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Full-Endoscopic Lumbar Discectomy vs Standard Discectomy: A Noninferiority Study on Clinically Relevant Changes

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ABSTRACT

Background: Surgery for lumbar disc herniation (LDH) has had a remarkable technological development during the past 20 years. Microscopic discectomy has traditionally been the gold standard method to treat symptomatic LDH before the introduction of full-endoscopic lumbar discectomy (FELD). The FELD procedure allows unsurpassed magnification and visualization and is currently the most minimally invasive surgical technique. In this study, FELD was compared with standard surgery for LDH, with a focus on medically relevant changes in patient-reported outcome measures (PROMs).

Purpose: The purpose of this study was to investigate whether FELD is noninferior to other surgical methods for LDH surgery in the most common PROMs, including postoperative leg pain and disability, while still reaching the necessary thresholds for relevant clinical and medical improvements.

Methods: Patients undergoing a FELD procedure at the Sahlgrenska University Hospital, Gothenburg, Sweden, between 2013 to 2018 were included. A total of 80 (41 men and 39 women) patients were enrolled. The FELD patients were matched 1:5 to controls from the Swedish spine register (Swespine) who had a standard microscopic or mini-open discectomy surgery. PROMs, including the Oswestry Disability Index (ODI) and the Numerical Rating Scale (NRS), as well as the patient acceptable symptom states (PASS) and the minimal important change (MIC), were used to compare the efficacy of the 2 surgical approaches.

Results: The FELD group achieved medically relevant and significant improvements noninferior to standard surgery within the predefined thresholds of MIC and PASS. No differences could be found in disability measured by ODI FELD −28.4 (SD 19.2) vs standard surgery −28.7 (SD 18.9) or leg pain NRS_{Leg} FELD −4.35 (SD 2.93) vs standard surgery −4.99 (SD 3.12). All intragroup score changes were significant.

Conclusions: The FELD results are not inferior to standard surgery 1 year postoperatively after LDH surgery. There were no medically significant differences regarding MIC achieved or final PASS in any of the measured PROMs, including leg pain, back pain, or disability (ODI) between the surgical methods.

Clinical Relevance: The present study highlights that FELD is noninferior to standard surgery in clinically relevant PROMs.

Level of Evidence: 2.

Endoscopic Minimally Invasive Surgery

Keywords: Lumbar disc herniation, full-endoscopic lumbar discectomy, minimal invasive spine surgery, FELD, PROMs

INTRODUCTION

Historically, lumbar disc herniation (LDH) surgery was an extensive procedure with significant morbidity.[1] With the introduction of full-endoscopic lumbar discectomy (FELD), a truly minimally invasive surgical technique has been developed.[2,3] Current research has yet to show that a FELD procedure has significant medical gains and advantages.[4] However, if proven noninferior to other methods, one can hypothesize that the potential for minimal tissue damage and decreased surgical and hospital length of stay might motivate the initial investment in equipment and training.[5]

MATERIALS AND METHODS

The hypothesis of the study was that patient-reported outcome measures (PROMs) in a FELD cohort matched to LDH patients having standard surgery were noninferior in regard to minimal important change (MIC) and postoperative patient acceptable symptom state (PASS) for all measured PROMs.[5–7]

Study Design

This study was conducted as a matched cohort study, comparing FELD patients operated at Sahlgrenska University Hospital, Gothenburg, Sweden between 2013 and 2018 with controls having standard LDH surgery (microscopic or mini-open procedure) from the Swespine register.[8] A total of 92 FELD patients were initially enrolled, and 80 patients with complete 1-year postoperative follow-up were analyzed in the study. Patients were matched according to age ±3 years, sex, preoperative leg pain duration, and lumbar level of disc herniation.

Patient-Reported Outcome Measures

The Oswestry Disability Index (ODI) was used to assess the disability.[9] Leg and back pain were rated with the Numerical Rating Scale (NRS 0–10).

