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1 **Introduction**

2 Lateral Epicondylalgia (LE), more commonly known as tennis elbow, is a tendinopathy of the wrist
3 extensors at the lateral epicondyle. LE is the most common chronic musculoskeletal pain condition
4 affecting the elbow [1], and has a prevalence of 1-3% [2]. In the UK, the incidence of lateral elbow
5 pain in general practice is 4.23/1000 people a year [3]. The burden of LE can be significant,
6 accounting for up to 219 workdays, with direct costs of US\$8099 per person [4,5], the greatest
7 burden being amongst manual workers [1].

8 The pathoaetiology of tendinopathy is not fully understood, there being a complex interplay
9 between structure, pain and function [6]. Notable advances have been made relating to both the
10 understanding and treatment of tendinopathies in the last couple of decades. The tendon
11 continuum [7] brought together three of the previously proposed stages of tendon pathology, which
12 has been recently updated [6]. However, despite these advances, LE still remains a challenge to
13 treat.

14 An audit cycle was initiated, clinical audit being an essential element of professional quality practice
15 and supporting continuous improvement in patient care and service delivery within the Health
16 Service [111,112]. It was perceived that, within the physiotherapy service, outcomes for LE patients
17 were sub-optimal. Which factors contribute to a sub-optimal outcome in LE is an area of much
18 debate. Various theories have been suggested including central pain mechanisms [126,127], self
19 efficacy [122], psychosocial factors [37-39, 48,49], metabolic factors [123-125] and sub-optimal
20 loading [114]. Recent work in patellofemoral pain have focused on sub grouping and targeted
21 intervention and have shown greater improvement short term [115].

22

23

24 **Methods**

25 A three phase audit cycle of physiotherapy treatment for LE was conducted in 2012 (Phase 1), 2014
26 (Phase 2) and 2015 (Phase 3) with each cycle reviewing the previous years' data (figure 1). The
27 location was the musculoskeletal outpatient department across four sites within Salford Royal NHS
28 Foundation Trust, a large teaching hospital NHS Trust in the northwest of England. Within the
29 department clinical diagnosis is commonly based on clinical history combined with positive clinical
30 tests of pain reproduction with resisted wrist extension, resisted middle finger extension and pain on
31 palpation of the common extensor origin at the lateral epicondyle.

32 **Insert Figure 1 here**

33 **Phase One.** Records of patients attending for initial physiotherapy assessment between 1st January
34 and 31st December 2011, with a diagnosis of LE were audited. Data extracted included the variety
35 and number of treatments, outcome measures used and the outcomes of treatment. Improvement
36 was measured using the VAS and a form of the Global Rating of Change Scale (GRCS), where patients
37 were asked on a scale of 1-10 how much better they were.

38 Following the audit a literature review of the evidence base for the treatment of LE was undertaken.
39 This highlighted that a number of non-evidence based treatments were being used. Across the Trust
40 a team consensus was subsequently developed so that the primary focus of treatment for all LE
41 patients would be on strengthening exercises [1] and that non-evidence based treatments would be
42 discontinued. It was agreed that the type of strengthening exercises and the specific muscle groups
43 targeted would be determined by the treating physiotherapist. Accompanying this change, a more
44 comprehensive set of outcome measures were implemented for LE patients across the
45 physiotherapy service [8-11].

46
47 **Phase Two.** The second audit took place between 1st May 2013 – 30th April 2014. The data
48 extraction was expanded to include risk factors, chronicity, occupation and patient anthropometrics.

