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Elbow replacement research methods, outcome domains and instruments in clinical outcome studies: a scoping review

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 Title: Elbow replacement research methods, outcome domains and instruments in clinical outcome studies: a scoping review

Abstract

Aim

Prosthetic joint replacement of the elbow including total elbow replacement, hemireplacement, radial head replacement and radiocapitellar replacement, are rare procedures. This scoping review aims to map current research to inform the development of future research.

Materials and Methods

A scoping review was undertaken adhering to the Joanna Briggs Institute (JBI) guidelines using Medline, Embase, CENTRAL and trial registries limited to studies published between 1st January 1990 and 7th February 2021. Endnote software was used for screening and selection and was limited to randomised trials, non-randomised controlled trials, prospective and retrospective cohort studies, case-control studies, analytical cross-sectional studies and case series of ten patients or more reporting clinical outcomes of elbow replacement. The results are presented as frequency counts of types of studies reported, sample size, length of follow up, clinical outcome domains and instruments used, funding sources and a narrative review.

Results

362 studies met the inclusion criteria. The majority were of total elbow replacement (246, 68%), followed by radial head replacement (100, 28%), distal humerus hemireplacement (11, 3%) and radiocapitellar replacement (5, 1%). Most studies were retrospective (326, 90%) and most were observational (315, 87%).

The median study sample size for all implant types across all studies was 36 implants. The median length of follow up for all study types was 56 months. A total of 583 unique outcome descriptors were used that were categorised into 18 domains. A total of 105 outcome instruments were used to measure 39 outcomes.

Discussion

This review has found the majority of published research into elbow replacement consists of retrospective observational studies with small sample sizes and short follow up. A large number of outcome descriptors were used with a high number of different outcome instruments employed indicating a need to define a core outcome set for elbow replacement.

Key words: Arthroplasty, Replacement, Elbow, Outcome, Methods, Funding

to Review Only

Introduction

Prosthetic joint replacement (elbow replacement) of all or part of the elbow has been performed routinely for a number of indications since the cemented replacement design of Dee in the 1960's, including inflammatory arthropathy, osteoarthritis, acute trauma, trauma sequelae, instability and (rarely) tumour.(1) The term elbow replacement is often taken to mean total elbow replacement, that is replacement of the distal humerus and proximal ulna with or without the radial head, but also includes distal humerus replacement in isolation (distal humerus hemireplacement), replacement of the capitellum of the humerus and radial head (radiocapitellar replacement) and radial head replacement in isolation. The purpose of elbow replacement is to relieve pain, restore function and quality of life for the patient.

Clinical practice should be underpinned by robust scientific evidence, and randomised controlled trials are viewed as the gold standard method for assessing interventions. Undertaking evaluations of the effectiveness of elbow replacement techniques and devices is challenging as the intervention is relatively rare. The National Joint Registry Annual Report for England, Wales and Northern Ireland reported a total of 834 cases of elbow replacement in the year 2019 (prior to the Covid-19 outbreak) divided between acute trauma (455 cases) and elective indications (379 cases) across 172 units and 249 surgeons.(2) These low numbers mean that innovative approaches to the design and delivery of trials are required to ensure surgical practice is underpinned by high quality evidence.

To inform the development of future research assessing the effects of elbow replacement it is important to have an understanding of the research methods that have been employed. In addition, with uncertainty as to the most appropriate outcomes to use in evaluation of elbow replacement, work is required to determine the outcome domains that have been assessed and the outcome instruments used to support development of a core outcome set as outlined in the COMET handbook.(3) Further, it is important to map the traditional sources of funding for elbow replacement research in order to understand the limitations and opportunities available. This mapping is best undertaken by a scoping review of evidence sources to examine how research is undertaken in this field.(4)

A preliminary search of Pubmed conducted on 28th December 2020 for previous systematic or scoping reviews on elbow arthroplasty or replacement identified eight relevant articles.

