4th Annual

AMPLIFY® SURGICAL

Endoscopic Spine Symposium

UCI Health | March 29, 2025

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Welcome

TO THE 4TH ANNUAL AMPLIFY SURGICAL ENDOSCOPIC SPINE SYMPOSIUM FEATURING DUALPORTAL AND DUALXSLIM TECHNOLOGIES

Amplify Surgical would like to welcome you to our 4th Annual Endoscopic Spine Symposium at the University of California, Irvine (UCI) Medical Center. The Symposium will offer a comprehensive understanding of our dualPortal and dualXSlim technologies through broad-gauging lectures, as well as a hands-on cadaver workshops. Leading the Symposium will be thirteen of the most prominent spine Experts from both, the United States and South Korea, who are here to present, demonstrate, and guide you through these innovative technologies and techniques. Please look forward to our cadaver labs, where our expert Faculty will demonstrate and then administer in-depth instruction on the novel two-portal endoscopic approach (dualPortal) and the newest dual-expanding interbody implant (dualXSlim). We hope that by experiencing first-hand just how powerful our dualPortal and dualXSlim technologies are, you will be inspired to incorporate these ultra-minimally invasive tools into your practices.

Dr. Don Park, our Symposium Chair, is Clinical Professor and Director of the Advanced Endoscopic and Outpatient Spine Program at University of California, Irvine Medical Center. We are honored to celebrate his Chairmanship and our partnership with UCI Medical Center for this 4th Annual Endoscopic Spine Symposium.

Over the past year, the dualPortal and dualXSlim technologies have seen tremendous expansion amongst U.S. practitioners and increased interest in the international community. In response to this rapidly growing interest, we have established bespoke regional training across the country and have welcomed countless physicians into our dualPortal and dualXSlim communities. We are proud to have members from these communities serve as our esteemed faculty.

Thank you for joining us at the 4th Annual Amplify Surgical Endoscopic Spine Symposium featuring dualPortal and dualXSlim technologies. Events such as this are integral to revolutionizing the world of minimally invasive spine surgery, and we are incredibly grateful for those who choose to attend and contribute to our symposia. We would also like to thank our corporate sponsors for supporting today's event. Lastly, we would like to recognize the following for their invaluable contributions to the 4th Annual Amplify Surgical Endoscopic Spine Symposium: our visiting Symposium Faculty, Dr. Don Park (Symposium Chair), UCI Medical Center, the UCI Department of Orthopaedic Surgery, and the UCI Surgical Skills Laboratory.

About Amplify Surgical, Inc.: Amplify Surgical is a privately-held spinal device company located in Irvine, CA. Our mission is to revolutionize minimally-invasive spine surgery by transforming ordinary procedures with groundbreaking surgical solutions that improve patient safety and outcomes.

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Irvine, CA 92618

Introduction from Symposium Chair

SYMPOSIUM CHAIR

Dr. Don Park

Clinical Professor

Advanced Endoscopic and Outpatient

Spine Program Director

UC IRVINE SCHOOL OF MEDICINE

As the symposium chair for the past 4 years, I have witnessed the great interest and enthusiasm for dualPortal spinal endoscopy grow year after year. Now in our 4th symposium, I am very eager to share the dualPortal endoscopic technique, which I believe is the future of minimally invasive spine surgery. I believe that one day dualPortal will be more ubiquitous and commonplace as one of the main techniques used in spine surgery.

The dualPortal approach is a truly enabling technique that significantly improves the visualization and magnification of the surgical anatomy. The dualPortal approach reduces the learning curve experienced with other endoscopic techniques because the visualization of the anatomy is so familiar. Once you see the technique, you will understand the wide-ranging capability of dualPortal in the spine surgeries that we perform every day.

We have assembled the world's greatest dualPortal surgeons from Korea and the US to not only lecture but more importantly, provide hands-on cadaver training. The small group cadaver sessions will enhance the learning experience provided in the didactic sessions. Our goal is to provide that the absolute best educational experience for all the participants.

I cannot wait to see the excited faces of the participants as they learn about the technique at the Symposium. I see so many surgeons with the same look as I teach the dualPortal technique across the US. I know that you too will come away from the Symposium blown away by dualPortal spinal endoscopy!

NOTES

Corporate Sponsors

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Symposium Faculty

Meet our expert faculty

Expert faculty from the United States and South Korea will be on hand to present and demonstrate the dualPortal endoscopic approach and dualXSlim technologies.

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Dr. Don Park
Orange, CA

UCI HEALTH

Dr. Cheol Woong Park
Daejeon, South Korea

DEAJEON WOORI HOSPITAL

Dr. Dong Hwa Heo
Seoul, South Korea

HARRISON SPINARTUS HOSPITAL

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New York, NY

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Philadelphia, PA

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Busan, South Korea

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HOUSTON METHODIST HOSPITAL

Dr. Sohaib Hashmi
Orange, CA

UCI HEALTH

Dr. Young San Ko
Daegu, South Korea

KYUNGPOOK NATIONAL UNIVERSITY

Symposium Agenda

6:30AM
Exhibitor Access Opens - Booth Installation

7:00AM
Registration Opens

7:00AM - 7:45AM
Continental Breakfast

PRESENTATIONS
7:45 AM - 9:50 AM
Location: Auditorium, Building 53

7:45AM - 8:00AM
Welcome Address
Don Park, MD
SYMPOSIUM CHAIR

8:00AM - 8:15AM
Getting Started with dualPortal Endoscopic Spine Surgery
Samuel Cho, MD

8:15AM - 8:30AM
What is dualPortal Endoscopic Spine Surgery and How Does it Differ from Uniportal Endoscopic Spine Surgery?
Jon J.W. Yoon, MD

8:30AM - 8:45AM
dualPortal Endoscopic Spine Surgery - Discectomy: Equipment Needed, How to Set Up the OR
Charla Fischer, MD

8:45AM - 9:00AM
dualPortal Endoscopic Spine Surgery - ULBD: Principles, Anatomy, Workflow
Andrew Chung, DO

9:00AM - 9:15AM
Enblock Removal of Ligamentum Flavum Including Thoracic Spine
Cheol Woong Park, MD

9:15AM - 9:30AM
Basic and Advanced Technique of dualPortal Endoscopic TLIF
Dong Hwa Heo, MD

9:30AM - 9:45AM
The Marriage of dualPortal + dualXSlim: Amplify dualLIF and dualPortal 2.0
Don Park, MD

9:45AM - 9:50AM
Presentations by Sponsors

9:50AM - 10:15AM
Break / Exhibits

CADAVER WORKSHOP
Location: Surgical Skills Lab, Building 55, Basement Floor

10:15AM - 12:30PM
Lab Session 1
dualPortal TLIF (dualLIF®) Demonstration

Station 1
Lead: Don Park, MD
SYMPOSIUM CHAIR

Station 2
Lead: Jon J. W. Yoon, MD

Station 3
Lead: Samuel Cho, MD

Station 4
Co-Lead: Cheol Woong Park, MD
Co-Lead: Ki Eun Chang, MD

Station 5
Co-Lead: Dong Hwa Heo, MD
Co-Lead: Charla Fischer, MD

Station 6
Co-Lead: Nam Lee, MD
Co-Lead: Meng Huang, MD

Station 7
Co-Lead: Man Kyu Park, MD
Co-Lead: Andrew Chung, DO

Station 8
Co-Lead: Young San Ko, MD
Co-Lead: Sohaib Hashmi, MD

12:30PM - 12:40PM
Break / Exhibits

LUNCH PRESENTATIONS
12:40 PM - 1:35 PM
Location: Auditorium, Building 53

12:40PM - 12:50PM
What is the Best Way to Learn dualPortal?
Ki Eun Chang, MD

12:50PM - 1:00PM
dualPortal Endoscopic Decompression for Bertolotti Syndrome, Far-Out Syndrome
Nam Lee, MD

1:00PM - 1:10PM
dualPortal Endoscopic Posterior Cervical Foraminotomy
Man Kyu Park, MD

1:10PM - 1:20PM
Pearls and Pitfalls to Overcome Learning Curves for dualPortal Lumbar Fusion
Young San Ko, MD

1:20PM - 1:30PM
Early Experience with dualPortal Endoscopic Spine Surgery
Sohaib Hashmi, MD

1:30PM - 1:35PM
Presentations by Sponsors

CADAVER WORKSHOP (CONT.)

1:35PM - 3:45PM
Lab Session 2
dualPortal TLIF (dualLIF) Hands-On

3:45PM - 4:00PM
Exhibits / Break

4:00PM - 6:00PM
Lab Session 3
Additional dualPortal TLIF (dualLIF) Hands-On

CADAVER WORKSHOP STATIONS

Lab Station 1

SYMPOSIUM CHAIR
Dr. Don Park
Orange, CA
LEAD

Lab Station 2

Dr. Jon J. W. Yoon
Philadelphia, PA
LEAD

Lab Station 3

Dr. Samuel Cho
New York, NY
LEAD

CADAVER WORKSHOP STATIONS

Lab Station 4

Dr. Cheol Woong Park
Daejeon, South Korea
CO-LEAD

Dr. Ki-Eun Chang
San Diego, CA
CO-LEAD

Lab Station 5

Dr. Dong Hwa Heo
Seoul, South Korea
CO-LEAD

Dr. Charla Fischer
New York, NY
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Dr. Meng Huang
Houston, TX
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Lab Station 7

Dr. Man Kyu Park
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Dr. Andrew Chung
Glendale, AZ
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Lab Station 8

Dr. Young San Ko
Daegu, South Korea
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Dr. Sohaib Hashmi
Orange, CA
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ORIGINAL ARTICLE

Check for updates

Single-Level Unilateral Biportal Endoscopic versus Tubular Microdiscectomy: Comparing Surgical Outcomes and Opioid Consumption

Yixuan Tong, Samuel Ezeonu, Yong H. Kim, Charla R. Fischer

BACKGROUND: **Unilateral biportal endoscopic (UBE) microdiscectomy is an emerging minimally invasive surgery technique for treating symptomatic lumbar disc herniation. There is limited literature regarding outcomes. Here, we assess surgical outcomes and pain medication consumption for UBE vs. tubular lumbar microdiscectomy.**

METHODS: **This was a retrospective cohort study of adult patients undergoing primary, single-level UBE or tubular lumbar microdiscectomy surgery at a high-volume institution between 2018 and 2023. Variables of interest included operative time, complications and reoperations, as well as postoperative opioid and nonopioid pain medication consumption from discharge to 6 months. Opioid consumption was converted to morphine milligram equivalents. Standard statistical analyses were performed for comparative analyses.**

RESULTS: **One hundred two patients—48 UBE and 54 tubular—were included. Average operative time (minutes) was higher for UBE patients (133.1 UBE vs. 86.6 tubular, $P < 0.001$), which trended downward over time but did not reach statistical significance ($P = 0.07$). There were no differences in complication or reoperation rates. Average daily MME was lower from discharge to 2-week follow-up in the UBE group (11.1 v. 14.1, $P = 0.02$), but were comparative thereafter. Nonopioid medication prescription was lower in the UBE cohort from discharge to 2 weeks (70.8% vs. 92.6%, $P = 0.01$) and 2 to 6 weeks (52.1% vs. 85.2%, $P < 0.001$), with no significant differences thereafter.**

CONCLUSIONS: **UBE microdiscectomy is associated with longer operating times. Both opioid and nonopioid pain medication consumption were lower for UBE patients during the initial postoperative period, perhaps owing to the less-invasive nature of the surgery.**

INTRODUCTION

The development of minimally invasive surgery (MIS) techniques was a major advancement in the field of spine surgery. Introduced in 1977, MIS lumbar discectomy surgery to treat symptomatic herniated discs aims to reduce procedural morbidity via smaller incisions and greater preservation of the paraspinous structures.[1-4] Tubular microdiscectomy is one popular MIS technique that involves the use of serial dilators for visualization of the pathology.[1,4,5] Prior literature has shown superior postoperative pain scores, shorter hospital stays and recovery time, and lower postoperative narcotic requirements when compared to traditional open microdiscectomy surgery.[6-11]

Fully endoscopic spine surgery is emerging as an innovative alternative to previous MIS techniques. Specifically, unilateral biportal endoscopy (UBE) is a novel technique for treatment of lumbar stenosis and disc herniation[12-14] that involves placement of same-sided viewing and working endoscopic portals for augmented visualization and flexibility. Theoretically, UBE technique would preserve more osseous and muscular structures compared to open and tubular approaches.[15] In fact, recent literature has reported improved pain and disability scores for UBE technique when compared to tubular technique for treatment of single-level

Key words
- Microdiscectomy
- Minimally invasive spine surgery
- MIS
- MLD
- UBE
- Unilateral biportal endoscopic decompression
- Tubular microdiscectomy

Abbreviations and Acronyms
BMI: Body mass index
MIS: Minimaly invasive surgery
MME: Morphine milligram equivalents
NSAIDs: Nonsteroidal anti-inflammatory drugs
UBE: Unilateral biportal endoscopy

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Citation: World Neurosurg. (2024) 190:e754-e761.
https://doi.org/10.1016/j.wneu.2024.07.215

*Journal homepage: **www.journals.elsevier.com/world-neurosurgery***

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lumbar stenosis,[16] however patient-reported outcomes are largely comparable between UBE, tubular, and open techniques thus far for treatment of lumbar disc herniations.[17,18]

While the use of UBE has shown early potential, there is still a paucity of literature that compares its effectiveness to other MIS techniques, particularly when assessing patterns in postoperative pain medication use. Hence, in this study, we aimed to compare the surgical outcomes of UBE versus tubular microdiscectomy and to provide a robust comparison of postoperative pain medication consumption.

MATERIALS AND METHODS

Patient Population

This was a retrospective cohort study of adult patients who underwent primary, elective, single-level UBE or tubular lumbar microdiscectomy surgery at a single tertiary academic institution between 2018 and 2023. All UBE cases were consecutive cases, and all microdiscectomy procedures and follow-up clinical visits were completed by experienced orthopedic spine surgeons. Patients were excluded if they had previously undergone surgery at the same lumbar level or underwent additional procedures at the same or additional levels during the same surgical event. Institutional review board approval was obtained prior to beginning the study.

Surgical Technique and Perioperative Protocol

Patients underwent either tubular or UBE microdiscectomy based upon surgeon's preference. Two board-certified orthopedic spine surgeons performed UBE procedures at our institution, and 3 surgeons performed the tubular procedures. For each type, there were neither significant variations in surgical technique nor in perioperative protocol. Intraoperatively, standard anteriorposterior and lateral fluoroscopy imaging were used to confirm correct operative level and positioning of key instrumentation in both techniques. Postoperatively, all patients were recommended to the same multimodal, opioid-sparing regimen. They also were advised to avoid strenuous activity in the initial postoperative period, as well as referred to physical therapy and counseled on lifestyle modifications to sustain long-term benefits. Standard postoperative follow-up visits were conducted.

Table 1. Overview of Patient Demographics for the UBE and Tubular Cohorts

	UBE	Tubular	*P*-Value
Age (years)	46.0 ± 18.2 (std)	45.5 ± 16.0	0.88
Gender (# female)	22 (45.8%)	28 (51.9%)	0.68
BMI (kg/m^2)	25.7 ± 26.7	28.7 ± 51.3	0.02*
Smoking Status	5 (10.4%)	11 (20.4%)	0.27
CCI	0.38 ± 0.32	0.41 ± 0.62	0.81
ASA class	1.81 ± 0.33	1.98 ± 0.40	0.16

UBE, Unilateral Biportal Endoscopic; std, standard deviation; BMI, Body Mass Index; CCI, Charlson Comorbidity Index; ASA, American Society of Anesthesiologists.
*$P < 0.05$.

Table 2. Overview of Surgical Variables for the UBE and Tubular Cohorts

	UBE	Tubular	*P*-Value
Preop Diagnoses*			
HNP	48 (100%)	54 (100%)	1.0
Radiculopathy	48 (100%)	51 (94.4%)	0.10
Stenosis	13 (27.1%)	14 (25.9%)	0.93
DDD	9 (18.8%)	11 (20.4%)	0.95
DSPL	1 (2.08%)	1 (1.85%)	0.53
Operative Level	-	-	0.93
L1/L2	0 (0%)	0 (0%)	1.0
L2/L3	1 (2.08%)	1 (1.85%)	0.53
L3/L4	6 (12.5%)	9 (16.7%)	0.55
L4/L5	18 (37.5%)	18 (33.3%)	0.66
L5/S1	23 (47.9%)	26 (48.1%)	0.98
Operative time (minutes)	133.1 ± 40.5	86.6 ± 26.5	< 0.001†
LOS (days)	0.47 ± 0.33	0.54 ± 0.53	0.41
Intraop complication	0 (0%)	2 (3.70%)	0.53
Comments	-	2 durotomies	-
Postop complication	1 (2.08%)	5 (9.26%)	0.26
Comments	1 synovial cyst	4 recurrent HNPs	-
Reop rate	0 (0%)	4 (7.41%)	0.16
Days to reop	-	10.7 ± 1698	-

UBE, Unilateral Biportal Endoscopic, Preop, Pre-operative, HNP, Herniated Nucleus Pulposus, DDD, Degenerative Disc Disease, DSPL, Degenerative spondylolisthesis, LOS, Length of stay, Intra-Op, Intra-operative, Post-Op, Post-operative, Reop, Reoperation.
*Patients may carry more than one preoperative diagnosis.
†$P < 0.05$.

Data Collection

The patient electronic medical record system from our institution (Epic Caboodle. Version 15; Verona, Wisconsin) was utilized to collect data regarding patient demographic variables, surgical variables, and postoperative pain medication consumption.

Patient demographic variables included age at time of surgery, gender, body mass index (BMI, kg/m^2), smoking status, medical comorbidities, and American Society of Anesthesiologists classification score. Surgical variables included preoperative diagnosis, operative level (L1/L2 through L5/S1), operative time (minutes), hospital length of stay (days), intraoperative and postoperative complications, as well as reoperation rates. Preoperative diagnosis was subdivided into herniated nucleus pulposus, radiculopathy, spinal stenosis, degenerative disc disease, and degenerative spondylolisthesis.

Postoperative pain medication type, dosage, and duration were recorded for each patient across 4 time intervals: from discharge to 2 weeks, 2 weeks to 6 weeks, 6 weeks to 3 months, and 3 months to 6 months follow-up. Both opioid and nonopioid pain medication prescriptions were recorded. Pain medications were prescribed only by the patient's spine surgeon or pain management physician. Opioid consumption was converted to total morphine milligram equivalents (MME) to standardize further data analyses.[19]

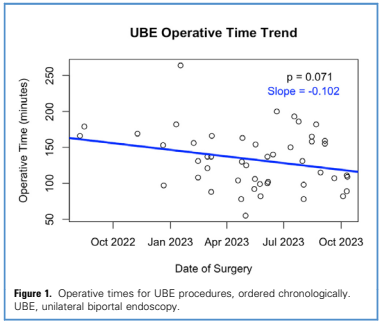

Figure 1. Operative times for UBE procedures, ordered chronologically. UBE, unilateral biportal endoscopy.

Data Analysis

Patients were divided into the UBE and tubular cohorts for data analysis. Continuous variables were represented as means with standard deviations, and categorical variables were represented as frequencies with percentages. Statistical differences between the 2 cohorts for continuous variables were evaluated using independent sample t-tests and multivariate analysis of variance tests, and differences in categorical variables were evaluated using chi-squared (χ^2) tests. For operative times in the UBE cohort in particular, linear regression analysis was utilized to evaluate for a significant trend over time. *P*-values less than 0.05 were considered statistically significant. All patient data were organized and collected using Microsoft Excel software (Microsoft Corporation, Redmond, Washington). All statistical analyses were performed using SPSS Statistics (IBM, Armonk, New York, USA).

RESULTS

One hundred two patients were included in the study, with 48 consecutive patients in the UBE cohort and 54 patients in the tubular cohort. With respect to patient demographic variables, there were no statistically significant differences in patient age, gender, smoking status, Charlson Comorbidity Index score, or American Society of Anesthesiologists class between the 2 cohorts (Table 1). The only exception was average BMI, which was significantly lower in the UBE cohort (25.7 kg/m^2 UBE v. 28.7 kg/m^2 tubular, $P = 0.02$). With respect to surgical outcome variables, there were no significant differences in preoperative diagnoses, operative level, hospital length of stay, intraoperative or postoperative complications, or reoperation rates between the 2 cohorts (Table 2). Of note, average operative time was significantly higher in the UBE cohort (133.1 minutes UBE vs. 86.6 minutes tubular, $P < 0.001$). Operative times in the UBE cohort chronologically decreased over time but did not reach statistical significance ($r = 0.26$, slope $= -0.10$, $P = 0.07$) (Figure 1).

Table 3. Postoperative Opioid Pain Medication Consumption Patterns Across Four Time Intervals

	UBE	Tubular	*P*-Value
Comparison of Opioid Consumption in MME Between Cohorts			
Average Daily MME			
Discharge to 2 weeks	11.1 ± 5.60	14.1 ± 6.86	0.02*
2 weeks to 6 weeks	0.13 ± 0.73	1.70 ± 7.94	0.16
6 weeks to 3 months	0	0.81 ± 4.02	0.15
3 months to 6 months	0	0.03 ± 0.24	0.32
ANOVA *P*-value	< 0.001*	< 0.001*	-
Percentage of Patients with Opioid Prescriptions			
Discharge to 2 weeks	45 (93.8%)	53 (98.1%)	0.25
Oxycodone	44 (91.7%)	50 (92.6%)	0.86
Hydromorphone	0 (0%)	3 (5.55%)	0.09
Hydrocodone	1 (2.08%)	0 (0%)	0.29
Tramadol	0 (0%)	4 (7.40%)	0.054
Morphine	0 (0%)	0 (0%)	1.0
2 weeks to 6 weeks	2 (4.17%)	8 (14.8%)	0.07
Oxycodone	2 (4.17%)	3 (5.55%)	0.75
Hydromorphone	0 (0%)	1 (1.85%)	0.34
Hydrocodone	0 (0%)	1 (1.85%)	0.34
Tramadol	0 (0%)	2 (3.70%)	0.18
Morphine	0 (0%)	1 (1.85%)	0.34
6 weeks to 3 months	0 (0%)	4 (7.40%)	0.054
Oxycodone	0 (0%)	1 (1.85%)	0.34
Hydromorphone	0 (0%)	0 (0%)	1.0
Hydrocodone	0 (0%)	1 (1.85%)	0.34
Tramadol	0 (0%)	2 (3.70%)	0.18
Morphine	0 (0%)	1 (1.85%)	0.34
3 months to 6 months	0 (0%)	1 (1.85%)	0.34
Oxycodone	0 (0%)	1 (1.85%)	0.34
Hydromorphone	0 (0%)	0 (0%)	1.0
Hydrocodone	0 (0%)	0 (0%)	1.0
Tramadol	0 (0%)	0 (0%)	1.0
Morphine	0 (0%)	0 (0%)	1.0

UBE, Unilateral biportal endoscopic; MME, morphine milligram equivalent; ANOVA, analysis of variance.
*$P < 0.05$.