At 1-year follow-up, a qualitative single-item leg/back pain question-global assessment ($GA_{Leg/Back}$) was formulated as "How do you rate your leg/back pain today as compared with before you had your back surgery?" with a 6-level response option: 0—had no preoperative leg/back pain, 1—pain free, 2—much better, 3—somewhat better, 4—unchanged, 5—worse.[10]

Minimal Important Change and Patient Acceptable Symptom State

To study clinically important differences, use of the MIC score and PASS have been suggested. The PASS gives a threshold on what a mean tolerable baseline level is for a PROM score ("feeling good"), whereas the MIC value states the minimum change needed to be perceived as meaningful for the patient and still being able to be registered on the PROM scale ("feeling better"). Values used in this study are in-line with and derived from previously published articles and are presented in Table 1.[11–19]

Table 1. MIC and PASS[a] values used in the study.

Outcome Measure	MIC	PASS Level	Comment
Leg pain NRS (0–10)	3.5	2	NRS
Back pain NRS (0–10)	2.5	2	NRS
Oswestry Disability Index (0–100)	−20	22	Composite score

Abbreviations: MIC, minimal important change; NRS, numerical rating scale; PASS, patient acceptable symptom state.
[a]PASS indicates the highest score on that scale that is acceptable to a generalized population.

Surgical Indication and Inclusion Criteria

The indication for a FELD discectomy was unsustainable leg pain for more than 6 weeks, with or without motor and sensory deficit, which failed to respond to conservative or physiotherapeutic treatment.[20] Exclusion criteria were cauda equina syndrome, previous spinal surgery, lumbar fracture, and incomplete preoperative data.

Surgical Techniques

Full-Endoscopic Lumbar Discectomy

The surgical FELD method has been described thoroughly in several original articles and was performed according to the description by Rutten et al.[20–22]

Standard Procedures

The control group had a conventional lumbar discectomy, either by a microscopic or mini-open approach. These techniques can be considered comparable in all relevant long-term outcomes.[6,23,24]

Statistical Analysis

The data from the FELD and control groups were compiled using SAS statistical software version 9.4 (SAS Institute Inc) for statistical analysis. Descriptive statistics for patient demographics and outcomes were reported as proportion and count for categorical variables. Continuous variables were reported as mean and SD and with median and the first and third quartiles. A post hoc power analysis for NRS_{Leg} was performed at 80% with an intergroup noninferiority difference of <2 to verify a sufficient sample size. The Fisher exact test was used for dichotomous variables, the Mantel-Haenszel χ^2 test was used for ordered categorical variables, and the Pearson χ^2 test was used for nonordered categorical variables. The Wilcoxon test was used for paired data. McNemar test was used to compare paired samples for nominal and dichotomous variables. All significance tests were 2 sided and conducted at the 5% significance level. The multilevel GA_{Leg} and GA_{Back} were dichotomized to allow for a robust comparison between the groups.

RESULTS

A total of 80 FELD patients were eligible for the study. They were matched to 400 controls from the Swespine register, creating a 1:5 inclusion ratio. The baseline values for the groups are shown in Table 2. Mean preoperative leg pain intensity measured by

Table 2. Demographic parameters at baseline.

Characteristic	FELD Group (n = 80)	Control Group (n = 400)	P Value	Difference Between Groups, Mean (95% CI)
Age, y,	n = 80	n = 400		
Mean (SD) (95% CI for mean)	32.4 (10.4) (30.1; 34.7)	33.2 (10.0) (32.2; 34.2)	0.53	−0.763 (−3.209; 1.682)
Sex, n (%)	n = 80	n = 400		
Men	41 (51.3%)	205 (51.3%)		0.0 (−12.7; 12.7)
Women	39 (48.8%)	195 (48.8%)	>0.99	0.0 (−12.7; 12.7)
Body mass index	n = 80	n = 400		
Mean (SD) (95% CI for mean)	25.0 (4.0) (24.1; 25.9)	25.3 (3.3) (25.0; 25.6)	0.46	−0.309 (−1.173; 0.504)
Smoker, n (%)	n = 69	n = 398		
No	59 (85.5%)	343 (86.2%)		−0.7 (−10.5; 9.1)
Yes	10 (14.5%)	55 (13.8%)	>0.99	0.7 (−9.1; 10.5)
Leg pain (NRS 0–10)	n = 56	n = 389		
Mean (SD) (95% CI for mean)	7.34 (1.98) (6.81; 7.87)	6.99 (2.18) (6.78; 7.21)	0.27	0.347 (−0.231; 0.936)
Back pain (NRS 0–10)	n = 56	n = 388		
Mean (SD) (95% CI for mean)	5.11 (2.74) (4.37; 5.84)	4.81 (2.83) (4.53; 5.09)	0.45	0.295 (−0.510; 1.080)
Duration of leg pain, n (%)	n = 80	n = 400		
<3 mo	6 (7.5%)	30 (7.5%)		
3–12 mo	49 (61.3%)	245 (61.3%)		
12–24 mo	13 (16.3%)	65 (16.3%)		
>24 mo	12 (15.0%)	60 (15.0%)	>0.99	
Oswestry Disability Index	n = 55	n = 392		
Mean (SD) (95% CI for mean)	46.5 (18.5) (41.5; 51.5)	46.5 (17.8) (44.7; 48.3)	0.97	−0.007 (−4.939; 4.958)
Lumbar disc herniation level, n (%)	n = 80	n = 400		
L4-L5	25 (31.3%)	153 (38.3%)		−7.0 (−19.0; 5.0)
L5-S1	55 (68.8%)	247 (61.8%)	0.29	7.0 (−5.0; 19.0)

