Prognostic factors associated with failure of total elbow arthroplasty

a systematic review

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Aims
The aims of this study were to identify and evaluate the current literature examining the prognostic factors which are associated with failure of total elbow arthroplasty (TEA).

Methods
Electronic literature searches were conducted using MEDLINE, Embase, PubMed, and Cochrane. All studies reporting prognostic estimates for factors associated with the revision of a primary TEA were included. The risk of bias was assessed using the Quality In Prognosis Studies (QUIPS) tool, and the quality of evidence was assessed using the modified Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) framework. Due to low quality of the evidence and the heterogeneous nature of the studies, a narrative synthesis was used.

Results
A total of 19 studies met the inclusion criteria, investigating 28 possible prognostic factors. Most QUIPS domains (84%) were rated as moderate to high risk of bias. The quality of the evidence was low or very low for all prognostic factors. In low-quality evidence, prognostic factors with consistent associations with failure of TEA in more than one study were: the sequelae of trauma leading to TEA, either independently or combined with acute trauma, and male sex. Several other studies investigating sex reported no association. The evidence for other factors was of very low quality and mostly involved exploratory studies.

Conclusion
The current evidence investigating the prognostic factors associated with failure of TEA is of low or very low quality, and studies generally have a moderate to high risk of bias. Prognostic factors are subject to uncertainty, should be interpreted with caution, and are of little clinical value. Higher-quality evidence is required to determine robust prognostic factors for failure of TEA.

Article focus
- What prognostic factors have been reported to be associated with the failure of total elbow arthroplasty (TEA), leading to revision surgery?

- What are the reported associations between those prognostic factors and failure of TEA?
- What is the quality of evidence investigating prognostic factors associated with failure of TEA?

Key messages

- The overall quality of evidence investigating the prognostic factors associated with failure of TEA is of low or very low quality, and most studies have a moderate to high risk of bias.
- The sequelae of trauma as an indication for TEA and male sex were reported to be associated with failure of TEA in more than one study, but the overall quality of evidence was low, and should be interpreted with caution.
- Prognostic factors associated with failure of TEA are currently subject to uncertainty and are of little clinical value. More high-quality evidence is required to determine robust prognostic factors for failure of TEA.
- Future studies should use advancements in prognostic factor research methodology led by the PROGnosis REsearch Strategy (PROGRESS) partnership and follow the REporting recommendations for tumour MARKer prognostic studies (REMARK) reporting guidelines, which are specific to research into prognostic factors.

Strengths and limitations

- This is the first systematic review to provide a comprehensive overview of prognostic factors for failure of TEA in patients, requiring revision surgery.
- This review followed the methodological advances in performing systematic reviews and meta-analyses in prognostic factor research, and used the recommended checklists and tools proposed by the PROGRESS and The Cochrane Prognosis Methods Group (PMG).
- Meta-analyses were not possible due to the heterogeneous nature of the methodology, statistical analyses, prognostic estimates, differences in how prognostic factors were categorized, and the high risk of bias in the studies.

Introduction

Total elbow arthroplasty (TEA) has evolved from an experimental salvage procedure into a recognized treatment for the painful arthritic elbow, and is being increasingly used for other indications such as trauma involving the elbow.[1] However, despite technological advances, TEA continues to have higher failure rates than arthroplasty of the hip and knee.[2-5]

There are several causes of failure of a TEA, such as breakage, disassembly, or instability of the prosthesis, aseptic loosening, infection, and periprosthetic fracture.[6] These can cause pain, as well as reduced function and quality of life.[7] Further surgery is usually required. This may include the addition, removal, or alteration of all or part of the arthroplasty.[8] The revision procedures are associated with a high risk of adverse events such as persistent pain, disruption of soft-tissues, infection, nerve injury, poor function, and increased costs for healthcare systems.[9,10]

Identifying factors associated with failure is essential to inform the future development of strategies designed to reduce the risk of failure and the need for revision surgery. A prognostic factor is defined as any variable that is associated with the risk of a health outcome among people with a particular condition.[11-13] In the context of this review, the outcome is failure leading to revision surgery in patients with TEA (the condition). A better understanding of prognostic factors is helpful clinically to explain the differences in the risk of failure between patients,[14] which may facilitate decisions about whether or not to proceed with TEA.[15]

An improved understanding of prognostic factors can aid the planning of future research, for example, into the development of ways to modify them or to use a prognostic factor to stratify patients during the recruitment or analysis phase of a study.[11] Studies of these factors could be used to develop a prognostic model for the outcome of TEA by making individualized predictions of risk to guide clinical decision-making. Prognostic factors, such as the type of implant, and the number of TEAs performed by surgeons and hospitals, could also be used by government and health bodies when planning services. Investigating these factors may, in the long term, reduce morbidity, reduce the need for revision surgery, and reduce the costs.

This systematic review aimed to identify, describe, appraise, and synthesize the current literature examining the prognostic factors associated with the failure of TEA. The review also identified gaps in the evidence, for planning future research.

Methods

This systematic review followed the PROGnosis REsearch Strategy (PROGRESS) and Cochrane Prognosis Methods Group (PMG) guidance for the conduct of systematic reviews and meta-analyses in research relating to prognostic factors.[12,16] It was registered at the international prospective register of systematic reviews (PROSPERO) and followed the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines (checklist included in the Supplementary Material).[17] The protocol has been published.[18] This section includes a brief overview of the methodology.

Eligibility

Studies were eligible if they: 1) evaluated any prognostic factors in patients who underwent primary TEA using revision surgery as an outcome, as summarized using the eligibility criteria based on the Population, Index prognostic factor, Comparator prognostic factor, Outcome, Time and Setting (PICOTS) model;[12] 2) were published in peer-reviewed journals; and 3) quantified the prognostic associations of any factors with the failure of a primary TEA.

The inclusion and exclusion criteria are summarized in Table I. Any studies that were published in a language other than English, with no English version available, were translated by PhD students at the lead author's institution who are native speakers of that language.

