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Patient-Centred Outcomes in Lateral Elbow Tendinopathy: a systematic review of available evidence in UK populations

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Patient-Centred Outcomes in Lateral Elbow Tendinopathy:
a systematic review of available evidence in UK populations

Key Words:

- Patient reported outcome measures
- Lateral elbow tendinopathy
- Lateral epicondylitis
- Tennis Elbow
- Psychometrics
- Validation

For Peer Review

Abstract

Aim

To systematically review the evidence for clinical ratings systems in the assessment of outcomes of UK patients with Lateral Elbow Tendinopathy (LET).

Methods

A systematic search was performed in Ovid MEDLINE, Embase and CINAHL. Studies were included if they reported the administration of PROMs in UK populations with LET. PROMs characteristics and the populations in which they had been used were assessed using a structured classification system. PROMs reporting in randomised controlled trials was assessed against CONSORT standards (PRO extension).

Results

A total of 16 articles were included based on eligibility criteria. Out of seven different PROMs, there was evidence of partial validation for five of them. The assessment of validity, reliability and responsiveness of all PROMs in LET UK populations extended to just 20 individual patients. No articles conformed to the CONSORT PRO extension standards.

Conclusion

There exists a huge paucity of data on the psychometrics and usability of PROMs in UK LET populations. Without these data, trial design and interpretation of health technology assessment are significantly hindered. The high prevalence of this condition allied with the significant volume of studies being conducted into novel treatments, highlight the need for this knowledge gap to be resolved.

Background

Lateral Elbow Tendinopathy (LET), known more commonly as Tennis Elbow, is a prevalent and potentially debilitating condition^(1, 2). Though the condition is regarded as benign and self-limiting, absenteeism due to LET in the UK is estimated to cost the economy £27 million per annum⁽³⁾. With a UK prevalence between 1.5-3%⁽²⁾, it is surprising that no clear treatment consensus exists^(4, 5). This treatment equipoise has driven a large volume of research activity, with over 80 registered trials currently ongoing⁽⁶⁾. However, to be confident in our treatments, we must be certain that the outcome measures used in these trials truly reflect patient benefit or harm.

Successful treatment in LET can be regarded as amelioration of pain and return of function. Constructs such as these are now commonly quantified through the use of Patient-Reported Outcome Measures (PROMS). Collaborative work by academics and clinicians has crystallised in the development of systematic, robust and valid ways of collecting health outcomes from patients that purport to quantify, in a meaningful way, how the patient feels their condition affects them⁽⁷⁾. In reference to musculoskeletal pathology, this has resulted in numerous PROMs used to quantify the burden of a specific disease, such as the use of the Oxford Hip and Knee scores in assessing the outcome of joint arthroplasty⁽⁸⁾.

Appropriate outcome measures must demonstrate that they are acceptable to patients, reliable, valid and responsive (sensitive to change)⁽⁹⁾. When the outcome measure has been developed in a different clinical or geographical population, there needs to be evidence of equivalence both in a disease-specific and cross-cultural context^{(10) (11)}.

A structured assessment of outcome measurement in LET in UK populations has not been undertaken. This study aimed to address this gap by systematically assessing the outcome measures used for measuring PROMs in Lateral Elbow Tendinopathy in a UK population, and to assess the reporting of randomised controlled trials using PROMs in LET. Only when

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8 valid outcomes have been identified, can recommendations on choice of outcome
9 measures for future research be made.
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11 Materials and Methods

12 PRISMA guidelines on the reporting of systematic reviews were followed ⁽¹²⁾. All articles
13 reporting the development, psychometric evaluation, or use of patient reported outcome
14 measures in Lateral Elbow Tendinopathy in UK adults (≥ 18 yrs) were included. Any measures
15 of symptoms and functioning in LETs that involved a patient-reported outcome
16 measurement (regardless of whether this also contained a physician-reported outcome
17 component) were included. Studies in paediatric populations, case-reports, case-studies
18 and conference abstracts were excluded.
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20 A search strategy was constructed using MeSH and free-text terms (appendix 1). The search
21 strategy development was guided by previously published search strategies for systematic
22 reviews of interventions in elbow pathology ⁽¹³⁾ and for the identification of outcome
23 measures ⁽¹⁴⁾, along with terms specifically selected in order to capture names of relevant
24 instruments published in previous systematic reviews of elbow-specific rating scales ⁽¹⁵⁻¹⁸⁾.
25 The strategy was further adapted to each database through the modification of thesaurus
26 terms, wildcards, and truncation. The search was run on the 1st May 2017 in Medline (Ovid
27 MEDLINE, 1948 to 2016 & Ovid MEDLINE In-Process & Non-indexed Citations) accessed
28 through OVIDSP, Embase (Embase 1974 to 2016) accessed through OVIDSP and CINHAL
29 (CINHAL 1981 to 2016) accessed through EBSCO host.
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31 The screening process was conducted in a step-wise manner. At each stage, one researcher
32 and a further researcher reviewed each title and abstract. In cases of disagreement, the
33 article proceeded to the next stage of review to ensure maximum sensitivity.
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35 At the full-text level, articles were also sub-categorised in two groups to: articles reporting
36 primary research on the development and/or psychometric evaluation of PROMs in LET in
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8 UK populations (development); and articles reporting the use of outcome measures in
9 clinical studies in UK populations (use).
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11 **Data synthesis**

