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Retrospective Study

Assessment of Clinical Outcome of Lumbar Transforaminal Foraminoplasty in Patients with Lumbar Spinal Stenosis

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Background: Lumbar spinal stenosis (LSS), a common spinal disorder that negatively affects quality of life, is a disabling condition accompanied by back pain, leg pain, and claudication. Lumbar foraminal stenosis (LFS) is often accompanied by lumbar central stenosis (LCS) and conservative treatment is often ineffective. A surgical approach, including a minimally invasive technique, is usually recommended for the conservative treatment of refractory conditions. To achieve effective decompression of LSS, a specially designed new instrument for lumbar transforaminal foraminoplasty (TFFP) can be considered before opting for surgical treatment.

Objective: To evaluate the clinical outcomes and safety of TFFP with a specially designed instrument.

Study Design: Retrospective design.

Setting: This research was conducted in a hospital outpatient surgical center.

Methods: The medical records of 112 patients who underwent TFFP from December 1, 2018 to January 1, 2020, were reviewed. Outcome measures were obtained using the numeric rating scale for pain (NRS pain), Oswestry Disability Index (ODI), and walking distance without pain for functional ability at preprocedure and 1, 3, and 6 months postprocedure. The clinical data and radiologic findings were analyzed to evaluate correlations between predictive factors and efficacy of TFFP.

Results: Among 112 patients who underwent TFFP, 110 were accessed and analyzed. The percentage of successful responders was 59.1%, 73.6%, and 74.5 % of 110 patients at one, 3, and 6 months, respectively. The NRS pain score, ODI, and duration of walking without radicular pain were improved significantly at the one-, 3-, and 6-month follow-up periods (all $P < 0.001$). No serious adverse events occurred during this study.

Limitations: The limitations of this study include the possibility of bias due to nonrandomized patient selection.

Conclusion: TFFP using the Foramoon® device (Mcarekorea, Seongnam-si, Gyeonggi-do, Republic of Korea) appeared to be effective for managing patients with LFS and LCS, who were refractory to conservative care.

Key words: Lumbar spinal stenosis, lumbar foraminal stenosis, lumbar central stenosis, transforaminal foraminoplasty, ligament flavum, transverse ligament, neural compression, radicular pain

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Lumbar spinal stenosis (LSS) is a degenerative disease accompanied by back pain, leg pain, and claudication. Based on anatomical types, spinal stenosis can be categorized into central and lateral forms. The degenerative process leads to a loss of disc height with associated disc bulging and hypertrophy of the ligamentum flavum (LF). Advanced facet osteoarthritis can protrude into the spinal canal, further compromising the space available for neural elements. LF thickening can compress the dural sac and nerve root, reducing spinal canal diameter, leading to lumbar central stenosis (LCS) (1-3). Lumbar foraminal stenosis (LFS) is a result of bony narrowing due to osteophytes on the superior articular process (SAP). A lateral extension of the LF, including its intra- and extraforaminal parts, may contribute to nerve root compression at the intervertebral foramen and lateral recess level (4,5). The associated transforaminal ligaments (TFLs) can increase hypertrophy along an adjacent articular surface due to degenerative changes, resulting in compression of existing nerve roots. The neural pathway in the foramen can also be disturbed by fibrotic adhesion with or without foraminal stenosis (6-8). These mechanisms can affect pressure on the venules surrounding the nerve roots. Venous engorgement, in turn, leads to a repetitive inflammatory reaction, fibrosis, increased epidural pressure, and ischemic neural impairment (8-9).

Various nonsurgical treatments have been attempted to treat LSS, but there have been no high-quality studies. Consequently, nonoperative treatment, including medication, physiotherapy, exercise therapy, and transforaminal epidural steroid injections (TFESI), is chosen based on clinical judgment. In patients with advanced spinal stenosis due to severe degenerative changes, these conservative treatments do not work (10,11). A surgical approach is usually recommended for these patients. Although classic laminotomy and facetectomy techniques for decompression are still applied, several specific minimally invasive procedures for LSS treatment have been introduced (12-16). In this study, a less invasive percutaneous technique was used to treat LCS and LFS with a specially designed device for lumbar transforaminal foraminoplasty (TFFP).

Methods

Patients

This retrospective study was approved by the Public Institutional Review Board (IRB) designated by the Ministry of Health and Welfare (P01-202007-21-003). After obtaining IRB approval, the medical records of the patients, who underwent TFFP between December 1, 2018, and January 1, 2020, were reviewed.

Inclusion criteria were: 1) patients between 45 and 85 years of age, with chronic lumbar radicular pain with intermittent claudication; 2) concordant imaging evidence of LFS and LCS (grade 1–3; grade 1 is mild, grade 2 is moderate, and grade 3 is severe) as demonstrated on preoperative magnetic resonance imaging (MRI) in accordance with clinical symptoms; 3) pain duration > 3 months; 4) a score of ≥ 5 on an 11-point numerical rating scale for pain (NRS pain) after receiving conservative treatment for at least 3 months, including oral medication, physical therapy, and TFESI; 5) unsuccessful pain relief from previous TFESI (pain intensity reduced by less than half and pain relief period less than one month).