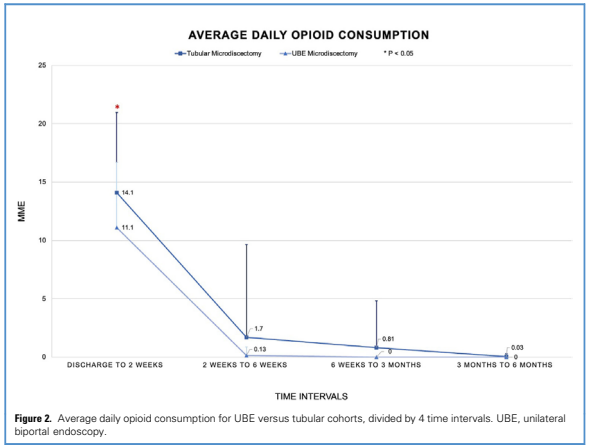

Figure 2. Average daily opioid consumption for UBE versus tubular cohorts, divided by 4 time intervals. UBE, unilateral biportal endoscopy.

With respect to postoperative pain medication prescription (Table 3), opioid consumption significantly decreased over time within both cohorts (Figure 2). Patients who underwent UBE microdiscectomy consumed on average 11.1 daily MMEs from discharge to 2-week follow-up, 0.13 average daily MMEs from 2 to 6 weeks, and 0 MMEs from six weeks to three months and three months to 6 months follow-up ($P < 0.001$). Similarly, average daily MME for patients who underwent tubular microdiscectomy decreased from 14.1 to 1.70, then 0.81, and then 0.03 over the 4 time intervals ($P < 0.001$). When comparing between the 2 cohorts, average daily MME was significantly lower from discharge to 2-week follow-up in the UBE cohort (11.1 UBE vs. 14.1 tubular, $P = 0.02$). However, there were no significant differences in the time intervals thereafter. Prescribed opioid medications included oxycodone, hydromorphone, hydrocodone, tramadol, and morphine, with a similar proportion of opioid agents prescribed at all-time points.

For nonopioid pain medication prescriptions (Table 4), common medications included acetaminophen, various nonsteroidal anti-inflammatory drugs (NSAIDs) such as meloxicam and ibuprofen, gabapentin or pregabalin, and various muscle relaxants and steroid agents. Overall, a smaller proportion of patients in the UBE group were prescribed nonopioid medications from discharge to 2 weeks (70.8% UBE v. 92.6% tubular, $P = 0.01$) and 2 weeks to 6 weeks (52.1% UBE vs. 85.2% tubular, $P < 0.001$) follow-up, with no further differences thereafter (Figure 3). More specifically, a smaller proportion of patients in the UBE cohort were prescribed acetaminophen (18.8% UBE vs. 37.0% tubular, $P = 0.04$), NSAIDs (41.7% UBE vs. 64.8% tubular, $P = 0.02$), and muscle relaxant medication (18.8% UBE vs. 61.1% tubular, $P < 0.001$) from discharge to two weeks as well as from 2 weeks to 6 weeks (acetaminophen 4.17% UBE vs. 16.7% tubular, $P = 0.04$; NSAIDs 27.1% UBE vs. 64.8% tubular, $P < 0.001$; muscle relaxants 12.5% UBE vs. 46.3% tubular, $P < 0.001$). Although there were no overall differences between cohorts at later time intervals, UBE patients were prescribed less gabapentin/pregabalin from 6 weeks to 3 months (4.17% UBE vs. 24.1% tubular, $P < 0.01$) and from 3 months to 6 months (0% UBE v. 9.26% tubular, $P = 0.03$).

DISCUSSION

In recent years, unilateral bilateral endoscopy has emerged as a promising MIS alternative to already established techniques (e.g. tubular microdiscectomy) for treating lumbar disc herniations and spinal stenosis pathology. For treatment of lumbar disc herniations in particular, UBE has been shown to be noninferior to tubular microdiscectomy in areas such as surgical complications, hospital length of stay, blood loss, and operative time.[18,20] UBE technique was also reported to yield comparable patient-reported pain and disability scores for up to 6 months following surgery.[18,20] Our study results are consistent with previous findings demonstrating comparable clinical outcomes. In fact, when compared to results from a systematic review by Lin et al. 2019, our UBE complication rates and hospital length of stay were lower by approximately 7% and 3 days, respectively.[21] However, UBE procedures in our cohort took significantly

Table 4. Postoperative Nonopioid Pain Medication Consumption Patterns Across 4 Time Intervals

	UBE	Tubular	*P*-Value
Discharge to 2 weeks	34 (70.8%)	50 (92.6%)	0.01*
Acetaminophen	9 (18.8%)	20 (37.0%)	0.04*
NSAIDs	20 (41.7%)	35 (64.8%)	0.02*
Gabapentin/pregabalin	10 (20.8%)	15 (27.8%)	0.42
Muscle relaxant	9 (18.8%)	33 (61.1%)	<0.001*
Steroid	8 (16.7%)	16 (29.6%)	0.12
2 weeks to 6 weeks	25 (52.1%)	46 (85.2%)	<0.001*
Acetaminophen	2 (4.17%)	9 (16.7%)	0.04*
NSAIDs	13 (27.1%)	35 (64.8%)	<0.001*
Gabapentin/pregabalin	10 (20.8%)	17 (31.5%)	0.22
Muscle relaxant	6 (12.5%)	25 (46.3%)	<0.001*
Steroid	2 (4.17%)	6 (11.1%)	0.19
6 weeks to 3 months	13 (27.1%)	21 (38.9%)	0.21
Acetaminophen	0 (0%)	0 (0%)	1.0
NSAIDs	6 (12.5%)	10 (18.5%)	0.40
Gabapentin/pregabalin	2 (4.17%)	13 (24.1%)	<0.01*
Muscle relaxant	5 (10.4%)	7 (13.0%)	0.69
Steroid	1 (2.08%)	6 (11.1%)	0.07
3 months to 6 months	3 (6.25%)	9 (16.7%)	0.10
Acetaminophen	0 (0%)	0 (0%)	1.0
NSAIDs	1 (2.08%)	4 (7.41%)	0.21
Gabapentin/pregabalin	0 (0%)	5 (9.26%)	0.03*
Muscle relaxant	2 (4.17%)	3 (5.56%)	0.75
Steroid	1 (2.08%)	0 (0%)	0.29

Patients are often prescribed more than one nonopioid pain medication.
UBE, Unilateral Biportal Endoscopic; NSAIDs, non-steroidal anti-inflammatory drugs.
*$P < 0.05$.

longer— on average around 46 minutes longer—compared to tubular procedures. Our mean operative time of 133.1 minutes was also longer than the mean time of 79.2 minutes that was reported by Lin et al.[21] This difference is most likely due to the steep learning curve associated with UBE technique. Indeed, UBE spine surgery involves learned proficiency with different equipment and working instruments, route of approach and visualization, and operative technique, as well as training the surgical assistant and other operating room staff.[22] As evidenced by our downward trend in operative times, the learning curve for UBE technique impacted the length of surgery, however it did not seem to impact the quality of surgery given the comparable complication and reoperation rates.

Pain medication consumption served as the proxy metric for postoperative pain in this study. This method was chosen in part due to the limited patient response to pain and disability surveys at our institution. None of the patients to our knowledge were taking high-dose narcotic medications preoperatively; however, we do acknowledge that different patients have different pain tolerance thresholds, which may have influenced the results in our study. In addition to opioid prescription decreasing over time to 0 or near 0 MME at 6 months follow-up in both cohorts, prescription was significantly lower in the early period following surgery for UBE patients by an average of 3 MMEs. This decrease in opioid usage suggests that the less minimally invasive nature of the UBE surgery may be associated with less postoperative pain from the get-go, which is encouraging especially in the face of a national opioid crisis.[23] This difference may also have prevented some opioid-related adverse symptoms. In fact, Zhao et al. 2004 reported that a 3 to 4 null mg increase in opioid consumption could be associated with one additional clinically meaningful event.[24] However, investigators have also cited an absolute reduction of 10 MMEs in the first 24 hours following surgery as the minimally important difference threshold,[25] yet this value

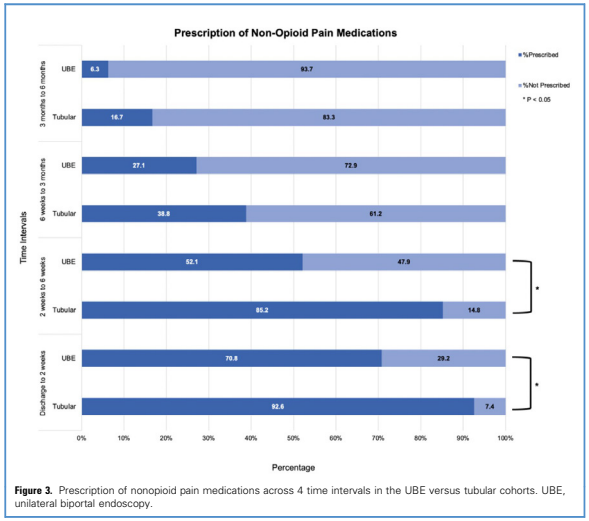

Figure 3. Prescription of nonopioid pain medications across 4 time intervals in the UBE versus tubular cohorts. UBE, unilateral biportal endoscopy.

would have been difficult to obtain with our retrospective study design, as most patients were discharged to home on postoperative day 0. Nevertheless, it has been shown previously that postoperative opioid prescription of less than 225 MMEs per week was associated better patient-reported outcome scores and less 90-day opioid dependency for elective spine procedures[26]; both patient cohorts in this study had less than 200 weekly MMEs of prescribed opioid medications at any time point, which bodes well for patient satisfaction.

Moreover, prescription of nonopioid pain medications decreased over time, with less than 20% of patients in either cohort requiring prescriptions at 3 to 6 months postoperatively. Similar to the trend in opioid medication prescription, a significantly smaller proportion of UBE patients were prescribed nonopioid pain medications of any type in the discharge to 2-week postoperative period, as well as from 2 to 6 weeks follow-up time period. This difference appears to be mainly driven by a decrease in prescription of acetaminophen, NSAIDs, and muscle relaxant agents when compared to the tubular patient cohort. Indeed, the efficacy of a multimodal approach to pain control in spine surgery has already been demonstrated.[27] The fact that both opioid and nonopioid pain prescriptions decreased in the UBE cohort during the early postoperative period indicates that the UBE procedure may be more pain sparing. There could also be an associated "ceiling effect." That is, there may be limited "room" to begin with for further decreasing pain medication consumption for such minimally invasive procedures.

Physicians must prioritize identifying effective strategies for enhancing pain management, as uncontrolled pain not only poses physical burdens but also carries significant financial implications. While both MIS techniques of UBE and tubular microdiscectomy are designed to reduce iatrogenic injury, patients still can experience significant back pain requiring intervention. A systematic review in 2008 assessing the health resource utilization of lower back pain in the US and internationally reported an economic burden as high as $624.8 billion, with 13% allocated to prescription pharmaceutical costs.[28] Moreover, Weir et al. 2017[29] in a study that tracked healthcare costs following lumbar surgery in the UK, found that persistent postoperative back pain was associated with a three-fold increase in drug prescription costs. Considering the additional financial toll brought on by pain medications, the findings of our study imply that UBE may not only facilitate reduced pain but also provide greater cost-benefit by relieving patients of further postdischarge pain requirements.

Finally, this study had several limitations. First, as there are a limited number of spine surgeons who perform the UBE and

tubular procedures at our institution, our patient sample size was limited, with associated patient selection bias. We plan to continue following patients who receive both types of surgeries, and particularly the UBE procedure, in order to obtain a larger study population, greater effect size, and longer time outcome data. Regardless, we believe that our patient cohorts in this study were sufficiently similar to each other (Table 1) so as to not have influenced our primary outcomes. We believe that, with the exception of BMI, there were no statistically or clinically significant differences. Yet the higher average BMI for the tubular cohort may be a confounding variable here; there is some evidence that higher pain sensitivity in obese individuals.[30] Although average BMI is not in the obese range, a confounding effect should still be considered here.

A future study that includes both patient-reported pain scores as well as postoperative pain medication prescription would aim to bridge the gap between patients' need for pain control and the actual amount of medication prescribed. Indeed, there are a limited number of conclusions that can be drawn from a retrospective study. The decision to adopt one MIS technique over another continues to largely depend on surgeon comfort and proficiency as well as institutional or cost-related constraints. As the UBE procedure continues to become established, a future prospective and/or randomized controlled trial would provide an even more robust comparison of existing MIS techniques, such as UBE versus tubular microdiscectomy.

CONCLUSIONS

UBE microdiscectomy is associated with longer operating times. Operative times trended downward over time, suggesting a learning curve with the newer UBE technique. Otherwise, clinical outcomes for UBE vs. tubular microdiscectomy were comparable, as is consistent with previously published literature. There is lower opioid and nonopioid pain medication consumption for UBE patients in the early postoperative period, which may be attributed to the less-invasive nature of the UBE surgery. Pain medication consumption is comparable thereafter, and pain medication requirement overall is minimal at 6 months follow-up.

CRediT AUTHORSHIP CONTRIBUTION STATEMENT

Yixuan Tong: Conceptualization, Formal analysis, Investigation, Methodology, Writing — original draft, Writing — review & editing. **Samuel Ezeonu:** Data curation, Project administration, Resources, Writing — original draft. **Yong H. Kim:** Conceptualization, Supervision, Validation, Writing — review & editing. **Charla R. Fischer:** Conceptualization, Methodology, Resources, Supervision, Writing — review & editing.

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Conflict of interest statement: The authors declare that the article content was composed in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Received 17 July 2024; accepted 29 July 2024

Citation: World Neurosurg. (2024) 190:e754-e761.
https://doi.org/10.1016/j.wneu.2024.07.215

Journal homepage: www.journals.elsevier.com/world-neurosurgery

Available online: www.sciencedirect.com

Neurospine 2023;20(1):110-118.
https://doi.org/10.14245/ns.2346116.058

Neurospine
pISSN 2586-6583 eISSN 2586-6591

Original Article

The Use of Dual Direction Expandable Titanium Cage With Biportal Endoscopic Transforaminal Lumbar Interbody Fusion: A Technical Consideration With Preliminary Results

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Received: January 25, 2023
Revised: February 27, 2023
Accepted: February 27, 2023

Objective: Expandable cage technology has emerged for lumbar interbody fusion to restore intervertebral disc space height and alignment through a narrow surgical corridor. The purpose of this study is to present the technique of biportal endoscopic transforaminal lumbar interbody fusion (TLIF) using dual direction expandable cage and provide early clinical results.

Methods: We performed the biportal endoscopic TLIF using a dual direction expandable titanium cage for height restoration and a larger footprint in 10 patients. Clinical parameters including Oswestry Disability Index (ODI), visual analogue scale (VAS), and complications were retrospectively analyzed. Also, we investigated radiologic parameters using preoperative and postoperative x-ray images.

Results: We successfully inserted dual direction expandable cages during biportal endoscopic TLIF. There was no significant subsidence or collapse of the expandable cages during the 6-month follow-up period. Lumbar lordosis and disc height were significantly increased after surgery. ODI and VAS scores were significantly improved at 6 months after surgery.

Conclusion: In this report, we describe the first use of a dual direction expandable interbody TLIF cage that expands in both width and height in biportal endoscopic TLIF surgery. Early clinical and radiographic outcomes of this TLIF technique may be favorable in early 6-month follow-up.

Keywords: Endoscopy, Lumbar vertebrae, Surgery, Biportal

INTRODUCTION

Minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) has demonstrated comparable clinical outcomes and safety profile as compared to open conventional TLIF with significant improvement of pain and disability.[1,2] More recently, endoscopic techniques to perform TLIF surgery have been introduced with similar success as MIS-TLIF, especially with biportal endoscopic techniques.[3-8] The biportal endoscopic TLIF technique is similar to the MIS-TLIF technique in that the technique utilizes a posterolateral interlaminar approach, while visualizing the spinal anatomy with an endoscopic camera.[7-9] Through the technique, direct decompression of the spinal canal can be achieved and interbody fusion can be completed through a transforaminal approach. This allows for restoration of intervertebral disc height and reduction of the spondylolisthesis, which has demonstrated significant correlation with clinical success.[10,11] The biportal endoscopic technique is less invasive as compared

to other MIS techniques with preservation of the lumbar musculoligamentous structures, which may reduce postoperative pain and facilitate recovery.[5,7,8,12]

Expandable cage technology has been developed for interbody fusion and has demonstrated the ability to restore intervertebral disc height and correct alignment.[13,14] However, subsidence of the vertebral endplates is a significant concern, especially with point loading of a narrow cage within the center of the intervertebral disc space.[15,16] A narrow cage is typically utilized for a TLIF approach due to the narrow corridor available within the neural foramen to introduce the implant. With subsidence, collapse of disc height, loss of reduction, and malalignment may occur, which can lead to suboptimal clinical outcomes. Recently, a novel dual direction expandable titanium TLIF cage has been developed that expands both in the medial to lateral dimension and in height. The cage can be placed through the neural foramen in the narrow, collapsed state. Once in the disc space, the medial to lateral expansion increases the surface area of endplate bony contact and provides contact with the apophyseal rings, which has been shown to be the strongest portion of the vertebral endplate.[17,18] With these advantages, complete expansion with this dual expandable cage may lead to less subsidence and restore lumbar lordosis.

The purpose of this study is to present the technique of biportal endoscopic TLIF utilizing the dual direction expandable titanium TLIF cage and provide preliminary results.

MATERIALS AND METHODS

1. Patients and Clinical Data Analysis

We enrolled patients who were obtained single level biportal endoscopic TLIF using the dual direction expandable TLIF cage (Dual-X TLIF, Amplify Surgical, Inc., Irvine, CA, USA) in this study (Fig. 1). The design of this study was a retrospective analysis of prospectively collected data with description of surgical technique. After obtaining Institutional Review Board (IRB) approval from the hospital where the author was affiliated (IRB approval No. CA-TR-1), the investigations was performed. The design of this study was a technical report with preliminary data. The indications of this TLIF technique included degenerative spondylolisthesis, lumbar central stenosis, Lumbar foraminal stenosis and isthmic spondylolisthesis. We excluded the revision surgery, infection, trauma, and multilevel disease. Only patients who had full clinical and radiographic data for at least 6 months after surgery were included in the study.

We analyzed clinical data including Oswestry Disability Index (ODI), visual analogue scale (VAS) of back and leg, operation time, estimated blood loss, and complications. Estimated blood loss included postoperative blood drainage amount. We obtained lumbar radiographs, including anteriorposterior (AP) and lateral x-rays including flexion and extension lateral views preoperatively, immediately postoperatively and 6 months after surgery. We measured disc height of operative segment (anterior height+posterior height/2), segmental lordotic angle of operative level, and lumbar lordotic angle using preoperative and postoperative x-rays. Significant cage subsidence was defined as a cage invading the vertebral body by more than 2 mm. Subsidence and collapse of the expandable cages were evaluated by disc height measurement.

Since the patient sample was small, nonparametric statistics were used. Statistical analysis was performed using Wilcoxon signed-rank test, and Kruskal-Wallis test. A $p<0.05$ was considered to be statistically significant. R 4.2.2 (R Foundation for Statistical Computing, Vienna, Austria) were used for statistical analysis.

Fig. 1. Pictures of the dual expandable titanium cage in the fully collapsed state and the fully expanded state. Fully collapsed (A), width expansion (B), and height expansion (C).

2. Surgical Procedure

The procedure utilizes biportal endoscopy, which consists of an endoscopic camera, endoscopic irrigation equipment, monitor, radiofrequency (RF) console with probes, high speed bur, bone cutting endoscopic shaver device, and standard surgical instruments.[4,9,12]

The dual direction expandable titanium TLIF cages start at a height of 7 mm that expand to 3-mm increments and width of 12 mm that expand to 21 mm with cage length options of 25 and 30 mm (Fig. 1). The cages are available in 0°, 8°, 12°, and 15° lordotic options. The cage is designed with a large center chamber for bone graft placement after expansion and an open structure design that allows bone graft to be placed through the cage and into the disc space. The cage is designed with 2 independent locking mechanisms to ensure that the cage remains expanded in both width and height. Initial locking occurs with an expansion locking mechanism and a secondary active locking occurs with insertion of a locking screw through the cage.

We preferred general endotracheal anesthesia for biportal endoscopic TLIF. After anesthesia, the patient is placed in the prone position on a Jackson table or a Wilson frame. Two incisions are made for the biportal endoscopic procedure (Fig. 2A). The first incision is made over the ipsilateral caudal pedicle below the disc space as the working portal, measuring approximately 2 cm (Fig. 2B). The surgical instruments, outflow cannula, interbody cage, and pedicle screw can all be introduced through this working portal. The second incision is for the viewing portal, which is a 5-mm stab incision made approximately 2 cm cephalad to the working portal and lateral to the pedicle (Fig. 2B). Two 18-gauge 90-mm length spinal needles are initially placed through the planned incision sites. Lateral fluoroscopic images are used to verify the correct spinal level and disc space as well as trajectories. Once the working portal incision is made, the lumbodorsal fascia is incised in the trajectory of the portal and serial dilators are inserted. The paraspinal musculature and adventitia are bluntly dissected off the cephalad and caudal laminae and a working space is created over the laminae. An outflow cannula is then placed in the working portal and the endoscopic camera is introduced after creating the viewing portal. After the endoscopic irrigation is started, the endoscopic camera and a RF probe are then triangulated over the cephalad lamina (Fig. 3A). Basically, our biportal endoscopic TLIF is similar to MIS-TLIF using tubular retractor systems. At this point, if patients have symptomatic central stenosis, a unilateral laminotomy with bilateral decompression can be performed as previously described (Fig. 3B).[4,6] After the decompression is complete, a complete facetectomy is performed with a straight osteotome under direct visualization of the endoscope. The bone from the facetectomy can be harvested and processed as autograft for later in the procedure. Once the disc space is identified, and the annulus fibrosis is then incised by a blunt annular knife. Serial disc space shavers are then introduced into the disc space to remove the disc material and cartilaginous endplate. The disc material can then be further removed with a series of pituitaries and angled curettes under direct endoscopic visualization (Fig. 4A). The complete preparation of the bony endplates with bleeding bony surfaces can be verified directly by the endoscope (Fig. 4B). Prior to placing the final implant, serial trials are inserted

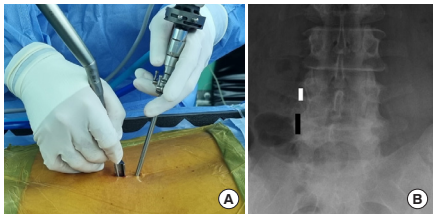

Fig. 2. (A) Overview of biportal endoscopic approach. Intraoperative photograph depicting the endoscope placed in the viewing portal and the surgical instrument placed in the working portal. (B) Intraoperative anteriorposterior fluoroscopy image depicting the location of the portals. The white line is the location of the viewing endoscopic portal and the black line is the location of the working portal.

