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The immediate effects of pelvic compression belt with a textured sacral pad on the sacroiliac function in pregnant women with lumbopelvic pain: A cross-over study

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Introduction

Lumbopelvic pain is a frequent complication of pregnancy (Wu et al., 2004). The prevalence of this condition has been estimated to occur in around 45% of all pregnancies (Wu et al., 2004), and its onset reported between the fifth and seventh months of pregnancy (Kristiansson, Svärdsudd and von Schoultz, 1996a; Mens et al., 1996). Women with pregnancyrelated lumbopelvic pain (PLPP) find difficulty with some daily activities such as turning over in bed, rising from a chair, prolonged standing, walking, stair ascending, and carrying objects (Mens et al., 1996; Robinson et al., 2006; Kristiansson, Svärdsudd and von Schoultz, 1996a). The dysfunction of the sacroiliac joint (SIJ) is the leading biological cause of PLPP (Stuge, 2015). The underlying mechanism in the development of the SIJ dysfunction is due to both hormonal and mechanical changes in the body during pregnancy (Vleeming *et al.*, 2008). It has been hypothesized that gaining weight during pregnancy imposes overloading stress on the supporting ligaments of the SIJ (Mogren and Pohjanen, 2005). A concurrent factor in the development of this condition is the effect of increased relaxin hormone, which induces ligamentous laxity hence decreasing the SIJ support (Kristiansson, Svärdsudd and von Schoultz, 1996b).

The function of the SIJ is to transmit loads of the upper body to the legs (Cohen, 2018). The optimal articular stability (form closure) and neuromuscular control (force closure) are necessary

to provide the pelvic stability required for the function of load transfer at the SIJ (Snijders, Vleeming and Stoeckart, 1993; Cusi, 2010). The disruption of either form closure or force closure mechanism has been indicated in the development of SIJ pain during the function of load transfer (Cusi, 2010). The diagnosis of SIJ dysfunction is based on a physical examination, which includes the "active straight leg raise (ASLR) test" (Mens *et al.*, 2001). The ASLR test is a valid and reliable clinical assessment to check load transfer through the SIJ (Mens *et al.*, 2001). The ASLR discriminates against people with SIJ dysfunction and healthy subjects (Wu *et al.*, 2004), and can also be used for scoring the PLPP (Mens *et al.*, 2002). The supine patient is instructed to raise their leg with their knee extended (hip flexion), 20 cm above the examination table (Mens *et al.*, 1999). The ASLR test is scored with a Likert scale for the perceived effort by the patient to complete the task, or quantified with the measurement of the generated force during hip flexion (de Groot *et al.*, 2008).

Several studies have shown that an application of pelvic compression across the ilium increases the mechanical stability of the SIJ (Vleeming *et al.*, 1992; Beales, O'Sullivan and Briffa, 2010; Nilsson-Wikmar *et al.*, 2005; Arumugam *et al.*, 2012) and alleviates painful symptoms (Arumugam *et al.*, 2012; Nilsson-Wikmar *et al.*, 2005; Van Benten *et al.*, 2014). The pelvic belt is a device that encompasses the ilium under the waist and superior to pubis (Ho *et al.*, 2009). This belt is widely used in people with SIJ dysfunction to provide external compression across the pelvis (Jowett and Bowyer, 2007). While most studies have investigated the effectiveness of a pelvic belt on the augmentation of mechanical stability of the SIJ through form closure concept (Jowett and Bowyer, 2007; Damen *et al.*, 2002; Snijders, Vleeming and Stoeckart, 1993; Vleeming *et al.*, 1992; Mens *et al.*, 2006), few studies have investigated the

effects of external compression on the neuromuscular control (force closure) required for SIJ stability (Jung *et al.*, 2013; Park, Kim and Oh, 2010; Soisson *et al.*, 2015).

