The Spine Journal 23 (2023) 1494–1505

Clinical Study

Anterolateral versus posterior minimally invasive lumbar interbody fusion surgery for spondylolisthesis: comparison of outcomes from a global, multicenter study at 12-months follow-up

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FDA device/drug status: approved (CD Horizon (TM) Spinal System, Medtronic).

Author disclosures: ***PP***: Consulting fee or honorarium: Medtronic (B); Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like: Medtronic (C, Paid directly to institution); Speaking and/or Teaching Arrangements: Medtronic (C). ***YP***: Nothing to disclose. ***VA***: Nothing to disclose. ***YC***: Royalties Stryker, Clariance - Level (C); Consulting Stryker, Clariance, Ceraver, Spinevision Level (B); Speaking and/or teaching Stryker Level (B); Trips/travel Clariance, Ceraver Level (B); Research support Medtronic, Phillips Level (C); Grants Stryker, Clariance Level (F). ***AK***: Grants: Investigator grant for clinical research supported by Medtronic (MIDDLS) (C, Paid directly to institution). ***WS***: Nothing to disclose. ***SP***: Nothing to disclose. ***JF***: Grant: Medtronic (B, Paid directly to institution); Fees for participation in review activities such as data monitoring boards, statistical analysis, end point committees, and the like: Medtronic (A); Royalties: Medacta (D), Medtronic (A); Consulting: surgalign (B), BD Bard (B); Speaking and/or Teaching Arrangements: globus (C), Medtronic (C), mainstay (B). ***SF***: Consulting: Medtronic, Stryker; Research Support (Investigator Salary, Staff/Materials)^: Medicrea, Medtronic. ***GB***: Speaking and/or Teaching Arrangements: Medtronic, Depuysynthes, Globus, Stryker (C); Trips/Travel: Medtronic, Depuysynthes, Globus, Stryker (B); Research Support (Investigator Salary, Staff/Materials)^: Medtronic (C, Paid directly to institution). ***YS***: Nothing to disclose. ***SH***: Nothing to disclose. ***EV***: Grant: Medtronic (A). ***SM***: Nothing to disclose. ***PV***: Medtronic: (B, Paid directly to institution); Speaking and/or Teaching Arrangements: DePuy Synthes (B). ***TH***: Consulting: Zimmer Biomet (A, per year). ***SB***: Nothing to disclose. ***JH***: Nothing to disclose. ***DV***: Nothing to disclose. ***PD***: Nothing to disclose.

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https://doi.org/10.1016/j.spinee.2023.05.013

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Received 6 January 2023; revised 30 March 2023; accepted 16 May 2023

Abstract

BACKGROUND CONTEXT: Several minimally invasive lumbar interbody fusion techniques may be used as a treatment for spondylolisthesis to alleviate back and leg pain, improve function and provide stability to the spine. Surgeons may choose an anterolateral or posterior approach for the surgery however, there remains a lack of real-world evidence from comparative, prospective studies on effectiveness and safety with relatively large, geographically diverse samples and involving multiple surgical approaches.

PURPOSE: To test the hypothesis that anterolateral and posterior minimally invasive approaches are equally effective in treating patients with spondylolisthesis affecting one or two segments at 3-months follow-up and to report and compare patient reported outcomes and safety profiles between patients at 12-months post-surgery.

DESIGN: Prospective, multicenter, international, observational cohort study.

PATIENT SAMPLE: Patients with degenerative or isthmic spondylolisthesis who underwent 1- or 2-level minimally invasive lumbar interbody fusion.

OUTCOME MEASURES: Patient reported outcomes assessing disability (ODI), back pain (VAS), leg pain (VAS) and quality of life (EuroQol 5D-3L) at 4-weeks, 3-months and 12-months follow-up; adverse events up to 12-months; and fusion status at 12-months post-surgery using X-ray and/or CT-scan. The primary study outcome is improvement in ODI score at 3-months.

METHODS: Eligible patients from 26 sites across Europe, Latin America and Asia were consecutively enrolled. Surgeons with experience in minimally invasive lumbar interbody fusion procedures used, according to clinical judgement, either an anterolateral (ie, ALIF, DLIF, OLIF) or posterior (MIDLF, PLIF, TLIF) approach. Mean improvement in disability (ODI) was compared between groups using ANCOVA with baseline ODI score used as a covariate. Paired *t*-tests were used to examine change from baseline in PRO for both surgical approaches at each timepoint after surgery. A secondary ANCOVA using a propensity score as a covariate was used to test the robustness of conclusions drawn from the between group comparison.

RESULTS: Participants receiving an anterolateral approach (n=114) compared to those receiving a posterior approach (n=112) were younger (56.9 vs 62.0 years, p <.001), more likely to be employed (49.1% vs 25.0%, p<.001), have isthmic spondylolisthesis (38.6% vs 16.1%, p<.001) and less likely to only have central or lateral recess stenosis (44.9% vs 68.4%, p=.004). There were no statistically significant differences between the groups for gender, BMI, tobacco use, duration of conservative care, grade of spondylolisthesis, or the presence of stenosis. At 3-months follow-up there was no difference in the amount of improvement in ODI between the anterolateral and posterior groups (23.2 ± 21.3 vs 25.8 ± 19.5, p=.521). There were no clinically meaningful differences between the groups on mean improvement for back- and leg-pain, disability, or quality of life until the 12-months follow-up. Fusion rates of those assessed (n=158; 70% of the sample), were equivalent between groups (anterolateral, 72/88 [81.8%] fused vs posterior, 61/70 [87.1%] fused; p=.390).

CONCLUSIONS: Patients with degenerative lumbar disease and spondylolisthesis who underwent minimally invasive lumbar interbody fusion presented statistically significant and clinically meaningful improvements from baseline up to 12-months follow-up. There were no clinically relevant differences between patients operated on using an anterolateral or posterior approach.

