

<b>Article details: 2015-0001</b>	
Title	The Canadian surgical wait list for lumbar degenerative spinal stenosis has a detrimental effect on patient outcomes during the first postoperative year.
Authors	Christopher S. Bailey MD, Kevin R Gurr MD, Stewart I. Bailey MD David Taylor MD, M. Patricia Rosas-Arellano MD PhD, Corinne Tallon BSc, Jennifer C. Urquhart PhD
<b>Reviewer 1</b>	S. Samuel Bederman MD PhD
Institution	Assistant Clinical Professor, Department of Orthopaedic Surgery, University of California — Irvine
General comments (author response in bold)	<p>Thank you for the opportunity to review this interesting paper. I commend the authors on a very thoughtful and important study that questions the effect of prolonged waiting time for surgical treatment of lumbar stenosis. I believe this paper is worthy of publication, however, I have one major concern I feel the authors should address.</p> <p>Major concern:</p> <p>1. It appears that the distribution of wait times likely follows a normal distribution without a very wide spread since the mean and median are similar and the SD is less than half the mean. In this case, it does not make sense to 'split' the normal curve in half since the majority of the patients will be in the middle -- just slightly over or slightly under the median. In other words, is a patient who waited 11M29D really going to be different from one who waited 12M1D? My recommendation would be to redo the analysis using the wait time as a continuous variable rather than dichotomize it arbitrarily based on the median. In this way, the effect of wait time will be better assessed. Alternatively, using multiple time categories or a high vs. low group may be sufficient as well.</p> <p><b>Thank you for this suggestion. The Pearson Product Moment Correlation was performed between wait time and outcome measures and added to the manuscript.</b></p> <p>Minor concerns:</p> <p>2. The title does not accurately reflect the results of this study as prolonged waiting did not have any effect on 2-year outcomes. If the updated analysis shows similar results, then emphasizing the detrimental effect on intermediate term outcomes would be preferred.</p> <p><b>As requested we have altered the title to better reflect the fact that outcomes are effected into the first year but not at the 2nd year. The revised title is "The Canadian surgical wait list for lumbar degenerative spinal stenosis has a detrimental effect on patient outcomes during the first postoperative year".</b></p> <p>3. Page 3 of 14, 2nd paragraph: "The effect [of] these..."</p> <p><b>Thank you, the correction has been made.</b></p> <p>4. The authors conclude that "strategies to reduce wait times .. are urgently needed". Can the authors elaborate on strategies they would recommend or propose?</p> <p>The following statement has been added to the concluding paragraph "Such strategies are slowly being implemented including education and quality based guidelines for primary care providers, multi-disciplinary assessment and treatment clinics for the acute and chronic low back pain patient, and utilization of cost and time efficient treatments including surgical options."</p>
<b>Reviewer 2</b>	Dr. Oliver Pascal Gautschi
Institution	Royal Perth Hospital, Orthopaedic Surgery
General comments (author response in bold)	<p>The authors performed a prospective study to analyse waits for elective spine surgery in the London Health Science Center. From 1126 patients available for screening, 166 (14.7%) were subsequently enrolled in the study. 144 patients (86.7%) had data available for the late 24 months follow-up. The authors analysed outcome measures including pain intensity, functional disability and health-related quality of life (HRQoL), as well as patient satisfaction with surgery. The authors found that patients scheduled for lumbar degenerative spinal stenosis surgery presented worsening in HRQoL irrespective of the length of waiting time. Although there was a benefit for the patients in the short wait group at 12 months, these differences were no longer statistically significant at the 24 months follow-up.</p> <p>The topic of the manuscript is of importance and the quality of the paper is high enough to recommend publication in the CMAJ Open not only to surgeons and medical practitioners, but definitively also for politicians and health-care professionals. However, there are some major revisions necessary.</p>

Although not the topic of this manuscript, the authors could re-analyse their indications for instrumented fusion, as I believe that a fusion rate of 81.9% for LDSS is rather high. A selective decompression for a LDSS (one level) takes a third to maximum half of the time than a fusion procedure. So, if a part of the LDSS patients would just have decompression surgery and not a fusion (if a fusion is biomechanically not necessary), more patients could benefit from surgery each week and the overall wait list could be significantly reduced.