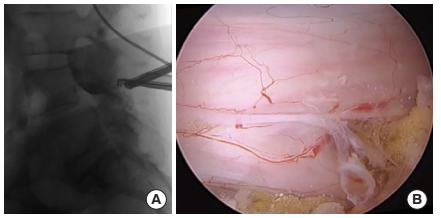

Fig. 3. (A) Intraoperative fluoroscopy image showing the endoscopic camera and radiofrequency probe triangulated over the L4 lamina and disc space of L4–5. (B) Intraoperative endoscopic photograph showing the dura and traversing nerve root exposed after completion of the unilateral laminotomy and bilateral decompression.

https://doi.org/10.14245/ns.2346116.058

into the disc space to determine the initial and final height that the disc space can accommodate. Only after proper trialing, the final implant is then selected.

Autograft can be introduced into the disc space using a specialized endoscopic funnel. The collapsed dual direction expandable cage is then inserted into the disc space with retraction of the thecal sac, traversing and exiting nerve root using specialized endoscopic retractors (Figs. 5, 6). A customized cage guidance helps to safely insert the cage into disc space. The cage is impacted to the anterior border of the disc space and across the midline under fluoroscopic guidance in both the AP and lateral projections (Fig. 5A, B). The cage is expanded initially in the medial to lateral direction (Fig. 5C). Once this is complete, the cage is then expanded to the final height position (Fig. 5D). After inserting the cage into the disc space, turning the insertion handle will initially expand the cage in the medial to lateral direction to the final width of 21 mm for increased surface area covered within the disc space. Once medial to lateral expansion is complete, then cage height expansion proceeds. The final height was previously determined by the trialing and the cage will expand in height by 3 mm to the final height with continued rotation of the insertion handle. Proper trialing and cage selection is paramount to prevent endplate damage and subsidence.

The secondary locking screw is then inserted and locked into final position. The inserter is then removed from the cage and fluoroscopic images are obtained in the AP and lateral projections.

Specialized bone graft cannulas are filled with allograft material such as demineralized bone matrix (DBM) putty and fiber and the cannulas are used to introduce the allograft material into the cage and disc space. The open architecture of the cage allows for the allograft to freely fill the cage and disc space. Typically, endoscopic fluid irrigation is paused during the insertion of the allograft material. A surgical drain is then placed into the laminotomy site to reduce the risk of epidural hematoma postoperatively. All endoscopic equipment is then removed, and percutaneous pedicle screws are placed in the standard fashion like MIS-TLIF (Fig. 6).

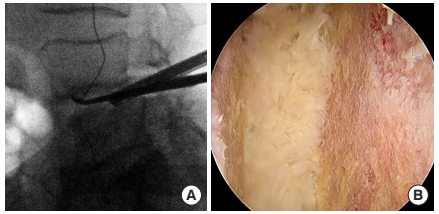

Fig. 4. (A) Intraoperative lateral fluoroscopy image showing the endoscopic camera within the intervertebral disc space during the discectomy and endplate preparation with an angled curette. (B) Intraoperative endoscopic photograph showing the intervertebral disc space after complete discectomy and endplate preparation with removal of the cartilaginous endplate for fusion.

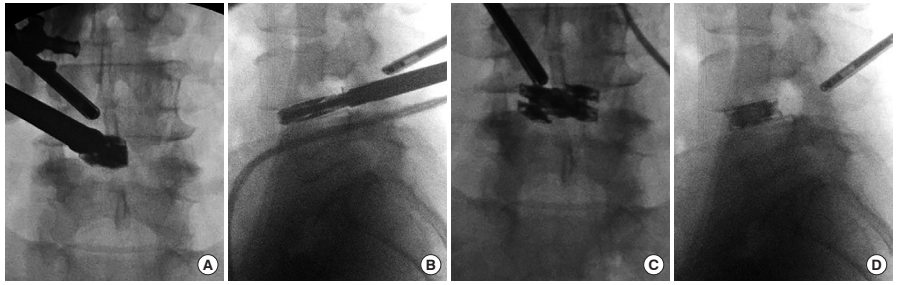

Fig. 5. Intraoperative anteroposterior (A) and lateral (B) fluoroscopy image during the initial placement of the dual expandable titanium cage into the disc space with endoscopic visualization. The cage has been placed near the ventral aspect of the disc space. (C) Intraoperative anteriorposterior fluoroscopy image after the cage has been fully expanded in the medial to lateral dimension in the midline of the disc space. (D) Lateral fluoroscopy image after the cage has been fully expanded in height.

RESULTS

1. Clinical and Radiological Results

We successfully performed biportal endoscopic TLIF surgeries using dual direction expandable cages in 10 patients. All surgeries included biportal endoscopic unilateral laminotomy, bilateral decompression with TLIF and percutaneous pedicle screw fixation as described. The average age was 68.5 ± 5.4 years old with 6 females and 4 males. The diagnoses included degenerative spondylolisthesis with concomitant central stenosis (9 cases) and isthmic spondylolisthesis (1 case). The levels involved included L4–5 (8 cases), L5–S1 (2 cases). The average operation time was 151.4 ± 30.6 minutes. The mean postoperative estimated blood loss as measured by drain output was 156.6 ± 74.2 mL (Table 1).

Preoperative VAS of back decreased significantly from 6.9 ± 1.19 to 2.1 ± 1.85 at 6 weeks postoperatively, 1.3 ± 1.57 at 3 months postoperatively, and 1.25 ± 0.63 at 6 months after surgery ($p < 0.05$). Preoperative VAS of leg decreased significantly from 8.3 ± 1.16 to 0.55 ± 1.57 at 6 weeks postoperatively, 1.6 ± 1.65 at 3 months postoperatively, and 1 ± 0.94 at 6 months after surgery ($p < 0.05$).

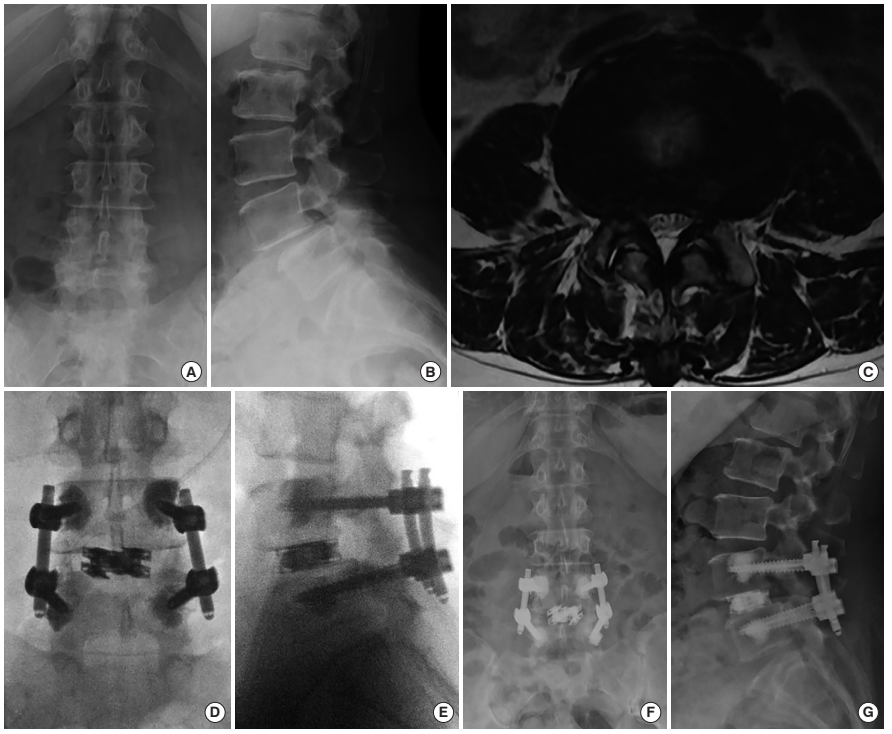

Fig. 6. A 63-year-old female presented with low back pain, left lower extremity. Biportal endoscopic transforaminal lumbar interbody fusion with unilateral laminotomy with bilateral decompression using a dual direction expandable titanium cage was performed with a left sided approach. Preoperative anteriorposterior (AP) (A) and lateral (B) x-ray images showing lower lumbar degenerative changes, facet arthropathy and grade 1 L4–5 spondylolisthesis with disc space narrowing. (C) Preoperative axial magnetic resonance imaging image demonstrating L4–5 severe central stenosis, facet and ligamentum hypertrophy. Intraoperative AP (D) and lateral (E) fluoroscopy images showed that dual expandable cage is inserted at L4–5 disc space. Intervertebral space is expanded after a cage insertion. Pedicle screws were placed with bone cement augmentation. Postoperative AP (F) and lateral (G) x-ray images taken 6 months after surgery revealed that the cage expansion was well maintained without subsidence or recollapse.

Preoperative ODI significantly improved from 55.2 ± 9.1 to 32.3 ± 17.3 at 6 weeks postoperatively, 29.1 ± 15.5 at 3 months postoperatively, and 26.6 ± 7.5 at 6 months after surgery ($p < 0.05$) (Table 2). There was one complication with an epidural hematoma causing a right ankle dorsiflexion weakness (G 3 of 5) postoperatively that required evacuation of the epidural hematoma on postoperative one day. After epidural hematoma removal, ankle weakness recovered well. Otherwise, there were no incidental durotomies, wound infections, implant failures, or medical complications in this clinical series.

Intervertebral disc height of operation segment was significantly widened and well maintained. The mean disc height of operation segment was significantly increased from 5.7 ± 2.7 mm to 13.2 ± 1.1 mm immediately after surgery, and 12.6 ± 1.1 mm at 6 months after surgery ($p < 0.05$). Also, preoperative segmental lordotic angle and lumbar lordotic angle were significantly increased and well maintained at 6 months after surgery ($p < 0.0.5$) (Table 3).

Postoperative radiographs at 6-month follow-up demonstrated no malposition or instrument failure with the cages or pedicle screws. There were no significant subsidence or recollapse of inserted cages.

Table 1. Characteristics of patients

Characteristic	Value
Age (yr)	68.5 ± 8.0
Sex, male:female	4:6
Operation segment	
L4–5	8
L5–S1	2
Diagnosis	
Degenerative spondylolisthesis with central stenosis	9
Isthmus spondylolisthesis	1
Mean operation time (min)	151.4 ± 30.6
Mean estimated blood loss (mL)	156.6 ± 74.2
Complication, epidural hematoma	1

Values are presented as mean ± standard deviation or number.

DISCUSSION

With advancements in cage technology, many types of expandable cages have been developed for lumbar interbody fusion surgery. However, one of the main issues and criticisms of expandable TLIF cages is the point loading of the endplate due to the narrow cage geometry and differing modulus of elasticity of titanium to bone that may contribute to subsidence.[15,16,19] This is especially true with osteopenic and osteoporotic bone, which is commonly seen in the older patient population that typically suffer from lumbar spondylolisthesis and stenosis.

The dual direction expandable titanium TLIF cage is a novel implant design that creates a wider footprint after placement within the disc space. Since the cage is initially in the collapsed and smaller state, it can be introduced endoscopically without difficulty. The wider footprint after initial expansion allows for greater surface area of vertebral endplate contact, which is advantageous for both disc height restoration and fusion purposes. The geometry of the cage contacts the anterior and posterior apophyseal ring, which is the stronger regions of the vertebral endplates, potentially reducing the risk of subsidence. With its open architecture, bone graft material such as flowable DBM allograft fibers can easily be packed into the cage and disc space after insertion of the cage. Alignment correction is achievable

Table 2. Clinical results

Variable	Preoperative	Postoperative		
		6 Weeks	3 Months	6 Months
VAS back*	6.9 ± 1.19	2.1 ± 1.85	1.3 ± 1.57	1.25 ± 0.63
VAS leg*	8.3 ± 1.16	0.55 ± 1.57	1.6 ± 1.65	1.0 ± 0.94
ODI*	55.2 ± 9.1	32.3 ± 17.3	29.1 ± 15.5	26.6 ± 7.5

Values are presented as mean ± standard deviation.
VAS, visual analogue scale; ODI, Oswestry Disability Index.
*$p < 0.05$.

Table 3. Radiographic results

Variable	Preoperative	Postoperative	
		Immediate	6 Months
Disc height of operative segment (mm)*	5.7 ± 2.7	13.2 ± 1.1	12.6 ± 1.1
Lordotic angle of operative segment (°)*	17.6 ± 7.7	21.1 ± 6.2	20.3 ± 6.0
Lumbar lordotic angle (°)*	34.3 ± 6.2	41.1 ± 2.6	42.9 ± 4.7

Values are presented as mean ± standard deviation.
*$p < 0.05$.

with the various lordosis options available for the cage. When performing endoscopic TLIF, it can be difficult for the surgeon to insert a standard cage using a small skin incision. In addition, neural injury may occur when a large-sized cage is inserted through the neural foramen during endoscopic TLIF. However, using an expandable cage may make it easier and safer to insert the cage in endoscopic TLIF. When inserting a large interbody cage in MIS-TLIF or endoscopic TLIF, nerve root injury is a concern given the anatomical constraints. On the other hand, inserting a cage that is too small can result in fusion failure or cage pullout. The dual expandable cage is inserted in a small state and expanded to a large state in 2 dimensions within the disc space, which can prevent pullout and subsidence from occurring. Therefore, if a dual expandable cage is used in biportal endoscopic TLIF, the cage can be safely inserted without damaging the nerve root, and complications associated with cage implant failure can be minimized. Although the expandable cages have various advantages compared to the static cages, long-term research is needed. A comparative study using a large cohort and long-term follow-up is needed to elucidate the advantages of an expandable cages compared to a static cage.

Biportal endoscopic TLIF combines the advantages of endoscopic spine surgery and the enhanced visualization using the endoscope with the advantages of MIS-TLIF. Although the experience is still early with biportal endoscopic TLIF, several studies have demonstrated the clinical effectiveness and safety of the technique, demonstrating the technique is similar in the clinical outcomes as compared to MIS-TLIF at 1-year follow-up.[3,5,7,8] Our early clinical experience of the initial 10 patients with at least 6-month follow-up demonstrated improvement of both back and leg pain as well as disability as compared to the preoperative state with no complications seen on postoperative radiographs. We did experience one case of epidural hematoma that necessitated reoperation with evacuation of the hematoma. Epidural hematoma is a known complication of biportal endoscopic TLIF due to more extensive bone work that leads to bony bleeding into a small, contained space within the spinal canal.[8] Given this, the routine use of postoperative drains is advocated to reduce the risk of epidural hematoma in these cases.[20]

The advantage of the biportal endoscopic TLIF is the minimally invasive nature of the surgery with very small incisions, minimal soft tissue trauma, yet without compromise of clinical effectiveness. The posterolateral interlaminar approach used in biportal endoscopic TLIF is very familiar to spine surgeons, whether they are trained in open or MIS surgery.[4,8] Complete and thorough spinal canal decompression can be performed even with severe stenosis that is often seen concurrently with spondylolisthesis in these patients. In addition, there is less risk of damage to the exiting and traversing nerve roots with the transforaminal approach as long as sufficient space is created with the laminotomy, decompression, and facetectomy.[8,9] Another key advantage is the direct visualization and confirmation of a full endplate preparation using the endoscope and instruments such as angled curettes and pituitaries used within the disc space along with the endoscope. Proper and complete endplate preparation is a crucial step in achieving successful arthrodesis with the TLIF technique, whether it be open, MIS, or endoscopic.[6,7] Prior studies have demonstrated that traditional TLIF techniques remove suboptimal disc material during the discectomy and the endplates may be insufficiently prepared during the procedure.[21,22] This may lead to lower fusion rates and worse clinical outcomes over the long-term since successful arthrodesis has been correlated with clinical success.[23] The verification of complete discectomy and endplate preparation with the endoscope may contribute to higher fusion rates based on the extent and completeness of the preparation. Multiple studies have shown that successful clinical outcomes after lumbar fusion are correlated with successful arthrodesis, disc height restoration, and alignment correction.[24-26]

There were several limitations of this study. Since this study focused as a novel technical note of biportal endoscopic TLIF using the dual direction titanium expandable cage, the number of patients was small and follow-up period was short. This study is not a comparative study, but a preliminary study that described a small case series. Therefore, in order to fully investigate the clinical effects of expandable cages in biportal endoscopic TLIF, larger, long-term multi-center prospective studies and randomized case control studies are necessary.

CONCLUSION

In this study, we introduced the novel technique of inserting a dual direction expandable cage with biportal endoscopic TLIF. This is the first description of its kind in the scientific literature. We successfully performed the insertion of a dual direction expandable cage in biportal endoscopic TLIF. In the preliminary results, the radiographic and clinical outcomes may be favorable. All inserted expanded cages were well maintained without significant collapse or subsidence in our early experience. Biportal endoscopic TLIF using a dual direction expandable cage may be a successful alternative surgical option for treatment of lumbar degenerative disease.

NOTES

Conflict of Interest: The authors have nothing to disclose.

Funding/Support: This study received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Author Contribution: Conceptualization: DHH; Data curation: DYP, DHH; Formal analysis: DYP, DHH; Methodology: DYP, DHH; Visualization: DYP, DHH; Writing - original draft: DYP; Writing - review & editing: DYP, DHH.

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The SPINE JOURNAL

The Spine Journal 23 (2023) 18–26

Clinical Study

Biportal endoscopic versus microscopic discectomy for lumbar herniated disc: a randomized controlled trial

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Received 12 June 2022; revised 11 August 2022; accepted 13 September 2022

Abstract

BACKGROUND CONTEXT: Biportal endoscopic discectomy has been frequently performed in recent years and has shown acceptable clinical outcomes. However, evidence regarding its efficacy and safety remains limited.
PURPOSE: This study aimed to compare the clinical efficacy and safety of biportal endoscopic with that of open microscopic discectomy in patients with single-level herniated lumbar discs.
STUDY DESIGN: Prospective, randomized, multicenter, open-label, assessor-blind, non-inferiority controlled trial.
PATIENT SAMPLE: Sixty-four participants suffering from low back and leg pain with a single-level herniated lumbar disc and required discectomy.
OUTCOME MEASURES: Outcomes were assessed with the use of patient-reported outcome measures (PROMs), visual analog scale (VAS) pain score for surgical site, low back and lower extremity, Oswestry Disability Index (ODI) for lumbar disabilities, European Quality of Life-5 Dimensions value for quality of life, and painDETECT for neuropathic pain. Surgery-related outcomes such as hospital stay, operation time, and opioid usage were collected. Adverse events occurring during the follow-up period were also noted.
METHODS: All participants were randomly assigned in a 1:1 ratio to undergo biportal endoscopic (biportal group) or microscopic discectomy (microscopy group). The primary outcome was the difference in ODI scores at 12-months post surgically based on a modified intention-to-treat strategy, with a non-inferiority margin of 12.8 points. The secondary outcomes included PROMs, surgery-related outcomes, and adverse events.
RESULTS: The ODI score at the 12-month follow-up was 11.97 in the microscopy group and 13.89 in the biportal group (mean difference, 1.92; 95% confidence interval [CI], -3.50 to 7.34), showing the non-inferiority of biportal group. The results for the secondary outcomes were similar to those for the primary outcome. Creatinine phosphokinase ratios were low in the biportal group. Early surgical site pain was slightly lower in the biportal group (mean difference of VAS pain score at 48-hr, -0.98; 95% CI, -1.77 to -0.19). Adverse events including reoperation showed no significant difference between the groups.

FDA device/drug status: Not applicable.

Author disclosures: ***S-MP:*** Nothing to disclose. ***H-JL:*** Nothing to disclose. ***H-JP:*** Nothing to disclose. ***J-YC:*** Nothing to disclose. ***OK:*** Nothing to disclose. ***SL:*** Nothing to disclose. ***H-JK:*** Nothing to disclose. ***JSY:*** Nothing to disclose.

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https://doi.org/10.1016/j.spinee.2022.09.003

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Abbreviations: MRI, Magnetic resonance imaging; VAS, Visual analog scale; eCRF, Electronic case report form; PCA, Patient-controlled analgesia; ODI, Oswestry Disability Index; PRO, Patient-reported outcome; EQ-5D, European Quality of Life-5 Dimensions; QOL, Quality of life; CPK, Creatinine phosphokinase; CT, Computed tomography; mITT, Modified intention-to-treat; PP, Per-protocol; CI, Confidence interval; MCID, Minimal clinically important difference

CONCLUSION: Biportal endoscopic discectomy was non-inferior to microscopic discectomy over a 12 month period. Biportal endoscopic discectomy is suggested to be a relatively safe and effective surgical technique with the slight advantage of reduced muscle damage. However, the clinical implications of surgical site pain should be carefully considered.

Keywords: Biportal endoscopic spinal surgery; Degenerative spine; Discectomy; Lumbar herniated disc; Microscopy; Oswestry disability index

Introduction

Lumbar disc herniation is one of the most common causes of pain in the lower back and extremities. While most treatments for lumbar disc herniation are conservative, surgery may be required for treatment-resistant cases [1]. Generally considered surgical treatments include open, microscopic, and endoscopic discectomies [2].

Conventional open spine surgery such as laminectomy and discectomy can damage normal spinal structures such as the paraspinal muscles, bone, and ligaments [3,4]. Minimally invasive techniques for lumbar disc herniation not only provide favorable outcomes similar to those of invasive surgery, but also reduce soft tissue injury and blood loss while accelerating recovery [4]. Among the minimally invasive surgical options, biportal endoscopy has been increasing in its use recently [5–9]. Biportal endoscopic surgery can be performed on the left or right side of the spine using two small separate portals. As the camera and instrument are nested within the sheath of a uniportal endoscope, mobility of the camera and instrument is restricted. Biportal endoscopic surgery passes solely through the skin portal and does not require a separate sheath. Thus, it has a wider range of motion compared to uniportal endoscopic surgery owing to the freedom of movement in the working portal (Fig. 1). In addition, surgeons may perform highly precise procedures in a magnified and clean surgical field with an endoscope equipped with a high-definition camera and continuous saline irrigation. With these advantages, several types of endoscopic surgeries can be performed, including discectomy, foraminotomy, laminectomy, and interbody fusion, as compared to uniportal endoscopy [7,10–15]. In previous retrospective studies, the clinical outcomes of lumbar discectomy with biportal endoscopy were similar to those of open microscopic surgery [16,17]. However, additional high-quality studies are required. Thus, we herein investigated whether biportal endoscopic discectomy was non-inferior to open microscopic discectomy in patients with single-level herniated lumbar discs.