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14 Development articles were classified according to three guiding concepts, using the
15 structured classification system proposed by Valderas and Alonso ⁽¹⁹⁾: construct (the
16 measurement object), population (based on age, gender, condition and culture) and
17 measurement model (dimensionality, metric and adaptability) ⁽¹⁹⁾.
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21 The assessment of construct denotes, for the purpose of this study, the range of
22 characteristics measured by the outcome measure, which are affected by LET. The
23 construct analysis has, at its foundation, the conceptual strengths of the Wilson and Cleary
24 model ⁽²⁰⁾, but is also integrated with the theoretical model that underpins the International
25 Classification of Functioning, Disability and Health (ICF). A strength of the model that is
26 particularly pertinent in the assessment of LET outcome measures, is the systematic
27 consideration of intended population of use. Within the axis of population consideration of
28 culture is also made, where there is information pertaining to the dyad of language and
29 country for which the outcome measures have been devised.
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33 It should be noted that this system is only descriptive and does not provide any
34 fundamental evaluation of measurement properties ⁽¹⁹⁾. But in the early stages of outcome
35 measure assessment, this approach provides the clearest method of identifying the
36 candidate pool of measures. Only once this is undertaken and deemed to be adequate, can
37 a systematic evaluation of measurement properties in a specific population of use be
38 undertaken.
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42 Articles reporting the use of PROMs (use) were peer-reviewed, published articles with
43 outcome measure evaluation in a population of LET patients. Date of publication, outcome
44 measure(s) chosen and population of use was extracted. For randomised control trials, the
45 CONSORT Patient-Reported Outcome (PRO) extension ⁽²¹⁾ was used to systematically assess
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8 the reporting of outcome measure choice and justification. The original CONSORT
9 statement aims to encourage transparent and complete reporting of clinical trials and is
10 associated with improved reporting practice⁽²²⁾.
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13 An a priori hypothesis was formulated with regard to informed choice of outcome
14 measures in UK populations. We hypothesised that articles reporting the use of PROMs
15 would more frequently use PROMs for which there would be evidence from studies of
16 validation of such measures in UK populations.
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21 Results

22 We identified 7,261 records from the electronic database search. A total of 16 articles met
23 the inclusion criteria: five articles reporting the development and/or psychometric
24 evaluation of outcome measures in LET-specific patients and 11 articles reporting their use
25 in a UK population (fig 1)(Appendix 2).
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29 *Measures*

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31 Five outcome measures were identified that were developed or had undergone
32 psychometric evaluation, on UK populations that at least, in part, contain patients with LET
33 (Table 1). They were all fully standardised measures that had all been developed for
34 measuring symptoms (mainly pain) and functioning in English speaking UK adults of either
35 gender. However, only one of them, the Patient-Rated Tennis Elbow Evaluation (PRTEE) was
36 LET specific, the remaining instruments were developed as elbow-specific tools designed
37 for varying pathologies, but including in their validation a sub-sample of LET patients. Two
38 outcome measures were originally developed for UK populations: the Oxford Elbow Score
39 (OES) and the Liverpool Elbow Score (LES). The remaining three outcome measures were
40 developed in the English language outside of the UK (US, Canada and Australia), but had
41 undergone some level of psychometric evaluation in UK populations. Of note, no
42 modification was deemed necessary in the wording or description of the symptoms or
43 activities measured for any of those instruments.
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8 Only the PRTEE has had its metric properties assessed in a UK cohort that was exclusively
9 diagnosed with LET. This was conducted on 57 patients to quantify the Minimally Important
10 Difference (MID) of the PRTEE. This study formed part of a larger prospective trial assessing
11 microcurrent therapy in LET and analysed data from 57 individuals with clinically and
12 sonographically diagnosed LET who all underwent microcurrent therapy. They report a
13 weak correlation between the PRTEE and global change scale, but no assessment of
14 construct validity or any other metric assessment is undertaken. For the four remaining
15 outcome measures, the proportion of patients included within their study cohorts who
16 were diagnosed of LET ranged from 11% to 12.7% (Table 1). None were evaluated in more
17 than 12 patients, and as multiple measures were reported on the same patients cohorts,
18 when all individual patients from these studies were tallied it reveals that this equates to 20
19 UK LET patients in total.
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28 Eleven additional articles reported using PROMs to evaluate disease impact in UK
29 populations with LET. These studies were published between 2003 and 2014 (Table 2). Out
30 of the five outcome measures for which there had been a previous psychometric
31 evaluation, only three were subsequently applied to evaluate LET outcomes (DASH, OES
32 and PRTEE). The outcome measures that were not utilised were the LES and the Mayo
33 Elbow Performance Score (MEPS). Perhaps more surprisingly, two additional measures
34 were used, namely the Nirschl score and the Patient-Rated Wrist Evaluation (PRWE),
35 although no evidence on the psychometric properties or even their cross-cultural
36 equivalence was available. Overall, the PRTEE (and precursor PRFEQ) was reported six
37 times, the DASH four times, the Nirschl score twice, the OES once and the PRWE once.
38 Seven of the 11 studies stated that the outcome measure was their study's primary
39 outcome.
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48 Four of these 11 studies were randomised controlled trials (RCTs). The level of adherence to
49 CONSORT standards for reporting PROMs outcomes for RCTS for the four trials suggested
50 substantial room for improvement (Table 3). No information was available for three
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standards for any RCT and only partial information was available for the other two standards in a minority of studies.

