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Disability, Health-Related Quality of Life and Mortality in Lumbar Spine Fusion Patients—A 5-Year Follow-Up and Comparison With a Population Sample

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Abstract

Study Design: Prospective follow-up study.

Objectives: We aimed to assess the effect of lumbar spine fusion (LSF) on disability, health-related quality of life and mortality in a 5-year follow-up, and to compare these results with the general population.

Methods: 523 consecutive LSF operations were included in a prospective follow-up. Disability was assessed by the Oswestry Disability Index (ODI), and HRQoL by the 36-item Short Form (SF-36) questionnaire using the physical and mental summary scores (PCS and MCS). The patients were compared with an age-, sex-, and residential area matched general population cohort.

Results: The preoperative ODI in the patients was 46 (SD 16), and the change at 5 years was −26 (95% CI: −24 to −28), $p < 0.001$. In the population, ODI (baseline 13, SD 16) remained unchanged. The preoperative PCS in the patients was 27 (SD 7), in the population 45 (SD 11), and the increase in the patients at 5 years was 8 (95% CI: 7 to 9), $p < 0.001$. The patients did not reach the population in ODI or PCS. The baseline MCS in the patients was 47 (SD 13), and the change at 5 years 4 (95% CI: 3 to 7), $p < 0.001$. MCS of the females reached the population at 5-year follow-up. When analyzing short and long fusions separately, comparable changes were seen in both subgroups. There was no difference in mortality between the patients (3.4%) and the population (4.8%), hazard ratio (HR) 0.86.

Conclusions: Although the patients who had undergone LSF benefited from surgery still at 5 years, they never reached the physical level of the population.

Keywords

lumbar spinal fusion (LSF), outcome, longer follow-up, population sample, mortality

Introduction

The incidence of lumbar spine fusion (LSF) surgery has increased markedly in the western countries during the past decades.[1] Spinal pathologies leading to LSF are heterogeneous.[2] Common indications for fusion are degenerative and isthmic spondylolisthesis and deformity corrections. The efficacy of the fusion surgery is established in several indications.[3,4] Some indications are more controversial: some recent studies question the need of combining fusion to decompression in degenerative spondylolisthesis,[5,6] and LSF in degenerative disc disease (DDD) is probably not reasonable in most cases.[7]

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The knowledge of the long-term consequences of LSF is important. On one hand, fusion surgery requires heavy hospital costs and long recovery periods from the patient. On the other hand, spinal disorders behind the surgery are often severely disabling. The health burden of lumbar spinal stenosis on health-related quality of life (HRQoL) is reported to equal to diabetes, heart disease, arthritis or stroke.[8]

We have previously shown disability and HRQoL in patients undergoing LSF to improve in several spinal disorders in a 2-year follow-up.[9] Many LSF reports with longer follow-up focus on specific diagnoses or selected patient material or compare interventions, such as operative and conservative treatment.[3,7] To our knowledge, no one has previously published a health-care district based study evaluating the disability, HRQoL and mortality among LSF patients in a 5-year follow-up. The aim of the present study is to assess the changes from LSF to disability, HRQoL and mortality in a prospective, 5-year follow-up of non-selected patients. We also compare the results with a general population sample.

Material and Methods

Finland has a national health insurance system, and therefore a particular hospital mainly covers the population of a particular area. Tampere University Hospital and Central Finland Health Care District are 2 public units that exclusively perform spinal fusion surgery in Pirkanmaa and Central Finland districts covering together around 775 000 inhabitants. Since 2008 all patients undergoing non-urgent LSF surgery have been invited to a prospective follow-up study. Surgeons filled up the data in their daily practice and patients answered the questionnaires at strict time-points pre- and post-operatively. All patients signed a written consent, and ethical committees of both hospitals approved the study.

