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Clinical Orthopaedics and Related Research®

ISSN 0009-921X

Clin Orthop Relat Res
DOI 10.1007/s11999-013-3281-3

Springer

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Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

CLINICAL RESEARCH

Do Abdominal Cutouts in Thoracolumbosacral Orthoses Increase Pulmonary Function?

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Received: 19 February 2013 / Accepted: 4 September 2013

Abstract

Background Thoracolumbosacral orthoses (TLSOs) are effective in their intended purpose of limiting spinal movement but tend to restrict rib cage and abdominal motion. Incorporating an abdominal cutout, allowing abdominal excursion, may reduce the restraint on abdominal expansion associated with inhalation and thereby reduce pulmonary compromise.

Questions/purposes (1) For healthy adults, does a TLSO restrict pulmonary function at rest and after exercise compared with no TLSO (control)? (2) At rest, is pulmonary function increased by adding an abdominal cutout to the TLSO (open) compared with a traditional closed TLSO (no abdominal cutout)? (3) Are those results similar after exercise?

Methods Twenty healthy adults wore a custom-molded TLSO with a reattachable abdominal cutout. Forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV_1) were recorded at rest and after exercise in three conditions: (1) no TLSO (control); (2) TLSO (closed); and (3) TLSO (open).

Results Wearing a TLSO (closed or open) reduced FVC and FEV_1 similarly at rest ($p < 0.001$) and after exercise ($p < 0.001$) compared with controls. Adding an abdominal cutout (open) to the TLSO increased FVC at rest (95% confidence interval [CI], 3.79–4.76; $p = 0.007$) and postexercise (95% CI, 3.80–4.73; $p = 0.025$) compared with the closed TLSO, and FEV_1 increased postexercise (95% CI, 3.01–3.76; $p = 0.02$) but not at rest (95% CI, 2.96–3.73; $p = 0.053$).

Conclusions TLSOs restrict pulmonary function in healthy adults. An abdominal cutout in the TLSO increased pulmonary function, especially with activity, suggesting that cutouts should be considered when fabricating TLSOs for individuals with compromised breathing such as with neuromuscular disorders, scoliosis, or spine surgery.

Level of Evidence Level II, therapeutic study. See the Instructions for Authors for a complete description of levels of evidence.

Introduction

Thoracolumbosacral orthoses (TLSOs), or body jackets, are often prescribed by orthopaedic surgeons and neurosurgeons.

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
This work was performed at Rosalind Franklin University of Medicine and Science, North Chicago, IL, USA.

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They are used in rehabilitation to stabilize the spine for such conditions as spinal fractures and neuromuscular diseases and used to prevent the progression of scoliosis [4, 11, 14, 15, 25, 26]. The TLSO is a custom-made, total contact brace, which limits spinal movement in all three planes of motion (sagittal, coronal, and transverse) using a three-point pressure system through contact with bony skeletal landmarks (Fig. 1A). Although efficacious in controlling motion and restoring spinal alignment, the TLSO also tends to restrict rib cage and abdominal motion, thereby compromising the patient's breathing mechanics and exercise tolerance, leading to dyspnea and reduced adherence to wearing the brace [4, 6, 7, 15, 17, 20, 23, 27]. Other types of braces are available for spinal conditions, but this article focused on the TLSO.

Orthotists sometimes introduce an abdominal cutout to the TLSO design (Fig. 1B) to limit the risk of pulmonary compromise while controlling spinal motion and alignment. The abdominal cutout reduces the restraint on abdominal expansion that results from a rigid orthosis [12, 25] and is thought to improve visceral displacement as the diaphragm contracts and descends during inspiration [10]. An abdominal cutout should allow for improved diaphragmatic excursion and reduce the TLSO's deleterious effect on pulmonary function.

