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Design and Development of Thoracic Lumbar Sacral Orthosis Brace to Reduce Back Pain

Agus Santosa*, Andre Irwanto, Husnul Khotimah

Department of Medical-Surgical Nursing, Faculty of Health Sciences, Universitas Muhammadiyah Purwokerto, Indonesia

Corresponding Author: Agus Santosa
Email: agussantosa@ump.ac.id

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Abstract

Background: *Industrial workers are prone to experiencing back pain due to frequent activities that burden the back, such as bending for a long time and lifting weights in the wrong position. An estimated 577 million common cases worldwide are responsible for 7.50% of the global population. Thoracic Lumbar Sacral Orthosis Brace (TLSO Brace) is a tool used to support the spine to prevent this injury.*

Objective: *This research aims to design and pilot a new ergonomic TLSO Brace that can improve posture, reduce back pain and prevent back pain.*

Methods: *This research adopted Research and Development (R&D). This research was divided into three stages: designing, manufacturing, and testing.*

Results: *Product trial results on brick-making industry workers showed that the level of ergonomics is mainly in the Good category. The use of the TLSO Brace was proven effective in reducing back pain intensity ($p<0.0001$); the average pain was reduced after 14 minutes. The study also found that all respondents who used the brace while working did not feel back pain compared to before using it. It can be seen that the lordosis back arch became upright after using it, meaning the tool also improved posture.*

Conclusions: *The ergonomic TLSO Brace has been created and could improve body posture, reduce pain intensity and prevent back pain from recurring.*

Keywords*: back pain; lumbar brace; lordosis; orthotic devices; spine*

INTRODUCTION

The incidence of back pain globally reaches 577 million people or around 7.50%. Meanwhile, in Indonesia, it is estimated that 18%, primarily women (Saputra, 2020; WHO, 2020; Wu et al., 2020). Regarding their work, back pain is experienced mainly by health practitioners and industrial, agricultural, fishery, and forestry workers (Yang et al., 2016). The workers in the brick-making industry are also vulnerable to it. Several studies have found that around 55.3%-70% of brick-making workers report lower back pain due to awkward working postures for a long time (Das, 2015; Nurfajri et al., 2022).

In general, back pain is caused by too many activities that burden the back, or lifting weights in the wrong position, as well as the habit of bending over for a long time, causing tension in the vertebrae or surrounding tissues, such as muscles, blood vessels,

or nerves (Allegri et al., 2016). To avoid tension in the back, maintaining posture during activities or work is vital to minimize injuries to the spine that can result in back pain (Nowotny et al., 2011; Paolucci et al., 2019; Wernli et al., 2020). The impact of back pain surely will not result in death, but it causes limitations and difficulties in doing work or other activities (Grabovac & Dorner, 2019). Usually, back pain will improve with bed rest (Hagen et al., 2005; Rozenberg et al., 2002), drugs (Migliorini et al., 2021), the use of a corset or spinal brace (Schott et al., 2018) and physiotherapy (Karlsson et al., 2020). Only 1-2% require surgery (Varrassi et al., 2021).

A spinal brace is a device used to support the spine. Several studies have shown that using a corset can reduce tension and support the back, thereby preventing and reducing back pain (Myung et al., 2018; van Duijvenbode et al., 2008). Many investigations on the design of spinal corsets have been conducted, but most of them are to fix spinal disorders (Ali et al., 2020; Cooper et al., 2019). Meanwhile, the design of the spinal girdle specifically for brick-making industrial workers and its effectiveness has not been explored much. Several similar studies include the design of lumbar supports for assembly line workers (Bataller-Cervero et al., 2019), wearable lumbosacral support types for hospital workers (Hagiwara et al., 2017), designs of back belts aimed at preventing back pain due to prolonged sitting (Mokhtarinia et al., 2019).

Based on the previous studies, it can be seen that there are different corset designs and no specific corset designed for workers in the brick-making industry. They often bend over and lift loads that fall on their backs. A stooped posture and heavy loads on the back will increase the risk of shoulder, back, and even neck injuries, so a corset design is needed to minimize the risks. The different designs can also affect its effectiveness, so testing is needed. Therefore, this study aims to design and manufacture a new spinal girdle and perform functional tests to improve posture, reduce pain, and prevent pain for brick-making workers. It is hypothesized that the new corset design used in this study will improve their posture, reduce back pain and prevent it from recurring.