*Keywords:*Effectiveness; Fusion rate; Lumbar interbody fusion; Minimally invasive spine surgery; Patient reported outcomes; Spondylolisthesis

Introduction

Spondylolisthesis refers to the abnormal translation of one vertebra over another, represents a common pathology associated with the ageing lumbar spine, and can result in severe disability [1]. Most commonly, spondylolisthesis results from a defect in the pars interarticularis or from degeneration of the facet joints [2]. If conservative care does not produce satisfactory outcomes for the patient, surgery is considered. Several studies have demonstrated better outcomes after surgery compared to conservative treatment. For example, the Spine Patients Outcome Research Trial (SPORT) demonstrated the superiority of surgical versus conservative treatment at 2- and 4-years of follow-up, especially in those patients in whom neurogenic claudication predominates [3]. Despite this, there is no consensus on the surgical management of spondylolisthesis.

Minimally invasive (MI) spinal surgery techniques, for both decompression and fusion, have been associated with benefits over open approaches in perioperative parameters such as blood loss, postoperative pain control and mean hospital stay [4−8].

Minimally invasive techniques can be used for several lumbar interbody fusion approaches to treat spondylolisthesis, including anterolateral (ALIF), direct lateral trans-psoas (DLIF), oblique ante-psoas (OLIF), midline using cortical bone trajectory screws (MIDLF), posterior (PLIF) and transforaminal (TLIF). A growing body of literature exists that examines the safety, efficacy, and effectiveness of these surgical approaches, including systematic reviews, meta-analyses and cohort studies, but it is not without limitations. Some systematic reviews and meta-analyses make comparisons between approaches such as DLIF and PLIF [9] but include both open and MI procedures, while others compare open with MI techniques for a specific approach (eg, TLIF [10]). Similarly, existing cohort studies examining safety and effectiveness of these approaches are prospective in design but not comparative (eg, for MI-TLIF [11]); others are prospective and comparative but have small sample sizes and report outcomes only up to 3-months follow-up [12]. Others again might compare anterolateral and posterior approaches but include both open and MI procedures and are retrospective in design (eg, ALIF versus TLIF [13]). Overall, the current evidence suggests that the approaches are safe and effective for treating spondylolisthesis, but an evidence gap remains that considers a real-world patient group, reflecting standards of care. Further, physicians may also expect differences in outcomes because of the decompression possibilities of each technique and so there is a need to investigate anterolateral and posterior approaches further.

The current study was built upon this literature and an earlier study of MI TLIF and PLIF procedures that demonstrated effectiveness and safety within a predominantly European patient group up to 12-months [14−16]. It includes a more geographically diverse patient sample to investigate the long-term effectiveness of MI anterolateral and posterior surgical approaches. It is, to our knowledge, the first global multicenter, prospective, data monitored real-world trial including six different approaches for MI LIF in spondylolisthesis patients that examines differences between anterior and posterior approaches. Based on findings from the literature, including MI and open surgery, comparisons between single approaches [9,13], and the earlier related study [14−16], the hypothesis of the present research was that anterolateral and posterior MI approaches are equally effective in treating patients with spondylolisthesis affecting one or two segments.

Methods and materials

Study design

This global, prospective, data-monitored cohort study of patients who received fusion treatment via a MI anterolateral (ALIF, DLIF, OLIF) or posterior approach (MIDLF, PLIF, TLIF), with a 5-year follow-up, was designed by an expert advisory committee (comprised of orthopedic surgeons, neurosurgeons, and independent methodologist) and statisticians. The advisory committee was responsible for study oversight and advised on clinical safety. Participating, experienced surgeons determined the choice of approach for each participant and discussed this with the patient.

MASTERS-D 2 (this study) was registered at clinicaltrials.gov (NCT02617563) and, if required by local regulations, ethics approval (n=18) was obtained prior to patient recruitment. (See Supplementary File 1 for a full list of ethical committees from which approval was obtained.) The study is ongoing and adheres to the Declaration of Helsinki 2013, alternative standards, and requirements per applicable local laws.

Primary and secondary outcomes

The primary objective of this study was to compare results of MI lumbar interbody fusion by an anterolateral approach to a posterior approach, both supplemented with placement of pedicle screws, as measured by the primary endpoint: that is, improvement of Oswestry Disability Index (ODI) at 3-months compared to baseline. This timepoint was selected based on an earlier, related study, that indicated changes in ODI scores were maintained after 3-months [14]. An additional rationale for this decision was the fact that the ODI could be influenced by other concomitant conditions which may worsen over time, such as hip pathology. Establishing the primary endpoint at 3 months after surgery was considered a suitable strategy to reduce this effect.

Secondary objectives of the study were to examine improvements in disability, back pain, leg pain, quality of life and fusion rates at different time points until 5 years after surgery and the safety profile. This manuscript presents results up to 12-months follow-up as this is when we would expect most fusions to have taken place by (if at all).

Table 1
Participant selection criteria into MASTERS-D 2

Inclusion criteria	Exclusion criteria
Patient is ≥ 18 years of age (or minimum age as required by local regulations)	Patient that has already undergone a lumbar fusion surgery.
Patient has degenerative spine disease and an indication for a single or double level instrumented lumbar fusion for the treatment.	Patient that has already undergone open lumbar surgery other than standard decompression surgery.
Patient agrees to participate in the study and is able to sign the Data Release Form/Informed Consent.	Indications for the procedure other than degenerative spine disease like: osteoporotic vertebral fractures, spine trauma fractures or spine tumor
The procedure planned for the patient complies with the labeling of the devices that may be used in the surgical procedure.	Illiterate or vulnerable patients (eg, minors, participants incapable of judgment or participants under tutelage)
Patient is planned to be submitted to a MI fusion procedure using a posterior (PLIF, TLIF, MIDLF) or anterolateral (OLIF, ALIF, DLIF) technique*	Concurrent participation in another clinical study that may confound study results.
The patient is willing and can perform study procedures and required follow-up visits.	Patient refused to participate in the study.