One of the systematic reviews had been retracted leaving one scoping review and six systematic reviews.(5)(6)(7)(8)(9)(10)(11) Two studied the clinical outcomes of primary elbow replacement, two compared the clinical outcome of radial head replacement with osteosynthesis, one analysed the trends in indication for total elbow replacement and one was a review of revision of infected primary elbow replacement. The scoping review was also on the diagnosis and management of infected elbow replacement.(5) An additional internet search of Google Scholar conducted on 29th December 2020 identified a further seven systematic reviews, six of which reviewed the outcome of total elbow replacement and one reviewed the causes for failure of elbow replacement.(12)(13)(14)(15)(16)(17)(18) No systematic or scoping reviews have been identified that map the research methods, outcome domains and instruments, and funding sources used in elbow replacement research.

We therefore undertook a scoping review to identify and map the research methods, domains and outcome instruments used in elbow replacement research of clinical outcomes to inform future research in this field and to describe the sources of funding used for published elbow replacement research.

Review questions

 This scoping review addressed the following research questions:

- a) What research methods are used to study the clinical effectiveness of elbow replacement surgery?
- b) What outcome domains are assessed and which instruments have been used to evaluate clinical outcomes of elbow replacement surgery?
- c) What funding sources are identified in clinical outcome studies of elbow replacement?

Methods

The protocol was developed in accordance with the JBI guidelines(19) and is available online at Open Science Framework (https://osf.io/t6qyh/)

Eligibility criteria

Studies of adults with a diagnosis of inflammatory arthropathy, osteoarthrosis, post-trauma sequelae, and acute trauma undergoing primary elbow replacement were eligible for

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inclusion. Reports of replacement for tumour or other rare indications were excluded. Invitro studies and studies of surgical approaches, biomechanics, health economics and revision elbow replacement were excluded. Studies of populations with heterogeneous diagnoses were included as long as at least 90% of the participants had one of the eligible diagnoses.

The context for the scoping review was all primary elbow replacement studies published between 1st January 1990 and 7th February 2021 and any trials on international registries that met the inclusion criteria. The types of evidence included were randomised trials, nonrandomised controlled trials, prospective and retrospective cohort studies, case-control studies, analytical cross-sectional studies and case series of ten patients or more published in the English language. Review articles, surveys, case reports and conference abstracts were excluded.

Search strategy

An initial limited search of Medline was undertaken to perform an analysis of text words in titles and abstracts and index terms to inform the full search strategy. A full search was conducted, with support from an information specialist on 7th February 2021of Medline, Embase, and CENTRAL using the terms "Elbow Prosthesis", "Arthroplasty, Replacement, Elbow", "Hemiarthroplasty", "Radial head arthroplasty or replacement" and "Radiocapitellar arthroplasty or replacement". This was adapted for the other databases. A search was conducted of the reference lists of reports selected for inclusion in the review to identify any additional studies. The reference lists of prior reviews in elbow replacement were also searched. The ISRCTN Registry and Clinicaltrials.gov websites were reviewed to identify any ongoing trials meeting the inclusion criteria. No search of grey literature was undertaken. The full search strategy for Medline is included in table 1.

Evidence selection

Endnote software Version X9; Clarivate Analytics, Philadelphia, PA, USA was used for management of the results of the search. Duplicates were excluded before initial screening based on title and abstract was undertaken by two reviewers (AW, ZH) with independent selection of evidence based on the pre-specified inclusion criteria. The full article of potentially relevant records were obtained and screened by two reviewers (AW, ZH) to

identify eligible studies. Where there was disagreement the two reviewers reviewed the manuscripts together to reach consensus.

Data extraction

Pilot testing of a customised excel data extraction tool was undertaken using 25 articles selected at random and screened by AW and ZH. A meeting was held to review the screening results to determine whether any changes needed to be made, with 75% agreement required before the data extraction tool was accepted. Full text screening of the remaining articles was conducted by AW including citation details (author/s, date, title, journal, volume, issue, pages), the country in which research has been undertaken, further details of the research methodology (RCT, non-randomised controlled trials, prospective and retrospective cohort studies, case-control studies, analytical cross-sectional studies and case series of ten patients or more), implant studied, population (diagnosis, age and sex), setting, sample size, length of follow up (minimum, maximum, mean/median), outcome assessed, instruments used to assess outcomes and funding sources for the research.

