THE EUROPEAN SOCIETY OF MEDICINE
Medical Research Archives, Volume 12 Issue 11

RESEARCH ARTICLE

Minimally Invasive Cost-Effective Surgical Treatment of Lumbar Spondylolisthesis with Associated Spinal Stenosis

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OPEN ACCESS

PUBLISHED
30 November 2024

CITATION
Cruet, MP., et al., 2024. Minimally Invasive Cost-Effective Surgical Treatment of Lumbar Spondylolisthesis with Associated Spinal Stenosis. Medical Research Archives, [online] 12(11). https://doi.org/10.18103/mra.v12i11.6163

DOI
https://doi.org/10.18103/mra.v12i11.6163

ISSN
2375-1924

ABSTRACT

Purpose

The paraspinal approach and functional anatomy sparing nature of the minimally invasive transforaminal lumbar interbody fusion are thought to decrease operative morbidity while improving patient recovery and long-term outcomes. This paper presents a unique minimally invasive approach for the treatment of patients with lumbar spondylolisthesis and associated spinal stenosis. The novel technique described within allows for significant reduction of spondylolisthesis, while also utilizing a substantial amount of the patient's morselized surgical site autograft, thus limiting the use of costly bone graft extenders. We aim to validate this technique by performing a critical analysis of postoperative patient reported outcomes with comparison to traditional open midline transforaminal lumbar interbody fusion.

Methods

Data was reviewed for 19 patients who underwent the minimally invasive transforaminal lumbar interbody fusion technique described within and subsequently compared to 140 patients who underwent traditional open midline transforaminal lumbar interbody all of whom were within the control groups of an FDA approved IDE clinical trial (NCT03115983). Operative and demographic data were collected and compared including age, gender, BMI, comorbidities, operative level, procedure time, estimated blood loss, postoperative length of stay. Pre and postoperative patient reported outcome scores were also analyzed for both groups including visual analogue score (VAS) for back and leg/hip pain and Oswestry disability index (ODI).

Results

Procedure length (minutes), estimated blood loss (mL), and length of hospital stay (days) for the patient's undergoing minimally invasive transforaminal lumbar interbody fusion were 156 +/- 31, 72 +/- 32, and 2.6 +/- 1.8, respectively. Compared to traditional midline transforaminal lumbar interbody fusion procedure time, estimated blood loss, and length of hospital stay of 189 +/- 78, 273 +/- 252, 3.1 +/- 1.7, respectively. VAS back and leg/hip pre-operatively were 79.3, 85.3, and 52.2 versus 20.6, 20.3 and 16.9 points, respectively at 2-year follow-up for the minimally invasive approach. Compared to 69.7, 78.8, and 52.7 versus 27.9, 27.8 and 22.4 at 2-year follow-up for traditional midline approach. These improvements were all statistically significant at the 5% level.

Conclusion

The minimally invasive approach described in this paper, when compared to traditional midline transforaminal lumbar interbody fusion, resulted in shorter operative time, decreased estimated blood loss, shorter length of stay, and improvements in patient reported functional outcomes. This novel minimally invasive surgical approach to transforaminal lumbar interbody fusion is an excellent surgical treatment for refractory lumbar spondylolisthesis with associated stenosis.

Introduction

Low back pain is one of the most common causes of chronic pain and disability worldwide. Studies of American adults estimate that as much as 80% of the population will suffer from back pain during their lifetime. Depending on the etiology, back pain can be managed conservatively to temper symptoms while reducing the severity and incidence of pain exacerbations; however, patients suffering from refractory lumbar spondylolisthesis with associated stenosis can be surgically treated with laminectomy and fusion using either an open or minimally invasive approach[3-7].

A disadvantage of open surgery is the need to detach paraspinous muscles from the spine and remove bone elements that are unrelated to the underlying pathology, most notably the spinous processes[8]. These structures are vital to the long-term health of the spine and their removal can potentially lead to adjacent level pathology, scar formation, and the need for additional spine surgery[9]. This paper describes a technique that allows for direct decompression of the spinal canal while sparing the paraspinous muscles and spinous process through a muscle dilating approach. In addition, the primary fusion material is the patient's own morselized autograft harvested from the surgical site during decompression, which has been shown to reduce graft site morbidity, maintain cost effectiveness, and achieve high fusion rates[10]. Using percutaneous pedicle screws in combination with a unique interbody graft cage system, most spondylolisthesis can be reduced to grade 0. This is felt to improve long term patient generated outcomes by restoring canal and foraminal diameter and sagittal alignment[11-13].

Minimally invasive transforaminal lumbar interbody fusion (MI-TLIF) was developed as a safer, equally effective technique for lumbar spine fusion compared to the traditionally open transforaminal lumbar interbody fusion (TLIF). Several benefits of the MI-TLIF have been explored in the literature. MI-TLIFs have demonstrated consistently superior short-term outcomes when compared to open TLIFs as measured by blood loss, length of hospital stay, readmission rates, and postoperative recovery time[14-18]. Minimally invasive techniques also reduce opioid dependence in patients undergoing spine surgery by reducing the time spent in the in-patient setting[19,20]. Procedure related adverse events are also less common following MI-TLIF compared to open TLIF, and patients treated with an MI-TLIF are more likely to report improvements in both short and long-term functional status and pain indices[14-18]. Radiographically, the MI-TLIF has been shown to reduce pathological lordotic misalignment of the spine and achieve fusion with similar success as the open TLIF while minimizing blood loss[21,22].

While most of the benefits of a MI-TLIF result from the technique itself, improvements in postoperative outcomes may also be related to the innovation in instruments and technology. The MI-TLIF is commonly defined by 3 major operative features: a paramedian/lateral incision, the use of muscle sparing dilation, and enhanced visualization; however, this still allows for significant variability between MI-TLIF procedures[23]. Several contributions to the literature have explored nuances in instrument technology with the goal of improving fusion rates and patient reported outcomes while lowering rates of complication, subsidence, and pseudoarthrosis. The use of expandable cages, independent blade retractor systems, unique cage configurations, tubular dilators, and percutaneous pedicle screw systems underscores the fluidity of the MI-TLIF procedure[24,25]. Each of these variations seek to improve patient outcomes and fusion rates while mitigating the risk of complications. Notably, there is a relative paucity of clinical data regarding technical variations using existing technology and the impact on procedural adverse events and patient reported outcome.

This case series highlights a unique variation in the MI-TLIF instruments and technology with critical analysis of patient reported outcomes as part of an FDA IDE approved clinical trial. In this study, novel instruments and technology were developed that allow insertion of the patient's own surgical site morselized autograft into the disc space around the

interbody cage device. The autograft is contained by the anulus fibrosis of the disc and allows for off-loading of the cage to promote fusion via Wolff's law, thus minimizing cage subsidence and maximizing interbody autograft implantation to promote high fusion rates.