* For a double level instrumented fusion, the same procedure must be used for both levels.

Participants

Consecutive patient recruitment and enrollment was conducted by the participating surgeons between January 2016 and June 2019 at 26 sites across Europe, Asia, and Latin America. Informed consent was given by patients prior to any study-related procedure being undertaken. Supplementary File 2 includes a full list of participating study centers. Participant inclusion and exclusion criteria are presented in Table 1 and are consistent with an earlier, related study (MASTERS-D) [14]. Only participants with spondylolisthesis are included in this manuscript. Participants with degenerative lumbar disease without spondylolisthesis will be the focus of a future manuscript.

Site selection was based on surgeon experience, available patient population, interest in conducting clinical studies, 12-months fusion assessment being part of standard hospital practice and being willing and having the resources to comply with regulations stipulated in the protocol. Only experienced surgeons were selected to avoid learning curve effects. “Experienced” was defined as having completed at least 30 MI lumbar interbody fusion procedures. All participating centers and surgeons were trained for administrative procedures and data collection by Medtronic. To ensure a global contribution and distribution of the surgical approaches, recruitment limits were set per procedure, site, and region.

Sample size calculation

The primary objective was tested by between groups comparison of the improvement in function as measured by ODI at 3-months. To do so, the 95% confidence interval of the mean difference in ODI score at 3-months between patients with spondylolisthesis treated with anterolateral and posterior approaches respectively was required to be within a predefined equivalence range (-10, 10) [17,18]. The sample size calculations were based on the following assumptions: that the standard deviation for ODI improvement at 3-months was 20 points for both groups [14]; that there was no difference in the mean ODI improvement at 3-months between groups; 80% power; and 5% alpha. The sample size per group (anterolateral/posterior approach) was required to be a minimum of 70 (ie, 140 in total) to claim equivalence in improvement in ODI at 3-months. From MASTERS-D [14,16] approximately 50% of the patients with lumbar degenerative disease who were candidates for fusion had spondylolisthesis. Hence the required total sample size for the study (ie, patients with and without spondylolisthesis) and allowing for some loss to follow-up, was 140/0.5 = 280.

Surgical procedures

Minimally invasive (mini-open or percutaneous) procedures were used in this study. The minimally invasive procedure (defined in the study protocol as a muscle sparing surgical technique using an intermuscular or transmuscular fiber-splitting approach that minimizes detachment of the thoracolumbar fascia, paraspinal muscles, or the abdominal wall muscles) was used to address the spinal pathology and placement of instrumentation. In the mini-open technique, instruments were used under direct vision of target structures via an intermuscular or transmuscular approach. In the percutaneous technique, instrumentation was placed using fluoroscopic or navigation guidance via stab incisions without direct vision of target structures. The muscle-sparing MI approach could be performed unilaterally or bilaterally for instrumentation and spinal decompression at the surgeon’s discretion. One or two cages were placed in the intervertebral space to maintain or restore disc height. Either a percutaneous or mini-open technique could be used for posterior fixation.

To ensure some similarity within and make a clear distinction between the different techniques, the following definitions were applied. For the anterolateral procedures: ALIF was defined as an anterior incision, using a transperitoneal or retroperitoneal approach with disc access at L4-L5 or L5-S1; DLIF as fusion procedures with a lateral transpsoas approach via a small lateral abdominal wall incision and muscle-splitting through the psoas using tubular

dilatation (also referred to Lateral Lumbar Interbody Fusion in literature); and, OLIF as either OLIF25 with access to L2-L5, approach via oblique corridor between the aorta and the psoas avoiding the lumbar plexus and iliac crest or OLIF51 for access to L5-S1, approach via oblique corridor from the skin to reach the L5-S1 disc between the iliac vessels, both procedures with the patient in a lateral position. For the posterior procedures: MIDLF was defined as fusion procedures with a midline approach, decompression, interbody fusion and fixation using cortical bone trajectory pedicle screws (medial to lateral and caudal to cranial with the screw construct placed mainly into cortical bone); TLIF used fusion procedures targeting the disc space with a trajectory lateral to the medial pedicle wall and full facetectomy; and, PLIF used fusion procedures targeting the disc space with a trajectory medial to the medial pedicle wall.

Medical devices used in the study

This was a post market release study, in which all devices and products were commercially approved and required to be used within their intended use. Surgeons used commercially available MI access systems to complete the surgery. For anterior stabilization, any commercially available fixation could be used. For posterior stabilization though, all patients received the CD Horizon Spinal System (Medtronic PLC, USA, Inc.) which consists of a variety of rods, screws, and other connecting components. Regardless of other implants used, all patients received posterior fixation. The constructs were expected to be used in combination with cages, bone graft and/or bone graft substitutes/biologics to facilitate interbody fusion.

Patient reported outcomes

The primary outcome, the Oswestry Disability Index [19,20] is a cross validated, self-administered questionnaire measuring disability associated with lower back pain. It is widely used and has good psychometric properties [21,22]. Secondary PRO measures included visual analogue scales (VAS) of severity of back and leg pain [23] and the EuroQoL 5D (EQ-5D-3L [24]; hereafter referred to as the EQ5D). All patient reported outcome measures were administered using validated translated versions for the respective language at the sites.

Surgical and hospital data

Surgical data and outcomes following surgery included rehabilitation program use, time needed for first ambulation, surgery recovery day, and pain medication used throughout the study. Time needed for first ambulation was defined as the time, in days, needed for first ambulation with or without assistance. Surgery recovery day was defined as the day when the patient *could* be discharged based on their actual clinical condition rather than the actual day of discharge as this may be prolonged by factors other than the patient's clinical recovery (eg, social factors, comorbidity, health system regulations).

