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7 *Title* Evaluating a dynamic elastomeric fabric orthosis developed to aid in the management of
8 athletic pelvic pain

9

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20 *Word count* 2999

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27 **Objectives:** To evaluate a dynamic elastomeric fabric orthosis (DEFO) developed to aid the
28 management of athletic pelvic pain.

29 **Design:** A series of single case studies, with randomised onset of intervention. Daily
30 assessments were undertaken over 15 days (a minimum baseline and intervention period of 6
31 days). A follow up session was undertaken after 1 month.

32 **Setting:** Because of the demands of daily testing over a three week period, participants were
33 tested in locations convenient to them. This included Plymouth University, DM Orthotics and
34 the homes of participants.

35 **Participants:** Eight athletes, confirmed through clinical screening, as presenting with pain
36 affecting the pelvic girdle.

37 **Interventions:** During the intervention period the athletes wore a bespoke DEFO (in the form
38 of shorts).

39 **Main outcome measures:** Force produced on bilateral resisted hip adduction (squeeze test),
40 and self-scored pain (using a numerical rating scale 0-10) at rest and on completing an active
41 straight leg raise (ASLR) and a broad jump. A questionnaire on DEFO usage was administered
42 on completing the study.

43 **Results:** Athletes responded differently, but all but one case showed significant improvement
44 on at least one outcome measure.. People presenting with decreased force output on the
45 squeeze test, and a very asymmetric ASLR tended to show the greatest improvement. All
46 athletes reported they would continue to wear the DEFO.

47 **Conclusions:** This DEFO may support the physiotherapeutic management of athletic pelvic
48 pain.

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50 Word count: 241

51 Key words: DEFO, Athletes, pelvic, groin, pain, squeeze test

52 **Introduction**

53 Athletic pelvic pain is a common problem; sports like football, cricket and ice hockey
54 have notably high rates of groin injury (1). With different aetiologies affecting, and referring
55 pain to the pelvic region, athletic pelvic pain can be a difficult to manage phenomena made
56 harder by the common occurrence of more than one site of injury, and issues with accurate
57 assessment (2).

58 Weakness and/or delayed activation in local core stabilisers, particularly transversus
59 abdominus, has been associated with certain types of pelvic pain(1). Pelvic belts have been
60 used in the management of pelvic pain (3;4). Pelvic belts may act by addressing issues in
61 “force closure”; the stabilisation of joints through active and passive musculo-tendinous and
62 ligamentous actions. Pain affecting the lumbopelvic region has also been hypothesised to
63 result from impaired proprioceptive feedback (5) and pelvic belts may also have an effect on
64 proprioception ., In people with longstanding adduction pain pelvic belts reduce pain during
65 active hip adduction(the “ squeeze test”) and active straight leg raise (ASLR) in 50% and 25%
66 of participants respectively (6). Clinical experience suggests that in practice belts are difficult
67 to keep in position, especially during sporting activities, and therefore tend to be limited to
68 use in controlled rehabilitation and training sessions.

69 Dynamic elastomeric fabric orthoses (DEFO’s) are a recent advancement in orthotics;
70 increasingly used in the management of neurological (7), and musculoskeletal conditions (8).
71 These bespoke orthoses apply forces (through selectively positioned elastomeric panelling)
72 which act to stabilise and align body segments, in order to promote normal function and
73 reduce unwanted movements. The compression that these orthoses can provide, may offer an
74 opportunity to replicate the action of pelvic belts in a more dynamic form.

75 Based upon the use of pelvic belts and how they may aid management of pelvic pain
76 by improving force closure and / or proprioception (4), a study was undertaken to establish
77 whether diagonally applied force to the pelvis can be as / or more effective in reducing pain
78 during clinical tests compared to those delivered transversely, the usual line of action of a
79 pelvic belt (9). This work highlighted that diagonal forces towards the site of pain may have
80 additional benefits in improving pain and function, compared to no belt or a transverse
81 application. These results informed the development of a DEFO (figure 1) aimed at aiding the
82 management of athletic pelvic pain.

83 The aim of the current study is to evaluate the effectiveness of this novel, newly
84 developed DEFO on athletes pelvic pain and function using a series of single case studies.

85

86

87 **Methods**

88 *Study design*

89 An AB single case study design was used with a randomised onset of intervention. The study
90 was approved by the local ethics committee (Plymouth University) and athletes participated
91 after informed written consent was obtained.