Methods

As part of an FDA approved device investigation study (NCT03115983) with Western IRB approval, between March 2016 and June 2020 all patients undergoing MI-TLIF with a single surgeon at our institution were prospectively reviewed to determine compliance with study parameters. Inclusion criteria included the presence of at least Grade 1 lumbar spondylolisthesis (per Meyerding classification) with associated spinal stenosis at one level between L1-S1 on either CT myelogram or MRI of the lumbar spine (Figure 1). All patients had to have experienced symptoms of neurogenic claudication or lumbar radiculopathy persisting for ≥6 months despite conservative management. Baseline patient reported outcomes thresholds were ≥50/100 for VAS back scores, and ≥35/100 for ODI scores. Only skeletally mature patients between 25-80 years of age were included. Patient capacity was assessed, and after the relevant risk and benefits of the procedure were discussed, the required informed consent was obtained.

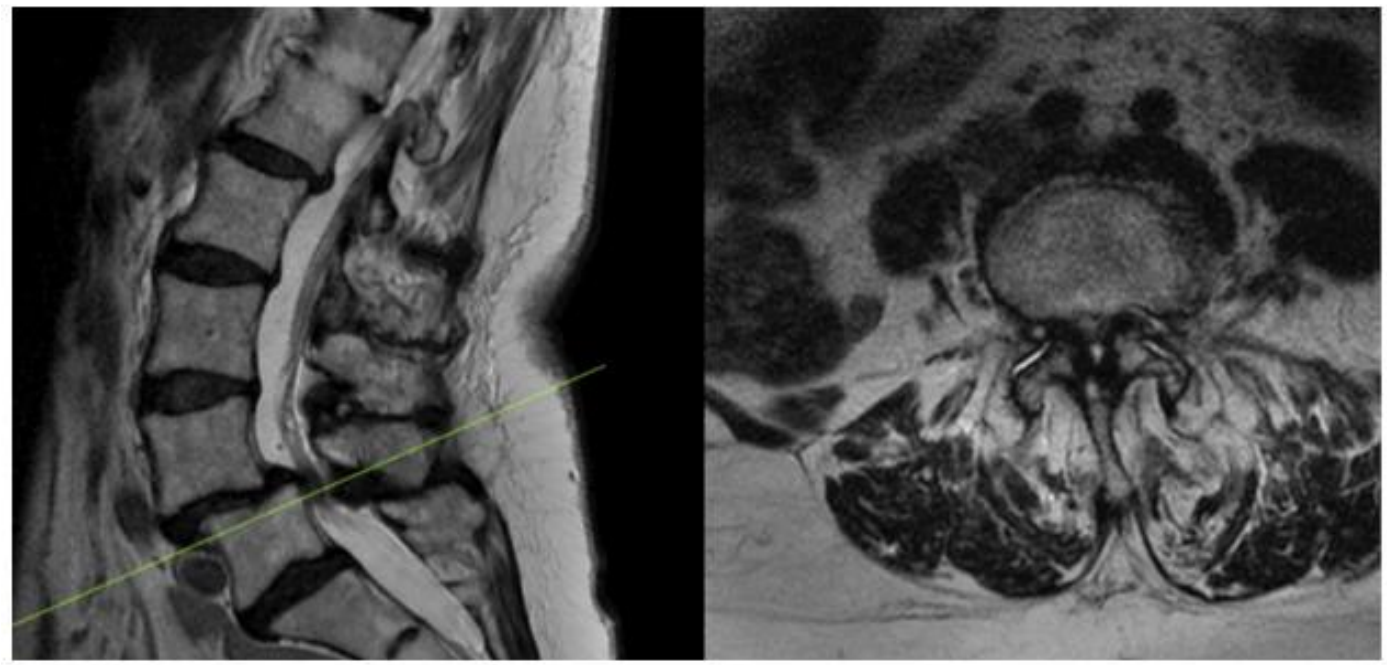

Figure 1. Preoperative MRI showing L4-5 Grade 1 Spondylolisthesis with associated stenosis

Several exclusion criteria were also outlined. Patients suffering from discogenic pain, facet mediated pain, or radicular pain without anatomical abnormalities were excluded. Patients with confounding comorbidities, including peripheral vascular disease, peripheral neuropathy unrelated to spinal stenosis, osteomalacia or osteoporosis were excluded. Patients who had suffered previous back injury or had undergone any operative procedure at the level of treatment were excluded. Patients with degenerative scoliosis with a Cobb angle >10° or ankylosed segment at the operative level were excluded. Patients who were allergic to titanium or polyethylene or actively receiving immunomodulatory medications were ineligible. Morbidly obese patients (BMI > 40), patients with a history of malignancy, or patients intending to become pregnant during the study period were excluded. Patients suffering from psychiatric illness or with a current/prior diagnosis of substance abuse were excluded. 245 patients were consented and underwent MI-TLIF during that time course, and after applying our inclusion and exclusion criteria, as visualized in figure 2, nineteen patients qualified for inclusion given our study

parameters. Patients undergoing traditional open midline TLIF were also put through the same screening process and 140 patients were included for analysis from that cohort during the same time course. Preoperatively, beyond their initial CT myelogram and/or MRI lumbar spine all patients also were evaluated with anteroposterior, lateral, flexion, and extension X-rays of the lumbar spine, Osteoporotic Self-Assessment Tool evaluation, and if there was an history of fragility fracture they also underwent a DXA or OCT scan for further evaluation. Lumbar spine X-rays were also repeated at discharge, 6 weeks, 3, 6, 12, 24, 36, 48, and 60 months postoperatively in accordance with the FDA device investigation study protocol.

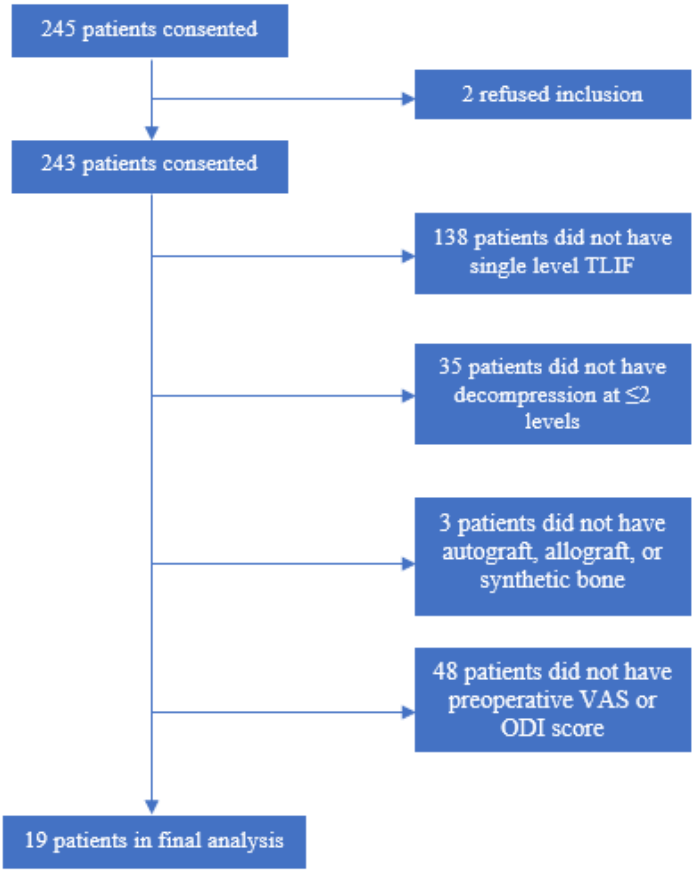

Figure 2. Flowchart Illustrating MI-TLIF Patient selection details

Detailed neurological examinations, physical/medical therapy utilization, pain medication usage, leg and back pain assessments utilizing visual analog scales (VAS), Zurich Claudication Questionnaires, Oswestry Disability Index (ODI), 12-Item Short Form Health Surveys (SF-12), ability to return to work, patient overall satisfaction, and adverse events were also evaluated and recorded at 6 weeks, 3, 6, 12, 24, 36, 48, and 60 months postoperatively. Demographic, procedural, pre- and post-operative outcomes data were critically reviewed for 19 patients who underwent MI-TLIFs and TLIFs per FDA investigational device exemption (IDE) monitoring guidelines[26]. Due to the concurrence of the COVID-19 pandemic, patient follow-up visits were transitioned from in-person office visits to scheduled telemedicine visits with visual neurological evaluations. Table 1 includes a demographic comparison of the control groups.