Analysis of the evidence

Data were tabulated and key study characteristics described. The planned analyses were frequency counts of types of studies reported, length of follow up, domains and outcome instruments used. Where possible, findings were stratified by diagnosis (inflammatory arthropathy, osteoarthrosis, post-trauma sequelae, and acute trauma) and type of elbow replacement (total elbow replacement, distal humerus hemireplacement, radial head replacement and radio-capitellar replacement). Outcomes were recorded verbatim from source and categorised into domains after extractions using the taxonomy described by Dodd et al.(20) For ease of reporting the most common outcomes for each domain were rationalised into a common term. For example, in the adverse events domain the outcomes "pain", "residual pain", "proximal forearm pain", "severe pain" and "post-operative pain" were recorded in the table as post-operative pain. The instruments were categorised according to the outcome that the source reported they were being used to assess. No assessment of the quality of the studies or reporting was undertaken, in keeping with guidelines for scoping reviews, as the review is not designed to inform clinical decision making.(21) A full list of included studies and outcomes is available from the corresponding author.

Results

The findings of the literature search are reported in a flow chart adhering to the PRISMA-ScR statement and PRISMA-S extension (Figure 1).(22)(23) From a total of 2,197 deduplicated titles identified from the searches, 402 full text articles were reviewed, of which 40 were excluded for the reasons stated in Figure 1, leaving 362 studies for final inclusion in the scoping review.

Scope of included studies

Of the 362 studies published between 1st January 1990 and 7th February 2021 the subject of the study was total elbow replacement in 246(68%), radial head replacement in 100(28%), distal humerus hemireplacement in 11(3%) and radiocapitellar replacement in 5(1%). Over this time period there has been an overall increase in the number of publications per annum, although a decrease in the annual number of publications on total elbow replacement has been observed since 2015 (Figure 2). Studies were reported from 34 countries, with one international collaboration. The top ten locations for published English language elbow replacement studies by country are listed in table 2.

The majority of studies were conducted in a hospital setting (329, 91%) with few communitybased studies (32, 9%). Most studies were retrospective (326, 91%) and most were observational (321, 89%). There were 23 administrative database studies, 21 of which were conducted in the USA and 8 national implant registry studies from Australia, Denmark (2 studies), Norway, Finland, Sweden and New Zealand. There were 6 prospective randomised controlled trials (RCT), (24)(25)(26)(27)(28)(29) one retrospective review of patients from a previous RCT(30) and three RCT protocols.(31)(32)(33) Two RCT sources described comparison of total elbow replacement to osteosynthesis of distal humerus fractures, one reporting study results at two years and one retrospective review of the same cohort at an average of 12.5 years.(25)(30) One source reports the outcome of total elbow arthroplasty with two different ulna components.(28) Three sources compare the outcome of radial head replacement to osteosynthesis for acute radial head fracture, and one compared radial head replacement to radial head excision.(24)(26)(29)(27) Two protocols described comparison of total elbow replacement to distal humerus hemireplacement for distal humerus fracture, and one protocol was for a study comparing distal humerus hemireplacement to osteosynthesis. (31)(33)(32) None of the RCTs compare elbow replacement to a non-surgical intervention.

Only one RCT had a stated source of funding which was from a commercial source.(25) In five RCTs it was stated that there was no funding or conflict of interest for the trial,(32)(24)(30)(27)(28) and for four it was not stated if there was any funding or conflict of interest.(31)(26)(33)(29) The median sample size by study design is given in table 3.

Properties of included studies

 The median study sample size by implant type was 17(range 10 to 44) implants for distal humerus hemireplacement, 20(range 10 to 31) for radiocapitellar replacement, 32(range 11 to 528) for radial head replacement and 41(range 10 to 56,379) for total elbow replacement. The indication for surgery by procedure type is presented in table 4. Differences were found between procedure types in the mean percentage of female study participants and mean age of participants (Table 5).

The median of the mean length of follow up for all study types was 56 months(range 1 to 216 months). It was longest for registry studies with a median follow up of 96 months(range 67 to 126 months). The median follow-up in observational case series, which was the largest group, was 57 months(range 6 to 216 months). For randomised trials the median of the mean follow-up was 29 months(range 15 to 151 months). The median of the mean reported follow up for studies of total elbow replacement was 60 months(range 1 to 216 months), for radial head replacement 42 months(range 10 to 145 months), distal humerus hemireplacement 35 months(range 12 to 82 months) and radiocapitellar replacement 59 months(range 23 to 100 months).