92 *Sample*

93 A mixed sex sample of eight athletes with pelvic pain, as determined by the screening
94 procedure below.

95 *Eligibility Criteria*

96 Potential athletes were over 18 years old; with a history of pelvic pain presenting
97 during sport or rest. There was no time minimum or maximum on duration of pain, to allow
98 for inclusion of both acute and chronic conditions.

99 *Inclusion criteria*

100 In line with European Guidelines a battery of tests was used for screening purposes
101 (11), ensuring the inclusion of tests to identify sacroiliac joint, symphysis pubis and adductor
102 pain:-

103 *ASLR* – This has shown to be a reliable measure of impaired load transfer through the
104 lumbopelvic region (5), and valid for use in athletes with groin pain (12). Athletes in supine
105 with their legs 20 cm apart, raised each leg 20 cm above the plinth. Athletes self-scored how
106 difficult they found this task using a rating of 0-5 (where 5 indicates most difficult). The final
107 score was determined by adding scores from both legs (range 0 – 10). Scores 1-10 were
108 defined as positive.

109 *Faber's test*- From supine the athlete was asked to position their leg into flexion, abduction
110 and external rotation (placing one foot across the knee of their opposite leg). pressure was
111 applied to the externally rotated knee, whilst stabilising the opposite ASIS; a positive test
112 was determined by pain being provoked by pressure (13).

113 *Resisted hip adduction* – In line with other studies examining groin pain (4;14), from a supine
114 position the athlete was asked to adduct their leg and maintain adduction against an external
115 resistance. The test was positive if pelvic pain was reproduced.

116 *Thigh thrust*- This was regarded as the most sensitive test of sacroiliac pain (15). The athlete
117 lay in supine , whilst the therapist flexed their knee and hip, before applying a downwards
118 force through the knee towards the pelvis. The test was positive if pain was provoked by
119 pressure (16).

120 *Gaenslens* – From supine, the therapist flexed the knee and hip, whilst extending the opposite
121 leg to lie off the plinth. Overpressure was applied to the flexed knee towards the pelvis, and to
122 the iliac crest of the abducted/extended leg. A positive test was determined by pain
123 provoked

124

125 When used in isolation these tests are limited in terms of sensitivity and specificity of
126 diagnosis. However, these increase when they are used as a battery of tests. Therefore, for
127 inclusion into the study people had to have a positive test on at least two of these five tests
128 (17)(16).

129 *Exclusion criteria*

130 People were excluded if they had:

131 i. Osteoporosis – to exclude risk of a pelvic fracture being responsible for pelvic pain

- 132 ii. Anorexia - to exclude those at risk of osteoporosis
- 133 iii. Neurological signs, determined by clinical examination, which may influence pain
- 134 perception, and to exclude lumbosacral radicular syndrome
- 135 iv. Pregnancy - to ensure the safety of the mother and foetus
- 136 v. Co-morbidities (rheumatological, neurological or systemic disease) which may
- 137 impact upon the outcome measures
- 138 vi. Suspected fracture based on clinical examination (e.g pain as measured on a numerical
- 139 rating scale (NRS) >8/10, deformity, acute swelling, significant leg-length discrepancy,
- 140 and mechanism of injury)
- 141 vii. Trochanteric bursitis
- 142 viii. Muscle / tendon rupture
- 143 ix. Inguinal herniation
- 144 x. Previous pelvic fracture

145

146 *Procedures*

147 Fifteen daily assessments were undertaken, with at least six during each phase

148 (baseline and intervention). The onset of the intervention was randomised for each subject

149 using random codes generated in Matlab (Mathworks UK). The intervention could either

150 commence on day 7, 8, or 9. In the intervention phase participants wore the DEFO for

151 activities of their choice and completed a training diary.

152

153 *Outcome Measures*

154 Outcome measures were self-reported pain on a numerical rating scale (NRS) at rest,

155 during a squeeze test, ASLR, and a 1m broad jump. Additionally the force applied during a

156 squeeze test was measured via a load cell. With the legs extended participants were asked to
157 squeeze the load cell as hard as possible. To avoid aggravating the pain with repeated
158 measures participants were instructed to stop squeezing if the pain exceeded 5/10 in the NRS.
159 This was not seen in any of the participants.

