Complications following total ankle arthroplasty

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Complications following total ankle arthroplasty: A systematic literature review and meta-analysis

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ABSTRACT

Background: Total ankle arthroplasty (TAA) is increasingly used as a treatment for end-stage ankle arthropathy. However, TAA may be more sensitive to complications, failure and subsequent re-operations compared to ankle arthrodesis. The aim of this systematic review and meta-analysis is to generate an overview of complications of TAA surgery.
Methods: PubMed, EMBASE and the Cochrane library were searched between 2000 and 2020 to identify all papers reporting on complications in TAA surgery. Meta-analysis was conducted based on type of complication in TAA surgery. Pooled estimates of complications were calculated using a random effects model. Risk of bias and quality was assessed using the Cochrane risk of bias and ROBINS-I tools. The confidence in estimates was rated and described according to the recommendations of the GRADE working group.
Results: One hundred twenty-seven studies were included in this systematic review. All combined, they reported on 16.964 TAAs with an average follow-up of 47.99 ± 29.18 months. Complications with highest reported pooled incidence were intra-operative fracture 0.06 (95 %CI 0.04–0.08) (GRADE Very low) and impingement 0.06 (95 %CI 0.04–0.08) (GRADE low) respectively.
Conclusion: Reported complication incidence of TAA surgery is still high and remains a significant clinical problem that can be severely hampering long-term clinical survival of the prosthesis. The results of this systematic review and meta-analysis can help guide surgeons in informing their patient about complication risks. Implementation of more stringent patient selection criteria might contribute to diminishing TAA complication rates.

Contents

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1. Introduction

In the last two decades, total ankle arthroplasty (TAA) has been increasingly used in clinical practice as an alternative to arthrodesis [1]. The preserved mobility of the ankle joint in TAA might be accompanied by a more successful functional outcome and a better protection of adjacent articulations [2,3].

Ever since TAA surgeries have been performed, patient satisfaction, pain relief and functional outcomes have changed for the better [4]. However, there are also disadvantages for TAA may be more sensitive to complications, failure and subsequent re-operations when compared to ankle arthrodesis [5]. A study conducted by Spirt et al. shows that 28 % of the patients that underwent ankle arthroplasty had to undergo one or more reoperation(s) due to complications [6]. The perioperative major complications in ankle arthrodesis occurred 1.8 times more often compared to TAA but had a 29 % lower risk of a minor complication after adjusting for patient and hospital factors, such as gender, age, and health-status [7]. Glazebrook et al. proposed a classification system for complications of total ankle replacement based on clinical outcomes. Insight in the risk of complications is important, since the risk of failure that is associated with the occurrence of complications [8].

The aim of this meta-analysis is to generate an overview of complications of TAA surgery and perform a meta-analysis on complication incidence. In this meta-analysis we defined a complication as any undesirable, unintended and direct result of the ankle replacement according to the definition by Sokol and Wilson [9]. Failure was defined in this meta-analysis as during interpretation of revision rates, revision of TAA was defined as removal of either the tibial or talar component or both components with subsequent placement of an antibiotic spacer, reimplantation of metal components, conversion to an arthrodesis, or amputation [10].

2. Materials and methods

2.1. Protocol

The protocol for this systematic review and meta-analysis was prospectively registered in PROSPERO (https://www.crd.york.ac.uk/prospero/, ID: CRD42018105062). This study was performed and reported according to the PRISMA-statement for reporting systematic reviews [11].

2.2. Eligibility criteria

Retrospective and prospective cohort studies, case series and randomized controlled trials reporting on complications of TAA were eligible for inclusion in this study. Only studies written in English and Dutch languages were included, and publication date inclusion was set at studies published 2000–2020. Participants of any age and gender undergoing TAA were eligible for inclusion. Other exclusion criteria were systematic reviews and/or meta-analysis, studies about only first-generation total ankle arthroplasty implants and studies which focused on revision TAA. All other generations of ankle replacement and all types of systems were eligible for inclusion.

2.3. Information sources and search strategy

The electronic databases of PubMed, Cochrane and EMBASE were systematically searched to find relevant articles. Keywords used to develop our search strategy were ‘ankle’, ‘joint replacement’. The literature search of published papers was performed on 31 December 2020. The search terms and methodology were checked by a librarian.

2.4. Study selection

Selection of relevant studies was independently performed by three reviewers (JV, EG, JH). The retrieved studies from the search were first screened on title. Selected studies abstracts were subsequently assessed based on the eligibility criteria previously mentioned. The full text was read when there was any doubt about inclusion or exclusion of a study. In case of a difference of opinion for inclusion, the judgment of the fourth reviewer (CA) was used for the final decision.

2.5. Data collection process

A data file was composed (JV, JH) to register extracted complications from the selected studies. Database was checked for completeness for all patients in dual assessment (JV/JH; EG/CA) Next to the outcome measures, also the sample size, demographics, TAA indication, follow-up duration, failure rate, functional outcome, type of implant used, including generation and bearing type, were extracted from the studies.

2.6. Level of evidence

For each included article, the level of evidence was assessed using the CEBM levels of evidence guideline of March 2009 document compiled by the Oxford Centre of Evidence-based Medicine [12].

2.7. Risk of bias

The ROBINS-I tool was used for assessing risk of bias in non-randomized studies of interventions [13]. This tool assesses seven domains through which bias might be introduced. The first two domains, covering confounding and selection of participants into the study, address issues before the start of the interventions. The third domain addresses classification of the interventions themselves. The other four domains address issues after the start of interventions: biases due to deviations from intended interventions, missing data, measurement of outcomes, and selection of the reported result. Because all studies used a retrospective or prospective cohort method, assessing bias according to random sequence generation, allocation concealment and blinding for the allocated intervention are irrelevant.

The confidence in estimates was rated according to the recommendations of the GRADE working group as each outcome was assessed for potential risk of bias, inconsistency, imprecision, indirectness, and publication bias [14].