Search strategy

Electronic searches were conducted using Ovid MEDLINE, Embase, PubMed, and Cochrane Library databases. The search strategy, using a combination of subject headings (MESH) and free-text was developed with guidance from an information scientist (see Acknowledgements). They were conducted on 13 December 2022. Screening of references of the included studies and relevant reviews was undertaken to

Table I. Inclusion and exclusion criteria.

Inclusion	Exclusion
Human population with primary total TEA for any indication	Non-TEA surgery (e.g. radial head arthroplasty, distal humeral hemiarthroplasty, or lateral resurfacing, arthroscopy, fixation)
The outcome is defined as revision surgery	Other definitions for failure (e.g. radiological, complications, or clinical)
Randomized/non-randomized trials, prospective/retrospective cohort, registry, analytical cross-sectional studies, and a case series with 50 TEAs or more	Review articles, surveys, case studies, case series with fewer than 50 TEAs, conference abstracts, studies of biomechanics, health economics, or outcomes of revision TEA
Report prognostic estimates (e.g. hazard ratio, risk ratio, odds ratio, or difference in means)	No prognostic estimates
In English or translation into English possible	No English-language manuscript and translation into English not possible

TEA, total elbow arthroplasty.

identify further studies that could have been missed in the electronic search ('Bibliography screening'). No search of the grey literature was undertaken. All duplicates were removed using EndNote v20 (Clarivate, USA).

Screening

The data were screened by two independent reviewers (ZH and either CKG or LMB) and was completed in two phases. In Phase 1, the titles and abstracts were screened, and Phase 2 included screening the full text of studies not excluded in Phase 1. The screening was conservative, and studies were only excluded if there was an agreement to remove them. Disagreements were resolved by discussion with a third reviewer (LKF, JCS, or ACW). The search results were managed using Rayyan software (USA).

Data extraction

Data were extracted by two independent reviewers (ZH and either CKG or LMB) using a standardized collection tool which was based on the Checklist for Critical Appraisal and Data Extraction for Systematic Reviews of Prediction Modelling Studies for Prognostic Factors (CHARMS-PF).[12] Disagreement was again resolved by discussion and the involvement of a third reviewer (LKF, JCS, or ACW).

Risk of bias

The risk of bias was assessed by two independent reviewers (ZH, TM) using the Quality In Prognostic Studies (QUIPS)[19,20] tool. Disagreement was resolved by discussion and the involvement of a third reviewer (JCS).

Data synthesis

All reported prognostic estimates and accompanying confidence intervals (CIs) were extracted. The p-value was only extracted if CIs were not reported. Due to the heterogeneous nature of the studies and their low quality, formal statistical evaluation was not possible and the results were discussed in a narrative synthesis. In a limited number of cases, forest plots were used to display prognostic estimates from different studies.

Quality of evidence

The quality of evidence for each prognostic factor was rated as high, moderate, low, or very low, using the modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework adapted for research into prognostic factors.[21] The evidence was initially rated as moderate or high, depending on the phase of investigation. Exploratory studies (phase 1) were initially ranked as moderate-quality, whereas confirmatory studies (phase 2) and studies examining the prognostic pathway (phase 3) were ranked as high-quality.[21] The quality of evidence was upgraded or downgraded based on the GRADE criteria.

Results

The searches yielded 8,697 studies, including 4,210 duplicates, 280 conference abstracts, and seven Cochrane protocols (Figure 1). The titles and abstracts of the remaining 4,200 studies were screened and 3,940 were excluded, leaving 260 studies, the full texts of which were retrieved and evaluated; 16 were translated into English.

A total of 19 studies met the inclusion criteria.[22-40] Two used the same dataset; however, they performed different analyses that met the inclusion criteria, and both were included.[24,29]

Nine (47%) were cohort studies,[22,23,27,28,30,33-35,40] six (32%) were joint registry studies,[24,29,31,37-39] and four (21%) used regional/national non-registry databases[25,26,32,36] (Table II). Most (16, 84%) were conducted in the USA[22,23,25,26,30,32,33,36] and Europe,[24,27,29,31,34,35,37,40] with one each in Australia,[39] Japan,[28] and New Zealand.[38] The characteristics of the studies, and their candidate prognostic factors, are shown in Table II.

There were 30,723 TEAs in 18 studies, excluding duplicate patients from two with the same cohort.[24] A total of 17 studies reported the number or percentage of male and female patients, the mean of which was 74% female (63% to 97%). The mean age of the patients within the studies was between 57 and 71 years with an overall range of 18 to 93 years. The indication for TEA was reported in 16 studies (89%),[22,23,25,27-3133-40] of which four (22%) included patients with inflammatory arthritis only,[27,28,35,37] and one investigated patients with acute trauma only.[23] Ten (56%) had heterogeneous diagnoses; inflammatory arthritis was the most prevalent

