Increasing reoperation rates and inferior outcome with prolonged symptom duration in lumbar disc herniation surgery
A prospective cohort study
Støttrup, Christian C; Andresen, Andreas K; Carreon, Leah; Andersen, Mikkel Ø

Published in:
The Spine Journal

DOI:
10.1016/j.spinee.2019.04.001

Publication date:
2019

Document version
Accepted manuscript

Document license
CC BY-NC-ND

Citation for published version (APA):

Terms of use
This work is brought to you by the University of Southern Denmark through the SDU Research Portal. Unless otherwise specified it has been shared according to the terms for self-archiving. If no other license is stated, these terms apply:

• You may download this work for personal use only.
• You may not further distribute the material or use it for any profit-making activity or commercial gain
• You may freely distribute the URL identifying this open access version

If you believe that this document breaches copyright please contact us providing details and we will investigate your claim. Please direct all enquiries to puresupport@bib.sdu.dk

Download date: 27. Sep. 2020
Increasing reoperation rates and inferior outcome with prolonged symptom duration in lumbar disc herniation surgery - A prospective cohort study

Christian C. Støttrup MD PhD student, Andreas K. Andresen MD PhD student, Leah Carreon MD Affiliate Professor, Mikkel Ø. Andersen MD Associate Professor

PII: S1529-9430(19)30120-2
DOI: https://doi.org/10.1016/j.spinee.2019.04.001
Reference: SPINEE 57890

To appear in: The Spine Journal

Received date: 16 January 2019
Revised date: 4 April 2019
Accepted date: 4 April 2019

Please cite this article as: Christian C. Støttrup MD PhD student, Andreas K. Andresen MD PhD student, Leah Carreon MD Affiliate Professor, Mikkel Ø. Andersen MD Associate Professor, Increasing reoperation rates and inferior outcome with prolonged symptom duration in lumbar disc herniation surgery - A prospective cohort study, The Spine Journal (2019), doi: https://doi.org/10.1016/j.spinee.2019.04.001

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.
Increasing reoperation rates and inferior outcome with prolonged symptom duration in lumbar disc herniation surgery - A prospective cohort study

Christian C. Støttrup\textsuperscript{1,2} – MD, PhD student; Christian.Stottrup@rsyd.dk
Andreas K. Andresen\textsuperscript{1,2} – MD, PhD student; Andreas.Andresen@rsyd.dk
Leah Carreon\textsuperscript{1,2} – MD, Affiliate Professor; Leah.Carreon@rsyd.dk
Mikkel Ø. Andersen\textsuperscript{1,2} – MD, Associate Professor; Mikkel.Andersen2@rsyd.dk

Affiliations:
1. Center for Spine Surgery and Research, Sygehus Lillebælt, Middelfart, Danmark – Østre Hougvej 55, 5500 Middelfart
2. Institut for Regional Sundhedsforskning, Syddansk Universitet, Danmark – Winsløwparken 19, 3. 5000 Odense C

Corresponding author:
Christian C. Støttrup
Email; Christian.Stottrup@rsyd.dk
Postal; Carl Bagger Allé 87 – 5250 Odense SV, Denmark
Telephone: +45 2966 0602

Background Context: Lumbar disc herniation (LDH) is associated with great morbidity and significant socioeconomic impact in many parts of the world. Studies have shown that most LDH can be treated effectively with nonoperative management. However, for some patients in whom pain and disability are unacceptable, surgical intervention provides effective clinical relief. Currently there is little consensus in the medical community on the timing of surgery for patients suffering from radicular pain due to LDH. Multiple studies suggest that prolonged symptom duration adversely affects clinical outcome.
Purpose: The aim of this study is to evaluate if prolonged symptom duration is correlated with less favorable outcome following surgery for LDH.

Study Design/Setting: Consecutive series of patients from a single-center, multi-surgeon, tertiary spine practice.

Patient Sample: Consecutive series of patients who underwent surgery for lumbar disc herniation.

Outcome Measures: Oswestry Disability Index (ODI), EuroQol-5D (EQ-5D) and Visual Analog Scale (VAS) for back and leg pain (0 to 100).

Methods: Patients with a first episode LDH were included. Data were prospectively collected in DaneSpine, the Danish National Spine Registry. Subjects were divided into three groups based on their preoperative self-reported duration of leg pain: <3-months, 3-12-months and >12-months. Associations between patient-reported outcomes (PROs), perioperative complications and duration of symptoms were evaluated. Statistical significance level was set at p-value <0.01.