Patient safety

Details of all adverse events (AEs), regardless of relatedness to surgical procedure, device, disease, or outcome were collected. Each AE was classified according to ISO14155 definitions. The relationship parameters were assessed and categorized as per MEDDEV 2.7.3 definitions of causality. AEs were classified as "related" if an investigator indicated that they were *causally related, probably*, or *possibly* related to the surgical procedure and/or devices. Adverse events that were solely attributed to disease progression are not included in this manuscript (which presents 12-months follow-up data) but will be reported at later timepoints and to the relevant regulatory authorities. For the purposes of reporting, AEs were provisionally aggregated by the first author (PP) and subsequently reviewed by the Advisory Committee, and independent methodologist.

The dataset will not be considered "final" until the 5-year follow-up period is complete.

Fusion evaluation

Fusion was evaluated using X-ray and/or CT scan, within a 12-months follow-up window (± 6 months) by either the participating surgeon or hospital radiologist. The criterion for fusion when assessed with a CT-scan was the presence of bony bridging. When assessed with X-rays the criteria were bony bridging, no motion (<4°) in flexion/extension views and integrity of instrumentation [25].

Data collection and monitoring

Data collection was undertaken by trained staff at the participating sites for continuous (ie, age, height, weight, duration of conservative care, PRO) and categorical (ie, gender, work status, smoking, medication use, neurological status, comorbidities prior to surgery) variables. Data monitoring was conducted by Medtronic to verify accuracy and completion of outcome measures. An overview of the completed and scheduled data collection is provided in Supplementary File 3.

Statistical analysis

To obtain an overview of the sample's characteristics, categorical variables (ie, gender, work status, smoking, medication use, neurological status, comorbidities prior to surgery) were summarized using frequencies; continuous variables (ie, age, height, weight, duration of conservative care, PRO) were summarized using mean and standard deviations.

To evaluate the primary endpoint, ANCOVA was performed with baseline ODI as covariate and the two-sided 95% confidence interval for the least square mean difference of ODI improvement at 3-months between anterolateral and posterior groups was calculated. If the 95% CI was within the equivalent range (-10, 10), then the primary objective was judged as having been met.

In addition, paired *t*-tests were carried out for anterolateral and posterior surgical approach group to test if the ODI, back pain, leg pain and EQ5D index score improvement at 4 weeks, 3- and 12-months from baseline were significant.

Since this study was observational, differences between baseline variables were possible (eg, age, proportions of patients in employment, with different types of spondylolisthesis and stenosis), and these differences could lead to biased estimations of treatment effects. To address this, additional analyses were carried out to evaluate the primary endpoint. The method replicated the original ANCOVA but included a propensity score as a covariate in addition to baseline ODI to balance the baseline variables in the two groups, and thus reduce the bias. The propensity score was defined as the conditional probability of a subject being treated with the anterolateral approach given the observed baseline variables and was constructed using logistic regression [26]. (See Supplementary File 4 for a list of all variables included in the propensity score.) The multiple imputation technique was applied for handling missing baseline data in the derivation of propensity score. Back pain, leg pain and EQ5D improvement at 3-months were checked by including the propensity score in the ANCOVA model in addition to the corresponding baseline value to test the robustness of conclusions drawn from the primary analyses.

Results

Study population and baseline characteristics

The study enrolled 365 patients to account for anticipated drop out over the course of the study. However, only 335 were treated according to protocol and were therefore retained for analysis. The outcomes associated with participants with spondylolisthesis (n=226) are the primary patient population of interest in this study and are reported here. Among them, 114 patients (50.4%) received MI lumbar interbody fusion using an anterolateral approach and 112 through a posterior approach as per surgeon's choice. The participant flow chart is presented in Fig. 1.

At 12-months follow-up 220/226 (97.3%) patients remained in the study. In the anterolateral group, 1 patient withdrew, 1 was excluded due to not being treated according to the CIP, and 1 was lost to follow-up. In the posterior group, 1 withdrew and 2 were lost to follow-up.

Baseline characteristics are presented in Table 2. The two subgroups differed on: age (patients who underwent a posterior approach were, on average, 5.1 years older), working status (49.1% of patients in the anterolateral group were employed, vs 25.0% in the posterior group); type of spondylolisthesis (38.6% of patients in the anterolateral group had isthmic spondylolisthesis compared to 16.1% in the posterior group); and types of stenosis (44.9% in the anterolateral group had only central stenosis compared to