160 In each phase measures were repeated after 10 minutes rest. At baseline regular sport
161 shorts were worn during both tests; during the intervention phase participants first wore the
162 DEFO and then ordinary shorts. This allowed an evaluation of the “orthotic effects “ of the
163 DEFO as well as any carry over effects that may be seen when not wearing the orthosis. At
164 one month post the initial testing period, participants were retested as for the intervention
165 period, and completed a questionnaire on their usage of the DEFO.

166

167

168 **Analysis**

169 Visual analysis of trend, level and slope was undertaken on all data (18). The mean (+/-
170 2 SD) (19) was plotted for the force data and pain scores. Celeration lines were fitted (19;20)
171 and the point of non-overlapping data (PND) statistic (21) was calculated where appropriate.

172

173 AB multiple-baseline randomisation tests (22) were undertaken using MatLab
174 (MathWorks, UK) for each outcome measure (with and without the DEFO) (22). This enabled
175 the data from the single case studies to be combined, and examined to see whether any
176 improvement in pain and/or function was due to the intervention or chance. Significance level
177 was $p= 0.05$.

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182 **Results**

183 Athletes from various sports, presenting with acute and chronic conditions were
184 assessed (table 1). The effects of the DEFO for each participant are summarised in table 2 and
185 examples of the visual analyses undertaken are demonstrated in figures 2-4. Visual analyses of
186 the single case studies, with the exception of number 5, demonstrated significant effects from
187 wearing the DEFO upon pain and/or function according to at least one measure of significant
188 change.

189

190 *Group Analysis*

191 The results of the group analysis, combining all 8 participants using a randomisation
192 test are shown in table 3. As a group there was no significant effect of the DEFO or control
193 conditions on the outcome measures tested.

194 *Trends*

195 Examination of the results for each outcome measures identified trends in patient
196 responses which may help build a profile of those benefitting the most from this DEFO.

197 *Force output:* Cases studies 1, 3, 4 and 7 demonstrated a significant improvement (above
198 mean + 2SD on 2 consecutive occasions) in force output on the squeeze test wearing the
199 DEFO, and all but study 5 for the intervention period wearing ordinary shorts. This was not
200 related to the site of pain (table 1). . When the forces produced in the squeeze test were
201 normalised by body weight, cases studies 1,3,4 and 7 had a lower baseline force (0.8; 1.3; 1.6;
202 and 1.5 N per kg respectively) compared to the other cases. One exception was case study 6
203 who also showed a low force output to body weight value (1.2 N per kg). Case 6 did show a
204 trend towards improved force output according to the celeration line; an extended intervention
205 period may have made any improvement clearer.

206 All of the cases (1, 3, 4 and 7) that showed an improvement in force production with
207 the intervention thus demonstrated a force output of less than 2 N per kg of body weight;
208 values above 2N were seen in the cases where the DEFO had no significant effect upon force
209 output. It is evident that these case studies presented with a fluctuating baseline on the squeeze
210 test; possibly indicating that daily variations in pain affected function.

211

212 *ASLR*

213 All case studies except number 6 demonstrated bilateral pain responses during the
214 ASLR. When the pain score differences between the right and left ASLR were calculated,
215 cases 1, 3 and 7 demonstrated the biggest differences highlighting a one-sided presentation in
216 pain. When resting pain score was subtracted from the ASLR score causing the most pain (to
217 examine functional impact upon pain), these same cases studies were observed as having the
218 biggest differences. That is, those cases that showed an improvement in force production
219 during the squeeze test, tended to have pain that was considerably aggravated by an ASLR,
220 mainly on the side of their symptoms.

221 The ASLR is used as a functional indicator of the pelvis' ability to effectively transfer
222 loads from upper to lower limbs (23). Mens et al (4) suggests that those who have a positive
223 ASLR will improve with the introduction of a belt; this has been supported by the work of Lee
224 (24) who has demonstrated this using hands to stabilise the pelvis. This suggests that cases 1,
225 3, and 7 may have load transfer deficits.

226 *Baseline and intervention resting pain levels*

227 A comparison of baseline and intervention resting pain levels showed cases 1 and 2
228 had the most benefit from the DEFO.