49 In addition to the data collected in the Phase one audit, process evaluation was also conducted to
50 seek feedback from the physiotherapy team regarding what they felt worked well, what could be
51 improved and to discuss any problems encountered, or any challenges hindering therapist fidelity
52 with the new treatment approach. One of the key themes to emerge from the process evaluation
53 was the variety of approaches to load setting adopted when prescribing exercises. Feedback was
54 then given on the Phase two audit, discussing areas highlighted both from the audit and the process
55 evaluation, including compliance with the use of outcome measures. Based on staff feedback, a
56 training session on pathophysiology of tendinopathy was delivered which included teaching on
57 different ways to explain tendinopathy to patients. At this training session the tendon continuum
58 [7], potential mechanical pathoaetiological mechanisms contributing to the development of
59 tendinopathy including stretch-shorten cycles [12,13] and compression theories [14-19], and the
60 conflicting approaches of pain provocation [20] or pain avoidance [21] with loading programmes
61 were discussed. A range of recognised loading programmes for tendinopathy were reviewed,
62 including isometric exercises, combined concentric and eccentric exercise, heavy slow resistance
63 (HSR) training, and eccentric exercises. Following the completion of the Phase two audit, an
64 evidence based standardised treatment protocol (Table 1) was implemented for the Phase three
65 audit, based on the current literature available at that time. This commenced with moderate to high
66 load isometric loading in a standardised position (figure 2a and 2b), progressing to a combined slow
67 concentric and eccentric exercise, which was then further progressed by increasing load (Table 1).
68 An area identified during the process evaluation with the physiotherapists was the use of very light
69 weights for eccentric exercise, and it was highlighted that finding suitable weights without cost to
70 the patient was problematic. An adjustable elbow crutch was used to increase the lever arm, once
71 extended to the full length it could be shortened and a small weight of 250g or 500g attached
72 securely to the end of the crutch so that slow progressive lengthening of the crutch could
73 recommence. An illustrated exercise instruction leaflet sheet was devised for the initial isometric
74 phase (Figures 2a & 2b) and issued to patients along with a table to record their exercises and to

75 monitor progress. The audit revealed that the use of outcome measures was inconsistent with high
76 physiotherapist fidelity at initial assessment but low fidelity at discharge. The importance of routine
77 outcome measurement on discharge was reinforced.

78

79 **Phase Three.** The third audit took place between 1st October 2014 – 30th September 2015. Data
80 extraction remained the same as for Phase two.

81

82 **Global Rating of Change Scale (GRCS)**

83 Two different GRCS were used. In phase one GRCSv1 was used. This ranged from 0-10, the cut
84 point for responders was 8 or higher. This accounted for 20% of the scale. Following the audit of
85 Phase one, it was identified that more robust outcome measures were required. The GRCSv2 was
86 then adopted, GRCCv2 is a balanced 21-point Likert scale with numerical descriptors at each point,
87 complimented by written descriptors of no change at the mid-point '0', whilst the extremes
88 displayed 'completely recovered' (+10) or 'very much worse' (-10) [10]. At the start of each
89 treatment session the following standardised question was asked: 'with respect to your tennis
90 elbow, how would you describe yourself now compared to a) last treatment b) when it first came
91 on?'. The cut point for the responders was +7 and above, which, identical to GRCSv1, accounted for
92 20% of the scale to the nearest whole number.

93

94 **INSERT FIGURE 2A, 2B HERE**

95 **INSERT TABLE 1 HERE**

96

97 **RESULTS**

98 **Insert table 2 here**

99 **Insert table 3 here**

100 **Insert figure 3 here**

101 **Insert table 4 here**

102 **Insert figure 4 here**

103 Of those patients completing treatment in Phase two, only 10 had initial and discharge PFGS data
104 recorded. Initial PFGS ranged from 0-30.3kg with a mean of 11.0 KG, whilst the discharge PFGS
105 ranged from 2-46kg with a mean of 22kg.

106 Of the 32 patients completing treatment in Phase three, 27 had initial and discharge PFGS data
107 recorded. Initial PFGS ranged from 0-38kg with a mean of 16.2 kg, whilst the discharge PFGS ranged
108 from 8-62kg with a mean of 27.5 kg.

109 The PRTEE therapist fidelity at discharge was low, with Phase two having 10 patients with both initial
110 and discharge data; whilst in Phase three only 5 patients had this data.

111 In Phase two average initial PRTEE score was 48.7 and average discharge score was 24.3, giving an
112 average improvement of 50%. In Phase three average initial PRTEE score was 33.7 and average
113 discharge score was 12.1, with an average improvement of 64%.

114 **Insert Table 5 here**

115 **DISCUSSION:**

116 The records of 182 patients were reviewed, with data extracted on the variety and number of
117 treatments, outcome measures used and the outcomes of treatment. The demographics of these
118 patients are presented in Table 2; they are considered typical patients that attend an NHS service
119 with LE. The average age of 50 years was in keeping with other studies [1,2,22]. Shiri et al. [2]
120 demonstrated that prevalence did not differ between men and women, however gender
121 demonstrated an unexplained variation in this audit. Phase one consisted of 51% male patients
122 however both Phases two and three consisted of a lower percentage (36%) of male patients (Table
123 2). Although sample sizes were smaller in the latter two phases this would not explain this

124 difference. Chronicity also demonstrated unexplained variation (Table 2), the relatively high
125 chronicity in both phases being typical for LE. LE commonly affects the dominant arm [1,23], our
126 data support this as, where this was recorded, 63% of the patients presented with symptoms on
127 their dominant side. The initial Phase one audit did not document side dominance, occupation,
128 chronicity and specific past medical history relating to risk factors, however, in the latter two phases
129 the audit was expanded to capture this information, which was a limitation for the phase one data.