**We agree that this fusion rate is high compared to the standards today. As this study was initiated almost ten years ago there has been some evolution of the surgeons' practice in keeping with the current treatment guidelines. Furthermore, the high overall fusion rate is influenced by the high fusion rate of senior surgeons in the group. Certainly, some patients in this cohort received fusion surgery who likely would not today at our centre. The majority of the spondylolisthesis patients received a fusion in this cohort as did many of the foraminal stenosis (vertical) patients. We agree that a less aggressive approach would be a more time and cost efficient treatment helping to reduce the overall wait list. As mentioned above, this concept was added to the concluding paragraph. This has also been added the limitations section with its potential to influence the studies generalizability.**

Major concerns:

1. Page 4, introduction, page 15: The authors should definitively include the (just recently) published eight-year results of the SPORT trial (Lurie JD, Spine 2015, 40(2):63-76, PMID 25569524), where the authors could show that patients with symptomatic spinal stenosis show diminishing benefits of surgery in as-treated analyses of the randomized group between 4 and 8 years, whereas outcomes in the observational group remained stable. Likewise, the authors should discuss and reference another landmark paper for these topic, published by Atlas et al (Atlas SJ, Spine 2005;30(8):936-43, PMID 15834339), where the authors showed that leg pain relief and greater back-related functional status continued to favour those initially receiving surgical treatment after 8 to 10 years (data from the maine lumbar spine study).

**We have altered the references and introduction as requested by the reviewer. The Lurie paper replaced the initial 2 year paper by Weinstein while leaving the 4 year paper referenced as well. The Atlas paper was added to the reference list.**

2. Page 6, 1st paragraph, line 13: The authors should specify how they assessed treatment satisfaction (e.g. with a four-fold Likert scale)?

**The following statement was added to the methods, as the last sentence under study methods: "Treatment satisfaction was initially assessed based on a 0-7 point score with 0 representing unsatisfied and 7 completely satisfied; but for the analysis a score of 6 or 7 represented satisfied."**

3. Page 7, 1st paragraph: As the authors present an extremely high fusion rate (81.9%), it would be important to know the degree of the spondylolisthesis from the 57.8% of patients with this pathology. Do the authors have these data? As spondylolisthesis per se is not an absolute indicator for fusion surgery, as many spondylolisthetic levels in elderly patients with advanced degenerative disc disease do not move in functional imaging (and therefore might be not symptomatic), it would be equally interesting if the authors could present data on the results of functional imaging (flexion/extension).

**As mentioned above we agree that the fusion rate is high and further data on the spondylolisthesis and functional imaging would be helpful in explaining it. This data was however not collected prospectively as it was not the purpose of the study. In retrospect, it would have been helpful in demonstrating the generalizability of our practice to public systems including our own.**

4. Page 7, 1st paragraph: Can the authors explain their extremely high rate of study participants undergoing decompression and instrumented fusion of 81.9%? Atlas et al. reported in the Mine Lumbar Spine Study (1-year outcomes of surgical and nonsurgical management of lumbar spinal stenosis), that only 3.7% (3/81) of the patients in the surgical group underwent primary fusion (Atlas SJ, Spine 1996;21(15):1787-94, PMID 8855463). Similarly, the SPORT trial presented that 3% in the randomized cohort (n=171) and 5% of the patients in the observational cohort (n=246) had instrumented fusion.