Discussion

This study has identified a lack of evidence with which to inform outcome measure choice in Lateral Elbow Tendinopathy in the UK. Future validation of outcome measures in UK populations is required in order to be able to ground any recommendations on a firm evidence base. Furthermore, some outcome measures are currently being used as primary outcomes in UK-based studies in the absence of any evidence for their cross-cultural appropriateness and psychometric properties.

We were able to retrieve at least some evidence of the evaluation of the psychometric properties of five outcome measures. The PRTEE is the only measure specifically designed for the evaluation of a LET population. All measures attempt to measure the domains of function and symptoms in adults. All but the DASH have been designed to assess these domains in reference to the elbow exclusively.

The total reporting of validity, reliability or reproducibility of outcome measures in UK LET patients is limited to 20 patients^(23, 24). All of these patients have been embedded in larger cohorts containing a heterogeneous group of elbow pathology. Due to the limited size of this LET sample, it has been unfeasible for the reporting authors to conduct a standardised psychometric assessment of the outcome measures using methods such as COSMIN or EMPRO.

The largest assessment outcome measure utility in UK LET patients was published by Poltawski et al⁽²⁵⁾ and included 57 patients. Although this is by far the largest sample of LET patients of any of the studies included here, outcome interpretability through derivation of MCID score was undertaken with no evaluation of other relevant psychometric characteristics. The PRTEE was not originally designed for a UK population and no evidence of formalised cross-cultural evaluation is presented. This would always be necessary when

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8 applying a new instrument to a different population, as the use of language across
9 continents, though English in origin, confers both linguistic and cultural differences. But in
10 this case the need was additionally increased by the fact that items in the PRTEE had been
11 altered prior to administration (the words coffee and milk were removed from the item
12 “Lift a full coffee cup or glass of milk to your mouth”, “pants” were replaced by “trousers”
13 and “washcloth or wet towel” by “wet cloth”). The authors acknowledge that the altering of
14 the outcome measure wording may have altered its measurement properties ⁽²⁵⁾.
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20 In many circumstances it will be completely appropriate and even highly advisable to alter
21 the wording of outcome measures. However, it should be undertaken under the principles
22 of cross-cultural adaptation ^(10, 26). It is widely recognised that if a measure is to be used
23 across cultures, the items must be both linguistically translated and culturally adapted to
24 maintain the content validity of the outcome measure at a conceptual level ⁽²⁶⁾. Guillemin et
25 al ⁽²⁷⁾ have proposed scenarios that should alert authors to situations where translation or
26 adaptation should be undertaken. In the situation of an outcome measure being used in
27 another country, but in the same language, cultural adaptation is required. For LET in UK
28 populations, this would be the case for the DASH, MEPS, PRTEE and Nirschl outcome
29 measures. Of note, the DASH and quickDASH score have been culturally adapted to UK
30 English since 2015 ⁽²⁸⁾. To the best of our knowledge, this score had not been utilised in any
31 of the identified studies.
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39 The process of cross-cultural adaptation has been well reported ⁽¹⁰⁾. A 10-stage process
40 proposed by the International Society for Pharmacoeconomics and Outcomes Research
41 (ISPOR) ⁽¹⁰⁾ involves forward and backwards adaptation by multiple reviewers, cognitive
42 interviewing with patient populations and pre-testing of the final questionnaire. Though
43 this may be seen as a laborious process, users of measures that have not been rigorously
44 adapted must also be aware that language alterations may alter measurement properties.
45 Therefore, reference values for group comparison, minimally important difference data or
46 power calculations may not be valid in the new cultural context of use.
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8 This study has identified that the reporting of outcome measures in UK LET randomised
9 controlled trials does not conform to the CONSORT-PRO guidance. Though two of the
10 studies were published prior to the guidance publication in 2010, the stark paucity of
11 reporting of outcome measure detail is concerning. This lack of reporting is in line with the
12 deficits in outcome measure validity highlighted through the Valderas⁽¹⁹⁾ classification
13 system. Though we hypothesised that there would be a preference for outcome measures
14 with published validity in the target population, we have identified that with the current
15 level of evidence this is not possible. This lack of suitable outcome measures has been
16 identified by other authors^(29,30). Long et al (2015)⁽⁴⁾ reported in their National Institute of
17 Health Research, Health Technology Assessment review of systematic reviews of
18 conservative treatments in LET, that a lack of standardised outcome measures hindered
19 interpretation and synthesis of results. They recommend that the inclusion of a patient-
20 reported measure of upper extremity function in interventional trials would ease results
21 synthesis. However, we have identified that the lack of a clear choice within the UK
22 population is likely to significantly hinder a researcher's ability to undertake this.
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32 The authors acknowledge the inherent limitations of this study. The search strategy may
33 have failed to identify all outcome measures used, and the identification of the study
34 populations' nationality in interventional trials can be prone to error. However, attempts
35 were made to ensure that the strategy was as robust as possible. Outcomes in LET can be
36 measured in numerous ways, including grip strength, pain provocation tests and visual
37 analogue scales to mention a few, this may be a highly legitimate method and was not
38 assessed as part of this study. The authors feel that this approach is justified owing to the
39 increasing view that the ultimate measure of success in health care is whether it helps
40 patients from their own point of view⁽³¹⁾. Outcome measures, that quantify patient's
41 health-related quality of life, with particular reference to PROMs, are recommended by
42 National bodies across the world, including the NIHR in the UK and FDA in the USA⁽⁷⁾.
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50 Furthermore, the use of condition-specific PROMs is increasingly common in
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8 musculoskeletal medicine and are collected as part of the English NHS PROMs programme
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10 ⁽⁷⁾. With the increasing use of PROMs used as primary outcomes in clinical trials, it is,
11 therefore, relevant that their use is rigorously assessed.
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14 This study has identified that, with current levels of evidence, it is not appropriate to
15 recommend any PROMs for LET studies in UK populations. Though the OES, PRTEE and
16 DASH show potential as patient-reported measures, with domains likely to be appropriate
17 in LET, further assessment is required in UK populations to quantify their validity, reliability,
18 responsiveness and patient acceptability.
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24 *Take home messages*