Results: There were 2,144 patients included in the study, with complete one-year follow-up on 1,694 patients (79%) and a reoperation rate of 8.4%. Incidence of surgical complications, specifically dural tears, was higher with increasing duration of leg pain, however, this did not reach statistical significance (p=0.039). Prolonged preoperative symptoms adversely influenced all PROs (EQ-5D, ODI, VAS) one year after surgery (p=0.001). Furthermore, reoperation rates increased with longer duration of preoperative symptoms. A statistically significant trend (p=0.008) of increasing incidence of reoperation was found with increasing length of symptom duration.

Conclusions: Delayed surgical intervention results in inferior outcomes and increased reoperation rates. Patients who had surgery within the first 3 months of leg pain achieved significantly better outcome one year after surgery when compared to the other groups.
Keywords: Herniated disc; discectomy; duration of symptoms; PROs, patient reported outcomes; complications

Introduction

Lumbar disc herniation (LDH) is associated with great morbidity and significant socioeconomic impact in many parts of the world [1-3]. Based on data from The Danish National Health Authority, 1-3% of the Danish population reported radicular pain due to LDH [4]. Approximately 2,000 Danes undergo operative treatment for this indication annually [5].

The majority of patients suffering from symptoms due to LDH can be treated effectively with non-surgical management. However, in some patients with severe pain and disability or whose recovery is unacceptably slow, surgical intervention can provide effective clinical relief [6-8].

Danish national clinical guidelines recommend that patients with LDH without neurologic deficits or intractable pain are managed with nonoperative treatment for up to 12 weeks before they are considered surgical candidates [9]. Currently there is little consensus in the medical community on the timing of surgery for patients suffering from radicular pain due to LDH.

Depending on the outcome measure used, 10-40% of patients report unsatisfactory results after lumbar disc surgery [10-12]. Many previous cohort studies have reported inferior results and adverse effects of prolonged preoperative symptoms [13-16]. Contrary to these, some randomized controlled trials (RCT) report no inferiority in outcome of patients with prolonged symptoms [10, 17, 18]. Systematic reviews on the subject find the same adverse effects as reported by most cohort studies [19]. Despite the relatively vast amount of literature available, no studies seem to have found the optimal time window to intervene and perform surgical treatment. Also, many of previously mentioned cohort studies suffer from relatively small patient populations, leading to uncertain results and conclusions. The largest previous study covering the subject is the SPORT
study, which found inferior outcomes with prolonged symptom duration [16, 20]. The aim of the current study is to investigate if prolonged symptom duration is correlated with less favorable outcome following surgery for LDH.

Materials and methods
The current study is a retrospective cohort study using prospectively collected data from the Danish national surgical spine database (DaneSpine) [21]. DaneSpine collects patient reported outcomes (PROs) using pre- and postoperative questionnaires, completed before surgery and at 1, 2, 5 and 10 years postoperatively. The preoperative data are entirely patient reported, including age, sex, height, weight, duration of back and leg pain prior to surgery, back and leg pain on a 0-100 VAS scale [22], health-related quality of life as measured by the EuroQol-5D (EQ-5D) [23, 24], and spine-related disability as measured by the Oswestry Disability Index (ODI) [25, 26]. Duration of symptoms are collected as categorical values of <3-months, 3-12 months and >12-months. Surgical data are entered by the surgeon at the time of discharge from hospital and include diagnosis, procedure, antibiotic prophylaxis and occurrence of complications.

At follow-up, the same data registered at baseline is collected. At 1-year follow-up, patients are asked about their attitude towards the surgical outcome, with the options being: satisfied, neither satisfied nor dissatisfied and dissatisfied.

All patients who had surgery at the Center for Spine Surgery and Research, Middelfart Hospital, for a lumbar disc herniation with radicular pain from June 1, 2010 to May 1, 2017 were included. They had all followed the Danish national guidelines for treatment of patients with lumbar disc herniation [27], having received physiotherapy or other relevant exercise therapy before being referred from primary care to a spine specialist. None of the patients had cauda equina syndrome or severe
neurologic deficits at the time of surgery. All had a magnetic resonance imaging (MRI) that demonstrated lumbar disc herniation, with the level and side corresponding with clinical symptoms. Baseline questionnaires were filled out no more than 1 week prior to surgery. Patients underwent discectomy by a senior consultant employed at the facility. Patients who had previous spine surgery were excluded from further analysis. Subjects were divided into three groups based on their self-reported duration of leg pain prior to enrollment into the registry: <3-months, 3-12 months and >12-months.