The data of 523 consecutive patients was available for the present study. The fusion indications were as follows: degenerative spondylolisthesis (48%), isthmic spondylolisthesis (15%), spinal stenosis (13%), postoperative conditions (9%), degenerative disc disease (8%), degenerative scoliosis (6%), others, like posttraumatic conditions and posttraumatic instability (1%). All patients underwent posterolateral instrumented fusion with or without posterior interbody fusion (PLIF/TLIF) combined with necessary decompression. Out of all LSF operations, 357 (68%) were short fusions (1 or 2 levels), while 166 (32%) of all fusions were long (over 2 levels).

The LSF patient cohort was compared with a general population sample (n = 682) matched by age, sex and residential area. Statistics Finland performed the sampling and collected the data from the same cohort in 2010 and 2015.[10] Data was collected twice to eliminate the possible effect of aging. The mortality data was extracted from Official Statistics of Finland.[10]

The main outcome measures were the Oswestry Disability Index (ODI) for disability and the Short-Form-36 Questionnaire (SF-36) for Health-Related Quality of Life (HRQoL). The ODI is one of most widely used back-specific disability measurement tools in both clinical work and research.[11] The ODI score represents the percentage the patient achieved of the maximum number of points. According to the original publication, the scores are grouped into 5 categories: 0–20 minimal, 20–40 moderate, 40–60 severe disability; 60–80 crippled and 80–100 indicates that the patient is either bed-bound or exaggerating his or her symptoms.[12] The Finnish validated version 2.0 of the ODI was used in this study.[13] The SF-36 is a generic patient-assessed health outcome measure for the health-related quality of life reflecting patients' health state and wellbeing.[9] In the analysis the 8 dimensions of the SF-36 score were aggregated into 2 summary measures. The Physical Component Summary Score (PCS) consists of Physical Functioning, Role Physical, Bodily Pain and General Health dimensions, and the Mental Component Summary Score (MCS) consists of Mental Health, Vitality, Social Functioning and Role-Emotional dimensions.

Statistics

Data is presented as means with standard deviation (SD) and as counts with percentages. Statistical comparisons between the population and the patients were made using t test for continuous variables and Pearson's Chi-Square (χ^2) for categorical variables. Repeated measures in changes in the physical and mental (MCS) component summary scores between groups were analyzed using mixed-effects models, with an unstructured covariance structure (Kenward-Roger method to calculate the degrees of freedom). As the use of mixed models allows for analysis of unbalanced datasets without imputation, we analyzed all available data, using the full analysis set. Cumulative mortality was estimated using Kaplan–Meier survival analysis and compared between groups with the log-rank test. We used Cox proportional hazards model to calculate the adjusted hazard ratios (HR) and 95% confidence intervals for death. The normality of variables was evaluated graphically and using the Shapiro–Wilk W test. Stata 15.1, StataCorp LP (College Station, TX, USA) statistical package was used for the analyses.

Results

The patient demographic and clinical characteristics are shown in Table 1. In a total of 523 patients (68% females), the mean age at surgery was 61 years (SD 12). In the general population (n = 682) (67% females) the mean age was 64 years (SD 12). The Body Mass Index (BMI) was statistically higher among the patients than in the general population, although both groups were by mean classified over-weighted according to the WHO classification (World Health Organization).[14] Cardiac and rheumatoid co-morbidities were overrepresented among the patients, whereas psychiatric disorders, other musculoskeletal disorders and cancer were more frequent in the population. 23% of the control population reported to have spinal problems.

Table 1. Baseline Demographic and Clinical Characteristics of the Patients and the Population.

	Population, n = 682	Patients, n = 523	*P* value
Women, n (%)	454 (67)	357 (68)	0.53
Age, mean y (SD)	64 (12)	61 (12)	<0.001
BMI, mean (SD)	26.9 (4.4)	28.6 (4.6)	<0.001
Co-morbidities, n (%)			
Cardiological	278 (41)	263 (50)	<0.001
Respiratory	66 (10)	49 (9)	0.86
Neurological	36 (5)	20 (4)	0.23
Rheumatoid	32 (5)	49 (9)	<0.001
Diabetes	87 (13)	57 (11)	0.32
Psychiatric	25 (4)	9 (2)	0.043
Musculosceletal	55 (8)	20 (4)	0.003
Cancer	14 (2)	3 (1)	0.031
Smoking, n (%)	88 (13)	82 (16)	0.20
Education, mean y (SD)	11.6 (4.0)	11.5 (2.7)	0.56