Due to the relatively small sample size, non-parametric Friedman ANOVA followed by Wilcoxon rank sum tests were conducted to investigate the statistical significance of functional and clinical improvements. An alpha level of 5% was used to assess statistical significance.

Table 1. Patient Demographic Data Undergoing Novel MI-TLIF versus Traditional TLIF

	Novel MI-TLIF	Traditional TLIF
Sex ratio (M:F)	7:12	40:100
Mean Age	65 +/- 9	64 +/- 9
BMI	32 +/- 6	30 +/- 6
L4-5 index level (n, %)	18 (95)	120 (86)
L5-S1 index level (n, %)	1 (5)	8 (14)

Surgical Technique

The patient is positioned prone on a spinal Jackson table the area of interest is prepped and draped in a sterile fashion. The index level is localized utilizing lateral fluoroscopy. An incision is then made 3 cm lateral to the midline overlying the appropriate disc space. The fascia is incised parallel to the spinous processes and the One-Step-Dilator (BoneBac/ Thompson MIS, Sandown, NH) is used to approach the spine in a muscle sparing fashion (Figure 3). The dilator is supported by a holder and once docked on the facet, counter clock-wise rotation opens the flanges of the dilator, separating the muscle tissue. A tubular retractor of the appropriate length is then placed over the one step dilator and the dilator is removed. The tubular retractor is attached to a support arm (Walter Arm, Zimmer Spine) which has been fastened to the operative table.

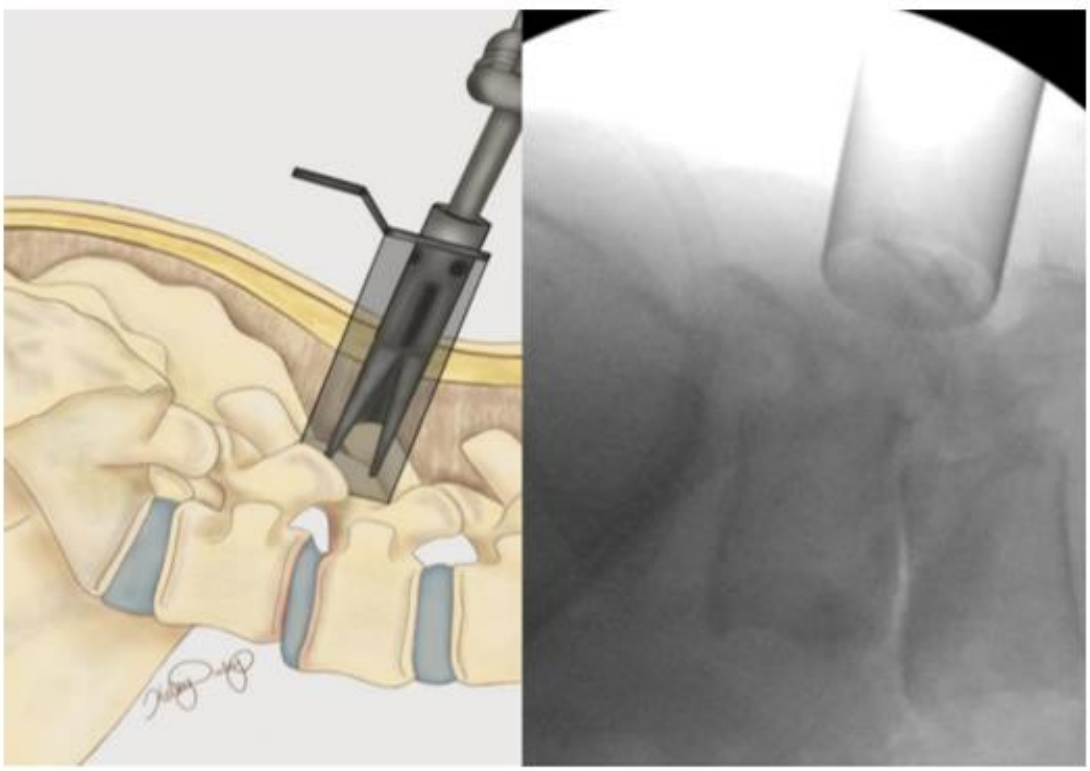

Figure 3. One-step dilator (Thompson MIS/Bonebac, Sandown, NH) placement

LUMBAR EXPOSURE AND DECOMPRESSION

Utilizing an operative microscope the soft tissue is removed to expose the facet complex laterally, and the ipsilateral lamina medially. A high-speed drill and M8 cutting burr are used to perform the laminectomy. All drilled bone is collected using the BoneBac™ Press (BoneBac/Thompson MIS, Sandown, NH). This bone autograft avoids graft site morbidity, has exceptional handling characteristics, and can be mixed with other bone graft material as needed. After the ipsilateral laminectomy (Figure 4A) is completed, the patient and retractor are then tilted 5-10 degrees away from the surgeon to expose the base of the spinous process and the contralateral lamina which is then undercut with a cutting burr as far as the medial border of the contralateral facet complex (Figure 4B). After adequate bony decompression has been achieved, the hypertrophied ligamentum flavum is removed bilaterally, first on the ipsilateral side (Figure 4C) and then on the contralateral side (Figure 4D) which provides improved space for safely removing the contralateral ligamentum flavum, and limits durotomy. Inspection using a ball ended micro-probe instrument assures adequate direct decompression of the spinal canal (Figure 4E).

