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Clinical Study

Effect of a prototype lumbar spinal stenosis belt versus a lumbar support on walking capacity in lumbar spinal stenosis: a randomized controlled trial

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Abstract

BACKGROUND CONTEXT: Lumbar spinal stenosis (LSS) can impair blood flow to the spinal nerves giving rise to neurogenic claudication and limited walking ability. Reducing lumbar lordosis can increases the volume of the spinal canal and reduce neuroischemia. We developed a prototype LSS belt aimed at reducing lumbar lordosis while walking.

PURPOSE: The aim of this study was to assess the short-term effectiveness of a prototype LSS belt compared to a lumbar support in improving walking ability in patients with degenerative LSS.

STUDY DESIGN: This was a two-arm, double-blinded (participant and assessor) randomized controlled trial.

PATIENT SAMPLE: We recruited 104 participants aged 50 years or older with neurogenic claudication, imaging confirmed degenerative LSS, and limited walking ability.

FDA device/drug status: Not applicable.

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OUTCOME MEASURES: The primary measure was walking distance measured by the self-paced walking test (SPWT) and the primary outcome was the difference in proportions among participants in both groups who achieved at least a 30% improvement in walking distance from baseline using relative risk with 95% confidence intervals.

METHODS: Within 1 week of a baseline SPWT, participants randomized to the prototype LSS belt group (n=52) and those randomized to the lumbar support group (n=52) performed a SPWT that was conducted by a blinded assessor. The Arthritis Society funded this study ($365,000 CAN) with salary support for principal investigator funded by the Canadian Chiropractic Research Foundation ($500,000 CAN for 5 years).

RESULTS: Both groups showed significant improvement in walking distance, but there was no significant difference between groups. The mean group difference in walking distance was −74 m (95% CI: −282.8 to 134.8, p=.49). In total, 62% of participants wearing the prototype LSS belt and 82% of participants wearing the lumbar support achieved at least 30% improvement in walking distance (relative risk, 0.7; 95% CI: 0.5−1.3, p=.43).

CONCLUSIONS: A prototype LSS belt demonstrated significant improvement in walking ability in degenerative LSS but was no better than a lumbar support.

Keywords: Intermittent claudication; LSS; Lumbar belt; Lumbar support; Nonoperative treatment; Randomized controlled trial; Walking.

Introduction

Lumbar spinal stenosis (LSS) is usually caused by age-related degenerative narrowing (stenosis) of the central and lateral spinal canals leading to compression and ischemia of the spinal nerves (neuro-ischemia) [1]. It is a leading cause of pain, disability, and loss of independence in older adults [2]. The prevalence and economic burden of LSS are growing due to the aging population. Limited walking ability is the dominant functional impairment due to LSS [3]. Those afflicted have greater walking limitations than individuals with knee or hip osteoarthritis [4] and greater functional limitations than those with congestive heart failure, chronic obstructive lung disease, or systemic lupus erythematosis [2]. The most common clinical syndrome associated with LSS is known as neurogenic claudication. It is characterized by bilateral or unilateral buttock and lower extremity pain, heaviness, numbness, tingling or weakness, precipitated by walking and standing, and relieved by lumbar flexion such as sitting or bending forward [3,5]. Claudication symptoms are believed to arise from ischemia of the spinal nerves secondary to venous congestion within the spinal canal [6, 7]. This is plausible based on the rapid symptom reduction with sitting and stooping forward. Standing and walking postures increase the lumbar lordosis, which leads to further narrowing of the canals [8−10]. Spinal canal narrowing impairs venous return and leads to engorgement of the venous plexus [6]. Venous congestion increases with time standing or walking and eventually compromises arterial perfusion and leads to hypoxia of the spinal nerves and symptoms of claudication [6]. Reducing lumbar lordosis increases the canal size and relieves epidural pressure and restores blood flow to the spinal nerves [10].