**Patient and Public Involvement**

The current study was done without patient involvement. As data originates from a database, it was not found feasible to involve patients in the study design nor the outcome measures, as these could not be changes. Patients were not invited to contribute to the writing or editing of this study for readability or accuracy.

**Statistics**

All statistical analysis was done using STATA 15 (StataCorp., College Station, TX). Categorical data are presented by frequencies and related percentages; continuous data are displayed by means of descriptive statistics (mean, confidence interval, number of observations). Continuous variables were analyzed for significant difference between the three groups using analysis of variance (ANOVA), categorical variables using Fisher’s exact test. Continuous variables found to change orderly across groups were analyzed using a Wilcoxon-type test for trend as developed by Cuzick (1985). Significance level was set at p-value <0.01. Adjustment for potential confounders was done using a forward stepwise regression analysis with an inclusion p-value of 0.10 and a confounding level of 15%.
Results

During the nearly 7 years of inclusion, a total of 2,586 patients had surgery for a lumbar disc herniation causing radiculopathy. Of these, 442 (17.1%) had a history of previous spine surgery and were excluded from further analysis. Of the remaining 2,144 patients, 1-year follow-up data was available on 1,694 (79.0%). Most patients had surgery within one year of radicular leg-pain onset, 613 (28.6%) with less than 3-months’ history of leg-pain, 1,095 (51.1%) with 3-12 months and 436 (20.3%) with more than 12 months.

Mean age for the entire cohort was 46.8 years and statistics indicating significant differences among groups, however only of 1-3 years. There were more males in the <3-month duration group (59.7% vs 52.2% vs 52.5%), with statistics indicating a significant difference in gender distribution. About one-third of the entire cohort (699, 32.7%) were active smokers at the time of surgery, and there was no statistically significant difference in the groups with longer history of leg pain (p=0.015).

There was no difference in pain medication use or comorbidities among the three groups (Table 1). When asked about welfare payments, 22.9% (393) reported to receive welfare support, with no difference among the three groups.

Incidence of surgical complications, specifically dural tears, was higher with increasing duration of leg pain, however, this did not reach statistical significance (Table 2). Post-operative complications were diverse (Table 2) with hematoma being the most common but no significant differences found among groups.

As of December 1st, 2018, 179 (8.4%) patients had undergone reoperation within one year of primary surgery, 132 cases underwent repeat discectomy, 16 received additional decompression, 16
had a hematoma removed, three underwent drainage of infection, and 12 received other non-specified surgery. A statistically significant trend of increasing incidence of reoperation was found with increasing length of symptom duration. Approximately 17% of all patients who underwent reoperation did so during their primary admission.

All groups had a significant improvement in EQ-5D, ODI, VAS leg pain and VAS back pain one year after surgery compared to baseline (Table 3). However, statistically significantly greater improvement in EQ-5D and ODI was seen in the <3-month pain duration group compared to the two other groups. In contrast, statistically significantly less improvement in VAS leg and VAS back was seen in the >12-month pain duration group compared to the two other groups (figure 1).

All of the above outcome variables have been tested for potential confounding with regards to age, gender, BMI, smoking status, duration of backpain and whether the patient received social welfare or not (data not shown). Longer duration of backpain had a borderline significant negative effect on the outcome (p = 0.022) and patients receiving welfare at the time of surgery also showed better outcome at one year compared to those not receiving welfare (p <0.001). Smoking shows no significant effect on surgical outcome (p = 0.038). Age and BMI was not included in the model as neither significance level nor confounding level was above the set limits.

**Discussion**

This retrospective cohort study divides patients surgically treated for LDH into groups dependent on the duration of their preoperative symptoms. The present study found worse self-reported outcomes in patients with duration of preoperative leg pain of >3 months. Furthermore, a strong trend of increasing risk of reoperation was found with increasing duration of preoperative leg pain.
Previous literature as well as the present study shows that surgery for LDH is an effective treatment regardless of symptom duration [15]. Like previous studies, the current study population are patients in their forties with a slight majority of men [10, 17, 20]. The current study comprises more smokers than found in the general Danish population (i.e. 32.7% vs. 23%) [28]. Overall, this study’s population seems comparable to that of earlier studies on symptom duration and outcome after surgery for LDH.