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26 There is some evidence for the psychometric properties of OES, PRTEE and DASH PROMs in
27 the assessment of patients with Lateral Elbow Tendinopathy. Robust evidence on the
28 validity, reliability and responsiveness of any PROM in UK populations of Lateral Elbow
29 Tendinopathy patients is lacking.
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35 36 References

- 37
38 1. Ahmad Z, Siddiqui N, Malik SS, Abdus-Samee M, Tytherleigh-Strong G, Rushton N. Lateral epicondylitis: a review of pathology and management. *Bone Joint J.* 2013;95-B(9):1158-
39 64.
40
41 2. Titchener AG, Tambe A, Fakis A, Smith CJ, Clark DI, Hubbard RB. Study of lateral
42 epicondylitis (tennis elbow) using the health improvement network database. *Shoulder &*
43 *Elbow.* 2012;4(3):209-13.
44
45 3. Hopkins C, Fu S-C, Chua E, Hu X, Rolf C, Mattila VM, et al. Critical review on the socio-
46 economic impact of tendinopathy. *Asia-Pacific Journal of Sports Medicine, Arthroscopy,*
47 *Rehabilitation and Technology.* 2016;4:9-20.
48
49 4. Long L, Briscoe S, Cooper C, Hyde C, Crathorne L. What is the clinical effectiveness and
50 cost-effectiveness of conservative interventions for tendinopathy? An overview of systematic
51 reviews of clinical effectiveness and systematic review of economic evaluations. *Health*
52 *technology assessment (Winchester, England).* 2015 Jan;19(8):1-34
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5. Masci L. Is tendinopathy research at a crossroads? *British journal of sports medicine* 49.16 (2015): 1030.
6. No authors listed. *clinicaltrials.org*. <https://clinicaltrials.gov/>; 2017 [last accessed 4/4/2017]
7. Devlin NJ, Appleby J. Getting the most out of PROMS. Putting health outcomes at the heart of NHS decision making. London: King's Fund. 2010.
8. Murray D, Fitzpatrick R, Rogers K, Pandit H, Beard D, Carr A, et al. The use of the Oxford hip and knee scores. *Bone & Joint Journal*. 2007;89(8):1010-4.
9. Dawson J, Doll H, Fitzpatrick R, Jenkinson C, Carr AJ. The routine use of patient reported outcome measures in healthcare settings. *BMJ*. 2010;340:c186.
10. Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, et al. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. *Value in Health*. 2005;8(2):94-104.
11. Alonso J, Bartlett SJ, Rose M, Aaronson NK, Chaplin JE, Efficace F, et al. The case for an international patient-reported outcomes measurement information system (PROMIS®) initiative. *Health and Quality of Life Outcomes*. 2013;11(1):1-5.
12. Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Annals of Internal Medicine*. 2009;151(4):264-9.
13. Buchbinder R, Johnston RV, Barnsley L, Assendelft W, Bell SN, Smidt N. Surgery for lateral elbow pain. *Cochrane Database Syst Rev*. 2011;3(3).
14. Gonçalves Bradley DC, Gibbons C, Ricci-Cabello I, Bobrovitz NJ, Gibbons EJ, Kotzeva A, et al. Routine provision of information on patient-reported outcome measures to healthcare providers and patients in clinical practice. *The Cochrane Library*. 2015.
15. The B, Reininga IH, El Moumni M, Eygendaal D. Elbow-specific clinical rating systems: extent of established validity, reliability, and responsiveness. *J Shoulder Elbow Surg*. 2013;22(10):1380-94.
16. Longo UG, Franceschi F, Loppini M, Maffulli N, Denaro V. Rating systems for evaluation of the elbow. *British Medical Bulletin*. 2008;87:131-61.
17. Turchin DC, Beaton DE, Richards RR. Validity of observer-based aggregate scoring systems as descriptors of elbow pain, function, and disability. *Journal of Bone and Joint Surgery American volume*. 1998;80(2):154-62.
18. de Boer YA, Hazes JM, Winia PC, Brand R, Rozing PM. Comparative responsiveness of four elbow scoring instruments in patients with rheumatoid arthritis. *Journal of Rheumatology*. 2001;28(12):2616-23.
19. Valderas JM, Alonso J. Patient reported outcome measures: a model-based classification system for research and clinical practice. *Quality of Life Research*. 2008;17(9):1125-35.
20. Wilson IB, Cleary PD. Linking clinical variables with health-related quality of life. *Jama*. 1995;273(1):59-65.