130 Phase one revealed a wide variety of treatments were being used (n=33), patients received between
131 1-17 treatments and with an average of 5.1 treatments (Tables 3 and 4). The outcome measures
132 used were limited in number (n=2) and lacked robustness; using the results from the GRCS for those
133 completing treatment (n=47), 64% (n=30) of patients responded to treatment (figure 3). As was
134 hoped the Phase two audit demonstrated a marked reduction in the variety of interventions
135 employed with greater emphasis on muscle strengthening (Table 4) and a reduction in the average
136 number of treatments to 3.11 (table 3) whilst maintaining similar outcomes; 63% (n=17) of patients
137 responded to treatment (figure 3). Phase three demonstrated complete cessation of non-evidence
138 based treatments. Therapist fidelity was high with the exercise component of the standardised
139 treatment protocol with 98% of patients receiving isometric loading (Table 4). The average number
140 of treatments reduced to 2.95 and outcomes were improved by 8% with 72% (n=23) of patients
141 responding to treatment. It is interesting to note that for some unexplained reason, phase two
142 demonstrated lower average initial PFGS than phase three, particularly considering similarities in
143 chronicity (table 2).

144 The aim of this project was to improve outcomes for LE patients and it was felt that to achieve this, a
145 core treatment intervention that was standardised and evidence based needed to be implemented,
146 so that all patients received the same quality of treatment irrespective of whether they saw a newly
147 qualified physiotherapist or an experienced physiotherapist, and irrespective of which clinic within
148 the Trust they attended. This is not to say that one size fits all, neither is it to say that everyone

149 needs the same treatment, however it is a method by which to ensure that there is good practice at
150 the core of all treatments across the department so that, once initiated, these treatments can be
151 individualised to meet the needs of individual patients [24]. As part of this audit process the
152 evidence base for treatments commonly being delivered in Phase one was reviewed. Many, with
153 the exception of muscle strengthening, were found to have a weak evidence base. For example a
154 Cochrane review by Green et al. [25] demonstrated no benefit lasting more than 24 hours following
155 acupuncture. Systematic reviews by Bisset et al. [26] and Bisset, Coombes and Vicenzino [22] found
156 Ultrasound to be no more effective than placebo for pain relief or self-perceived global
157 improvement in the short term. More recently Loew et al. [27] in their Cochrane review on LE found
158 there to be insufficient evidence to determine the effects of Deep Transverse Frictional Massage
159 (DTFM) on LE and there was no evidence of clinically important benefit. Despite conflicting evidence
160 for exercise in LE, a review by Bisset & Vicenzino [1] concluded that there was evidence from several
161 RCTs of sound methodological quality that exercise may be more effective at both reducing pain and
162 function compared to other treatment modalities, however there may be no difference in effect
163 between different types of exercise.

164 In Phase one 69% of patients received strengthening exercises which were predominantly eccentric
165 exercises in isolation (90%). Concentric/eccentric exercises were only given to 5 patients and
166 isometric exercises were not prescribed. The specific exercise prescription was often poorly
167 documented, with no reference to being pain-free or painful, how long each contraction should last
168 (speed of contraction), and frequently either a light weight was used (<1kg) or no weight was
169 documented. However it was clearly perceived that eccentric exercise was the 'best' form of
170 strengthening exercise. In Phase two the situation had improved considerably with 98% of patients
171 receiving some form of strengthening exercise (table 4). Of these 54 patients 76% were given
172 eccentric exercises (n=41) with 15 of these patients being given eccentric exercises in isolation.
173 Isometric exercises were used in 15% of those receiving strengthening whilst 12 patients received
174 concentric/eccentric exercises. An increase in the prescription of supinator strengthening was also