Abbreviations: FELD, full-endoscopic lumbar discectomy; NRS, numerical rating scale.

NRS_{Leg} for the FELD group was 7.34 SD (1.98), and mean back pain (NRS_{Back}) was 5.11 (SD 2.74). The patients were, according to their mean ODI of 46.5 (SD 18.5), severely affected by their LDH, resulting in significant disability. There were no significant differences between the groups at inclusion.

At the 1-year follow-up, the FELD group rated their residual leg pain NRS_{Leg} 2.69 (SD 2.68), and their NRS leg pain change score (ΔNRS_{leg}) showed a –4.35 (SD 2.93) difference (baseline – 1 year follow-up) or a 60.2% (SD 36.7%) decrease in leg pain. A comparison with the control group revealed no differences in any of the recorded PROMs as illustrated in Table 3.

In analogy with the postoperative decrease in $NRS_{Leg + Back}$, for the FELD group, the reported mean residual disability measured by the ODI 17.3 (SD 16.7) was below the PASS without any differences between the groups. Among the FELD patients, 58.2% reached PASS in NRS_{Leg} compared with open surgery (71.7%). The difference was not significant ($P = 0.055$). As illustrated in Table 4 , by using the predefined PASS score for ODI set at 22, the FELD group attained a similar proportion of patients achieving PASS as the control group.

The MIC values are provided in Table 5. In NRS_{Leg}, 60.5% (FELD) and 73.6% (controls), respectively, attained the MIC or better. No significant differences between the groups were recorded for the NRS or ODI.

DISCUSSION

The main finding in the study is that FELD is noninferior to standard surgery and showed medically relevant improvements in clinically used PROMs, within specified MIC and PASS values. No clinically relevant differences could be discerned regarding leg and back pain–specific outcomes, disability, or quality-of-life scores at 1-year follow-up.

Leg pain (sciatica) and its detrimental effect on quality of life is the most common complaint for LDH. In our study, the entire study population had severe preoperative leg pain (NRS_{Leg} with a mean 7.04 [SD 2.15]) that responded positively to surgery. The FELD group achieved a high level of pain reduction measured in NRS_{Leg}, where 60.5% reached the MIC threshold and 58.2% reached PASS, which were comparable with that of standard surgery. The intergroup differences were not statistically significant, but a very slight benefit could be noted for the standard surgery group in postoperative residual leg pain, perhaps illustrating a potential benefit for the extensive decompressive approach of a standard procedure vs the ultraminimal invasive FELD in certain cases. This is in analogy with a previously published randomized controlled trial that also could not discern medically relevant differences between the surgical methods.[25,26]

However, back pain can also be a significant factor in the symptomatology of LDH patients. Moreover,

Table 3. Postoperative patient-reported outcome measures for FELD and Swespine controls.