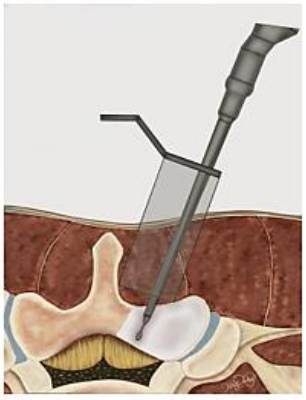

Figure 4a. Illustration showing cross-section view of ipsilateral laminectomy and facetectomy

Figure 4b. Illustration showing cross-section view of contralateral facet and lamina decortication

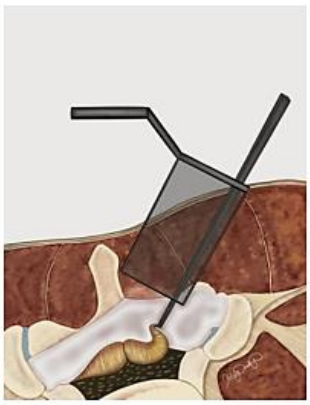

Figure 4c. Illustration showing cross-section view of ipsilateral ligamentum flavum removal

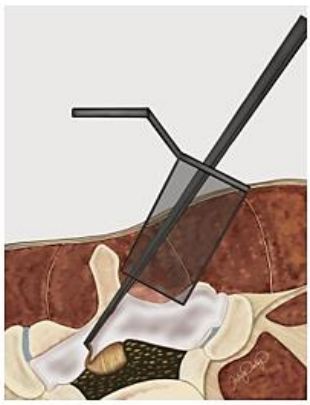

Figure 4d. Illustration showing cross-section view of contralateral ligamentum flavum removal

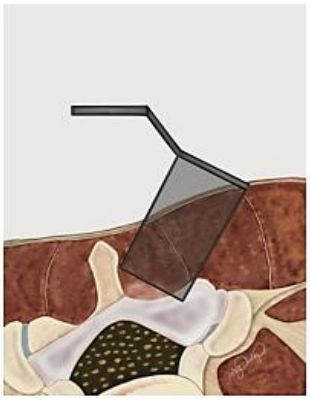

Figure 4e. Illustration showing cross-section view of decompressed spinal

INTERBODY FUSION

Once adequate decompression is achieved, a high-speed cutting burr is used to perform an ipsilateral facetectomy after which the disc space is identified using fluoroscopy, and an annulotomy is then performed to enter the disc space. A series of disc space reimers, curettes, and rongeurs help prepare the disc space for interbody arthrodesis. Care is taken to adequately prepare the vertebral end plates by removing the cartilaginous portions to promote arthrodesis. Once the disc space is thoroughly prepared, implant sizing is determined using the BoneBac/Thompson MIS reimers and trials.

The BoneBac/Thompson MI-TLIF interbody system is an insert and rotate device. Lateral fluoroscopy identifies proper implant depth within the disc space and, once adequate depth is confirmed, the implant is rotated 90 degrees to restore disc space height and foraminal diameter (Figures 5-7). The implant is made from polyether ether ketone (PEEK) which facilitates implant rotation within the disc space and spondylolisthesis reduction as the curved surface of the implant corresponds to that of the vertebral endplates. Additionally, the soft nature of PEEK allows for an easier reduction of spondylolisthesis by limiting the frictional coefficient between implant surface and vertebral endplates. This unique design allows for easier access to the disc space as well as adequate restoration of sagittal alignment and disc height and foraminal diameter restoration after implant rotation. Moreover, larger implants can be introduced through a relatively smaller profile prior to rotation, thereby minimizing nerve root retraction and reducing the risk of nerve injury or dural tear. A torque limiting handle assures that the implant is not placed under undue forces during rotation. Once the implant is rotated, then the original bone graft injector handle can be reattached to the implant for bone graft application. Typically, an implant with dimensions of 7-mm width, 11- or 12-mm height, and 26 mm length is used in most cases. Thus the 7 mm width allows ease of placement within the disc space to rotate and restore disc height to 11- or 12-mm height.

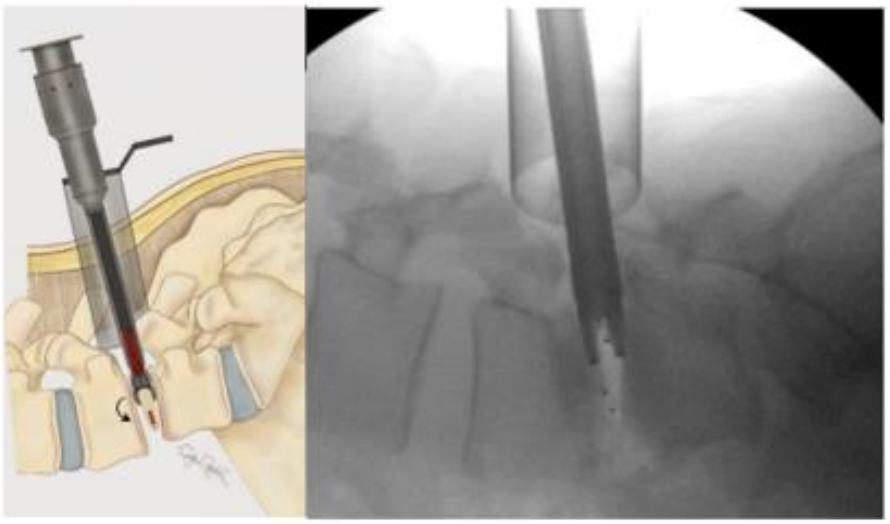

Figure 5. Illustration and lateral view of initial disc implant placement

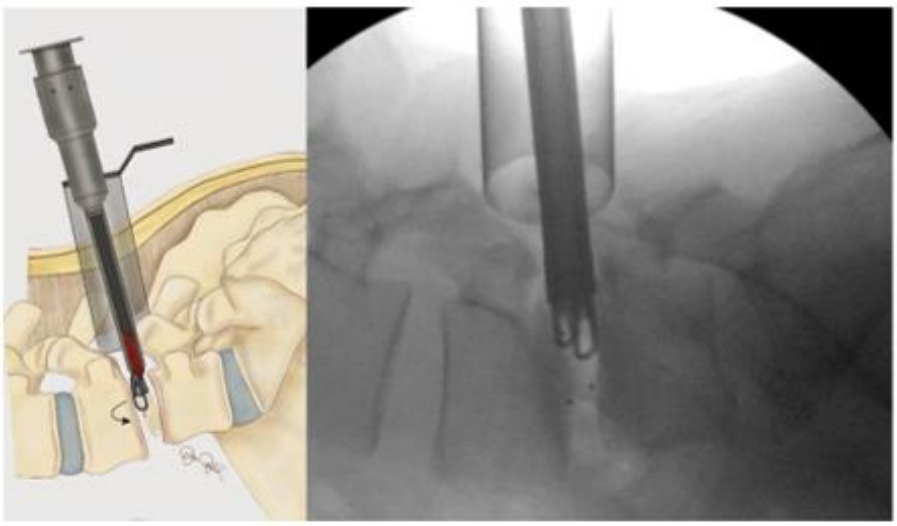

Figure 6. Illustration and lateral view of implant rotation

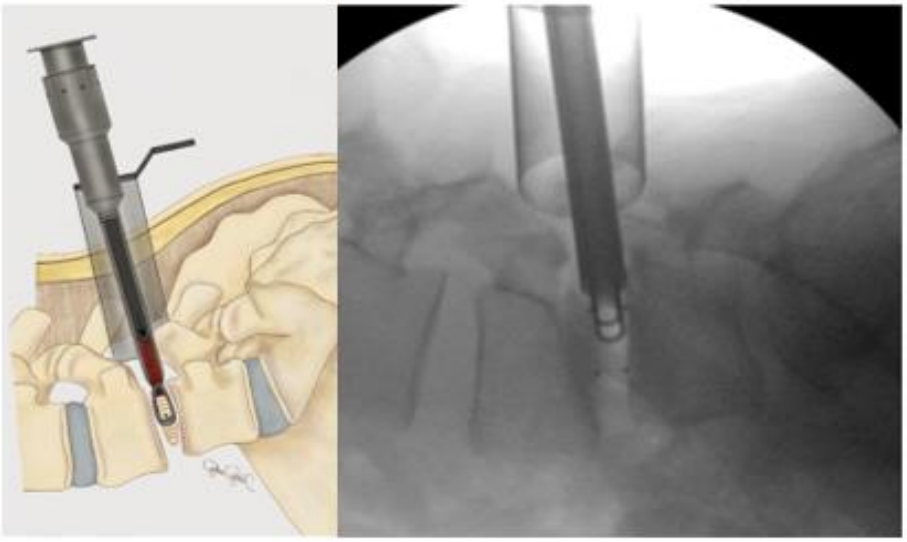

Figure 7. Illustration and lateral view of implant after 90 degree rotation showing final implant positioning to restore disc height