21. Calvert M, Blazeby J, Revicki D, Moher D, Brundage M. Reporting quality of life in clinical trials: a CONSORT extension. *The Lancet*. 2011;378(9804):1684-5.
22. Turner L, Shamseer L, Altman DG, Schulz KF, Moher D. Does use of the CONSORT Statement impact the completeness of reporting of randomised controlled trials published in medical journals? A Cochrane review. *Systematic reviews*. 2012;1(1):1.
23. Dawson J, Doll H, Boller I, Fitzpatrick R, Little C, Rees J, et al. The development and validation of a patient-reported questionnaire to assess outcomes of elbow surgery. *J Bone Joint Surg Br*. 2008;90(4):466-73.
24. Sathyamoorthy P, Kemp G, Rawal A, Rayner V, Frostick S. Development and validation of an elbow score. *Rheumatology*. 2004;43(11):1434-40.
25. Poltawski L, Watson T. Measuring clinically important change with the Patient-rated Tennis Elbow Evaluation. *Hand Therapy*. 2011;16(3):52-7 p.
26. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. *Spine*. 2000;25(24):3186-91.
27. Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. *J Clin Epidemiol*. 1993;46(12):1417-32.
28. Hammond A, Prior Y, Tyson S. 172. Development and Psychometric Testing of a British English Version of the Disabilities Arm Shoulder and Hand Questionnaire. *Rheumatology*. 2015;54(suppl 1):i117-i117.
29. de Vos RJ, Windt J, Weir A. Strong evidence against platelet-rich plasma injections for chronic lateral elbow tendinopathy: a systematic review. *Br J Sports Med*. 2014;48(12):952-6.
30. Ahmad Z, Brooks R, Kang SN, Weaver H, Nunney I, Tytherleigh-Strong G, et al. The effect of platelet-rich plasma on clinical outcomes in lateral epicondylitis. *Arthroscopy*. 2013;29(11):1851-62.
31. Berwick D, Hiatt H, Janeway P, Smith R. An ethical code for everybody in health care. *BMJ*. 1997;315(7123):1633-4.
32. Dawson J, Doll H, Boller I, Fitzpatrick R, Little C, Rees J, et al. Comparative responsiveness and minimal change for the Oxford Elbow Score following surgery. *Qual Life Res*. 2008;17(10):1257-67.
33. Dawson J, Doll H, Boller I, Fitzpatrick R, Little C, Rees J, et al. Specificity and responsiveness of patient-reported and clinician-rated outcome measures in the context of elbow surgery, comparing patients with and without rheumatoid arthritis. *Orthop Traumatol-Sur*. 2012;98(6):652-8.
34. Overend TJ, Wuori-Fearn JL, Kramer JF, MacDermid JC. Reliability of a patient-rated forearm evaluation questionnaire for patients with lateral epicondylitis. *Journal of Hand Therapy*. 1999;12(1):31-7.
35. Hudak PL, Amadio PC, Bombardier C, Beaton D, Cole D, Davis A, et al. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder, and hand). *American Journal of Industrial Medicine*. 1996;29(6):602-8.

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- 8 36. Solway S, Beaton DE, McConnell S, Bombardier C. The DASH Outcome Measure User's
- 9 Manual. Toronto, Ontario: Institute for Work & Health 2002.
- 10 37. Morrey B, Adams R. Semiconstrained arthroplasty for the treatment of rheumatoid
- 11 arthritis of the elbow. *J Bone Joint Surg Am.* 1992;74(4):479-90.
- 12 38. Morrey BF, Sanchez-Sotelo J. *The elbow and its disorders*: Elsevier Health Sciences;
- 13 2009.
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Fig 1: PRISMA Flowchart of the systematic literature review.