Exclusion criteria were: 1) large contained or sequestered disc herniation on lumbar MRI; 2) lack of correlation between the patient's radicular pain and MRI findings; 3) progressive neurological symptoms such as motor weakness, cauda equina syndrome; 4) cancer, fracture, or infection finding on lumbar MRI; 5) segmental instability at the level of the symptomatic disc; and 6) coagulation disorder, general infection, fever, or local infection at the puncture site.

Administration of analgesics, including nonsteroidal anti-inflammatory drugs, tramadol or other opioids, and adjuvants such as anticonvulsants and antidepressants was allowed to continue during the study. In addition, administration of a rescue dose of opioid was allowed for 1–2 weeks to control procedure-related pain. During the follow-up period, additional medication or therapies, including trigger point injections and TFESI, were not allowed, except for physical therapy.

Procedure

All TFFP procedures were performed by a single pain specialist (DEM). We used a specially designed instrument, Foramoon® (Mcarekorea, Seongnam-si, Gyeonggi-do, Republic of Korea) consisting of a stylet with 14.5 cm length, cannula with a 2.6 mm outer diameter and 13 cm length, dissector with a 1.9 mm outer diameter and 16 cm length, and a balloon catheter 18 cm in length. The working part of the dissector for scraping and grinding consists of a cup-shaped spoon and grinder with 1.1 cm length (Fig. 1). We used a stylet and cannula complex by bending 10°, 2 cm away from the tip of the needle (Fig. 2).

After preparation and draping in a sterile manner, the TFFP procedure was performed under fluoroscopic

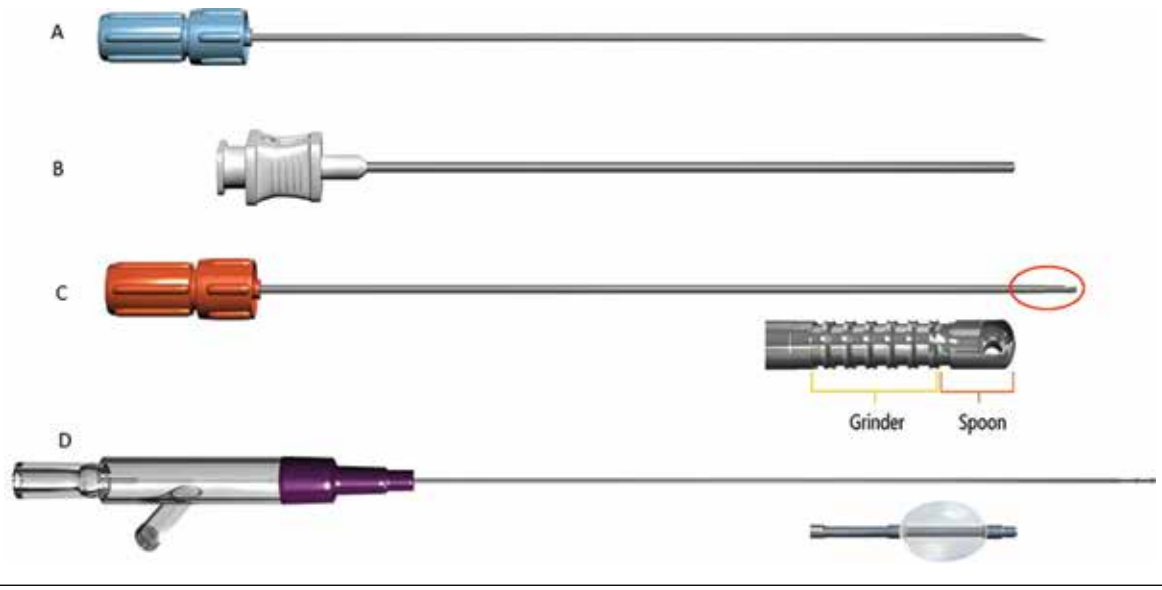

Fig. 1. *Specially designed instruments for the transforaminal foraminoplasty procedure. The Foramoon® instrument consists of a stylet with 14.5 cm length (A), a cannula with a 2.6 mm outer diameter and 13 cm length (B), a dissector with a 1.9 mm outer diameter and 16 cm length (C), and a balloon catheter 18 cm in length (D). The working tip of the dissector consists of a grinder and cup-shaped spoon, 1.1 cm in length, for scraping and grinding (the tip of C).*