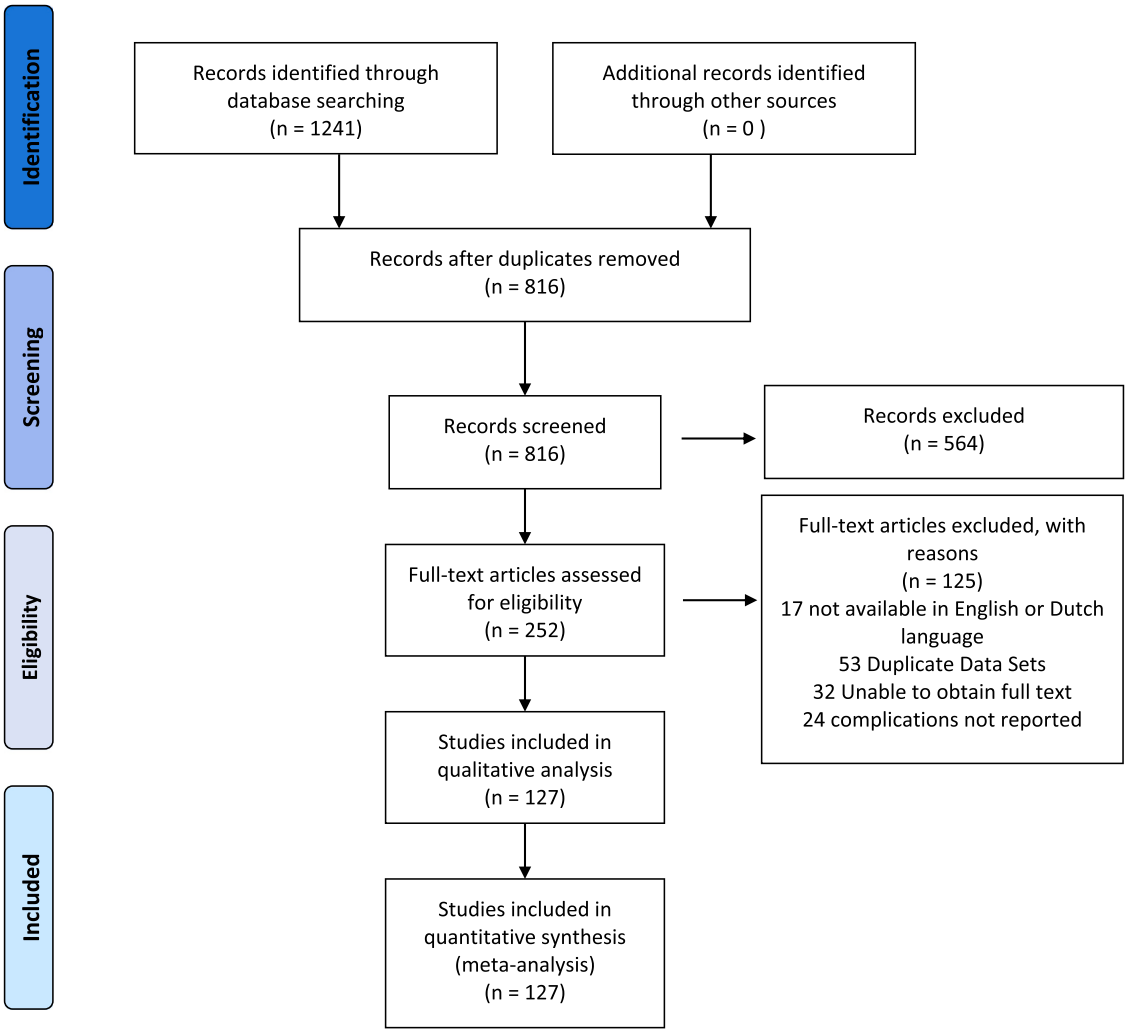

Fig. 1. Flow-chart of the study PRISMA selection process.

2.8. Statistical analysis

A meta-analysis was performed for the ten most reported complications. Meta-analyses were performed whenever three or more studies reported on a complication. When study populations overlapped, the study with the most recent data was used in the meta-analyses.

Despite anticipated heterogeneity, the individual study proportions were pooled. Pooled proportions with their corresponding 95 % confidence intervals were calculated using Freeman-Tukey double arcsine transformation within a random effects model framework. Heterogeneity of combined study results was assessed by visual inspection of forest plots, use of the I^2 statistic and connected χ^2 test, and 95 % prediction intervals (PIs) were calculated to present the expected range of true effects in similar studies. Between-study variance was quantified using the τ^2 statistic, estimated using the Sidik-Jonkman estimator. The Hartung–Knapp method was used for adjustment of the estimates and confidence intervals (CIs).

Publication bias was assessed only if 10 or more studies were included in the meta-analysis using funnel plots and Peters' test (for proportions) for funnel plot asymmetry [15].

Statistical analyses were performed using R version 4.0.3 (R Foundation for Statistical Computing, Vienna, Austria) with package 'meta'.

2.9. Source of funding

None.

3. Results

3.1. Selected studies

A total of 816 reports were identified through PubMed, EMBASE, ScienceDirect, Clinical registries and Cochrane Library, and after removal of duplicates 816 remained. Based on title screening, 564 of those reports were discarded, since it was clear that these articles did not adhere to the inclusion criteria leaving 252 reports. After reading the full text, 127 articles were included in this meta-analysis (Fig. 1).

3.2. Methodology assessment

Results level of evidence: Using the CEBM levels of evidence guideline of 2009, the level of evidence for each article was assessed [12]. Most included studies were cohort studies, with mostly a 4 on the level of evidence assessment because of poor methodological quality or the lack of control group (74.7 %). The studies that included a control group (25.3 %) were 2b level of evidence studies.

Table 1
ROBINS-I assessing risk of bias in non-randomized studies of interventions.