Restricting the thorax and/or abdomen in healthy adults has long been known to reduce pulmonary function [7, 10, 23]. Clinical research confirms similar findings for patients restricted by wearing a TLSO who have restrictive lung conditions such as in neuromuscular diseases [9, 20] or idiopathic scoliosis [3, 17], supporting the hypothesis that TLSOs without abdominal cutouts lead to a reduction in pulmonary function during activity and at rest. Although logical in theory, to date there is no comparable evidence to support improved pulmonary function with the use of an abdominal cutout.

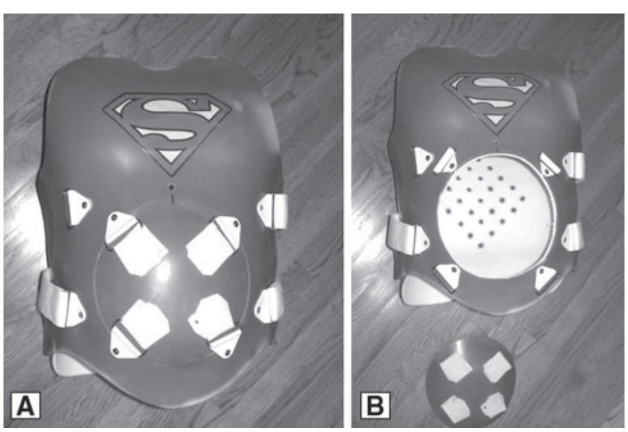

Fig. 1A–B (**A**) A full-contact TLSO fabricated with a reattachable abdominal cutout is shown with the abdominal cutout attached (closed condition). (**B**) A full-contact TLSO is shown with the abdominal cutout removed (open condition).

We therefore examined the effect of wearing a TLSO (with and without an abdominal cutout) on pulmonary function for healthy adults at rest and after a functional exercise activity (12-minute walk test). In healthy adults, we asked the following specific questions: (1) Does wearing a TLSO restrict pulmonary function at rest and after exercise compared with no TLSO (control)? (2) At rest, are pulmonary functions increased by adding an abdominal cutout to the TLSO (open) compared with a traditional closed TLSO (no abdominal cutout)? (3) Are those results similar after exercise?

Participants and Methods

Research Design

A randomized controlled pretest/posttest design was selected to assess the effects of an individually custom-fitted TLSO with and without an abdominal cutout on pulmonary function.

Study Participants

Twenty healthy adults between 23 and 55 years of age (mean, 32 years) volunteered to participate in the study and provided written informed consent in accordance with university institutional review board regulation. Participants were recruited from a university community, constituting a sample of convenience. Participants were screened for exclusion criteria with a brief standardized medical history and by observation and palpation of the chest wall and spine for posture and mobility by a physical therapist (DF) who is a cardiovascular and pulmonary specialist certified by the American Board of Physical Therapy Specialists. Exclusions included neuromusculoskeletal, pulmonary, cardiac, spine, or rib dysfunction or any other condition (such as obesity) that would limit a participant's ability to wear a TLSO or perform a 12-minute walk test.

Randomization

Participants were randomly assigned to the order of TLSO test conditions: TLSO with an abdominal cutout and TLSO without an abdominal cutout. Investigators were blinded to the TLSO condition by use of a large shirt, which covered the orthosis.

TLSO Fabrication

A bivalve thermoplastic TLSO was vacuum-formed from a custom-molded cast of each participant's torso. The TLSO was modified with a reattachable abdominal cutout (Fig. 1). At the initial fitting, the location of an abdominal cutout was marked so that the diameter on the midsagittal line extended from a point 24 mm inferior to the xiphoid process to a point 96 mm superior to the symphysis pubis, making the round cutout proportional to the height of the patient. The diameter of the cutout ranged from 124 to 144 mm. Four equally spaced buckles were attached to the plastic cutout and straps were attached to the TLSO at 90° angles from each other so that the circular cutout could be firmly reattached to the TLSO. The TLSO was fabricated from 3/16-inch copolymer plastic with a 3/16-inch polyethylene foam liner. The straps were 2-inch Velcro® with Dacron® backing.