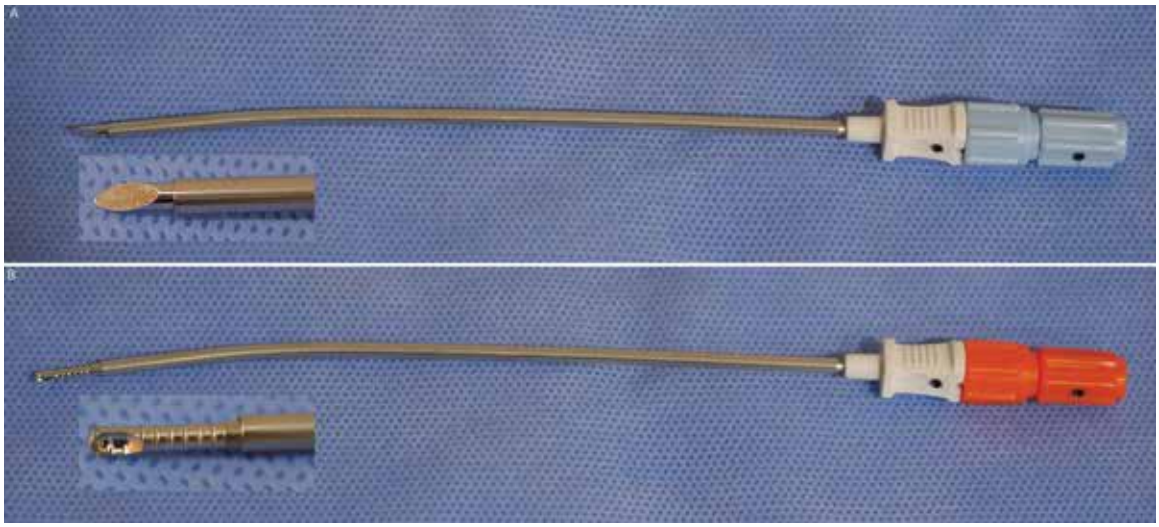

Fig. 2. *The stylet and cannula complex (A) and dissector and cannula complex (B) bent about 10° were used for the transforaminal foraminoplasty procedure. Inserts indicate enlarged tips of the instruments.*

guidance with the patient prone. A bent stylet with a cannula complex was inserted following skin puncture with a 17G disposable needle under anteroposterior (AP) fluoroscopic guidance after 6 mL of 1% lidocaine infiltration (Fig. 3A). The entry point of this complex was kept 12–14 cm away from the midline of the vertebral body, while the trajectory of this complex was planned in accordance with the preoperative MRI scan. In the oblique view, the tip of the bent stylet with the cannula complex was aimed at the tip of an SAP of the affected caudal vertebra with the concave part of this complex facing posteriorly, confirmed with AP and lateral fluoroscopic

view (Figs. 3B-D). Then, it was rotated with the concave part facing anteriorly and advanced approximately 0.3 cm further medially through the intervertebral foramen (Fig. 3E). It was then rotated back until the concave part was facing posteriorly and advanced until its tip in the AP view was at the medial pedicle line (Figs. 3F,3G). After confirming the epidural space with 2 mL of contrast medium (isohexol, 300 mg iodine per mL; GE Healthcare,