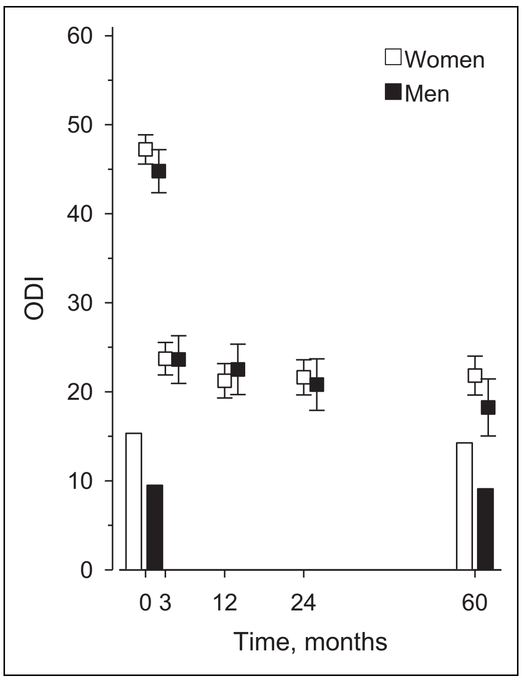

Figure 1. The mean (95% CI) Oswestry Disability Index (ODI) in the patients and the population (blocks and bars), divided to females and males (white and black). Groups adjusted by age, sex and education years.

The preoperative ODI in the patients was 46 (SD 16). A significant improvement was seen at 3 months, and the ODI change remained −26 (95% CI: −24 to −28), $p < 0.001$ at 5 years. In the population, the baseline ODI was 13 (SD 16) remaining stable at 5 years, [−1 (95% CI: 0 to −2)]. Throughout the 5-year follow-up period, the ODI was significantly poorer in the patients than in the population, $p < 0.001$. Figure 1 shows the ODI in the patients and the population divided by sex.

In HRQoL, the preoperative PCS in the patients was 27 (SD 7). The change was 8 (95% CI: 7 to 9), $p < 0.001$ at 5 years. The baseline PCS in the population was 45 (SD 11) and remained unchanged [0 (95% CI: −1 to 1)]. The patients did not reach the population in the 5-year follow-up. Figure 2A shows PCS in the patients and the population divided by sex.

The preoperative MCS in the patients was 47 (SD 13), and the change was 4 (95% CI: 3 to 7), $p < 0.001$ at 5 years. In the population, the baseline MCS was 53 (SD 11), and it remained unchanged [0, (95% CI: −1 to 1)]. While the baseline MCS was significantly lower in the patients than in the population, the statistical difference disappeared at 3 months. Females preserved this benefit at 5 years, while MCS in males deteriorated slightly. Figure 2B shows MCS in the patients and the population divided by sex.

When analyzing the short and the long fusion subgroups separately, ODI was higher and PCS lower before and 5 years after surgery, but the changes were comparable (Figure 3). MCS did not differ at any timepoint between the short and the long fusion subgroups. Neither of the subgroups reached the population at any timepoint.

The 5-year mortality of the patients was 3.4% (95% CI: 2.2 to 5.4). It did not statistically differ from the mortality of 4.8% (95% CI: 3.5 to 6.7) in the population. The age, sex and co-morbidity adjusted HR was 0.86 (95% CI: 0.48 to 1.53). Three most common causes of death in the patients were cardiogenic (63%), cancer (21%) and external causes (11%), and in the population, they were cardiogenic (45%), cancer (24%) and respiratory causes (12%).

Discussion

The present study shows the 5-year outcome of LSF in function, HRQoL and mortality in a consecutive patient series. The overall trend was that the considerable benefits of surgery were mostly preserved still at 5 years. According to the ODI or the physical component of HRQoL, the patients, however, did not reach their general population controls matched by age, sex and residential area.