Neuromuscular control is defined as the activation of muscular restraints to restore joint stability under a functional demand (O'Sullivan and Beales, 2007). There is some evidence to indicate that acuity of hip proprioception could influence the functional joint stability of the pelvic region in people with painful musculoskeletal conditions (Onishi et al., 2017; Wang et al., 2016). The pelvic belt provides a compression force around the pelvis and thereby enhances proprioceptive feedback to the muscles stabilizing the SIJ (Jung et al., 2013; Flack et al., 2015). Previous research has shown that the application of textured surfaces over the skin could increase the sensory function in the perception of body segments (Hijmans et al., 2007; Alfuth and Rosenbaum, 2012). Textured surfaces with semicircular projections have been reported to be effective in stimulating sensory inputs and improving neuromuscular control (Lirani-Silva *et al.*, 2017; Salari-Moghaddam, Sadeghi-Demneh, and Ja'farian, 2015). The role of proprioception and motor control in the function of SIJ has been recognized (Cusi, 2010), but no previous study has investigated the sensory effects of a pelvic belt in PLPP. Whilst pelvic belt impacting neuromuscular control in PLPP and its effects on sensory stimulation is promising, the sensorimotor effects of a pelvic belt in PLPP need to be investigated further. The objective of this study was to investigate the effectiveness of a pelvic belt with a sensory induced sacral pad in women with PLPP. We hypothesized that a pelvic compression belt with a sensory-enhanced sacral pad would show a greater improvement in the function of the SIJ in PLPP.

Methods

Participants

Twenty-eight women with PLPP aged 20 to 40 years volunteered in this study. The main inclusion criteria were: being from 20th to 35th week of pregnancy and complaining of pelvic pain due to SIJ dysfunction. The main exclusion criteria were: a history of pelvic or back pain before pregnancy (Full details of the inclusion/exclusion criteria are presented in Table 1). The optimal sample size required for this study was twenty-four participants calculated with G.Power software (version 3.1, Universitat Dusseldorf, Germany). The maximum flexion force at 20cm raising height was selected for this analysis as it had been shown to be a sensitive measure for SIJ function (de Groot *et al.*, 2008). The power of the study was set at 0.8 and the alpha level was 0.05.

Participants were recruited through a convenience sampling method once diagnosed by an obstetrics and gynecology specialist with PLPP symptoms. This was a crossover study, during which participants acted as their controls (no pelvic belt) and compared to two pelvic belts (a routine pelvic belt and pelvic belt with a textured sacral pad) in a single session. The order of intervention and testing conditions were randomized and determined by taking a concealed draw from a hat. For all measurements, the test was explained to the participant. The testing protocol was started after pelvic belts were fitted and 5 minutes acclimatization. Participants were given 10 minutes rest before the crossed-over to the next pelvic belt. Ethical approval was obtained from the ethical committee of University, before the recruitments of participants.

Orthoses

Pelvic belt effects were investigated under three random conditions: without pelvic belt application, with a pelvic belt, and adding a textured sacral pad inside the same pelvic belt. The belt used in this study was a non-stretchable material made of nylon webbing, which was about 5 cm wide anteriorly and 7 cm on the posterior side. Four different sizes of the belt were available, which were selected according to the pelvic circumference of each participant. The belt was fastened with a Velcro and positioned just below the anterior superior iliac spine. The compression force applied on the fastening Velcro was set at 50N and controlled within the study conditions using a force measurement apparatus (Digital Force gauge, Model SF-500, MeterTo, China). The sacral pad was an equilateral triangle (each side: 12 cm) made by silicone rubber (thickness of base: 1.5cm, shore value: A40). Twelve convex circular spikes (with 1cm height) were incorporated over the sacral pad; the pick-to-pick distance of the spikes was 2 cm (figure 1).

Outcome Measures

The sensory effects of the application of pelvic belts were determined with the measurement of hip proprioception. The stability of SIJ during load transfer was quantified with measurements of effort (subjective and objective) during ASLR and maximum isometric hip flexion.

Hip proprioception was evaluated by measurement of the active angle reproduction in hip abduction. The participant's eyes were closed during proprioceptive testing. Participate were positioned supine and instructed to abduct the thigh with an extended knee until it reached 20 degrees abduction at the hip and the assessor indicated "stop". They were asked to concentrate on this target angle for 5 seconds and memorize it. The lower limb passively returned to the starting position by the assessor. Participants attempted to reproduce the target angle with an active thigh abduction. Each test was repeated three times for each side, and angle error was calculated as a mean absolute error and used as the proprioceptive outcome measure. The joint angle was

measured using a printed protractor on a 3 mm plastic sheet that was placed under the legs to minimize the friction between the moving leg and supporting surface.

To assess perceived effort, participants were asked to rate their effort in performing ASLR on a five-point Likert scale: 0=not difficult, 1=minimally difficult, 2=somewhat difficult, 3=fairly difficult, 4=very difficult, and 5=unable to perform. The score of both legs was counted; therefore, the overall effort score ranged from 0 to 10 (Mens *et al.*, 2001).