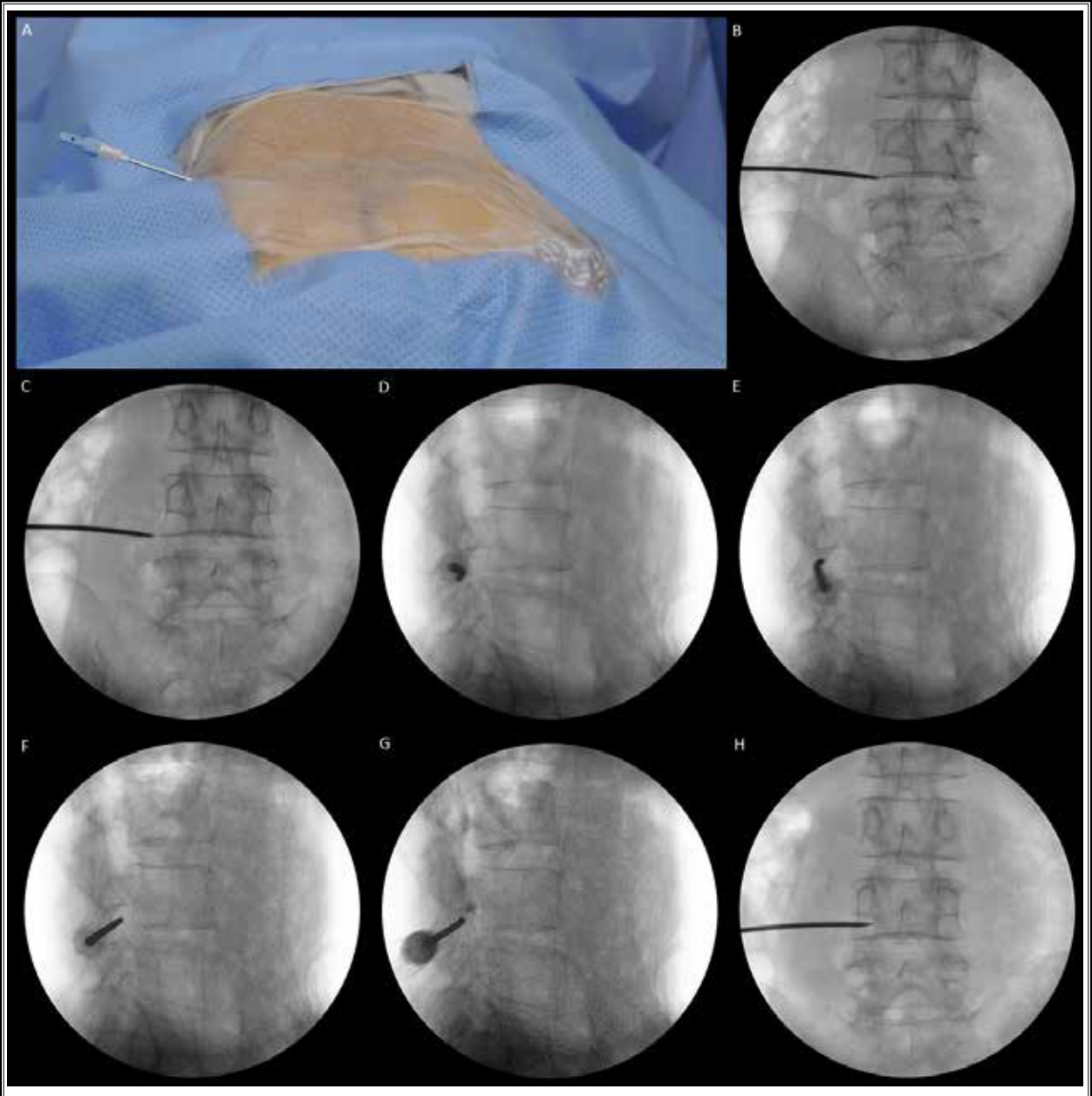

Fig. 3. *Transforaminal foraminoplasty procedure. A skin entry point of stylet and cannula complex was 12–14 cm away from the midline of the vertebral body. A tip of this complex aimed at a tip of a superior articular process (SAP) of the L5 vertebra in the oblique and anteroposterior (AP) fluoroscopic view (B,C). At first, a concave tip of this complex facing posterior was advanced until it contacted the SAP (D), and then it was rotated with the concave tip facing anteriorly and advanced approximately 0.3 cm further medially in the lateral view (E). Then, it was rotated back until the tip was facing posteriorly again (F) and was advanced until the tip reached the medial pedicle line (G). G and H images show AP and lateral view of epidurogram confirming epidural space after injecting 2 mL of contrast medium.*

Piscataway, NJ) and negative blood aspiration, 5 mL of 0.7% lidocaine was injected through the cannula (Figs. 3G,3H).

The next step was to pull out the stylet and put in a bent dissector into the cannula (Fig. 4A). Then, curettage and grinding were performed with the dissector and cannula complex. During this procedure, the bevel of the cup-shaped spoon of the dissector and concave part of this complex was facing the posterior part of the foramen and spinal canal to avoid neurovascular