Testing Procedures

Pulmonary function tests (PFTs) of forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV_1) were measured in standing at rest and after exercise (12-minute walk test [12MWT]) under three conditions: (1) no TLSO (control); (2) closed TLSO (no abdominal cutout); and (3) open TLSO (abdominal cutout). FVC measures the ability to take in a deep breath and to exhale forcefully and fully. FEV_1 measures the ability to quickly and forcefully exhale in 1 second. A single examiner (KS) administered the tests according to American Thoracic Society protocols [1, 13] using a metabolic cart (Vmax® Spectra 229LV; Viasys, San Diego, CA, USA) calibrated before each session according to the manufacturer's standardized protocol. The 12MWT was used as a measure of functional exercise capacity and performed according to American Thoracic Society protocols [2]. The longer 12MWT was used rather than the shorter 6-minute walk test (6MWT) because the participants were healthy and were more likely to reach a ceiling effect with the less physically demanding 6MWT. The 12MWT was originally designed as a functional measure of physical fitness for healthy persons and later adapted to a 6MWT for patient populations with endurance impairments [2]; thus, the 12MWT was deemed more appropriate for our participants.

Session Protocol

Participants attended three testing sessions. In Session 1, participants were informed about the study, including that they may feel a little fatigued from the walk test (12MWT) and may feel some mild discomfort during the measurement and fitting of the TLSO. All participants provided their informed written consent before formal inclusion. Baseline PFTs were then measured for the control condition (no TLSO) at rest and after exercise (12MWT), and measurements were taken for the fabrication of the custom-made TLSO by a nationally certified, licensed orthotist who was not an investigator. During Session 2, the fit of the TLSO was evaluated and adjusted by the same orthotist. Participants were randomly assigned to one of the two TLSO test conditions: closed TLSO or open TLSO. Each participant wore a shirt over the TLSO, blinding the investigator to the test condition. Participants were allowed 5 minutes to adapt to the orthosis before being tested. PFTs were then recorded at rest and after exercise (12MWT) during that session. Session 3 followed the same protocol as Session 2 for the other TLSO condition as determined by the random assignment. An average of 2 weeks was scheduled between data collection sessions. No pulmonary or cardiac health issues were reported by the participants over the three data collection sessions.

Statistical Analysis

Repeated-measures analysis of variance was performed for FVC and FEV_1 for the three conditions at rest and after exercise: (1) no TLSO (control); (2) closed TLSO (no abdominal cutout); and (3) open TLSO (abdominal cutout). Post hoc testing was conducted with Bonferroni paired t-tests. Effect size was calculated using multivariate partial eta squared (η_p^2). Statistical analysis was conducted using SPSS® software (Version 21; SPSS Inc, Chicago, IL, USA). Significance was set at $p < 0.05$.

Results

This study found that wearing a TLSO, regardless of orthotic design, restricted pulmonary function at rest and after exercise for healthy adults. There was a significant main effect of TLSO (closed and open conditions) compared with control on FVC at rest ($F[2,18] = 78.45$, 95% confidence interval [CI], 4.38–5.54; $p < 0.001$, $\eta_p^2 = 0.897$) and postexercise ($F[2,18] = 53.93$, 95% CI, 4.30–5.47; $p < 0.001$, $\eta_p^2 = 0.857$; Tables 1, 2). The results for FEV_1 were similar, showing a significant main effect of TLSO on FEV_1 at rest ($F[2,18] = 101.06$, 95% CI, 3.50–4.37; $p < 0.001$, $\eta_p^2 = 0.918$) and postexercise ($F[2,18] = 47.44$, 95% CI, 3.43–4.30; $p < 0.001$, $\eta_p^2 = 0.841$; Tables 3, 4).

