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Translation and Validation of the Danish Version of the Zurich Claudication Questionnaire

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Abstract

Study Design: Validation study.

Objectives: To translate and validate the Zurich Claudication Questionnaire (ZCQ) into a Danish version of the disease-specific patient-reported outcome measure (PROM) for patients with lumbar spinal stenosis (LSS), which assesses symptom severity, physical function, and satisfaction after surgery.

Method: Translation into a Danish version of the original questionnaire by back- and forward-translating the questionnaire and finally transforming a prefinal test version into a final and cross-cultural adapted version. Validation was performed as a cohort study assessing floor-ceiling effects, internal consistency, test-retest reproducibility, criterion validity, discriminant validity, and responsiveness to change.

Results: Fifty-three patients were consecutively included in the study, 53 healthy controls were matched. Floor effect was seen in the postoperative data. Internal consistency, Cronbach's alpha was good to excellent. Substantial test-retest reproducibility was found using Cohen's weighted kappa. The Danish ZCQ showed moderate to strong association with similar domains of Oswestry Disability Index, Short Form 36, Euro QoL 5D, visual analogue scale–leg and back. The questionnaire showed significant responsiveness to change and a significant discriminant validity between LSS patients and healthy controls.

Conclusion: This study shows the Danish translation of the original ZCQ to be well understood by Danish patients. The Danish version is furthermore a reliable and valid questionnaire, which is responsive to change.

Keywords

Zurich Claudication Questionnaire, lumbar spinal stenosis, translation, validation, Danish version

Introduction

Lumbar spinal stenosis (LSS) is one of the leading indications for spinal surgery in Denmark.[1] It is a degenerative disorder characterized by a narrow spinal canal compressing the spinal neurovascular structures causing leg pain, with or without back pain, leg numbness and gait disturbance.[2,3] Lumbar spinal stenosis is a clinical syndrome. Patients report reduced functional capacity and the main symptom is neurogenic claudication expressed by reduced walking distance and leg pain aggravated by walking, relieved by sitting or leaning forward. Patients tend to walk in a stopped fashion also called "the shopping cart sign."

The Zurich Claudication Questionnaire (ZCQ), also known as the Swiss Spinal Stenosis Measure or the Brigham Spinal Stenosis Questionnaire was developed in 1996 by Gerald Stucki et al.[4] The ZCQ was designed specifically to develop a short, self-administered questionnaire assessing symptom severity, physical function, and patient satisfaction in LSS patients undergoing decompressive surgery. The questionnaire is disease specific and is divided into 3 main scales which address the clinical syndrome of LSS patients. The symptom

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severity is focusing on balance disturbance, pain, and neuroischemic symptoms in the back and legs. Physical function mainly focuses on the patients' ability to mobilize by walking. Patient satisfaction is focusing on patients' overall satisfaction with the surgical procedure, pain relief, walking ability, and ability to do housework or job after the operation. Since its introduction, the ZCQ has become one of the primary outcome measures to report on treatment results in patients with LSS.[5] The ZCQ has been translated and validated into several languages[6-14] and has shown to be a reliable and valid disease-specific questionnaire for patients with LSS. There have been 9 language translations, with over 120 articles published using the ZCQ. The questionnaire has not yet been culturally adapted and translated into Danish. The aim of this study was to translate and adapt the ZCQ from the original English version into Danish and to test the psychometric properties of the Danish ZCQ version. As LSS is common in the elderly, a Danish translation of the ZCQ is needed as English is not the primary language of our target population in Denmark.

Methods

This study was performed at the Center for Spine Surgery and Research, Lillebaelt Hospital, Denmark as a prospective cohort study including patients who had degenerative LSS and healthy asymptomatic controls. The study was approved by the Danish data protection agency (Ref. No. 16/1586) and the Ethical Committee of Medical Health Sciences, Region Sjaelland (Ref. No. SJ-505). All patients gave informed consent before participating in this study.

Questionnaire

The ZCQ is an 18-item, self-administered, disease-specific questionnaire and consists of 3 different domains: Symptom Severity, Physical Function, and Satisfaction. Higher scores denote higher degrees of dysfunction. All responses are reported on a Likert-type scale. The Symptom Severity domain consists of 7 items and is subdivided into a 3-item Pain subdomain and 4-item Neuroischemic subdomain all with scale score 1 to 5, except from item 7, which has been transformed into a scale score 1-3-5. The 5 items in the Physical Function domain have scale score of 1 to 4 and the Satisfaction domain has 6 items with scale score 1 to 4. The domain scores are calculated as an unweighted mean of all answered items, if more than 2 items are missing the domain scores are also considered missing.

