

The role of dynamic elastomeric fabric orthoses in aiding the management of peri partum pain:

A case study approach

Introduction

The problem: Pelvic pain

The incidence of pelvic pain in post-partum women is extremely difficult to quantify due to difficulty in diagnosis. Vleeming et al (2008) claim the incidence of posterior pelvic pain in post partum women to be at 20%. On the other hand symphysis pubis dysfunction (SPD) is believed to affect 1:36 to 1:300 (Jain et al 2006). As discussed by Stones and Vits (2005) incidence is very much dependent upon how this type of pain is classified. Typically several types of pain will be present, affecting the pubic symphysis, the lower back and even the sacroiliac joints (SIJ).

SPD arises when hormones cause the ligaments stabilising the joint to relax and the result is pelvic instability. It is normal for the pubic symphysis to widen during pregnancy, only becoming a problem when this gap becomes excessive and presents itself symptomatically. A gap of 10mm or more is recognised as diastasis of the pubic symphysis (Jain et al, 2006).

What is apparent is that such conditions can have a very debilitating affect upon the quality of life.

One management tool that has provided some success in terms of pain management is the application of pelvic belts (Lee 2004). These have been utilized in several ways, with common application usually just below the level of the ASIS, at the greater trochanter or at the symphysis pubis. It is theorized that their mechanism of action lays with aiding recoup any deficit in force closure at the pelvis.

Despite being a commonly used tool, the construction of such belts doesn't really facilitate comfort during application, particularly in sitting posture.

DEFO's

Orthoses have played a significant role in supporting the management of musculoskeletal abnormalities. Over the years there has been a move away from the rigid design of such devices, with a growing trend towards lighter, flexible and more user-friendly orthoses. Dynamic elastomeric fabric orthoses (DEFO's) are now playing an increasing role as orthotic supports, and have been used clinically in several domains (Matthews and Crawford 2006).

The main component of DEFO's, Spandex, is an elastomeric fiber, which is also known as Elastane. Developed by Shivers in 1959 for DuPont, Lycra® is probably the best known brand of this material. It is a synthetic fibre which is stronger than rubber, and is highly elastic. Making it a potentially useful material in terms of its application as an orthosis, is the fact that it is very comfortable, is abrasion resistant, is extremely durable, provides control and support through compression, permits full range of active movement and can be stretched over 500% without breaking (Wikipedia 2009). From the very nature of DEFO's it appears that it may be feasible to imitate the action of a pelvic belt, underpinned by a customized and comfort driven approach.

The proceeding case study does not try to offer an experimental approach, as reflected by its very being i.e. a case study. Whilst this is not an example of an experimental design, it does offer its own advantages, ones which are commonly ignored by those advocates of a purely quantitative approach. A case study offers a unique opportunity to examine the effects of a clinical intervention, within the 'real' world, where confounding variables do exist. From this perspective, the proceeding case studies examine the development and effect of a DEFO on two women suffering from chronic peri partum pelvic pain.

Case studies

The initial single case study was undertaken with the following aims:

- To improve the quality of life (reduce pain and improve function) in a lady (a paediatric physiotherapist; gravida 2 para 1 mobilising with bilateral elbow crutches due to pelvic pain and instability) with peri partum pelvic and bilateral hip pain, using a custom designed DEFO aimed at meeting her needs.
- To develop a DEFO which could be subjected to a future evaluation, in order to measure its effectiveness in reducing peri partum pelvic pain.

The conclusions from the resulting study and development of a DEFO were that this was an attempt to produce a DEFO aimed at reducing pain levels and subsequently improving quality of life in a lady with pregnancy associated pelvic and hip pain. To this aim, success has been attained as two specific DEFOs were developed.

Limitations were that that is obviously a very individual experience, and attempts to record objective data in terms of pain diaries were not successful. The success of the DEFO's in this case is a subjective phenomenon; one that provides a starting point but now requires an objective input.

This was a case study; therefore there are those who will argue that generalizations should therefore not be made from these findings. However, rather than proffer maybes, may we not consider that if a DEFO can help one person in providing pain relief, then why cannot it help another?

Furthermore "The choice of method should clearly depend on the problem under study and its circumstances" (Flyvbjerg 2006 P226), and in this case the DEFO's were developed and tested because there was no other successful management strategy.