Reported outcomes

A total of 583 unique outcome descriptors were used across 362 included studies and were categorised into 18 domains (Table 6). Many of these outcome descriptors reported the same outcome using different terms and in 76 cases the outcome instrument was reported without specification of what was being assessed. The largest group of outcomes are categorised in the adverse events domain (311, 53%) despite the fact that complications were not a prespecified outcome in most studies. The physical function domain contains the second largest number of outcome descriptors (93, 16%). These can be grouped into four outcomes: function/disability, range of movement, strength and activities of daily living. Strength was often poorly defined but most commonly described an assessment of strength of elbow extension as a measure of triceps function. Radiographic appearance of the elbow was

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assessed by 19 separate outcomes in the musculoskeletal domain including implant alignment, congruency, fixation, success, lengthening, head size, stem size, stem positioning, implant positioning, prosthetic sizing, quality of cementing technique, bone graft integration or incorporation, cortical fit, cement mantle, valgus tilting, congruence of the proximal radioulnar joint, cement technique, and joint congruity.

Outcome instruments

A total of 105 outcome instruments were used to measure 39 outcomes, of which 26 were clinical and 13 were radiographic. The average number of instruments used per outcome where an instrument was described was 5(range 1 to 26). The list of instruments used to assess each of the 39 outcomes is provided in table 7. For implant survival the listed instruments are methods of analysis but are included for completeness. Some instruments are included in more than one outcome category and may be listed for outcomes and domains that may seem inappropriate, but these are taken verbatim from the included studies.

Discussion

Randomised controlled trials (RCTs) are considered the gold-standard for evaluation of healthcare interventions but in orthopaedic surgery the number of RCTs undertaken is consistently low. A systematic review of orthopaedic literature found that only 20% of procedures had at least one low risk of bias RCT supporting the operative intervention when compared to non-operative treatment.(34) <u>We did not identify any for elbow replacement.</u> Many different reasons have been proposed for this and the cause is likely to be multifactorial.(35)(36) One of the challenges of performing a randomised trial in some areas of orthopaedics where the condition is rare is the feasibility of recruiting sufficient participants to address the research question.

The European Union defines rare diseases as those with a prevalence of less than 50 per 100,000 population for the purposes of orphan drugs, where normal economic models prevent research and development.(37) Elbow replacement is a "rare" procedure with an annual incidence estimated from Scottish data as 1.4 per 100,000 population and the same economic and scientific challenges apply, with low investment in research and barriers to conventional frequentist approaches to investigate clinical outcomes due to the feasibility of randomised controlled trials (RCTs). (38)

This scoping review has found that the literature on elbow replacement consists largely of unfunded retrospective observation studies with small sample sizes. It is interesting to note that the number of studies on total elbow replacement has declined in recent years. The cause of this is unknown, but it may be due to the contracting usage resulting from improved medical management of inflammatory joint disease. Only 9 prospective randomised controlled trials were identified, three of which are protocols of ongoing trials rather than reports of trial results. The sample size of these RCTs ranges from 20 to a maximum of 60 participants. Only one randomised trial had a stated source of funding, and that funding was from a commercial body. This review has not identified any RCTs comparing joint replacement to non-operative treatment in the elbow. It is beyond the scope of this review to determine the causes for the quality of the evidence but there remain many questions regarding elbow replacement that require robust unbiased scientific investigation. Researchers designing future RCTs in elbow arthroplasty will need to explore solutions for investigation of rare diseases with multi-centre and possibly international collaborations to ensure sufficient statistical power and exploration of alternative trial designs. The moral hazard of enrolment of patients into underpowered trials could be avoided through a planned meta-analysis of duplicate studies.(39) However, this would require co-ordination and establishment of a musculoskeletal rare intervention trials registry and a mechanism to ensure data sharing and individual patient data (IPD) meta-analysis.(40)(41) Alternative trial designs have been explored for investigation of rare diseases including crossover designs, Nof-1 trials and adaptive designs, but most are not suitable for surgical research due to the irreversible nature of surgical interventions and the time period required to determine the outcome of the intervention. (42)(43) Bayesian analysis methods, however, could be used to exploit all available data to strengthen the findings from smaller RCTs.(44) Appropriate funding will be required to ensure the successful delivery of these more complicated investigations and qualitative research may be needed to understand the barriers and facilitators within the elbow replacement community that may be affecting research practice.