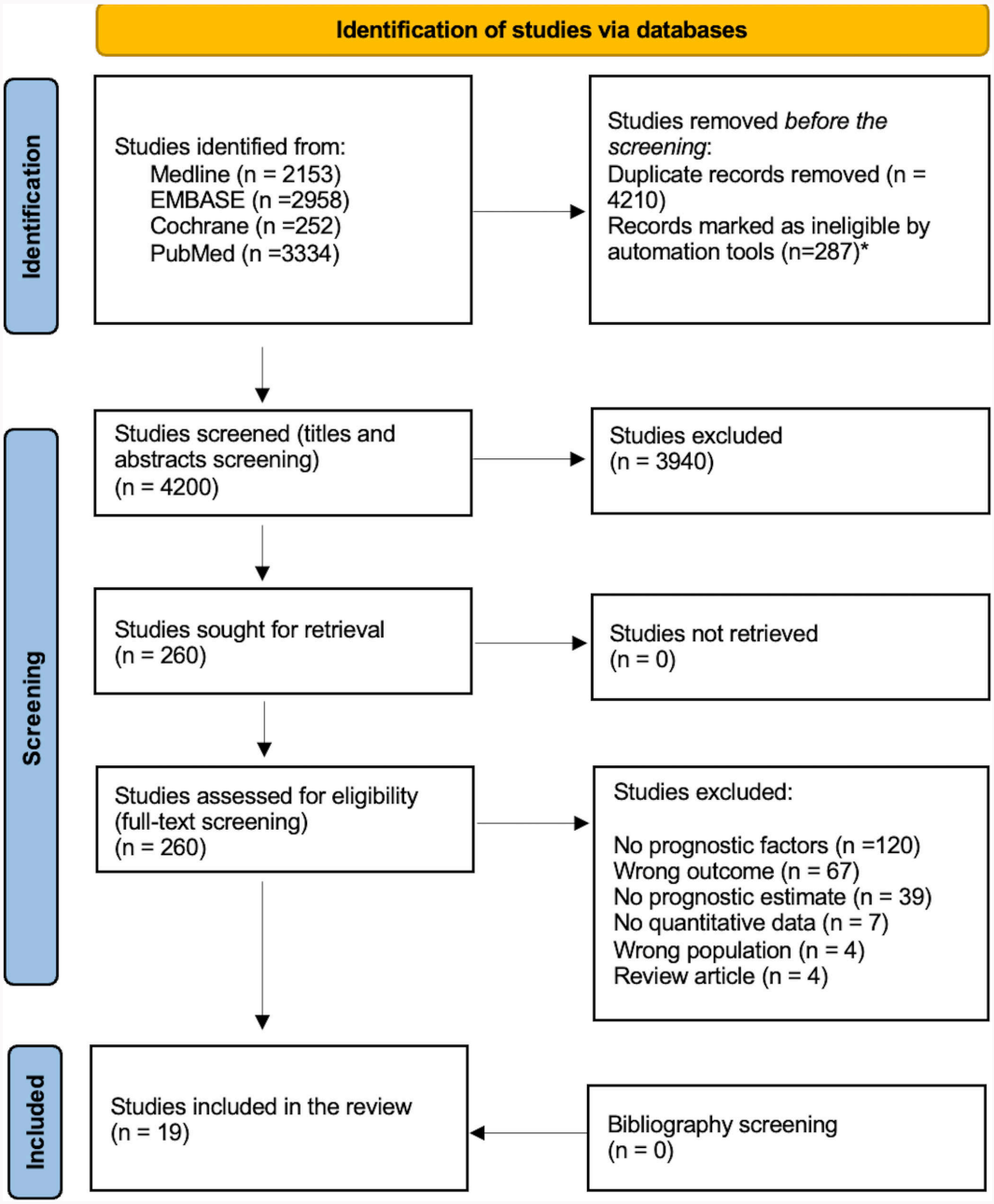

Fig. 1
Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) flowchart outlining the selection of studies.

in eight studies including between 52% and 88% of the patients,[22,29-3133,34,38,,40] and trauma or its sequelae in three studies (range 53% to 63%).[25,36,39]

Outcome

Revision for any indication was investigated in 16 studies (84.2%). One (5.3%) examined revision for humeral loosening only,[35] one (5.3%) included revision for aseptic loosening only,[27] and one (5.3%) included a combination of revision or aseptic loosening as the outcome.[28] A total of 11 studies (59.7%) defined revision in the manuscript,[22,24,27,29-3133,34,37,39,,40] and five (26.3%) used the International Classification of Diseases (ICD) codes.[25,26,32,35,36] Three (15.8%) did not include a definition of revision.[23,28,38]

Statistical methods

Eight studies reported prognostic estimates from univariable analyses (i.e. resulting in unadjusted estimates) and 16 included multivariable analyses (i.e. resulting in adjusted estimates) using various methods of statistical modelling.[22-2527-3133-39] For the multivariable analyses, 12 studies used Cox regression,[22-2427,29,31,33-3537-39] three used logistic regression,[28,30,36] and one used generalized estimating equations.[25] Three used univariable analysis only,[26,32,40] two used a chi-squared test,[26,32] and in one study it was not clear what statistical method was used but the authors stated that the results were unadjusted.[40] The effect estimates differed between studies. In the 12 studies which used a Cox regression model, six reported hazard ratios (HRs),[22,23,33,35,38,39] four labelled their reported estimates as relative risks,[24,29,31,34] and

Table II. Summary of the characteristics of the studies.