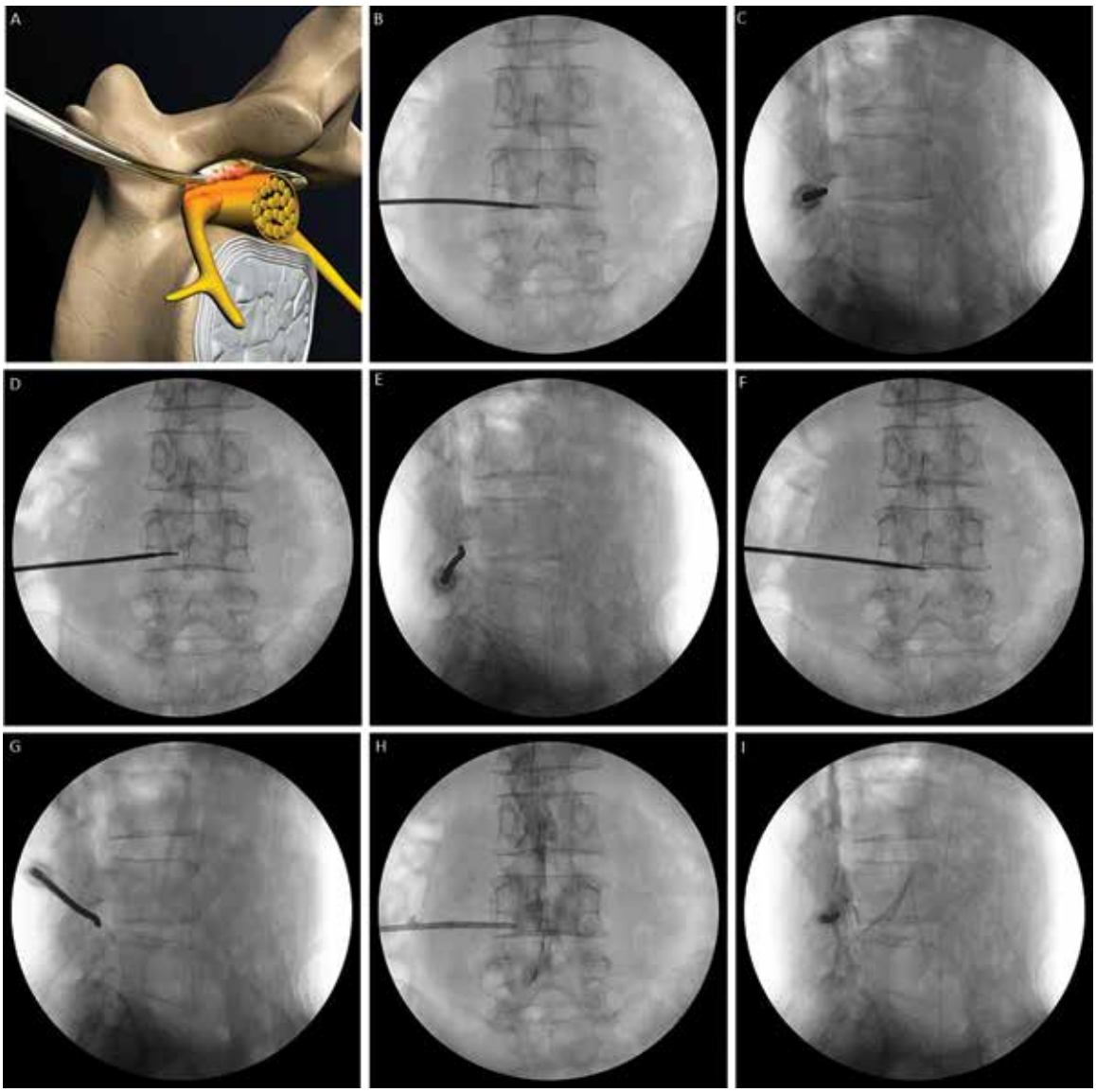

Fig. 4. *Schematic diagram and fluoroscopic images of transforaminal foraminoplasty procedure. A schematic diagram of the concave part of the bent dissector and cannula complex facing the posterior side of the foramen and spinal canal (A). B and C images show anteroposterior (AP) and lateral (LAT) views of this complex for dissecting and scraping transforaminal ligaments (TFLs), ligamentum flavum (LF), and neural adhesions from the neural foramen to the middle of the spine transversally. Then, AP and LAT images of this procedure performed longitudinally the lateral recess zone of the adjacent superior (D, E) and inferior vertebral pedicles (F, G) were taken.{this sentence needs to be re-written for clarity} H and I images show AP and LAT view of an epidurogram obtained after injection of contrast medium for confirming no filling defects after the procedure.*

injury. Scraping and dissecting of thickened TFLs, LF, and neural adhesion were repeated dozens of times by advancing and withdrawing this complex. The tip of this complex should reach the middle of the spine to scrape the hypertrophied LF at the central canal (Figs. 4B,4C). The range of work in the longitudinal direction should cover the lateral recess zone of the adjacent superior (Figs. 4D,4E) and inferior vertebral pedicles (Figs. 4F,4G).

Cut and scraped fragments were dropped in a spoon attached to the end of the dissector. Epidurography was performed after injection of 3 mL of contrast medium through the cannula directly or through the balloon catheter to confirm no filling defect after the procedure (Figs. 4H,4I). As a last step, 1,000 IU hyaluronidase diluted with 2 mL of normal saline and a mixture of 5 mL of 0.4% lidocaine and 1–2 mg of dexamethasone was injected.

To treat the upper or lower level of the same side of the spine, the bent stylet and cannula complex was pulled out to the subcutaneous layer and re-entered to the target level. The rest of the procedure and treatment was the same. The problem on the other side can be treated in the same way. All patients were monitored for occurrence of any complications in the recovery room for at least 2 hours, transferred to the ward and then were discharged the next day.

Outcome measurement

Symptoms were evaluated by follow-up interviews (visit or telephone) at one, 3, and 6 months postprocedure. The patients' pain severity was assessed using the NRS pain with 0 as the lowest score (no pain at all) and 10 as the highest score (worst pain possible). Functional outcomes were assessed using the Oswestry Disability Index (ODI) (17). The distances that patients could walk without pain were assessed through the question "How far can you walk without a break because of pain?" The modified MacNab criteria were used for the evaluation of patient-reported subjective satisfaction, rated as excellent, good, fair, or poor. A successful response was defined as: 1) 50% reduction from baseline NRS and no increase from baseline ODI and decreased walking distance, or 2) 30% reduction from baseline NRS with any one of the following criteria: simultaneous 30% reduction in ODI from baseline, or 30% increase in walking distance from the baseline (18). The severity of LFS and LCS on MRI, with compression of the dural sac, perineural fat obliteration, and nerve root collapse, were graded based on the practical grading system for LFS and LCS reported by Lee et al (19,20). Any adverse events of TFFP during the follow-up period were noted and evaluated at each visit.