Maximum isometric hip flexion was used to determine patient effort objectively, which was measured during ASLR. A non-elastic 5 cm width belt restricted the hip flexion once the ankle reached 20 cm height and the force that applied to the belt was recorded using a digital force gauge (Ergometer Model: Z2S-ZXPX-CLJ, NCC, China).

Data analysis

The one-way repeated measures analysis of variance (ANOVA) was carried out to compare the outcomes measured across different interventions. The normality, linearity, and sphericity of the data were checked prior to inferential testing to confirm parametric assumptions had been met. If the ANOVA test showed a statistically significant difference, a Post-hoc analysis (Bonferroni test) was used to explore pairwise differences between testing conditions. The statistical calculations were carried out using SPSS version 19, and the level of significance was set at 0.05.

Results

Twenty-eight pregnant women participated in this study. All participants completed the testing. The demographic characteristics of the participants are outlined in Table 2. One-way repeated measures ANOVAs showed a significant difference between all outcome measures while using different pelvic belts. The change in the study's outcome measures across the testing condition is reported in Table 3.

Post hoc pairwise comparisons indicated significance differences in the error of joint position reproduction at 20 degrees of hip abduction using a pelvic band (p=0.001, 95% CI: 0.45 to 1.99, Cohen's d=0.5) and pelvic band with textured sacral pad (p<0.001, 95% CI: 2.1 to 3.95, Cohen's d=1.89) indicating medium and large clinical significance, respectively. There was a significant reduction in the error of hip position reproduction using a textured sacral pad with the pelvic belt (p<0.001, 95% CI: 1.3 to 2.3, Cohen's d=1.26) suggested a large clinical significance.

The effort in ASLR was significantly reduced using a pelvic belt (p=0.02, 95% CI: 0.1 to 1.19, Cohen's d=0.5) and pelvic band with textured sacral pad (p=0.002, 95% CI: 0.59 to 2.91, Cohen's d=1.89) indicating medium and large clinical significance, respectively. There was a significant reduction in the effort using a textured sacral pad with the pelvic belt (p=0.003, 95% CI: 0.35 to 1.86, Cohen's d= 1.26) suggested a large clinical significance.

Post hoc pairwise comparisons also revealed that both pelvic bands (with and without sacral pad) significantly increased the maximum isometric hip flexion; (p<0.001, 95% CI: 1.15 to 4.13, Cohen's d= 0.24) and (p<0.001, 95% CI: 5.2 to 9.37, Cohen's d= 0.67), respectively. There was a significant increase in the strength of hip flexion while using a textured sacral pad with the pelvic belt (p<0.001, 95% CI: 2.77 to 6.47, Cohen's d=0.4) suggested a moderate clinical significance. The results of post hoc pairwise comparisons are presented in Table 4.

Discussion

The main finding of the study was that the pelvic pressure belt improved the function of the SIJ in pregnant women who had PLPP. The study also demonstrated the superiority of the pelvic belt with an incorporated sacral pad over the pelvic belt without a sacral pad. Installation of a textured sacral pad in the pelvic belt showed moderate to high effects in the improvement of all study outcomes (Table 3). These results suggest that the addition of a textured sacral pad could have relatively high effectiveness on the SIJ function through additional sensory stimulation around this joint.

Regardless of pelvic belt type, improvement in the SIJ function and hip sensation have shown in this study. It is thought that compression on the pelvic ring provides two interrelated therapeutic mechanisms, mechanical and neuromuscular effects (Cusi, 2010). Compression on the pelvis with a belt increases the intra-articular compression in the SIJ (Damen *et al.*, 2002). The induced pelvic stiffness with a pelvic belt can unload sensitized ligaments, fasciae, and muscles and this allows normalized motor activity during ASLR (Arumugam *et al.*, 2012). The results of this study indicate that women with the pelvic belt stabilize their pelvic joints more effectively and with less effort, whereas without the pelvic belt they need to exert more muscle force to perform the ASLR. This assumption is in accordance with the paradigm of force closure of the SIJ (Snijders, Vleeming and Stoeckart, 1993).

Perceived effort and maximum hip flexion strength in ASLR were measured to quantify the SIJ function in this study. It has been shown in the previous studies that the ASLR is associated with the severity of the SIJ laxity (Mens *et al.*, 2002) and is an appropriate diagnostic test with good sensitivity and specificity (0.87 and 0.94 respectively) to assess the function of the SIJ (Mens *et al.*, 2001). We measured both subjective (effort) and objective (flexion force) scores on the ASLR test given by the participants and a digital apparatus, respectively (de Groot *et al.*, 2008). This was to control the detection bias. Previous research showed that wearing a pelvic belt could have a subjective effect on the participant's response while performing the ASLR test (Mens *et al.*, 2010).