Our study also showed that the pulmonary restrictions caused by wearing a TLSO could be reduced for healthy adults when an abdominal cutout (open) was added to the orthotic fabrication. The open TLSO increased FVC at rest (95% CI, 3.79–4.76; $p = 0.007$) and postexercise (95% CI, 3.80–4.73; $p = 0.025$) compared with the traditional

Table 1. Forced vital capacity (L): at rest

Condition	Mean	SD	95% confidence interval	
			Lower bound	Upper bound
Control	4.96	1.25	4.38	5.54
Closed TLSO	4.08	1.08	3.58	4.59
Open TLSO	4.27	1.04	3.79	4.76

Closed TLSO = thoracolumbosacral orthosis without abdominal cutout; Open TLSO = thoracolumbosacral orthosis with abdominal cutout.

Table 2. Forced vital capacity (L): postexercise (12MWT)

Condition	Mean	SD	95% confidence interval	
			Lower bound	Upper bound
Control	4.88	1.23	4.30	5.47
Closed TLSO	4.06	1.10	3.55	4.58
Open TLSO	4.20	0.99	3.80	4.73

12MWT = 12-minute walk test; Closed TLSO = thoracolumbosacral orthosis without abdominal cutout; Open TLSO = thoracolumbosacral orthosis with abdominal cutout.

Table 3. Forced expiratory volume in 1 second (L/sec): at rest

Condition	Mean	SD	95% confidence interval	
			Lower bound	Upper bound
Control	3.93	0.93	3.50	4.37
Closed TLSO	3.22	0.76	2.86	3.57
Open TLSO	3.35	0.82	2.96	3.73

Closed TLSO = thoracolumbosacral orthosis without abdominal cutout; Open TLSO = thoracolumbosacral orthosis with abdominal cutout.

closed TLSO (no abdominal cutout). The open TLSO likewise increased FEV_1 postexercise (95% CI, 3.01–3.76; $p = 0.02$) compared with the closed TLSO and showed a trend, but not a significant increase, at rest (95% CI, 2.96–3.73; $p = 0.053$) (Table 5).

The clinical significance of these results was examined using percent change, referencing a reduction of FVC by 20% as indicative of a pulmonary restrictive state [19]. Compared with a control, FVC decreased at rest by 18% for the closed TLSO and 14% for the open TLSO, indicating less restriction for the open TLSO condition. A similar relationship was seen after exercise; FVC decreased 17% for the closed TLSO and 13% for the open TLSO. With both TLSO conditions, our participants were at the clinical low end of normal FVC and reported increased work of breathing while wearing the TLSO at rest and more so with exercise.

The ratio of mean FEV_1 to FVC was consistent at 78% to 79% throughout all three conditions, reflecting normal ratios, indicating no restriction to expiratory flow [28], consistent with known ratios expected in healthy adults [5].

Discussion

Several bracing options are available to manage scoliosis and postspinal surgical conditions and have been shown to be an effective treatment modality for these conditions [11, 14, 18, 22]. In our clinical community, orthotists often use a TLSO (with/without internal padding) to prevent the progression of scoliosis, especially for neuromuscular conditions; thus, we chose to study the TLSO brace and its effect on respiration. Yet, if the patient does not wear the TLSO, it cannot be effective [8, 16, 21]. The total contact TLSO, although effectively providing spinal stabilization [18], restricts rib cage mobility and diaphragmatic and abdominal excursion [4, 7, 11, 14, 24–26]. The chest wall restriction may lead to shortness of breath [23, 25], which in turn may contribute to decreased adherence to wearing the TLSO [16, 25]. We studied healthy adults to answer the following questions: (1) Does wearing a TLSO decrease pulmonary function at rest and after exercise compared with no TLSO (control)? (2) At rest, are pulmonary functions increased by adding an abdominal cutout to the TLSO (open) compared with a traditional closed TLSO (no

Table 4. Forced expiratory volume in 1 second (L/sec): postexercise (12MWT)

Condition	Mean	SD	95% confidence interval	
			Lower bound	Upper bound
Control	3.87	0.93	3.43	4.30
Closed TLSO	3.22	0.78	2.85	3.58
Open TLSO	3.38	0.80	3.01	3.76

12MWT = 12-minute walk test; Closed TLSO = thoracolumbosacral orthosis without abdominal cutout; Open TLSO = thoracolumbosacral orthosis with abdominal cutout.