Materials and methods

Trial design

This trial (registered as NCT03924700 on ClinicalTrials.gov) was an investigator-initiated, prospective, randomized, multicenter, open-label, parallel-group, non-inferiority trial. Written informed consent was obtained from each patient or their legal representative before enrollment. This trial was conducted in accordance with the Declaration of Helsinki, and its clinical data were monitored by an independent researcher. The participants were recruited from April 2019 to November 2020.

Trial population

Sixty-four participants with single-level herniated lumbar discs and radicular radiating pain in the lower extremities

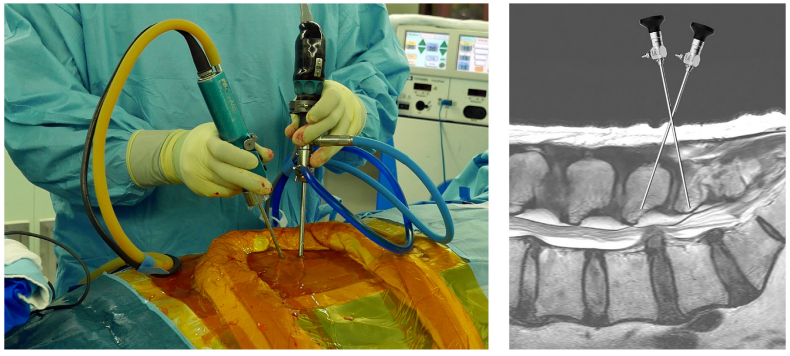

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Fig. 1. (A) Photo of the operative field showing a biportal endoscopic discectomy by a right-handed surgeon on left side. (B) Biportal endoscopy can be performed with fewer restriction and has wider range of motion.

were recruited across two tertiary institutions. Participants aged 20–80 years were required to have radiographic evidence of a single-level herniated lumbar disc on magnetic resonance imaging (MRI), without any improvements after proper conservative treatment (more than 6 weeks medication treatment with at least two administrations of nerve block), and with lumbar radiculopathy (visual analog scale [VAS] pain score >4) for inclusion in the study. Exclusion criteria were as follows: spondylolisthesis with Meyerding grade 2 on lateral simple radiograph; lumbar instability (motion of >3 mm at the surgical level, as measured on flexion-extension radiographs of the lumbar spine); previous lumbar spinal surgery at the same level; degenerative lumbar scoliosis (Cobb angle >20°); history of spine tumor, fracture, or spondylitis in the lumbar spine; history of psychological disorders or currently receiving mental health treatment (eg, dementia, anxiety disorder, or depression); and other difficulties that would have prevented trial participation.

Randomization, blinding, and follow-ups

All participants were randomized into biportal endoscopic (biportal) and microscopic (microscopy) discectomy groups by a clinical researcher who was not involved in this trial prior to enrollment, with a computer-generated randomized list with a block size of four. The list of randomizations was integrated into a web-based eCRF platform accessible by approved researchers and used to conceal assignments. The allocation was concealed and presented to the surgeons immediately preceding surgery. Two orthopedic spine surgeons, each with 6–10 years of spine surgery experience, performed the operations at tertiary institutions. Given the nature of the trial, both surgeons and participants knew which operation they underwent. Therefore, only the assessor and data analysts were blinded.

Upon surgery, all participants completed preoperative questionnaires for their demographic characteristics, medical history, and patient-reported outcome instruments. All participants were followed up at 2 weeks, 3 months, 6 months, and 1 year following surgery. An independent researcher collected the participants' clinical and radiographic outcomes during follow-up. Patients who were unable to attend in-person follow-ups were evaluated by telephone.

Interventions

Microscopic discectomy

Microscopic discectomy was performed as previously described [17,18]. Briefly, the operation level was examined using C-arm and a 3-to-4-cm midline incision was made. Thereafter, the paraspinal muscle was dissected from the bone. A laminotomy was made on the lamina, and the ligamentum flavum around the disc was removed. After the location of the dura and root was confirmed, the root was retracted to identify the location of the herniated disc. After the removal of the herniated disc material, the remaining disc section was examined, and the operation was completed.

Biportal endoscopic discectomy

Biportal endoscopic discectomy has been described in previous studies [7,17,19]. The incision location for two portals began approximately lateral to the spinous process. The working portal was first made on the interlaminar space, and the viewing portal was made 1 cm proximal to the working portal with a 7-mm incision on the left side (for right-handed individuals). Subsequently, a narrow Cobb elevator was placed through the working portal. The paraspinal muscles were then separated from the bone to create a working space. A thirty-degree endoscope was inserted through the viewing portal with saline irrigation at a pressure of 40 mmHg. The operation was performed through the working portal using conventional spinal instruments, with the exception of bipolar radiofrequency electrocautery. Thereafter, the surgery was performed similarly to microscopic discectomy.

Postoperative pain control

Pain at the surgical site was controlled using an intravenous patient-controlled analgesia system (PCA, AceMedical, Seoul, Korea). The PCA mode in this trial was a continuous infusion at 1 mL/hour with 1 mL patient-controlled bolus and a 15-minute lock out (25 μg/kg fentanyl in 100 ml PCA volume). If pain was not controlled, only additional fentanyl injections were used at the patient's request (VAS pain score at the surgical site >8). No other pain relievers were used during the first 48-hours following surgery. After this period, pelubiprofen was administered twice daily for 2 weeks instead of PCA.

Measurements and outcomes

Participant characteristics were collected. Prior to randomization, each participant was assessed preoperatively to obtain demographic information and past medical history using the Charlson Comorbidity Index and the American Society of Anesthesiologists physical status classification.

Primary outcome

The primary outcome was the Oswestry Disability Index (ODI), version 2.0, score [20] at 12 months following surgery between the control and intervention groups. The ODI score is a patient-reported outcome (PRO) questionnaire for lumbar disease commonly used in hospital settings. This 10-section questionnaire evaluates various activities of daily life. Each section is scored on a scale of 0–5, with a score of five representing the greatest disability. ODI is expressed as the percentage of the combined score from all sections out of the total possible score. Therefore, for unanswered questions, the total possible score was reduced by five. If the patient marked more than one statement in a question, the statement with the highest score was recorded as an indication of the actual disability.

Secondary outcomes

The secondary outcomes of this trial were PROs, clinical and radiographic outcomes, and adverse events. The PROs included the VAS pain score for low back pain, lower-extremity radiating pain, surgical site pain, ODI, European Quality of Life-5 Dimensions (EQ-5D) score, and painDETECT score for neuropathic pain. The VAS pain score contained a 10-cm line with ''none'' (0) on one end of the scale and ''absolute maximum pain'' (10) on the other end. The EQ-5D, which measures quality of life (QOL), contains five questionnaires with five responses [21]. The total score is converted into an EQ-5D value ranging from -0.066 to 1.000 with a score of one indicating the best QOL. The painDETECT, which measures neuropathic pain in the lower extremities, contains nine questions with a final score ranging from -1 to 38 points. A total score under 12 points indicates that neuropathic pain is unlikely to be present, while a score over 19 indicates that the likelihood of neuropathic pain is high (>90%) [22]. To evaluate clinical outcomes during follow-up, we analyzed serial changes in the VAS pain score for the lower back and lower extremities, ODI scores, EQ-5D value, and painDETECT preoperatively and postoperatively until the final follow-up. To analyze postoperative surgical site pain, we measured the VAS pain scores at 4, 8, 16, 24, and 48 hours and 2 weeks after surgery.

Surgery-related outcomes such as total postoperative drainage (mL), operation duration (minutes), postoperative hospital stay (days), serum creatine phosphokinase (CPK) ratio, [23] and total fentanyl usage, were analyzed. Total postoperative drainage was defined as the drainage amount that flowed into the Hemovac drain system until the second postoperative day. Operation duration was defined as the time from skin-to-skin closure, as noted in the anesthesia record. The CPK ratio was the ratio of serum CPK level at postoperative day 1 to its preoperative level. Total fentanyl usage was the fentanyl amount in intravenous PCA and additional intravenous fentanyl injection during the hospital stay.

We performed MRI or computed tomography (CT) scans on all participants immediately following surgery. If disc recurrence was suspected due to worsening pain throughout the follow-up period, MRI was repeated. Plain radiographs were taken periodically during outpatient visits. For radiographic outcomes, the degree of disc removal and facet joint injury was measured by postoperative MRI or CT. Residual disc was confirmed if extruded or migrated discs were detected on immediate postoperative MRI or CT. Facet joint injury was defined as an injury covering more than one-third of the facet joint. Other radiographic complications were measured with simple radiographs during the follow-up period.

Trial safety was analyzed by evaluating all adverse events and surgery-related outcomes. Additionally, adverse events were divided into complications during and after surgery.

Statistical analysis

The hypothesis was that the ODI of the biportal group at 12 months after surgery would not be inferior to that of the microscopy group. The non-inferiority margin was 12.8 ODI points, based on the minimal clinically important difference (MCID) in the ODI of the spine surgery [24]. Assuming a 20% 12 month dropout rate, a sample size of 64 participants (32 in each group) was calculated to provide at least 80% power for non-inferiority demonstration, with a one-sided alpha level of 0.05 using PASS 15.0 (NCSS statistical software, Kaysville, UT).

Outcomes were analyzed using the modified intention-to-treat (mITT) strategy. The mITT population consisted of all participants with randomly assigned surgery and had available data after randomization. In cases of missing data, the imputation, "last observation carried forward" or "last observation carried backwards" was used. An additional per-protocol (PP) sensitivity analysis of non-inferiority was carried out with available primary outcome data of patients, who did not undergo reoperation and were not subjected to a major protocol violation. Non-inferiority for biportal endoscopic discectomy was declared if detected in both mITT and PP analyses.

For the primary outcome, between-group differences and 95% confidence intervals (CIs) were calculated. A linear mixed model was used for all repeated-measures continuous outcomes (VAS pain scores, ODI, EQ-5D, and painDETECT scores). Time was analyzed as a categorical variable, and intervention-time interactions were included to analyze the intervention effects at each follow-up timepoint. A linear repeated-measures mixed model was also used to analyze between-group differences during the follow-up period, with the baseline and follow-up time points as categorical variables. Other secondary outcomes were analyzed using the Fisher's exact test for categorical variables and the Student's t-test for continuous variables. All tests were performed using Stata/MP 17.0 (StataCorp LLC, College Station, TX, USA). Two-sided p-values <.05 were considered statistically significant.

Results

Participants' characteristics

From April 28, 2019, to November 29, 2020, 69 participants (microscopy, n=35; biportal, n=34) from two tertiary institutions were enrolled, and 56 participants had available data at the 12 month follow-up. No crossover was observed in any randomized surgical strategies. Five patients were excluded from the mITT analysis (four due to violation of surgery randomization protocol, and one due to consent withdrawal, Fig. 2). Four patients were excluded from the PP analysis (two due to a reoperation in the microscopy group, one due to reoperation in the biportal group, and one due to a treatment history of recurrent herniated disc with interventional nerve root block). Baseline clinical

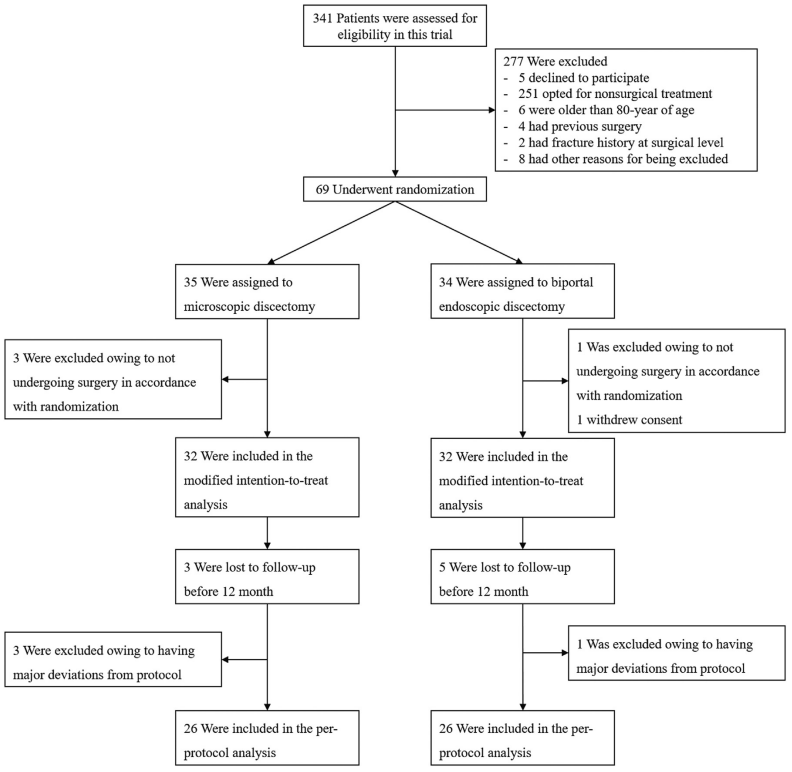

Fig. 2. Flowchart of the trial design.

characteristics of the study participants are presented in Table 1. Demographic data were similar between both groups (p>.05).

Primary outcome at 1 year

In the mITT population at 12 month follow-up, the mean ODI was comparable between the microscopy (11.97, 95% CI: 7.77–16.17) and biportal (13.89, 95% CI: 10.30–17.48) groups (p=.240). The between-group mean difference was 1.92 (95% CI: -3.50–7.34). In the PP population at 12 month follow-up, the mean ODI was not statistically different between the microscopy (9.76,95% CI: 6.16–13.38) and biportal (12.35, 95% CI: 9.50–15.19) groups (p=.127). The between-group mean difference was 2.58 (95% CI: -1.91–7.06). For both analyses, the upper boundaries of the 95% CI for the between-group mean differences were within the margin of 12.8 ODI points, confirming the non-inferiority of biportal endoscopic discectomy (Table 2).

Secondary outcomes

There were no significant interventional effects on any clinical outcomes during the 12 month follow-up period (Fig. 3). However, there were significant interventional effects on the VAS pain score for the surgical site during the 2 week follow-up period. The postoperative surgical site pain significantly improved during the 2-week period. However, in the biportal group, VAS pain scores for the surgical site were significantly lowered from 12 to 48 hours (Table 3).

Surgery-related outcomes (including total fentanyl use, operation duration, length of hospital stay, and drainage), adverse events, and recurrent herniated discs did not show

Table 1
Baseline characteristics of the included patients

Characteristic	Group IMicroscopy (n=32)	Group IIBiportal endoscopy (n=32)
Age (years) *	50.3 (13.5)	45.7 (12.7)
Male / Female†	18 / 14	14 / 18
BMI (kg/m^2) *	24.6 ± 2.9	25.6 ± 3.6
CCI score‡	0 (0–1)	0 (0–0)
ASA score‡	1 (1–2)	2 (1–2)
Smoking status, n (%)†		
Non / Ex-smoker	18 (56%)	19 (59%)
Current smoker	14 (44%)	13 (41%)
Alcohol consumption, n (%)†		
None	17 (53%)	18 (56%)
≥1 drink/month	15 (47%)	14 (44%)
VAS for back pain‡	4 (1.5–6)	4 (2.5–6)
VAS for buttock pain‡	7 (5.5–8)	7 (6–8)
VAS for leg pain‡	8 (6.5–9)	8 (7–9)
ODI*	58.3 ± 16.9	57.1 ± 17.8
EQ-5D*	0.419 ± 0.180	0.391 ± 0.167
painDETECT*	13.8 ± 7.3	11.4 ± 6.3
HIVD type, n (%)†		
Extrusion	29 (97%)	30 (97%)
Sequestration	1 (3%)	1 (3%)
Migration	8 (27%)	10 (32%)
HIVD canal compromise, n (%)†		
Mild (less than 1/3)	2 (7%)	1 (3%)
Moderate	17 (59%)	16 (52%)
Severe (over 2/3)	10 (34%)	14 (45%)
HIVD zone, n (%)†		
Central	8 (27%)	9 (29%)
Paracentral	28 (93%)	30 (97%)
HIVD calcification, n (%)†	1 (3%)	1 (3%)
Approach side, n (%)†		
Right	10 (31%)	15 (47%)
Left	22 (69%)	17 (53%)
Operation level, n (%)		
L2-3	1 (3%)	0 (0%)
L3-4	6 (19%)	2 (6%)
L4-5	19 (59%)	24 (75%)
L5-S1	6 (19%)	6 (19%)

BMI, body mass index; CCI, Charlson Comorbidity Index; ASA, American Society of Anesthesiologist; VAS, visual analog scale; ODI, Oswestry disability index; EQ-5D, European Quality of Life-5 Dimensions; HIVD, herniated intervertebral disc.
* Data are presented as given as mean ± standard deviation.
† Data are presented as No. of patients.
‡ Data are presented as given as median and interquartile range in parenthesis.

statistically significant differences between the two groups. The CPK ratio was lower in the biportal group. Asymptomatic hematoma and wound dehiscence were observed more frequently in the microscopy group, but without any statistically significant difference. Severe adverse events, such as thromboembolism, stroke, or surgery-related death, were not observed. Two cases of neurologic deterioration in each group were observed along with wrong site surgery in the biportal group (Table 4).

Discussion

In this trial, biportal endoscopic discectomy was non-inferior to microscopic discectomy with regard to the postoperative 12 month ODI within a margin of 12.8 points. The minimally invasive procedure of biportal endoscopy demonstrated slightly improved outcomes in postoperative surgical site pain and CPK ratio. Other secondary outcomes were generally comparable between the two study groups.

Endoscopic surgery is widely used in minimally invasive spinal surgeries. While uniportal endoscopy was first developed and remains widely used, it has a steep learning curve and a high rate of complications [25,26]. Biportal endoscopy is a surgical technique with an arthroscope similar to that used in knee or shoulder arthroscopy. This technique has a better camera system with a wider viewing field via the use of a 30° endoscope and more convenient operation that allows free movement of both hands [27,28]. However, there is a disadvantage that postoperative headaches may occur in patients due to high water pressure during surgery [11,29,30].

The results of this study are not significantly different from those of previous studies [6,7,16,17]. In previous studies, there were no significant differences in serial changes in clinical outcomes, but it has been reported that low postoperative pain, short hospital stay, low opioid use, long operation time, and high postoperative drainage were observed compared to microscopic discectomy. In our study, postoperative pain and CPK ratio were low in the biportal endoscopy group; therefore, it was thought to be slightly beneficial for pain control immediately after surgery. However, the VAS pain score difference at surgery site was approximately one. In a previous study, the MCID

Table 2
Mean Oswestry Disability Index (ODI) scores at 12 months after surgery. Data are presented using both modified intention-to-treat (mITT) and per-protocol (PP) analyses

Analysis	Number of participants	Mean ± standard deviation	95% CI	Mean difference	95% CI of difference	p-value
mITT	Microscopy (n=29)	11.97 ± 11.04	7.77–16.17	1.92	−3.50 to 7.34	0.240
	Biportal endoscopy (n=27)	13.89 ± 9.25	10.30–17.48			
PP	Microscopy (n=26)	9.76 ± 8.94	6.16–13.38	2.58	−1.91 to 7.06	0.127
	Biportal endoscopy (n=26)	12.35 ± 7.05	9.50–15.19			

mITT, modified intention-to-treat; PP, per protocol; CI, confidence interval.
Data are presented as given as mean ± standard deviation.

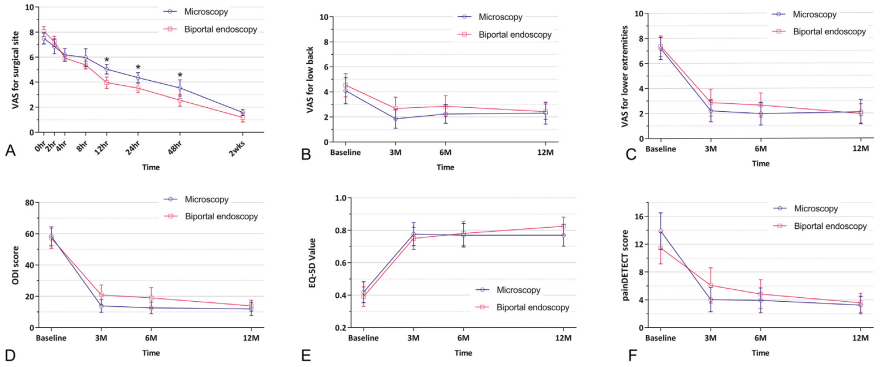

Fig. 3. Changes in secondary outcomes between the two interventions. Changes in mean VAS scores for surgical site (A), low back pain (B), lower extremities (C), mean ODI score (D), mean EQ-5D value (E), mean painDETECT score (F). *Statistical significance between the two groups on linear mixed-effect model. Error bars indicate 95% CI. EQ-5D, European Quality of Life-5 Dimensions; ODI, Oswestry disability index; VAS, visual analog scale.

Table 3
Secondary clinical outcomes during follow-up period (Modified intention-to-treat population)

Variables	Microscopy	Biportal endoscopy	Mean difference (95% CI)	p-value
VAS pain score for surgical site				
Immediate	7.50 ± 1.17	8.04 ± 0.98	0.54 (−0.06 to 1.14)	0.088
2 hours	6.86 ± 1.53	7.24 ± 1.01	0.38 (−0.34 to 1.11)	0.227
4 hours	6.18 ± 1.31	5.92 ± 0.64	−0.26 (−0.84 to 0.32)	0.415
8 hours	5.96 ± 1.82	5.36 ± 0.76	−0.60 (−1.39 to 0.18)	0.057
12 hours	5.04 ± 1.00	3.96 ± 1.10	−1.08 (−1.65 to -0.50)	0.001
24 hours	4.36 ± 1.03	3.52 ± 0.87	−0.84 (−1.37 to -0.31)	0.008
48 hours	3.54 ± 1.61	2.56 ± 1.16	−0.98 (−1.77 to -0.19)	0.004
2 weeks	1.58 ± 0.51	1.18 ± 0.80	−0.40 (−0.83 to 0.03)	0.451
Overall intervention effect*	NA	NA	NA	< 0.001
VAS pain score for lower back				
3 months	1.86 ± 2.00	2.68 ± 2.33	0.82 (−0.33 to 1.97)	0.115
6 months	2.24 ± 1.96	2.86 ± 2.17	0.62 (−0.48 to 1.71)	0.214
12 months	2.31 ± 2.32	2.43 ± 1.57	0.12 (−0.94 to 1.17)	0.679
Overall intervention effect*	NA	NA	NA	0.720
VAS pain score for lower extremities				
3 months	2.21 ± 2.29	2.86 ± 2.74	0.65 (−0.69 to 1.99)	0.237
6 months	1.97 ± 2.38	2.50 ± 2.41	−0.53 (−0.74 to 1.81)	0.317
12 months	2.10 ± 2.57	1.96 ± 1.99	−0.14 (−1.36 to 1.08)	0.946
Overall intervention effect*	NA	NA	NA	0.687
ODI score				
3 months	13.83 ± 10.72	20.89 ± 16.49	7.07 (−0.29 to 14.42)	0.051
6 months	12.66 ± 9.83	19.00 ± 17.09	6.34 (−1.02 to 13.71)	0.079
12 months	11.97 ± 11.04	13.89 ± 9.25	1.92 (−3.50 to 7.34)	0.567
Overall intervention effect*	NA	NA	NA	0.143
EQ-5D value				
3 months	0.776 ±0.187	0.749 ± 0.177	−0.026 (−0.123 to 0.704)	0.524
6 months	0.769 ± 0.191	0.780 ± 0.192	0.011 (−0.090 to 0.113)	0.866
12 months	0.769 ± 0.178	0.825 ± 0.143	0.056 (−0.030 to 0.142)	0.260
Overall intervention effect*	NA	NA	NA	0.393
painDETECT score				
3 months	4.03 ± 4.57	6.07 ± 6.53	2.04 (−0.95 to 5.02)	0.058
6 months	3.93 ± 4.69	4.82 ± 5.36	0.89 (−1.78 to 3.56)	0.271
12 months	3.24 ± 3.31	3.57 ± 3.54	0.33 (−1.49 to 2.15)	0.476
Overall intervention effect*	NA	NA	NA	0.078

VAS, visual analog scale; NA, not available; ODI, Oswestry disability index; EQ-5D, European Quality of Life-5 Dimensions
Data are presented as given as mean ± standard deviation, unless otherwise indicated.
* P-value is from linear mixed models for repeated measures comparing between interventions during 12-month follow-up period.