With the implant positioned properly within the disc space, BoneBac TLIF bullets are filled with morselized autograft collected from the BoneBac Press which are then loaded on top of the implant inserter T-handle, and the morselized bone graft material is pushed through the implant holder using a plunger to exit either side of the PEEK cage within the disc space (Figures 8 and 9). Typically, 10-15 bullets are used to completely fill the disc space with morselized autograft. Each bullet contains about 1.5 cc of bone graft material. If additional graft material is needed, 1-5 ccs of morselized allograft (Trinity Elite, Orthofix, Lewisville, TX) or other suitable bone graft extender is mixed with morselized autograph bone graft material. The system allows for adequate quantity of bone to be injected into the interspace to ensure compression of graft material rather than the implant itself, thereby reducing the incidence of implant subsidence and improving arthrodesis rates. After the disc space is sufficiently filled with graft material, the implant is disengaged in the disc space which is then inspected using microscope visualization and a ball-ended probe to ensure that the bone graft material is entirely within the disc space. The facet complex is then reconstructed using a combination of morselized autograft mixed with allograft material.

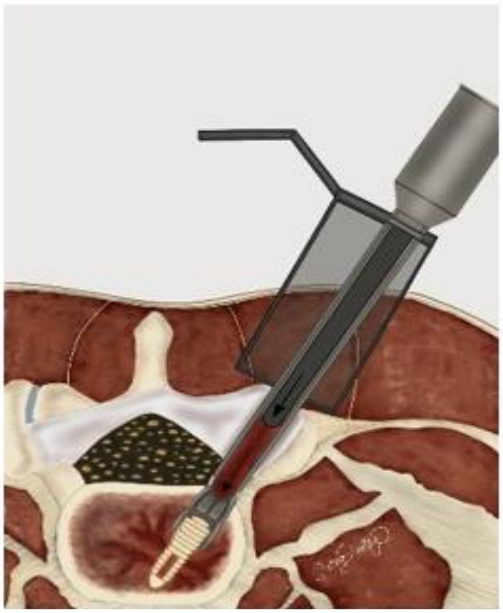

Figure 8. Transverse illustration of implant within disc space during bone autograft implantation

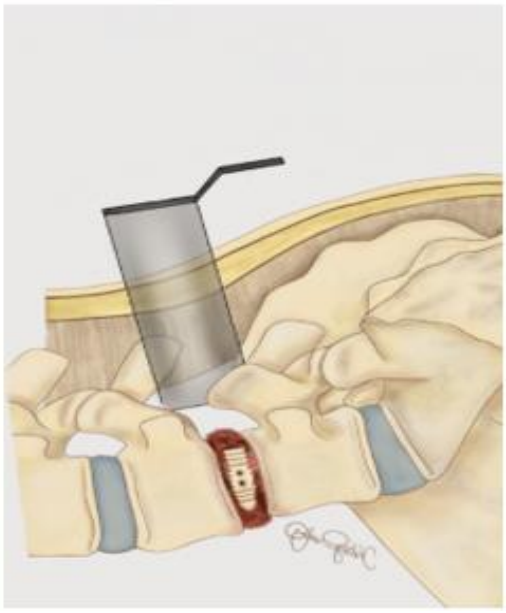

Figure 9. Sagittal illustration showing disc space filled with autograft material

PERCUTANEOUS PEDICLE SCREW INSTRUMENTATION

Once adequate decompression, interbody placement and complete hemostasis are achieved, the tubular retractor is removed, and an incision is made on the contralateral side, equidistant from the midline (3 cm), for the interbody fusion. AP and lateral fluoroscopy are used to target the pedicles for percutaneous pedicle screw fixation and place initial K-wires. Once the K-wires are placed they are then stimulated with concurrent neuromonitoring. A stimulation threshold less than 8 mAmps requires repositioning of K-wire or later pedicle screw. Percutaneous pedicle screws are placed bilaterally and segmentally to ensure suitable fixation to promote arthrodesis.

Total reduction of spondylolisthesis is performed by securing the rod to the most dorsal pedicle screw head (i.e., L5 seen in L4-5 spondylolisthesis) (Figure 10) and subsequently bringing the ventral pedicle screw head up towards the rod (Figure 11). This is done simultaneously bilaterally to reduce rotation and achieve total spondylolisthesis reduction thus restoring sagittal alignment. The advantages of this technique specifically arise from significant increases in the diameter of the neural foramen and spinal canal, and the larger surface area for fusion between adjacent vertebrae. The unique design of the PEEK Thompson MIS BoneBac TLIF device, with curved ends that correspond to the vertebral endplates, helps to facilitate reduction of the spondylolisthesis (Figures 10 and 11). Final tightening is performed, and the towers are removed allowing the paraspinous muscles to return to their normal anatomical position. Excellent long-term clinical outcomes and fusion rates using the MI-TLIF technique described have been achieved (Figures 13 and 14). More recently, but not within the patients covered in this data set, we began trialing augmented reality image guided navigation to place percutaneous pedicle screws in an effort to further reduce radiation exposure to both the patient and surgical team (Figure 15).

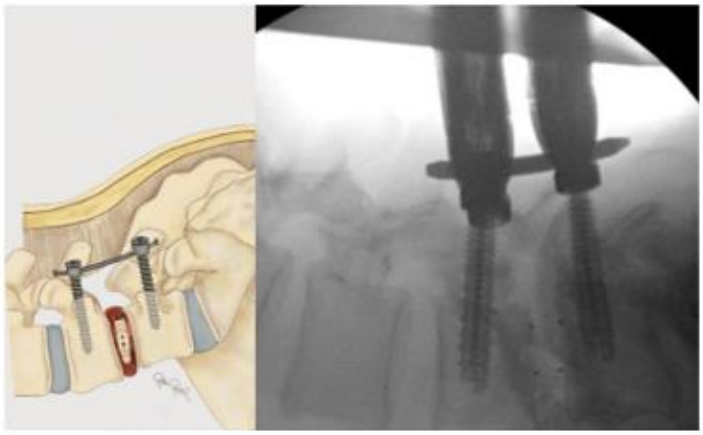

Figure 10. Lateral view of percutaneous pedicle screw fixation prior to correction of spondylolisthesis