METHOD

Generally, this research was divided into two stages: the design and manufacture stage and the product trial stage (Bhuiyan, 2011).

Product designing and manufacturing stage

At this stage, the research began with a literature study, conducting a preliminary survey, designing and manufacturing the initial product, validating the design or expert test, and revising the design until the final design and product were developed.

Literature Study

At this stage, various kinds of literature on the anatomy and physiology of the spine were referred to design the TLSO Brace to suit the spine's shape. We also compared tools of back pain therapy from previous studies, including the design and materials used to manufacture the products.

Preliminary Survey

The preliminary survey was to determine the sizes of the TLSO Brace. It was conducted on 29 normal adults. The indicators include height, back height, and back curvature of adults. The results of literature studies and preliminary surveys were then used to design and manufacture initial products.

Design Validation

Two physiotherapists did the design validation with clinical experience. The indicator used was the feasibility of the product (design, material, and functional).

Design Revision and Final Product Development

The feedback from the experts was then used as a guide for revising the design and making the final product.

Trial stage

Research Design

The research design used in this trial was a pre-post-test design (Handley, Lyles, McCulloch, & Cattamanchi, 2018).

Population and Sample

The trial was conducted in Karangduren Village, Sokaraja District, Banyumas Regency, Central Java, Indonesia. The population was the workers in the brick-making industry. The samples included in this

study were 47 respondents with criteria aged 25-65 years, complaining of back pain in the cervical, thoracic and lumbar regions. Meanwhile, the respondents indicated osteoporosis, musculoskeletal trauma, history of spinal surgery, spinal tumors, and bone abnormalities were excluded (Charan & Biswas, 2013).

Procedure

The first trial was to determine the effectiveness of the TLSO Brace in reducing back pain. The procedure was carried out by assessing the respondents' back pain position and level of pain using the Nordic Body Map and the pain scale (Numeric Rating Scale (NRS)) (Haefeli & Elfering, 2006; Kuorinka et al., 1987). Furthermore, they were asked to use the TLSO Brace for a certain period in which their pain level was re-evaluated (whether or not there was a pain reduction).

The second trial examined the brace's effectiveness in preventing back pain at work. The procedure was done by having the respondents wear the brace while working; wearing it 6-8 hours/day for four weeks is recommended. At the end of the session, all respondents were interviewed regarding their back pain (whether or not they got back pain as they had the brace in their body). Its ergonomics level was evaluated by asking them a questionnaire. The improvement in the body posture, direct observations were conducted.

Data Analysis

The effectiveness of the TLSO Brace in reducing pain was analyzed using the Wilcoxon Signed Ranks Test. Meanwhile, a simple descriptive analysis analyzed its ergonomics level, pain prevention at work, and improvement effect on posture.

RESULT

The Results of TLSO Brace Design and Development

(see figure 1)

Figure 1 is the final product of the TLSO Brace, of which the design has been revised several times. The final product was designed considering the experts' feedback (expert test) and the survey results. This tool used 3 mm acrylic material as the back support, and foam and Neoprene fabric as the coating. Based on the survey results, the acrylic material was made into a curve to adjust the back arch of ordinary people. It was also made into various sizes, namely Small (S), Medium (M), Large (L), and Extra Large (XL), based on the survey of standard adult height, average back height, and regular back arch (Table 1).

(see table 1).

The result of the TLSO Brace Test

(see table 2)

The trial was conducted on 47 respondents of brick-making workers who experienced back pain problems in Banyumas Regency, Central Java. Most respondents were women; their age was 25-65 years. Most of them had worked for more than five years (72.3%), with working hours per day of >8 hours (Table 2). The characteristics of their back pain were mainly in the back (63.8%), at the waist (27.7%), and below the neck (8.5%). The characteristics of the respondents' back pain are displayed in Figure 2.

