DANISH MEDICAL JOURNAL

Original Article

Dan Med J 2023;70(9):A08220508

Improvement in physical function and reduced pain after instrumented lumbar interbody fusion

Peter Muhareb Udby[1, 2], Mikkel Østerheden Andersen[3] & Søren Ohrt-Nissen[2]

1) Spine Unit, Department of Orthopaedic Surgery, Zealand University Hospital, Koege, 2) Spine Unit, Department of Orthopaedic Surgery, Copenhagen University Hospital – Rigshospitalet, 3) Spine Surgery and Research, Spine Center of Southern Denmark, Lillebaelt Hospital, Middelfart, Denmark

Dan Med J 2023;70(9):A08220508

ABSTRACT

INTRODUCTION. Instrumented lumbar fusion has been used as surgical treatment for severe disability with associated low back pain. The overall effect and risks of the most commonly used instrumented lumbar fusion techniques are controversial. The objective of the study was to describe clinical and patient-reported outcomes in patients undergoing single-level instrumented interbody fusion surgery with either posterior or transforaminal lumbar interbody fusion.

METHODS. This was a registry-based cohort study on patients from the national Danish surgical spine database - DaneSpine. The primary outcome was Oswestry Disability Index (ODI) score at two-year follow-up. Secondary outcome measures were the 3-Level European Quality of Life-5 Dimensions (EQ5D-3L), a visual analogue scale (VAS) score, patient satisfaction and the rate of intraoperative complications.

RESULTS. The cohort included 460 patients. ODI improved from 48 ± 15 preoperatively to 33 ± 20 at the two-year follow-up ($p < 0.001$). The EQ5D-3L score improved from 0.279 ± 0.311 to 0.542 ± 0.340, the VAS score for leg pain from 60 ± 28 to 40 ± 32 and back pain from 70 ± 20 to 47 ± 30. Patient satisfaction was obtained in 58%; 24% were undecided, whereas 18% were not satisfied with the treatment outcome at their two-year follow-up.

CONCLUSIONS. Patients suffering from severe back-related disability after failed conservative treatment may expect an improvement in physical function and reduced pain after instrumented lumbar interbody fusion.

FUNDING. None.

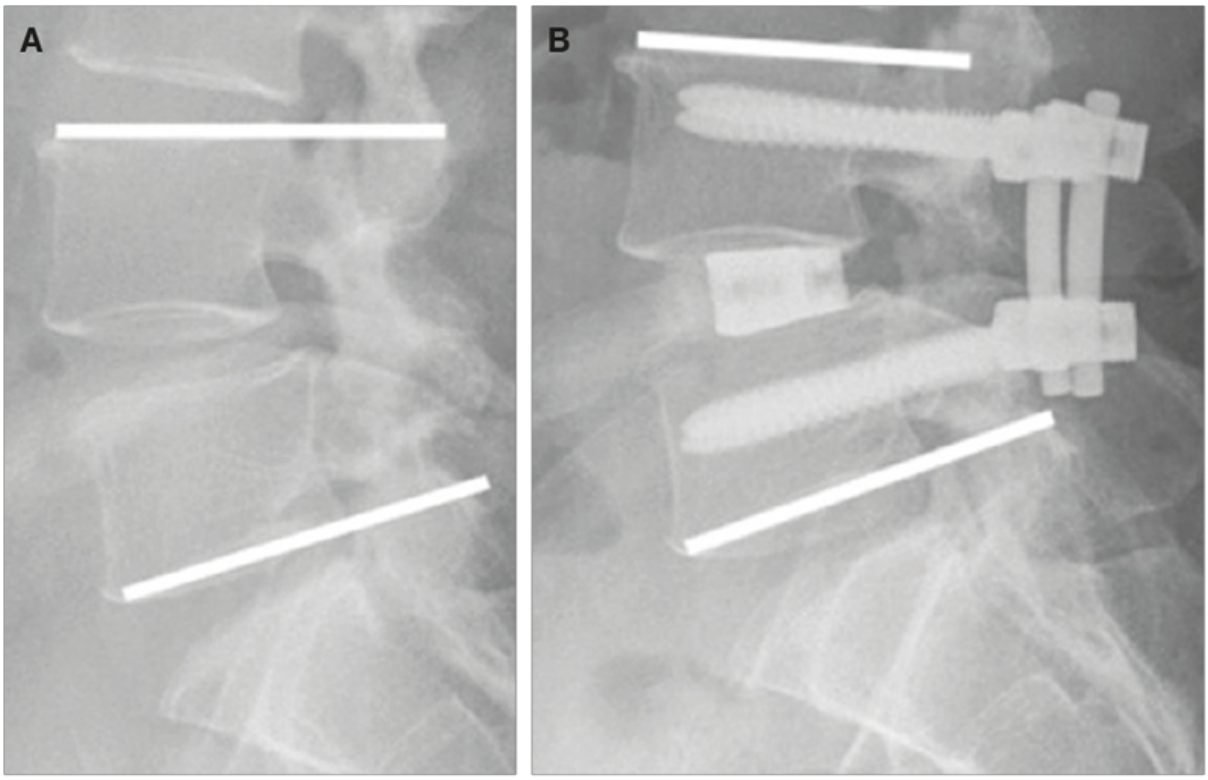
TRIAL REGISTRATION. The national Danish DaneSpine registration.