Patient-Reported Outcome Measure	FELD Group (*n* = 80)	Control Group (*n* = 400)	*P* Value	Difference Between Groups, Mean (95% CI)
NRS_{Leg} (1 y)	*n* = 67	*n* = 223		
Mean (SD) (range)	2.69 (2.68) (2.03; 3.34)	1.97 (2.49) (1.64; 2.30)	0.065	0.718 (−0.040; 1.429)
NRS_{Leg} decrease	*n* = 43	*n* = 219		
Mean (SD) (range)	−4.35 (2.93) (−5.25; −3.45)	−4.99 (3.12) (−5.40; −4.57)	0.24	0.637 (−0.421; 1.657)
NRS_{Leg} % change	*n* = 43	*n* = 219		
Mean (SD) (range)	−60.2 (36.7) (−71.4; −48.9)	−65.3 (65.0) (−73.9; −56.6)	0.57	5.13 (−18.07; 22.31)
NRS_{Back}(1 y)	*n* = 62	*n* = 224		
Mean (SD) (range)	2.56 (2.38) (1.96; 3.17)	2.34 (2.46) (2.02; 2.67)	0.54	0.221 (−0.444; 0.891)
NRS_{Back} decrease	*n* = 36	*n* = 200		
Mean (SD) (range)	−2.72 (2.59) (−3.60; −1.85)	−2.47 (3.05) (−2.89; −2.04)	0.66	−0.257 (−1.310; 0.848)
NRS_{Back} % change	*n* = 36	*n* = 200		
Mean (SD) (range)	−46.5 (47.8) (−62.7; −30.3)	−32.1 (108.1) (−47.1; −17.0)	0.47	−14.4 (−57.0; 14.6)
ODI (1 y)	*n* = 64	*n* = 225		
Mean (SD) (range)	17.3 (16.7) (13.2; 21.5)	15.6 (14.7) (13.7; 17.6)	0.46	1.67 (−2.79; 5.89)
1-y ODI decrease	*n* = 41	*n* = 223		
Mean (SD) (range)	−28.4 (19.2) (−34.5; −22.3)	−28.7 (18.9) (−31.2; −26.2)	0.92	0.336 (−5.833; 6.645)
ODI % change	*n* = 41	*n* = 223		
Mean (SD) (range)	−61.7 (38.6) (−73.9; −49.5)	−62.9 (35.1) (−67.6; −58.3)	0.84	1.22 (−11.43; 13.17)
EQ-VAS (1 y)	*n* = 64	*n* = 218		
Mean (SD) (range)	72.1 (19.1) (67.3; 76.8)	76.4 (16.9) (74.2; 78.7)	0.095	−4.35 (−9.14; 0.65)
EQ-VAS increase	*n* = 42	*n* = 208		
Mean (SD) (range)	28.1 (21.5) (21.4; 34.8)	27.1 (25.2) (23.6; 30.5)	0.80	1.03 (−6.71; 9.38)
EQ-VAS % change	*n* = 42	*n* = 205		
Mean (SD) (range)	98.3 (121.3) (60.5; 136.1)	98.6 (160.9) (76.4; 120.7)	0.96	−0.284 (−56.365; 43.688)
GA_{Leg}				
GA_{Leg} 1–2[a]	42 (71.2%)	183 (81.3%)		−10.1 (−23.8; 3.6)
GA_{Leg} 3–5[b]	17 (28.8%)	42 (18.7%)	0.13	10.1 (−3.6; 23.8)
GA_{Back}				
GA_{Back} 1–2[a]	44 (80.0%)	154 (76.6%)		3.4 (−9.9; 16.6)
GA_{Back} 3–5[b]	11 (20.0%)	47 (23.4%)	0.74	−3.4 (−16.6; 9.9)

Abbreviations: FELD, full-endoscopic lumbar discectomy; GA, global assessment; NRS, Numerical Rating Scale; ODI, Oswestry Disability Index.
GA was measured using a 5-level Likert-scale patient recall question.
[a]GA values 1–2 = pain free and much better.
[b]GA values 3–5 = better, somewhat better, and worse.

residual back pain is known to be a major patient complaint following LDH surgery.[27] Perceived increased back pain after spinal procedures is such an established concept that it has become an entity of its own, with thousands of people suffering from *failed back surgery syndrome* or, more recently and perhaps more adequately named, *chronic pain after spinal surgery*.[28] A method to decrease the amount of tissue trauma in LDH surgery could potentially offer huge advantages for patients and doctors alike.

Regarding disability, both the FELD and control group had more than 63% of patients reaching MIC in ODI, whereas only 24.9% did not attain the PASS limit. Both groups had similar changes in ODI, and FELD was noninferior in ODI.