However there is a need for more work into the use of DEFO's with women with pelvic pain during pregnancy, but there is an optimism derived from this case study. As there is currently very little on the market in terms of providing pain relief for pelvic pain (other than pelvic belts), a DEFO could be a very practical way of achieving this.

Obviously individual factors play a significant role in the effectiveness of such an orthosis, but scope exists for these to be addressed. With regards to the second aim of the study, what has been undertaken here has resulted in the development of a DEFO. This has provided the groundwork for a further case study to be undertaken, in order to attempt to objectify the findings observed.

Subject

A paediatric nurse in her late thirties, gravida 2 para 1, experiencing moderate –severe peri partum pelvic pain, primarily presenting as symphysis pubis dysfunction (SPD).

Previous history of sciatica; ongoing.

Method

AB design involving a baseline period of 11 days, before a customised DEFO was introduced as the intervention. The DEFO was worn and its effect upon pain monitored through pain diaries, as the gestational period progressed.

The Subject kept a pain diary using the numerical rating scale (NRS) to rate her pain on a scale of 0 (no pain) to 10 (worse pain imaginable). The NRS was used as an objective measure of a subjective marker.

Intervention period lasted until 35 weeks of gestation, when the DEFO was no longer able to be worn due to pain severity.

Analysis

Visual analysis of trend, level and slope was undertaken on all data. Mean (+/- 2 SD) was plotted for pain scores, preceded by celeration lines and point of non-overlapping data (PND) statistic.

A further analysis was undertaken by examining the difference between daily NRS scores. This clearly demonstrates incidences where pain stabilised, as well as any fluctuating scores of both high and low nature.

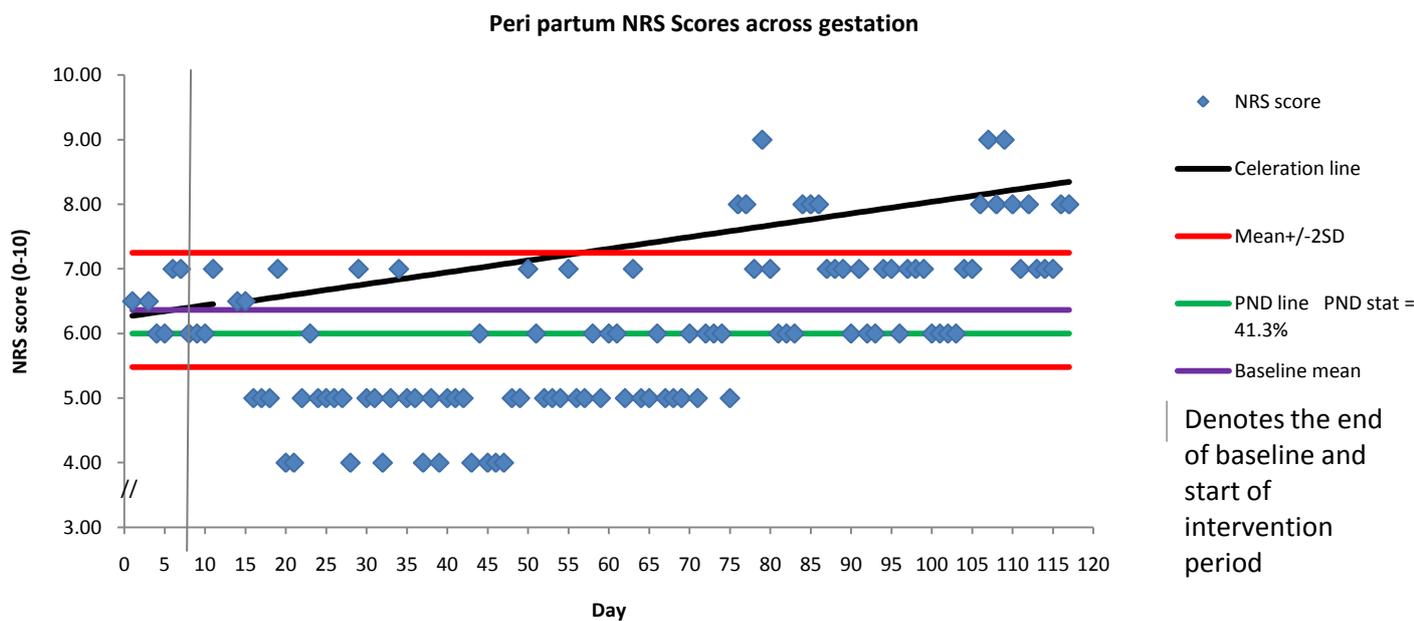
Results

On examination of the celeration line during the intervention period, over 88% of NRS scores lie below the predicted trend; being highly suggestive that the wearing of the DEFO had a positive effect upon pain.

