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

Author names and affiliations Leanne Sawle[ab], Jennifer Freeman[b], Jonathan Marsden[b], Martin Matthews[a]

[a]DM Orthotics. Unit 2 Cardrew Way, Cardrew Industrial Estate, Redruth, Cornwall TR15 1SH

[b] Plymouth University. Faculty of Health, Education and Society. Peninsula Allied Health Centre, Derriford Road, Plymouth, Devon PL6 8BH

Corresponding author Leanne Sawle. DM Orthotics. Unit 2 Cardrew Way, Cardrew Industrial Estate, Redruth, Cornwall TR15 1SH. 01209219205 l.sawle@dmorthotics.com

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

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

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

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

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

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

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

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

Word count: 241

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

Introduction

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

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

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

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

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

Methods

Study design

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

Sample

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

Eligibility Criteria

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

Inclusion criteria

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

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

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

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

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

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

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

Exclusion criteria

People were excluded if they had:

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

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

Procedures

Fifteen daily assessments were undertaken, with at least six during each phase 9baseline and intervention).The onset of the intervention was randomised for each subject using random codes generated in Matlab (Mathworks UK). The intervention could either commence on day 7, 8, or 9. In the intervention phase participants wore the DEFO for activities of their choice and completed a training diary.

Outcome Measures

Outcome measures were self-reported pain on a numerical rating scale (NRS) at rest, during a squeeze test, ASLR, and a 1m broad jump. Additionally the force applied during a squeeze test was measured via a load cell. With the legs extended participants were asked to squeeze the load cell as hard as possible. To avoid aggravating the pain with repeated measures participants were instructed to stop squeezing if the pain exceeded 5/10 in the NRS. This was not seem in any of the participants.

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

Analysis

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

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

Results

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

Group Analysis

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

Trends

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

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

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

ASLR

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

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

Baseline and intervention resting pain levels

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

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

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

Subjective responses

Athletes reported that they would continue to wear the DEFO.

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

Excluding participant 1, who only intended to the wear the DEFO during rehabilitation, the remaining participants reported that they would continue to wear the DEFO for purposes including pain control/ injury prevention, improved posture, and feelings of stability.

Potential Explanations

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

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

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

Group Comparisons: Randomisation tests

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

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

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

Limitations

Outcome measures

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

Analyses methods

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

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

Future Work

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

Conclusion

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

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

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

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

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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

Table 1.Demographics

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

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

Cl indicates the change relative to the celeration line whilst msd indicates the change relative to the mean +/- 2 standard deviation line. Figures indicate the PND score, ↑ indicates that in phase B measures were above the celeration. ↓ indicates that in phase B measures were below the celeration. *Indicates that the pain dropped to zero. Increases above the celeration line (↑) for the resisted adduction test indicates improvement in force production, whilst for the measures of pain a decrease (↓) indicates a decrease in pain

Table 2: Summarising the change in l outcome measures.