		Domain 1: Confounding	Domain 2: Selection of participants	Domain 3: Classification of interventions	Domain 4: Deviation from interventions	Domain 5: Missing data domain	Domain 6: Measurement of outcomes	Domain 7: Selection of reported results	ROBINS-I overall
Adams et al.	2014	2	2	1	1	1	1	2	2
Ahn et al.	2020	2	1	1	2	1	2	1	2
Anderson et al.	2003	3	2	2	2	1	2	2	3
Asencio et al.	2014	3	3	1	1	1	1	2	3
Bai et al.	2010	2	2	1	1	1	1	2	2
Barg et al.	2011	2	3	1	2	1	1	2	3
Barg et al.	2011	2	2	1	1	1	1	1	2
Barg et al.	2018	2	1	1	1	2	2	1	2
Benich et al.	2017	2	1	1	2	2	2	1	2
Bennett et al.	2018	2	2	1	1	3	1	1	3
Berlet et al.	2020	1	1	1	1	1	1	1	1
Besse et al.	2009	3	3	2	1	1	1	2	3
Bianchi et al.	2012	2	2	1	1	1	2	3	3
Bonnin et al.	2011	2	2	3	1	2	1	3	3
Borenstein et al.	2018	2	1	1	1	2	1	2	2
Bouchard et al.	2015	3	3	2	1	2	3	3	3
Brunner et al.	2013	2	1	1	1	2	1	1	2
Buechel et al.	2003	2	1	1	1	1	3	2	3
Chao et al.	2015	2	1	1	1	1	1	1	2
Choi et al.	2013	3	2	2	1	1	1	2	3
Choi et al.	2014	3	3	2	1	1	1	2	3
Claridge et al.	2009	3	1	2	2	2	2	3	3
Cody et al.	2019	2	3	1	2	3	1	1	3
Cody et al.	2019	2	1	3	2	4	1	1	4
Currier et al.	2019	3	2	1	4	3	2	1	4
Daniels et al.	2015	2	1	1	1	1	1	1	2
Day et al.	2020	2	1	2	2	3	1	1	3
Demetracopoulos et al.	2015	2	1	1	2	1	1	2	3
Demetracopoulos et al.	2019	2	1	2	2	1	1	2	2
Di Iorio et al.	2017	1	1	1	2	2	1	1	2
Doets et al.	2006	2	1	2	1	2	2	1	2
Eckers et al.	2017	3	2	2	1	3	1	1	3
Escudero et al.	2020	3	1	2	2	1	1	1	3
Esparragoza et al.	2011	3	1	2	2	1	1	2	3
Faber et al.	2018	1	1	1	1	1	1	1	1
Gaudot F et al.	2014	2	2	1	1	1	1	2	2
Giannini et al.	2010	2	1	1	1	1	1	2	2
Giannini et al.	2011	2	1	1	1	1	1	2	2
Gramlich et al.	2018	2	1	1	2	3	1	1	3
Gross et al.	2015	3	2	1	1	1	1	1	3
Gross et al.	2016	2	1	2	1	1	1	2	2
Gross et al.	2017	3	3	1	2	1	2	1	3
Harston et al.	2017	2	1	1	2	2	1	1	2
Heida et al.	2017	2	2	1	2	1	1	1	2
Henricson et al.	2010	3	1	1	1	2	1	2	3
Henricson et al.	2015	2	1	1	1	1	1	1	2
Henricson et al.	2020	2	2	1	2	3	1	1	3
Hintermann et al.	2004	2	1	1	1	2	1	1	2
Hobson et al.	2009	2	2	2	1	1	2	1	2
Hofmann et al.	2016	3	2	1	2	2	2	1	3
Hsu et al.	2015	3	1	1	2	1	1	1	3
Hurowitz et al.	2007	2	1	1	1	2	1	1	2
Johnson-Lynn et al.	2018	2	1	1	2	4	2	1	4
Jung et al.	2015	2	2	3	1	2	2	1	3
Kamrad et al.	2017	1	2	3	1	4	1	2	4
Karantana et al.	2010	2	1	1	2	2	1	1	2
Kerkhoff et al.	2016	3	2	1	1	3	2	1	3
Kerkhoff et al.	2016	3	1	1	1	2	2	1	3
Knecht et al.	2004	2	1	1	2	3	4	1	4
Kofoed et al.	2004	2	3	2	1	3	1	1	3
Koivu et al.	2017	1	3	1	2	3	1	1	3
Koo et al.	2018	1	1	1	2	3	1	1	3
Kopp et al.	2006	2	1	1	2	2	2	1	2
Kraal et al.	2013	3	1	1	1	1	4	1	4
Lagaay et al.	2010	1	2	3	1	1	1	1	3
Lampley et al.	2016	3	2	2	1	2	1	1	3
Lee et al.	2008	1	1	1	1	1	1	1	1
Lee et al.	2020	1	1	1	1	1	1	1	1
Lewis et al.	2015	1	3	2	2	3	3	1	3
Loewy et al.	2019	2	2	1	2	1	1	1	2

(*continued on next page*)

Table 1 (*continued*)

		Domain 1: Confounding	Domain 2: Selection of participants	Domain 3: Classification of interventions	Domain 4: Deviation from interventions	Domain 5: Missing data domain	Domain 6: Measurement of outcomes	Domain 7: Selection of reported results	ROBINS-I overall
Mann et al.	2011	2	1	1	1	2	2	1	2
McConnell et al.	2017	1	1	3	1	1	2	2	3
Morgan et al.	2010	2	1	1	1	2	2	1	2
Mosca et al.	2020	2	1	1	2	4	1	1	4
Muir et al.	2013	3	1	1	2	3	2	1	3
Myerson et al.	2003	2	1	1	1	2	2	1	2
Natens et al.	2003	2	1	1	1	2	1	1	2
Nieuwe Weme et al.	2015	1	1	2	2	2	1	1	2
Noelle et al.	2013	3	1	1	2	3	2	1	3
Oliver et al.	2016	3	2	2	1	4	3	2	4
Pangrazzi et al.	2018	3	2	1	2	1	2	1	3
Pedersen et al.	2014	1	1	3	2	4	4	1	4
Penner et al.	2018	2	1	1	2	1	1	1	2
Preis et al.	2017	2	1	1	1	1	2	1	2
Preis et al.	2017	3	2	1	1	1	2	1	3
Queen et al.	2013	2	1	3	1	2	2	1	3
Ramaskandhan et al.	2014	1	2	1	2	1	3	2	3
Reuver et al.	2010	1	2	1	1	1	1	1	2
Richter et al.	2020	2	2	1	1	2	1	1	2
Rodrigues-Pinto et al.	2013	2	2	1	1	2	1	1	2
Rodriguez et al.	2010	3	1	1	1	3	2	1	3
Roselló Añón et al.	2014	3	4	1	1	3	2	2	4
Rushing et al.	2020	1	2	2	1	3	2	1	3
Saito et al.	2018	1	1	1	2	3	1	1	3
Saltzman et al.	2009	2	3	2	2	1	1	2	3
San Giovanni et al.	2006	2	1	1	1	2	1	1	2
Schenk et al.	2011	2	3	1	1	3	1	1	3
Schipper et al.	2016	2	1	1	2	1	2	1	2
Schuberth et al.	2006	1	2	1	1	2	2	2	2
Schuberth et al.	2020	2	1	1	2	1	1	1	2
Schutte et al.	2008	2	1	1	2	1	2	1	2
Schweitzer et al.	2013	2	1	1	2	3	1	1	3
Shi et al.	2015	3	1	3	1	2	2	2	3
Skyttä et al.	2010	3	2	1	1	2	2	2	3
Spirt et al.	2004	1	3	2	1	2	1	2	3
Sproule et al.	2013	1	1	1	1	1	1	1	1
Stewart et al.	2017	2	2	1	2	1	2	1	2
Strauss et al.	2014	2	1	1	1	1	1	1	2
Summers et al.	2012	2	1	1	1	3	4	3	4
Sung et al.	2014	3	2	3	1	2	2	1	3
Tan et al.	2016	2	1	1	1	3	3	1	3
Tan et al.	2018	2	2	1	2	3	1	1	3
Tedder et al.	2018	3	2	1	1	2	3	1	3
Tenenbaum et al.	2016	2	1	1	1	2	2	1	2
Tiusanen et al.	2020	1	1	1	1	2	2	1	2
Trajkovski et al.	2013	1	1	1	1	1	1	1	1
Usuelli et al.	2016	3	2	1	1	3	1	1	3
Usuelli et al.	2017	3	1	1	1	2	1	1	3
Usuelli et al.	2019	1	2	1	1	2	4	1	4
Valderrabano et al.	2004	2	2	1	2	1	1	1	2
Wood et al.	2000	1	3	1	1	2	3	1	3
Wood et al.	2003	3	1	1	1	1	2	1	3
Wood et al.	2008	3	1	1	1	1	2	1	3
Wood et al.	2010	2	3	1	1	2	2	2	3
Zafar et al.	2020	2	2	1	2	2	1	1	2