229 Case number 2 not only experienced the biggest reduction in pain for pain at rest, but
230 also for ASLR right, and pre-jump pain scores. They also showed significant decreases in
231 ASLR left and post-jump pain scores. This was a case which had a clinically significant
232 improvement in pain, not force. This may be explained in that this participant demonstrated
233 SIJ hypomobility. SIJ hypomobility was diagnosed through thorough clinical assessment
234 (including tests of lumbo-sacral mobility), as this was a historical patient prior to being
235 involved in the case study. This finding suggests that the DEFO may have another mechanism
236 other than force closure. Case study 2 may provide support for the notion that the DEFO is
237 influencing proprioception.

238 Considering the various pelvic presentations (pain location; duration, history etc.), it
239 may be expected that some participants would show a stronger effect in terms of function (4);
240 whilst in others an effect upon pain is more apparent. More insight into the mechanism(s),
241 and/or pathology associated with pelvic pain may explain this, but this is an issue already
242 acknowledged as being challenging (2).

243 *Subjective responses*

244 Athletes reported that they would continue to wear the DEFO.
245 DEFO usage varied considerably; from participant 1 only wearing his DEFO for activities
246 which caused pain (football and squash), to participant 2 who wore the DEFO when playing
247 rugby, and for 8-9 hours a day during periods of acute pain. Participant 8 chose to wear their
248 DEFO to aid their learning of a new skill, ski-ing, because they felt that it aided their stability.
249 Participants 2, 3, 4, 6, 7 and 8 reported that wearing the DEFO improved their balance and/or
250 posture; case study 6 also reported that the DEFO improved their power training.

251 Excluding participant 1, who only intended to wear the DEFO during
252 rehabilitation, the remaining participants reported that they would continue to wear the DEFO

253 for purposes including pain control/ injury prevention, improved posture, and feelings of
254 stability.

255 *Potential Explanations*

256 An athletic DEFO and its effect upon pelvic pain is a novel concept. However, findings
257 from pelvic belt literature may offer some explanations. Belts have been shown to
258 significantly reduce pain and improve force output (as measured by the squeeze test) on
259 athletes with adductor pain (4), and reduce pain in those with posterior pelvic pain (25).

260 Adductor pain and osteitis pubis have been discussed as examples where pain may
261 arise from instability (6). This DEFO may address force closure deficit (26), by providing
262 cylindrical pressure to improve loading and enhance stability. Decreased force closure may be
263 associated with some pelvic presentations, but other mechanisms need to be considered. Mens
264 et al (5) explained how proprioceptive deficit and impaired muscle function may also be a
265 cause of lumbopelvic pain. Case study 2, where there was SIJ hypomobility, supports the
266 notion that other mechanisms may be involved.

267 In this case consideration should be given as to whether this DEFO addresses other
268 causes of pelvic dysfunction. Kraemer et al (27), for example, demonstrated the ability of
269 compression shorts to improve proprioception at the hip, suggesting that enhancement of
270 cutaneous receptors may have resulted in improved joint position sense. A similar finding was
271 observed by McNair and Heine (28), finding lumbar bracing improves trunk proprioception;
272 more so in those with a proprioceptive deficit. Even elastic bandage compression has been
273 shown to enhance knee proprioception (29). Therefore enhancing proprioception may
274 improve pain response.

275 *Group Comparisons: Randomisation tests*

276 Randomisation tests showed no significant effect of intervention on any outcome
277 measure. Pre-jump pain score (for the control) demonstrated a trend towards decreased pain
278 scores ($p = 0.054$); this may reflect some degree of carryover from wearing the DEFO, but is
279 mentioned with caution as trends were not seen in other scores.

280 Results support the conclusions drawn from the visual analyses, which highlighted
281 variation between the athletes in responding to the DEFO. Some reacted by significantly
282 increasing their squeeze test force, others responded with significantly decreased pain scores,
283 others showed little effect e.g. case 5. This mixed picture may be explained by numerous
284 factors. Firstly by the differing pelvic conditions that presented and therefore the existence of
285 varying aetiologies. Secondly in that some patients had more than one site of pain, and thus
286 can be expected to respond differently. Finally, the low pain scores invoked by many of these
287 tests may have influenced the non-significant findings; more stressful tests, as discussed by
288 Verrall et al (30) may be useful.

289 These explanations may help inform the development of patient profiles to categorise
290 patient subgroups who may respond to this DEFO with reduction in pain and/or functional
291 improvements.

292 Limitations

293 *Outcome measures*

294 The selected outcome measures were based on standardised, validated tests used
295 clinically, and/or in pelvic belt research. However, some measures e.g. ASLR did not
296 challenge this group of athletes as much as expected, and more stressful tests may have been
297 appropriate for the mixture of pelvic presentations tested (30).