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

Table 3 Randomisation test p values for each outcome measure

Figure 1: The DEFO

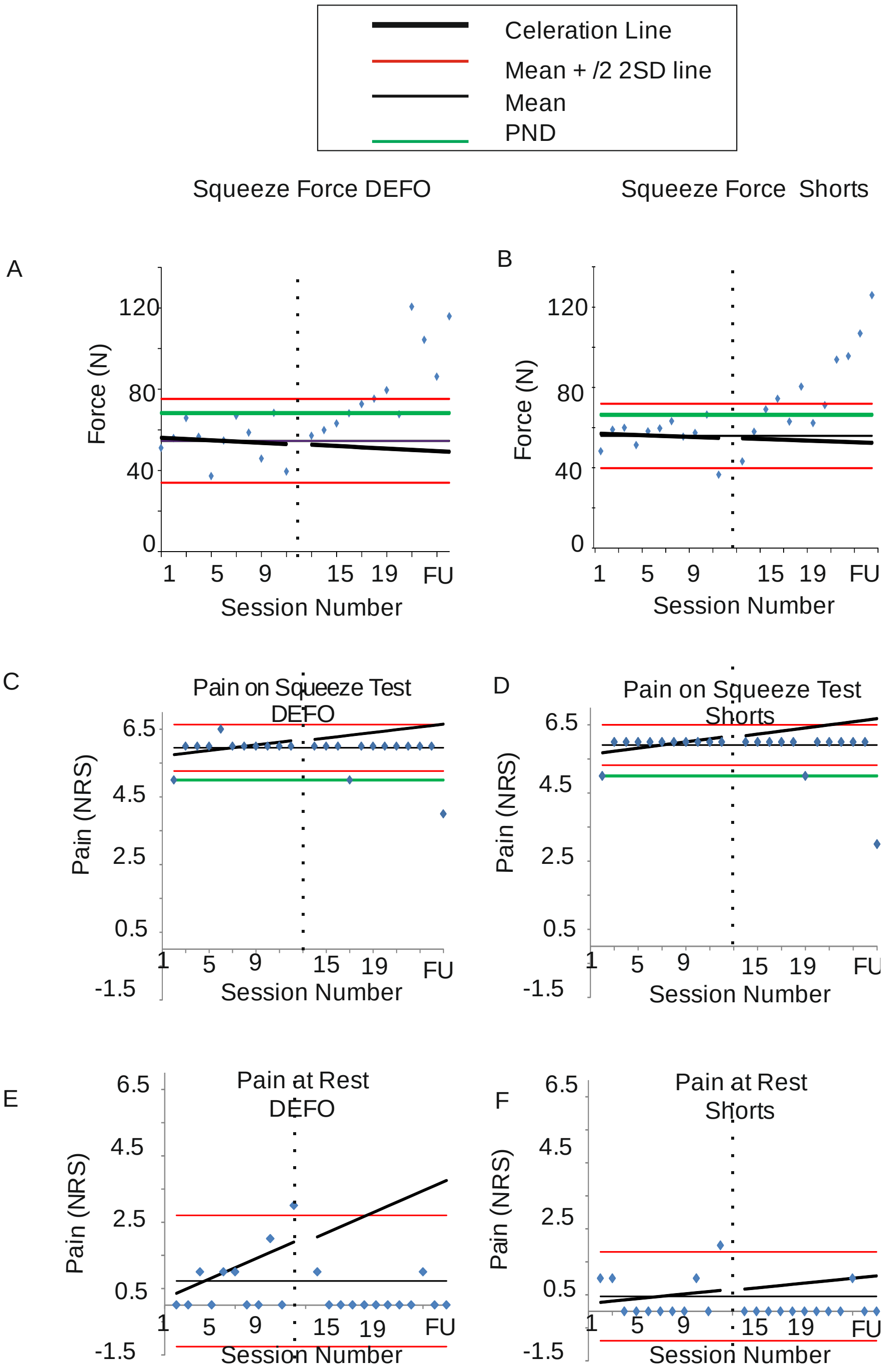


Figure 2: An example of improved force output

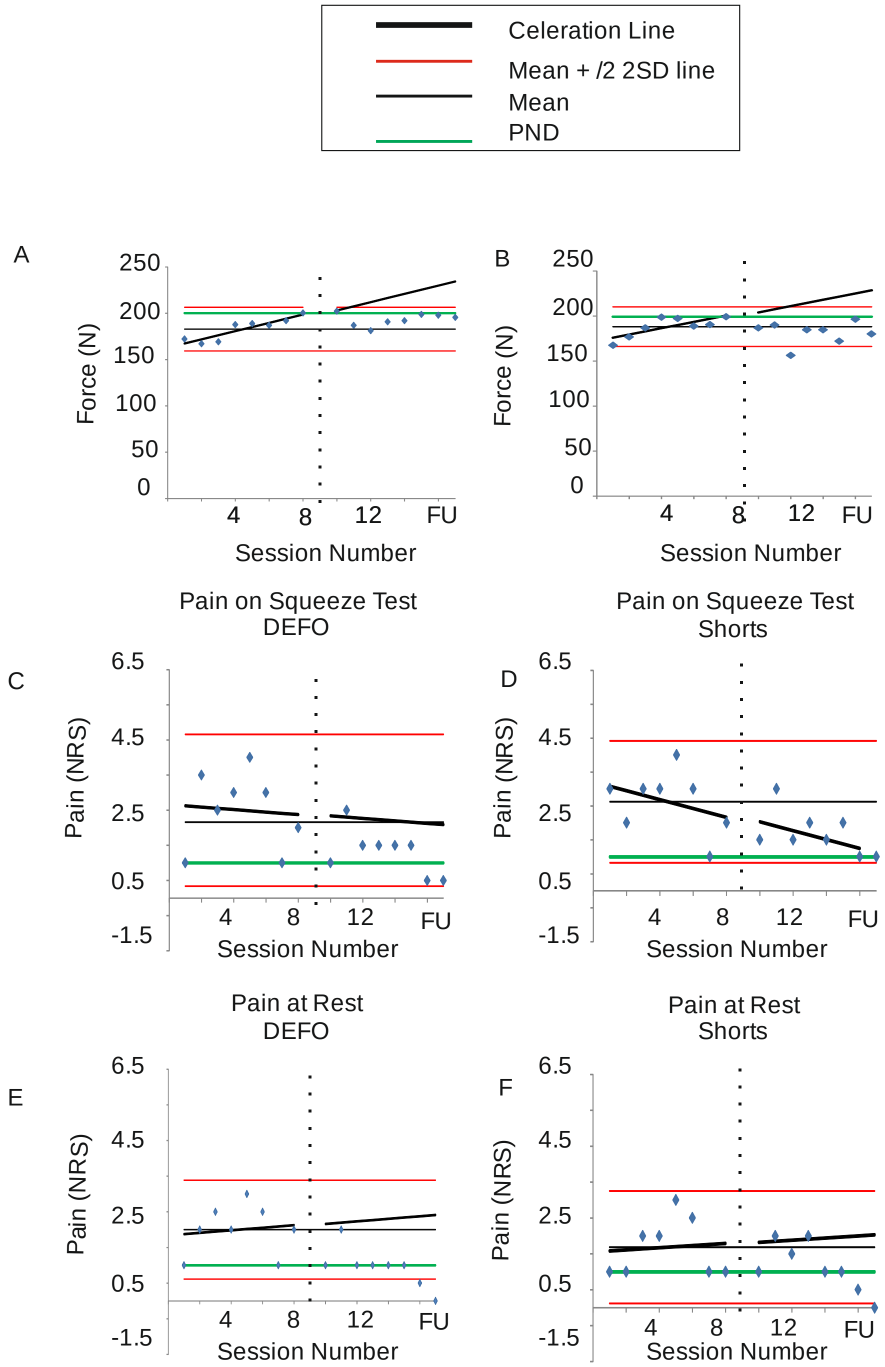