The first ever spinal fusion procedure was performed in 1891. Subsequently, improvements have been achieved in surgical technique and the annual number of fusion surgeries performed has increased streadily [1]. The first Danish lumbar fusion was performed at the Department of Orthopaedic Surgery at Odense Hospital in the 1960s. During the 1990s, medical spending related to back pain increased massively and the number of surgical procedures surged accordingly [1].

Globally, back-related pain is the leading cause of disability, ranked way ahead of any other disease entity [2]. In most cases, back pain is a self-limiting condition typically classified as non-specific back pain. In some patients, a chronic condition can develop that may be associated with specific degenerative spine conditions [3]. Spine

fusion is a surgical treatment option in patients suffering from moderate to severe loss of physical function (disability) [1, 4], often associated with debilitating low back pain (LBP) due to pathological structural changes of the spine affecting either the spinal alignment, neural structures or both. Spinal fusion surgery is utilised to restore spinal alignment, facilitate neural decompression and/or reduce motion in an unstable/pain-generating vertebral segment [5]. This may be achieved by an uninstrumented procedure using only bone graft to achieve fusion or an instrumented approach using pedicle screws and rods to immobilise the vertebral segment. Instrumented fusion may be supplemented with an interbody device as a way of restoring disc height (indirect decompression) or/and correcting lordosis, see **Figure 1**.

FIGURE 1 Example of surgical lordosis correction with combined instrumented and interbody fusion. **A.** Preoperative angle: 21°. **B.** Post-operative angle: 27°.



Several surgical techniques have been described, but the most commonly used techniques are transforaminal or posterior lumbar interbody fusion (TLIF or PLIF) [4, 6].

In Denmark, national recommendations are in place forthe treatment of patients with chronic LBP and disability [7]. These guidelines include an initial conservative treatment approach consisting of pharmacological treatment, cognitive functional therapy, physiotherapy/chiropractic treatment, weight loss and supervised training [4]. Referral to a spine surgeon should be considered in cases with a persistent, severe back-induced disability after six months of conservative treatment [4, 7]. Upon consultation with the spine surgeon, the majority will present with a history of current or previous opioid use, severe disability and back-related sick leave [4, 8].

The purpose of this study was to report two-year outcomes after the most commonly used lumbar instrumented interbody fusion procedures in patients with LBP-induced disability.

METHODS

This was a registry-based data study based on patient-reported outcomes (PROs) from the national Danish spine registry database – DaneSpine.

In DaneSpine, data are collected prospectively and include demographic patient information collected through pre- and postoperative questionnaires and surgical data collected postoperatively. Questionnaire data include age, gender, height, weight, smoking, low-back-related disability as measured by the Oswestry Disability Index (ODI) [9, 10], health-related quality of life as measured by the 3-Level European Quality of Life-5 Dimensions (EQ5D-3L) [11], back and leg pain on a 0-100 visual analogue scale (VAS) [12], previous spine surgery and duration of back and leg pain prior to surgery.