Both pelvic belts successfully improved the ASLR scores (including effort and flexion force). These results indicate that women with PLPP who use a pelvic belt had less difficulty to lift their leg and were more able to exert hip flexion on the force gauge. These findings are in line with previous studies that have reported the effectiveness of external pelvic compression on the SIJ function (Damen *et al.*, 2002; Beales, O'Sullivan and Briffa, 2010; Mens *et al.*, 1999; Mens *et al.*, 2006; Mens *et al.*, 2010). If the mechanism of action for a pelvic belt in the ALSR is accepted, it can be assumed that these changes also occur in the mobility and activities of daily life in which the loads need to transfer at the SIJ.

Previous research has shown that low back pain (including SIJ pain) alters body perception (Wand *et al.*, 2014) and two-point discrimination in the same area (Moseley, 2008); this could underlie the mechanisms for kinesophobia and fear avoidance (Beales and O'Sullivan, 2011). This study showed that pelvic compression belts provided an improvement in the awareness of hip joint position. This finding is in line with previous research, which substantiated the effectiveness of pelvic compression belt on the hip joint awareness (Jansen, 2010). Furthermore, the pelvic belt could stimulate the cutaneous and deep mechanoreceptors, as has shown with studies on compressive garments (Kraemer *et al.*, 1998; MacRae, Cotter and Laing, 2011). It also could decrease the tension on the muscles and ligaments supporting the SIJ

(Pel *et al.*, 2008; Park, Kim and Oh, 2010) and act as a pseudo-fascia to keep the underlined muscles snugly (Arumugam *et al.*, 2012). A similar effect also has reported for the effectiveness of lumbar orthoses on the trunk proprioception (McNair and Heine, 1999).

The hip proprioception was measured using joint position reproduction. This measurement was a simple, non-invasive method and did not require sophisticated equipment; therefore, it could be easily used in the clinical setting of this study. The hip abduction was selected because it is more reliable than hip flexion (Arvin *et al.*, 2015). Participants actively perform the joint position reproduction test because, in the large synovial joints, proprioception awareness mainly relies on the mechanoreceptors embedded in muscle spindles (Benjaminse *et al.*, 2009). The target angle was set at 20 degrees of hip abduction to prevent possible discomfort or limitation caused by an excessive range of motion (Pickard *et al.*, 2003).

The SIJ function and hip proprioception showed greater improvements once a textured sacral pad was added inside the pelvic compression belt. This change could be due to two interrelated mechanisms, including sensory stimulation and induced posterior pelvic tilt. Textured material increases the joint position sense through stimulation of cutaneous mechanoreceptors (Steinberg *et al.*, 2016; Salari-Moghaddam, Sadeghi-Demneh, and Ja'farian, 2015) and thereby could improve the motor control required for the force closure mechanism of the SIJ (Cusi, 2010). The posterior pelvic tilt is known as an intervention to reduce pelvic pain (Day et al. 1984). The application of a sacral pad inside the pelvic belt provides a greater contact area with the lower back and sacrum; hence is more effectively aligned and supports the pelvis in the posterior tilt posture. The posterior pelvic tilt tightens the SIJ ligaments and increases compression across the SIJ (Snijders, Vleeming and Stoeckart, 1993).

There are some limitations to this study that must be addressed. Using a repeated measures design had the potential risks for carry-over or learning effects. However, the randomization process is expected to partition the learning effect between three conditions. Examiner and participants could not be blinded in the current study since they could see which pelvic belt was used. The blindness of the examiners was attenuated by the use of patient-rated scores and automated equipment to reduce assessor judgment bias. This study was an exploratory trial of the immediate effects of the pelvic band with a textured surface. It fulfilled its aim and demonstrated that accessory sensory feedbacks provided by a textured sacral pad improved the function of the SIJ in pregnant women with PLPP. This result warrants further trials to develop an optimal intervention, particularly investigating the effects of longer-term use before stepping forward to a definitive study.