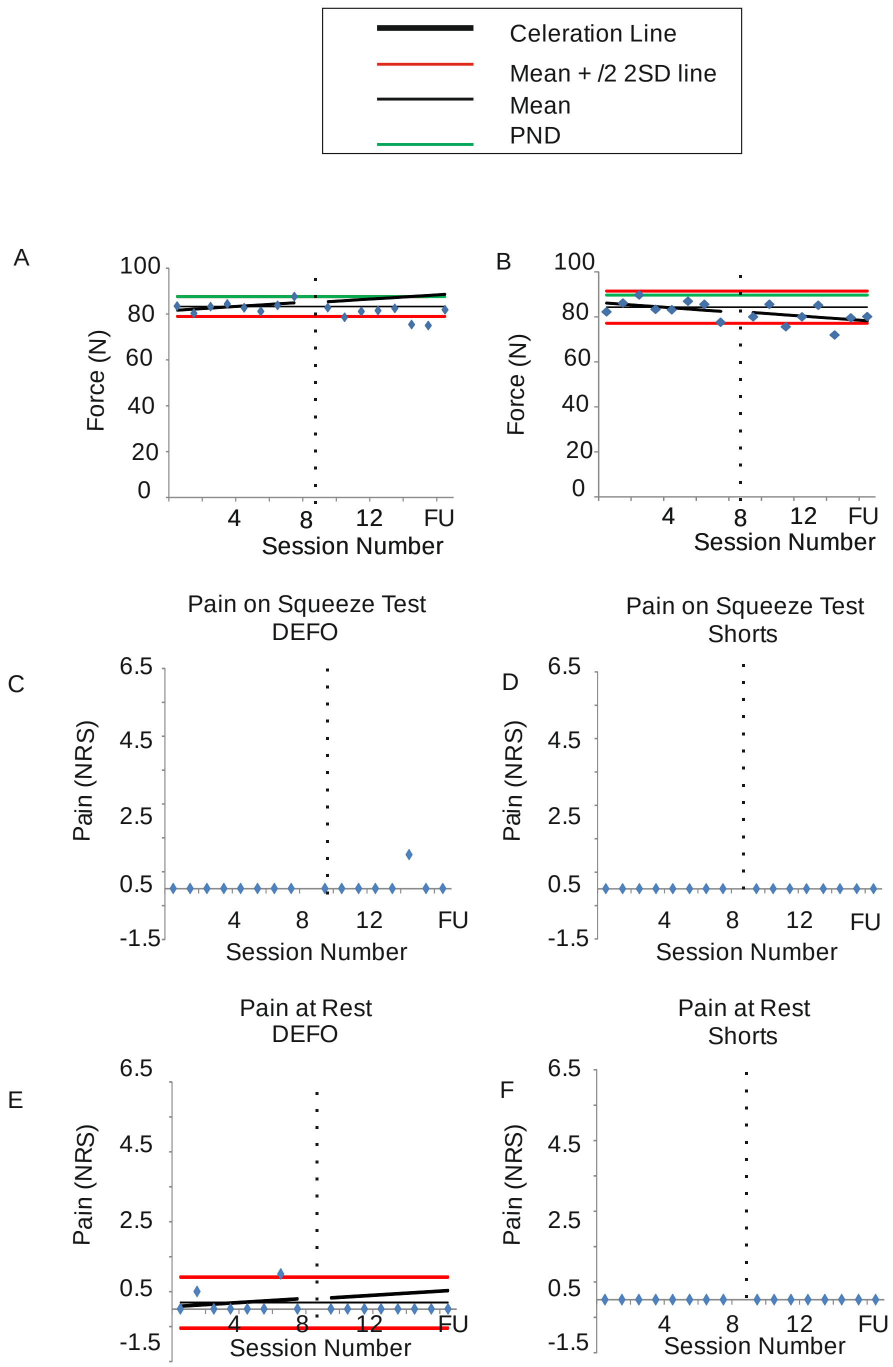


Figure 3: An example of decreased pain scores



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483 Figure 4: An example of no significant change observed

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