Nationally, 16 spine hospital/clinic units report to DaneSpine. For this study, two hospitals, Zealand University Hospital and Middelfart Hospital, were selected for inclusion.

Inclusion criteria

This study included patients with degenerative lumbar changes who underwent single-level fusion surgery with either the TLIF or the PLIF technique. Furthermore, only patients with a surgery date between 1 June 2010 and 31 May 2018 were included.

Exclusion criteria

Patients with spondylolisthesis were excluded along with patients with incomplete pre-operative and/or two-year follow-up on the ODI questionnaire and patients with a previous spinal procedure on the same level, other than single-level discectomy.

The primary outcome measure was ODI, which ranges from 0 (no disability) to 100 (bedridden) [12, 13].

The secondary outcome measures were an EQ5D-3L ranging from –0.596 to 1, with higher scores indicating better quality of life. Furthermore, VAS scores were used to measure back and leg pain, ranging from 0 (no pain) to 100 (worst possible pain). Patient satisfaction was measured by reported perioperative complications including dura lesion, vascular injury and nerve injury.

Surgical data were recorded by the surgeon after the procedure and included diagnosis, procedure specifications and occurrence of surgical complications such as dural tears and vascular or neural lesions. The surgical method depended on the operating surgeon's preference. All PRO data were collected two years postoperatively.

Statistical analyses were performed in R version 4.0.3.

Categorical data are presented by frequencies and related percentages. Continuous data are reported as mean standard deviation. Continuous data were analysed using paired t-test and categorical variables were compared using Pearson's χ^2 test. The significance level was set at 0.05.

RESULTS

From 2010 to 2018, a total of 460 patients, with two-year follow-up data available, had undergone spinal fusion with either PLIF or TLIF. The mean age at the time of surgery was 49 ± 11 years and 56% were female. Compared with the background population, we found a higher percentage of smokers (29%) among the patients.

A total of 69% reported having had LBP for more than two years (**Table 1**).

TABLE 1 Baseline characteristics of the entire cohort (N = 460).

Age, mean ± SD, yrs	49.1 ± 11
Gender, n (%)	
Females	256 (55.7)
BMI, mean ± SD, kg/m²	27 ± 4
Smokers, n (%)	133 (29)
Previous spine surgery, n (%)	273 (59)
Duration of back pain, n (%)	
No back pain	4 (1)
< 3 mos.	9 (2)
3-12 mos.	52 (11)
12-24 mos.	76 (17)
> 24 mos.	317 (69)
Duration of leg pain, n (%)	
No leg pain	30 (7)
< 3 mos.	19 (4)
3-12 mos.	107 (23)
12-24 mos.	102 (22)
> 24 mos.	199 (44)

SD = standard deviation.

ODI improved from 48 ± 15 preoperatively to 33 ± 20 at the two-year follow-up ($p < 0.001$), corresponding to a mean improvement of 15 ± 18. The EQ5D-3L score improved from 0.279 ± 0.311 to 0.542 ± 0.340, the VAS score for back pain improved from 70 ± 20 to 47 ± 30, and leg pain improved from 60 ± 28 to 40 ± 32. Dural tears occurred in 5.7% of all surgeries. No reports of intraoperative vascular or neurological injury were observed.

The percentage of patients who were able to walk > 1,000 m improved from 21% preoperatively to 49% of the cohort at two years postoperatively ($p < 0.001$).

Patient satisfaction was 58%, 24% were undecided, whereas 18% were not satisfied with their treatment outcome (**Table 2**).

TABLE 2 Two-year follow-up.