Table 4
Additional secondary outcomes (Modified intention-to-treat population)

Characteristic	Group IMicroscopy (n=32)	Group IIBiportal endoscopy (n=32)	p-value
Total fentanyl usage (μg)	532.6 ± 495.4	565.7 ± 585.2	0.767
Operative time (min)	62.0 ± 20.8	63.9 ± 16.1	0.349
Length of hospital stay (days)	4.6 ± 1.4	4.7 ± 2.4	0.839
Drainage	33.2 ± 39.8	44.7 ± 36.0	0.092
CPK ratio*	2.03 ± 0.53	1.51 ± 1.05	0.016
Complications during surgery†			
Incidental durotomy	2 (6.3%)	0 (0%)	0.492
Facet injury	1 (3.1%)	5 (15.6%)	0.195
Wrong site surgery	0 (0%)	1 (3.1%)	1.000
Remnant disc (Incomplete discectomy) ‡	7 (21.9%)	4 (12.5%)	0.320
Neurologic deterioration	0 (0%)	0 (0%)	1.000
Complications during follow-up§			
Hematoma resulting in reoperation	0 (0%)	0 (0%)	1.000
Asymptomatic hematoma	14 (43.8%)	7 (21.9%)	0.055
Wound dehiscence	5 (15.6%)	0 (0%)	0.053
Surgical site infection	1 (3.1%)	0 (0%)	1.000
Recurrent disc herniation resulting in reoperation	1 (3.1%)	1 (3.1%)	1.000
Recurrent disc herniation not required reoperation	3 (9.4%)	6 (18.8%)	0.474
Neurologic deterioration	1 (3.1%)	1 (3.1%)	1.000

Continuous data are presented as given as mean ± standard deviation. Categorical data are presented as No. of patients.
CPK, creatine phosphokinase
* CPK ratio = postoperative day 1 CPK/preoperative CPK
† Complications that occurred during surgery that were confirmed during or immediately after surgery
‡ Remnant disc refers to a state in which all of the existing discs have not been removed on postoperative MRI.
§ Complications identified until the final follow-up after surgery.

value for lower back pain was approximately 1.2 [24]. A VAS pain score of less than one was not clinically meaningful; therefore, although there was a difference in pain at the surgical site in this study, the clinical significance should be carefully considered.

However, unlike the results of previous studies, in our trial the postoperative hospital stay was not shorter, opioid use was not lower, and the operation times were similar. Adverse events did not differ between the two groups. There were seven and five patients with asymptomatic hematoma and wound dehiscence in the open microscopic discectomy group, respectively; however, the difference was marginally better in biportal endoscopy, but not statistically significant. Facet joint injuries and wrong site surgery occurred more frequently in the biportal group, which is likely to be the result of an orientation error caused by the use of a 30-degree endoscope, but there was no statistical difference shown.

To our knowledge, this study was the first randomized controlled trial to examine the outcomes of biportal endoscopic vs those of microscopic discectomy at 12 months after surgery. Biportal endoscopic discectomy is suggested to ab a relatively safe and effective surgical technique with slight advantages of reduced surgical site pain and muscle damage. However, this study has several limitations. First, this was an open-label clinical trial, in which blinding was only conducted for the outcome assessors and data analysts. Second, due to the absence of an evidence-based non-inferiority margin, a MCID value of 12.8 ODI points was empirically chosen. Given the exclusion criteria, we conducted both mITT and PP analyses to reduce selection bias. Third, generalized conclusions could not be drawn due to the small sample size. However, given a compliance of over 88% and an assumed dropout rate of 20%, our results may have had a better statistical power than expected. Fourth, a 12-month follow-up period may be insufficient to determine the surgical outcomes. However, since 12-month outcomes were shown to accurately reflect those at 24 months, our results may offer clinical significance [31]. Finally, since multiple comparisons in the secondary outcome analysis increased the risk of type I error, the interpretation of these results must include these potential limitations.

In conclusion, biportal endoscopic discectomy was noninferior to microscopic discectomy at 12-month follow-up in this study. No differences in the clinical and radiographic outcomes and adverse events between the two interventions were observed, with slightly less surgical site pain and muscle damage in the biportal group. Therefore, for patients with herniated lumbar discs, biportal endoscopic discectomy is suggested to be a relatively safe and effective surgical option.

Declarations of competing interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

This study was supported by a Korea Health Technology R&D Project grant (HC20C0163) through the Korea Health Industry Development Institute (KHIDI), funded by the Ministry of Health & Welfare, Republic of Korea, and grants from Daewon Pharmaceutical Corporation in Seoul, Republic of Korea.

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The Spine Journal 20 (2020) 156–165

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Clinical Study

Biportal endoscopic versus microscopic lumbar decompressive laminectomy in patients with spinal stenosis: a randomized controlled trial

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Received 10 July 2019; revised 13 September 2019; accepted 16 September 2019

Abstract

BACKGROUND CONTEXT: Biportal endoscopic decompressive laminectomy is a widely performed procedure and shows acceptable clinical outcomes. However, the evidence regarding the advantages of biportal endoscopic surgery is weak, a randomized controlled trial is therefore warranted.
PURPOSE: To compare the clinical efficacies of biportal endoscopic and microscopic decompressive laminectomy in patients with lumbar spinal stenosis.
STUDY DESIGN: Randomized controlled trial.
PATIENT SAMPLE: Sixty-four participants suffering from low back and leg pain with single-level lumbar spinal stenosis who required decompressive laminectomy.
OUTCOME MEASURES: Outcomes were assessed with the use of patient-reported outcome measures, visual analog scale (VAS) score for low back and lower extremity radiating pain, Oswestry disability index (ODI), European Quality of Life-5 Dimensions (EQ-5D) score, and painDETECT for neuropathic pain. Surgery-related outcomes including operation time, length of hospital stay, postoperative drainage, and serum creatine phosphokinase were evaluated. Perioperative (<30 days) and late (1−12 months) complications were also noted.
METHODS: All participants were randomly assigned in a 1:1 ratio to undergo biportal endoscopic or microscopic decompressive laminectomy. The primary outcome was the ODI score at 12 months after surgery based on a modified intention-to-treat strategy. The secondary outcomes included VAS score for low back and lower extremity radiating pain, ODI scores, EQ-5D score, and painDETECT score. There were no sources of funding and no conflicts of interest associated with this study.
RESULTS: There was no significant difference between groups in the mean ODI score at 12 months after surgery (30 in the microscopy vs. 29 in the biportal endoscopy group, p=.635). There were also no significant differences in low back and lower extremity pain VAS scores, ODI, EQ-5D scores, and painDETECT scores at the 3-, 6-, or 12-month follow-up. Operation time, length of hospital stay, serum creatine phosphokinase, and perioperative complications, such as durotomies and symptomatic hematoma, showed no significant differences between the groups; however, one participant underwent additional revision surgery 9 months after the index surgery in the microscopy group.

FDA device/drug status: Not applicable.

Author disclosures: ***S-MP***: Nothing to disclose. ***JP***: Nothing to disclose. ***HSJ***: Nothing to disclose. ***YWH***: Nothing to disclose. ***HH***: Nothing to disclose. ***H-JK***: Nothing to disclose. ***B-SC***: Nothing to disclose. ***C-KL***: Nothing to disclose. ***JSY***: Nothing to disclose.

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https://doi.org/10.1016/j.spinee.2019.09.015

CONCLUSIONS: Despite the study design limitation of relatively short duration of follow-up, this trial suggests that biportal endoscopic decompressive laminectomy is an alternative to and offers similar clinical outcomes as microscopic open surgery in patients with symptomatic lumbar spinal stenosis.

Keywords: Biportal endoscopic spinal surgery; Degenerative spine; Laminectomy; Lumbar spinal stenosis; Microscopy; Oswestry disability index

Introduction

Lumbar spinal stenosis is characterized by a narrowed spinal canal, which leads to nerve compression. Patients with spinal stenosis complain of low back and lower extremity pain and present with decreased function, walking ability, and quality of life. Thus, patients who present with low back and leg pain due to lumbar spinal stenosis are commonly treated surgically rather than nonoperatively [1–4]. However, conventional open decompressive laminectomy can damage spinal structures such as paraspinal muscles, bone, and ligaments [2–5]. Decompression through laminectomy also has a potential risk of future instability and deformity [6]. Minimally invasive laminectomy was introduced as a tissue-sparing alternative and applied to lumbar central stenosis. Minimally invasive laminectomy revealed good clinical outcomes comparable to those of conventional surgery [3–5,7–12]. It also showed a reasonable operative time, shorter hospital stay, and reduced blood loss, time to mobilization, postoperative pain, and narcotic use when compared to that seen with conventional surgery [3–5,7–12]. However, it presents some disadvantages, including poor visualization, difficulty of instrument manipulation, potential to induce inadequate decompression, and longer operative time than other minimally invasive surgeries [3,5,7–12].

Recently, endoscopic decompressive laminectomy for lumbar stenosis has been used to treat lumbar stenosis [13,14]. However, endoscopic surgery needs specialized instruments and extensive training to reach surgical competency [15,16]. Due to the easier use of instruments and cost reduction, biportal endoscopy has been introduced and used in lumbar surgeries, such as discectomy, laminectomy, and foraminotomy [17–35]. Biportal endoscopic decompressive laminectomy has demonstrated satisfactory clinical outcomes, but evidence suggesting the advantages of biportal endoscopic surgery compared to other minimally invasive laminectomy techniques is weak; therefore, a randomized controlled trial is warranted. Thus, the purpose of this study was to assess the clinical efficacy of biportal endoscopic decompressive laminectomy compared to that of microscopic lumbar decompressive laminectomy in patients with lumbar spinal stenosis.

Materials and methods

Study design and participant population

The design and protocol of this prospective, randomized, noninferiority clinical trial was approved by the institutional review board of our hospital (B-1708/417-003) and registered on ClinicalTrials.gov (NCT03302507). All participants gave written informed consent before enrollment. In this trial, all participants were randomly assigned in a 1:1 ratio to undergo biportal endoscopic or microscopic lumbar decompressive laminectomy. We recruited participants from November 2017 to July 2018.

We included participants 30 to 80 years old with degenerative lumbar stenosis, radiating pain to lower extremities (visual analog scale [VAS] score>4), and definite lumbar central stenosis (Schizas grade [36] ≥B) on magnetic resonance imaging. The exclusion criteria were spondylolisthesis (Meyer grade ≥II), history of lumbar spinal surgery for spinal stenosis or instability at the same level, stenosis caused by a herniated intervertebral disc, degenerative lumbar scoliosis (Cobb angle >20°), other spinal diseases (eg, ankylosing spondylitis, spine tumor, fracture, or neurologic disorders), psychological disorders (eg, dementia, intellectual disability, or drug abuse), and other disorders which the surgeon considered as inappropriate for participation.

Randomization and follow-ups

After evaluating baseline characteristics, participants were randomized to microscopic or biportal endoscopic surgery at a 1:1 ratio, following a computer-generated randomization list with block sizes of 4 prepared by a researcher not involved in any other aspect of this trial prior to enrollment. The randomization lists were incorporated in a web-based electronic case report form (eCRF) site (Research Electronic Data Capture [REDCap]) that was accessible to authorized researchers and used to conceal allocation. Participants did not know which surgical technique they were assigned to (single-blind). All randomized participants were operated on by a single orthopedic spine surgeon (SMP) at our tertiary institution.

Participants were actively followed up for a minimum of 12 months. The primary and secondary outcomes were collected by an independent researcher during in-hospital visits or telephone calls. The outcomes were assessed at baseline, during surgery, after surgery, at discharge, and at 3, 6, and 12 months.

Interventions

Microscopic unilateral laminectomy and bilateral decompression

The microscopic decompressive laminectomy procedure has been previously described [4]. In brief, we made a 4-cm

midline incision after fluoroscopic confirmation of surgical level. After skin incision, the multifidus muscle was dissected unilaterally from the spinous process and lamina using a Cobb elevator and retracted by a Taylor retractor. After detachment of paraspinal muscles, ipsilateral laminectomy was performed using a burr and Kerrison punches, followed by flavectomy using microscope. To view the contralateral side, the operation table and microscope were tilted approximately 10 to 20°. For decompression, undercutting of the spinous process and contralateral lamina was performed using a burr and Kerrison punches, followed by flavectomy. After contralateral laminectomy and flavectomy, complete neural decompression was confirmed by restoration of dural pulsation (Fig. 1A).

Biportal endoscopy

The biportal endoscopic decompressive laminectomy has also been previously described in several studies [17,21,33,37]. This technique is similar to microscopic decompressive laminectomy except for two portals being used. The point of this technique is to create both a viewing portal for the scope and a working portal for the spinal instruments, which also provides working space. The portal location was 0.5 to 1 cm lateral to the spinous process. The working portal was located at the lower margin of the lamina with a 1-cm incision, when the surgery was performed on the left side. The viewing portal was made vertically 1 cm proximal to the working portal with a 7-mm incision. A left side decompressive laminectomy is recommended for a right-hand dominant surgeon. After creating the two portals, detachment of the paraspinal muscles from the lamina was performed using a narrow Cobb elevator to achieve an adequate working space. A 4-mm and 30° arthroscope was inserted through the viewing portal under saline irrigation with a pressure of 30-40 mm Hg. Instruments for laminectomy, such as a bipolar radiofrequency cautery, burr, punch, and pituitary, were inserted through the working portal. Fraying muscle and soft tissue were debrided using a shaver and bipolar radiofrequency cautery. Following the creation of the working space, the laminectomy technique is the same as that of microscopic laminectomy (Fig. 1B).

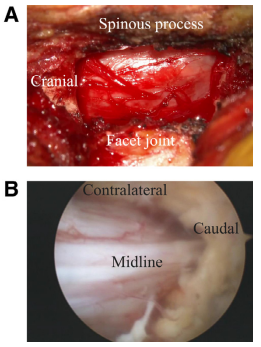

Fig. 1. Intraoperative images of the two interventions. (A) Operative field of microscopic decompressive laminectomy with a left-side approach. (B) Endoscopic image with fully decompressed dura after biportal endoscopic decompressive laminectomy.

Outcomes and measurements

Baseline participant characteristics were collected by researchers who were blinded to the randomization details. Before randomization, each participant was preoperatively evaluated to obtain demographics, past medical history using the Charlson comorbidity index (CCI), and the American Society of Anesthesiologists (ASA) physical status classification. Patient-reported outcomes (PROs) were also collected from participants at baseline and at 3, 6, and 12 months after surgery. The primary outcome measure was the ODI scores at the 12-month follow-up after surgery. The secondary outcome measure was the change in the PROs, includes VAS score for low back and lower extremity radiating pain, Oswestry disability index (ODI), European Quality of Life-5 Dimensions (EQ-5D) score, and painDETECT score for neuropathic pain, during follow-up periods and surgery-related outcomes. The VAS score for low back and leg pain questionnaires contains a 10-cm line with ''none'' (0) on one end of the scale and ''severe pain'' (10) on the other end. The ODI is a specialized questionnaire for low back-associated disability and quality of life (QOL). This questionnaire contains 10 questions with 6 responses for each question (scored from 0 to 5); the total ODI score is a sum of these scores which is converted into a 0 to 100 score, with higher scores indicating more severe disability and poorer QOL [38]. The EQ-5D is a general instrument for evaluating QOL. This questionnaire contains five questions with five responses for each question, and the total score is converted into the final EQ-5D value, ranging from 0 to 100, with higher scores indicating better QOL [39]. The painDETECT questionnaire is a specialized instrument to evaluate neuropathic pain. This questionnaire contains nine questions, with the final score ranging from −1 to 38 points. A score under 12 points denotes neuropathic pain is unlikely to be present, whereas a score over 19 indicates that neuropathic pain is highly likely (>90%) [40].

Surgery-related outcomes including operation time, length of hospital stay, postoperative drainage, and serum creatine phosphokinase (CPK) level were collected. Operation time was the duration of operation from skin incision to skin closure. Length of hospital stay was the duration of hospital stay after operation. Drainage was the total amount of postoperative drainage, which flowed into the Hemovac drain system (Zimmer Biomet, Warsaw, Indiana, USA). Serum CPK level, which is an indicator of muscle injury, was measured at 48 hours after operation [41]. Perioperative

(<30 days) and late (1–12 months) complications were also recorded. Perioperative complications were defined as intraoperative or postoperative complications within 30 days after surgery. Late complications were defined as complications after 30 days to the final follow-up. Recurrent pain was defined as recurrent low back or leg pain with a VAS score ≥4 during the follow-up period.

Statistical analysis

For the primary outcome analysis, we calculated that a sample size of 64 patients (32 patients in each group) would provide at least 80% power to show the noninferiority of biportal endoscopy relatively to microscopy with a one-sided alpha level of 0.05 and a noninferiority margin of 12.8 points for the ODI scores, assuming a 20% dropout rate at 12 months [42].

We analyzed primary and secondary outcomes based on the modified intention-to-treat (mITT) strategy, which indicates that participants were analyzed on whether they had undergone a randomly assigned surgery, except for participants with no ODI scores at the 12-month follow-up. Imputation, "last observation carried forward" or "last observation carried backwards," was used for missing values. We performed an additional sensitivity analysis of noninferiority using per-protocol (PP) data which included patients who were not subjected to a major protocol violation.

The Shapiro-Wilk test was used to evaluate the distribution of the collected data. Normally distributed continuous variables are presented as mean and standard deviation (SD), whereas non-normally distributed variables are presented as median and interquartile range (IQR). Categorical variables are presented as numbers and percentages (%). For the primary outcome, 12-month ODI score, a one-sided 95% confidence interval (CI) for the group difference was calculated using a Student's *t* test. Noninferiority of biportal endoscopy was confirmed if the upper-limit of 95% CI of ODI score at 12 months was lower than the predefined noninferiority margin of 12.8 points. For serial measurements of secondary clinical outcomes (VAS pain score of back and lower extremities, ODI score, EQ-5D score, painDETECT score), we used a linear repeated-measures mixed model. We analyzed time as a categorical variable (3, 6, or 12 months) and included intervention—time interactions to analyze intervention effects at each follow-up point. We also analyzed intergroup differences during the 12-month period, controlling for baseline and follow-up time points as categorical variables, using a linear repeated-measures mixed model. Other secondary outcomes between the two groups were analyzed using analyzed using Student's *t* test (normally distributed continuous variables), the Mann-Whitney *U* test (non-normally distributed continuous variables), or the Fisher's exact test (categorical variables). All tests were conducted using Stata/MP 15.0 (StataCorp LLC, College Station, TX). A two-sided p value <.05 was considered to indicate statistical significance, except for the p value from noninferiority test, which is one-sided.

Results

Participants

A total of 70 participants were screened for eligibility; 1 participant declined to participate in this trial and 5 participants did not meet our inclusion criteria. The remaining 64 participants consented to undergo randomization into one of the treatment groups. All participants were randomly assigned to the microscopic (32 participants) or biportal endoscopic (32 participants) lumbar decompressive laminectomy groups. There was no crossover from each randomized treatment strategy. A total of five participants who were lost to follow-up immediately after surgery and did not answer our clinical outcome assessment were censored and excluded from the mITT analysis. A further six participants were also censored and excluded from the PP primary outcome analysis (one revision surgery, two traffic accidents, one burst fracture at other vertebral level, one cerebral infarction after 6 months, and one case of lower limb herpes zoster), but these participants were included in the mITT analysis. Fig. 2 shows the study and follow-up flow diagram.

The baseline characteristics of participants assigned to each treatment group are shown in Table 1. There were no significant differences in the baseline clinical and radiographic characteristics between the two groups (all p>.05), except for the approach side (p=.025).

Primary outcome at 1 year

In the mITT analysis, there was no significant difference between two intervention groups in the primary outcome at 1 year after decompressive laminectomy. The mean ODI score at 1 year was 18.03 (95% CI, 11.01–25.05) in the microscopy group and 19.79 (95% CI, 12.15–27.41) in the biportal endoscopy group (p=.635). The ODI score decreased from baseline by 28.97 points in microscopy group and by 26.41 points in the biportal endoscopy group.

In the PP analysis, there was also no significant difference between the two intervention groups in the primary outcome 1 year after decompressive laminectomy. The mean ODI score at 1 year was 17.04 (95% CI, 9.69–24.39) in the microscopy group and 17.12 (95% CI, 8.53–25.71) in the biportal endoscopy group (p=.551). The ODI score decreased from baseline by 29.96 points in microscopy group and by 29.08 points in the biportal endoscopy group. Noninferiority of biportal endoscopic decompressive laminectomy was confirmed by the mITT and PP analyses (Table 2 and Fig. 3).