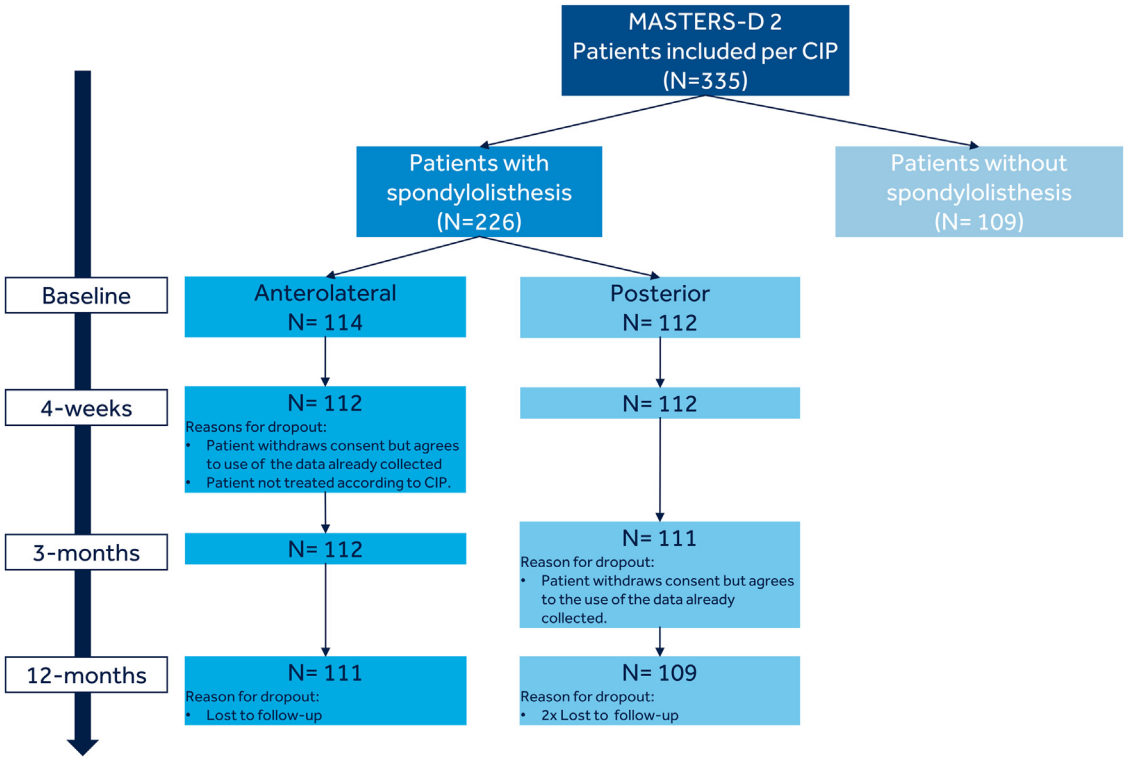

Fig. 1. Participant flow chart.
CIP: Clinical Investigation Plan.

Table 2
Baseline characteristics of the population

	Total (n=226)	Anterolateral (n=114)	Posterior (n=112)	p-value
Gender (% females)	63.3	60.5	66.1	.410
Age, mean+SD (years)	59.4±10.7	56.9±10.3	62.0±10.4	<.001
BMI, mean+SD (Kg/m^2)	27.1±4.4	27.4±4.2	26.8±4.5	.332
Tobacco use (%)	18.1	22.8	13.4	.084
Working status (% employed)	37.2	49.1	25.0	<.001
Duration of conservative care, mean+SD (months)	23.2±27.0	25.9±29.4	20.2±23.8	.120
Spondylolisthesis type				<.001
- Degenerative (%)	72.6	61.4	83.9	
- Isthmic (%)	27.4	38.6	16.1	
Spondylolisthesis grade				.078
- Grade 1	82.7	78.1	87.5	
- Grade 2	17.3	21.9	12.5	
Stenosis present at 1- or 2-levels	87.1	86.0	88.3	.692
Stenosis type				.004
- Central/lateral recess only (%)	56.6	44.9	68.4	
- Foraminal only (%)	22.4	29.6	15.3	
- Both (%)	20.9	25.5	16.3	

68.4% in the posterior group). There was a higher proportion of smokers in the anterolateral group (22.8% vs 13.4%), but this difference was not statistically significant.

The most common comorbidities among these patients were hypertension (47.3%), dyslipidemia (23.5%) and diabetes (11.9%) and were evenly distributed between the subgroups. Previous nonfusion lumbar surgeries had been performed in 10 patients who underwent an anterolateral fusion and in 4 patients in the posterior fusion group (p= .166).

Surgical procedures and perioperative data

In the anterolateral approach group, 43 patients underwent an OLIF procedure, 40 patients a DLIF and 31 an ALIF. The posterior group included 53 patients who received a TLIF, 48 a MIDLF and 11 a PLIF procedure. A two-level surgery was performed in 14.9% of patients in the anterolateral group and 13.4% in the posterior group (p= .849). Taking the first and second levels operated on together, the anterolateral fusions included the L4-L5 level in 47.3% and L5-S1 in 31.3%, whereas the posterior fusions included L4-L5 in 70.9% and L5-S1 in 14.2% of surgeries. The L2-L3 level was operated only in 3 patients (1 anterolateral and 2 posterior approaches) and no surgery was performed above this level.

The mean operative time was approximately 30 minutes longer for the anterolateral approach and estimated mean blood loss was 174mL higher for the posterior approach; total fluoroscopy time was similar for both groups and shows large standard deviations (Table 3). These differences and similarities held when reported by the number of levels treated except for estimated fluoroscopy time for participants who had two-levels treated. Blood transfusion was required for 1 patient in the anterolateral group and 2 patients in the posterior group. Early postoperative recovery parameters, such as mean time to first ambulation, time to the protocol-defined "surgery recovery day" and total length of stay were similar between groups (Table 3).

Table 3
Perioperative data

	Anterolateral		Posterior		p-value
		n		n	
Operative time, mean±SD (hours)	3.5±1.3	112	3.0±1.0	110	.003
• 1-level, mean ±SD (hours)	3.3±1.2	95	2.9±0.9	95	.011
• 2-level, mean ±SD (hours)	4.2±1.6	17	3.4 ±1.2	15	.156
EBL, mean±SD (mL)	128.6±108.6	107	303.0±217.8	108	<.001
• 1-level, mean±SD (mL)	124.0±110.4	91	271.0±175.9	93	<.001
• 2-level, mean±SD (mL)	155.0±96.6	16	501.3±331.9	15	<.001
Fluoroscopy time, mean±SD (secs)	146.9±157.2	104	128.9±194.1	108	.460
• 1-level mean ±SD (secs)	130.8±150.7	89	139.9±205.9	93	.736
• 2-level mean ±SD (secs)	242.5±166.5	15	60.9±61.2	15	<.001
TFA, mean±SD (days)	1.7±1.5	113	1.8±1.5	112	.426
TSRD, mean±SD (days)	4.7±3.9	113	5.1±6.1	112	.521
Length of stay, mean±SD (days)	7.0±6.0	113	7.6±6.7	112	.505

EBL – estimated blood loss, TFA – time to first ambulation, TSRD – time to “surgery recovery day”.