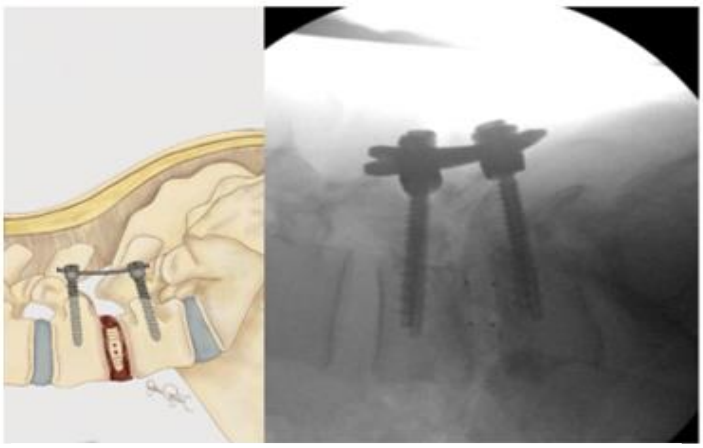

Figure 11. Lateral view of showing final instrument positioning after correction of spondylolisthesis

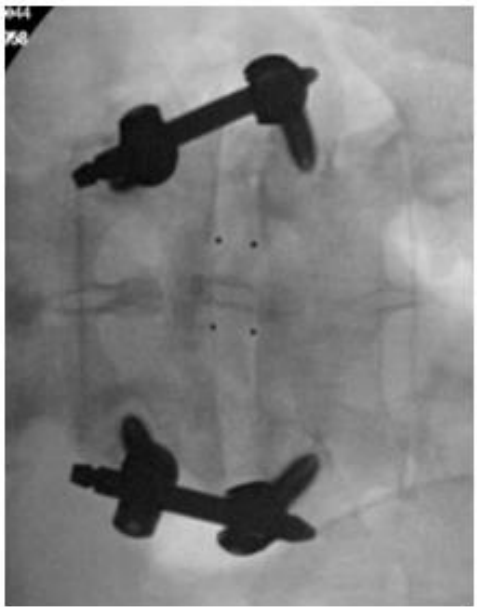

Figure 12. AP view showing final instrument positioning

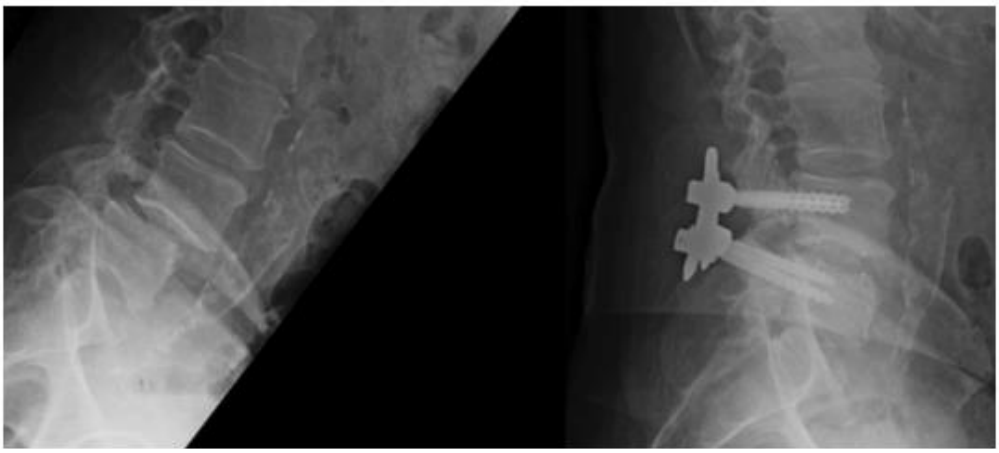

Figure 13. Pre- (left) and postoperative (right radiographs demonstrating instrumented correction of spondylolithesis

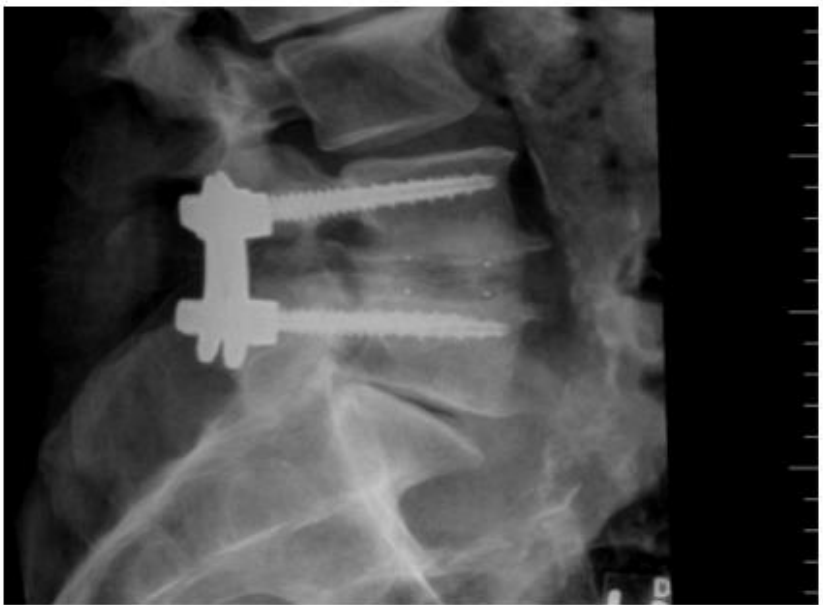

Figure 14. Lateral view of final fusion construct on follow-up imaging evidencing osteogenesis and satisfactory arthrodesis

Figure 15. Use of augmented reality image guidance navigation at our ambulatory surgery center (Waterford Surgery Center, Waterford, MI) for percutaneous pedicle screw placement (Augmedics Arlington Heights, IL)

Results

DEMOGRAPHICS AND OPERATIVE LEVELS

Cases from the 19 patients who underwent a MI-TLIF with the described technique were included in this series. All procedures were conducted by the primary author (MPC). The mean patient age at the time of operation was 65 years (47-78 years range), and the average height and BMI were 1.65m and 32 respectively. From the sample, 13 patients (68.4%) had no associated comorbidities as measured by the Charlson comorbidity index (CCI), 4 patients (21.0%) had mild grade comorbidities (CCI scores of 1, n=2 or 2, n=2), and 2 patients (10.5%) had moderate grade comorbidities (CCI scores of 3, n=2 or 4, n=0)[27]. Almost all procedures (18/19, 94.7%) were performed at the L4-L5 level (1 procedure was conducted at L5-S1 level). Adjacent level decompression was done at L5-S1 for 2 patients who underwent a L4-5 primary fusion. All procedures were conducted prior to August 2020.

PATIENT REPORTED OUTCOMES

The procedure time (minutes), estimated blood loss (mL), and length of hospital stay (days) for MI-TLIF were 156 +/- 31, 72 +/- 32, and 2.6 +/- 1.8, respectively. Compared to traditional TLIF procedure time, estimated blood loss, and length of hospital stay of 189 +/- 78, 273 +/- 252, 3.1 +/- 1.7 (Table 2). VAS back and leg/hip pre-operatively were 79.3, 85.3, and 52.2 versus 20.6, 20.3 and 16.9 points, respectively at 2-year follow-up for novel MI-TLIF. Compared to 69.7, 78.8, and 52.7 versus 27.9, 27.8 and 22.4 at 2-year follow-up for traditional midline TLIF. These improvements were all statistically significant at the 5% level (Figure 16). Importantly, 18 of 19 MI-TLIF patients (94.7%) reported symptomatic improvement across all PRO measures at 6 weeks, 6 months, 1 year and 2-year follow-up relative to preoperative levels. One patient reported mild deterioration in VAS score relative to preoperative levels (63 at baseline, 70 at 6 weeks and 6 months), but had continuing improvements compared to baseline in ODI and worst LH scores at all follow-ups. Moreover, this patient experienced an improvement in VAS score at the 2-year follow-up visit compared to baseline.