1 low risk of bias, 2 moderate risk of bias, 3 serious risk of bias, 4 critical risk of bias.

Results risk of bias: The results of the ROBINS-I risk of bias assessment are summarized in Table 1 and they indicate that the overall ROBINS-I score for most studies was subject to serious or critical risk of bias.

3.3. Study characteristics

One hundred twenty-seven studies were included in this systematic review. All combined, they reported on 16.964 TAAs with an average follow-up of 47.99 ± 29.18 months. A variety of aetiologies were reported as an indication for TAA with posttraumatic osteoarthritis, primary osteoarthritis and rheumatoid arthritis being the most prevalent aetiologies. The age of subjects ranged between 17 and 95 years, with an average of 60.04 years. So according to the indication for TAA and the range in age, the population of present review is very heterogeneous.

3.4. Complications

A total of 127 articles reported on complications (Table 2**)**. With 67 papers reporting on intra-operative fracture and 48 papers on impingement, these were the most frequently reported complications among the included papers.

Table 2
Overview of all clinical outcomes and complications reported by the included studies.

Study	N ankles	age (yrs)	Follow-up (mo)	TAA generation type	AOFAS		VAS		SF-36		ROM (°)		Failure (%)	Pain	Wear	Impinge-ment	Aseptic loosening	PAO	Infection		Malalign-ment/ deformity	Fracture		Insta-bility	Wound-problem	Other (n[type complication])
					Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op							Deep	Superf		Intra-op	Post-op			
Adams 2014	194	64	44.4	2	39.7	78.0	7.02	1.36	50.0	68.1		22.5	11				*		5	4		4	3		6	6[1], 4[2], 1[3], 2[4], 2[5]
Ahn 2020	16	44.1	81.6	3,4			5.5	0.9			30.8	37.3	0													314
Anderson 2003	39	57	52	2		74						28	23.5	1			7				2				2	26
Asencio 2014	32	44	52.8	3,4	40.2	83.4					23.6	35.9		1												1[7], 1[8], 1[9]
Bai 2010	67	52	38	3	49	86.5						37.5	2.7			1		5	1			8			8	3[1], 4[2], 2[10]
Barg 2011d	19	65.2	61.2	3	38	75	7.5	1.2			29.5	37.8	10.5				2				1					
Barg 2011e	123	62.4	62.4	3	35	70	7.0	1.4			26.9	35.3	7.0	7		5					4	7		1	8	2[2], 8[3]
Barg 2018	55	67	26.6	4			7.9	0.8			22.9	40.2	7.0				3			2		2			2	
Benich 2017	103	65.9	36	3						157																
Bennett 2018	173	62.5	24	4									1.7	1		7	1		3			1	2		1	
Berlet 2020	121	62.88	28.51	4									5.0				2		3	9		3	1		1	1[1], 9[5], 1[42]
Besse 2009	50	56	40	3	36.9	85.4					33.7	44.8	8.0									4	1		1	1[2], 1[3], 1[11], 1[12], 1[13], 1[14]
Bianchi 2012	62	57.3	42.5	3	35.1	78	6.8	2.0					8.1	2			2		1			2				1[14], 1[4]
Bonnin 2011	87	56	106.8	3	26.7	79.3						26.7	15	3		2	1		1							5[6], 19[14], 1[15]
Borenstein 2018	65	62.4	16.6	4									3.0				4		1					1	1	
Bouchard 2015	39	62.44	46	3,4					84.7	92.3			6.7				3		1							26
Brunner 2013	77	56.9	148.8	2	25	73	3.9	1.8			18.2	22.8	38	17	1	4			1	1	7			2		11[6], 5[2], 1[14]
Buechel 2003	50	49	60	2							27	28	6.5		1		1		2			2	1		7	2[16], 1[5]
Chao 2015	23	68.6	36	3	42.7	88	76	13					4.4							5		3				15
Choi 2013	67	63	43.5	3,4	47.8	82.8					25.8	30.7	7.5				2					6	3		3	5[1], 13[2]
Choi 2014	173	66	58	4	55.8	82.7							13.9				5		1			1			13	
Claridge 2009	28	68.5	59.8	2	34.9	76.4							0				2		4	2		2	3			2[5], 2[2], 1[17], 1[18]
Cody 2019	159	63	20	4									10				6		6							