Author (Year)	Data source	Country	Diagnoses	TEA; total patients (proportion female)	Mean age, yrs (SD)	Mean follow-up, mths	Implant included	Prognostic factors			
								Patient factors	Implant factors	Surgical factors	Other
Baghdadi et al[22] (2014)	Cohort	USA	Inflammatory (52%), TS (34%), AT (9%), OA (3%), Other (2%)	723 (76%)	62 (13.7)	69.6*	CM	A1, A2, A7, A13			
Barco et al[23] (2017)	Cohort	USA	AT	44 (75%)	71 (13.6)	NR	CM	A1, A7, A13			
Borton et al[40] (2021)	Cohort	UK	Inflammatory (64%), OA (25%), TS (11%)	67 (63%)	67*	98.5	Discovery	A3			
Fevang et al[24] (2009)†	Joint registry	Norway	Inflammatory (86%), TS (7%), OA (5%), Other (3%), AT (2%)	562 (80%)	62	74.4*	GSB-3, IBP, Kudo, NES, Norway	A1, A7, A13	B2, B7		D3
Gay et al[25] (2012)	Regional database	USA	AT + TS (63%), Inflammatory (23%), OA (7%), Other (7%)	1,155 (71%)	58 (17.2)	NR	NR	A7		C4	
Griffin et al[26] (2015)	National database	USA	NR	7,580 (81%)	NR	NR	NR	A2			
Ikävalko et al[27] (2010)	Cohort	Finland	Inflammatory	522 (92%)	57 (NR)	127	SS		B3, B8		
Kodama et al[28] (2017)	Cohort	Japan	Inflammatory	45 (97%)	59 (NR)	141	Kudo-5	A3, A9			
Krukhaug et al[29] (2018)†	Joint registry	Norway	Inflammatory (79%), TS (8%), OA (5%), AT (5%), Other (4%)	828 (78%)	63 (13.3)	106.8*	Discovery, GSB-3, IBP, Kudo, NES, Norway, Other	A1, A7, A13	B2, B5, B7		D3
Perretta et al[30] (2017)	Cohort	USA	Inflammatory (62%), AT + TS (27%), OA (9%), Other (2%)	102 (81%)	61 (12)	73.2	CC, CM, Discovery	A1, A7, A13	B7		
Plaschke et al[31] (2014)	Joint registry	Denmark	Inflammatory (73%), TS (17%), OA (5.6%), Other (2.5%), AT (2%)	324 (82%)	62	105	CC, CM, Discovery, GSB-3, Kudo-3, Pritchard ERS, SS	A1, A7, A13	B5, B7		D3
Poff et al[32] (2022)	National database	USA	NR	7,256 (71%)	63 (16)	NR	NR			C2	
Sanchez-Sotelo et al[33] (2016)	Cohort	USA	Inflammatory (88%), TS + AT (12%)	461 (79%)	64 (11)	108*	CM	A12, A13	B6		
Schoni et al[34] (2013)	Cohort	Switzerland	Inflammatory (69%), TS (19%), Other (12%)	293 (75%)	57 (NR)	109*	GSB-3	A1, A7, A10, A11, A13			D2
Shah et al[35] (2000)	Cohort	UK	Inflammatory	186 (NR)	NR	NR	SS			C3	

(*Continued*)

(*Continued*)

Author (Year)	Data source	Country	Diagnoses	TEA; total patients (proportion female)	Mean age, yrs (SD)	Mean follow-up, mths	Implant included	Prognostic factors			
								Patient factors	Implant factors	Surgical factors	Other
Singh et al[36] (2021)	National database	USA	AT + TS (53%), Other (25%), Inflammatory (12%), OA (10%), AVN (0.1%)	7,992 (68%)	60 (0.29)	NR	NR	A1, A5, A6, A7, A8, A13			D1
Skyttä et al[37] (2009)	Joint registry	Finland	Inflammatory	1,457 (87%)	59 (NR)	NR	CM, Discovery, IBP, Kudo, NES, Norway, Pritchard-2, SS, other		B7	C1	D3
Viswanath et al[38] (2020)	Joint registry	New Zealand	Inflammatory (55%), TS (26%), Other (19%)	468 (80%)	67 (NR)	NR	CM, Latitude		B7		
Viveen et al[39] (2019)	Joint registry	Australia	AT (36%), OA (34%), Inflammatory (28%), Other (2%), AVN (< 1%)	1,220 (73%)	70 (NR)	NR	CM, Comprehensive, Discovery, IBP, Latitude, Mutars, Nexel, SS	A7	B4, B5, B7		

A1, age; A2, BMI; A3, dominant elbow; A4, duration of rheumatoid arthritis before TEA; A5, ethnicity; A6, income; A7, diagnosis/indication for TEA; A8, morbidity using Deyo-Charlson score[41]; A9, preoperative flexion/extension arc range of motion; A10, previous corticosteroids use; A11, previous elbow surgery; A12, prior elbow trauma; A13, sex; B1, fixation of the ulnar component; B2, fixation type; B3, humeral implant design; B4, if a radial head is used; B5, implant design (linked/unlinked); B6, implant surface finish; B7, implant type; B8, ulnar implant design; C1, hospital type; C2, hospital's volume; C3, implant positioning; C4, surgeon's volume; D1, insurance status; D2, subsequent surgical procedures; D3, year of TEA surgery.
*Median value.
†Two studies using the same dataset.
AT, acute trauma; CM, Coonrad-Morrey; GSB, Gschwend/Scheier/Bähler prosthesis; IBP, instrumented bone preserving; NES, Norway Elbow System; NR, not reported; OA, osteoarthritis; SD, standard deviation; SS, Souter Strathclyde; TER, total elbow arthroplasty; TS, trauma sequelae.

two reported risk ratios (RRs).[27,37] Six studies reported odds ratios (ORs),[25,26,28,30,32,36] including the three that used logistic regression, the study that used generalized estimating equations, and the two that used chi-squared tests. Relative risk was reported by the study that had no clear statistical method.[40]

Risk of bias

Of 114 QUIPS domains which were assessed, 49 (43%) were rated as moderate, 47 (41%) as high, and 18 (16%) as low risk of bias (Figure 2). The low risk domains related to participation (eight), attrition (one), measurement of prognostic factors (one), measurements of outcome (six), and statistical analysis and reporting (two). A detailed risk of bias assessment is included in Supplementary Table i.

In the participants domain, studies were mainly rated as moderate or high risk of bias if it was not possible to establish whether all patients within the stated timeframe were included in the analysis,[24,27-2935,40] they had limited descriptions of baseline characteristics,[24,25,27,31] and/or the inclusion/exclusion criteria were not reported.[24,27,29,31,32,36]

In the attrition domain, most studies did not report the response rate, or it was < 80%.[23,25-3032,34-36,38] In those that reported the response rate, the reasons and characteristics of the patients lost to follow-up were not described or discussed.[22-3537,38]

The measurement of prognostic factors domain was largely associated with a moderate to high risk of bias because the methods of measuring the factors were not clearly defined in most studies,[22,23,25-38] and continuous variables were categorized at unexplained cut-off points.[24,25,28,29,31,32,36] The extent of missing data was also not reported in most studies, and in the few studies in which it was reported, there was no explanation of how missing data were handled.[23,25,28,29,31-35,40]

In the measurement of outcome domain, studies were associated with a moderate or high risk of bias because the outcome was not defined clearly,[23,25,26,28,32,36,38] and/or the methods to ensure that all revision procedures were included were not clear or reliable.[23,25-3032,33,35,36,40]