Table 4. Attained PASS scores for the groups.

PASS Scores	Total (*N* = 480)	FELD Group (*n* = 80)	Control Group (*n* = 400)	*P* Value	Difference Between Groups, Mean (95% CI)
NRS_{Leg} ≤2, *n* (%)					
No	91 (31.4%)	28 (41.8%)	63 (28.3%)		13.5 (−0.6; 27.7)
Yes	199 (68.6%)	39 (58.2%)	160 (71.7%)	0.055	−13.5 (−27.7; 0.6)
Missing	190	13	177		
NRS_{Back} ≤2, *n* (%)					
No	112 (39.2%)	28 (45.2%)	84 (37.5%)		7.7 (−7.3; 22.6)
Yes	174 (60.8%)	34 (54.8%)	140 (62.5%)	0.34	−7.7 (−22.6; 7.3)
Missing	194	18	176		
Oswestry Disability Index ≤22, *n* (%)					
No	72 (24.9%)	18 (28.1%)	54 (24.0%)		4.1 (−9.2; 17.5)
Yes	217 (75.1%)	46 (71.9%)	171 (76.0%)	0.60	−4.1 (−17.5; 9.2)
Missing	191	16	175		

Abbreviations: FELD, full-endoscopic lumbar discectomy; NRS, Numerical Rating Scale; PASS, patient acceptable symptom state.

Table 5. MIC values for the different surgical groups.

MIC	FELD Group (n = 80)	Control Group (n = 400)	P Value	Difference Between Groups, Mean (95% CI)
NRS_{Leg} change ≥3.5, n (%)				
No	17 (39.5%)	58 (26.4%)		13.2 (−3.9; 30.3)
Yes	26 (60.5%)	162 (73.6%)	0.12	−13.2 (−30.3; 3.9)
Missing	37	180		
NRS_{Back} change ≥2.5, n (%)				
No	23 (59.0%)	125 (56.8%)		2.2 (−16.1; 20.4)
Yes	16 (41.0%)	95 (43.2%)	0.94	−2.2 (−20.4; 16.1)
Missing	41	180		
Oswestry Disability Index change ≤20, n (%)				
No	26 (63.4%)	148 (66.4%)		−3.0 (−20.4; 14.5)
Yes	15 (36.6%)	75 (33.6%)	0.84	3.0 (−14.5; 20.4)
Missing	39	177		

Abbreviations: FELD, full endoscopic lumbar discectomy; MIC, minimal important change; NRS, Numerical Rating Scale.

The GA_{Leg} and GA_{Back} have been suggested to be used as surrogate variables for assessing surgical outcomes, and, in analogy with the other measured PROMs in this study, no intergroup differences were found.

The standard LDH surgery still offers excellent efficacy and value, and FELD should be considered an alternative surgical approach but perhaps still in search of its true signature indication where superiority can be proven. Decreasing the amount of tissue trauma and postoperative back pain is a tantalizing prospect for physicians and patients alike. The increasing prevalence of obesity poses a particular risk for operative and postoperative management and complications, and this might be the perfect indication for FELD, especially for lateral or foraminal disc herniations.

During the past 15 years, FELD has evolved to become a viable alternative to other visualized operative techniques for discectomy.[24,29–31] Theoretically, there are several advantages with the method that would facilitate a safer and less invasive surgery with potential for enhanced recovery and superior results. Modern endoscopes offer an incomparable overview, illumination, and visualization of the operative field when compared with either microscopic enhancement or simple loupes, and the decreased amount of intraoperative trauma has the potential to reduce the risk of postoperative persistent back pain.

Limitations

This study comprised a consecutive cohort from a single center. The study cohorts were matched on gender, age, preoperative pain duration, and level of disc herniation only. While all of these parameters are relevant and important in a preoperative selection process, none of them are very strong predictors for currently used PROMs. A more extensive matching procedure might eliminate some of the inherent bias in this study design.

CONCLUSION

The FELD results are not inferior to standard surgery 1 year postoperatively for LDH. There were no significant differences regarding MIC achieved or final PASS in any of the measured PROMs, including leg pain, back pain, or disability (ODI) between the surgical methods. FELD is an alternative to standard surgery for LDHs.

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