Translation

The guidelines used for translation and cross-cultural adaption of the Danish ZCQ was published by Beaton et al[15] and Guillemin and Bombardier[16] and followed the recommendations published by ISPOR (International Society for Pharmaeconomics and Outcomes Research) task force for translation and cultural adaptation.[17]

The questionnaire was translated from English to Danish by 2 professional translators from an independent company (Ad-Astra). Both translators were naive to the questionnaire, with no informed knowledge about the clinical perspective of the questionnaire. The translators made a forward translation T1 and T2, which was made from the source language to the target language and transformed into a T1-2 version. To improve applicability to the Danish population, item 8 was transformed from miles and blocks into International Metric System (IMS) in meters. The T1-2 version was reviewed by an expert committee of 2 spine surgeons and a research nurse with more than 30 years of experience and a language professional with more than 10 years of experience, all with Danish as their native language. The panel evaluated the Danish T1-2 version. The T1-2 version was backward translated into English (original language) by 3 bilingual individuals (both English and Danish): An orthopedic resident (not naïve to the questionnaire), a financial consultant, and an English teacher (both naïve to the questionnaire) made 3 versions BT1-BT2-BT3. This process is a validity check to make sure that the item content is the same as the original version. The 3 backward translations were evaluated and compared with the original version by the expert committee. After consolidating all versions of the translations, the committee created a prefinal version of the Danish ZCQ. Naïve translators were involved to increase acceptability and generalizability for patient use in the clinic setting. Nonnaïve translators were involved to ensure that the intent of the questions remained the same through the forward and backward translations.

Pretesting

The prefinal version of the Danish ZCQ was administered to a convenience sample of 50 patients who already had surgical decompression for LSS at the Department of Spine Surgery in Lillebaelt Hospital, Denmark from November to December 2015. The patients were able to answer all 3 domains in the questionnaire. The pretesting was made to evaluate the conceptual understanding exploring both the meaning of the items and the responses. We expected some of the patients would have reduced symptoms and increased functionality due to the surgical treatment, some would have remaining or even no changes in symptoms and disability. The prefinal version was tested using a wide variety of patients in order to evaluate the performance of the prefinal questionnaire across different age groups. Patients were asked to complete the ZCQ and to comment on confusing questions and potentially problematic sections. The expert committee addressed these potential issues and a final version of the Danish ZCQ was created and tested for reliability and validity.

Validation

The final version of the Danish ZCQ, the Short Form 36 (SF-36),[18] Oswestry Disability Index (ODI),[19,20] and European Quality of Life–5 Dimensions (EQ-5D)[21] were administered

by mail to 76 participants preoperatively. This would provide at least 4 respondents for every item. The ZCQ was sent as a single questionnaire to the participants again 6 months postoperatively, where maximal benefit of the treatment was expected[4] and compared with the SF-36, ODI, EQ-5D, VAS-leg, and VAS-back, which was sent out 1 year postoperatively. To evaluate test-retest reproducibility, ZCQ was administered 14 days after the preoperative questionnaire, before surgery was performed, for comparison of Symptom Severity scores and Physical Function scores. The 14-day interval was introduced to reduce the risk of patients remembering their primary response. The Satisfaction domain was administered 14 days after the 6-month postoperative questionnaire and comparing only the satisfaction part of the postoperative questionnaire. At the same time, the final version of ZCQ was given to 50 healthy asymptomatic volunteers with Danish as their native language. They were recruited as the spouse to an LSS patient in the study. They were invited to participate if they had no previous history of spine surgery and felt they had a "healthy spine."