We developed a prototype LSS belt aimed at reducing the lumbar lordosis while walking. There are no randomized controlled trials (RCTs) evaluating the effectiveness of a lumbar belt, support, or brace applied while walking for patients with neurogenic claudication due to LSS. One case series study demonstrated improved pain and walking distance when using a lumbosacral corset in 21 patients with neurogenic claudication [11]. A case report of a patient with scoliosis and neurogenic claudication also demonstrated improved walking distance with the use of a custom formulated lumbar brace [12]. Lumbar supports, belts, and corsets are commonly used for the management of low back pain, but recent treatment guidelines do not recommend their use [13].

We conducted an RCT comparing the effectiveness of a new prototype LSS belt to a lumbar support in improving walking capacity among individuals with neurogenic claudication. We hypothesized that the prototype LSS belt applied while walking would improve walking distance compared to a lumbar support applied while walking.

Methods

The hospital institutional review board approved the study (certificate #14-0020-E). There was no commercial sponsorship. No remuneration was provided to participants, except reimbursement for travel costs, and all interventions were provided free of charge. This study was a nested within the context of a larger RCT [14].

Study design: We conducted a two-arm double-blinded (participant and assessor) single session RCT (Fig. 1), meaning that the intervention and the assessment of walking ability occurred at the same time in a single session.

Source population: Using an eligibility checklist, interested and potentially eligible participants were referred to the study by medical specialists, family physicians, and chiropractors from participating local hospitals and community