175 observed. Supination exercises have been observed in previous studies [28,29]. Supinator has
176 attachments to the annular ligament, lateral epicondyle and lateral ligament so is intimately related
177 to lateral elbow structures. Erak, Day and Wand [30] demonstrated a biomechanical basis for the
178 involvement of the superficial head of supinator in the aetiology of lateral epicondylitis, whilst
179 Stroyan and Wilk [31] suggested that supinator has a role in the stability of the radio-humeral and
180 superior radio-ulnar joints particularly with tasks in pronation, such as gripping and lifting. More
181 recently Ranger et al. [32] suggested that the radial head may act as a cam in pronation, mitigating
182 the load on the origin of extensor carpi radialis brevis (ECRB), all of which certainly require
183 consideration clinically. In Phase three all 56 patients received strengthening exercises, 55 of which
184 were commenced on the standardised isometric loading programme. In phase three, 100% of
185 patients that completed treatment received isometric loading (n=32). Of those responding to
186 treatment (n=24) 67% of patients (n=16) received isometric exercise in isolation and were
187 sufficiently improved not to require further treatment progression, whilst only 7 patients responding
188 to treatment were progressed onto slow concentric/eccentric exercises. Interestingly greater gains
189 were seen in phase three, which consisted mainly of isometric strengthening (figure 4). Whether
190 this was attributable to the isometric strengthening regime, the improved load setting, the
191 hypoalgesic effect of isometric exercises seen [33] and the resultant improved compliance, or a
192 combination of reasons is impossible to differentiate.

193 The standardised loading programme that developed as a result of this audit placed increased
194 emphasis on patient specific load setting, ensuring that load was as high as tolerable. Pain during
195 exercise was allowed. Historically there are conflicting views regarding whether tendinopathy
196 exercises should be painful or pain-free. Curwin & Standish [21] advocated pain-free strengthening,
197 whilst Alfredson et al. [20] required exercise to be painful, so if no pain was felt, the load was
198 increased until pain was felt. Both painful [34,35] and pain-free [29,36] exercise regimes, however,
199 have demonstrated favourable results for LE. Avoiding pain could potentially contribute to re-
200 enforcing erroneous beliefs regarding exercise [37,38], whilst increasing the chance of the load being

201 insufficient [20]. Furthermore, exercising into discomfort in a graduated manner has been shown to
202 assist in normalising any over-prediction of pain [39, 126] and by altering pain memories [119], with
203 a painful loaded exercise programme potentially having a therapeutic impact on the central nervous
204 system [120]. A recent systematic review on exercise in chronic musculoskeletal pain [121] found
205 painful exercise to have a small but significant benefit over painfree exercise. Clinicians were
206 specifically educated re the current understanding of tendinopathy, and had a better understanding
207 of the theory behind progressive loading. This was likely to improve patient education and
208 understanding, whilst giving the clinicians more confidence and indirectly improving patient
209 confidence in the physiotherapist, which could be a factor in improving patient compliance with the
210 loading programme [40].

211 Stretching, manual therapy, epiclasps, soft tissue techniques and 'other' treatments all significantly
212 reduced by phase three whilst outcomes improved. Techniques such as mobilisation with
213 movement (MWM's) combined with exercise were superior to wait and see at 6 weeks and a
214 reasonable alternative to corticosteroid injections in the mid- to long-term [28]. Whether the
215 addition of MWM's into the standardised programme could improve outcomes further remains to
216 be seen. Historically, static stretching has been commonly used in the treatment of LE. The basis of
217 stretching in tendinopathy is questionable, with conflicting evidence regarding the effect of static
218 stretching on tendon stiffness in various tendons, with some studies concluding that tendon stiffness
219 remains unchanged [41-43] whilst other studies demonstrated a decrease in tendon stiffness
220 [44,45]. Anatomically, stretching for LE would certainly increase the risk of tendon compression,
221 which is a proposed risk factor for tendinopathy [15]. This data demonstrates that outcomes can
222 improve despite stretching being all but omitted from treatment, casting further doubt on its place
223 in the treatment of LE. Similar observations were made regarding the use of soft tissue techniques
224 such as DTFM and massage, in keeping with the findings of Loew et al. [27].

225 Education was highlighted as a core component, to address patient expectations and encourage
226 empowerment. However, it was only documented in 45% of patients. Although this was an
227 improvement on phase one (27%) and similar to phase two (44%), it was much lower than expected
228 considering the therapist fidelity with the loading programme. Possible explanations would be that
229 it was poorly documented due to it being written in the standardised protocol and perceived by the
230 clinician of not being necessary to document thus being under-reported, or that it is an area
231 requiring further improvement. Certainly this audit data would not capture the quality of the
232 information being given, which, based on the delivery of the evidenced based training package prior
233 to Phase three, should have improved from phase two. Patients were given an exercise chart to take
234 home so that they could record their daily exercise, which could highlight improvements more easily
235 and objectively thus being motivational. Having an illustrated exercise sheet could also contribute to
236 improving patient recall of the correct technique [46]. Issuing the elbow crutch as a means of
237 lengthening the lever arm meant the patient had all the necessary equipment to progress to the
238 level required, without incurring cost or inconvenience trying to find an object suitable.