Statistical Analysis

Statistical analysis was conducted by an independent statistician using IBM SPSS Statistics 20.0.0 (IBM Corporation, Armonk, NY). Data are expressed as mean ± standard error of the mean. A comparison between pre- and postprocedure clinical outcomes in pain scores and functional status was performed using repeated measure analysis of variance (ANOVA) and paired t-test with Bonferroni method for the adjustment of multiple comparisons. $P < 0.05$ was considered statistically significant. Differences between responders and nonresponders at each period were tested using the Mann-Whitney test for nonparametric data and Fisher's exact test for parametric data. Considering that the data were observed several times for successful follow-up up to 6 months, a logistic regression for clustered data (generalized estimating equations [GEE] method) was used to assess clinical factors to account for an unsuccessful response.

Result

Of the 112 patients who underwent TFFP using Foramoon® assessed for eligibility, 2 patients were lost to follow-up. The remaining 110 patients (60 women, 50 men) with a mean age of 61.5 ± 10.2 years, were included in the analysis. The average duration of symptoms was 21.4 ± 11.1 months. The severity of LFS based on Lee et al's MRI grading system (19) was assessed as grade 1 LFS (mild), grade 2 (moderate), and grade 3 (severe) in 4, 18, and 88 patients, respectively. Based on Lee et al's MRI grading system for LCS (20), grade 1 LCS (mild), grade 2 LCS (moderate), and grade 3 LCS (severe) were observed in 10, 75, and 25 patients, respectively. The procedures were performed on the left side in 35 patients, in the right side in 20 patients, and bilaterally in 55, based on radiologic findings and clinical symptoms.

Most patients underwent multiple levels of treatment. Only 3 patients received a single level procedure, 69 patients received 2 levels, and 38 patients received 3 levels. Spondylolisthesis and a history of previous lumbar surgery were present in 19 and 15 patients, respectively (Table 1).

An NRS pain score of 4.5 ± 1.9, 3.6 ± 1.5, and 3.4 ± 1.5 at one, 3, and 6 months, respectively, showed a statistically significant difference compared with the

Table 1. *Baseline characteristics and demographics.*

Characteristic		n = 110
Age (years)		61.5 ± 10.1
Gender (female/male)		60/50
Duration of Symptoms (months)		21.4 ± 11.1
Level of Vertebrae	L4-5	1
	L5S1	2
	L3-4 and L4-5	14
	L4-5 and L5S1	55
	L3-4, L4-5 and L5S1	38
Side	left/ right/ both	35/ 20/ 55
MRI Grade of Foraminal stenosis	Grade 1	4
	Grade 2	18
	Grade 3	88
MRI Grade of Central stenosis	Grade 1	10
	Grade 2	75
	Grade 3	25
History of Spine surgery (Yes/ No)		15/95
Spondylolisthesis (Yes/No)		19/91

preprocedure value of 7.3 ± 1.1 (F = 317.1; all 3 $P < 0.001$) (Fig. 5A). There was also a difference when the pain scores after 3 and 6 months were compared with those after one month (both $P < 0.001$). The walking distance (m) without pain at one, 3, and 6 months was 1257.0 ± 709.2, 1416.8 ± 625.8, and 1430.5 ± 609.6, respectively, which was significantly different compared with the preprocedure value of 876.3 ± 702.1 (F = 53.96; all 3 $P < 0.001$) (Fig. 5B). The ODI scores at one, 3, and 6 months were 29.3 ± 14.3, 25.1 ± 12.0, and 24.1 ± 12.0, respectively, which were significantly different compared with a preprocedure value of 43.6 ± 22.7 (F = 70.07; all 3 $P < 0.001$) (Fig. 5C). The ODI score steadily showed a difference up to 6 months, showing a statistically significant difference between 3 and 6 months ($P = 0.003$). The percentage of patients who responded good or excellent in the MacNab criteria were 51.8%, 67.3%, and 78.2% of 110 patients at one, 3, and 6 months.

Adverse events during this study period were minor and temporary. Eighteen patients (16.4%) complained of procedure-related pain that subsided within a few days with rescue doses of an opioid. Transient paresthesia in the lower extremities was seen in 3 patients and resolved spontaneously without any neurological sequelae. There were no serious adverse events such as epidural hematoma, persistent motor or sensory impairment, or infection.