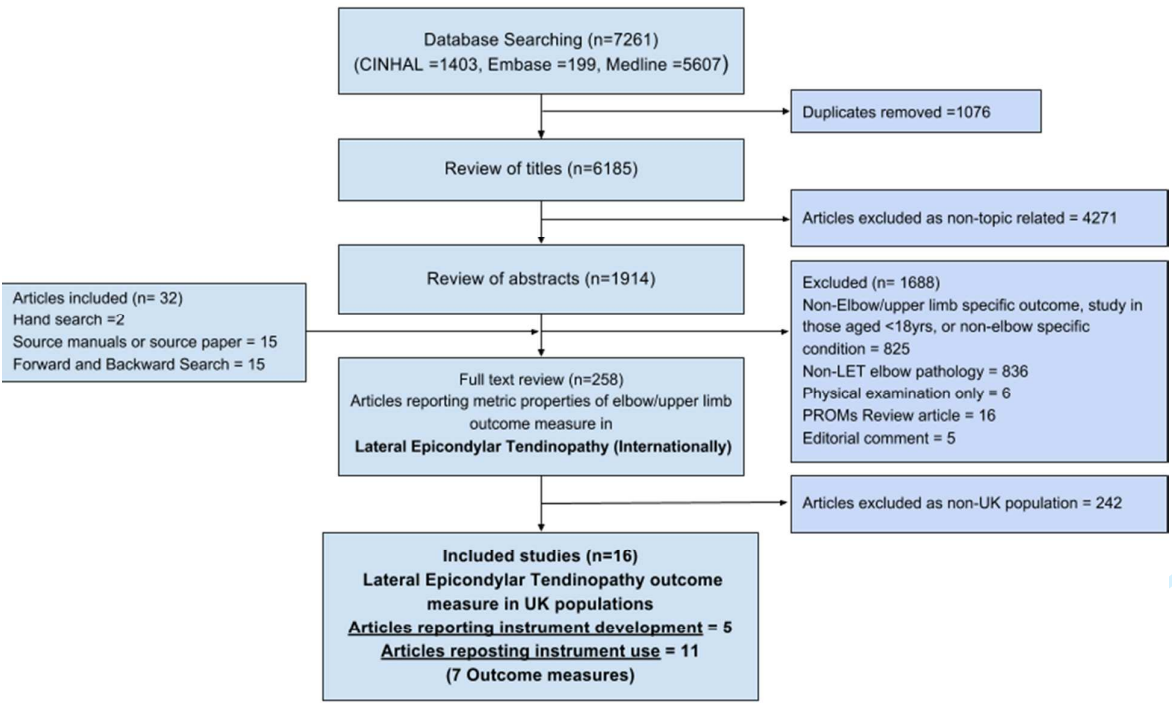


Table 1: Outcome measures for the assessment in Lateral Elbow Tendinopathy (LET) with psychometric evaluation in UK population						
Outcome measure	Country of origin	Exclusively Patient Reported (no. items)	Construct (no. items)	Population*	Measurement model §	UK LET assessment
Oxford Elbow Score (OES) ⁽²³⁾	United Kingdom	Yes (12)	A1. Symptoms Pain (4) A2. Function Elbow function (4) Psychosocial (4)	Assessment of outcome of surgery of the elbow ⁽²³⁾	C1. Profile C2. Psychometric C3. Completely Standardised	Surgically treated LET patients make up 11.2% (n= 12/107) of the total development and validation cohort ^(23, 32, 33)
Liverpool Elbow Score (LES) ⁽²⁴⁾	United Kingdom	No, physician administered (15)	A1. Symptoms Pain (1) A2. Function Range of motion (4) Strength (1) Ulnar nerve function (1) Activity (8)	B1. Adults B2. All genders B3. Assessment of elbow pathology in tertiary care setting ⁽²⁴⁾ B4. UK English	C1. Index C2. Psychometric C3. Completely Standardised	Tertiary care patients with LET make up 12.7% (n=8/63) of the total development and validation cohort ⁽²⁴⁾
Patient-rated Tennis Elbow Evaluation (PRTEE) ⁽³⁴⁾	Canada	Yes (15)	A1. Symptoms Pain (5) A2. Function Activity (10)	B1. Adults B2. All genders B3. Lateral Elbow Tendinopathy patients ⁽³⁴⁾ B4. UK English	C1. Index C2. Psychometric C3. Completely Standardised	57 LET patients (100% of cohort) ⁽²⁵⁾ (PRTEE delivered in a modified form but not formally cross-culturally validated)
Disabilities of the Arm Shoulder and Hand (DASH) ⁽³⁵⁾ 2x Optional modules Work Sporting/performing arts	US, Canada, Australia	Yes (30)	A1. Symptoms Pain (5) A2. Function Physical function (21) Psychosocial (4)	B1. Adults B2. All genders B3. Applied to multiple elbow pathologies ⁽³⁶⁾ B4. UK English	C1. Index C2. Psychometric C3. Completely Standardised	Surgically treated LET patients make up 11.2% (n= 12/107) of the total development and validation cohort ^(23, 32, 33) . Tertiary care patients with LET make up 12.7% (n=8/63) of the total development and validation cohort ⁽²⁴⁾ (DASH delivered in original form, without any modifications) (UK English DASH translation available from 2015 ⁽²⁸⁾)
Mayo Elbow Performance Score (MEPS) ⁽³⁷⁾ Physician administered 8 Items: 1x pain 1x Range of motion 1x Instability 5x Function	United States	No, physician administered (15)	A1. Symptoms A2. Function	B1. Adults B2. All genders B3. Applied to multiple elbow pathologies ⁽³⁸⁾ B4. UK English	C1. Index C2. Clinometric C3. Completely standardised	Surgically treated LET patients make up 11.2% (n= 12/107) of the total development and validation cohort ^(23, 32, 33) (MEPS delivered in original form, without any modifications)

* All measures were developed for English-speaking adults of either gender. § All measures were fully standardised.

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Table 2: Studies reporting the use of PROMs in patients with Lateral Elbow Tendinopathy.