As shown in both Table 3 and Figure 1, longer preoperative duration of symptoms adversely affects clinical outcome in both EQ-5D, ODI and VAS leg pain. All groups reached clinically relevant improvements in the before mentioned parameters. The present study found a total postoperative complications risk of approximately 2%. The risk of reoperation increased with longer symptom duration and a trend analysis indicates that the timing of surgery is important, not only because of the poorer outcome, but also due to the risk of reoperation. The higher reoperation rates might also be affected by a lower surgeon and patient threshold in patients with longer preoperative leg pain if outcome is worse than expected. A subgroup analysis showed no difference in reoperation rates during primary admission.

Previous literature has found similar results, however with inconsistency regarding the timing of surgery. Nygaard et al. has previously found that surgical outcome is more favorable in patients with less than 6-months preoperative symptoms, when compared to both 6-12 months and >12-months of preoperative symptoms [13]. In a subsequent cohort study by the same lead author, patients with more than 8 months of preoperative leg pain were found to have less favorable outcome [14]. Both studies featured a relatively low number of patients, 93 and 132 respectively.
In 2015, Pitsika et al. [15] found statistically significant improvement in ODI regardless of preoperative duration, and advocated that surgery is indicated even after 1-2 years of symptoms. However, they also found a downward trend of improvement in ODI with increasing duration of symptoms. The study was a single surgeon sample, with follow-up on 97 patients (90.7%). Thus, the sample size is relatively small, leading to small subgroups for further analysis. In a larger study, based on the SPORT cohort, prolonged duration of symptoms was also found to have adverse effects on outcome, following both surgical and non-surgical treatment [16].

The major limitation of the present study is the retrospective analysis of data from a database and subsequent lack of full 1-year follow-up on all patients. A previous drop-out analysis on a similar population found that non-responders often were younger males, who were back at work and with better self-reported outcomes [29]. Thus, lack of complete follow-up is not likely to negatively affect results. Another major limitation is the fixed categorical intervals of duration of leg pain prior to surgery. Previous literature has suggested the “golden cut-off” timepoint to be somewhere around 6 months. The current intervals were chosen as a result of the data available in DaneSpine, however future studies should aim to measure duration of preoperative symptoms as continuous variables, thereby allowing for more detailed analysis to be performed.

Being a publicly funded institution, there are no economic barriers to undergo surgery at any time, and no bias in timing of surgery is instituted by insurance companies in the present study population. The study includes a large population of 2,144 consecutive patients, well dispersed in subgroups and no significant preoperative demographic differences. Patients are included consecutively, and all data collected prospectively at a single center for spine surgery.

All outcome variables were tested for potential confounders, and analysis showed borderline significant correlation with duration of backpain. This is, however, most likely due to collinearity
with duration of leg pain as one is rarely present in complete absence of the other. If patients received social welfare at the time of surgery, they also had greater improvement in the beforementioned outcome variables at one-year follow-up. This might not be due to confounding, as an unsettled social welfare case would most likely lead to a surgical delay. However, as delayed surgery has negative correlation with outcome, it would be more plausible that social welfare status is simply an isolated predictor. As published by Andersen et al., patients with prolonged sick leave have significantly lower return to work rate, compared to those with shorter duration sick leave prior to surgery [30]. This might also explain the poorer outcome in especially life quality at one-year follow-up, as patients are highly affected by their ability to take part in society i.e. work. Smoking, BMI and age could all have been relevant confounders, or even mediators, but no such relation was found.

The causal relation for prolonged duration of leg pain to cause inferior outcome is not immediately apparent. One might speculate in both psychological and somatic explanations. Previous literature suggests that prolonged sick leave, which would be more likely with prolonged symptom duration, leads to a lower chance of speedy return-to-work and therefore also a state of well-being with regards to serving society and a more purposeful living. There might also be a more biological relation both in respect of inflammatory processes and the tissue's ability to repair/regenerate, or the brain's more complex perception of pain and modulation of such. We know that surgery leaves a large immunological inflammatory response in the tissue, leading to great remodulation. If a disc herniation creates a similar response, and it persists for a prolonged duration of time, it might cause the surrounding tissue and structures to be less susceptible to recovery after the removal of the herniation. As a result, the pain may persist, thereby giving the patient an inferior surgical outcome.