Alternative approaches to tackling the paucity of information may mean pooling data from multiple sources. The combination of data for meta-analysis is hindered, however, by the diversity of outcome domains and instruments used to measure outcomes. The 583 individual descriptors identified in this scoping review for clinical outcomes of elbow arthroplasty can be rationalised to 41 outcomes over 18 domains using the taxonomy adopted by the COMET

 initiative, however this is still a large number of domains and it is unclear which of these might be considered most important by patients, carers and treating clinicians.(20) An average of five instruments have been used for the 39 outcomes where an outcome instrument has been described. This review has not sought to analyse the psychometric properties of the instruments used but rather to map the domains, outcomes and instruments without an assessment of quality or validity. Once core outcomes have been defined it will be necessary to undertake an assessment of relevant instruments to determine if any meet the criteria of truth, discrimination and feasibility.(45)

This review has highlighted a clear need to define the core outcome domains for elbow replacement research that can then lead to the development of a set of core outcome instruments.

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Legends

Table 1: Medline search string.

Table 2: The 10 countries with the highest number of recorded publications on elbow replacement (frequency, % of total).

Table 3: Sample size of studies by study type.

Table 4: Primary diagnosis at the time of surgery by type of procedure.

Table 5: Sex and Age of patients included in studies by type of procedure.

Table 6: Reported outcomes categorised by domain.

Table 7: Outcome instruments used in included studies (no assessment of psychometric properties has been conducted). (ASES – American Shoulder and Elbow Score; DASH – Disabilities of the Arm Shoulder and Hand; HSS – Hospital for Special Surgery; JOA – Japanese Orthopaedic Association; PREE – Patient Rated Elbow Evaluation; SANE – Single Assessment Numeric Evaluation; VAS – visual analogue score; RAND-36 – early version of SF-36; MMSE – Mini-Mental State Evaluation)

Figure 1. PRISMA flow chart

Figure 2. Histogram of the number of publications per year categorised by type of procedure.

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19	1	Elbow Prosthesis/ or Arthroplasty, Replacement, Elbow/ 485	
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Table 2.

Country	Number	%
USA	91	25%
UK	52	14%
France	25	7%
Japan	19	5%
Italy	18	5%
Netherlands	18	5%
Canada	16	4%
Germany	16	4%
Sweden	12	3%
Finland	11	3%
Table 3	Z.	I

Table 3

	Mean	Median	Min	Max
Observational studies	67	32	10	1441
Randomised trial	38	40	20	60
Admin database	7819	1625	176	56379
Registry study	692	584	126	1457

Table 4

	RA	OA	Post Trauma	Acute Trauma	Other
Total elbow replacement	61%	5%	16%	18%	2%
Distal humerus hemireplacement	0%	0%	15%	85%	0%
Radial head replacement	<1%	<1%	12%	87%	<1%
Radiocapitellar replacement	11%	58%	27%	1%	3%

Table 5

Table 5	5			
	Mean % female	Mean of minimum age in years (range)	Mean of maximum age in years (range)	Mean of mean age in years (range)
Total elbow replacement	76	36 (5-75)	81 (40-97)	61 (28-85)
Distal humerus hemireplacement	85	47 (16-62)	81 (63-90)	67 (45-79)
Radiocapitellar replacement	51	31 (25-40)	74 (69-82)	55 (53-61)
Radial head replacement	46	23 (14-62)	75 (50-93)	49 (31-67)