None of the studies were rated as having a low risk of bias for the adjustment for other domains of prognostic factors. Three studies used unadjusted analyses only.[26,32,40] Most studies adjusted for a limited number of prognostic factors (e.g. only age and sex), and did not report the rationale for selecting the factors that were adjusted for.[22-2427-2933-3537-40] One study did not report the prognostic factors that were adjusted for.[25]

In the statistical analysis and reporting domain, most studies did not report the results for all prognostic factors from

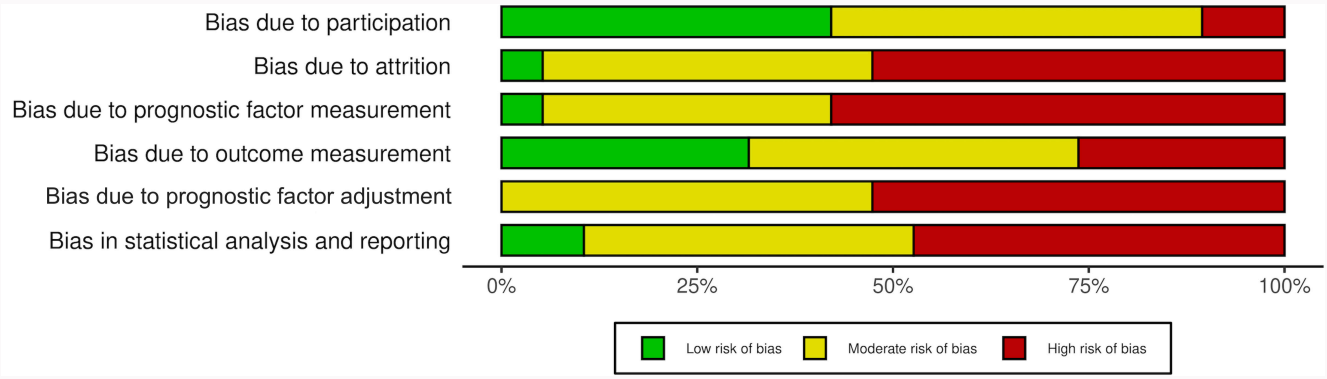

Fig. 2
Assessment of the risk of bias.

the multivariable model,[27,29,31,37-39] and/or lacked information about the statistical modelling strategy.[22,23,25-2931-3537-39] Six studies were thought to have incorrectly labelled HRs as relative risks or RR while using a Cox regression model.[24,27,29,31,34,40] The first author from each study was contacted by email. In three, they confirmed the effect estimate which was used represented the HR;[24,29,37] in one, the author stated that "RR" represented relative risk,[31] and the authors from the remaining two studies did not respond.[27,34]

Data synthesis

A total of 28 prognostic factors were investigated. These were grouped into patient, implant, surgical, and other factors. These results, including prognostic estimates and their confidence intervals, are summarized in Supplementary Tables ii to iv. Meta-analyses were not possible due to the heterogeneous nature of the methodology, statistical analyses, reported prognostic estimates, differences in how prognostic factors were categorized, and the high risk of bias in the studies.

Patient factors

A total of 13 patient factors were investigated in 14 studies. Age, diagnosis/indication for surgery, and sex were the most frequently investigated. Age was investigated in eight studies.[22-2429-3134,,36] Three investigated the impact of increasing age per year,[22,30,34] and one investigated increasing age per decade.[23] Only one of these studies reported a protective effect against failure for each year of increased age (adjusted-HR 0.98; 95% confidence interval (CI) 0.96 to 0.99).[22] Three studies dichotomized age according to whether patients were aged ≥ or < 60 years,[24,29,31] and one study categorized age into four categories (< 50, 50 to 64, 65 to 79, and ≥ 80 years), all reporting, in adjusted analyses, no association with failure of TEA.[36] The overall quality of evidence investigating age as a potential prognostic factor was very low, because all studies had serious or very serious limitations, lacked precision, and there was inconsistency in the findings between studies.

The indication for TEA was reported in nine studies.[22,23,25,29-3134,36,,39] Two, rated as low-quality evidence, reported the sequelae of trauma associated with failure of TEA compared with inflammatory arthritis (Figure 3). Low-quality evidence from two studies also reported trauma, including acute trauma and the sequelae of trauma associated with failure compared with inflammatory arthritis (adjusted-HR 3.48; 95% CI 2.34 to 5.27 and adjusted OR 3.40; 95% CI 1.10 to 10.00).[22,30] One study also reported that osteoarthritis (OA) had an increased hazard of failure compared with inflammatory arthritis (adjusted HR 2.00; 95% CI 1.30 to 3.10) or acute trauma (adjusted HR 1.80; 95% CI 1.10 to 3.00).[39] However, this was inconsistent with other studies comparing similar categories; therefore, the quality of evidence was again rated as very low.[29,31,36]

Sex was investigated as a multivariable prognostic factor in eight studies, using a range of prognostic effect estimates, and the results are summarized using a forest plot (Figure 4).[22-2430,31,33,34,,36] Four studies reported that male sex was associated with failure of TEA, with significant effect sizes (three HR and one RR) between 1.75 and 2.49.[22,23,31,33] The remaining four studies reported no association between sex and failure of TEA: three in which the CIs crossed the 'no association' threshold (HR 1.70, OR 2.10, and OR 0.85 for males),[24,30,36] and one in which CIs were not given but the result was reported to be non-significant, and it is therefore not included in the forest plot (RR 1.34 in males).[34] The quality of evidence was rated as low due to limitations in the studies investigating sex as a prognostic factor, lack of precision, and low effect size.