The preoperative ODI of 46 points indicates severe disability.[12] The clinically significant improvement of 26 points in the ODI was seen at 5-year follow-up. The minimum clinically important difference (MCID) in the ODI is reported to be 12.8 points.[15] The literature presents preoperative ODI variation from 40 to 63, and postoperative changes from −12 to −44.[3,16-18] Endler et al. found the postoperative ODI to remain stable in a long follow-up (mean 6.9 years) of fused isthmic spondylolisthesis patients.[3] Also in the RCT of Ekman et al. concerning isthmic spondylolisthesis patients, the ODI did not significantly change between 2 and 5 years after surgery.[19] Zigler et al. observed 64.8% of fused DDD patients to have at least 15% improvement in the ODI at 2 years.[16] 83.3% of those patients retained the benefit still at 5 years. Hoy et al. found no deterioration in ODI from 2 to 5-10 years postoperatively in patients fused due to heterogeneous indications.[18] Therefore, our results are comparable with the earlier studies, that indicate the improvement in functioning to persist even in a longer follow-up.

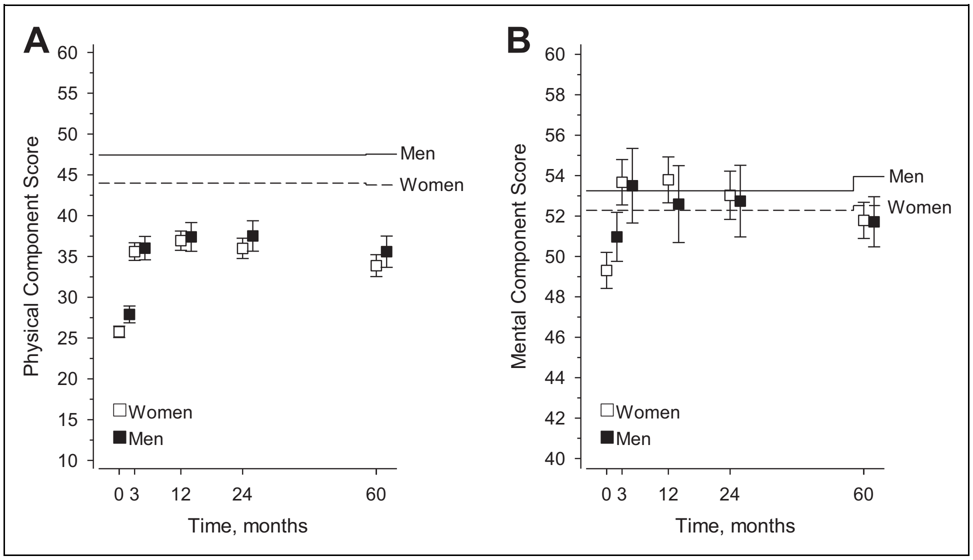

Figure 2. A and B, The mean (95% CI) physical and mental component summary scores of SF-36 (HRQoL) in the patients (blocks and bars) and the population (lines), divided to females and males (white/dashed and black). Groups adjusted by age, sex and education years.