Statistical Analysis

Domain score, total score, and mean values were calculated for the ZCQ. Floor and ceiling effects were evaluated by looking at percentage of participants scoring the minimum and maximum scores in each domain. Internal consistency was tested if the items in the domains or subdomains were homogenous and correlated and measuring the same concept. It was measured using Cronbach's alpha coefficient (acceptable coefficient cut-off point >.7).[22] Domain and subdomain internal test-retest reproducibility was determined by comparing the preoperative test and retest 14 days after using Cohen's weighted kappa (agreement interpretation 0.1-0.20 = slight, 0.21-0.40 = fair, 0.41-0.60 = moderate, 0.61-0.8 = substantial, and 0.81-1.0 = almost perfect).[23,24]

This was supported by Bland Altman plots[25] (which are featured in the online supplemental materials) for the Symptom Severity domain, Pain subdomain, Neuroischemic subdomain, and Physical Function scale. Weighted kappa was used to take randomness into account and the further apart the test-retest answer is, the less weight is given to agreement.[24]

Criterion-concurrent validity was evaluated by calculating Spearman correlation between the ZCQ and ODI, EQ5D, VAS-leg, VAS back, and SF-36. Interpretation of the Spearman correlation was proposed as follows: 0.00–0.10 = negligible, 0.10-0.39 = weak, 0.40-0.69 = moderate, 0.70-0.89 = strong, 0.90-1.00 = very strong.[26]

Discriminant validity was evaluated by the differences in ZCQ scores between LSS patients and the healthy controls using unpaired *t* test and Wilcoxon rank-sum test. Responsiveness, comparing pre- and postoperative domain score were analyzed using paired *t* test or Wilcoxon signed rank test. Effect size (ES) was calculated by differences in SD pre- and postoperatively divided by baseline SD. Standardized response means (SRM) were calculated by differences in SD pre- and postoperatively divided by SD of the difference. All analyses were performed using STATA version 15; significance level .05.

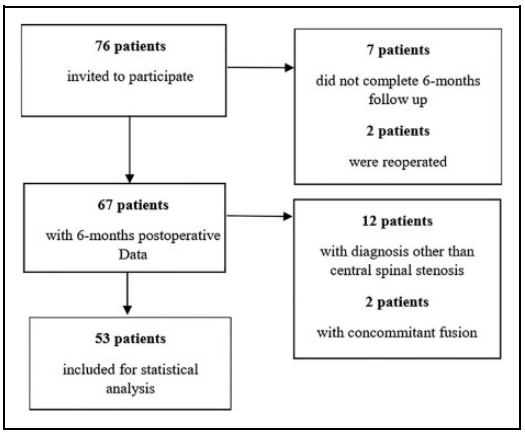

Figure 1. Case Flow.

Results

Translation and Cross-Cultural Adaptation

For the convenience sample of 50 patients who had surgical decompression for LSS, the mean age of the respondents was 66 years (range 19-86). None of the respondents reported the questions as confusing or saw any potential problematic sections. Sixteen respondents had written comments on their questionnaire, mainly regarding item 16, as they had only recently had surgery and had not begun physical activity. Respondents also commented on the Symptom Severity scale because the questions were addressing leg, feet, and back at the same time. Often patients would point out which part of the body they were referring to in their response.

Psychometric Testing of the Final Version

A total of 53 patients with LSS (Figure 1) completed the questionnaires. In the LSS group, 22 (42%) were females, mean age 66.7 years (range 39-85). The majority (92%) had leg pain symptoms for at least 3 months (Table 1). All the patients had a laminectomy only without a fusion. Fifty-three healthy asymptomatic volunteers (Figure 2) completed the questionnaires and were considered to be the control group. There were 30 females with mean age 64.8 years (range 16-81). There were no differences in the demographic characteristics between the 2 groups. Preoperative domain scores were normally distributed. Postoperative scales and subdomains data were not normally distributed.

Floor Ceiling Effects. Although no ceiling effect was noted in any subdomain, a floor effect was seen in all the postoperative subdomains: Pain (25%), Neuroischemic (21%), Physical Function (29%), and Satisfaction (31%) (Table 2).

Internal Consistency and Test-Retest Reproducibility. Cronbach's alpha for internal consistency was reported as good (Table 3)

Table 1. Demographics Characteristics: Lumbar Spinal Stenosis Cases and Healthy Asymptomatic Controls.

	Lumbar spinal stenosis cases	Healthy asymptomatic controls	*P*
N	53	53	.000
Females, n	22	30	.12
Age, years	66.7 (39-85)	64.8 (range 16-81)	.40
Smokers, n	18	NA	NA
Symptom duration (leg pain/back pain), n (%)			
No leg pain/no back pain	1/4 (1.89/7.55)		
Less than 3 months	3/3 (5.66/5.66)		
3 months or more but less than 12 months	19/11 (35.85/20.75)		
12 months or more but less than 24 months	15/12 (28.30/22.64)		
24 months or more	15/23 (28.30/43.40)		
Surgery type, n			
Decompression only	53		
Decompression and fusion	0		

Abbreviation: NA, not applicable.