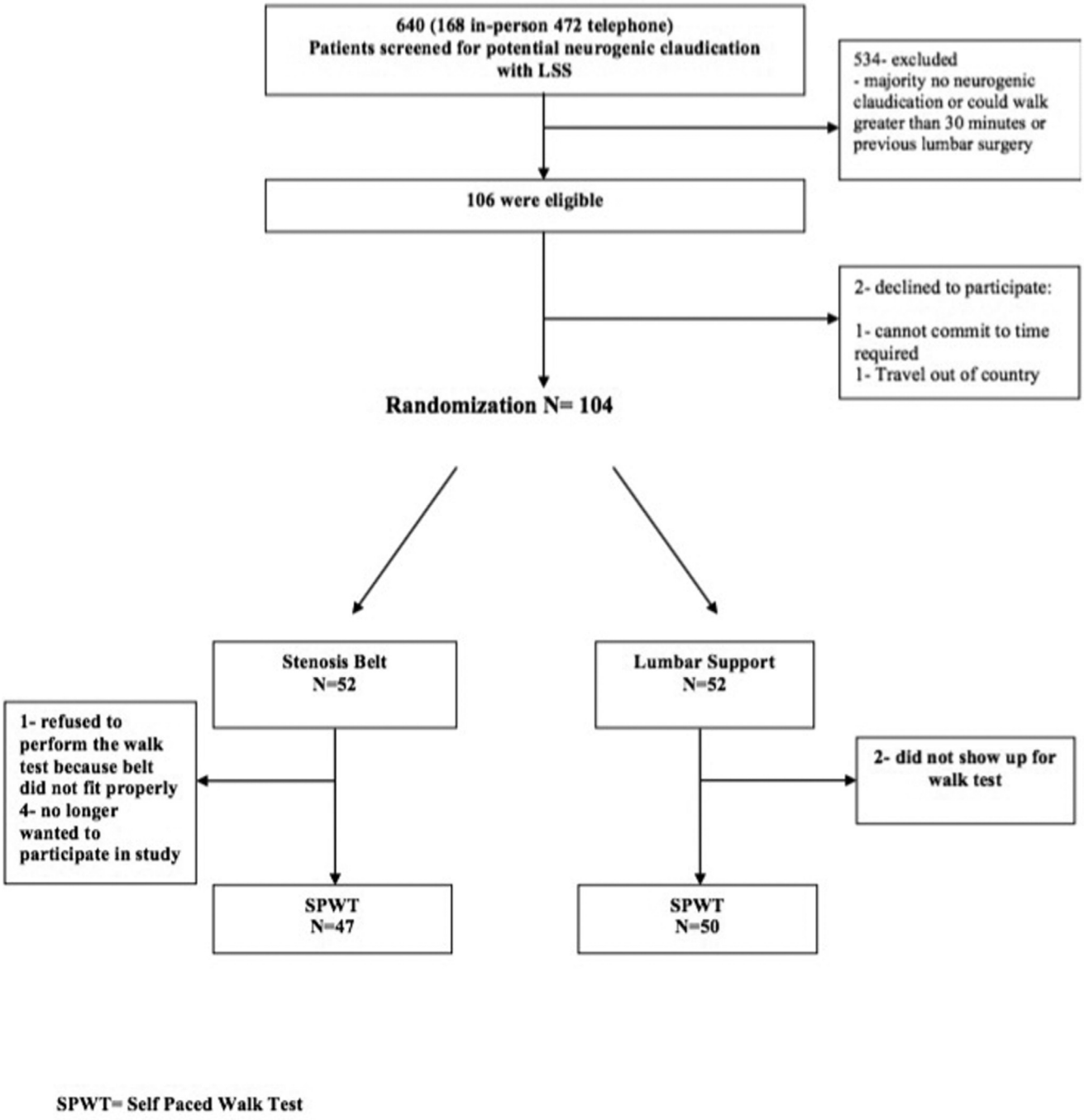

Fig. 1. Flow diagram of enrolment and randomization.

clinics. Local newspaper advertisements were also used to recruit potential participants. Eligible participants were aged 50 years or older, had symptoms of neurogenic claudication for at least 3 months, had imaging-confirmed degenerative spinal canal narrowing, and were able to walk without assistance for at least 20 m but less than 30 minutes. Those who had previous surgery for LSS or had other conditions impacting walking ability were excluded from participating in the study (Table 1). A trained study coordinator assessed eligibility by initially screening by phone and then by in-person assessment. All participants provided written informed consent. Eligible and consenting participants completed a baseline questionnaire, a short physical performance battery [15], and performed a baseline self-paced walking test (SPWT) [16]. The SPWT involves participants walking until their LSS symptoms require them to sit down and rest.

Randomization: Eligible and consenting participants were randomized to either the prototype LSS belt or the lumbar support group. A biostatistician prepared the randomization sequence using a computerized random number table [NQuery Advisor 7.0]. Sequentially numbered and sealed opaque envelopes containing the sequence were

Table 1
Inclusion and exclusion criteria

Inclusion criteria
1. Age greater than or equal to 50 years
2. Clinical symptoms of back and/or radiating lower limb or buttock pain; fatigue or loss of sensation in the lower limbs aggravated by walking and/or standing and relieved by sitting.
3. Intermittent or persistent pain without progressive neurological dysfunction
4. Symptoms and signs for more than 3 months
5. Imaging-confirmed spinal canal narrowing using MRI, CT scan
6. Clinical signs and symptoms corresponding to segmental level of narrowing identified by imaging
7. Patients with degenerative spondylolisthesis are included
8. Not considered to be a surgical candidate (in the next 12 months) or patient unwilling to have surgery
9. Able to perform mild-moderate exercise
10. Able to walk without assistive devices for at least 20 m and less than 30 minutes continuously
11. Able to give written informed consent and complete interviews and questionnaires in English.
Exclusion criteria
1. Severe degenerative stenosis with intractable pain and progressive neurological dysfunction
2. Lumbar spinal stenosis not caused by degeneration
3. Lumbar herniated disc diagnosed during the last 12 months
4. Previous back surgery for lumbar spinal stenosis or instability
5. Underlying spinal disorder such as ankylosing spondylitis, neoplasm, infection, or metabolic disease
6. Intermittent claudication due to vascular disease
7. Severe osteoarthrosis or arthritis of lower extremities causing limited walking ability
8. Neurologic disease causing impaired function of the lower limbs, including diabetes
9. Psychiatric disorders and/or cognitively impaired

stored in a locked drawer. For each enrolled participant, the study coordinator (not involved in the preparation of the allocation sequence) retrieved and opened the next sequentially numbered envelope and assigned the participant according to the random allocation scheme.

Procedures: All participants performed an SPWT with their assigned orthotic (prototype LSS belt or lumbar support) within 1 week of their baseline assessment and SPWT.