In terms of the mean -2SD analysis, 43 data points fell below the line; several periods of two or more consecutive pain scores below this level indicating a significant effect of the DEFO upon pain.

Observation of the NRS scores at 29 weeks of gestation and onwards, demonstrates increases in pain which never fall below 6 on the NRS. The overall result is a PND statistic of 41.3%, whereas up to 29 weeks the PND statistic was 69.4%.

The proceeding graph demonstrates the results and the analysis undertaken.



Discussion

It has been established that both during and after gestation, pelvic pain is a common phenomenon (Jain et al 2006; Vleeming et al 2008).

Furthermore peri partum pelvic pain can be expected to increase as the gestational period develops. This is associated with increasing stress upon the symphysis pubis resulting from foetal growth, in addition to the effects of Relaxin upon ligamentous structures.

For some women the pain becomes severe enough to have a profoundly detrimental effect upon quality of life and activities of daily living.

The two cases discussed, involved examples of this very phenomenon, and thus gave their informed consent to partake in the development and trialing of a possible management tool for improving pain and function.

Taking all of this into consideration, the orthoses developed from the initial case study and subsequently tested as case study with pain scores as the objective measure, has shown that there is some benefit in wearing the two styles of DEFO's.

Subjective discussion from each of the clinicians involved in the case studies, further supports the beneficial effect of these DEFO's upon pain, which whilst is not an objective measure, does reinforce the subjective nature of what we are attempting to measure i.e. pain.

Accepting that this type of pain is often a self resolving manifestation, and that the very nature of gestation indeed increases the stress on the pelvis, this second case study has sown seeds that there does exist a period within gestation, where pain can be effectively managed. Although as pain is entirely subjective, and gestation represents a quite unique experience, there will be differences in the longevity of this management period. Initial indications of the best outcomes from the application of these DEFO's are observed up to the early to mid third trimester (PND statistic = 69.4%).

Conclusions

After a case study to inform the design and development of DEFO's to aid in the management of peri partum pelvic pain, and the subsequent case study which has tried to utilize an objective marker to ascertain the effects of such DEFO's upon pain, the indication is that there is scope for further objective testing from which to formalize conclusions.

At this stage there is an indication of the possible benefits of these DEFO's upon peri partum pelvic pain; thus concluding remarks are suggestive of a potentially useful and non invasive management tool, which would benefit from further case studies in order to establish a clinical evidence base for its application.

Ethical approval

"This paper is a report of a routine clinical intervention, which, although somewhat innovative, is akin to that which typically occurs in this kind of scenario during everyday practice. The work did not in any way form part of a formal research project and thus ethical approval was not sought. The authors have confirmed that this is in keeping with local requirements for the submission of reports of case studies."

References

Flyvbjerg, B. (2006) Five Misunderstandings

About Case-Study Research. *Qualitative Inquiry* **12** (2), 219-245

Jain,S., Eedarapalli, P., Jamjute, P. and Sawdy, R. (2006)Review Symphysis pubis dysfunction: a practical approach to management. *The Obstetrician & Gynaecologist* **8**, 153–158

Lee,D. (2004). *The Pelvic Girdle*. Elsevier

Matthews, M. and Crawford, R.(2006) The use of dynamic Lycra orthoses in the treatment of scoliosis: A case study. *Prosthetics and Orthotics International*. **30** (2) 171-174

Pool-Goudzwaard,A.L., Vleeming, A., Stoeckhart, R., Snijders, C.J. and Mens, J.M.A. (1998) Insufficient lumbopelvic stability: a clinical, anatomical and biomechanical approach to a "specific" low-pain pain.*Manual Therapy* **3**(1), 12-20

Stones, R.W. and Vits, K. (2005)Pelvic girdle pain in pregnancy. *British Medical Journal* **331**, 249-250

Vleeming, A., Albert, H.B., Ostgaard, H.B., Sturesson, H.B. and Stuge, B. (2008) European guidelines for the diagnosis and treatment of pelvic girdle pain. *European Spine Journal* **17** (6), 794-819

Wikipedia (2009)Spandex. <http://en.wikipedia.org/wiki/Spandex> (accessed 14th September 2009)