	Baseline	2-yr follow-up [change in score]	p value
ODI score, mean ± SD, %	48 ± 15	33 ± 20 [15 ± 18]	< 0.001[a]
EQ5D-3L UK score, mean ± SD	0.30 ± 0.30	0.54 ± 0.35 [0.24 ± 0.32]	< 0.001
VAS score, mean ± SD			
Back pain	70 ± 20	47 ± 30 [23 ± 31]	< 0.001[a]
Leg pain	60 ± 28	41 ± 32 [19 ± 35]	< 0.001[a]
Regular use of pain medicine, n (%)	440 (96)	255 (70)	0.004[b]
Self-reported walking distance, n (%)			< 0.001[c]
< 100 m	134 (29)	73 (16)	
100-500 m	83 (18)	73 (16)	
500-1,000 m	144 (31)	86 (19)	
> 1,000 m	98 (21)	225 (49)	
Treatment satisfaction, n (%)	-		
Satisfied	-	258 (58)	
Not satisfied	-	84 (18)	
Undecided	-	111 (24)	

EQ5D-3L = 3-Level European Quality of Life-5 Dimensions; ODI = Oswestry Disability Index; SD = standard deviation; VAS = visual analogue scale.
a) Paired t-test.
b) χ^2 test.
c) Wilcoxon signed rank test.

No significant difference was observed in PROs preoperatively or at the two-year follow-up based on surgical technique, TLIF versus PLIF ($p > 0.05$).

Data on patients who were undecided in regards to patient satisfaction were re-analysed separately. This comparison included surgical techniques and PROs (ODI, EQ5D-3L, VAS, pain medication, walking distance and treatment satisfaction). No significant difference was recorded between the group of patients that were undecided in regards to patient satisfaction compared with the overall satisfied group ($p > 0.05$).

DISCUSSION

Lumbar spine fusion is used as a surgical treatment option for patients suffering from disability and chronic LBP secondary to structural changes of the lumbar spine. This study reported on the outcomes following the

procedure.

The included cohort was comparable to those of previously reported studies on lumbar fusion [4, 13]. Overall, the patients were affected by severe physical disability with 65% having a preoperative ODI exceeding 40, which is commonly considered a threshold for severe disability. Furthermore, 30% had a total walking distance of less than 100 m, illustrating that patients selected for lumbar fusion have severe physical impairment.

At the two-year follow-up, a significant improvement was recorded in disability, pain and walking distance in the cohort. The mean improvement in ODI exceeded the minimally important change, which is 12-13 points [14]. Similar to previous studies and data from all included spine centres in Denmark, the improvement was less profound than that of spinal surgery for lumbar disc herniation (LDH) and spinal stenosis [15].

Patient satisfaction was evaluated at the two-year follow-up by asking the patients how they felt about the outcome after their spine surgery – satisfied (yes/no), undecided (yes/no) or not satisfied (yes/no). Of the total number of patients, 24% were undecided in regards to outcome. Several factors have previously been associated with limited/poor patient satisfaction after lumbar fusion. Among these, the most consistent seem to be discrepancies in preoperative surgeon-patient outcome expectations, pre- or post-operative psychiatric disease, high body mass index and patient frailty [16]. In this registry-based study, data on patient expectations, psychiatric disease or frailty were unavailable, and therefore not adjusted for. However, the rates of patient satisfaction found in the study are in line with those of previous studies [16].

With the available knowledge, should we use lumbar fusion as a treatment option in patients suffering from severe disability secondary to structural spinal changes and associated LBP? There is an ongoing global discussion regarding the use of spine fusion in elective lumbar spine surgery [1, 4]. In Denmark, LBP are handled in accordance with Danish Health Authority guidelines, stating that patients should not be referred for spine surgery evaluation before conservative treatment options have been fully explored. The results from our study indicate the same, with 69% of all included patients having experienced LBP for at least two years prior to fusion surgery. This study did not include data on non-successful conservative treatment or re-operations since such information is not available in DaneSpine and the registry has not been validated for reporting of these data.