(a) Prototype LSS belt: Participants randomized to this group wore a prototype LSS belt that had a Velcro waist strap and two Velcro straps that wrapped around the upper thighs. A rubber inflatable diaphragm was positioned by the research coordinator in a pouch located at the back of the belt and placed just below the apex of the sacrum (Fig. 2). The research coordinator inflated the diaphragm until the participant felt moderate but comfortable pressure over the sacrum just before their walk test.

(b) Lumbar support: Participants randomized to this group wore a lumbar support (Tensor 3M Canada) that wrapped around the lower lumbar spine and was secured by Velcro. Just before the walk test, the research coordinator placed the lumbar support just above the iliac crest and secured it firmly but comfortably fitted around the participants' waist (Fig. 3).

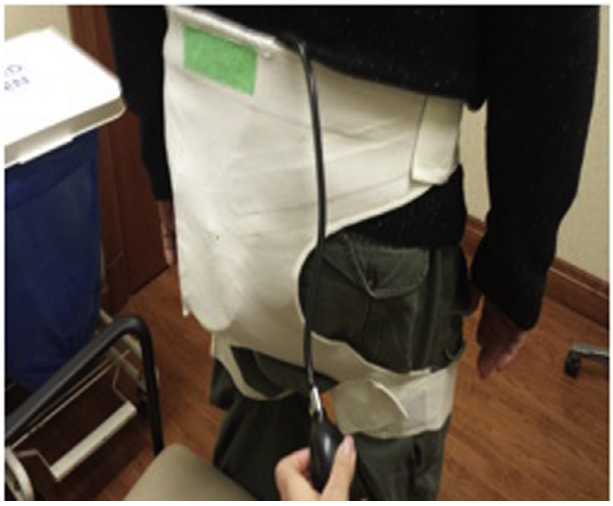

Fig. 2. Prototype lumbar spinal stenosis belt.

Fig. 3. Lumbar support.

Participants performed a single SPWT while wearing their assigned LSS belt or lumbar support. All SPWTs were performed and recorded by blinded assessors. Hospital gowns were worn over the LSS belt or lumbar support in order to conceal them and blind the assessor. Participants were instructed not to communicate with the assessor beyond answering questions related to the SPWT. A licensed practitioner was nearby during the assessment to intervene in the event that the participant experienced any discomfort or difficulties related to the wearing the LSS belt or lumbar support. Every effort was made to ensure the assessor did not become un-blinded during the assessment.

Outcomes

Primary measure

Objective walking capacity: Walking capacity was assessed using the SPWT. The test required participants to walk on a level surface without support at their own pace until forced to stop due to symptoms of LSS or a time limit of 30 minutes [17]. Test termination was defined as a complete stop of 3 seconds. A blinded assessor followed one meter behind the subject, without conversing, with a distance instrument (Lufkin Pro-Series Model PSMW38), and stopwatch. Distance walked and time to test termination was recorded. The SPWT is considered the gold standard with high validity for assessing walking capacity in this population since it directly observes walking ability under conditions representative of a real-world setting [16,18]. It has shown high test-retest reliability (ICC=0.98) [17]. The primary outcome was the proportion of participants who achieved at least 30% improvement in walking distance (estimated minimum clinically important difference or MCID). We also calculated the proportion of participants who achieved at least 50% improvement in walking distance from baseline.

Statistical issues

Sample size

We estimated the sample size for the primary outcome of objective walking capacity based on an estimate of the difference in the proportion of participants who achieved the MCID in walking distance from baseline. Since the MCID for the SPWT is unknown, we estimated it to be an improvement in walking distance from baseline of 30% or more. We estimated that 30% of participants would achieve the estimated MCID in the lumbar support group and 60% in the prototype LSS group. Based on an estimate of 30% difference in proportions, a power of 0.8, an alpha of 0.05, and an estimated dropout rate of 20%, a minimum of 52 participants per group were estimated to achieve significance using a two-tailed *t*-test for two independent proportions [19].

Statistical analysis

Baseline status of treatment groups was compared using two-tailed independent samples *t* tests, chi-squared tests of independence, and Mann-Whitney *U* tests as indicated. Our analyses were based on the "intention to treat" principle.