Table 6

Domain	Outc	ome
Adverse	Post-operative pain	Implant related
events (311)	Radiographic complications	Wound problems
	Infection	Stiffness
	Triceps weakness	Bone problems
	Neurological	Transfusion
	Effusion/Synovitis	Medical complications
Physical	Function/disability	Strength
function (93)	Range of movement	Activities of daily living
MSK	Radiographic appearance	
connective tissue (37)	Elbow stability	
Need for further	Re-operation	
intervention (34)	Implant revision/survival	
Nervous	Pain	
system (30)	Neurological status	
Delivery	Satisfaction	
of care (15)		
Social	Sport participation	
function (13)	Social-psychological status	
Hospital	Length of stay	Return to operating room
resources (11)	Re-admission	Length of surgery
Role	Return to work	
function (8)		
Perceived	General health	
health (7)		
Economic	Hospital costs	
resource (7)	Non-routine discharge costs	
Mortality	Mortality	
/Survival (6)		
Psychiatric (3)	Mental health	
Quality	Quality of life	
$f_{ife}(2)$		
Emotional	Well-being	
well-being (2)	Role emotional	
Cognitive	Cognitive status	
function (1)	Cognitive status	
Personal	Patient autonomy	
circumstances (1)		
Societal	Non-homebound discharge	
carer burden (1)		
carer burden (1)		

Table 7

Outcome	Instrument
	Liverpool elbow score. Mayo elbow performance index. Mayo elbow performance
Activities of daily living	score. UCLA Activity score. Wrightington score
Cognitive status	MMSE
Complications	Voloshin
Cost utility analysis	
Deformity	Ewald scoring system IOA score
beronney	Andrews score ASES score Broberg Morrey score DASH score Elbex score Elbow
	functional assessment Ewald score Inglis score IOA score Khatri score likert
	scale. Liverpool elbow score. Mayo elbow performance index. Mayo elbow
	performance score, numerical rating scale, Oxford score, PREE, QuickDASH, SANE,
Function	SECEC. Souter. Stanford health assessment questionnaire. VAS
Global Health	EQ5D
Grip strength	ASES, Broberg Morrey, Dynamometer, NK hand evaluation system
Implant Survival	Dobbs. Kaplan-Meier, Life table. Murray
loint position sense	Propriometer
Mental health	SE-12 Mental
	ASES, Broberg Morrey, DASH, Elbow functional assessment, Ewald score, Inglis
	score IOA score Khatri score likert scale Mayo elbow performance score
	Modified Andrews score, numeric rating scale, Oxford elbow score, Liverpool elbow
Pain	score. Pain intensity scle. PREE. VAS
Patient Autonomy	Katz
Physical health	SE-12 physical
Quality of life	RAND-36, SF-36
Radial Nerve Palsy	Hirachi, Electrophysiology
	ASES Broberg Morrey Cassebaum Elbow functional assessment Ewald score HSS
	score IOA score Inglis score Khatri score likert Liverpool elbow socre Mayo
	elbow performance index. Mayo elbow performance score. Modified Andrews. NK
Range of motion	hand evaluation system. Propriometer
Return to Work	binary
Satisfaction	ASES, binary, Jungbluth, likert scale, numerical rating scale, SANE, VAS
Sport participation	Allain Liverpool elbow score
- P P	ASES Broberg Morrey Elbow functional assessment IOA score likert Mayo elbow
Stability	nerformance index. Mayo elbow performance score. Modified Andrews score
	ASES Broberg Morrey HSS score Isobey Kindeyn Dynamometer Lido workset
	Mayo elbow performance index. Mayo elbow performance score. MRC scale, likert
Strength	liverpool elbow score
Success of treatment	VAS
Tenderness	ASES
Illpar perve function	Electonhysiology, Liverpool elbow score, McGowan grade
Radiographic alignment	Figgie Hindey O'Driscoll RSA analysis Storen's line II index Wrightington
Radiographic bushing wear	Gill Llamas Lee Mayo Ramsey Schoeberger
Radiographic capitellum erosion	Broherg Morrey likert scale Llamas
Padiographic betaratonic assification	binany Brooker, Hastings and Graham Ilabi likert
	Berschhack binany Cil Gill and Morrey Goldberg Grewal Harris King likert scale
Radiographic loosening	Madsen Mayo Morrey and Adams Ponovic Schneeherger Wagener Wrightington
	hinary Eehringer Gruen Kodde Kudo and Iwano Morrey Souter Tanaka
Radiographic lucency	Wrightington
Radiographic medial collateral ligament healing	Illtrasound
	hinary Broberg Morrey Kellgren Lawrence, Knirk and Juniter, Lindenbovius, likert
Radiographic osteoarthrosis	scale
Radiographic overstuffing	Rowland Van Riet
Radiographic quality coment technique	Schnachargar
Radiographic radial head prominence	Doornberg
Radiographic synovitis	Forster
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