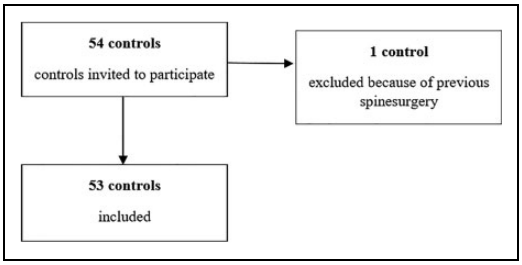

Figure 2. Flow for asymptomatic controls.

except from the Neuroischemic subdomain (Cronbach's α = .62). Cohen's weighted kappa for test-retest reproducibility was used looking at weighted disagreement for ordinal variables (Table 3) and showed substantial reproducibility for Symptom Severity Pain subdomain, Physical Function domain, and Satisfaction domain. Kappa for the Symptom Severity Neuroischemic subdomain was found to be moderate (kappa of .51). This was supported by Bland-Altman plots in all scales and subdomains (Figure 3 Supplementary Material).

Criterion Concurrent Validity. The Danish ZCQ showed significant moderate to strong associations[26] with similar domains of the ODI, SF-36, EQ-5D, VAS-leg pain, and VAS-back pain (Table 4). Spearman's correlation coefficient for the ZCQ Pain subdomain and SF-36 Bodily Pain domain was $r = 0.68$, the ODI Pain domain was $r = 0.75$, EQ5-D Pain domain $r = 0.66$ and VAS-leg pain was $r = 0.67$. The correlation coefficient for the ZCQ Physical Function domain and the ODI Pain domain was $r = 0.61$, personal care was $r = 0.63$, sex life was $r = 0.68$, social life was $r = 0.70$ and Physical Function domains of the ZCQ and SF-36 were $r = 0.74$. Correlation between ZCQ Physical Function and EQ5D usual activity was $r = 0.57$) (Table 4).

Responsiveness. The questionnaire showed a significant responsiveness to change (Table 5) in both scales and all subdomains. The effect size and SRM (Table 5) were substantial for Symptom Severity score scale, Pain subdomain, Neuroischemic subdomain, and Physical function scale.

Discriminant Validity. The ZCQ showed a significant difference in scores between the patients and the healthy controls in all subdomains (Table 6).

Discussion

Floor-Ceiling Effects

As more than 20% of patients had the lowest scores possible in all subdomains, a floor effect is present. Floor and ceiling effects are present if more than 15% of scores are the minimum or the maximum possible score.[22] This suggests that additional responses to the current items or new items may need to be added to the ZCQ in order to correct this floor effect. A similar floor effect at the 6-month postoperative follow-up period was found by Wertli et al[7] in the Physical Function subdomain. Alternatively, the floor effect could be explained by patients reaching maximal improvement in their disease specific disability score 6 months after surgery.

Internal Consistency

The results of the current study showed good internal consistency for all domains and subdomains except for the Neuroischemic subdomain, in which the internal consistency was low at 0.62.[27] This finding is similar to what was found in the original study by Stucki et al[4] where Cronbach's alpha for the Neuroischemic subdomain was .63. This is in contrast to the Spanish translation performed by Hidalgo et al,[13] which showed good internal consistency for the Neuroischemic subdomain with Cronbach's alpha of .796. Since there are only a handful of items that pertain to the different subdomains, any missing values will lead to the inability to separate the symptom severity scale into subdomains for unidimensional scores. A way of handling this issue could be to transform the

Table 2. Descriptive Statistics: Case Domain Scores.

Domain	Mean	SD	Minimum	Maximum	% Floor	% Ceiling
Preoperatively						
Symptom Severity score	23.96	4.48	13	33	1.89	1.89
Pain	11.32	2.17	3	15	1.89	9.43
Neuroischemic	12.64	3.15	4	18	1.89	3.37
Physical Function	12.28	2.97	7	17	3.85	3.85
Postoperatively						
Symptom Severity score	15.35	5.89	7	28	15.38	1.92
Pain	6.87	3.06	3	12	25.00	7.69
Neuroischemic	8.48	3.69	4	17	21.15	1.92
Physical Function	8.10	3.05	5	17	28.85	1.92
Satisfaction	10.13	4.27	6	24	30.77	1.92

Table 3. Internal Consistency Coefficient and Reproducibility, Cronbach's Alpha, Cohen's Weighted Kappa: Zurich Claudication Questionnaire Domains and Subdomains.