We analyzed the primary outcome (SPWT) by calculating the differences in proportions meeting the MCID between the two groups using the Pearson chi-squared test with 95% confidence intervals (CI). We also calculated the relative risk (RR) with 95% CI among participants in both groups who achieved the MCID. To control for potential confounding (sex, education, perceived health status, dominant leg or back pain, and hospital), logistic regression models and generalized estimation equation methods were used [20]. These models were controlled for baseline differences not balanced by randomization.

Protection of human subjects and assessment of safety

Protection of human subjects

The study protocol was approved by the hospital Research Ethics Board (Certificate number 14-0020). This trial was registered with ClinicalTrials.gov ID: NCT02592642.

Adverse events

We measured the presence of adverse events associated with each intervention during the SPWT. We defined adverse events as unintended signs or symptoms of the intervention. These included significant increase in back and/or lower extremity pain, numbness, tingling, tiredness, or claudication symptoms beyond those normally experienced when walking. We computed the incidence (95% CI) of each adverse event listed above. The total number of participants was used as the denominator.

Results

From August 2014 to January 2016, a total of 640 potential participants were screened for eligibility; 106 were eligible and 104 were randomly allocated to the lumbar stenosis belt or lumbar support (Fig. 1). The two groups were similar at baseline (Table 2). The mean age of the study sample was 70.6 years, 57% were female, 86% had leg symptoms for more than 12 months, and the mean maximum distance walked in 30 minutes or less at baseline was 328.7 m. Two participants (4%) randomized to the lumbar support group did not show up for their SPWT. One participant (2%) randomized to the lumbar stenosis belt group refused to perform the SPWT because the belt did not fit properly, and four participants withdrew from the study (8%).

Both the LSS belt participants and the lumbar support participants showed significant improvement in walking distance during the SPWT adding additional 125.0 m and 167.1 m, respectively. However, the between group differences were not significant with a mean adjusted difference of −74.0 m, 95% CI −282.8 to 134.8, and p = .49 (Table 3).

In total, 62% of LSS belt participants demonstrated at least 30% improvement in walking distance compared to

82% of lumbar support participants adjusted. The RR was 0.7, 95% CI 0.5 to 1.1, and p = .087.

In total, 60% of LSS belt and 78% of lumbar support participants demonstrated at least 50% improvement in walking distance; adjusted RR was 0.899, 95% CI 0.8 to 1.3, and p = .43.

Table 2
Baseline characteristics of the study participants*

Variable	Stenosis belt (N=52)	Lumbar belt (N=52)
Age (y)	68.9±8.6	72.3±8.6
Sex, no. (%)		
Male	23 (44)	22 (42)
Female	29 (56)	30 (58)
Marital status, no. (%)		
Single, never married	5 (10)	3 (6)
Married	31 (60)	28 (54)
Common-law	4 (8)	4 (8)
Divorced	6 (12)	9 (17)
Widowed	6 (12)	7 (13)
Separated	0 (0)	1 (2)
Expectations, no. (%)		
Get better soon	8 (15)	12 (23)
Get better slowly	15 (29)	21 (40)
Never get better	9 (17)	5 (10)
Don't know	20 (38)	14 (27)
Global health rating†	68.5±14.5	68.6±15.5
Comorbidities, no. (%)‡		
Yes	38 (73)	37 (71)
No	14 (27)	14 (27)
Unknown	0 (0)	1 (2)
Duration of back pain, no. (%)		
<3 months	1 (2)	0 (0)
3–12 months	6 (12)	8 (15)
>12 months	45 (87)	44 (85)
Duration of leg pain, no. (%)		
3–12 months	7 (13)	10 (19)
>12 months	45 (87)	42 (81)
Dominant pain, no. (%)		
Leg	34 (65)	32 (62)
Back	12 (23)	10 (19)
Equal	6 (12)	10 (19)
Zurich Claudication Questionnaire (ZCQ)		
ZCQ Function score§	0.6±0.1	0.6±0.1
ZCQ Symptoms score‖	0.6±0.1	0.6±0.1
Oswestry Disability Index (ODI)¶	0.4±0.1	0.4±0.1
ODI walk, no. (%)♯		
No limitations	0 (0)	0 (0)
2 km	4 (8)	5 (10)
1 km	14 (27)	14 (27)
500 m	33 (63)	32 (62)
Gait aid	1 (2)	1 (2)
Bedridden	0 (0)	0 (0)
Numeric Rating Scale (NRS)		
NRS-Back Pain**	5.3±2.9	5.6±2.5
NRS-Leg Pain††	7.0±2.0	7.1±2.2
Falls Efficacy Scale‡‡	31.2±22.3	30.3±19.0
SF36 Subscales§§		
SF36-PF	38.9±22.8	36.3±20.6
SF36-MH	70.8±18.5	70.8±19.2
SF36-BP	43.5±18.5	38.1±16.4
Center for Epidemiological Studies-Depression (CES-D) scale‖‖	12.5±9.6	10.7±9.8
Self-paced walking test (SPWT) (m)¶¶	328.5±96	328.9±95