(see figure 2)

(see table 3)

The survey results of its ergonomics fell into the "Good" category (in terms of appearance, comfort, ease of use, and reduction of pressure on the back). The results can be seen in Table 3. Most respondents stated using the TLSO Brace was good in improving their body posture (83.0%), while the rest stated it was fair enough (17.0%). An upright back was seen as they put the brace on, as shown in a sample of the respondents in Figure 3. It was also found that all respondents wearing the brace at work did not report any complaints of back pain. Most respondents revealed the tool was in a suitable category for preventing pain.

(see figure 3)

The pain intensity of most respondents before using the TLSO Brace was moderate (61.7%). However, after using it, their pain was primarily mild (74.5%). The results of the analysis showed that the use of the TLSO Brace was proven to be effective in reducing the intensity of back pain ($p<0.0001$) (Table 4). Most respondents felt a decrease in pain intensity 15 minutes after putting the brace on (the

fastest time was 5 minutes, and the longest was 30 minutes after using it).

(see table 4)

DISCUSSION

In line with the hypothesis proposed, the new corset design can reduce back pain, prevent back pain from recurring, and improve posture. The results of this study proved that the use of the TLSO Brace could significantly reduce the back pain scale compared to before ($p<0.0001$). The average back pain scale felt by respondents before using the TLSO Brace was on a scale of 4.61 ± 4.47-4.76 (moderate pain). Meanwhile, after using the TLSO Brace, it decreased to 2.25 ± 2.12-2.38 (mild pain). This study also revealed the time of the pain reduction felt by the respondents, namely 15 minutes after using the tool. This finding is similar to those from previous studies; they found the use of a lumbar orthosis improved functional capacity and significantly reduced pain in patients with low back pain (Schott et al., 2018).

In this study, the respondents were asked to wear the TLSO Brace while working for four weeks. After wearing the brace at work, the study found that all respondents did not report any back pain complaints as before. It indicated its use prevented recurring back pain. The back pain usually heals in 1-8 weeks. Back pain arises due to problems in the vertebrae and excessive activity. The use of the TLSO Brace for four weeks in this study was felt to improve spine problems in respondents so that complaints of pain that were felt before using the tool did not recur. Research has also been conducted on the long-term use of a lumbosacral corset in patients with low back pain. The result showed that its use in high pressure and normal pressure for four weeks could reduce low back pain significantly compared to the control group ($p < 0.001$) (Samani et al, 2019). Likewise, the literature review results showed moderate evidence of the use of a lumbar corset in preventing low back pain than other interventions such as health education or no intervention (van Duijvenbode et al., 2008).

Back pain occurs due to a painful stimulus to nociceptors. The stimulus can be chemical (certain drugs) or mechanical (heavy load lift). The stimulus will be transferred to the local blood vessels, which will be received by the mast cells. Here, it will stimulate the mast cells to release histamine. Through histamine, the sensation of pain is then felt by the person. Most patients experience back pain due to mechanical reasons, such as lifting heavy weights, bending too long, and excessive pressure on the spine, which can cause an injury to one or more spinal joints (Allegri et al., 2016; Petersen & Marziale, 2014; Urits et al., 2019; Wong et al., 2017). It is the case for the respondents in this study.

The workers in the brick-making industry often bend over and lift loads that fall on their backs (Das, 2015). Heavy loads cause the spine to curve, making it more susceptible to injury (Fares et al., 2020). Mechanical factors and poor posture can cause back pain. The use of the TLSO Brace in this study has been proven to improve the respondent's posture, as shown in one of the samples in Figure 3. Its design has been adapted to the shape of the spine of ordinary people. When used, the brace can reduce pressure on the back and force the spine to be in a straight position. It helps prevent maximum back use, preventing back pain and further injury. In addition, the extension torque generated by the increased intra-abdominal pressure on this device can reduce muscle activity, tension, and fatigue and reduce the spine load to prevent back pain (Ali et al., 2020; Weiss & Turnbull, 2019). It is supported by previous studies concluding that using a lumbosacral corset could improve posture and lower back pain (Kang et al., 2016).

The limitations of this study are the trial design which did not involve a control group, and the duration of the TLSO Brace use at work was not appropriately controlled. The respondents are workers in the traditional brick-making industry. Thus, it cannot be generalized, especially to those in the modern brick-making industry.