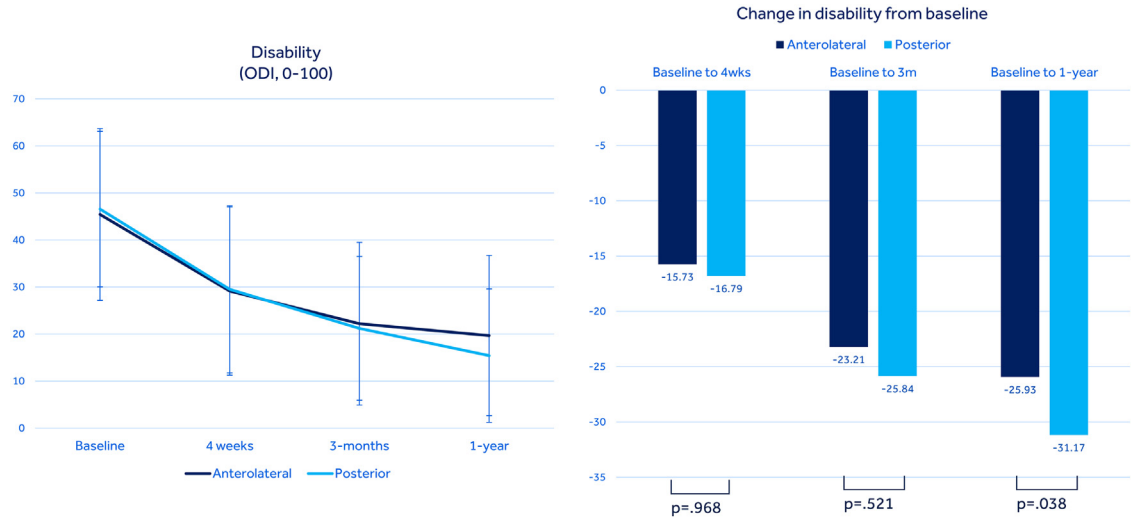

Fig. 2. Evolution of disability (ODI) from baseline to 12-months follow-up.
***p<.001, paired within group t-test. For between group comparisons, the p-value is obtained after controlling for baseline values.

Primary outcome

Baseline mean ODI score was 45.4/100 (± 18.3) for the anterolateral group and 46.6/100 (± 16.5) for the posterior group (p= .622). At 3-months follow-up there was a statistically significant and clinically meaningful improvement of 23.2 ± 21.3 centesimal points in the anterolateral group and 25.8 ± 19.5 in the posterior (both p-values < .001; minimal clinically important difference [MCID] = 14.3 [27]), with 95% CI of (-5.8, 2.9) for mean difference, which was within the equivalent range (-10, 10) (Fig. 2). At 12-months, a statistically significant, but not clinically meaningful, difference in the amount of improvement had emerged between the two groups (p = .038). The conclusions drawn from the ANCOVAs for both the primary and secondary outcomes were consistent with those drawn from the propensity score analyses. The propensity score analyses are reported in Supplementary File 4.

Secondary outcomes

Patient-reported outcomes

Back and leg pain were both significantly reduced at 12-months follow-up, regardless of whether an anterolateral or posterior procedure was performed, with no statistical differences between groups (Fig. 3). Mean reductions in back pain from baseline to 12-months ranged between 3.32 (posterior group) to 3.83 (anterolateral group), while reductions in leg pain ranged from 4.31 (anterolateral group) to 4.73 (posterior group) points; both of which are above the magnitude considered to be of minimal clinical important difference (MCID, ie, 1.2 for back pain; 1.6 for leg pain) [28,29]. Patient-reported quality of life, as assessed by the EQ-5D-3L index score, significantly improved from baseline to 12-months postoperatively in both groups (p<.001). The improvement in quality of life was statistically lower in the anterolateral (mean improvement = 0.27) compared to the posterior group (mean improvement = 0.30) at 12-months although not clinically meaningful (MCID = 0.19 [30]) Fig. 4.

Fusion evaluation

Due to the COVID-19 pandemic, there was a large amount of missing data for the fusion assessment at 12-months. Of those assessed at 12 (±6)-months (n=158/226, 69.9%), the overall fusion rate was 84.2%. The fusion rate for the anterolateral group was 81.8% (72/88 patients assessed; 27 with X-ray, 40 with CT, and 21 with both X-ray and CT) and for the posterior group 87.1% (61/70 patients assessed; 22 with X-ray, 25 with CT, and 23 with X-ray and CT; between groups, p =.39). Post hoc tests indicated that there were no statistically significant differences in fusion rates between or within anterolateral and posterior groups by fusion assessment modality.

Patient safety

Table 4 shows clinically relevant AEs (n=41) related to either surgery, medical device, or both. There was no difference in the rate of AE between anterolateral and posterior approaches. Up to 12-months follow-up 12 patients had a total of 12 additional spinal surgeries at the index levels only (5 anterolateral group, 7 posterior group). The reasons given for the additional surgeries at the index levels included: cage dislocation (n=3); screw misplacement (n=3); epidural hematoma (n=2); radicular pain (n=2), dural tear (n=1); and vascular injury (n=1). Two additional spinal surgeries were recorded at adjacent or other levels (one anterolateral, one posterior).