Conservative treatment versus operative treatment has demonstrated good results in patients undergoing supervised training at a high frequency – patients admitted to a patient hotel and trained three times a day for 12 weeks [17]. Such a setup is costly, patient-compliance dependent and only available in few institutions globally. Often the crossover in randomised clinical trials (RCTs) on surgery versus conservative treatment can be misleading with patients not being able to withstand the pain/discomfort associated with physical training crossing over to the surgical treatment group of the RCT [18]. Another bias exists concerning conservative treatment. The term conservative treatment may include everything from no treatment (inactivity) to several daily moderate-to-high intensity physiotherapist-supervised training sessions occasionally combined with cognitive and pharmacological therapy. In addition, the patient who is enrolled in the trial may have already undergone failed conservative treatment before being scheduled for inclusion into an RCT offering the same type of conservative treatment [1].

As in this study, the majority of patients who undergo lumbar fusion suffer from severe disability, chronic pain and long-term opioid use, and have previously been subjected to a series of non-successful conservative treatments. Such factors are often associated with a non-successful outcome after any type of medical intervention [5].

LBP has been associated with an increased overall mortality rate and an increased risk of depression, obesity and reduced physical activity. An improvement, allthough limited, in LBP and physical function may therefore have

profound consequences for the trajectory of the patient's life and the quality thereof.

One might argue that a patient satisfaction of approximately 60% and an overall reduction in both back and leg pain and use use of pain medication is very encouraging in a group of patients typically characterized by year-long costly non-operative treatment attempts. On the other hand, almost 20% of the patients are unsatisfied with the surgical outcome two years after receiving surgery. Spine surgeons must improve patient selection to bring this percentage down. In the Danish surgical spine community, extensive efforts are currently being made to utilize artificial intelligence and machine learning on DaneSpine data to build prognostic models on the surgical outcome [19]. In the near future, these models will hopefully reduce the number of unsatisfied patients in a shared decision setting.

From a societal viewpoint, lumbar fusion is more expensive than conservative treatment. However, in a socio-economic context, the incremental cost-effectiveness ratio has demonstrated extra effect units gained by lumbar fusion compared with conservative treatment [20].

Weaknesses of the present study include the lack of a conservatively treated/placebo group. However, sham fusion surgery would be unethical. The majority of patients included had undergone conservative treatment, including physiotherapy and pharmacological treatment, with limited effect before they were finally treated with spinal fusion surgery. The study was registry-based and comprised a selected cohort from two hospitals in Denmark. The surgical intervention performed does not differ significantly between hospitals in Denmark and the cohort is representative of patients undergoing fusion at other institutions across Denmark [15].

Strengths of the study include prospectively collected data from questionnaires pre- and post-operatively, two-year follow-up data from two hospitals and a fairly large cohort.

Lumbar instrumented fusion is a surgical option in patients suffering from severe back-related physical disability where conservative treatment has failed. Elective spine surgery for degenerative spine conditions should always adhere to an evidence-based approach. This includes thorough evaluation of the individual patient. The patient should be included in the decision-making process and be well informed of the risks, benefits and alternative treatment options.

CONCLUSIONS

Patients suffering from severe back-related disability after failed conservative treatment may expect an improvement in physical function and reduced pain after instrumented lumbar interbody fusion. Patient selection and careful information are key in ensuring a full understanding of the post-operative trajectory including risks, outcomes and improvement in physical function.

Correspondence *Peter Muhareb Udby.* Email: peterudby@gmail.com

Accepted 15 June 2023

Conflicts of interest none. Disclosure forms provided by the authors are available with the article at ugeskriftet.dk/dmj

Cite this as Dan Med J 2023;70(9):A08220508

REFERENCES

1. Harris IA, Traeger A, Stanford R et al. Lumbar spine fusion: what is the evidence? Intern Med J. 2018;48(12):1430-4.
2. GBD 2015 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence,

and years lived with disability for 310 diseases and injuries, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. Lancet. 2016;388:1545-602.