298 *Analyses methods*

299 The mean \pm 2SD often represented a value less than 0. In terms of participants' rating
300 of their pain on the scale of 0-10, less than 0 is an invalid value. Therefore using this form of
301 analysis did not always show a significant result even if a participant's pain was consistently
302 lower during the intervention period. Russo (31) describes how these "floor effects"
303 demonstrate that this is a poor measure of performance. This supports the selection of more
304 stressful measures of performance, in order to avoid this.

305 A The PND line was of limited use with low pain levels; one very low pain score in the
306 baseline period results in the PND line being set at this level e.g. 0. This criticism has been
307 noted in literature (32).

308

309

310 *Future Work*

311 Considering the subjective responses which related to performance benefits, examining the
312 impact of the DEFO on a functional measure of balance and a field test of power is a good
313 starting point for evaluating performance.

314

315 **Conclusion**

316 The nature of these single case studies and the time-scale involved enabled detailed
317 data to be collected. These results have indicated that this DEFO may have a positive effect
318 upon the pain and / or function of some athletes with pelvic pain. Furthermore, the studies
319 provide preliminary information which is helpful in identifying a patient profile who appear to
320 respond positively to wearing this DEFO. There is evidence indicating that a low force output,
321 and/or asymmetric ASLR could be a useful predictor in terms of responding to the DEFO.

322 In conclusion this DEFO may have a role in supporting the physiotherapeutic
323 management of athletic pelvic pain. Further work examining its impact upon performance
324 measures may help in understanding of the mechanisms behind its function, and to ascertain if
325 there are effects on performance markers. This may assist in understanding those patients who
326 experience the most benefit from wearing this DEFO.

327

328 Ethical Approval: Granted by Plymouth University (08/2009)

329

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331 University and DM Orthotics . Funding was provided by the Department of Health and DM
332 Orthotics.

333

334 Conflict of interest: The DEFO evaluated was developed and patented by DM Orthotics.

335

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Single Case Study Number	Sex	Sport	Age (yrs)	Height (m)	Weight (Kg)	Site of pain	Duration of Pain
1	Male	Football, running, cycling, squash	37	1.86	73	Adductor	3 months
2	Male	Rugby, running, cycling	31	1.81	84.4	SIJ	3-4 years
3	Female	Power walking	62	1.67	63.4	Adductor and SIJ	6 months
4	Female	Yoga, aerobic/ power training programmes	29	1.72	87.5	SIJ	3 years; worse last 18months
5	Female	Boxing training	53	1.53	39.4	SIJ	2 years
6	Female	Aerobic/ power training programmes	26	1.65	58.1	SIJ	2 years
7	Female	Ski-ing	42	1.60	68.2	SIJ	17years

8	Female	Cycling, swimming	34	1.68	54	SIJ	20 years
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433 Table 1.Demographics

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Subject/ Outcome measures	1	2	3	4	5	6	7	8
Resisted	CI↑	↑ CI	↑ CI	↑ CI	↓ CI	PND	↑CI	↑CI
Adduction	Msd↑	PND =	Msd↑	Msd↑	Msd↓	=0%	Msd↑	PND
Force‡	PND =58.3%	12.5%	PND =62.5%	PND =100%	PND = 0%	CI =variable	PND =33.3%	=25%
Pain on resisted adduction	CI↓ PND = 8.3%	↓ CI PND = 25%	PND = 12.5%	PND = 0%	PND =0%	* PND =0%	↓CI PND = 88.9%	↓CI Msd↓ PND =100%
ASLR	CI↓	↓ CL	↓CI	↓CI	PND	PND	↓CI	↓CI

Right	PND= 0%	PND = 0%	PND =0%	PND =14.3%	=0%	=0%	PND =0%	PND =0%
ASLR	CI ↓	↓CI	↓CI	↓CI	PND	PND	↓CI	↓CI
Left	PND= 0%	PND =0%	PND =0%	PND = 14.3%	=0%	=0%	PND =0%	PND =0%
PAIN	CI ↓	↓CI	PND	↓CI	↓CI	PND	↓CI	↓CI
REST	PND= 0%	PND =25%	=0%	PND =0%	PND =0%	=0%	PND =0%	PND =12.5%
PRE JUMP	CI ↓ PND = 25%	↓CI PND = 37.5%	PND = 0%	↓CI PND= 14.29%	PND =0%	PND =0%	↓CI PND =0%	↓CI PND =0%
POST	CI ↓	↓CI	PND	↓CI	PND	PND	↓CI	↓CI
JUMP	PND = 8.3%	PND =75%	=37.5%	PND =14.29%	=0%	=0%	PND =0%	PND =0%