Domain	Cronbach' alpha	Weighted kappa (agreement %)
Preoperatively		
Symptom Severity score	.75	.56 (88.16)
Pain	.89	.66 (92.48)
Neuroischemic	.62	.51 (87.50)
Physical Function	.84	.74 (92.33)
Postoperatively		
Satisfaction	.93	.64 (88.73)

subdomains into actual scale scores and expand the number of questions.

Test-Retest Reproducibility

For the test-retest reproducibility, we found the Danish ZCQ to be reliable with a substantial weighted kappa coefficient in all domains except from Symptom Severity scale score and Neuroischemic subdomain, where we found a moderate weighted kappa coefficient (Table 3).

Concurrent Validity

The Danish version of ZCQ showed good concurrent validity especially when comparing similar dimensions of the questionnaires. This study is to our knowledge the only one separating both The ZCQ questionnaire and the generic questionnaires into subdomains (Table 4). For the subdomain scores, we found a strong correlation between ZCQ subdomain Pain and ODI Pain scores, SF36 Bodily Pain, EQ5D Pain scores and VAS-leg. A strong correlation was also found for overall Symptom Severity scale score tested against Generic Pain subdomains. No substantial correlation was found for ZCQ Neuroischemic sudomain.

We found a strong correlation between ZCQ Physical Function scale score and ODI Personal Care subdomain, Sex life, Social life, and ODI Total score, which was similar to what was found by Thornes et al,[8] and a strong correlation between ZCQ Physical Scale score and SF-36 Personal Function, was also found by the Japanese group.[10]

Responsiveness

Good responsiveness to change was seen with both effect sizes >1 and SRM >0.99 (Table 5). This supports the results seen in both the Norwegian and the Korean studies,[8,14] Likewise, standardized response means were equal to or better than the original study by Stucki et al.[4] Pratt et al[28] showed the ZCQ and ODI questionnaires to be both responsive and reproducible, with ZCQ showing a slight superiority to the more generic ODI in terms of reproducibility.

Discriminant Validity

Data showed good responsiveness validity between patients treated for LSS in relation to healthy controls, which indicates that the questionnaire is measuring LSS as a disease specific questionnaire (Table 6). The results showed a statistically significant difference between the "case group" in relation to the "control group" for all subdomains in the ZCQ questionnaire.

Strength and Weaknesses

The major strength of the ZCQ is that it is disease specific, dealing with neurogenic claudication, the symptom that is pathognomonic for LSS. Comer et al[29] performed a Rasch analysis on the ZCQ and showed that the Pain subdomain and the Neuroischemic subdomain had a good item and person fit,[29] but highlighted that the Symptom Severity score was multidimensional with the 2 subdomains measuring 2 different latent variables. The current study is one of few psychometric studies separating the Symptom Severity scale into the unidimensional Pain subdomain and Neuroischemic subdomain.

To our knowledge, the Danish version of the ZCQ is the first disease-specific questionnaire for Danish patients with LSS.

This study followed current guidelines.

The floor effect may be seen due to maximum improvement at the early 6-month follow-up. Furthermore, this may give

Table 4. Concurrent Validity, Spearmans correlation and (p-value): Zurich Claudication Questionnaire, Short Form 36, Oswestry Disability Index, EuroQoL 5D, Visual Analogue Scale (Back and Leg).