3. Ohrt-Nissen S, Carreon LY, Andresen AK et al. Clinical and patient-reported outcomes after posterior versus transforaminal lumbar interbody fusion - a propensity score-matched cohort study on 422 patients with 2-year follow-up. Spine (Phila Pa 1976) 2022;47(2):180-5.
4. Eck JC, Sharan A, Ghogawala Z et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 7: lumbar fusion for intractable low-back pain without stenosis or spondylolisthesis. J Neurosurg Spine. 2014;21(1):42-7.
5. Reid PC, Morr S, Kaiser MG. State of the union: a review of lumbar fusion indications and techniques for degenerative spine disease. J Neurosurg Spine. 2019;31(1):1-14.
6. Udby PM, Bech-Azeddine R. Clinical outcome of stand-alone ALIF compared to posterior instrumentation for degenerative disc disease: a pilot study and a literature review. Clin Neurol Neurosurg. 2015;133:64-9.
7. Sundhedsstyrelsen. Anbefalinger for tværsektorielle forløb for mennesker med kroniske lænderygsmerter. Danish Health Authority, 2017. www.sst.dk/-/media/Udgivelser/2017/Anbefalinger-tværsektorielle-forløb-kroniske-lænderygsmerter.ashx?la=da&hash=38D5B6EDBA107C705381B6F1D176CFB8FD22EFF0 (May 2023).
8. Hägg O, Fritzell P, Ekselius L et al. Predictors of outcome in fusion surgery for chronic low back pain. A report from the Swedish Lumbar Spine Study. Eur Spine J. 2003;12(1):22-33.
9. Roland M, Fairbank JC. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. Spine (Phila Pa 1976). 2000;25(24):3115-24.
10. Lauridsen HH, Hartvigsen J, Manniche C et al. Danish version of the Oswestry disability index for patients with low back pain. Part 1: Cross-cultural adaptation, reliability and validity in two different populations. Eur Spine J. 2006;15(11):1705-16.
11. Sørensen J, Davidsen M, Gudex C et al. Danish EQ-5D population norms. Scand J Public Health. 2009;37(5):467-74.
12. Williamson A, Hoggart B. Pain: a review of three commonly used pain rating scales. J Clin Nurs. 2005;14(7):798-804.
13. Yavin D, Casha S, Wiebe S et al. Lumbar fusion for degenerative disease: a systematic review and meta-analysis. Clin Neurosurg. 2017;80(5):701-15.
14. Copay AG, Glassman SD, Subach BR et al. Minimum clinically important difference in lumbar spine surgery patients: a choice of methods using the Oswestry Disability Index, Medical Outcomes Study questionnaire Short Form 36, and pain scales. Spine J. 2008;8(6):968-74.
15. Andersen M, Nielsen M, Bech-azeddine R et al. Rygkirurgi i Danmark. Årsrapport 2020. Dansk Rygkirurgisk Selskab, 2020. http://drks.ortopaedi.dk/wp-content/uploads/2021/06/Årsrapport-DRKS-2020.pdf (May 2023).
16. Macki M, Alvi MA, Kerezoudis P et al. Predictors of patient dissatisfaction at 1 and 2 years after lumbar surgery. J Neurosurg Spine. (online 22 Nov 2019).
17. Brox JI, Reikerås O, Nygaard Ø et al. Lumbar instrumented fusion compared with cognitive intervention and exercises in patients with chronic back pain after previous surgery for disc herniation: a prospective randomized controlled study. Pain. 2006;122(1-2):145-55.
18. Fritzell P, Hägg O, Wessberg P et al. 2001 Volvo Award winner in clinical studies: lumbar fusion versus nonsurgical treatment for chronic low back pain. Spine (Phila Pa 1976). 2001;26(23):2521-32.
19. Pedersen CF, Andersen MØ, Carreon LY et al. Applied machine learning for spine surgeons: predicting outcome for patients undergoing treatment for lumbar disc herniation using PRO Data. Global Spine J. 2022;12(5):866-76.
20. Fritzell P, Hägg O, Jonsson D et al. Cost-effectiveness of lumbar fusion and nonsurgical treatment for chronic low back pain in the Swedish Lumbar Spine Study: a multicenter, randomized, controlled trial from the Swedish Lumbar Spine Study Group. Spine (Phila Pa 1976). 2004;29(4):421-34.