Secondary outcomes and complications

The linear mixed model showed no significant intervention effect in back and leg pain, disability, QOL, and

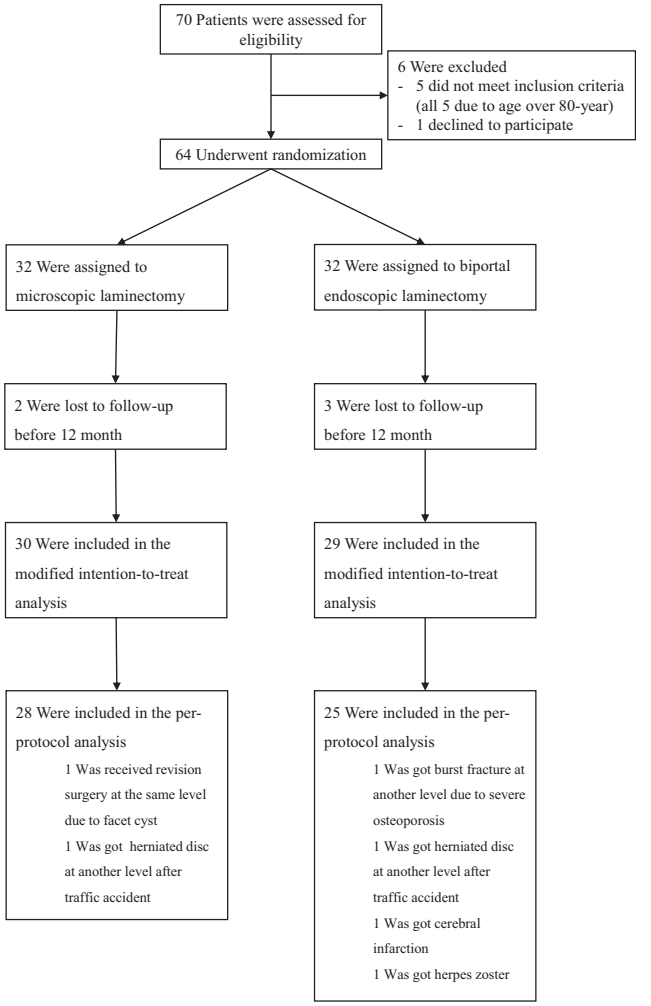

Fig. 2. Enrollment, randomization, treatment, and follow-up flow diagram.

neuropathic pain during the 12-month follow-up (Fig. 4). There were also no between-group differences in VAS back pain score, VAS lower extremity pain score, ODI score, EQ-5D score, and painDETECT score at the 3-, 6-, or 12-month follow-up (Table 3).

The operation time, length of hospital stay, and serum CPK level did not show difference significantly (p>.05). The length of hospital stay was lower in the biportal endoscopy group than in the microscopy group with marginal insignificance (p=.067). Postoperative drainage was significantly

Table 1
Characteristics of the participants at baseline

Characteristic	Microscopy (n=32)	Biportal endoscopy (n=32)
Age (y)*	67.1 (45–79)	66.2 (41–80)
Male/female†	18/14	13/19
BMI (kg/m^2)	24.8±2.3	25.4±3.7
CCI score	0.3±0.7	0.4±0.8
ASA score	1.9±0.7	2.0±0.6
Smoking status, n (%)		
Non/ex-smoker	23 (72%)	23 (72%)
Current smoker	9 (28%)	9 (28%)
Alcohol consumption, n (%)		
None	20 (63%)	20 (63%)
≥1 drink/month	12 (38%)	12 (38%)
VAS for back pain	6.1±2.4	6.1±2.6
VAS for leg pain	7.4±2.1	6.5±1.7
ODI	47.0±14.4	46.2±20.5
EQ-5D	0.496±0.216	0.527±0.216
Central stenosis grade, n (%)		
Grade B	2 (6%)	1 (3%)
Grade C	21 (66%)	19 (59%)
Grade D	9 (28%)	12 (38%)
Approach side, n (%)		
Right	10 (31%)	3 (9%)
Left	22 (69%)	29 (91%)
Operation level, n (%)		
L1–2	3 (9%)	0 (0%)
L2–3	3 (9%)	2 (6%)
L3–4	7 (22%)	5 (16%)
L4–5	17 (53%)	25 (77%)
L5–S1	2 (6%)	0 (0%)

BMI, body mass index; CCI, Charlson comorbidity index; ASA, American Society of Anesthesiologist; VAS, visual analog scale; ODI, Oswestry disability index; EQ-5D, European Quality of Life-5 Dimensions.
Data are presented as given as mean±standard deviation.
* Data are presented as given as mean and range in parenthesis.
† Data are presented as no. of patients.

higher in the biportal endoscopy group than in the microscopy group (p<.001; Table 3).

Recurrent low back and lower extremity pain occurred similarly in both groups (p=.472 and .209). Incidental durotomies and symptomatic hematoma occurred in two (7%) and one (3%) participants in both groups. One participant underwent additional revision surgery at 9 months after the index surgery in the microscopy group. No major complications, such as surgery-related death, thromboembolic events, pneumonia, infection, stroke, and neurological damage were observed (Table 3).

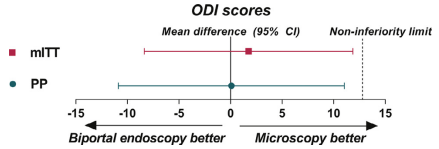

Fig. 3. Graph showing the lack of difference in ODI scores between the two interventions 1 year after surgery for both the modified intention-to-treat and per-protocol analyses. The dashed line indicates the noninferiority margin of 12.8 points. Noninferiority of biportal endoscopy is confirmed if the upper boundary of the two-sided 95% CI is below this margin.

Discussion

This randomized controlled trial, which included 64 participants with lumbar central stenosis, was designed to compare the clinical outcomes between microscopic and biportal endoscopic laminectomy at 12 months after surgery and confirmed the noninferiority of biportal endoscopy compared to microscopy. The more technically advanced procedure of biportal endoscopy showed similar clinical improvements and complication rates during the 12-month follow-up after surgery in our study.

Recently, to save normal vertebral structures, the endoscopic decompressive laminectomy technique has been introduced [13,14,20,37,43]. However, laminectomy using uniportal endoscopy has a steep learning curve and a high rate of complications [15,44]. Biportal endoscopy has several advantages over previous uniportal endoscopic surgery [22,24]. The endoscope used in biportal surgery is the same as those used in knee arthroscopy. Therefore, the endoscopy instruments can be shared with sports medicine surgeons for knee or shoulder arthroscopy; this can reduce medical costs. The endoscope has a wider field of view than uniportal endoscope, and has very similar view to those with a microscope, which is commonly used by spine surgeons. Viewing and working portals are separate, so both hands can be freely used to view. Especially, when using the 30-degree endoscope, the contralateral sublaminar space

Table 2
Mean Oswestry disability index (ODI) scores at 12-month after surgery

Analysis	Number of participants	Mean±standard deviation	95% CI	Mean difference	95% CI of difference	p Value
mITT	Microscopy (n=30)	18.03±18.80	11.01–25.05	1.75	−8.37–11.87	.635
	Biportal endoscopy (n=29)	19.79±19.67	12.15–27.41			
PP	Microscopy (n=28)	17.04±18.96	9.69–24.39	0.08	−10.88–11.05	.506
	Biportal endoscopy (n=25)	17.12±20.80	8.53–25.71			

mITT, modified intention-to-treat; PP, per protocol; CI, confidence interval.
Data are presented as given as mean±standard deviation.
Data are presented using both modified intention-to-treat (mITT) and per-protocol (PP) analyses.

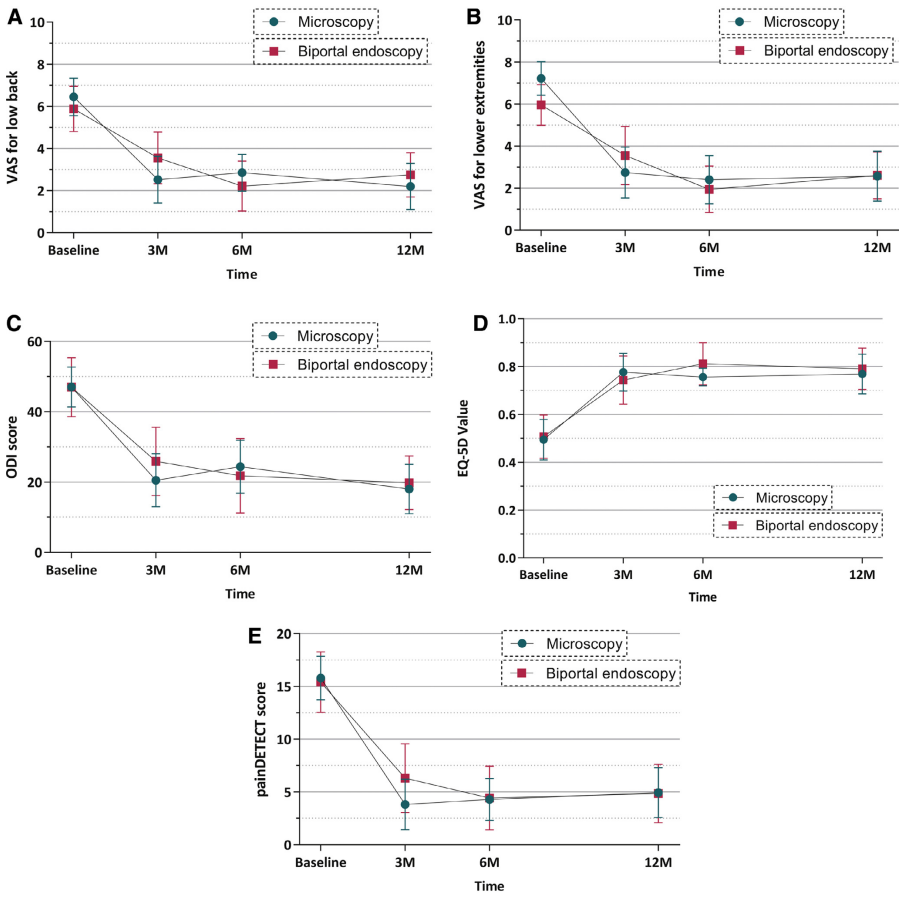

Fig. 4. Changes in secondary outcomes between the two interventions during the 12-month follow-up period. (A) Changes in mean VAS low back pain score, ranging from 0 (no pain) to 10 (worst pain). (B) Changes in mean VAS lower extremity pain score, ranging from 0 (no pain) to 10 (worst pain). (C) Changes in mean ODI score, ranging from 0 (no disability) to 100 (high disability). (D) Changes in mean EQ-5D value, ranging from 0 (worst quality of life) to 100 (best quality of life). (E) Changes in mean painDETECT score, ranging from −1 (neuropathic pain less likely) to 38 (neuropathic pain most likely). Error bars indicate 95% CIs. VAS, visual analog scale; ODI, Oswestry disability index; EQ-5D, European Quality of Life-5 Dimensions.

can be seen easily. Therefore, this technique is quite convenient because the manipulation of spine instruments is easier than that of the tubular endoscopic or microscopic ULBD. As previously reported, after about 30 cases, surgical competency is comparable to that of microscopic ULBD [19,21]. However, the disadvantage is that the bleeding control is more challenging, but it can be decreased by continuous saline irrigation. High water pressure can cause intracranial pressure elevation and cause postoperative headache [19]. The rate of complications, such as root injury, durotomy, symptomatic hematoma, has been reported to be approximately 6% [22], which is similar to the rate of early complications in our study.

The results of this trial are only valid for patients who had lumbar central stenosis at one vertebral level. The mITT and PP analyses confirmed the noninferiority of

Table 3
Secondary outcomes and complications for microscopy and biportal endoscopy groups after surgery during 12-month follow-up

Variables	Microscopy	Biportal endoscopy	Mean difference (95% CI)	p Value
VAS back				
3 months	2.52±2.57	3.55 ±2.63	1.03 (−0.58 to 2.63)	.132
6 months	2.85±1.87	2.21±2.46	−0.64 (−2.05 to 0.78)	.688
12 months	2.20±2.94	2.75±2.70	0.55 (−0.93 to 2.04)	.493
Overall intervention effect*	NA	NA	NA	.109
VAS lower extremities				
3 month	2.74±2.80	3.55±2.95	0.81 (−0.96 to 2.58)	.332
6 month	2.40±2.44	1.95±2.30	−0.45 (−1.99 to 1.09)	.488
12 month	2.57±3.19	2.61±2.86	0.04 (−1.56 to 1.64)	.991
Overall intervention effect*	NA	NA	NA	.486
ODI				
3 month	20.48±17.45	25.90±20.73	5.42 (−6.33 to 17.18)	.426
6 month	24.35±16.14	21.79±21.92	−2.56 (−15.00 to 9.88)	.541
12 month	18.03±18.80	19.79±19.67	1.75 (−8.37 to 11.87)	.630
Overall intervention effect*	NA	NA	NA	.571
EQ-5D				
3 month	0.777±0.184	0.744±0.198	−0.033 (−0.156 to 0.091)	.530
6 month	0.756±0.079	0.812±0.183	0.056 (−0.034 to 0.147)	.244
12 month	0.769±0.223	0.791±0.224	0.022 (−0.096 to 0.140)	.672
Overall intervention effect*	NA	NA	NA	.505
painDETECT				
3 month	3.83±5.52	6.30±6.98	2.47 (−1.38 to 6.33)	.284
6 month	4.30±4.26	4.42±6.27	0.12 (−3.34 to 3.59)	.774
12 month	4.93±6.31	4.86±7.12	−0.08 (−3.61 to 3.46)	.929
Overall intervention effect*	NA	NA	NA	.576
Surgery-related outcomes				
Operative time (min)	70.2±22.8	67.2±19.8		.586
Length of hospital stay (hours)	58.4±33.9	45.6±16.2		.067
Drainage†	27.5 (12.6−53.9)	97.5 (70.0−163.0)		<.001
CPK (IU/l)†	151.0 (107.0−216.8)	111.0 (83.3−230.3)		.250
Recurrent pain, No. (%)‡,§				
Low back	3 (10%)	5 (17%)		.472
Lower extremities	9 (30%)	4 (14%)		.209
Complications, No. (%)‡				
Incidental durotomy	2 (7%)	2 (7%)		1.000
Symptomatic hematoma with revision surgery	1 (3%)	1 (3%)		1.000
Revision surgery due to recurrent pain	1 (3%)	0 (0%)		1.000

95% CI, 95% confidence interval; VAS, visual analog scale; NA, not available; ODI, Oswestry disability index; EQ-5D, European Quality of Life-5 Dimensions; CPK, creatine phosphokinase.

Data are presented as given as mean±standard deviation, unless otherwise indicated.

* p value is from linear mixed models for repeated measures comparing between interventions during 12-month follow-up period.

† Data are presented as median (interquartile range).

‡ The Fisher's exact test was used and the values are presented as numbers and percentages (%).

§ Recurrent pain was defined as recurrent low back or leg pain over VAS score 4 during follow-up period.

biportal endoscopy in relation to microscopic surgery, with only minor differences in the overall results between the two interventions during the follow-up period, which is in accordance with previous studies [24,35]. Another trial with a 6-month follow-up also showed that the clinical outcomes were similar to those of open surgery [35]. In addition, biportal surgery also showed a lower operating time, less postoperative drainage, and shorter hospital stay. But, our trial showed no significant difference in operation time, and length of hospital stay. In the preliminary study to this trial, we found faster surgical site pain recovery and lower fentanyl usage [33]. These clinical results demonstrate that biportal endoscopic decompressive laminectomy is a good alternative to and offers clinical advantages in terms of faster pain relief in comparison with open microscopic decompressive laminectomy.

The most important advantage of endoscopic surgery is the preservation of normal spine anatomy. Previous studies demonstrated less postoperative pain and opioid use after biportal endoscopic surgery [33,35]. Also the other study showed significantly lower C-reactive protein in biportal endoscopy at postoperative 1 week after surgery [24]. But, this trial could not demonstrate lower muscle injuries in biportal endoscopy. Although the biportal endoscopy needed a small incision and muscle stripping during surgery, it requires muscle splitting and shaving of the working

space, which may have elevated the serum CPK level in the biportal endoscopy group. The drainage volume after surgery was significantly larger in the biportal endoscopic surgery. The reason is the irrigation saline during operation infiltrated into surrounding muscle and leaked into the drain after surgery. Another reason for this is that bleeding controlled by the water pressure during operation may have drained out postoperatively.

To our knowledge, this trial is the first to investigate the clinical outcomes between microscopic and biportal endoscopic laminectomy at 12 months after surgery. We found no intervention effect on 12-month clinical outcomes after laminectomy. However, our trial has several limitations. First, this trial had a small sample size, which prevents more generalized conclusions on the potential differences between the two interventions. The initial sample size calculation determined 32 participants would be necessary in each group, considering a 20% drop-out rate. At the last follow-up time point, a compliance above 92% was observed. Therefore, this trial analyzed more participants than planned. Second, the 12 months end-point of our trial was not long enough to assess the benefit or disadvantage of biportal endoscopic or microscopic surgery. Continued follow-up is planned. Third, there was no regular follow-up of validated and reliable imaging studies to evaluate instability or re-stenosis in all participants. Due to the high cost and low repeatability [45], magnetic resonance imaging and dynamic radiographs could not be performed for evaluation. Fourth, our trial clinicians were not blinded to intervention allocation. Since the surgeon was not blinded to patient allocation, we were compelled to do a single-blind study. However, the outcome measures were performed by an independent researcher who was not aware of the allocation; participants were also blinded to their allocation. Therefore, the single-blind design is not likely to have affected the results. Finally, multiple comparisons, which were used for analyzing secondary outcomes, increase the risk of type 1 error. The interpretation of the statistical effects of interventions on secondary outcomes should be done considering this potential limitation.

Conclusions

In this randomized controlled trial of patients with lumbar central stenosis, the results confirmed the noninferiority of biportal endoscopy to microscopic decompressive laminectomy. Our findings revealed no differences in clinical outcomes between the two interventions at 12 months after surgery. Therefore, for patients with lumbar central stenosis who are considered for lumbar decompressive laminectomy, biportal endoscopic decompressive laminectomy is a feasible surgical procedure option.

Acknowledgments

This study was partially supported by research grants from Daewon Pharmaceutical Corporation in Seoul, Republic of Korea. The funder had no role in the study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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EVIDENCE-BASED ENDOSCOPIC SPINAL SURGERY (ESS) - SPECIAL SECTION

Indications, Contraindications, and Complications of Biportal Endoscopic Decompressive Surgery for the Treatment of Lumbar Stenosis: A Systematic Review

Dong Hwa Heo[4], Don Young Park[1], Hyun Jin Hong[2], Young Ho Hong[3], Hungtae Chung[4]

BACKGROUND: **Biportal endoscopic spine surgery is gaining popularity in managing degenerative lumbar diseases and has optimal indications and contraindications. The perioperative complications related to the biportal endoscopic approach affect the postoperative outcomes. Therefore, this study aimed to review the indications, contraindications, and complications of biportal endoscopic decompression for lumbar stenosis.**

METHODS: **For this systematic review, articles on biportal endoscopic decompressive surgery for lumbar stenosis, including central, lateral recess and foraminal stenoses, were searched for and reviewed. Additionally, the complications, indications, and contraindications of biportal endoscopic surgery for lumbar stenosis were reviewed.**

RESULTS: **Forty-one articles were included in this study. The indications for biportal endoscopic decompression are central lumbar stenosis, central stenosis with lipomatosis, lateral recess stenosis, foraminal stenosis, and the far-out syndrome. The contraindications include trauma, infection, tumor, instability, high-grade spondylolisthesis, isthmic spondylolisthesis, and severe scoliosis. Perioperative complications are typically minor; major complications include durotomy, epidural hematoma, incomplete decompression, infection, facet joint injury, neural injury, increased epidural pressure, and postoperative instability.**

CONCLUSIONS: **Favorable indications for a biportal endoscopic approach are central lumbar, lateral recess, foraminal, extraforaminal stenoses, and the Bertolotti syndrome. Incidental durotomy and postoperative epidural hematomas are common complications of biportal endoscopic decompression.**

INTRODUCTION

Techniques and instruments for endoscopic spine surgery have been actively developed,[1] and biportal endoscopic approaches have been introduced and attempted for the treatment of degenerative spinal disease in the past.[1,2] In the past, endoscopic spine surgery was usually attempted to treat lumbar disc diseases, such as disc degeneration, ruptured extrusion, and protrusion. Additionally, central lumbar stenosis, lumbar foraminal stenosis, foraminal recurrent disc herniation, lumbar spondylolisthesis, and segmental instability have been treated with endoscopic spine surgery.[2,3] As the indications for endoscopic spine surgery have increased, the indications for biportal endoscopic spine surgery continue to expand as well.[3,4] The biportal endoscopic approach has been used for discectomy and decompression to fusion surgery from the cervical to lumbosacral area. The biportal endoscopic approach has a relatively shorter learning curve than uniportal endoscopic surgery as the surgical anatomy is familiar, the spinal instruments are easy to handle, and the endoscopy is magnified. However, an absence of depth perception exists, and the procedure is technically difficult compared to microsurgery.

There are certain contraindications and complications of biportal endoscopic spine surgeries and their awareness is

Key words
- Biportal
- Complications
- Contraindications
- Endoscopy
- Indications
- Lumbar
- Stenosis

Abbreviations and Acronyms
CSF: Cerebrospinal fluid
MRI: Magnetic resonance imaging
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses

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Citation: World Neurosurg. (2022) 168:411-420.
https://doi.org/10.1016/j.wneu.2022.09.023
Journal homepage: www.journals.elsevier.com/world-neurosurgery
Available online: www.sciencedirect.com

essential. The prevention and management of perioperative complications significantly influence the postoperative outcomes of this approach. Through a systematic literature review, this study aimed to investigate the indications, contraindications, and complications of biportal endoscopic surgery for lumbar stenosis.