Cody 2019	533	62	84	3,4									6.4				7		3		4					2, 2[19], 5[14]
Currier 2019	70	59.5	54	2,3,4											3		22							2		13[14], 1[6]
Daniels 2014	281	64.1	62.4	2,3									17				41		3							4[9], 12[2]
Daniels 2015	281	61.9	108	2									18		2				3	1		1				1[9], 1[3], 2[5], 1[14], 1[10]
Day 2020	85	63.5	85.2	3									2.4			12	1		1		1		3			1[15], 1[16], 18[14]
Demetracopoulos 2015	395	62.3	41.2	3,4									5.1						3	4					19	119
Demetracopoulos 2019	80	66.5	42	4									8						1						2	
Di Iorio 2017	50	56	120	4	36	75				69			32	2					2							1514
Doets 2006	93	57.6	91.2	4,2	26.5	77					26.3	31.9	16				6		5		5	27	18	1	7	7[7], 3[20]
Eckers 2017	17	43	115.2	2,3,4		81					16	26	17.6		1		3					2				5[8], 5[24],2[26], 3[20], 1[1], 1[11]
Escudero 2020	67	61.5	35.4	4									3.0													2714
Esparragoza 2011	14	64	25.2	3	33	62			33,6	59,8			0							2		2				
Faber 2018	52	70	50.4	3		85							6	1			2		1			3			3	
Gaudot 2014	56	64	24	3	34.5	87.5					23.5	31.5	1.5				1			1		8			2	1[2], 1[21], 6[13], 9[14]
Giannini 2010	51	62	29.7	4	38.5	79							3	1							1	1			3	
Giannini 2011	158	60.5	17.7	3	36.3	79					16.1	24.6	1.3	4		1					1	3	2		4	
Giannini 2017	76	62	78	4	37.4	78.9					16.1	24.6	1.3	3		1			1			2			3	
Gramlich 2018	60	56	59	3		55.2							42			3										12[14], 2[38]
Gross 2015	105	59.6	37.5	3,4	42.8	81.1	6.5	1.4	63.9	64.8			3.8			5	2				2				1	15,214
Gross 2016	455	61.8	44.2	3	40.7	77.7			48.0	71.2			3.1			38										
Gross 2017	762	62.7	13.2	3,4									23.1						8						16	219
Harston 2017	149	63.2	71	4	40.1	76.2	7.1	1.4	51.9	71.9			9.4			21	7		4			1		4		4[5], 14[4], 1[19]
Heida 2017	404	65.1	*	*															1	2						1[33], 3[34], 2[35], 1[36]
Henricson 2010	93	57	42	3									10			7	3		4	3	2	5	1			314
Henricson 2015	324	*	*	2									53	10	19		62		14		17		2	1		
Henricson 2020	267	61	50.4	4	49	80							7.9						1	4		8	6			13
Hintermann 2004	122	56.4	18.9	3	40	85						39	6.6	1		2	4	4		1	11		1		4	21,113
Hobson 2009	123	64	48	4		79.3						19.4	14.6	2		1	1	3			1	4	9	7	12	2[13], 1[1]
Hofmann 2016	81	64.3	62.4	3				1.7			35.5	39.9	2.5			12	4			3		5	6		7	25
Hsu 2015	59	57.2	35	1,2	44.1	87.3	8.1	1.6			29	38	7									1	2			15[2], 9[22]
Hurowitz 2007	62	54.5	39.6	2									34			1	8		3	1	3				9	5[5], 1[9], 1[23], 1[14]
Johnson-Lynn 2018	76	63	60	4									4	1			1			3		2	2	2		
Jung 2015	54	62.9	30.4	3,4	45.5	85.1	8.1	2.4			40.6	51.7	9.3			11			3	6	3	5			3	8[1], 2[24], 1[13], 1[14], 1[14]
Kamrad 2017	241	62	24	4									1.7													
Karantana 2010	52	62	80	2		78						23	16	1		2	1	1	1	3	5	5	3			2[6], 1[5], 1[14]
Kerkhoff 2016	134	59	90	2									22			7			3	7	9		5		1	9[14], 15[5], 2[1]
Kerkhoff 2016	64	63	40	4				2.0					5	2		4			2	1		1	1			2[2], 1[14], 1[1], 1[29], 1[5], 1[14], 1[19]
Knecht 2004	132	61	109	2								18	11.9			1	4		3	3	1					1[3], 1[1], 4[15], 2[2]
Kofoed 2004	58	59.1	112.8	1									27.3		3	2	5			1	2					1[5], 2[1], 1[13]
Koivu 2017	130	56.4	38.4	4							31	30	25.1				1		2			24			8	7[13],91[14], 5[1], 3[21]
Koo 2018	55	70	60	3		50							5.5	1			1		1							1[37], 1[14]
Kopp 2006	40	62.7	44.5	2	33.6	83.3				50			2.6				1				7	4		5	3	3[18], 1[3], 1[9]
Kraal 2013	93	57.6	121.2	4,2	26.5	80.4							20		3		9	1	2		7		1		1	2[13], 2[14], 1[8]
Lagaay 2010	95	59	*	2									1						1	1				7	8	3[3], 5[18], 12[14]

(Continued on next page)