BMI was investigated by two studies only.[22,26] One reported no association between a unit increase in BMI and failure of TEA,[22] but reported that patients with BMI between 35 and 40 kg/m^2 had an increased HR of failure compared with those with a BMI < 30 kg/m^2 (adjusted-HR 3.08; 95% CI 1.61 to 5.45).[22] Another study, with very serious limitations, reported in unadjusted analysis, that patients with a BMI between 30 and 40 kg/m^2 and BMI > 40 kg/m^2 had higher odds of failure than those with BMI < 30 kg/m^2.[26] The quality of evidence was rated as very low due to limitations in the studies, inconsistency in the categories used, and the small effect sizes.

Nine other patient factors were investigated with very low quality evidence, by one exploratory study each with serious to very serious limitations. Some of these factors were reported to be associated with failure of TEA including a preoperative arc ROM of ≥ 85°, previous trauma to the elbow, no previous use of corticosteroid medication, rheumatoid arthritis for < 15 years before TEA, and patients who had

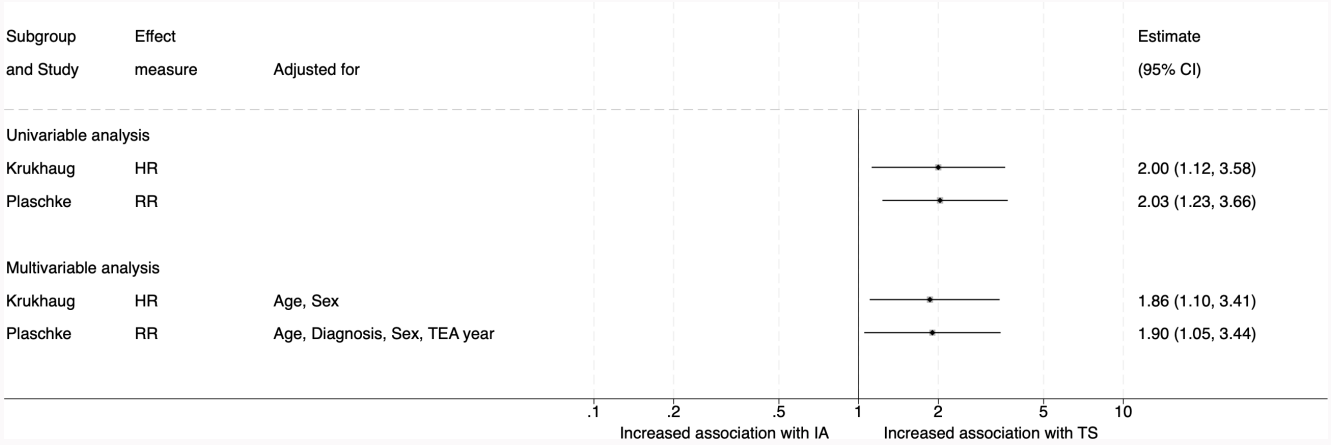

Fig. 3
The association between the diagnoses of trauma sequelae (compared to inflammatory arthritis) and total elbow arthroplasty (TEA) failure requiring revision. The overall effect estimate is not reported due to low quality of the evidence and the heterogeneous nature of the studies. CI, confidence interval; HR, hazard ratio; IA, inflammatory arthritis; RR, risk ratio; TS, trauma sequelae.

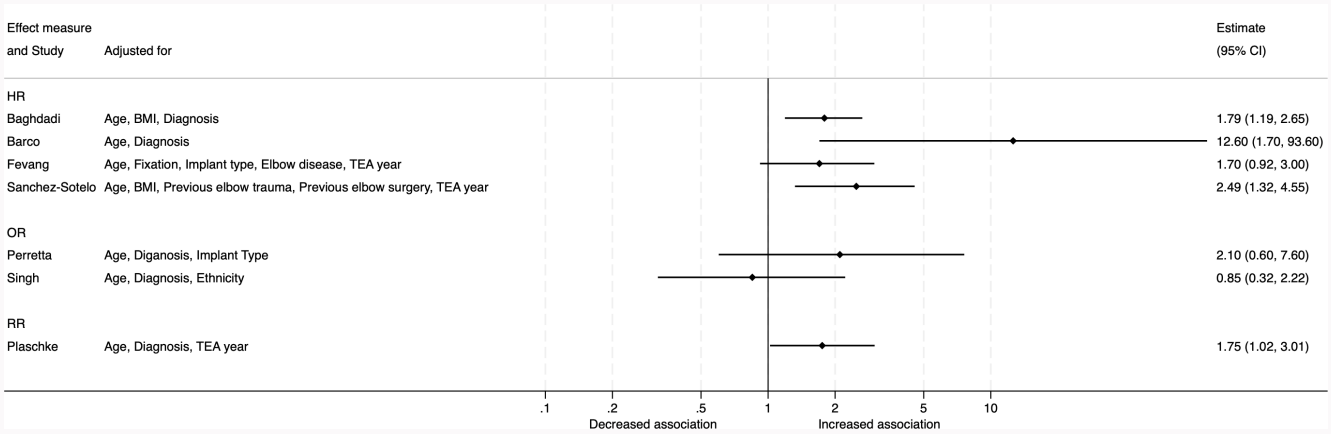

Fig. 4
The association between male sex and failure of total elbow arthroplasty (TEA) requiring revision in multivariable analyses. The overall effect estimate is not reported due to low quality of the evidence and the heterogeneous nature of the studies. CI, confidence interval; HR, hazard ratio; OR, odds ratio; RR, risk ratio.

TEA in their dominant arm (Supplementary Table ii). Ethnicity, income, and morbidity (using the Deyo-Charlson score)[41] were reported to have no association with failure of TEA (Supplementary Table ii).

Implant factors

Eight different implant factors were evaluated in nine studies.[24,27,29-3133,37-39] One reported a higher risk of failure in unlinked compared with linked implants (RR 1.88; 95% CI 1.10 to 3.20),[31] and two reported no association.[29,39] The quality of evidence was again very low.