**Please see the comments above which pertain to our high fusion rate.**

5. Page 8, 2nd paragraph, line 8-20: See also minor concern 5: Also here, a multivariate

	<p>logistic regression analysis would be helpful in order to exclude that the instrumentation is responsible for these findings (as the patients in the short wait group were sicker, had more leg pain and had probably more listhesis and need for fusion surgery).</p> <p><b>Please see the response to your minor concern #5.</b></p> <p>6. Page 9, 2nd paragraph, line 48: The Canadian Spine Society 2005 judged the total wait of 24 weeks as an acceptable wait-time for elective spinal stenosis surgery. The reference is okay, but it has to be discussed. We should ask the patients who are suffering from pain, functional disability and impaired HRQoL, what an acceptable wait-time is, and not surgeons. The authors should discuss this issue.</p> <p><b>We believe this is a good suggestion and the following statement was added following the Canadian Spine Society reference: "Likely, one might expect a much shorter benchmark if asked to the patients who are suffering from the pain and disability associated with lumbar degenerative spinal stenosis?" We hope it addresses your concern.</b></p> <p>7. Page 10, 1st paragraph, line 1-3: This statement can also be explained by the underlying pathophysiology of LDSS, as it is usually a slow progressive disease.</p> <p><b>Yes, we agree that LDSS is a slow and progressive disease and could explain why the SF 36 does not detect change.</b></p> <p>8. Page 19, table 2: The authors should add length of surgery for the different types of surgery.</p> <p><b>Unfortunately, this data has not been collected so we are unable to add it to the table.</b></p> <p>Minor concerns:</p> <ol style="list-style-type: none"> <li>Page 4, introduction, line 8: chronic obstructive pulmonary disease (COPD)</li> <li>Page 4, 2nd paragraph, line 29: instead of Canadian society, the authors could also write: ... with the aging demographic of the population in industrialized countries, these wait time times... (as this is a general affect concerning all industrialized countries).</li> <li>Page 4, 2nd paragraph, line 32. Therefore, the primary objective was ...</li> </ol> <p><b>These changes have been added to the manuscript.</b></p> <p>4. Page 5, study measures, line 55: ..., the numeric-rating scale (NRS) for back and leg pain (the authors use the abbreviation later in the manuscript).</p> <p><b>Thank you but the editor has asked us to remove these abbreviations in the manuscript.</b></p> <p>5. Page 8, line 1: Could the authors perform a multivariate logistic regression analysis to exclude that the adjunct of instrumented fusion is the reason for the deep wound infection?</p> <p><b>This would certainly be an interesting discussion point, particularly for a spinal surgeon. However, we at this point have elected not to do so as we feel that the study was not designed to answer this potential correlation nor is the power appropriate to do so.</b></p> <p>6. Page 9, 2nd paragraph: The title of the paragraph could be changed to Discussion</p> <p>7. Page 9, 2nd paragraph, line 27: ... to surgery for LDSS patients was ... (abbreviation already introduced beforehand)</p> <p>8. Page 10, 2nd paragraph, line 41: (SF-36-MCS)</p> <p><b>Thank you for noticing the required changes. They will be made in accordance to the editor's directions. Please see editor comments above.</b></p>
<b>Reviewer 3</b>	Dr. James P. Waddell
Institution	St. Michael's Hospital, Orthopaedic Surgery
General comments (author response in bold)	<p>Page 3</p> <p>1. It is a supposition that the wait times will worsen with time – there are significant ongoing interventions to try and decrease wait times for all patients and therefore this is an inflammatory statement which really does not belong in a scientific publication.</p> <p><b>We have changed the statement to "wait times are long" so to not be inflammatory. Hopefully as you have mentioned these will decrease in the</b></p>

**future with the ongoing interventions which are now starting in Ontario for spine surgery specifically.**

2. What is the “null” hypothesis for your research?

**Our null hypothesis is that there is no correlation between wait time and outcome measures. This can be added to the manuscript if recommended.**

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3. Did you include any patients who declined surgical treatment – did you follow them 24-48 months to see if they improved, worsened or remained the same?

**We did follow the patients who were treated without surgery, however our efforts were not as successful as was those for the surgical patients as the follow-up and missing data was much poorer. Furthermore, we did not differentiate in our collected data between those patients who were not offered surgery and those that declined surgical treatment.**

Study Design

4. Did patients have the impression that if they agreed to participate in the study they would be seen sooner?

**We stated in the information letter mailed to the patient that “Your information will not be used to evaluate your specific situation, prior to seeing you at your first appointment” and we stated that the initial consultation appointment was already made and we would be seeing them for there consultation on that date. Therefore, we believe that the impression was not such. We were reviewed by our ethics department on that point as well.**

5. Presumably all these patients had to have an MRI and/or CT prior to their referral to your centre and that MRI or CT had to be positive for spinal stenosis. Is this your routine – do you request that all patients referred for consultation have these diagnostic images done prior to you seeing them?

**Yes, in almost all cases we do receive cross sectional imaging to assist in our screening of surgically appropriate candidates. For this study all patients had the cross sectional imaging at the time of referral. This is listed in the inclusion criteria.**

Results

6. This perhaps relates to my previous question but how could there be an improper spinal stenosis diagnosis referral in 24% of these patients?

**In most cases, although they had radiographic evidence of spinal stenosis they did not have the clinical symptoms. Often they would have symptoms of mechanical back pain but not of spinal stenosis. In some cases, the radiographic report over estimated the degree of stenosis and they did not have clinical symptoms. This is an interesting, although not surprising finding, which we have presented at a peer reviewed spine conference but not yet published.**

7. Also, in reference to my previous question I am not sure why non-operative management was not reviewed also.

**Although, this comparison would be interesting from a wait time perspective, we did not collect data completely enough for this patient cohort to allow for a valuable comparison. However, the SPORT trials have demonstrated that surgical treatment remains superior to conservative management of spinal stenosis patients. (Weinstein et al, Surgical versus nonsurgical therapy for lumbar spinal stenosis, NEJM 2008 and Spine 2010).**

8. Effect of wait length on preoperative function: I don't understand why people with short waits would have more disability than those with long waits unless you stratified these patients on the basis of their disability. From a random perspective there should not be any difference between these two groups and the fact that the short waits had greater disability suggests that they were operated on sooner because of their degree of disability – is that correct? Most patients with degenerative disease worsen over time if the disease is progressive and has not reached an end stage at the time of consultation. That would appear to be the case with this group.