Study	N ankles	age (yrs)	Follow-up (mo)	TAA generation type	AOFAS		VAS		SF-36		ROM (°)		Failure (%)	Pain	Wear	Impinge-ment	Aseptic loosening	PAO	Infection		Malalign-ment/ deformity	Fracture		Insta-bility	Wound-problem	Other (n[type complication])
					Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op	Pre-op	Post-op							Deep	Superf		Intra-op	Post-op			
Lampley 2016	642	61.9	35.6	3	40.4	78.8			48.4	73.6			3.1			53	11		6						26	3^{5}, 8^{14}
Lee 2008	50	57.35	3	3									2			1		3	1			5			6	3^{1}, 2^{2}
Lee 2020	195	64.4	90	3	51.6	86.4	6.9	1.8	44.0	60.9	32.2	34.9	4.9				4		1						1	17^{14}, 5^{5}, 11^{40}
Lewis 2015	249	63.2	34.8	1,2	40.2	79.2	7.2	1.4	48.8	71.5			8.4			2	10		6			9	5		16	1^{4}, 8^{5}, 7^{23}
Loewy 2019	139	61.5	105.6	4									15.2						4	8	8				4	2^{10}, 9^{6}
Mann 2011	84	61.4	109.2	2	42.7	81.9					32	39.2	14		0		2		3	2		4	3			3^{5}, 2^{14}, 1^{6},
McConnel 2017	140	63.5	57.8	3	42.8	78.3	6.8	1.0	48.4	71.4																
Morgan 2010	45	64.6	57.8	3		88.1							5.3				1						1		1	2^{5}, 10^{28}
Mosca 2020	73	61.7	31.2	4	45	88.9	8.2	1.2			16.7	35.6	2.6				1		5							399
Muir 2013	129	64	48	4									5.6	11		3			3		4		1			15
Myerson 2003	25	55.5	*	2																6		7			2	2^{1}, 2^{2}
Natens 2003	27	53.9	15.8	4			8.4	2.8			13.6	25.4	0			11				1		1	2		2	125
Nieuwe Weme 2015	90	56	60	2,4	36	85,2					32.8	40.3	16.6				8		1		4	11			7	10^{20}, 11^{14}
Noelle 2013	114	63	36	3	36.9	76							18.4	1		10	6		4	6		2				
Oliver 2016	245	65.5	38.9	*	41.1	84.6	6.7	1.8					3.1	5		10	3		4			1		1	13	111
Pangrazzi 2018	104	65	46	3									15.6			6	4		3			1	2		9	2^{7}, 2^{5}, 3^{1}
Pedersen 2014	100	58.5	64.7	4,3,4,2									12				9		1		5				1	26
Penner 2018	67	61.5	35.4	3					33.7	45.9			3				2		1							
Preis 2017	6	53.3	40.8	3	15.8	68.7	8.7	1.5	27	74	-5.8	35.7	0							1						
Preis 2017	14	51.4	69.4	3	23.0	76.6	8.5	1.3			9.9	28.4	7.1	2								1			2	
Queen 2013	103	*	*	3,4	32.9	81.4	5.4	0.9	39.7	73.9									1	1		1	1		13	45
Ramaskadhan 2014	112	58.5	24	4	29	77.2							1			2				2			7			113
Reuver 2010	59	57	36	3		75						33	11.9	2			5		3	3		3				
Richter 2020	1074	62	105.6	4									12		14		34		11					41		1214
Rodrigues-Pinto 2013	119	55.6	38.7	3	27.7	90.1					16.3	35.4	1.7						2		1	6		1	4	2^{20}, 1^{14}, 1^{13}
Rodriguez 2010	18	57.6	39.4	4	52.2	86.6							9.5			1		1			1					2214
Roselló 2014	18	58	37	3	31	83					27.5	34.4	0	1		3				1		2		1		
Rushing 2020	55	59	22	4									5.5	1					2	2		1	2		4	15
Saito 2018	64	60.8	24.5	4									4.7			5				1	1		1		1	45,114
Saltzman 2009	593	63.1	24	2			7.5	1.7					0	218					8	19		36	44		124	1^{19}, 130^{1}, 47^{28}, 33^{27}
San Giovanni 2006	31	61	99.6	2		81					17	23	6.6	1					1			10	4		4	17
Schenk 2011	218	56.8	42.3	3	50.9	82.2	7.4	2.0			25.2	33.1	13	19			4		3		2	5	5		5	1^{1}, 4^{5}
Schipper 2016	97	56.5	95.4	2,3									37.1			11	6		4	8	13		3	1	9	6^{14}, 4^{10}, 2^{19}, 4^{30}, 31^{5}, 9^{14}
Schuberth 2006	50	57.6	24.2	2									16						1	9	8	19				4^{5}, 6^{16}, 6^{7}, 1^{19}
Schuberth 2020	77	58.9	99.6	2,3,4,3,4	33	75	8	3			16.5	20.1	14.3			9			1	10		8	2			55
Schutte 2008	49	57.1	28	4							23	27	8.2			1	2		2		4	11	1		2	1^{1}, 1^{15}, 1^{17}
Schweitzer 2013	67	63	33.7	3	39.1	78.7	7.0	1.5	41.4	74.5			4			4	3			3	3	2	1			1^{1}, 1^{3}, 3^{10},
Shi 2015	22	58	29.3	4,4,3,4	38.9	70.1	5.3	2.1	40.6	67.6			0	2								1			3	1^{1}, 1^{14}
Skytta 2010	489	55	38.4	3									17				23		4		5		1	23		36
Spirt 2004	306	53.5	33	2									20	4			22		8				3			14^{19}, 8^{19}, 1^{5}, 1^{26}
Sproule 2013	88	63.5	40	3	38.2	74.8							11.6	7		4	6	4	1	1	1	2	3		2	2^{5}, 1^{19}, 1^{24}, 3^{28}
Stewart 2017	106	61.9	81.1	3	43.4	79.4	7.0	1.2	45.1	69.8	16	26	4.2	2		9	2								1	2^{16}, 2^{30}, 1^{14}, 3^{31}
Strauss 2014	11	49	36	3	21.5	68	7.6	1.9			23.2	25	9.1						2							
Summers 2013	58	65	32	4	42.6	64.6							12			16	7	2		1		8	2	2		7^{1}, 1^{2}, 1^{9}
Sung 2014	103	63.2	31	3,4	45.8	80.3	8.4	3.5			37.9	39.5	4.9	1			1		1			10			1	1^{1}, 2^{3}, 2^{21}, 1^{13}
Tan 2016	19	63.7	18	4			7.5	2.2			21.4	51.5	0	2		1			1							
Tan 2018	41	59.4	29.4	4	35	72	7.0	3.0					9.7			14	2		1	1		2				
Tedder 2018	591	64.7	1	*															1	3						
Tenenbaum 2016	42	65	26.8	4	31.2	80.8	7.9	1.7			16.2	19.3	0													
Tiusanen 2020	104	60.7	43.6	4							30	33	2.9	18		3			3	9	4	2	1		1	8^{1},1^{18}, 3^{41}
Trajkovski 2013	72	63	34.7	3,4,4	27.6	81.5							8.3	1	1	5			2		5	1		1		1^{5}, 1^{20}, 1^{13}, 3^{39}, 2^{14}
Usuelli 2016	31	60.1	24	3	43.4	69.9	8.5	2.4				25.1	3.2	1			1		1			6				
Usuelli 2017	76	56	12	3	32.8	72.6	8.7	2.2																		
Usuelli 2019	89	53.2	12	4	33.8	88.5	8.1	1.4			15.8	42.3	1.1						1						2	
Valderrabano 2004	68	56.1	44.4	4	24.7	84.3		3.2					13		3	2	5			1	2					2^{1}, 1^{5}, 1^{13}
Wood 2000	13	60.7	86.4	4									14.3	3								1			1	
Wood 2003	200	59.6	46	4									7.3	7			14	1	1		1	9	10		28	1^{5}, 9^{28}, 1^{7}, 7^{24}
Wood 2008	200	*	88	4									19.7	6			25					9	10		5	1^{6}, 9^{28}, 1^{24}
Wood 2010	100	66	43	4			8.5	2.1					6.4	6		1			1		2	2	5		6	7^{28}, 5^{14}, 1^{5}, 1^{13}
Zafar 2020	322	60	144	2,3									32	3			34		7		6		3			7

