropath* or arthros*).mp.
18	16 and 17
19	11 or 18
20	limit 19 to (English language and yr = “1981 -Current“)

[mp = title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] [50].

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