**If you would please see the response to the editor major concerns point 4, as we believe the response to your question is the same.**

9. Effect of wait time on postoperative outcome: The short wait patients experience

	<p>greater gains in improvement but they were more disabled prior to surgery so one might reasonably anticipate that their gain would be greater if the overall gain from surgery is uniform.</p> <p><b>To help control for this potential co-founder we did adjust for the baseline outcome value. As well, our new analysis utilizing the Pearson correlation has suggested that worse disability was correlated with greater wait times for surgery. These have been discussed above and in the manuscript in the limitations section.</b></p> <p>Interpretation 10. On what basis was 24 weeks selected as a reasonable wait time for surgery? This appears to be an opinion published in a non-peer reviewed newsletter. Your data suggests that long wait times are not associated with worse outcomes. While I would strongly support the suggestion that earlier surgery is better for patients with significant orthopaedic disability regardless of etiology your data does not support a special case being made for the spine patient.</p> <p><b>This is a valid criticism. We also had originally included this reference to a reasonable wait time which was cut during final manuscript preparation: "Access to Care, the service delivery agency for the Ontario Ministry of Health and Long-Term Care's Wait times strategy, has set the access target for patients requiring a lumbar laminectomy to be between 8 -26 weeks depending on how one defines the severity of the symptoms and impact on function." However, we are unsure how this bench mark was determined, due to patient heterogeneity that benchmark is a range across two wait time categories, and it only represents a small portion of this studies cohort receiving only a laminectomy. Although the survey is not peer reviewed it is determined by "experts" in field. We have added this statement in hopes of addressing your concern: "A survey of the Canadian Spine Society (completed by 86% of the membership but published in a non peer reviewed newsletter) performed in 2005 judged the total wait of 24 weeks as an acceptable wait-time for elective spinal stenosis surgery [17]"</b></p>
Reviewer 4	Nicholas M. Desy,
Institution	University of Calgary, Calgary, Alta.
General comments (author response in bold)	<p>This manuscript is an important article regarding the state of wait times for spine surgery in Canada. It is clear that wait times for several surgeries are too long and need to be studied and addressed appropriately. The strengths of this paper are that it is prospective and includes a large study period (2006 to 2010). It is well written and I believe this article is appropriate to be published in a Canadian medical journal with a few modifications.</p> <p>1) The title and conclusion should be modified to reflect that the longer wait times lead to a delayed improvement compared to the shorter wait times as both groups had equal outcomes at 24 months.</p> <p><b>This suggestion has been incorporated into the title and conclusion of our manuscript.</b></p> <p>2) Introduction, 2nd sentence: should type out the words for COPD</p> <p><b>We have addressed this change.</b></p> <p>3) Methods, Study design: Were any surgeries triaged differently? For example, were patients triaged into the shorter wait time group because they had more severe disease? And did the longer wait time group have less severe disease? It would be worthwhile to include a sentence to say that patients were not triaged according to disease severity if that is in fact true, even though in the discussion you state the a potential bias exists whereby surgeons may have triaged according to symptoms. This should be discussed more. Is it possible that the shorter wait time group improved quicker because they had more severe disease?</p> <p><b>Thank you for your comments. There was no defined attempt to triage patients based on the severity of the disease. This has also been questioned by other reviewers. As mentioned above, we have addressed the finding in our discussion and limitation section. Please see point 4 under the response to editors' comments.</b></p> <p>4) Results: It would be worthwhile to include a sentence or two to say that both groups had an equal complication rate, an equal re-operation rate and an equal mortality rate and refer the reader to Table 2.</p>

**Thank you. This suggestion has been added to the manuscript under “Baseline and treatment characteristics compared between groups”**

5) Interpretation: It would be nice to see some discussion as to what your thoughts are on why the 2 groups then ended up having similar outcomes at 2 years. Is it because that the longer wait time group had longer symptoms and therefore took longer to recover and improve following surgery?

**Yes, we believe that is the case; that it is the degree of deconditioning associated with the spinal stenosis disability which leads to a longer recovery period but not ultimate outcome. We hope that this sentence found in the discussion is sufficient in addressing your comment “Although, we demonstrated significant improvement in both wait time groups, the delayed recovery of function and mental health demonstrated in patients waiting longer likely reflects the advanced deconditioning that occurred secondary to prolonged immobility from spinal stenosis”.**