1. Nerve injury, 2. Tendon injury or tendinitis, 3. Thromboembolic event, 4. Metallic component fracture, 5. Subsidence, 6. Polyethylene liner fracture, 7. Fixation failure or fracture non-union, 8. Per-operative cardiogenic shock, 9. Bleeding episode or vascular complication, 10. Tarsal tunnel syndrome, 11. Hematoma, 12. Plantar scab related to an analgesic popliteal nerve block, 13. Polyethylene liner displacement or (sub)luxation, 14. Bone cysts or osteolysis, 15. Synovial cysts, 16. Reflex sympathetic dystrophy, 17. Artery injury, 18. Syndesmosis non-union, 19. Amputation, 20. Arthritis or infection elsewhere, 21. Osteonecrosis, 22. Arthrofibrosis, 23. Failure of ingrowth prosthesis, 24. Migration, 25. Achilles tendinitis, 26. Soft tissue edema, 27. Bony changes, 28. Edge-loading, 29. Neurinoma, 30. Tendon adhesion. * Denotes inconclusive or missing data.

Fig. 2. Forest plots of the included studies reporting on (a) Aseptic loosening, (b) deep infection, (c) intra-operative fracture, (d) impingement, (e) wound healing problems, (f) impingement, (g) postoperative fracture, (h)malalignment or deformity, (i) component subsidence, (j) ongoing pain and (k) instability. Forest plots display the mean proportion of complications (a-f), 95 % confidence interval and the relative weight of the individual studies. The diamond indicates the pooled estimate and its 95 % confidence interval. The red bar indicates the 95 % prediction interval. Prediction intervals illustrate the range of true effects expected to occur in similar studies in future settings.

A meta-analysis was performed for the ten most reported complications (Fig. 2).

The pooled complication rates for the ten most reported complications were according the classification by Glazebrook: deep infection 0.02 (95%CI 0.01–0.02 in 221 events in 12,963 ankles, 77 studies), aseptic loosening 0.05 (CI 0.03–0.06 in 486 events in 9425 ankles, instability 0.02 (95 %CI 0.01–0.04 in 103 events in 3297 ankles, 23 studies), post-operative fracture 0.03 (95 % CI 0.02–0.03 in 437 events in 6388 ankles, 56 studies), component subsidence 0.04 (95 %CI 0.02–0.06 in 154 events in 3915 ankles, 37 studies), ongoing pain 0.04 (95 %CI 0.03–0.06 in 396 events in 5794 ankles, 45 studies), post-operative malalignment or deformity 0.04 (95 % CI 0.03–0.06 in

Table 3
Summary of reported complications and conclusion of GRADE assessment.

Complication	No. of studies	Number of TAA	Effect estimate (95 %CI)	Quality of evidence (GRADE)
Deep infection	77	12.963	0.02 (95 % CI 0.01–0.02)	⊕⊕⊙⊙ LOW
Instability	23	3.297	0.02 (95 %CI 0.01–0.04)	⊕⊙⊙⊙ VERY LOW
Postoperative fracture	56	6.388	0.03 (95 %CI 0.02–0.03)	⊕⊙⊙⊙ VERY LOW
Component subsidence	37	3.915	0.04 (95 %CI 0.02–0.06)	⊕⊙⊙⊙ VERY LOW
Ongoing pain	45	5.794	0.04 (95 %CI 0.03–0.06)	⊕⊙⊙⊙ VERY LOW
Wound healing problems	61	7.988	0.04 (95 %CI 0.03–0.06)	⊕⊕⊙⊙ LOW
Postoperative malalignment /deformity	38	4.936	0.04 (95 %CI 0.03–0.06)	⊕⊙⊙⊙ VERY LOW
Aseptic loosening	71	9.425	0.05 (CI 0.03–0.06)	⊕⊙⊙⊙ VERY LOW
Intra-operative fracture	64	6.100	0.06 (95 %CI 0.04–0.08)	⊕⊙⊙⊙ VERY LOW
Impingement	47	5.203	0.06 (95 %CI 0.04–0.08)	⊕⊕⊙⊙ LOW

GRADE Working Group grades of evidence [17].
High certainty: We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

180 events in 4936 ankles, 38 studies), 71 studies), impingement 0.06 (95 %CI 0.04–0.08 in 333 events in 5203 ankles, 47 studies), wound healing problems 0.04 (95 % CI 0.03–0.06 in 443 events in 7988 ankles, 61 studies) and intra-operative fracture 0.06 (95 %CI 0.04–0.08 in 348 events in 6100 ankles, 64 studies).

There was considerable heterogeneity (Fig. 2). The 95 % prediction intervals (PIs) present heterogeneity in the same metric as the original effect size measure, illustrating the range of true effects that can be expected in future settings [16].

Results GRADE assessment: The confidence in the estimates from the meta-analyses according to the GRADE assessment concerning the complications was low to very low (Table 3) [14].

4. Discussion

TAA is an emerging treatment and might be a valid alternative to ankle arthrodesis in the treatment of end-stage ankle arthroplasty. The aim of this systematic review was to generate an overview of complications of TAA surgery and perform a meta-analysis on complications incidence.