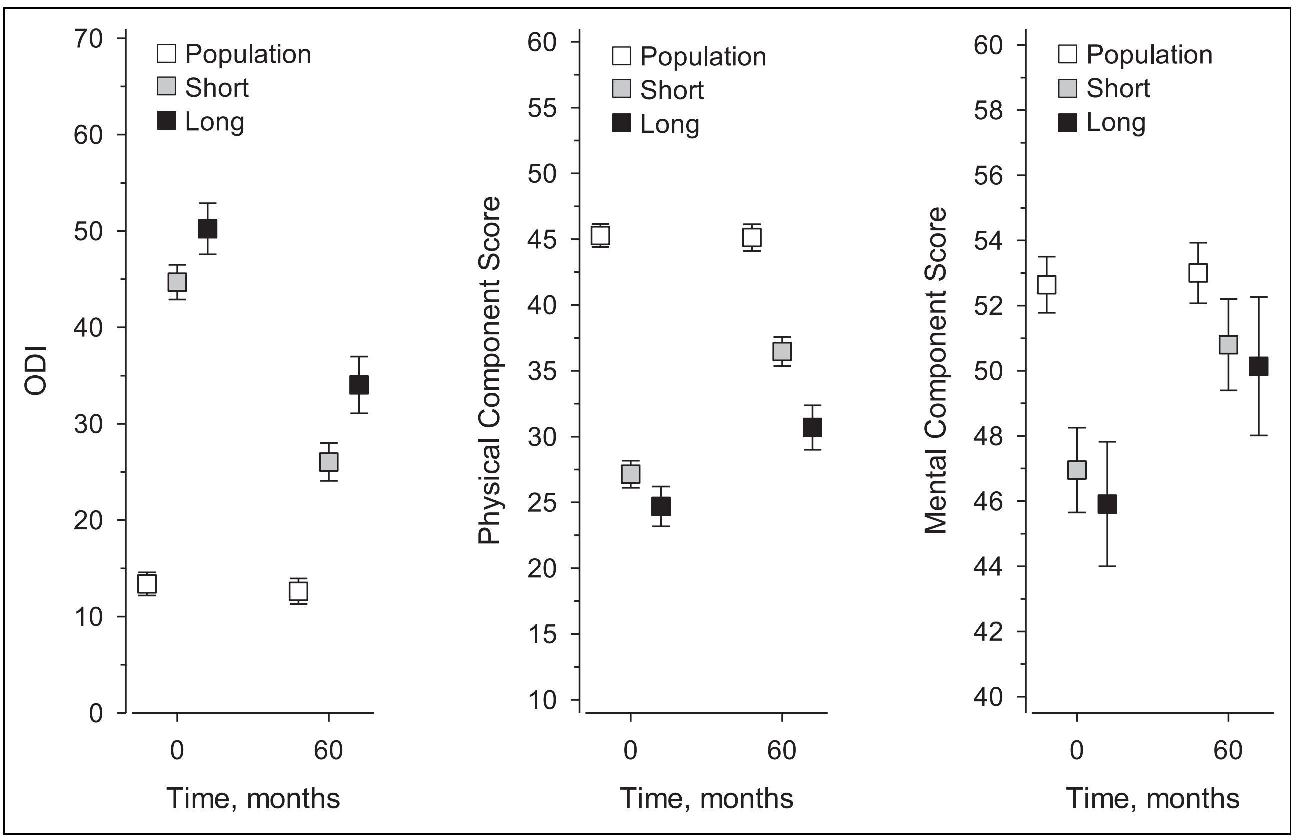

Figure 3. The mean (95% CI) Oswestry Disability Index (ODI), the physical and mental component summary scores of SF-36 (HRQoL) in the patients divided by fusion length (gray = short fusion = 1 to 2 levels, black = long fusion = more than 2 levels; white = population). Groups adjusted by age, sex and education years.

The improvement in the physical aspect of HRQoL was clear from the early recovery phase and remained quite stable. The PCS change of 8 (95% CI: 7 to 9) points at 5 years exceeds 4.9, which is reported to be the minimum clinically important difference (MCID) for PCS.[15] Rampersaud et al. show PCS change of 10.4 points at 2 years after LSF in degenerative spondylolisthesis patients.[20] In the register-based LSF study of Endler et al., there was no deterioration in PCS between 2 and 5 years after surgery.[3] The PCS changes compares with the ODI changes, which supports the assumption that they partly describe the same aspects of functioning.

The MCS change also was statistically significant during the whole follow-up period. The change was 4 (98% CI: 3-5) points at 5 years. Clinical relevance of this is, nevertheless, difficult to determine, since the MCID for MCS in a lumbar spine surgery specific context has not been published. In the SF-36 instrument, a low PCS score tend to raise the MCS score, which may lead to underestimation of the mental component change in conditions with remarkable physical disability.[21] There was a difference between the sexes: only females reached their general population controls at 5 years in MCS.