Note: Values having ± symbol are means±SD.

* There were no significant between group differences in any of the remaining baseline characteristics using p<.05.

† Global health rating scores range from 0 to 100, with higher scores indicating better health.

‡ Comorbidities include problems with other muscle, bone or joint conditions, allergies, breathing, hypertension, heart and circulation, digestive system, diabetes, kidney and genitourinary, neurological, headaches, mental or emotional and cancer.

§ ZCQ Function scores range from 0.25 to 1.0, with lower scores indicating less severity (score range converted from 1 to 4).

‖ ZCQ Symptom scores range from 0.20 to 1.0, with lower scores indicating less severity (score range converted from 1to 5).

¶ ODI scores range from 0 to 1.0, with lower scores indicating less disability.

♯ ODI walk allows for six possible responses on walking ability; no limitations, 2 km, 1 km, 500 m, gait aid, and bedridden.

** NRS-Back Pain scores range from 0 to 10, with 0 indicating no pain and 10 indicating "pain as bad as you can imagine."

†† NRS-Leg Pain scores range from 0 to 10, with 0 indicating no pain and 10 indicating "pain as bad as you can imagine."

‡‡ Falls Efficacy Scale scores range from 10 to 100, with lower scores indicating less severity.

§§ SF36 Subscales range from 0 to 100, with lower scores indicating poorer health. PF, Physical Function, MH, Mental Health, BP, Bodily Pain.

‖‖ CES-D scores range from 0 to 60, with lower scores indicating less depressive symptomatology.

¶¶ SPWT measures objective walking distance in meters without stopping due to neurogenic claudication symptoms.

Among LSS belt participants who completed the SPWT, 13 (28%) reported experiencing discomfort while wearing the belt and this negatively impacted their ability to walk. One (2%) participant in the lumbar support group reported the lumbar support was uncomfortable to wear while walking.

Discussion

In this study, we found that a prototype LSS belt significantly improved walking distance but was not superior to the improvement observed wearing a lumbar support. We also observed that the majority of participants wearing either orthotic achieved at least 50% improvement in their walking ability. This is an important finding since walking limitation is the dominant impairment and the most common reason for seeking care in this population. This is the first RCT to evaluate a lumbar belt or support specifically for patients with neurogenic claudication due to LSS. The mechanism for improved walking observed in this study by both groups is uncertain. The aim of the new prototype LSS belt was to place a posterior to anterior force over the lower

Table 3
Intention to treat analysis comparing stenosis belt and lumbar support while walking

Outcome	Baseline	Stenosis belt	Lumbar support	Treatment effect	p-Value
		Mean difference from baseline with 95% CI		Adjusted treatment effect with 95% CI	
Primary outcomes					
No. of participants	104	47	50		
SPWT distance (m)		125.0 (5.6 to 244.4)	167.1 (48.6 to 285.6)	−74.0 (−282.8 to 134.8)	.49
		Percentage with 95% CI		Relative risk with 95% CI	
≥ 30% improvement in SPWT (%)		62 (49, 74)	82 (70, 91)	0.7 (0.5, 1.1)	.09
Secondary outcome					
≥ 50% improvement in SPWT (%)		60 (46, 72)	78 (65, 87)	0.8 (0.5, 1.3)	.43