We have little certainty and knowledge about how the brain and spinal cord receives, modulates and
translates pain, however science suggest that pain is very subjective and that the human brain has
great power with regards to its modulation. One might speculate that with prolonged pain stimuli,
i.e. that of a persistent disc herniation, the brains modulation of pain might change, and of such the
conscious perception of pain would also change. This might in turn lead to a more permanent state,
in which, the conscious part of the brain would perceive pain, despite the fact, that the painful
stimulus has been removed. Such hypothesis has previously been suggested and tested, but no clear
evidence or consensus has been reached [31].

**Conclusion**

In line with previous literature, the present study shows, that prolonged preoperative symptom
duration adversely affects clinical outcomes in patients with LDH. Despite present data suggesting
that the greatest treatment effect is achieved with the shortest duration of preoperative symptoms,
the optimal timing of surgical treatment in LDH may be found in the interval of 3-12 months.
Furthermore, the present study finds a greater risk of reoperation with longer duration of
preoperative symptoms.
References


10.1007/s00586-010-1603-7


15. Pitsika M, Thomas E, Shaheen S, Sharma H. Does the duration of symptoms influence outcome in patients with sciatica undergoing micro-discectomy and decompressions? The


Figure Legends

1. Change in PROs at 1-year follow-up (mean; CI)
Table 1 - Characteristics of the subgroup populations

<table>
<thead>
<tr>
<th></th>
<th>All (n = 2,144)</th>
<th>&lt;3 months (n = 613)</th>
<th>3-12 months (n = 1,095)</th>
<th>&gt;12 months (n = 436)</th>
<th>p-value of difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (95 % CI)</td>
<td>46.8</td>
<td>48.1 (47.1)</td>
<td>46.7 (45.8 ; 47.5)</td>
<td>45.2 (43.8 ; 46.6)</td>
<td>0.003</td>
</tr>
<tr>
<td>Males, n (%)</td>
<td>1,167</td>
<td>366</td>
<td>572 (52.2)</td>
<td>229 (52.5)</td>
<td>0.008</td>
</tr>
<tr>
<td>Smokers, n (%)</td>
<td>699</td>
<td>173</td>
<td>369 (33.8)</td>
<td>157 (36.2)</td>
<td>0.015</td>
</tr>
<tr>
<td>Pain medication, n (%)</td>
<td>1,939</td>
<td>556</td>
<td>1,001 (91.6)</td>
<td>382 (88.0)</td>
<td>0.101</td>
</tr>
<tr>
<td>Comorbidities, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heart disease</td>
<td>16 (0.8)</td>
<td>2 (0.3)</td>
<td>12 (1.1)</td>
<td>2 (0.5)</td>
<td>0.181</td>
</tr>
<tr>
<td>Neurological disease</td>
<td>31 (1.5)</td>
<td>9 (1.5)</td>
<td>12 (1.1)</td>
<td>10 (2.3)</td>
<td>0.193</td>
</tr>
<tr>
<td>Cancer</td>
<td>13 (0.6)</td>
<td>2 (0.3)</td>
<td>9 (0.8)</td>
<td>2 (0.5)</td>
<td>0.468</td>
</tr>
<tr>
<td>Other, affecting</td>
<td>74 (3.5)</td>
<td>17 (2.8)</td>
<td>35 (3.2)</td>
<td>22 (5.1)</td>
<td>0.122</td>
</tr>
<tr>
<td></td>
<td>&lt;3 months (n = 613)</td>
<td>3-12 months (n = 1.095)</td>
<td>&gt;12 months (n = 436)</td>
<td>p-value of trend</td>
<td></td>
</tr>
<tr>
<td>--------------------------</td>
<td>---------------------</td>
<td>-------------------------</td>
<td>----------------------</td>
<td>-----------------</td>
<td></td>
</tr>
<tr>
<td><strong>All (n = 2.144)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Surgical complication, n (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dural tear</td>
<td>11 (1.8)</td>
<td>32 (2.9)</td>
<td>17 (3.9)</td>
<td>0.039</td>
<td></td>
</tr>
<tr>
<td>Vascular damage</td>
<td>2 (0.1)</td>
<td>-</td>
<td>1 (0.1)</td>
<td>1 (0.2)</td>
<td>0.235</td>
</tr>
<tr>
<td>Postoperative complications, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Trombosis</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Emboli</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