CONCLUSION

A newly developed TLSO Brace was proven to be ergonomic, improve body posture, reduce pain intensity, and prevent back pain from recurring. Occupational health nurses should use this study's findings to educate industrial workers to use the TLSO Brace to maintain normal spinal posture and

prevent back pain. Trials of this tool for health practitioners, such as a nurse, are suggested for further research.

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Table 1. Survey of Height, Back Height, and Back Arch of Ordinary People to Determine The Tool Specifications

Height (cm)	Respondents (n)	Height of the back (Mean±SD, cm)	Back Arch (Mean±SD, cm)	Size
150-159	10	48±1.76	21±1.76	S
160-166	7	53±1.82	24±1.29	L
167-172	6	55±1.26	29±1.67	M
173-178	6	59±1.09	33±1.41	XL

Table 2. The Characteristics of the Respondents (n=47)

Characteristics	n (%)
Gender	
Male	18 (38.3%)
Female	29 (61.7%)
Age (Years)	
25-34	3 (6.4%)
35-44	10 (21.3%)
45-54	16 (34%)
55-65	18 (38.3%)
Working Experience	
1-5 years	13 (27.7%)
>5 years	34 (72.3%)
Working hours/day	
<8 hours	0 (0%)
≥8 hours	47 (100%)

Table 3. Descriptive Analysis of Ergonomic Levels, Posture Improvement, and Pain Prevention (n=47)

Category	Poor	Fair	Good	Very Good
Its ergonomics				
Appearance	0 (0%)	1 (2.1%)	36 (76.6%)	10 (21.3%)
Comfort	0 (0%)	0 (0%)	28 (59.6%)	19 (40.4%)
Lightness (weight)	0 (0%)	5 (10.6%)	42 (89.4%)	0 (0%)
Ease of use	0 (0%)	4 (8.5%)	41 (87.2%)	2 (4.3%)
Tension reduction on the back	0 (0%)	4 (8.5%)	35 (74.5%)	8 (17.0%)
Posture improvement	0 (0%)	8 (17.0%)	39 (83.0%)	0 (0%)
Pain prevention	0 (0%)	0 (0%)	47 (100%)	0 (0%)

Table 4. The Difference Between the Pain Scale Before and after using the TSLO Brace (n=47)

Variable		Parameter		Mean±SD	Mean Rank	p-value
		Mild, n (%)	Moderate, n (%)			
Pain intensity	**Before**	18 (38.3%)	29 (61.7%)	4.61± 0.49	24.00	0.0001
	After	35 (74.5%)	12 (25.5%)	2.25±0.44		

Pain scale after Intervention < Pain Scale before Intervention = 47
Pain scale after Intervention > Pain scale before Intervention = 0
Pain scale after Intervention = Pain scale before Intervention = 0

Figure 1. Design of TLSO Brace

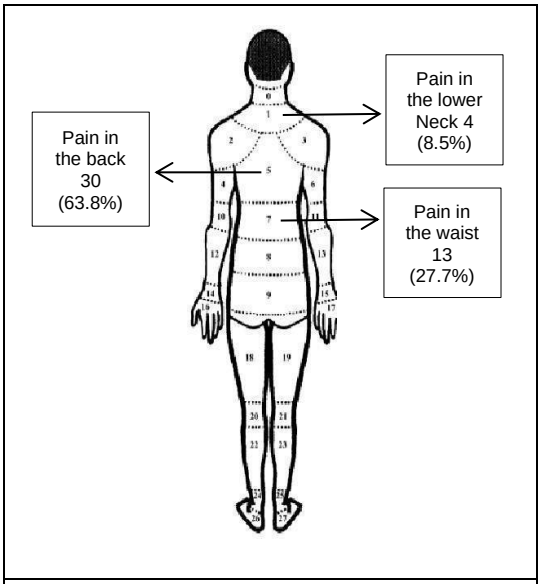

Figure 2. Position of the Respondents' pain (assessment using Nordic Body Map)

Figure 3. Use of TLSO Brace. A lordosis back is seen in (A), with the TLSO Brace on, and the back is upright (B).