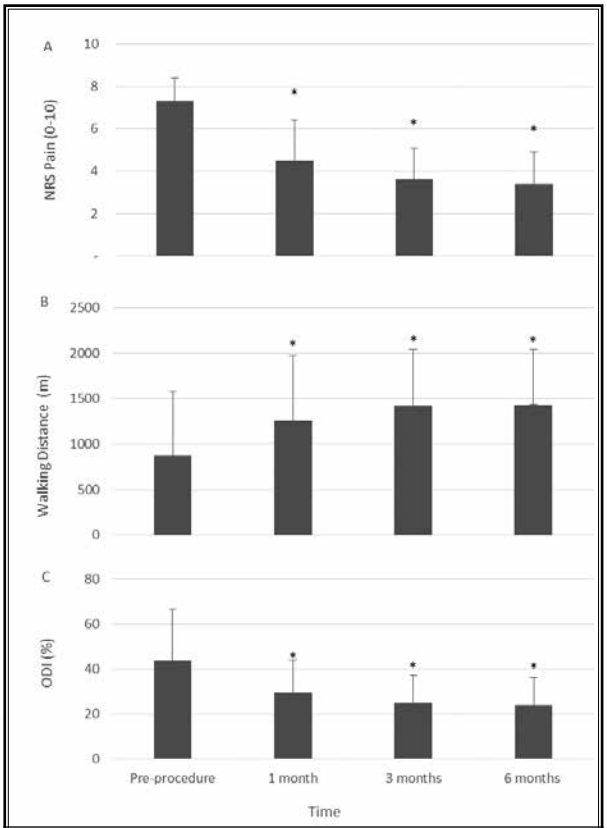

Fig. 5. *Changes in the numeric rating scale for pain (NRS pain) (0-10) (A), walking distance (m) (B), Oswestry Disability Index (ODI) (%) (C). *P < 0.05 compared with baseline.*

The percentage of successful responders was 59.1%, 73.6%, and 74.5 % of 110 patients at one, 3, and 6 months. In order to distinguish the factors affecting the success of treatment, after univariate analysis, only statistically significant factors, that is, the grade of LCS, LFS, preprocedure pain, and preprocedure ODI score were selected, and the GEE analysis was performed considering repeated measurements over time (Table 2). There was a numerical difference in the history of surgery in the successful and unsuccessful groups, but the difference was not statistically significant ($P = 0.56$). The presence or absence of spondylolisthesis was also statistically associated with a successful outcome ($P = 0.10$). A grade of LCS, LFS, preprocedure NRS pain, and ODI had a statistically significant correlation with the success of the procedure with univariate analysis ($P = 0.004$, $P = 0.03$, $P = 0.007$, $P = 0.004$, respectively). In the multivariate analysis, which analyzed each factor together considering the effect over time, only preprocedure ODI score was statistically significant ($P = 0.02$).

Table 2. *Generalized estimating equations results for predicting successful transforaminal foraminoplasty.*

Variable	Univariable		Multivariable 1		Multivariable 2		Multivariable 3		Multivariable 4		Multivariable 5	
	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value	OR (95% CI)	*P*-value
Age	1.0 (0.99-1.06)	0.09	1.0 (0.98-1.05)	0.4	1.0 (0.98-1.06)	0.3	1.0 (0.99-1.06)	0.1	1.0 (0.98-1.05)	0.3	1.0 (0.97-1.04)	0.7
Gender (F/M)	1(reference)/ 0.8 (0.43-1.52)	0.5	1(reference)/ 0.9 (0.46-1.59)	0.6	1(reference)/ 0.8 (0.43-1.51)	0.5	1(reference)/ 0.9 (0.50-1.73)	0.8	1(reference)/ 0.9 (0.51-1.7)	0.9	1(reference)/ 0.9 (0.49-1.70)	0.8
Previous Surgery (No/Yes)	1(reference)/ 0.7 (0.28-1.90)	0.5										
Spondylolisthesis (No/Yes)	1(reference)/ 1.9 (0.88-4.20)	0.10										
LCS	2.1 (1.28-3.60)	0.004**	1.93 (1.1-3.38)	0.02*							1.5 (0.87-2.73)	0.1
LFS	1.9 (1.06-3.60)	0.03**			1.8 (0.89-3.57)	0.1					1.4 (0.59-3.26)	0.4
Preprocedure NRS Pain	1.5 (1.12-2.00)	0.007**					1.5 (1.09-1.97)	0.012*			1.3 (0.97-1.84)	0.08
Preprocedure ODI	1.0 (1.01-1.05)	0.004**							1.0 (1.01-1.04)	0.006**	1.0 (1.00-1.03)	0.02*

Generalized estimating equations method was used. *P* value is comparison between the responder and nonresponder group with generalized estimating equations. $^{*}P < 0.05$, $^{**}P < 0.01$ LCS, lumbar central stenosis; LFS, lumbar foraminal stenosis; NRS Pain, numeric rating scale for pain; ODI, Oswestry Disability Index; OR, odds ratio; CI, confidence interval.

Discussion

This study shows that the percentage of successful responders was 59.1%, 73.6%, and 74.5 % of 110 patients at one, 3, and 6 months, respectively. Pain scores improved gradually for 3 months, and the result was maintained until 6 months postprocedure. ODI scores and distance walked without pain were also improved. All patients were discharged the day after the procedure without any serious adverse events.