The definition of a complication is debatable. Ricketts et al. emphasized that there need to be some clarity about the definition of a complication. The National Health Service defined a complication as any less than perfect outcome that increases the cost of treatment [18]. Sokol and Wilson defined a complication as any undesirable, unintended and direct result of the ankle replacement [9]. Henry et al. suggests using an algorithm detailing evaluation and management of a painful total ankle replacement but does not propose to report pain as a complication. Therefore, it could be suggested to report this in further research as a complication as it is an unintended, undesirable result of its initial treatment [19]. McKenna et al. defined failure as removal of either the tibial or talar component or both components with subsequent placement of an antibiotic spacer, reimplantation of metal components, conversion to an arthrodesis, or amputation [10]. In our meta-analysis we only reported complications inherent to the ankle replacement.

In our meta-analysis the most occurred complications in ankle replacements were intra-operative fracture 0.06 (95 %CI 0.04–0.08) (GRADE Very low) and impingement 0.06 (95 % CI 0.04–0.08) (GRADE low) respectively. Clough et al. reported a rate of intraoperative fractures of 9.7 % of the medial malleoli and 1.4 % of the lateral malleoli [20]. Most intra-operative fractures are iatrogenic, associated with inadequate exposure by the jig itself or size of the resection guide, together with inadvertent use of the saw blade [21].

Our meta-analysis shows a rate of intra-operative fractures of 5.6 % (range 0–40 %); 4.9 % medial malleoli and 1.7 % lateral malleoli. Only seventy-seven percent of the intra-operative fractures were operated; 65.6 % of the medial malleoli and 60.3 % of the lateral malleoli. Therefore, the suggestion by Lazarides et al. that in all periprosthetic TAR fractures fixation is recommended seems debatable.

Another frequent complication in ankle replacement is impingement, also called gutter pain. The pain is derived from either soft-tissue or bony impingement in one of the gutters in ankle replacement. The largest study of impingement after TAA by Schuberth et al. reported that impingement can be caused by component design and sizing issues, subsidence and avascular necrosis, hypertrophic bone, and uncontrolled varus or valgus thrust. They performed prophylactic widening of the medial and lateral gutters to diminish the prevalence of impingement [22]. Najefi et al. changed their axial rotation of ankle, after their learning curve, by reducing the impingement occurrence to 1.9 %. CT scanning confirmed their internal rotation of the tibial component and medial impingement [23].

Nunley et al. noticed that the reoperation rate was higher in mobile bearing total ankle replacements compared to fixed bearing total ankle replacements to relieve impingement [24]. Our meta-analysis could not certify this hypothesis, because most included studies did not make a distribution of impingement between the different types of ankle replacement.

Glazebrook et al. proposed a classification system for complications of total ankle replacement based on clinical outcomes. In which they divided the complications in high-grade (deep infection, aseptic loosening, and implant failure), medium-grade (technical error, subsidence, and postoperative bone fracture) and low-grade (intra-op bone fractures and wound healing problems) [8]. Simonson et al. stressed out that 16.2 % were unclassified [25]. The unclassified complications included nerve and tendon injuries and were not explicitly defined by Glazebrook et al. Gadd et al. simplified the complication system of Glazebrook to two types: high and low. They found it unlikely that intra-operative bone fractures and wound healing problems would lead to TAA failure [26]. While Lazarides et al. has proven that intra-operative talar fractures were related to a higher failure rate. Consensus in the literature is necessary and the use of a coding system, as reported by Glazebrook et al., and Vancouver foot and ankle WNS classification system could according to the authors be a vast improvement [8,27].

In our meta-analysis the population was very heterogeneous according to the indication for TAA and age of the patients. Spirit et al. mentioned that age was the only significant predictor of reoperation [6]. Additionally, the Swedish national register of 780 TAA's and as our Dutch national register of 810 TAA's showed a higher hazard ratio in older patients [17,28]. A limitation of the present systematic review is that because of the heterogeneity of the

included studies no correlation between age and complications could be established. This finding is in contrast with Steck et al. who reported that patient selection, surgeon experience, implant features, and prosthetic device selection all could influence the incidence of complications [29].

While that there are several reports showing that TAA has a higher complication rate than arthrodesis [30,31], the meta-analyses of Fanelli et al. and Li et al. showed no difference in complications and reoperation rate between TAA and arthrodesis [32,33]. Future research needs to identify which risk factors cause complications, reoperations, failure, and therefore could lower patient satisfaction.

As a result of the high variable of the definition of a low- and high-level center across the studies, we could not discriminate between the occurrence rate of complications in high and low volume centers. Zaidi et al. found in the NJR database that early revision rates are significantly higher in low volume centers, while this was contrasted with a Norwegian registry study that examined 257 TARs and found no difference in survival by unit volume [34,35]. This is also confirmed by our study of the Dutch national registry which could not find a difference in high and low volume centers [28]. However, whether this relationship could be assessed at surgeon volume instead of center volume, as suggested by Baker et al., remains to be proven [36].

As for all systematic reviews, this study is limited by the quality of evidence available. In most meta-analyses of reported complications, the evidence according to GRADE working group methodology was graded as low to very low. Apparently, there is a higher level of evidence concerning complications in TAA according to our meta-analysis. Nonetheless, it was not possible to draw any conclusions on these factors which influence the complication rates. In addition, we could not account for the assumed abbreviated learning curve period of current-generation TAR systems as opposed to older generations that likely involved a higher incidence of various complications during the surgeon learning curve period.

Furthermore, only studies written in English or Dutch were included in this systematic review which could be a potential limitation of this study.

Moreover, considerable variation was identified between studies in (the choice of) the complications reported and in their definitions.

In addition, this systematic review and meta-analysis showed considerable heterogeneity. To account for the encountered heterogeneity, a random effects model was used, especially the range in age, type of prosthesis and aetiology as indication for TAA differs greatly across studies.

These factors might be of importance in determining which patient subgroups benefit the most from this treatment and could steer the potential benefit of more stringent patient selection.

5. Conclusion

TAA is a proven effective procedure to relief pain and preserve function in end-stage ankle arthritis. The complications rate of TAA is highly variable across studies. The evidence according to GRADE working group methodology was graded as low to very low. In this study multiple factors, such as the surgeon's experience, patient's specific health factors and activity pattern, that could be additional determinants of TAA outcome, were not assessed. Awareness of these complications which occur in TAA is necessary, to achieve a decrease in complication rates in TAA surgery. Further research should focus on a more thorough patient selection to preserve the functional outcome improvements while reducing the complication and revision rates to increase long-term clinical survival.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.fas.2022.07.004.

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