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442 CI indicates the change relative to the celeration line whilst msd indicates the change relative to the
443 mean +/- 2 standard deviation line. Figures indicate the PND score, ↑ indicates that in phase B
444 measures were above the celeration. ↓ indicates that in phase B measures were below the celeration.

445 *Indicates that the pain dropped to zero. Increases above the celeration line (↑) for the resisted
446 adduction test indicates improvement in force production, whilst for the measures of pain a decrease
447 (↓) indicates a decrease in pain

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449 Table 2: Summarising the change in l outcome measures.

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Outcome measure	Intervention (DEFO)	Control (shorts)
Pain at rest	0.15	0.40
Force on squeeze test	0.26	0.38
Pain on squeeze test	0.17	0.54
Pain on right ASLR	0.25	0.23
Pain on left ASLR	0.19	0.16
Pain pre broad jump	0.15	0.054
Pain post broad jump	0.17	0.51

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462 Table 3 Randomisation test p values for each outcome measure

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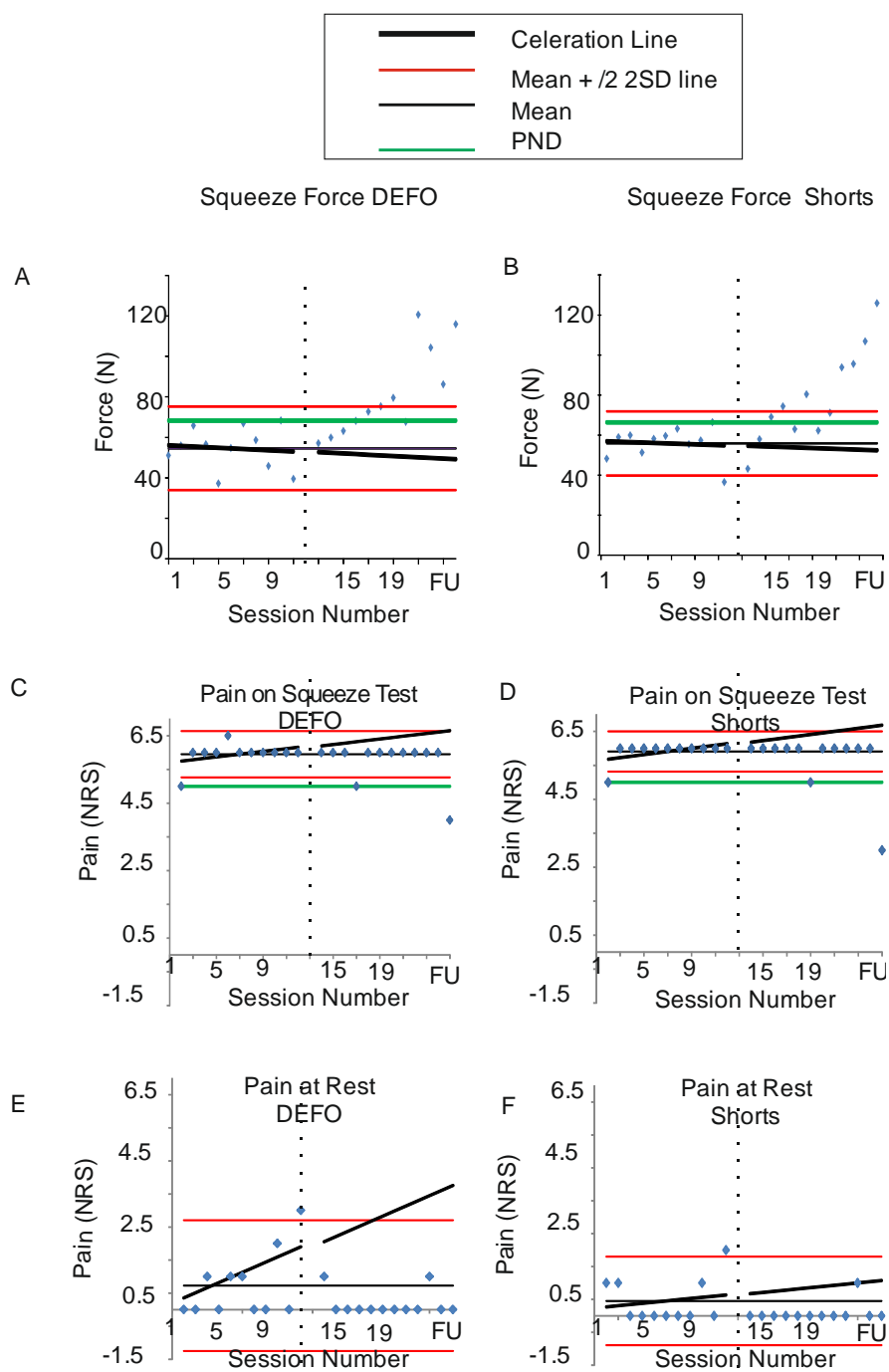
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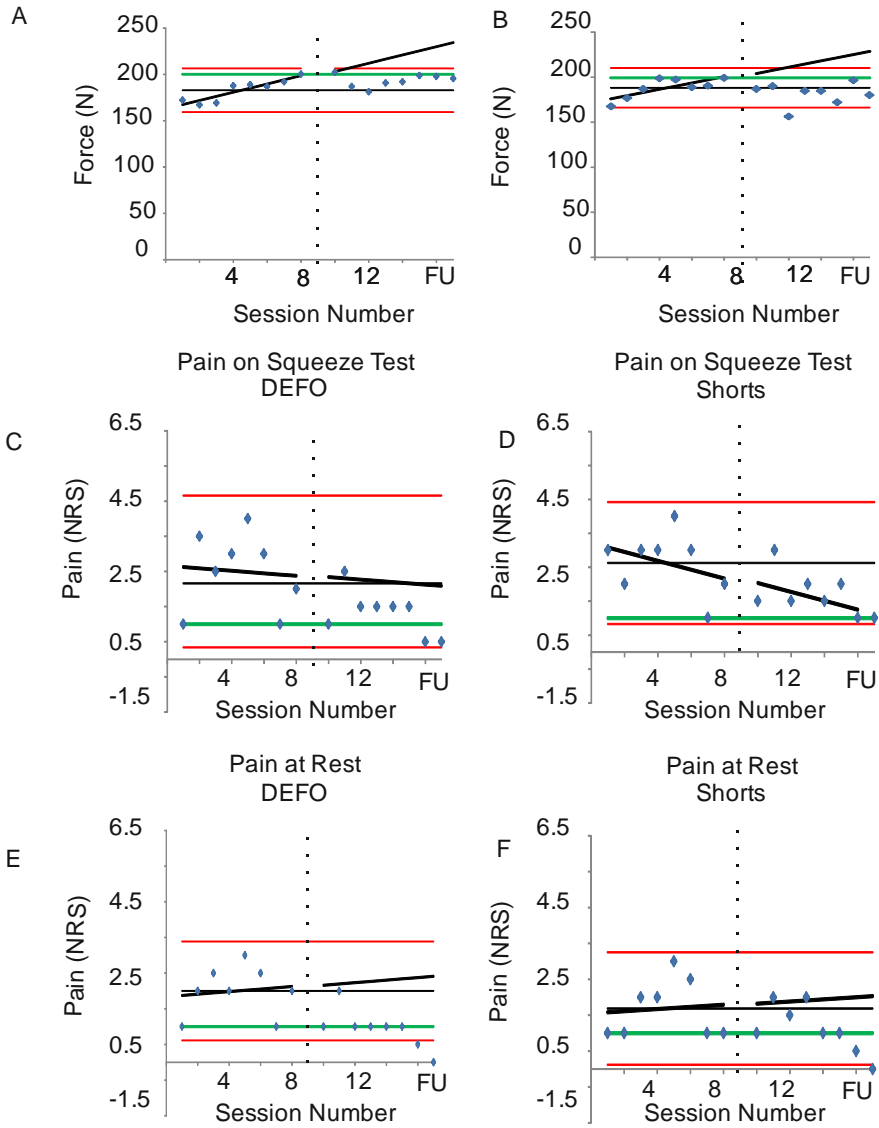
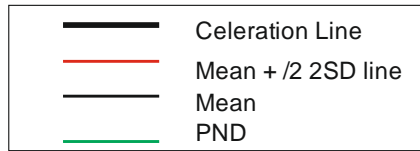
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473 Figure 1: The DEFO