Six studies investigated the type of implant with different categorizations used between studies. There was very low-quality evidence from one study reporting that the Norway Elbow System was associated with an increased risk of failure compared with the Norway arthroplasty (adjusted HR 2.57; 95% CI 1.29 to 5.10) and Kudo elbow arthroplasty (adjusted HR 4.70; 95% CI 1.20 to 18.20). In very low-quality evidence, the Kudo arthroplasty was associated with an increased hazard of failure compared with the Norway arthroplasty ten years postoperatively (adjusted HR 2.58, 95% CI 1.16 to 5.76). In addition, very low-quality evidence from one study suggested that the Discovery elbow arthroplasty had lower odds of failure compared with the Coonrad-Morrey arthroplasty (adjusted OR 5.90; 95% CI 1.30 to 27.00), and another study with very serious limitations reported that the Coonrad-Morrey arthroplasty had a decreased hazard of failure compared with the Latitude elbow arthroplasty (adjusted HR 0.33, 95% CI 0.16 to 0.66).

The type of fixation was investigated in one study, which reported with very low-quality evidence that uncemented ulnar components had an increased risk of failure compared with cemented components (adjusted HR 2.98; 95% CI 1.55 to 5.72).[29] The authors also reported, in unadjusted analysis, that uncemented components had an increased risk of failure (HR 3.00; 95% CI 1.56 to 5.75) compared with cemented components.[29] Another study, with very low-quality evidence, reported that polymethyl methacrylate (PMMA) pre-coated ulnar components were associated with failure of

TEA (HR 4.57; 95% CI 1.27 to 29.23) compared with modern plasma sprayed ulnar components.[33]

One study examined Souter-Strathclyde arthroplasties only and reported that metal-backed ulnar components, retentive ulnar components, and long-stemmed humeral components have a protective effect against failure compared with all polyethylene ulnar components, non-retentive ulnar components, and short-stemmed humeral components (Supplementary Table iii).[27] The study had very serious limitations, and the quality of evidence was very low. One study reported no significant difference in the hazard of failure with the use of a radial head component with the Latitude arthroplasty (adjusted HR 1.50; 95% CI 0.70 to 2.90); however, only 43 (3.52%) of the 1,220 TEAs that were included had a radial head component.[39]

Surgical factors

In one study, also with very low quality of evidence, it was reported that the intraoperative positioning of the humeral component of the Souter Strathclyde arthroplasty as examined on postoperative radiographs, influences the risk of failure.[35]

The type and volume of the hospital were investigated in one study each with evidence of very low quality.[32,37] One study compared specialized hospitals with non-specialized hospitals, reporting a higher risk of failure in the non-specialized hospitals (adjusted RR 1.50; 95% CI 1.10 to 2.20).[37] In an unadjusted analysis only, one study examined the impact of the average number of TEAs performed in a hospital in one year on the risk of failure within 90 days of surgery, reporting that hospitals in which between six and 17 TEAs were performed per year had a higher odds of failure compared with those in which ≥ 18 TEAs were performed per year (OR 1.01; 95% CI 1.00 to 1.01). It also suggested that hospitals in which between one and five TEAs were performed per year had lower odds of failure compared with those in which between six and 17 TEAs were performed per year (OR 0.15; 95% CI 0.05 to 0.45), and that there was no difference between hospitals in which between one and five and ≥ 18 TEAs were performed per year (OR 1.00, 95% CI 0.99 to 1.01). This study also had very low-quality evidence.

Another study, with very serious limitations, examined the association between the surgeon's cumulative volume with failure of TEA. This compared the odds of failure if surgeons had performed a total of between one and 19 TEAs with those who had performed ≥ 20 TEAs, but no difference was observed (adjusted OR 2.8) although 95% CIs and p-values were not reported.[25]

Other factors

Three other prognostic factors were investigated. One study investigated the prognostic effect of insurance status in the USA, reporting no association between private, self-funding, health insurance, and (Medicaid and Medicare) and TEA failure (Supplementary Table iv).[36] Another reported that subsequent non-revision surgical procedures after TEA were associated with failure (adjusted relative risk = 1.74, 95% CI not reported; p = 0.049).[34] The authors did not describe the procedures which were included, and the study had very serious limitations.

Three studies examined the association between the year during which the TEA was performed and failure. Two studies used unadjusted analyses only and reported no association.[29,31] One, of very low-quality evidence, suggested that patients who had TEA between 1994 and 2006 had a lower risk of failure compared with those who had a TEA between 1982 and 1993 (adjusted RR 0.60; 95% CI 0.40 to 0.80).[37]

Discussion

This is the first systematic review to evaluate the evidence relating to the prognostic factors which are associated with failure of TEA requiring revision surgery. Methodological guidance and best practice recommendations for systematic reviews of research into prognostic factors were followed.[12,16] Meta-analyses were not possible due to the heterogeneous nature of the studies and their methodological limitations. The diagnoses and implants which were used in the studies also varied, making comparisons difficult.

We found that the literature lacks high- or even moderate-quality evidence, assessed using GRADE methodology, and that most prognostic factors were only investigated in exploratory studies. Almost all studies had a high risk of bias in at least one QUIPS domain. Only three factors were reported to have a consistent association with failure of TEA in more than one study, but the quality of the evidence, using the GRADE criteria, was again low for all three factors as all these studies had serious or very serious limitations with a lack of precision, and low effect sizes.[22,23,29,31,33,42–46]

Two of these factors were the indications for TEA: the sequelae of trauma and trauma. Two studies reported that TEA performed for the sequelae of trauma was associated failure compared with those which were performed for inflammatory arthritis,[29,31] and two other studies also reported that surgery performed for trauma, which included acute trauma and the sequelae of trauma, was associated with failure compared with those performed for inflammatory arthritis. However, for the latter two studies, while it was not possible to distinguish if this difference was driven by acute trauma, the sequelae of trauma, or both,[22,30] the difference was more likely to be determined by the inclusion of the sequelae of trauma because studies that compared acute trauma with inflammatory arthritis as the indication for surgery reported no increased association with failure of TEA.[29,39]

Sex was the third factor with some evidence of association. Four (one registry and three cohort) of eight studies reported that male sex was associated with failure of TEA, three reporting an increased HR one reported an increased RR.[22,23,31,33] The remaining four studies showed no association between sex and failure of TEA.[24,30,34,36] However, two of these studies demonstrated potential prognostic value, with an effect of a similar direction and magnitude to the studies that reported an association between male patients and failure of TEA, but the CIs crossed the null value, which was probably caused by the small sample size in both studies.[24,30] Nevertheless, one study reported no association between sex and failure of TEA and this study had the largest sample size with 7,992 TEAs, compared with 723 in the second largest study investigating this association.[36] These conflicting results mean that although sex is a potential factor, further high-quality research is required to investigate this further.