Author	Year	Title	Study Type and Population	Outcome measure
Melikyan, E. Y., et al.	2003	Extracorporeal shock-wave treatment for tennis elbow: a randomised double-blind study	RCT LET patients who failed conservative treatment	DASH
Dunkow, P. D., et al.	2004	A comparison of open and percutaneous techniques in the surgical treatment of tennis elbow	RCT LET patients who failed conservative treatment	DASH*
Connell, D. A., et al.	2006	Ultrasound-guided autologous blood injection for tennis elbow	Prospective Cohort LET patients who failed conservative treatment	Nirschl*
Alizadehkhayat, O., et al.	2007	Pain, functional disability, and psychologic status in tennis elbow	Cross-sectional LET with symptoms lasting >3 months	DASH PRWE PRFEQ
Connell, D., et al.	2009	Treatment of lateral epicondylitis using skin-derived tenocyte-like cells	Prospective Pilot Study (Not Randomised) LET patients who failed conservative treatment	PRTEE*
Clarke, A. W., et al.	2010	Lateral elbow tendinopathy: correlation of ultrasound findings with pain and functional disability	Prospective Cohort LET who had not undergone invasive treatment	PRTEE*
Creaney, L., et al.	2011	Growth factor-based therapies provide additional benefit beyond physical therapy in resistant elbow tendinopathy: a prospective, single-blind, randomised trial of autologous blood injections versus platelet-rich plasma injections	RCT LET patients who failed conservative treatment	PRTEE*
Nazar, M., et al.	2012	Percutaneous Tennis Elbow Release Under Local Anaesthesia	Prospective Cohort LET patients who failed conservative treatment	DASH* OES
Stenhouse, G., et al.	2013	Do blood growth factors offer additional benefit in refractory lateral epicondylitis? A prospective randomized pilot trial of dry needling as a stand-alone procedure versus dry needling and autologous conditioned plasma	Prospective Pilot Study (Randomised) LET patients who failed conservative treatment	Nirschl
Maffulli, G., et al.	2014	Assessment of the Effectiveness of Extracorporeal Shock Wave Therapy (ESWT) For Soft Tissue Injuries (ASSERT): An Online Database Protocol	Online Database Protocol of Clinically or Radiologically confirmed LET	PRTEE*
Tonks, J. H., et al.	2007	Steroid injection therapy is the best conservative treatment for lateral epicondylitis: a prospective randomised controlled trial.	RCT LET patients who had not had treatment for the preceding 6 months.	PRTEE

* Primary outcome

Table 3: Adherence to CONSORT reporting standards (PRO extension) of UK-based Lateral Elbow Tendinopathy RCTs.

CONSORT 2010 statement	PRO Extension	Studies meeting the requirements
Structured summary of trial design, methods, results, and conclusions	The PRO should be identified in the abstract as a primary or secondary outcome	1/4
Specific objectives or hypotheses	The PRO hypothesis should be stated and relevant domains identified, if applicable	0/4
Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Evidence of PRO Instrument validity and reliability should be provided or cited if available, including the person completing the PRO and methods of data collection (paper, telephone, electronic, other)	0/4 (validity of PROM in UK population) vs 2/4 (validity of PROM in another LET population) 1/4 (data collection method)
Statistical methods used to compare groups for primary and secondary outcomes	Statistical approaches for dealing with missing data are explicitly stated	0/4
Trial limitations addressing sources of potential bias, imprecision, and, if relevant multiplicity of analyses	PRO-specific limitations and implications for generalisability and clinical practice should be discussed	0/4

Appendix 1:

Search Strategy – MEDLINE – Run 1/5/2017

Medline

1. exp Elbow/
2. elbow.tw.
3. exp Elbow joint/
4. exp Tennis Elbow/
5. epicondylitis.tw.
6. common extensor origin.tw.
7. epicondylalgia.tw.
8. 1 or 2 or 3 or 4 or 5 or 6 or 7
9. exp "Outcome Assessment (Health Care)"/
10. (Outcome? adj2 assessment).tw.
11. patient reported outcome?.tw.
12. outcome? measure?.tw.
13. exp health status/
14. health status.tw.
15. exp "quality of life"/
16. quality of life.tw.
17. (QL or QoL or HRQL or HRQoL).tw.
18. (function* adj2 (status or psychological or mental or physical or social)).tw.
19. disabilit*.tw.
20. exp "Activities of Daily Living"/
21. activities of daily living.tw.
22. (wellbeing or well being).tw.
23. exp happiness/
24. (happi* or happy).tw.
25. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
26. assessment.tw.
27. index.tw.
28. indices.tw.
29. instrument?.tw.
30. measure?.tw.
31. profile?.tw.
32. rating?.tw.
33. report*.tw.
34. scale?.tw.
35. schedul*.tw.
36. scor*.tw.
37. exp health surveys/
38. survey?.tw.
39. 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38
40. (symptom? adj2 (assessment or index or indices or instrument? or measure? or profile? or rating? or report* or scale? or schedule? or scor* or survey?)).tw.
41. 25 or 40
42. exp Self-Assessment/
43. self-assess*.tw.
44. exp Questionnaires/
45. questionnaire?.tw.
46. self report*.tw.
47. 42 or 43 or 44 or 45 or 46
48. (Validation Studies or Comparative Study).pt. or exp psychometrics/ or psychometr*.tw. or clinimetr*.tw. or clinometr*.tw. or exp observer variation/ or observer variation.tw. or exp Health Status Indicators/ or exp reproducibility of results/ or reproducib*.tw. or exp discriminant analysis/ or reliab*.tw. or unreliab*.tw. or valid*.tw. or coefficient.tw. or homogeneity.tw. or homogeneous.tw. or internal consistency.tw. or (cronbach* and (alpha or alphas)).tw. or (item and (correlation* or selection* or reduction*)).tw. or agreement.tw. or precision.tw. or imprecision.tw. or precise values.tw. or test-retest.tw. or (test and retest).tw. or (reliab* and (test or retest)).tw. or stability.tw. or interrater.tw. or inter-rater.tw. or intrarater.tw. or intra-rater.tw. or intertester.tw. or inter-tester.tw.