Table 2 - Per- and postoperative complications
<table>
<thead>
<tr>
<th>Condition</th>
<th>n</th>
<th>%</th>
<th>n</th>
<th>%</th>
<th>n</th>
<th>%</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urinary tract infection</td>
<td>1 (0.2)</td>
<td>4 (0.4)</td>
<td>2 (0.5)</td>
<td>0.393</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urin retention</td>
<td>5 (0.2)</td>
<td>3 (0.3)</td>
<td>2 (0.5)</td>
<td>0.121</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematoma</td>
<td>16 (0.8)</td>
<td>4 (0.7)</td>
<td>6 (0.6)</td>
<td>6 (1.6)</td>
<td>0.233</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wound infection</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Nerveroot lesion</td>
<td>6 (0.3)</td>
<td>1 (0.2)</td>
<td>4 (0.4)</td>
<td>1 (0.2)</td>
<td>0.775</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cauda Equina</td>
<td>5 (0.2)</td>
<td>1 (0.1)</td>
<td>3 (0.7)</td>
<td>0.121</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>8 (0.4)</td>
<td>3 (0.5)</td>
<td>5 (0.5)</td>
<td>-</td>
<td>0.229</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reoperation, n (%)</td>
<td>179</td>
<td>38 (6.2)</td>
<td>94 (8.6)</td>
<td>47 (10.8)</td>
<td>0.008</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within 12 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>During primary admission</td>
<td>30</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.313</td>
</tr>
<tr>
<td>(% of reoperated)</td>
<td></td>
<td>6 (15.8)</td>
<td>13 (14.0)</td>
<td>11 (23.4)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 3 - 1-year PROM follow-up

<table>
<thead>
<tr>
<th></th>
<th>All (n = 2,144)</th>
<th>&lt;3 months (n = 613)</th>
<th>3-12 months (n = 1,095)</th>
<th>&gt;12 months (n = 436)</th>
<th>p-value of trend</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EQ-5D; mean</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative</td>
<td>0.45 [0.44;0.46]</td>
<td>0.39 [0.37;0.42]</td>
<td>0.47 [0.45;0.48]</td>
<td>0.48 [0.45;0.50]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Post-operative</td>
<td>0.77 [0.76;0.78]</td>
<td>0.78 [0.76;0.80]</td>
<td>0.77 [0.76;0.79]</td>
<td>0.72 [0.70;0.75]</td>
<td>0.001</td>
</tr>
<tr>
<td>Difference</td>
<td>0.31 [0.30;0.33]</td>
<td>0.39 [0.35;0.42]</td>
<td>0.30 [0.28;0.32]</td>
<td>0.24 [0.20;0.27]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>ODI; mean</strong></td>
<td>47.76 [46.97;48.55]</td>
<td>52.14 [50.47;53.80]</td>
<td>46.55 [45.54;47.56]</td>
<td>44.69 [43.05;46.32]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Post-operative</td>
<td>26.72 [25.62;27.83]</td>
<td>32.87 [30.71;35.03]</td>
<td>25.96 [24.49;27.43]</td>
<td>19.68 [17.41;21.94]</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
### VAS leg; mean (95% CI)

<table>
<thead>
<tr>
<th></th>
<th>Pre-operative</th>
<th>Post-operative</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean (95%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-operative</td>
<td>67.76 [66.74;68.78]</td>
<td>24.39 [23.07;25.72]</td>
<td>43.16 [41.53;44.80]</td>
</tr>
<tr>
<td></td>
<td>67.92 [65.85;69.99]</td>
<td>23.05 [20.72;25.37]</td>
<td>45.92 [41.86;47.99]</td>
</tr>
<tr>
<td></td>
<td>67.94 [66.58;69.29]</td>
<td>22.51 [20.72;24.30]</td>
<td>45.10 [42.87;47.34]</td>
</tr>
<tr>
<td></td>
<td>67.10 [64.87;69.33]</td>
<td>31.51 [28.17;34.85]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>p = 0.138</td>
<td>p = 0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

### VAS back; mean (95% CI)

<table>
<thead>
<tr>
<th></th>
<th>Pre-operative</th>
<th>Post-operative</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>mean (95%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>43.75 [41.39;46.12]</td>
<td>23.88 [21.67;26.10]</td>
<td>19.88 [17.00;22.77]</td>
</tr>
<tr>
<td></td>
<td>48.82 [47.11;50.52]</td>
<td>25.99 [24.21;27.78]</td>
<td>21.32 [19.13;23.52]</td>
</tr>
<tr>
<td></td>
<td>52.41 [49.69;55.12]</td>
<td>34.03 [30.73;37.32]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>p &lt; 0.001</td>
<td>p &lt; 0.001</td>
<td>0.436</td>
</tr>
</tbody>
</table>