When dividing the patients to short and long fusion subgroups, a comparable improvement was seen in all variables between the subgroups. Disability was higher in the long fusion subgroup before and after surgery. Even the short fusion subgroup did not reach the population in functioning.

To our best knowledge, there are not many studies comparing the LSF outcome with a matched population. This makes the present study novel. In the field of orthopaedics, the efficacy of big joint arthroplasties is well documented due to comprehensive arthroplasty registries and rich literature.[22] The outcome of arthroplasty surgery can be used as a benchmark in the assessment of LSF benefits.

Mokhtar et al. compared LSF patients and total hip and total knee arthroplasty (THA and TKA) patients with an age matched general population.[23] The spinal patients had a single level degenerative spondylolisthesis, and they were treated with decompression and a single level fusion. They found the HRQoL of LSF patients to approach the population in a 2-year follow-up. Improvement in PCS (of SF-12) was 11 points in the LSF and THA cohorts, while it was 8 points in the TKA cohort. The MCS improvement in the LSF cohort was 4 points, and the postoperative MCS scores were congruent between the cohorts and the population. Our patients, however, did not reach the population in PCS at any time-point. The key explanation for this discrepancy is probably the difference in indications for surgery. We included all elective surgeries, also multilevel pathologies and postoperative conditions in contrast to a single diagnostic entity. Revisions were not analyzed separately here. Rampersaud et al. have also compared spinal stenosis surgery (decompression with or without fusion) with THA and TKA surgery between matched patient cohorts.[24] They found similar cost-utility ratios in a combined spine surgery cohort (decompression only and fusion) as THA and TKA cohorts. The 5-year health utility was nevertheless lower after spinal stenosis surgery than after arthroplasties. Mannion et al. compared different types of degenerative lumbar spine surgeries with THA and TKA.[25] They found joint replacements more successful at 12 months than spine surgery, even though the baseline level was better among THA patients. Considering these, LSF surgery in general does not seem to produce the same level of functional benefit as arthroplasties.

Our patient cohort was quite comparable with the population cohort in most of the comorbidities (Table 1). The differences in psychiatric or musculo-skeletal comorbidities or cancer prevalence are most probably caused by patient selection in the surgical decision making. The self-reported prevalence of spinal problems (23%) in the control population is congruent with previous epidemiological studies.[26] Rheumatoid diseases were overrepresented in the patient group (9% to 4%). It is possible that rheumatoid diseases are related to an increased need for spinal surgery.[27] Cardiac conditions were also more prevalent among the patients than in the general population (50% to 41%). However, this study shows the mortality of the patients to be at the same level with the mortality of the population. Despite the chronic nature of the spinal disease, it did not increase mortality—even despite of higher cardiac co-morbidity prevalence. Of course, bias probably exists here: the patients with better condition more often end up in LSF. To our knowledge, no study with this long follow-up has compared the mortality of LSF patients with a matched population. Lurie et al. reported the 8-year mortality in an RCT comparing operative and conservative treatment in lumbar spinal stenosis.[28] The mortality of the operative group (8%) was lower than would have been expected on the basis of the age- and sex-specific mortality rate (13%). Perhaps here also existed positive selection bias with the patients ending up in RCT as surgical candidates. In the review article of Yavin et al., mortality was not associated with any treatment modality in 20 studies concerning degenerative lumbar spine.[2]

Studies with long-term follow-ups are necessary to assess the possible benefits of LSF. Need for these operations is increasing with the aging population. It is estimated that one fifth of people over 65 years suffers from lumbar spinal claudication, and half of those have serious daily limitations and disability.[2,29]

Conclusion

LSF surgery benefits a heterogeneous group of patients in disability and HRQoL. The positive change is mostly sustained in a 5-year follow-up. Despite the improvement, the patients did not reach the physical level of the population. The mortality of the patients is at the same level as in the population.

Authors' Note

Leevi Toivonen and Liisa Pekkanen contributed equally to the writing of the manuscript. This study was approved by ethics committees of Tampere University Hospital and Central Finland Health Care District. Informed consent was obtained from all individual participants included in the study.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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