MATERIALS AND METHODS

A systematic review was performed on previously published articles. Web-based electronic databases — PubMed, Embase, the Cochrane Library, and Web of Science — were searched systematically to identify articles on biportal endoscopic decompression of lumbar stenosis. In addition, a systematic search was performed by 2 spine neurosurgeons with abundant experience in biportal endoscopic surgery to reduce selection error and missed articles. The search terms were "biportal," "endoscopic," "decompression," "lumbar stenosis," "complications," "indication," and "contraindications and combinations." Article titles and abstracts were reviewed using the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist (Figure 1). The full text of each article was reviewed. Cadaveric studies, commentaries, laboratory articles, non-English articles, and articles related to cervical lesions, thoracic lesions, and tumorous lesions were excluded. Traumatic lesions and biportal endoscopic fusion procedures were also excluded, as this review

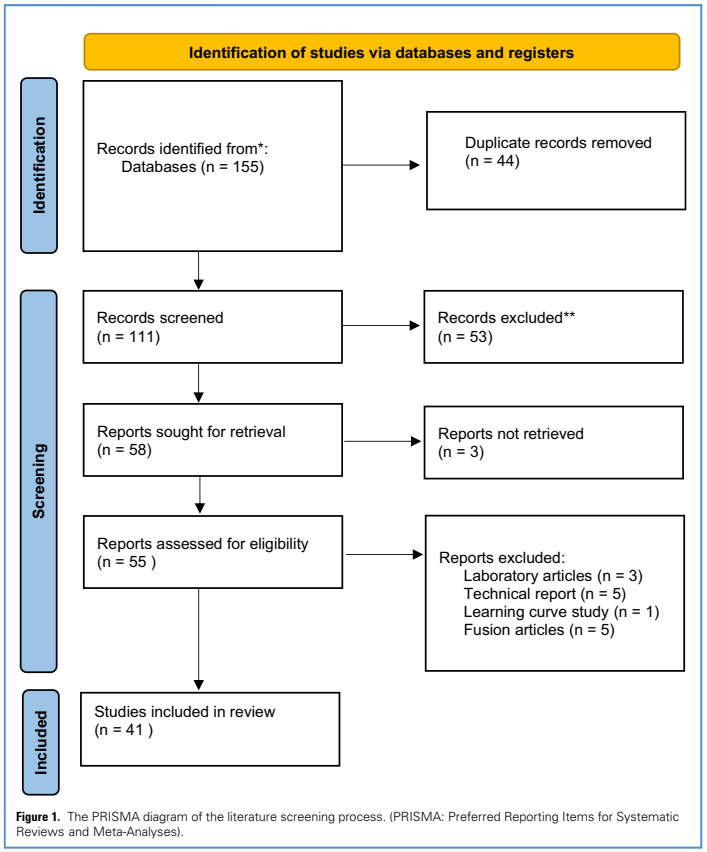

Figure 1. The PRISMA diagram of the literature screening process. (PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses).

was focused on degenerative lumbar disease and only decompressive procedures without fusion or fixation.

The indications and contraindications of biportal endoscopic spine surgery for lumbar stenosis were reviewed using the full text of each article. In addition, all the complications and the management approach of these complications related to biportal endoscopy for lumbar stenosis were investigated.

RESULTS

A total of 155 articles were found in the databases. After duplicate articles were removed and the exclusion criteria were applied, 55 relevant articles were identified. The full text of each of these studies was reviewed. Laboratory studies, technical reports, fusion studies, and learning curve studies were excluded (Figure 1). Finally, 41 articles were selected for analysis (Figure 1)[1,2,5-43] comprising 25 articles that were related to lumbar central or lateral recess stenosis, 8 related to lumbar foraminal or extraforaminal stenosis, and 8 related to the complications of the biportal endoscopic approach.

Indications and Contraindications

The biportal endoscopic approach has been successfully used to treat lumbar central or lateral recess stenosis (23 articles), central stenosis with lipomatosis (1 article),[19] lumbar foraminal and extraforaminal stenosis (6 articles), and the far-out syndrome (2 articles, extraforaminal entrapment of the L5 nerve root by lumbosacral transitional vertebrae) (Figure 2)[6,7,9-11,19-24,28,30,32,35,40,42,44] Therefore, these stenotic lesions were considered the most favorable indications for the biportal endoscopic approach (Table 1).

Traumatic lesions, infections, tumors, musculoskeletal disorders, instability, high-grade spondylolisthesis, isthmic spondylolisthesis, and severe scoliosis (deformity) were contraindications to biportal endoscopic decompressive surgery (Table 1).[1,2,6,9,14,20,28,30]

Complications

The overall incidence of clinically symptomatic complications was below 10%.[15,40,41] Most complications were minor,[38] and none were life-threatening complications, such as thromboembolism, sepsis, severe bleeding, or pulmonary complications.[38,40] The complications reported for biportal endoscopic decompression of lumbar stenosis were dural tears (incidental durotomy) (Figure 3), cerebrospinal fluid (CSF) leak, pseudo-meningocele, postoperative epidural hematoma, incomplete decompression, infection, facet joint injury, neural injury, headache, neck pain, and postoperative instability (Table 2).[5,9,14,18,21,25,27,36,39] Headache and neck pain may be related to increased epidural pressure due to continuous saline irrigation.[5,14,17] Neural injuries usually induce transient weakness or hypesthesia (Table 2).[1,14] These minor complications were treated conservatively. Symptomatic epidural hematomas or uncontrolled CSF leaks required surgical revision.[5,25]

Two articles on postoperative epidural hematomas reported its incidence to be 24.7%[1] and 23/6%.[2] Most epidural hematomas were asymptomatic and identified as incidental findings on postoperative magnetic resonance imaging. Only 1.9% of patients who developed a postoperative epidural hematoma needed revision surgery.[1,2]

In biportal endoscopic foraminal or extraforaminal decompression cases, hydroperitoneum and retroperitoneal fluid collection rarely occurred.[10,13] Arterial bleeding from the radicular artery was another reported complication (Table 2).[6,10]

DISCUSSIONS

Indications and Contra-indications of Biportal Endoscopy for Lumbar Stenosis

Indications for the biportal endoscopic approach may be similar to those for minimally invasive microscopic surgery using tubular retractor systems in cases of lumbar stenosis. There were central, lateral recess, foraminal, and extraforaminal stenoses in lumbosacral transitional vertebrae (Bertolotti's syndrome, far-out syndrome) caused by lumbar stenosis.[1,2,6,9,11,13,19,21,23,24,30,35,40-42]

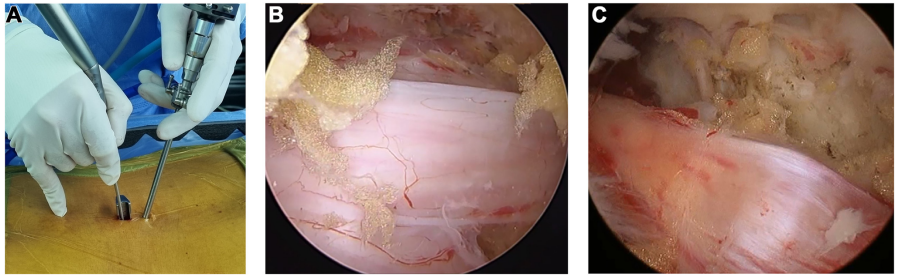

Figure 2. Overview of biportal endoscopic lumbar surgery (**A**). A working sheath is inserted into the working portal (**A**). An endoscopic image of central canal decompression (**B**) an intraoperative endoscopic image of the decompression of an exiting nerve root for foraminal stenosis (**C**).

Table 1. Indications and Contraindications of Biportal Endoscopic Decompression for Lumbar Stenosis

Indications	Contraindications
Lumbar Central stenosis	Instability
Lumbar Lateral recess stenosis	High grade spondylolisthesis
Lumbar Foraminal stenosis	Infection
Lumbar Extraforaminal stenosis	Scoliosis
Lumbosacral transitional vertebrae (far out syndrome)	Tumor Trauma
	Isthmic spondylolisthesis
	Musculoskeletal disorder

All degenerative lumbar stenotic lesions were indications for biportal endoscopic lumbar decompression. Lumbar central or lateral recess stenoses were treated using biportal endoscopic unilateral lumbar laminotomy with bilateral decompression. Lumbar foraminal or extraforaminal stenoses were treated with biportal endoscopic lateral foraminotomy using the paraspinal approach.[6,10,22-24,26] Multilevel stenosis can also be treated using the biportal endoscopic approach. This approach may be used to treat most lumbar stenoses, as is the case for microscopic surgery.

The contraindications for biportal endoscopic decompression were instability, high-grade spondylolisthesis, deformity, infectious lesions, and stenosis with a concomitant congenital anomaly.[9,20,30] These contraindications usually require lumbar interbody fusion rather than biportal endoscopic decompression surgery.

Complications Related to Biportal Endoscopic Decompression

Although various complications can occur during biportal endoscopic decompression, most perioperative complications are minor.[9,14,38,40] The prevention and early management of complications related to biportal endoscopic procedures influence the postoperative outcomes.[31]

Dural Tear. Incidental durotomy (dural tear) is a complication of biportal endoscopic decompression (Figure 3).[11,16,21,30,31,36,39] This approach causes 2 types of dural tears as follows: intraoperative recognized and intraoperative unrecognized incidental durotomy (Table 3). Incidental durotomy is usually detected endoscopically (Figure 3, intraoperatively recognized incidental durotomy). Durotomy usually occurs during the removal of the hypertrophied ligamentum flavum. Anatomically, the posterior epidural ligament (Figure 4A and B) and Hoffmann's ligament (anterior dural ligament) (Figure 4C) may be related to dural tears. The posterior epidural ligament is connected between the posterior dura and ligamentum flavum, and Hoffmann's ligament is connected between the anterior dura and posterior longitudinal ligament. These 2 ligaments may be anatomical factors in incidental durotomy during the biportal endoscopic approach.

The biportal endoscopic approach is performed using continuous saline irrigation. However, continuous saline irrigation influences the elevation of epidural pressure. Moreover, in a large durotomy area, continuous saline may flow into the intradural space. Finally, there is a high possibility of increased epidural and intracranial pressures due to intradural fluid inflow. Therefore, the dural tear site should be repaired to prevent nerve rootlet herniation and inflow of irrigation fluid. If the primary dural repair fails, conversion from endoscopic surgery to microscopic surgery was recommended for a successful dural repair.

The primary dural repair was attempted using direct sutures or sutureless nonpenetrating clips (Figure 5A).[12,36] Small size (within 1 cm) durotomy could be repaired using several pieces of a fibrin sealant patch (TachoSil) (Figure 5B).[12,14,15,18,36]

If CSF leaks through an epidural drainage catheter and bag or skin wound, hydration with bed rest is recommended from 5–7 days postoperatively. If the CSF leak is not controlled with conservative management, lumbar puncture and CSF drainage (CSF perioperative diversion) should be considered for 3–5 days. Autologous epidural blood patches may be another option for CSF leakage. Revision surgery for dural sutures should be considered in patients with an uncontrolled continuous CSF leak (Table 3).

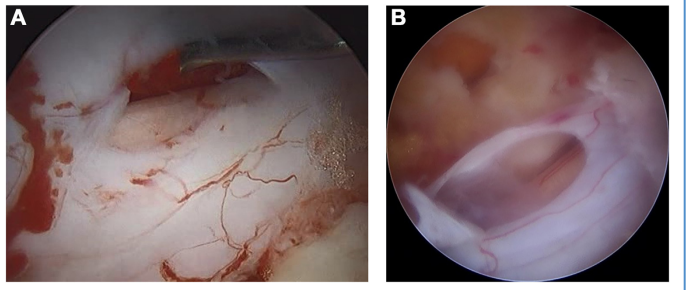

Figure 3. Incidental durotomy occurred during biportal endoscopic decompression for central stenosis (**A** and **B**).

Table 2. Complications of Biportal Endoscopic Decompression for Lumbar Stenosis

Lumbar Stenosis	Complications
Central or lateral recess stenosis	Dural tear (CSF leak)
	Pseudo-meningocele
	Postoperative epidural hematoma
	Incomplete decompression
	Increased epidural pressure (headache, neck pain)
	Neural injury
	Transient weakness
	Hypesthesia
	Postoperative instability
	Facet joint injury
Foraminal or extraforaminal stenosis	Hydroperitoneum
	Arterial bleeding of radicular artery
	Retroperitoneal fluid collection

Table 3. Incidental Durotomy and Its Management

Dural Tear	Treatment
Intraoperative recognized incidental durotomy	Durotomy size >1 cm Primary repair with suture or clips Durotomy size <1 cm Application of fibrin sealant patch Primary repair with suture or clips
Intraoperative unrecognized incidental durotomy (CSF drainage through catheter and its bag)	Bed rest more than 3 days Removal of drainage catheter insertion Autologous epidural blood patch
Postoperatively uncontrolled CSF leakage	Lumbar puncture and CSF drainage Revision and exploration surgery

Unsuccessful dura repair or untreated durotomy may lead to the development of a pseudo-meningocele.[18]

Another form of incidental durotomy is an unrecognized intraoperative dural tear. Although no durotomy was identified during the biportal endoscopic procedure, CSF sometimes leaked into the epidural drainage bag postoperatively. If more than 200-fluid is drained into the drainage bag, CSF leakage should be suspected. In these cases, the epidural drainage catheter must be removed, and bed rest is maintained for 3–5 days postoperatively. Most unrecognized intraoperative durotomies are treated conservatively. However, if the patient complains of persistent headache and CSF collection inside the wound is suspected, lumbar puncture and CSF drainage should be considered. If an unrecognized intraoperative durotomy and CSF leak do not respond to these conservative treatments, revision and exploration surgery should be performed to identify the durotomy site and perform primary dura repair (Table 3).

Postoperative Epidural Hematoma. An epidural hematoma can occur postoperatively.[5,15,16,21,23,27,31] A small postoperative epidural hematoma is usually asymptomatic or causes only mild symptoms (Figure 6A).[27] However, a large postoperative epidural hematoma can induce intractable radiating pain and neurological deficits, such as hypesthesia and motor weakness (Figure 6B).[21] In such cases, postoperative magnetic resonance imaging should be performed and checked.[27] If a symptomatic epidural hematoma occurs, revision surgery should be considered (Figure 6B).[5,21] An epidural hematoma can be effectively removed using revision biportal endoscopic surgery.[23,25,27] If bleeding is difficult to control using a biportal endoscopic approach, biportal endoscopic surgery should be converted to microscopic surgery.

To prevent an epidural hematoma, ensuring meticulous bleeding control, applying a hemostatic matrix (gelatin-thrombin matrix) and inserting an epidural drainage catheter (Figure 7A and B)[29] have been attempted. The most significant risk factors for postoperative epidural hematoma are the use of anticoagulant or antiplatelet medications.[5,25]

Increased Epidural Pressure. Continuous saline irrigation is necessary during biportal endoscopic spine surgery.[17,41,45] However, it may increase the epidural pressure[41] and ,subsequently, result in meningeal irritation, indicated by neck pain or headache.[17,45] There are 2 possible mechanisms of increased epidural and intracranial pressure by continuous saline irrigation. The first is the direct pressure effect by continuous irrigation of saline. The second is direct cranial movement of irrigation fluid.[45] Prolonged operating time or poor patency of the irrigation fluid can increase epidural pressure during biportal endoscopic surgery.[17] In the biportal endoscopic approach, continuous saline is passed from the endoscopic portal to the working portal. The patency of saline outflow and constant flow is important for maintaining epidural pressure.[17,45] An infusion pump pressure >50 mmHg can increase the cervical epidural pressure in this surgery.[17,45] Reducing the operation time and maintaining the pump pressure below 40 mmHg may be useful in reducing the complications caused by the increase in epidural pressure. Additionally, postoperative epidural Hemovac insertion

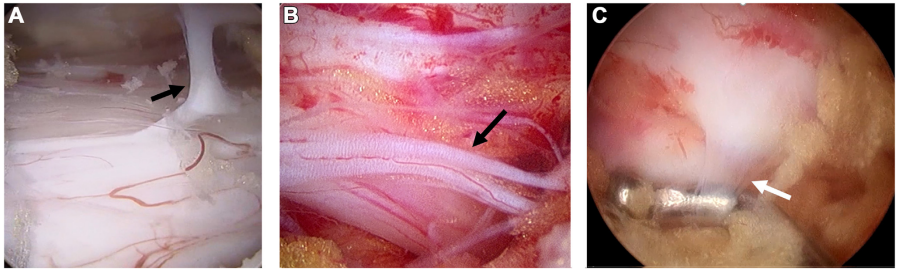

Figure 4. Anatomical cause of a dural tear. A posterior epidural ligament is connected between the dura and ligamentum flavum (**A** and **B**, *black arrow*). A Hoffmann's ligament is connected between the dura and the disc or posterior longitudinal ligament (**C**, *white arrow*).

may help to drain excessive irrigation fluid.[45] Neck pain or headache can be improved with bed rest and conservative treatments.[14]

Neural Injury. Neural injury can occur during the biportal endoscopic approach, as it can occur in microsurgery. Neural injuries can be caused by surgical instruments, and retraction are usually temporary and not severe. The patients present with transient muscle weakness or hypesthesia.[14] These symptoms are usually improved with conservative management, including physical therapy, bed rest, and medications.

Postoperative Instability and Facet Joint Injury. Postoperative segmental instability or facet joint injury is another complication of biportal endoscopic laminotomy.[6,23,26] In addition, iatrogenic inferior articular process fractures can occur during laminotomy (Figure 8), and these complications are similar to those from conventional or microscopic surgery. Therefore, preoperative instability is a contraindication to biportal endoscopic lumbar decompression.

Specific Complications Related to Foraminal or Extraforaminal Stenosis Decompression. The biportal endoscopic paraspinal approach (Wiltse approach) has been used to treat foraminal and extraforaminal stenosis. The lateral locations of the 2 portals can induce hydroperitoneum. Irrigation fluid can leak into the abdominal cavity through the muscles. Therefore, endoscopic and surgical instruments must be placed around the foraminal ligament and bony structures, including the isthmus, transverse, and superior articular processes. If only muscle is seen, then the 2 ports may be located too laterally, and there is a high possibility of irrigation leakage into the abdominal cavity.[10] Paracentesis should be considered for a symptomatic hydroperitoneum.[10]

Retroperitoneal fluid collection is a biportal endoscopic extraforaminal decompression complication of the far-out syndrome.[13] It can occur during decompression under the pelvic ala or

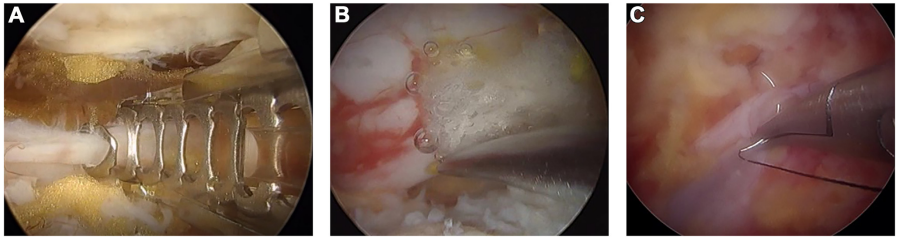

Figure 5. Intraoperative primary dura repair is performed with sutureless non-penetrating clips (**A**), TachoSil (**B**) and simple sutures (**C**).

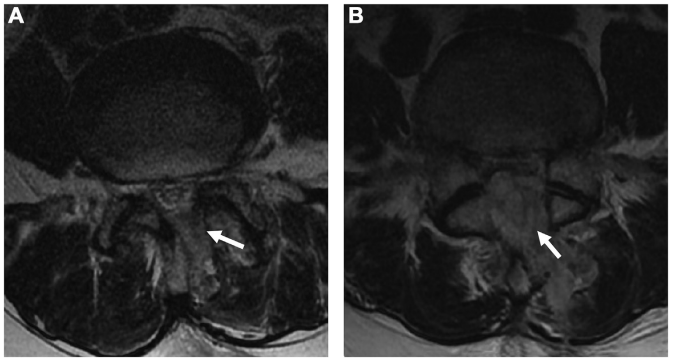

Figure 6. Postoperative magnetic resonance imaging images depicting a postoperative epidural hematoma. Small postoperative epidural hematomas are usually asymptomatic and treated conservatively (**A**). Symptomatic large epidural hematoma compressing the thecal sac and infiltrating the muscle layer (**B**).

pseudoarthrosis between the ala and transverse process.[13] Good drainage of irrigation fluid through the working portal is important for preventing a retroperitoneal fluid collection.[13] Decompression around the ala area should be performed quickly to reduce the possibility of irrigation fluid leakage into the retroperitoneal area.[13]

Arterial bleeding from the radicular branch of the segmental artery is another complication of the biportal endoscopic paraspinal approach (Figure 9A).[6,10] Radicular arteries are found around the foramen and exiting nerve roots (Figure 9B). Therefore, when performing foraminal decompression, attention should be paid to avoid arterial injury. Bleeding from the radicular artery can be controlled using radiofrequency ablation.

CONCLUSIONS

Central lumbar, lateral recess, foraminal, extraforaminal stenoses, and the far-out syndrome are favorable indications for a biportal endoscopic decompressive approach. In contrast, traumatic lesions, infections, neoplastic condition, instability, deformity, high-grade spondylolisthesis, and isthmic spondylolisthesis are

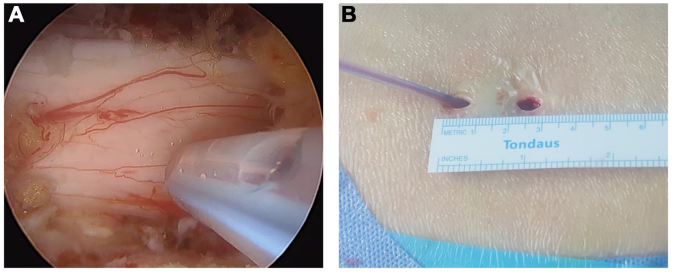

Figure 7. Epidural drainage catheter is inserted after a biportal endoscopic approach (**A** and **B**).

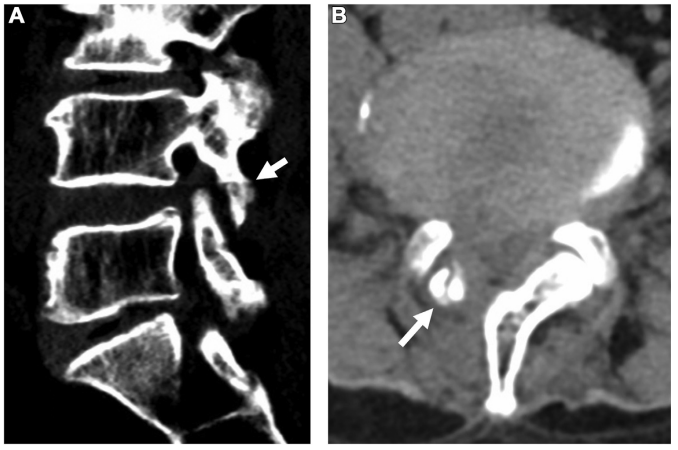

Figure 8. Computed tomography images reveal an inferior articular process fracture (**A**: sagittal view; **B**: axial view) (*white arrow*).

contraindications for a biportal endoscopic decompressive approach.

Complications of biportal endoscopic decompressive surgery are mostly minor. Dural tears and postoperative epidural hematomas are common complications, while increased epidural pressure from irrigation fluid and neural injury are other complications that are observed. Abdominal fluid collection is a specific complication of the paraspinal approach of biportal endoscopy. Recognizing indications, contraindications, and complications may be necessary to perform biportal endoscopic decompressive surgery effectively.