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475 Figure 2: An example of improved force output



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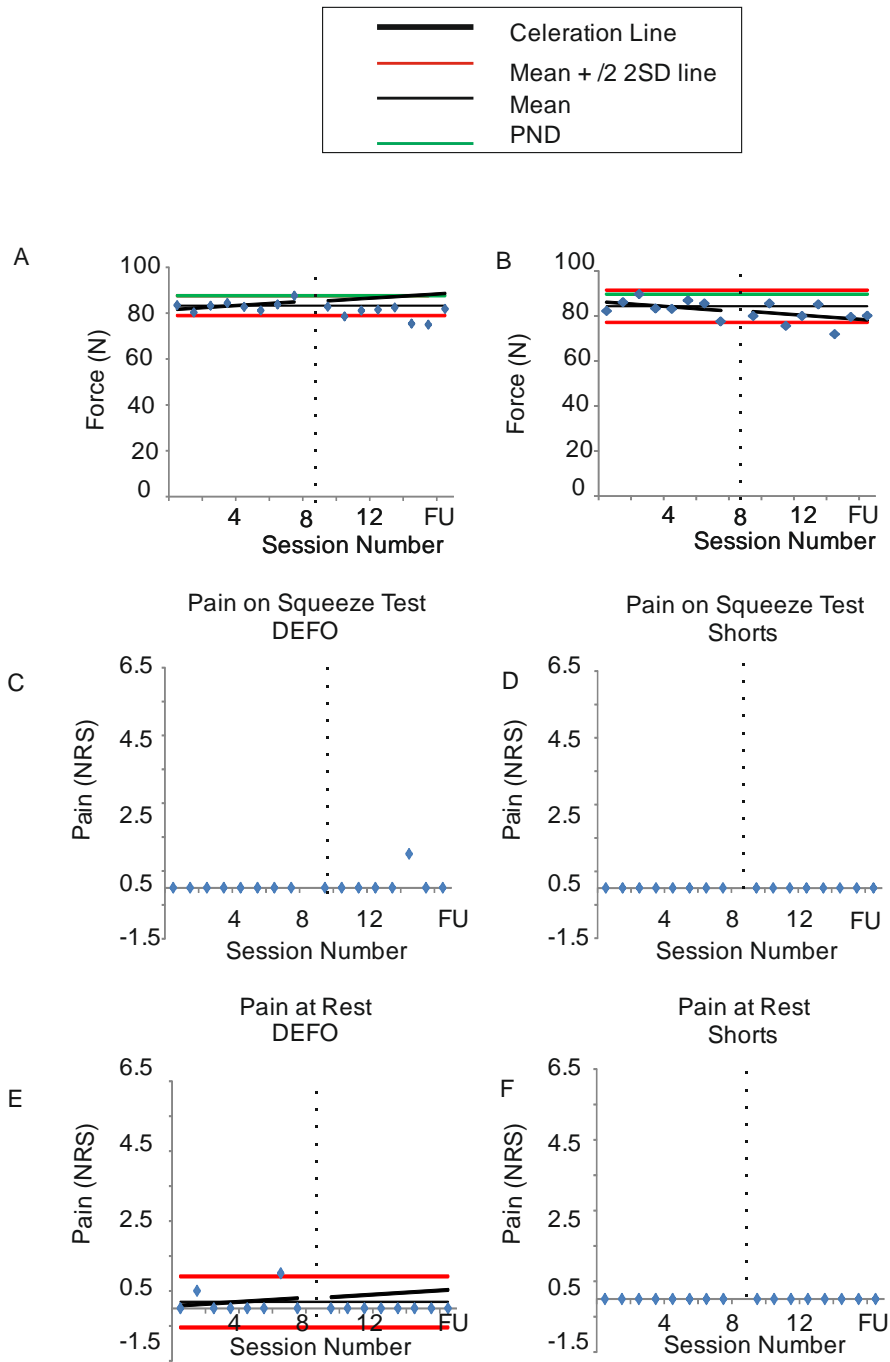
477 Figure 3: An example of decreased pain scores

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483 Figure 4: An example of no significant change observed

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