Further work is needed to identify the most effective pattern for textured material incorporated in the belt, the magnitude of compressive force needed to fasten the belt around the pelvis, and the exact place that compressive belt would have its optimal effectiveness in the pregnant women. Subjects were recruited using a convenience sampling through a gynecologist referral; therefore, the sampling procedure might involve some degree of selection bias. The application of pelvic compression belt is in accordance with guidelines for women with PLPP (Vleeming *et al.*, 2008), and no study has reported any deleterious effect on the fetus in immediate use (Pennick and Liddle, 2013), it would be useful to investigate the effects of more prolonged use of pelvic belt on the fetus in future research. In this study some participants had symphysis pain combined with PLPP, future studies, therefore, can focus on the characteristics of the pregnant women with painful symptoms on the pelvis to identify who is likely to be benefited from the pelvic belt with a textured surface.

Conclusion

The results support previous studies reporting that a pelvic compression belt improves the sensorimotor function of the pelvis in women with PLPP. This study further indicated that the application of a textured sacral pad could amplify the effectiveness of such a pelvic belt. Such information may be used for the future development of pelvic belts.

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Figure and Table Legends

Figure 1: A: Pelvic compression belt with sacral pad; B: The sacral pad.

Table 1: Inclusion and exclusion criteria of the study

 Table 2: Demographic characteristics of participants.

Table 3: The change of outcome measures across the study conditions.

Table 4: The results of pair-wise comparisons between study conditions.



Figure 1: A: Pelvic compression belt with sacral pad; B: The sacral pad.

Inclusion criteria:	Exclusion criteria:		
• Age: 20 to 40 years	History of back or pelvic pain before pregnancy		
• At least two weeks experience of pain	History of surgery or bony lesion in back, pelvic, or knees		
 Pain≥30mm on the visual analog scale 	Pain radiation to the leg		
• Production of pelvic pain in:	• Contraindications for the use of pelvic compression belt		
a. Palpation of SIJ	(e.g. Placenta Previa)		
b. Turning the body in bed	Taking a steroid medication		
c. Performing the ASLR test			
Pain reduction with rest			

Table 2: Demographic characteristics of participants.				
Characteristic	Values [*]			
Age, y	31±3 (22-36)			
Height, cm	163±6 (154-176)			
Weight, kg	67±10 (42-85)			
Number of pregnancies	2±1 (1-5)			
Gestational age, w	24±3 (20-32)			
Duration of complication, w	9±6 (1-26)			
Job-status, n (%)				
 With Prolonged standing 	5 (18)			
- With routine standing	7 (25)			
- Unemployed/housewife	16 (57)			
*Values are mean±SD and (minimum-maximum) unless another indicated.				

Outcome Measures	Conditions			One-way repeated
	No Orthosis	Pelvic Belt	Pelvic Belt with Sacral Pad	measures ANOVA
Hip Proprioception (Degrees)	4±2 (2-14)	3±2 (2-11)	1±1 (0-7)	Wilk's Lambda=.21, F(2,26)=48.6, p<.001*, Partial eta squared=.79
Perceived Effort in ASLR (0-10 Score)	3±2 (0-8)	2±2 (0-8)	0±1 (0-4)	Wilk's Lambda=.64, F(2,26)=7.27, p=.003*, Partial eta squared=.36
Objective effort: Maximum hip flexion force (Newton)	23±12 (8-48)	26±13 (9-56)	31±12 (14-61)	Wilk's Lambda=.25, F(2,26)=38.6, p<.001*, Partial eta squared=.75

Pair-wise compa		wise comparisons bety Hip Proprioception (Degrees)	Effort in ASLR (0-10 Score)	Maximum hip flexion force (Newton)		
No Orthosis- Pelvic Belt	P-value (95% CI)	.001* (.45 to 1.99)	.02* (.1 to 1.19)	<.001* (1.15 to 4.13)		
	M.D (SE)	1.2 (.3)	.64 (.21)	2.64 (.58)		
No Orthosis- Pelvic Belt with Sacral Pad	P-value (95% CI)	<.001* (2. 1 to 3.95)	.002* (.59 to 2.91)	<.001* (5.2 to 9.37)		
	M.D (SE)	3.03 (.36)	1.75 (.45)	7.26 (.58)		
Pelvic Belt - Pelvic Belt with Sacral Pad	P-value (95% CI)	<.001* (1.3 to 2.3)	.003* (.35 to 1.86)	<.001* (2.77 to 6.47)		
	M.D (SE)	-1.81 (.2)	1.11 (.3)	4.6 (.72)		
* indicates a statistically significant difference between groups (p<.05).						