Table 2. Patient Operative Data Undergoing Novel MI-TLIF versus Traditional TLIF

	Novel MI-TLIF	Traditional TLIF
Procedure time(min)	156 +/-31	189 +/- 78
EBL (ml)	72 +/- 32	273 +/- 252
LOS (days)	2.6 +/- 1.8	3.1 +/-1.7

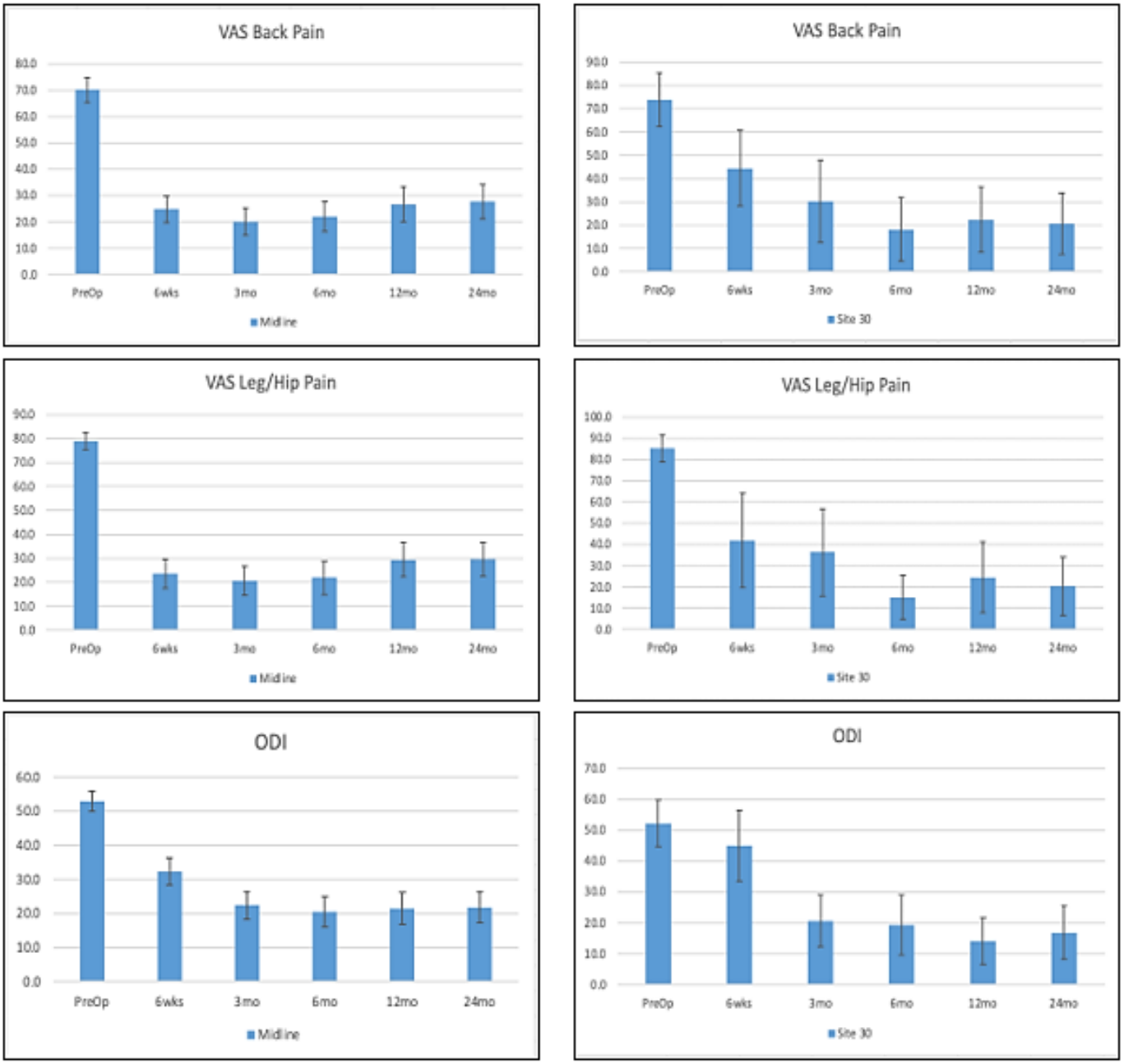

Figure 16. Patient reported outcome including visual analogue scores for back and leg/hip pain and Oswestry disability index (ODI) for midline vs novel MI-TLIF (Site 30) approach. Note more significant improvement in patient reported outcomes for novel MI-TLIF vs misline TLIF aaproach

VAS scores improved from the preoperative mean of 73.9 (SD 22.3, n=19) to 44.5 at 6 weeks (SD 29.1, n=16), and 19.1 at 6 months (SD 30.4, n=15) (Table 3). The mean VAS score increased moderately to 22.3 (SD 26.7, n=18) at 1 year compared to 6 months, but was still significantly lower than baseline. This increase in VAS scores between 6 months and 1 year follow-up was not statistically significant (p=1.000). Average VAS scores improved from the moderate/severe pain categorization preoperatively, to mild pain (VAS score 5-44mm) at 1 year follow-up[28]. While the relative change from baseline to 6 weeks was not significant (p=.79), the changes from baseline to 6 months and baseline to 1 year of follow-up showed statistically significant improvement in VAS scores (p=.000 and p =.000 respectively). There was also a statistically significant improvement in VAS scores between the 6 week and 6 month visits (p =.034) (Fig.14). Patient reported outcomes were better for the novel MI-TLIF compared to open TLIF approach.

Mean ODI back scores improved from a baseline of 51.3 (SD 15.0, n=19) to 45.0 at 6 weeks (SD 21.2, n=17), 18.2 at 6 months (SD 17.5, n=18), and 14.0 at 1 year of follow-up (SD 14.1, n=18) (Table 1). Overall, patients improved from subjective feelings of severe disability (ODI score 41-60) preoperatively to minimal disability (ODI score 0-20) at 1 year follow-up[29]. Similar to the trend in VAS scores, the improvements in ODI scores from baseline to 6 weeks were not significant (p=1.000), while those from baseline to 6 months and baseline to 1 year were both statistically significant (p=.001 and p=.000 respectively). Statistically significant improvements in ODI scores were also observed between 6 week and 6-month follow-up visits as well as the 6 month and 1 year follow-up visits (p =.004 and p =.000 respectively).