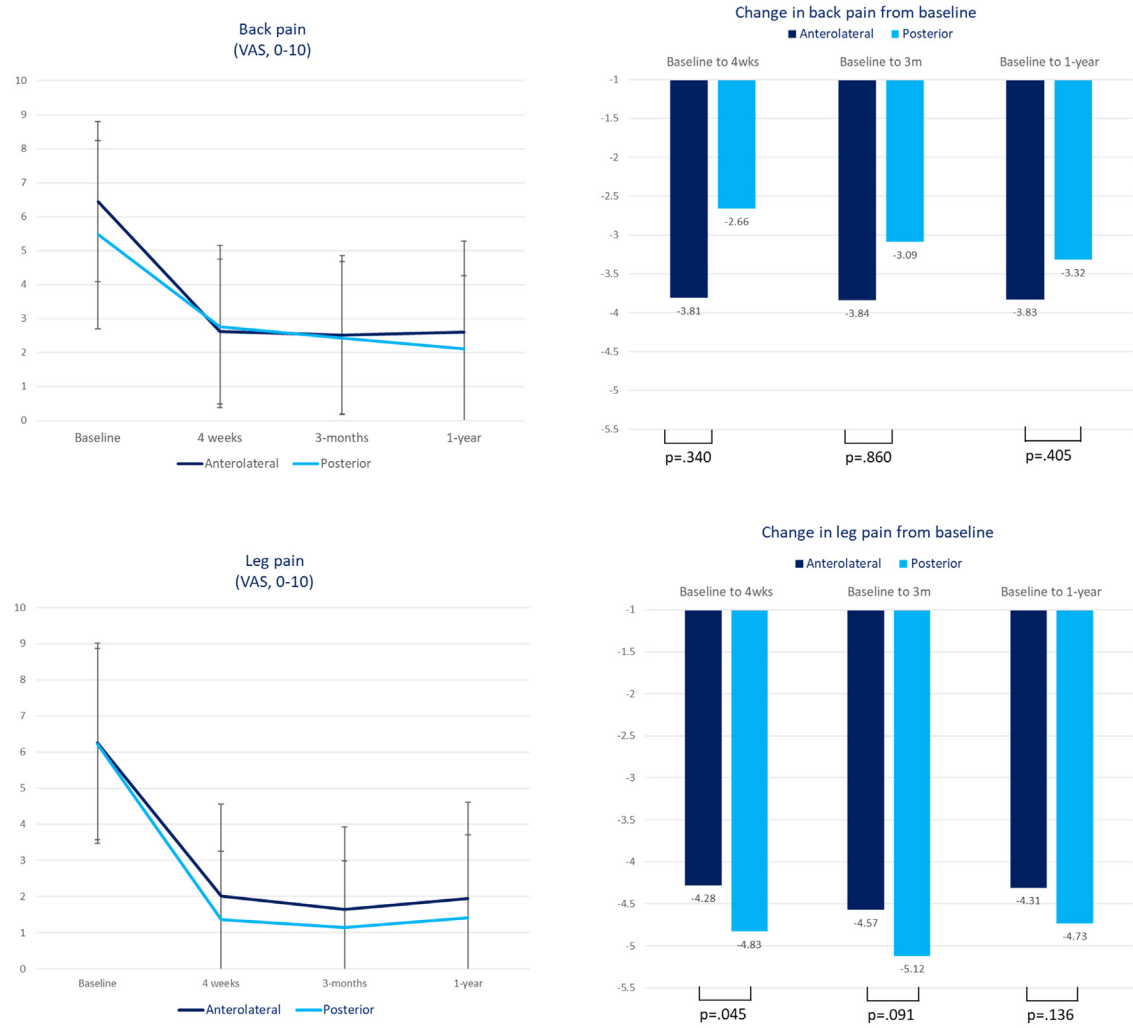

Fig. 3. Evolution of back pain and leg pain (VAS) from baseline to 12-months follow-up.
***p<.001, paired within group t-test. For between group comparisons, the p-value is obtained after controlling for baseline values.

Table 4
Clinically relevant adverse events related to device or surgical procedure

Adverse event	Anterolateral	Posterior	Total
Cage migration	2		2
Dural tear		1	1
Epidural hematoma	1	1	2
General complications	1	8	9
Ileus	2		2
Peripheral nerve injury	2		2
Peritoneal tear	1		1
Peritonitis	1		1
Radicular pain	3	2	5
Radiculopathy	2	2	4
Screw misplacement	2	3	5
Surgical site infection	1	3	4
Vascular injury	1		1
Wound dehiscence	1	1	2
Total	**20**	**21**	**41**

Discussion

Though MI lumbar interbody fusion techniques have shown an improvement in blood loss [31], postoperative pain [32], and length of hospital stay [31] over traditional open procedures, no observational study with such a large and geographically diverse sample of patients has compared anterolateral to posterior MI approaches until now. The current study found that patients with spondylolisthesis undergoing MI lumbar interbody fusion had statistically and clinically significant improvements in PRO compared to baseline up to 12-months after surgery. Both groups exceeded the MCID value for improvement in ODI but did not differ significantly between them. In addition, there were no clinically significant differences between patients operated on using anterolateral or posterior approaches at 3- or 12-months follow-up.

There is a paucity of literature comparing anterolateral and posterior MI lumbar fusion approaches. Of the available evidence, Sembrano et al. reported that two-year

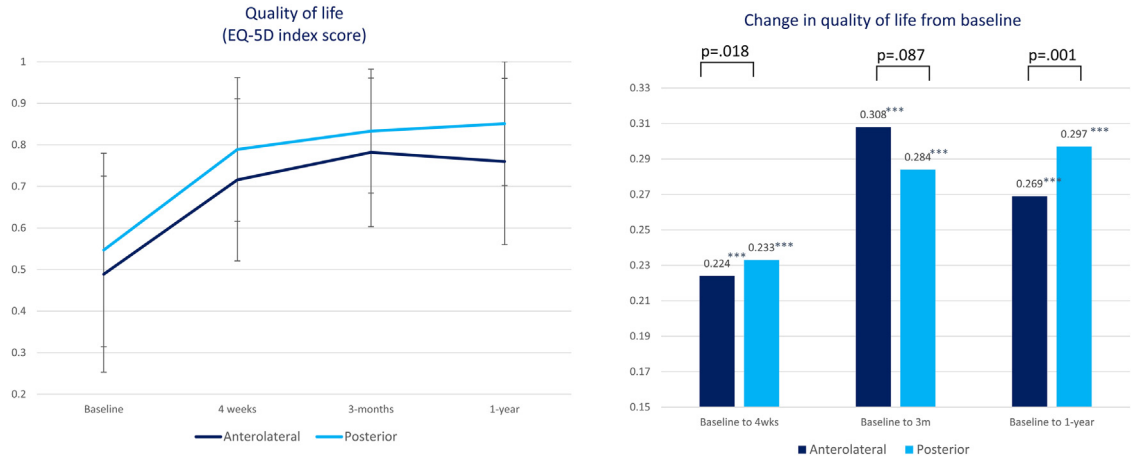

Fig. 4. Evolution of quality of life (EQ-5D index score) from baseline to 12-months follow-up.
***p<.001, paired within group t-test. For between group comparisons, the p-value is obtained after controlling for baseline values.