239

240 In Phase one outcome was measured using two simple generic tools the VAS and a form of the
241 GRCSv1, where patients were asked on a scale of 1-10 about their improvement. In phases 2 and 3,
242 Pain Free Grip Strength (PFGS), Patient-Rated Tennis Elbow Evaluation (PRTEE), Tampa Scale for
243 Kiniesiophobia-11 (TSK-11) and an improved GRCSv2 were added. It is interesting to note that the
244 majority of patients had baseline evaluations recorded on these measures at initial assessment but
245 there were relatively few discharge measures recorded. There are two possible explanations for
246 this: firstly that a number of patients discharged themselves by telephone or secondly that the
247 physiotherapists found the burden of completing these instruments too great. The limited data we
248 have available on these measures suggests that both PFGS and PRTEE in Phases 2 and 3 recorded pre

249 and post intervention improvements that easily exceeded the Minimum Clinically Important Change
250 (MCIC) of 1.4kg for PFGS and a reduction in score of 10 points on the PRTEE [47].

251 Therapist fidelity collecting PRTEE discharge data was low. Bisset & Vicenzino [1] suggested a
252 prognostic continuum where poor prognosis was suggested if a patient presents with poor
253 prognostic factors including an initial PRTEE score >54 then a more chronic pain approach should be
254 considered. In Phase two non-responders 70% scored 54 or greater, whilst in the responders 44%
255 scored 54 or more. In Phase three, of the nine non-responders 71% scored >54, Of the responders
256 41% scored >54. Identification of patients more likely to respond to physiotherapy treatments is an
257 excellent aim; however our data did not fully support their proposed model. Further work on this
258 topic would be of great clinical value.

259 No discernible differences were observed in the initial scores of the TSK-11 between responders
260 (range 12-33, median 20) and non-responders (range 12-29, median 27), neither were differences
261 observed when broken down into somatic focus (TSK-SF) and activity avoidance (TSK-AA). TSK-11
262 scores of those that completed treatment and those that did not complete treatment also displayed
263 similar characteristics. These findings are in contrast to those of Das De et al. [48], however they are
264 consistent with the findings of a recent systematic review by Mallows et al. [24]. Although the TSK-
265 11 failed to provide any meaningful information, psychological factors still should be explored. In a
266 recent study on shoulder pain, the formal assessment of psychological factors such as patient
267 expectation and pain self-efficacy, using standardised measures, were recommended [49].

268 PFGS has been shown to be more sensitive than maximum grip strength for measuring change over
269 time [8]. Phase two only had complete data for 10 patients, showing an average improvement of
270 8.67 kg (figure 4), whilst in Phase three there were 27 patients with complete data, showing an
271 average improvement of 11.27 kg (figure 4). This improvement could be explained by a number of
272 reasons: The use of isometric and slow concentric/eccentric exercise; the improved patient specific
273 load setting using high load; improved education of both therapists and patients, empowering

274 patients and improving compliance [40]; the use of the elbow crutch as a strengthening tool; the use
275 of an exercise chart.

276 Hypoalgesic effects have been shown in healthy adults with the use of acute exercise, whilst in
277 adults with chronic pain both a hypoalgesic and hyperalgesic effects have been seen [33]. PFGS was
278 found to increase even after a few short (10 second) sustained isometric contractions, supporting
279 the findings of Naugle et al. [33]. Demonstrating this improvement in PFGS to patients at initial
280 assessment may be of benefit to highlight improvements in strength, even if no change to pain level
281 is observed, to re-inforce the functional benefits of exercise that patients otherwise might not be
282 aware of due to their focus on pain. This may also have the potential to improve patient compliance
283 with treatment [40].

284

285 **Conclusion:**

286 The standardised tendon loading programme in Phase three demonstrated superior outcomes
287 compared to both previous phases. High load Isometric exercises should be considered when
288 making clinical decisions about exercise prescription, as should ensuring sufficient load setting for
289 each individual. Exercising into pain can be effective. Strengthening should be a core part of the
290 treatment of LE, whilst other treatments such as stretching and soft tissue techniques are of
291 doubtful significance/effectiveness.

292 This three phase audit has documented a service evaluation and improvement project and has
293 demonstrated that standardising treatment has helped to improve baseline quality for the
294 treatment of LE. It is important to note that one size doesn't fit all therefore this standardisation
295 should be used in conjunction with evidence based clinical reasoning.

296

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