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49. 39 or 47 or 48

50. 41 and 49

51. (Oxford elbow score or Liverpool Elbow Score or Elbow Self-Assessment Score or Elbow Function Assessment or (American Shoulder and Elbow Surgeons-elbow) or (Modified American Shoulder and Elbow Surgeons) or Mayo Elbow Performance Score or Hospital for Special Surgery score or Hospital for Special Surgery short version or patient-rated elbow evaluation or Patient-Rated Tennis Elbow Evaluation or Elbow Functional Assessment or (Disabilities of the Arm, Shoulder and Hand questionnaire) or subjective elbow value or (Broberg and Morrey) or Ewald).mp. or Pritchard.tw. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, tn, dm, mf, dv, kw]

52. (OES or LES or ESAS or ASES or ASES-e or MEP or PREE or PRTEE or EFA or DASH or quickDASH).mp. [mp=ti, ab, ot, nm, hw, kf, px, rx, ui, tn, dm, mf, dv, kw]

53. 8 and 52

54. 8 and 50

55. 51 or 53 or 54

56. exp ANIMALS/ not humans.sh.

57. 55 not 56

Appendix 2 : Included reference from systematic search

1. Dawson J, Doll H, Boller I, Fitzpatrick R, Little C, Rees J, et al. The development and validation of a patient-reported questionnaire to assess outcomes of elbow surgery. *J Bone Joint Surg Br.* 2008;90(4):466-73.
2. Sathyamoorthy P, Kemp G, Rawal A, Rayner V, Frostick S. Development and validation of an elbow score. *Rheumatology.* 2004;43(11):1434-40.
3. Dawson J, Doll H, Boller I, Fitzpatrick R, Little C, Rees J, et al. Comparative responsiveness and minimal change for the Oxford Elbow Score following surgery. *Qual Life Res.* 2008;17(10):1257-67.
4. Dawson J, Doll H, Boller I, Fitzpatrick R, Little C, Rees J, et al. Specificity and responsiveness of patient-reported and clinician-rated outcome measures in the context of elbow surgery, *Orthopaedics & Traumatology: Surgery & Research* 98.6 (2012): 652-658.
5. Poltawski L, Watson T. Measuring clinically important change with the Patient-rated Tennis Elbow Evaluation. *Hand Therapy.* 2011;16(3):52-7.
6. Melikyan EY, Shahin E, Miles J, Bainbridge LC. Extracorporeal shock-wave treatment for tennis elbow. *Bone & Joint Journal.* 2003;85(6):852-5.
7. Dunkow PD, Jatti M, Muddu BN. A comparison of open and percutaneous techniques in the surgical treatment of tennis elbow. *Bone & Joint Journal.* 2004;86(5):701-4.

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8. Connell DA, Ali KE, Ahmad M, Lambert S, Corbett S, Curtis M. Ultrasound-guided autologous blood injection for tennis elbow. *Skeletal radiology*. 2006;35(6):371-7.
 9. Alizadehkhayat O, Fisher AC, Kemp GJ, Frostick SP. Pain, functional disability, and psychologic status in tennis elbow. *The Clinical Journal of Pain*. 2007;23(6):482-9.
 10. Connell D, Datir A, Alyas F, Curtis M. Treatment of lateral epicondylitis using skin-derived tenocyte-like cells. *British Journal of Sports Medicine*. 2009;43(4):293-8.
 11. Clarke AW, Ahmad M, Curtis M, Connell DA. Lateral Elbow Tendinopathy Correlation of Ultrasound Findings With Pain and Functional Disability. *The American Journal of Sports Medicine*. 2010;38(6):1209-14.
 12. Creaney L, Wallace A, Curtis M, Connell D. Growth factor-based therapies provide additional benefit beyond physical therapy in resistant elbow tendinopathy: a prospective, double-blind, randomised trial of autologous blood injections versus platelet-rich plasma injections. *British Journal of Sports Medicine*. 2011;45(12):966-71.
 13. Nazar M, Lipscombe S, Morapudi S, Tuvo G, Kebrle R, Marlow W, et al. Percutaneous tennis elbow release under local anaesthesia. *Open Orthop J*. 2012;6:129-32.
 14. Stenhouse G, Sookur P, Watson M. Do blood growth factors offer additional benefit in refractory lateral epicondylitis? A prospective, randomized pilot trial of dry needling as a stand-alone procedure versus dry needling and autologous conditioned plasma. *Skeletal Radiology*. 2013;42(11):1515-20.
 15. Maffulli G, Hemmings S, Maffulli N. Assessment of the effectiveness of extracorporeal shock wave therapy (ESWT) for soft tissue injuries (assert): an online database protocol. *Translational medicine@ UniSa*. 2014;10:46.
 16. Tonks JH, Pai SK, Murali SR. Steroid injection therapy is the best conservative treatment for lateral epicondylitis: a prospective randomised controlled trial. *International Journal of Clinical Practice*. 2007;61(2):240-6.