clinical outcomes of MI lateral lumbar interbody fusion (LLIF) and MI TLIF were similar and both groups significantly improved from baseline [33]. Isaacs et al. reported in a subsequent study that two-year radiographic outcomes of MI LLIF and MI TLIF were similar, except that disc and foraminal height were better maintained in the lateral group and increase in central canal area was higher in the transforaminal group [34]. In a comparative study of ALIF and TLIF for L5-S1 isthmic spondylolisthesis with a minimum of one-year follow-up, ALIF showed better clinical outcomes and greater restoration of segmental lordosis and disc height [35,36]. In a systematic review and meta-analysis of comparative studies regarding anterior and posterior approaches for isthmic spondylolisthesis, no significant difference was found in the global assessment of fusion rate and clinical outcomes, despite a higher rate of complications in the anterior approach [36]. A cost-effectiveness study has also reported that TLIF was superior to anterior-posterior fusion [37].

In the present study, no significant difference was found in ODI improvement at postoperative 3-months between anterolateral and posterior approaches. Further, PRO including back pain, leg pain, and quality of life showed similar results. Only the mean operative time was longer for the anterolateral approaches and estimated blood loss was higher for the posterior approaches as reported in other studies [38–40]. These results suggest that both anterolateral and posterior approaches are effective in improving PROs for patients with spondylolisthesis and the decision of surgical approach can be made considering various factors, such as surgeon preference, patient characteristics, surgical goals, and available hospital resources and equipment. The relatively small difference in mean operative time between anterolateral and posterior approaches might be due to the efficiencies associated with the experienced physicians participating in this study. Length of hospital stay was longer than often reported on MI LIF procedures [39,41]. This difference and the large standard deviations associated with fluoroscopy time could be explained by the differences between policies and procedures between the participating hospitals and global regions.

Our study has several limitations. First, there is a concern about potential selection bias with the sample. We tried to minimize the impact of this though by (1) using a prospective study design with sequential enrollment; (2) ensuring geographical diversity within the patient sample and a balanced distribution of approaches recruiting patients from 26 centers across Europe, Asia, and Latin America; and (3) conducting a propensity score analysis as a method of checking the robustness of the conclusions drawn from the primary analysis. Ultimately, patients' allocation of treatment was the result of the surgeon's decision making (and so was neither blinded nor randomized) and represent real world practices. Second, current results are limited to 12-months, which is relatively short to evaluate outcomes after fusion surgery. Though, according to the study protocol, patients will be followed up to 5 years, and these results will be reported when available. Third, both isthmic and degenerative spondylolisthesis patients were included in the study and combined within the analyses which could blur the interpretation of results. Subgroup analyses (not presented) however, with one exception, did not find statistically significant differences between these patients on baseline and 12-months follow-up scores for disability, back pain, leg pain or quality of life. (Note: the exception was for leg pain scores at baseline between degenerative and isthmic spondylolisthesis who received an anterolateral approach; 6.7 [degenerative spondylolisthesis] vs 5.6 [isthmic spondylolisthesis], p=.035). This is also consistent with an earlier, retrospective study that reported no differences at 6-months follow-up between isthmic and degenerative spondylolisthesis patients who received MI-TLIF [42]. Fourth, sagittal alignment parameters were not collected routinely across all participating sites prior to surgery or at follow-up time points, given the observational design of the study. This information could have been of

value in further informing surgeon decision making regarding surgical approach alignment with the long-term outcome goals. Finally, as previously stated, the COVID-19 pandemic significantly impacted the possibility of performing 12-month imaging assessments in many centers, so fusion data is based on approximately 70% of patients. To obtain a more complete picture of fusion status, fusion assessments will continue at annual follow-up evaluations if the patients have not otherwise been assessed and/or achieved fusion. It is also noted that the protocol allowed for surgeons or radiologists using either CT or X-ray to assess fusion. While this facilitated usual standard care, it did so at the cost of increased heterogeneity and inter-observer agreement on fusion status at 12-months follow-up was not assessed (not within the scope of the study).

In conclusion, both MI anterolateral and posterior approaches using devices within the scope of their intended use, provided clinical improvement for patients with spondylolisthesis, with no clinically significant difference in outcomes between them. This result might not be "new" in and of itself, but this is the first time, to our knowledge, that this conclusion can be made based on such a large, multicentric, prospective, observational study using numerous anterolateral and posterior MI approaches with an inclusive real world patient sample. Appropriate surgical procedure selection considering spinal pathology, patient factors, and surgeon experience likely contributes to the overall success. Further research is needed to understand whether specific factors should be included in the surgeon decision making rationale when selecting a specific procedure that could be helpful in the provision of personalized care.

Funding

This global, multicenter study was funded by Medtronic. The clinical research department of Medtronic was involved with the design of the study in collaboration with an Advisory Committee and methodologist but had no influence on the interpretation of the data. Medtronic research staff participated in recruitment of surgeons, data monitoring, analysis of data, drafting the methods and materials section of the manuscript in accordance with Good Publication Practice (GPP3) guidelines, and coordinating communications between investigators in the writing, review, and revision of the manuscript. The authors had final responsibility for the content of the manuscript and decision to submit for publication and were not paid to write the article by Medtronic or any other agency.

Acknowledgments

We would like to thank all the patients and MASTERS-D 2 investigators who participated in the study.

Declaration of competing interest

One or more of the authors declare financial or professional relationships on ICMJE-TSJ disclosure forms.

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.spinee.2023.05.013.

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