The basis of the therapeutic effect of TFFP is elimination of the pathophysiological causes of LFS and LCS by removing thickened LF, TFLs, and perineural adhesion tissues. Thickening of the LF can compress the dural sac and nerve root, reducing the diameter of the central spinal canal and contributing to sciatica and lower back pain. Foraminal degenerative lumbar stenosis is traditionally considered a result of bony narrowing due to osteophytes of the SAP (21,22). However, clinical experience reveals that significant additional neural compression is due to degenerative hypertrophy of the LF. Winkler et al (4) showed in their cadaveric study that a lateral extension of the LF, including its intra- and extraforaminal parts, may contribute significantly to nerve root compression at the level of the intervertebral foramen and lateral spinal recess. One hypothesis for LFS pathology is the adhesion of numerous TFLs, which have a protective effect on the nerve root in normal circumstances, but under abnormal conditions, TFLs may cause back pain and radiculopathy (23,24). According to a previous study, hypertrophy of TFLs can occupy a mean cross-sectional area of the lumbar foramen up to a maximum of 89.2% (25). A characteristic narrowing of the foramen causes mechanical compression of the spinal nerve root.

Neural compression can inhibit perineural microvascular blood flow, axonal transport, and nerve function by increasing intrafascicular pressure. These changes lead to upregulation of inflammatory

mediators. Inflammation can ultimately lead to spinal nerve adhesions within or at the entrance of the lumbar foramen (26,27). In addition to removing thickened LF and TFLs, the TFFP procedure eliminates adhesions of neural and ligamentous structures mechanically. Presumably, mechanical removal of adhesions is primarily achieved through the TFFP procedure, and over time, the microvascular blood flow around the spinal nerves may gradually improve. This proves that the patient's pain score decreased significantly at 3 and 6 months rather than at one month postprocedure, and the functional index, ODI, and walking distance without pain steadily improved up to 6 months.

Most patients with symptomatic LSS are treated with various conservative treatments. A number of different surgical techniques are recommended for patients not responding to conservative treatments (2). However, a high rate of serious complications has been shown to be associated with increasing age and comorbidities. To treat these patients, percutaneous foraminoplasty techniques have been introduced to widen the foramen by removing the hypertrophied facet capsule and/or ligament via a paraspinal approach using an endoscopic technique. However, this procedure carries a risk of procedure-related adverse events due to the relative invasiveness of the procedure (12–16).

Recently, 2 papers about minimally invasive transforaminal techniques were introduced (28,29). These procedures showed similar efficacy as our study, reducing venous stasis and perineural edema, eventually promoting the distribution of injected medication in the foramen. In contrast to our study, these 2 procedures were indicated only for patients with LFS.

The biggest advantage of our TFFP procedure is the treatment of LFS including LCS. The walking distance without pain NIC at one, 3, and 6 months showed a statistically significant difference compared to preprocedure measures. The improvement in neurogenic intermittent claudication after this procedure was not only due to treating LFS and LCS together; the bent dissector and cannula complex can be advanced safely by facing and contacting the posterior part of the foramen and spinal canal, allowing access to the midline of the spine without direct contact of the nerve root, dorsal root ganglia, and dura.

Another advantage of our technique is its safety. The largest outer diameter of the cannula is as small as 2.6 mm. It minimizes damage to the nerve and surrounding tissues and reduces pain during the procedure. No skin incision is necessary because of the small diameter of the cannula. In addition, this instrument is used in a 10° bent state, making its approach to the SAP easy and safe without damaging the neural tissue. The bent dissector, consisting of a cup-shaped spoon, grinder, and cannula complex, also adds safety and effectiveness. In addition, it is easy to access the L5-S1 level with the use of bent instruments, even in patients with a high iliac crest. Even better, this procedure can be performed at multiple levels with a single procedure. Even if multiple levels of foramen are treated at the same time, it only takes about 30 minutes.

Limitations of the present study include its retrospective design and lack of a control group for comparison. Determination of the clinical utility of TFFP for LFS and LCS will require assessment in larger randomized controlled trials, in comparison with other minimally invasive procedures. This study is insufficient to present improvements in imaging after the procedure. After treatment with a dissector, an epidurogram was obtained using contrast medium to confirm that there was no filling defect, but this was not recorded as objective numerical data. We did not compare the improvement by obtaining a postprocedure MRI. However, it is likely that it is difficult to determine the changes in adhesions and ligaments using MRI. Moreover, TFLs are difficult to identify even when radiologists are trained to look for them (30).

Conclusion

For this study's patients with LFS and LCS, TFFP using the Foramoon® device resulted in safe, meaningful, and sustained improvements at the 6-month follow-up visit. This procedure should be considered before opting for a surgical treatment in patients with LFS and LCS, who do not respond to conservative treatment.

Acknowledgments

Authors' contributions: DE.M and SH.L conceptualized and designed the study; HM.B,YK.M acquired data; SH.H, SH.L and YK.M analyzed and interpreted data; SH.L and DE.M drafted the article; all authors critically revised the article and reviewed a submitted version of the article; DE.M supervised the entire study.

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