Table 5. Forced vital capacity (FVC) (L) and forced expiratory volume in 1 second (FEV_1) (L/sec) by TLSO condition (open versus closed)

FVC or FEV_1	Closed TLSO, mean (SD)	Open TLSO, mean (SD)	p value
FVC at rest (L)	4.08 (1.08)	4.27 (1.04)	0.007*
FVC postexercise (12MWT) (L)	4.06 (1.10)	4.26 (0.99)	0.025*
FEV_1 at rest (L/sec)	3.22 (0.76)	3.35 (0.82)	0.053
FEV_1 postexercise (12MWT) (L/sec)	3.22 (0.78)	3.39 (0.80)	0.02*

* Significant at the 0.05 level; TLSO = thoracolumbosacral orthosis; 12MWT = 12-minute walk test.

abdominal cutout)? (3) Are those results similar after exercise (12MWT)?

There were limitations to this study. All the participants were healthy and did not have a history of pulmonary disease or difficulty breathing; therefore, they cannot be directly generalized to a diseased population. Individuals with conditions that impair pulmonary functions such as neuromuscular weakness, skeletal deformities such as adolescent idiopathic scoliosis (AIS), or lung diseases would likely experience greater decrease in their pulmonary function in either of the braced conditions and should be targeted in future studies. We hypothesize that the abdominal cutout would ease their work of breathing, increase pulmonary function, and potentially increase wearing adherence, although this would need to be studied in these populations to be certain. Second, although the abdominal cutout in the TLSO allowed our participants to take a deeper breath as indicated by the increase in FVC at rest and after exercise, we did not attempt to test spinal stability with radiologic methods because of the undue health risk to the participants. The end point control remained intact in both TLSO conditions (open and closed); thus, control of coronal movement should not be compromised by the abdominal cutout. Spinal stability was clinically affirmed by the participating orthotist and physical therapist, but further studies confirming/refuting spinal stability of the TLSO with an abdominal cutout would help to determine the efficacy of using such a modification.

The durability of the TLSO with an abdominal cutout has not been formally tested and reported to the best of our knowledge. Anecdotally, orthotists and physical therapists in our community have been using TLSOs with abdominal cutouts for over 30 years to manage scoliosis and sagittal plane alignment for patients with neurologic weakness such as spinal cord injury and spinal muscular atrophy. Clinicians and families using these TLSOs have not reported any decrease in durability in wear compared with the traditional TLSO, but further studies are warranted. Lastly, studies are needed to further examine factors that influence functional activities in a TLSO and wearing adherence.

Our results confirm our first hypothesis: pulmonary functions were decreased when wearing either TLSO compared with not wearing a TLSO (control) both at rest and after exercise for healthy individuals. This was expected and concurred with previous studies on closed TLSOs and simulated chest constrictors [3, 5, 7, 12, 17, 20, 23]. A prior study by Cline et al. [5] using a chest restriction device with normal healthy adults at rest in both sitting and standing found FVC and FEV_1 progressively declined as the restriction of the chest wall increased in both postures. Adding exercise with a chest restrictor with normal healthy adults, O'Donnell et al. [23] likewise noted pulmonary restrictions and increased sensation of dyspnea (shortness of breath) limiting the subjects' ability to continue exercising. Our findings concurred with theirs; FVC was reduced with bracing for both exercise and rest conditions. The novelty of our research was showing that these prior known restrictions to breathing were eased by adding an abdominal cutout to the fabrication of the TLSO. Because testing on this fabrication style was not previously reported, we studied healthy subjects and suggest that future studies test diseased populations.