	ZCQ			
Domain	Symptom severity	Pain	Neuroischemic	Physical function
SF-36				
PF	−0.56 (0.000)	−0.45 (0.001)	−0.51 (0.000)	−074 (0.000)
RP	−0.47 (0.000)	−0.42 (0.002)	−0.40 (0.003)	−0.47 (0.000)
BP	−0.62 (0.000)	−0.68 (0.000)	−0.45 (0.001)	−0.70 (0.000)
GH	−0.34 (0.013)	−0.32 (0.0018)	−0.27 (0.055)	−0.43 (0.002)
VT	−0.34 (0.013)	−0.40 (0.003)	−0.25 (0.074)	−0.39 (0.005)
SF	−0.41 (0.002)	−0.49 (0.000)	−0.31 (0.018)	−0.53 (0.000)
RE	−0.31 (0.023)	−0.18 (0.202)	−0.33 (0.017)	−0.33 (0.015)
MH	−0.49 (0.000)	−0.47 (0.000)	−0.40 (0.003)	−0.45 (0.001)
ODI				
1	0.61 (0.000)	0.75 (0.000)	0.44 (0.001)	0.61 (0.000)
2	0.57 (0.000)	0.60 (0.000)	0.45 (0.001)	0.63 (0.000)
3	0.35 (0.010	0.28 (0.045)	0.31 (0.026)	0.36 (0.008)
4	0.27 (0.060)	0.19 (0.166)	0.27 (0.054)	0.59 (0.000)
5	0.39 (0.005)	0.35 (0.011)	0.32 (0.020)	0.33 (0.019)
6	0.39 (0.004)	0.39 (0.004)	0.31 (0.024)	0.58 (0.000)
7	0.45 (0.001)	0.48 (0.000)	0.31 (0.023)	0.50 (0.000)
8	0.58 (0.001)	0.50 (0.004)	0.52 (0.003)	0.68 (0.000)
9	0.48 (0.000)	0.50 (0.000)	0.37 (0.007)	0.70 (0.000)
10	0.48 (0.000)	0.46 (0.000)	0.41 (0.003)	0.57 (0.000)
Total	0.58 (0.000)	0.57 (0.000)	0.47 (0.003)	0.76 (0.000)
EQ-5D				
Mobility	0.15 (0.300)	0.14 (0.329)	0.15 (0.277)	0.22 (0.114)
Self-care	0.63 (0.000)	0.52 (0.000)	0.58 (0.000)	0.47 (0.001)
Usual activity	0.41 (0.002)	0.42 (0.002)	0.34 (0.012)	0.57 (0.000)
Pain	0.61 (0.000)	0.66 (0.000)	0.47 (0.001)	0.46 (0.001)
Anxiety/Depression	0.37 (0.006)	0.34 (0.014)	0.35 (0.010)	0.28 (0.045)
VAS–back	0.52 (0.000)	0.55 (0.000)	0.37 (0.006)	0.52 (0.000)
VAS–leg	0.56 (0.000)	0.67 (0.000)	0.42 (0.002)	0.40 (0.004)

Abbreviations: ZCQ, Zurich Claudication Questionnaire; SF-36, Short Form 36; PF, personal functioning; RP, roles–physical; BP, bodily pain; GH, general health; VT, vitality; RE, roles–emotional; MH, mental health; ODI, Oswestry Disability Index; EQ-5D, EuroQoL 5D; VAS, visual analogue scale.

Table 5. Responsiveness to Change, Effect Size, and Standard Response Mean (SRM): Zurich Claudication Questionnaire Domains and Subdomains.

Domain	Preoperatively, mean (SD)	Postoperatively, mean (SD)	*P*	Effect size	SRM
Symptom Severity score	24.02 (4.51)	15.35 (5.89)	.000	1.92	1.23
Pain	11.37 (2.17)	6.87 (3.06)	.000	2.07	1.23
Neuroischemic	12.65 (3.18)	8.48 (3.68)	.000	1.31	0.99
Physical function	12.33 (2.98)	8.04 (3.05)	.000	1.44	1.27

Table 6. Discriminant Validity: Zurich Claudication Questionnaire Domains and Subdomains.

Domain	LSS, mean (SD)	Normal, mean (SD)	*P*
N	53	53	NA
Females	22	30	NA
Preoperatively			
Symptom Severity score	23.96 (4.48)	11.98 (6.10)	.000
Pain	15.10 (2.78)	7.30 (3.99)	.000
Neuroischemic	9.07 (2.78)	4.68 (2.44)	.000
Physical function	12.47 (2.78)	6.66 (3.17)	.000

Abbreviation: NA, not applicable.

reduced correlation when testing against questionnaires at 1-year follow-up.

Conclusion

This study shows the Danish translation of the original Zurich claudication questionnaire to be a reliable and valid questionnaire, easy to understand, and responsive to change. The Danish ZCQ can be used to measure treatment effectiveness in patients with LSS. Additional responses to current items or new items may be needed to resolve both the floor effects seen in the postoperative domain scores and challenges with the multidimensional Symptom Severity scale score.

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Declaration of Conflicting Interests

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Supplemental Material

Supplemental material for this article is available online.

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