Chou et al,[47] in a systematic review published in 2020, examined some prognostic factors associated with failure of TEA in patients with rheumatoid arthritis. They found that younger patients and unlinked designs of TEA were associated with a higher risk of revision.[2-5] There were, however, methodological concerns. Several studies were rated as good quality [47] using the NIH Quality Assessment Tool for Case Series Studies.[48] However, most domains of the same studies were rated as having a moderate to high risk of bias using the QUIPS tool,[19,20] which was specifically designed for research into prognostic factors. There have been no previous systematic reviews which have included patients with any indication for TEA and followed best practice guidelines for systematic reviews of research into prognostic factors, using the PICOTS, CHARMS-PF, and QUIPS tools.

We found that the sequelae of trauma and male sex, which are reported in more than two studies, were associated with an increased risk of failure of TEA failure, compared with those undertaken for inflammatory arthritis or in females. These findings may have some limited prognostic value for clinicians and patients. However, their prognostic value needs to be confirmed in future studies. Currently the evidence for the prognostic factors which are associated with failure of TEA is of poor quality and should be interpreted with caution. The evidence for the remaining factors was of very low quality with little confidence in the effect estimates and the true effect may be very different from the estimates which were reported. Most of the evidence was of very low quality, as it was mostly based on exploratory studies with very serious methodological limitations, such as the way the variables were categorized and small sample sizes, and were judged to be indirect and imprecise using GRADE.

Although the overall quality of evidence is low to very low, we were able to summarize which prognostics need evaluating further, and the need for new factors to be investigated. Of particular importance is the reporting of key domains such as attrition, missing data, measurement of the prognostic factors, statistical strategies, sample size calculation, and the selection rationale for the adjustment of prognostic factors, which were associated with a moderate to high risk of bias in this review. Future studies can build on the advances in the methodology, which may be used for investigations involving prognostic factors described by the PROGRESS partnership. Four themes for research into prognosis were described. Research using prognostic factors is theme 2 (PROGRESS-2).[11] Several studies have been published by PROGRESS in high-impact journals to guide researchers in undertaking high-quality research into prognostic factors. Furthermore, following reporting guidelines such as the REporting recommendations for prognostic studies of tumour MARKer (REMARK), for which investigation using prognostic factors is appropriate, can play a key role in improving the quality of research in this area.[49]

There are many opportunities available to apply these advances in methodology to investigate the prognostic factors which are associated with failure of TEA. For example, there are large datasets from several joint registries which have not been used in research using prognostic factors, including from the National Joint Registry (NJR), which collects data from England, Wales, Northern Ireland, the Isle of Man, and the States of Guernsey.[8] Additionally, the studies published from the Danish and Finnish registries were published between nine and 14 years ago,[31,37] and these studies could be repeated with a larger sample size and capitalizing on methodological advances. Combining data from joint registries may also be used to increase the number of TEAs available for analysis. This may allow for the adjustment of prognostic factors while limiting the potential for overfitting. However, this would be difficult due to differences in the quality of the data and methodology. Prognostic factors which are not collected by national joint registries can be investigated in high-quality cohort or single-centre case series studies. However, given the low number of TEAs that are undertaken, even high-volume centres will struggle to obtain enough cases and events for high-quality prognostic factor research.

Our review has limitations. While our use of broad search terms means it is unlikely that studies published in academic journals were missed, the grey literature and preprint papers were not searched, which could have introduced publication bias. We also excluded 39 studies because they did not report prognostic estimates. Although we acknowledge that indirect methods used to estimate HRs from survival curves, rates, and p-values exist, these methods would result in unadjusted prognostic estimates, which have limited value. Also, in most of the studies which were excluded, the HR would be imprecise because the survival curves did not provide sufficient data to estimate it, and most studies did not report p-values or reported them to one decimal place only. Thus, we decided not to use these indirect methods, as they would add negligible value to the analyses. However, these studies suggested several other possible factors that could be associated with failure of TEA, including preoperative radiological evaluation, a history of infection or of having undergone a synovectomy, the length of the stem in the Coonrad-Morrey arthroplasty, the use of a modular TEA compared with a standard TEA for tumour surgery, and TEA for a primary tumour compared with for a metastasis. The prognostic value of these factors is therefore not known, and it may be useful for future high-quality studies to assess these factors. Finally, in most studies, only estimates of prognosis with statistical significance were reported, which might reflect publication bias.

We focused on failure of TEA leading to revision surgery due to the lack of standardized core outcomes in elbow arthroplasty surgery.[50] However, the Core Outcome Domains - Elbow Replacement (CODER) is an ongoing research project aiming to define these domains. This will provide further opportunities for research which can be summarized in systematic reviews and meta-analyses.[51]

To conclude, the evidence about the prognostic factors which are associated with failure of TEA requiring revision is of low or very low quality and there is a moderate to high risk of bias. The sequelae of trauma and male sex were reported to be associated with an increased risk of failure of TEA in two or more studies. However, the results from all studies should be interpreted with caution. Further research is required to provide robust evidence about the prognostic factors for revision following primary TEA.

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Supplementary material

Tables summarizing details of prognostic factors, and PRISMA checklist.

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Data sharing

All data generated or analyzed during this study are included in the published article and/or in the supplementary material.

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