sacrum using an inflatable diaphragm in an effort to introduce a passive anterior tilt of the pelvis. An anterior pelvic tilt can lead to a reduction of the lumbar lordosis and an associated increase in the volume of lumbar spinal canal that can result in improved blood flow to the spinal nerves. However, it is not known whether this was achieved in this study. Improved walking capacity in both groups may have been due to regression to the mean [21], the Hawthorne effect [22], and/or other biomechanical, physiological and psychophysical effects derived from wearing the respective orthotic [23–27]. It is not likely that the improvements seen in this study were due to natural history since the intervention and SPWT took place less than a week after the baseline SPWT and because participants had chronic symptoms (over 85% of participants had leg symptoms for more than one year). In a recent natural history study of LSS improvements in symptoms were common over time but improvements in walking distance were less likely [39]. There is evidence that lumbar orthotics reduces movement of the lumbar spine [25,27], and this may have provided added mechanical support while walking. However, the ability of lumbar orthotics to reduce axial loading and to improve muscular strength, endurance, or proprioception has not been proven [24,25,27]. Psychophysical and other placebo and contextual factors may have contributed to improved walking ability. The orthotics may have resulted in a perceived sense of added stability and balance, improved walking confidence, and/or decreased pain that may have translated into increased walking distance. Both groups may have experienced altered beliefs and the hope that the respective orthotic might be helpful [28,29]. Patients with neurogenic claudication due to LSS have high levels of anxiety, depression, and hopelessness [30]. Engendering hope when participants feel hopeless about their condition can be therapeutic and patient expectations may produce independent and powerful placebo analgesic effects [31, 32].

There have been two studies evaluating the effectiveness of lumbar orthotics for neurogenic claudication: one a before-and-after study [11] and the other a case report [12]. Both showed improved walking ability but were of very poor methodological quality. Lumbar supports, belts, and corsets are commonly used for low back pain, but recent clinical guidelines and a Cochrane review do not recommend their use [13,33].

There have been a number of published RCTs assessing various nonoperative treatments for LSS. Systematic reviews of these RCTs concluded that current trials were of low methodological quality; therefore, no conclusions could be made about the effectiveness of nonoperative interventions including their benefit on walking ability [34–38].

Although demonstrating significant improvement in walking ability, 28% of participants who wore the prototype LSS belt during the SPWT found it uncomfortable to wear.

The results of our study suggest that a lumbar support may significantly improve walking ability although the mechanism of action is unknown. Since there is a strong possibility that the improvements in walking distance were due to placebo effects, we cannot recommend the use of a lumbar support or the prototype LSS belt as effective interventions for patients with neurogenic claudication due to LSS.

The strengths of this study were the use of a randomized controlled design where participants and assessors were blinded, a low dropout rate, and the use of a valid and objective primary outcome measure, which is highly meaningful to patients with LSS [30].

We did not have a “no treatment” or “placebo” arm, and therefore, we cannot make any conclusions on the effectiveness of either the new prototype LSS belt or lumbar support for neurogenic claudication.

Our study had only one follow-up assessment within a week of the baseline evaluation, and therefore, the durability of the benefits seen with either lumbar orthotic is uncertain.

Further studies will aim at redesigning and testing the prototype LSS belt with more consideration regarding ease of use and comfort. The benefits seen in this study using either lumbar orthotic warrant additional study using high-quality methods. Future studies should also assess the sustainability of improved walking over time using various lumbar orthotics and their impact on performance (improved walking distance over days, weeks, or months).

Conclusions

A new prototype LSS belt demonstrated significant and meaningful improvement in walking distance, but similar improvements were seen using a lumbar support. The underlying mechanism(s) for the improvements seen in walking capacity is uncertain, and the influence of a strong placebo effect cannot be ruled out.

Authors' contributions

CA conceived the study, participated in its design, and led the preparation of drafts and final manuscript. PC, AA, and RR were responsible for the design and drafting of the protocol and editing drafts and final manuscript. DS participated in re-designing the study protocol and editing the draft versions and final manuscript. MS, CB, and GH provided input on the original design of the study and edited the drafts and final manuscript.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.spinee.2018.07.012.

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