Cline et al. [5] and O'Donnell et al. [23] also found FEV_1 reduced. Similarly, we found FEV_1 was reduced after exercise (both TLSO conditions) and at rest for the closed TLSO condition. Like in the studies of Cline et al. [5] and O'Donnell et al. [23], our study showed a consistent ratio of mean FEV_1/FVC across conditions (78%–79%), indicating normal expiratory airflows, as would be expected in subjects without lung disease [5, 28]. For patients who already have impaired pulmonary functions and needed spinal bracing, studies have shown similar patterns for closed TLSOs (no abdominal cutout). To date, no studies have tested/reported the effect of an abdominal cutout (open TLSO) on pulmonary function in healthy or diseased populations, so direct comparison to other studies is not possible. Looking at similar breathing restrictions associated with bracing, Margonato et al. [17] used a closed TLSO type of bracing and found FVC and FEV_1 were reduced in patients with AIS at rest. This restriction may adversely influence wearing adherence, which is necessary for the success of the bracing program. For AIS, a moderate correlation was noted between increased wear time and improved treatment outcomes by Lou et al. [16], yet their study showed adherence was highly variable. Nicholson et al. [21] added a sensor to the closed TLSO (no abdominal cutout) of patients with AIS that accurately tracked wearing time, finding adherence varied from 8% to 90% even when the patients knew they were being monitored. A feeling of restriction was one of the reasons given for nonadherence for six of 10 subjects who were followed for 14 months. Our findings suggest that the pulmonary restriction may be reduced if an abdominal cutout was included in the fabrication. This in turn may increase compliance, especially for patients who indicated breathing restrictions as a major reason for nonadherence. Similar decreases in pulmonary function have been noted for patients with neuromuscular restrictions while wearing a closed TLSO [9, 20, 27]. In our study, the pulmonary restriction was reduced for healthy participants by adding an abdominal cutout to the TLSO (open). This design may be beneficial to populations that already have pulmonary restrictions before wearing a TLSO (ie, scoliosis, neuromuscular disease, and other related conditions) and warrants further study.

The novelty of our research was showing that use of an abdominal cutout (open) in the fabrication of a TLSO (Fig. 1), which allowed for abdominal excursion associated with diaphragmatic breathing, increased pulmonary function. With the open TLSO (abdominal cutout), FVC increased compared with the traditional closed TLSO (no abdominal cutout) both at rest and after exercise. FEV_1 also increased with exercise and showed a trend, but not a significant increase, at rest. We suggest further study on this question. For patients who already have impaired pulmonary functions such as with skeletal deformities or neuromuscular weakness, we hypothesize that use of an abdominal cutout in the TLSO fabrication may positively influence wearing adherence and spinal outcomes by easing the breathing restriction, although we did not study compliance with brace wear in the current study.

The results of our study demonstrated that TLSOs compromise pulmonary function in healthy adults. Adding an abdominal cutout to the TLSO, allowing for greater diaphragmatic excursion, increased pulmonary function compared with the traditional closed TLSO. This suggests that a cutout should be considered when fabricating TLSOs for individuals with compromised breathing such as with neuromuscular disorders, scoliosis, or spine surgery. The abdominal cutout (open) may ease the work of breathing and may increase wearing adherence, although we suggest further studies in patients with these conditions to confirm that abdominal cutouts will improve brace compliance.

Acknowledgments We thank Ballert Orthopedics and Travis Carlson for donation and fabrication of the TLSOs in preparation for the study; Dr Dale Schuit for administrative support; Dr Wendy Rheault, Dr Roberta Henderson, and Dr Victoria Moerchen for statistical analysis, Dr Judith Stoecker, and Dr Elizabeth Dean for assisting with support and manuscript preparation; and Carl Holzman for proofreading.

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