PROCEDURAL DATA AND ADVERSE EVENTS

Adverse events were noted in 4/19 (21%) of MI-TLIF patients. Three patients had superficial surgical site infection (SSI) within 2 weeks of the operation, all of which were treated with oral antibiotic therapy for 7 days. All 3 patients suffered from obesity, a well described risk factor for postoperative infections[30]. Of these 3 patients, 1 developed a SSI during their hospital stay; 2 patients both noted symptoms of SSIs 10 days after the procedure, after both had been discharged home. All surgical site infections resolved after patients were placed on appropriate oral antibiotic therapy.

Almost all (18/19, 95%) patients achieved fusion of the lumbar spine confirmed by radiographic imaging on follow-up visits. One patient required repeat fusion due to posterior cage displacement complicated by adjacent segment disease. Six months after undergoing a primary L4-5 MI-TLIF, mild retropulsion of the interbody device was noted, but the patient denied any symptomatic manifestations. The patient presented 2 years and 6 months after the primary operation with complaints of difficulty walking and standing as well as shooting pains extending down the anterolateral right lower extremity. At this time, imaging confirmed posterior cage migration as well as concomitant adjacent segment stenosis at L2-3 and L3-4. Adjacent levels stenosis was felt to be a continuation of the patient's underlying degenerative disc disease leading to lumbar stenosis. This patient was re-treated 2 years and 7 months after the primary procedure with a repeat MI-TLIF at the index level (L4-5) and additional laminectomy and fusion at L2-3 and L3-4 due to progressive adjacent segment disease confirmed radiographically. The patient made an unremarkable recovery.

Table 3. Patient-Reported Outcome (PRO) Measures for MI-TLIF

PRO measures, mean (SD)	Preoperative (Baseline)	6 weeks postoperative	6 months postoperative	1 year postoperative
Worst LH score	87.9 (10.1) n=16	41.9 (39.6) n=16	14.2 (17.7) n =16	24.0 (29.6), n=17
Change from baseline		-46.0 p=0.071	-73.7 p=.000*	-63.9 p=.000*
Change from previous follow-up		-46.0, p=0.071	-27.8, p=.199	9.8, p= 1.000
ODI	51.3 (15.0) n=19	45.0 (21.2) n=17	18.2 (17.6) n=18	14 (14.1) n=18
Change from baseline		-6.3 p=1.000	-33.0 p=.001*	-27.3 p=.000*
Change from previous follow-up		-6.3, p=1.000	-26.8, p= .034*	-4.2, p=1.000
VAS Back	74.0 (22.3) n=19	44.5 (29.1) n=16	19.1 (24.7) n=15	22.3 (26.6) n=18
Change from baseline		-29.5 p=.790	-54.8 p=.000*	-51.6 p=.000*
Change from previous follow-up		29.5 p=.790	-25.4 p= 0.04*	3.2 p=1.000

Discussion

Ensuring high rates of fusion while minimizing procedural complications is paramount to the success of vertebral stabilization. While patient-specific factors certainly influence the likelihood of achieving long-term stabilization, the notion that the operative technique itself plays an important role should be investigated. Currently, innovators are exploring a variety of improvements in MI-TLIF instruments to improve patient outcomes after spine surgery including newer cage designs, variations in percutaneous pedicle screws, and entirely new technologies[31-36]. However, modifications utilizing existing surgical technology can play an important role in improving patient outcomes following MI-TLIF spine surgery.

Expandable cages (ECs) are a significant area of technological exploration in the search for methods to improve outcomes after spine surgery. Studies have shown that clinical and radiographic outcomes after EC instrumentation are sufficient at treating the underlying pathology[34-36]. Retrospective reviews by Kim et al. and Alimi et al. demonstrated that MI-TLIFs utilizing PEEK-based ECs had statistically significant improvements in patient reported function and pain indices and average disk height increases without a significant risk for intraoperative complications[35,36]. A case series by Wang demonstrates parallel clinical and radiological improvements in 25 patients treated with MI-TLIFs employing expandable mesh cages, noting that no complications pertained to the EC itself[37].

However, while several analyses directly compare outcomes and adverse events after MI-TLIFs utilizing ECs to those done with static cages, conflicting evidence exists on the presence of clinical improvements resulting from the utilization of expandable technology. A retrospective cohort study by Canseco et al. found increased clinical improvements in procedures utilizing static cages while noting no difference in complication rates[38]. Solely assessing differences in radiological outcomes, a study by Yee et al. found no significant difference between procedures that employed ECs versus those that employed static cages[39].

However, studies have found that expandable cages may in fact worsen postoperative outcomes. Chang et al. found that while expandable cages were non-inferior to static cages in regards to radiographic improvements, patients treated with an expandable cage were 5.6 times more likely to experience cage subsidence[40]. A review by Rymarczuk et al., noted that, while they did not result in an increased risk for complications, MI-TLIFs using expandable cages did not hold any significant clinical or radiological advantages over those that utilized static cages[41]. Broadly, these unfavorable findings when comparing the efficacy of expandable and static cages, taken in conjunction with the higher cost of expandable cages, support the search for potential improvements in patient outcomes that can be made utilizing existing instrument technology. In addition, significantly more bone graft material can be introduced into the interbody space using the above-described methods, averaging 10-20cc of bone grafter per level, when compared to EC technology.

This case series highlights a unique operative nuance to the MI-TLIF that utilizes morselized autograft collected from the surgical site, direct decompression of the neural elements with preservation of the spinous process and contralateral lamina, rotation of the interbody cage to restore disc height and foramina diameter, injection of morselized autograft into the disc space through the implant holder to promote fusion and restoration of normal sagittal alignment. This method achieved excellent fusion rates while minimizing procedure related complications. Significant cost savings while improving interbody arthrodesis rates have been shown in a previous study of MI-TLIF using same site drilled morselized autograph[10].

The significant costs associated with use of various allograft osteobiologics, both to the patient and to the hospital system, can be largely avoided with a technique such as this that relies heavily on the patient's own morselized bone. Patients reported significant improvements in patient reported outcomes after undergoing the MI-TLIF technique described. Average decreases in VAS back and ODI scores were 29.65 and 6.3 respectively at the short-term 6 week follow-up visit. These decreases were even greater at 6 months of follow-up, improving to 73.7, 54.8 and 33.1 respectively. These improvements in patient reported outcomes, taken in conjunction with the absence of procedural adverse events, underscore the potential utility of this MI-TLIF technique in achieving spinal stabilization for patients suffering from lumbar spondylolisthesis with associated stenosis.

Conclusion

The MI-TLIF technique described within this paper utilizing largely morselized autograft obtained during spinal element decompression, as well as a rotating static PEEK interbody cage, allows surgeons to prioritize preservation of normal anatomy while maintaining high fusion rates, minimizing biologic costs, and maximizing improvement of long-term improvement in patient reported outcomes.

Limitations

This study has certain limitations that must be taken into consideration. First, although the patients were rigorously monitored per FDA IDE procedure guidelines, this study is a case-series following a relatively small (n=19) number of patients, limiting the robustness and generalizability of the results. Two patients were operated on at the L5-S1 level, while all others were operated on at L4-5; the impact of this difference is not factored into the results. Furthermore, all procedures were conducted by a single provider. Additionally, this study lacks a comparison group of patients operated upon using the same technology without the operative nuances highlighted herein.

Disclosures:

Mick Perez-Cruet

Thompson MIS/Bonebac:

Stock ownership

Thieme Publishing Inc.:

Royalties

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