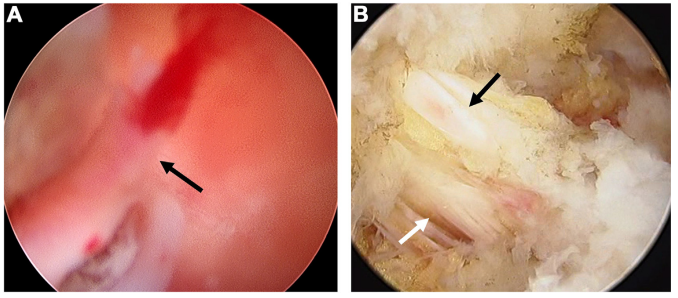

Figure 9. Radicular artery is detected during the biportal endoscopic surgery using the paraspinal approach. Endoscopic view showing active bleeding from a radicular artery (**A**. *black arrow*). Radicular artery (*black arrow*) is located around an exiting nerve root (**B**. *white arrow*).

CRediT AUTHORSHIP CONTRIBUTION STATEMENT

Dong Hwa Heo: Conceptualization, Methodology, Investigation, Resources, Writing – original draft, Writing – review & editing. **Don Young Park:** Conceptualization, Investigation, Data curation, Writing – original draft, Writing – review & editing. **Hyun Jin Hong:** Conceptualization, Validation, Supervision, Project administration. **Young Ho Hong:** Conceptualization, Validation, Supervision. **Hungtae Chung:** Validation, Supervision.

ACKNOWLEDGMENT

Dong Hwa Heo and Don Young Park are co-first-authors and have contributed equally to the manuscript.

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Conflict of interest statement: The authors declare that the article content was composed in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Received 6 August 2022; accepted 5 September 2022

Citation: World Neurosurg. (2022) 168:411-420.
https://doi.org/10.1016/j.wneu.2022.09.023

Journal homepage: ***www.journals.elsevier.com/world-neurosurgery***

Available online: ***www.sciencedirect.com***

Neurospine 2020;17(Suppl 1):S129-137.
https://doi.org/10.14245/ns.2040178.089

Neurospine
pISSN 2586-6583 eISSN 2586-6591

Review and Technical Note

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Received: April 3, 2020
Revised: June 7, 2020
Accepted: June 8, 2020

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See the commentary "Why Should We Perform Endoscopic Spine Surgery?" via https://doi.org/10.14245/ns.2040374.187.

Technique of Biportal Endoscopic Transforaminal Lumbar Interbody Fusion

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Biportal endoscopic transforaminal lumbar interbody fusion (TLIF) may have advantages of minimally invasive fusion surgery as well as those of endoscopic surgery. The purpose of this study was to present the biportal endoscopic TLIF technique along with video presentations and a review of the literature on this technique. Basically, the biportal endoscopic TLIF technique is similar to minimally invasive TLIF with a tubular retractor. There were 2 options in the biportal endoscopic TLIF procedures. The first was the insertion of one long TLIF cage and the other was the insertion of 2 short posterior lumbar interbody fusion (PLIF) cages. After the interbody fusion procedures, percutaneous pedicles screw fixation was performed. Biportal endoscopic TLIF achieved complete neural decompression through laminectomy and facetectomy like conventional TLIF. Endplate preparation was performed completely under a clear and magnified endoscopic view. It was also feasible to insert a large TLIF cage or 2 cages for PLIF without exiting nerve root injury. Biportal endoscopic TLIF might have the advantages of endoscopic surgery as well as minimally invasive fusion surgery. Direct neural decompression, endplate preparation under endoscopic guidance, and the insertion of a large TLIF cage or 2 PLIF cages may be the merits of biportal endoscopic lumbar fusion procedures.

Keywords: Endoscopy, Fusion, Lumbar, Minimally invasive surgery

INTRODUCTION

Minimally invasive (MIS) spine surgery has the advantages of early recovery and the preservation of normal structures.1 MIS spine procedures include percutaneous pain procedures, endoscopic spine surgery, microsurgery with tubular retractor systems, lateral lumbar interbody fusion surgeries, and transforaminal lumbar interbody fusion (TLIF) surgeries.[1] Recently, endoscopic lumbar interbody fusion procedures have been attempted for lumbar degenerative disease and instability.[2-6] Regarding the instrumentation systems, there are 2 kinds of endoscopic lumbar interbody fusion surgeries. The first is uniportal endoscopic lumbar interbody fusion and the other is biportal endoscopic lumbar interbody fusion.[5,6] With regard to surgical approaches or corridor, one approach is a trans-Kambin approach using uniportal endoscopic surgery[6-10] and the other is a posterolateral approach like MIS TLIF using uniportal or biportal endoscopic surgery.[5,11,12] The trans-Kambin approach is similar to transforaminal endoscopic lumbar discectomy via the Kambin triangle. And, the technique of posterolateral endoscopic TLIF is similar to MIS TLIF involving tubular retractor systems.[4,5,12]

Although endoscopic TLIF by the trans-Kambin approach may be less invasive than the posterolateral approach, the trans-Kambin approach might exhibit a higher possibility of exiting nerve root irritation or injury and limitations in direct neural decompression compared to the posterolateral approach.[7,13] The biportal endoscopic TLIF technique uses a posterolateral ap-

proach similar to MIS TLIF involving tubular retractor systems. Through biportal endoscopic procedures, it was feasible to perform direct neural decompression through a laminectomy, contralateral sublaminar decompression, discectomy, foraminotomy, and facetectomy as well as indirect decompression by disc space restoration, and the reduction of spondylolisthesis.[4,5,11,14-16] Also, the endoscopic approach is the least invasive and may preserve the normal structure.[6,17] Biportal endoscopic TLIF is hypothesized to have advantages of minimally invasive fusion surgery as well as those of endoscopic surgery.[5,11] Herein, we present the biportal endoscopic TLIF technique along with a video presentation and review of the literature on this technique.

SURGICAL PROCEDURES

We present 2 illustrated cases with surgical videos. The lumbar interbody fusion procedures were performed by biportal endoscopic surgery[5,11,18] (Fig. 1). There were 2 options of biportal endoscopic lumbar interbody fusion surgical procedures performed. The first was a cage insertion procedure (Supplementary video clip 1) and the second was a 2-cage insertion procedure (Supplementary video clip 2).

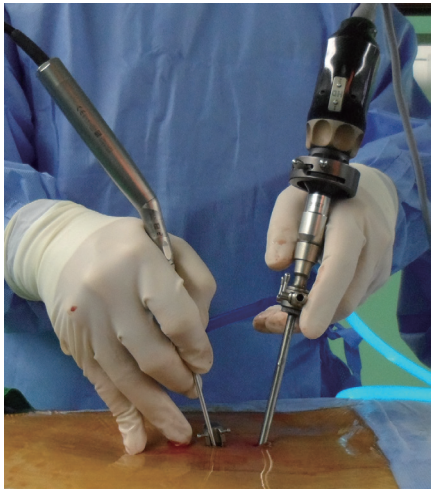

Fig. 1. Overview of biportal endoscopic lumbar interbody fusion. Usually, the dominant hand was used for the working portal and the nondominant hand was used for the endoscopic portal.

1. Surgical Instruments

The biportal endoscopy systems include a console, camera, endoscopy irrigation equipment, and tool kits, which are essential for the surgery. A waterproof surgical drape is essential for endoscopic spine surgeries and must be prepared. Also, a radiofrequency (RF) console and RF probes should be prepared for tissue cauterization and bleeding control. General spinal operation instruments for MIS TLIF were used. Angled curettes are helpful for endplate preparation of the contralateral side. A long straight TLIF cage (width, 11 mm; length, 34 mm; height, 9–18 mm) was usually used for interbody fusion, and short-length PLIF cages (width, 11 mm; length, 25 mm; height, 9–18 mm) are available. After the interbody fusion procedures, percutaneous pedicle screws were inserted under C-arm fluoroscopic guidance.

2. Anesthesia and Position

We prefer general endotracheal anesthesia. Epidural anesthesia with intravenous sedation is also available for single-level fusion. The patient is in a prone position during the interbody fusion procedure and insertion of the percutaneous pedicle screws. A Jackson table or a Wilson frame is used for this procedure.

3. Surgical Procedures

First, we make 2 skin incisions over the ipsilateral pedicles for

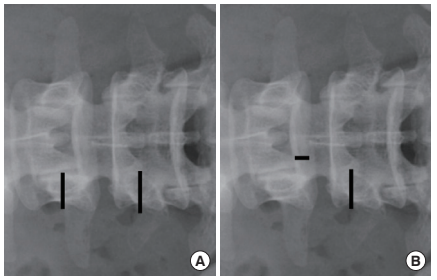

Fig. 2. Two skin incision points for biportal endoscopic transforaminal lumbar interbody fusion. (A) Ordinary skin incision points were made over the pedicle area in the anteroposterior x-ray view. (B) Modified skin incision points. (B) An endoscopic portal incision was made near the intervertebral space for good visualization of the superior and inferior endplates.

decompression and insertion of the cages under C-arm fluoroscopic guidance (Fig. 2). If the dominant radicular pain site was in the leg or buttock, biportal endoscopic approaches are tried at the dominant pain side. Modified skin incisions, different from routine incisions, were used. Typically, a 5-mm-long skin incision for an endoscopic portal is made close to the disc space of the medial pedicular line and the other skin incision is made on the working portal over the pedicle (Fig. 2B). These 2 skin incisions are also used for ipsilateral percutaneous pedicle screw insertion. A small-sized endoscopic portal is used for passing a drainage catheter. The purpose of the modified skin incision is to achieve optimal visualization of the superior and inferior endplates during endplate preparation.

Serial dilators are inserted through the working portals. The lower portion of the cranial lamina is gently dissected using a dissector under C-arm fluoroscopic guidance. The docking point of the endoscopic and working portals is over the lower portion of the cranial lamina. Ipsilateral unilateral laminotomy with an ipsilateral facetectomy is performed. Ipsilateral laminotomy of the upper and lower laminae is performed until full exposure of the ligamentum flavum from the proximal end to the distal end. The unilateral inferior articular process is removed using Kerrison punches and osteotomes. The superior articular process is partially removed. In cases with foraminal stenosis or foraminal disc herniation, the superior articular process is removed for decompression of the exiting nerve root. Facet and laminae bone chips are collected for fusion materials.

The ligamentum flavum is removed for ipsilateral traversing nerve root decompression (Fig. 3A). The contralateral side of the ligamentum flavum is completely removed for decompression of the central canal and contralateral traversing nerve root (Fig. 3B, C). The medial portion of the contralateral facet joint is fully released for the reduction of spondylolisthesis or distraction of the intervertebral disc space. Annulus fibrosus of the disc is incised using a blunt knife or an RF probe with a small diameter. The disc materials are removed using pituitary forceps and shavers. We perform complete endplate preparation under the endoscopic view. A small-diameter shaver is inserted and rotated in disc space. Larger shavers are used serially for endplate preparation. The endoscopy of biportal endoscopic systems can be inserted into disc space. The dissection plane between the cartilaginous endplate and osseous endplate is explored under a clear, magnified endoscopic view. The cartilaginous endplate is separated from the osseous endplate using angled dissectors and curettes (Fig. 4A). Only the cartilaginous endplate can be completely removed from the osseous endplate under a clear endoscopic view

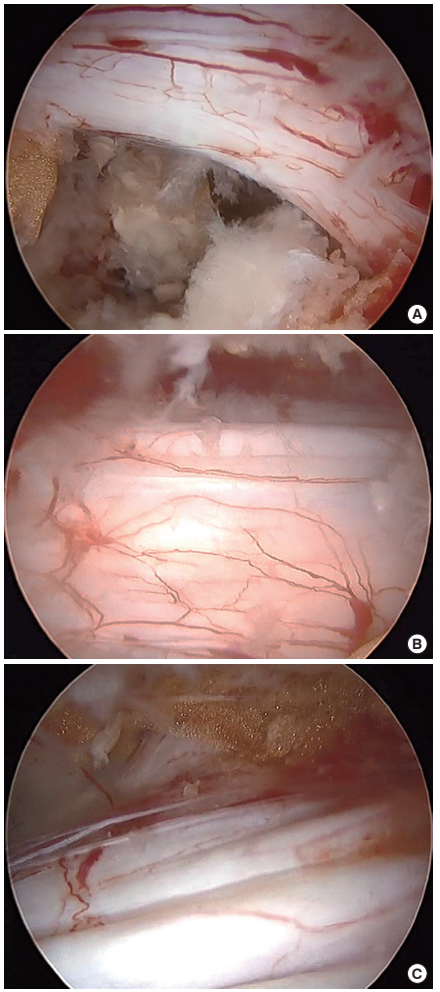

Fig. 3. Biportal endoscopic view after neural decompression. (A) Ipsilateral traversing nerve root. (B) Central canal. (C) Contralateral traversing nerve root.

(Fig. 4B). The intervertebral disc space is distracted by serial insertion of cage trials or serial dilators. The contralateral side of endplate is prepared using angled curettes and an upward angled

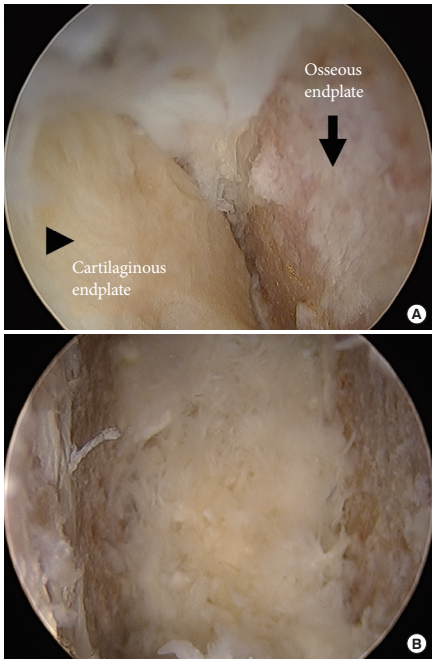

Fig. 4. Endoscopic images during endplate preparation. (A) The cartilaginous endplate (arrowhead) was separated from the osseous endplate (arrow). (B) Final view of the endoscopic endplate preparation. The cartilaginous endplate was completely removed without injury to the osseous endplate.

pituitary. For good visualization of the contralateral endplate, a 30° endoscopy is used. Sometimes we change the endoscopy from 0° to 30°. After confirmation of complete endplate preparation under endoscopic view, allogenous or autogenous bone chips are inserted using a specialized funnel under C-arm fluoroscopic guidance (Fig. 5A, B). Continuous saline irrigation is stopped during the insertion of fusion materials.

Finally, a long TLIF cage is inserted through the working portal after dura retraction. C-arm fluoroscopy was used during cage insertion. The cage is repositioned obliquely or transversely using a cage pusher device. If we use short PLIF cages, we usually put in 2 cages for interbody fusion. The first cage is obliquely and deeply inserted into the midline or contralateral side. After insertion of the first cage, the second short cage is inserted. The specialized dura retractor is deeply inserted for protection, covering the dura as well as the first inserted cage. Since the remnant of the superior articular process can protect the exiting nerve root during cage insertion, the ipsilateral exiting nerve root is decompressed after cage insertion. Finally, the exiting nerve root is additionally decompressed in cases with foraminal lesions with exiting root indentations. A drainage catheter is inserted to prevent postoperative epidural hematoma.

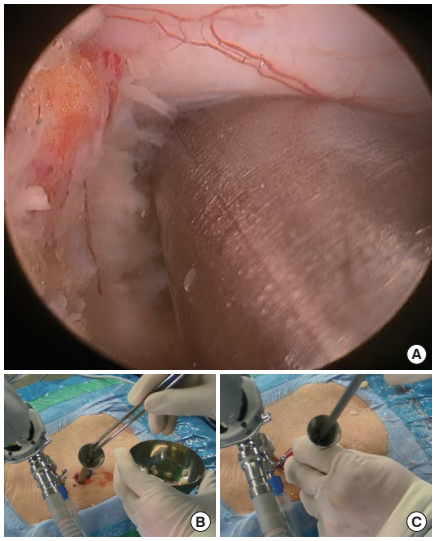

Fig. 5. The fusion materials were inserted into the intervertebral space using a funnel before cage insertion (A. endoscopic view). (B, C) Overview of fusion material insertion using a funnel and an impactor.

CASE PRESENTATIONS

1. Case 1 (1 cage insertion technique)

A 56-year-old female patient presented with back pain, claudication, and radicular pain in both the legs. The more painful side was the right leg. The preoperative magnetic resonance imaging (MRI) and x-ray images demonstrated degenerative spondylolisthesis with stenosis at L4–5 (Fig. 6). We performed biportal endoscopic TLIF of the L4–5 level. Biportal endoscopic TLIF was performed with the right approach. The postoperative MRI showed a reduction in spondylolisthesis and good decompression status of the central stenosis (Fig. 6). Postoperatively, the patient's symptoms were significantly improved. (Supplementary video clip 1).

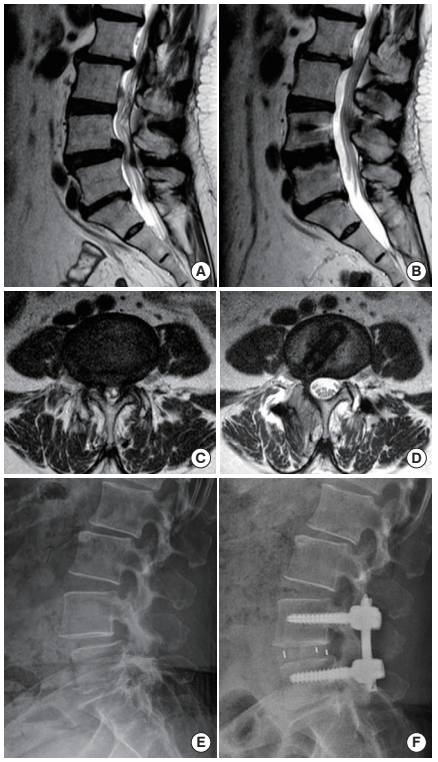

Fig. 6. Radiologic images of a 56-year-old female patient. (A) The preoperative magnetic resonance images show degenerative spondylolisthesis of L4–5. (B) After biportal endoscopic transforaminal lumbar interbody fusion (TLIF), the spondylolisthesis was well-resolved. Central stenosis of L4–5 (C) was decompressed after surgery (D). (E) The preoperative x-ray also revealed spondylolisthesis of L4–5. (F) The postoperative x-ray showed the large TLIF cage and percutaneous pedicle screw inserted.

2. Case 2 (2 cages insertion technique)

A 55-year-old female patient presented with radicular pain in both legs and neurological intermittent claudication. The preoperative MRI and x-ray images revealed degenerative spondylolisthesis with central and foraminal stenosis at L4–5 (Fig. 7). The patient underwent biportal endoscopic TLIF with a 2-cage insertion technique. The postoperative MRI and x-ray images

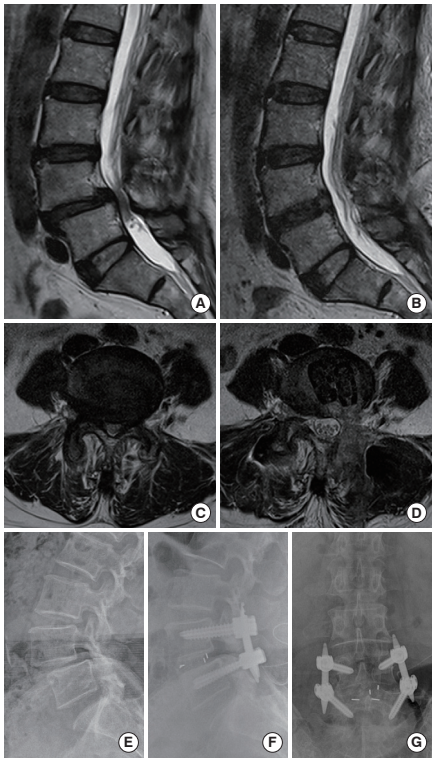

Fig. 7. A 55-year-old female patient presented with pain with claudication in both legs. (A) The preoperative magnetic resonance imaging showed degenerative spondylolisthesis with central stenosis at L4–5. (B) This patient received biportal endoscopic transforaminal lumbar interbody fusion using the 2-cage insertion technique. Preoperative spondylolisthesis (A) and central stenosis (C) were significantly resolved postoperatively (B, D). (E) The preoperative x-ray image demonstrates degenerative spondylolisthesis of L4–5. (F, G) The postoperative x-ray images reveal a reduction in spondylolisthesis and the presence of 2 inserted cages. The pain was significantly improved after surgery.

demonstrated a significant reduction in spondylolisthesis and good decompression of the neural structures (Fig. 7). The pain was resolved after the biportal endoscopic TLIF (Supplementary video clip 2).

DISCUSSION

Conceptually, this biportal endoscopic TLIF approach might have the advantages of both MIS fusion and endoscopic surgery. Theoretically, biportal endoscopic fusion surgeries may be suitable for endoscopic assistant fusion surgery. However, the term seems to be confused with air-based microendoscope-assisted fusion surgeries. Microendoscope-assisted TLIF was performed using tubular retractor systems. Therefore, we suggested that the term of endoscopic TLIF may be better than endoscope-assisted TLIF in the water-based endoscopic lumbar interbody fusion surgeries. This technique is based on conventional microscopic TLIF procedures.[1] Therefore, it is possible to achieve the direct decompression of neural tissue by biportal endoscopic TLIF,[14,15] and insert large, long TLIF cages, like in MIS TLIF.[4,5] The contralateral nerve root could be fully decompressed through the contralateral sublaminar approach.[4,14] The contralateral sublaminar approach for contralateral nerve root decompression is one of the advantages of the biportal endoscopic approach.[3,15] Also, indirect decompression was achieved by the reduction of spondylolisthesis and the restoration of the collapsed disc space. Since we could insert a large, long cage for conventional TLIF, the narrowed disc space was distracted by the insertion of a large-sized cage.[5]

The direct decompression of central canal and nerve roots was performed by removing the ligamentum flavum, and by laminectomy and facetectomy.[5,14] Since there was a possibility of exiting nerve root injury during insertion of a cage, we usually decompressed the ipsilateral exiting nerve root after a cage insertion. The lateral remnant of the superior articular process imparted protection to the exiting nerve root during cage insertion. If patients had severe foraminal stenosis or foraminal disc herniation, we performed direct foraminal decompression through a total facetectomy.

The distraction of narrowed disc space was important to cage insertion and for performing indirect decompression. The placement of serial dilators or cages trials into the disc space led to disc space distraction without endplate injury. It was further hypothesized that contralateral medial facet release may be important for the reduction of spondylolisthesis and the restoration of disc height. We performed contralateral facet release

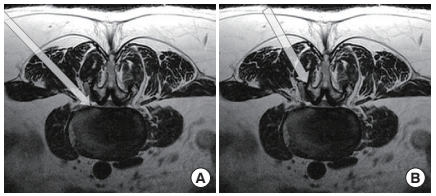

Fig. 8. Two types of endoscopic transforaminal lumbar interbody fusion (TLIF). The trans-Kambin approach (A) and the posterolateral approach (B). The trans-Kambin approach was similar to transforaminal lumbar discectomy and the posterolateral approach was similar to minimally invasive TLIF with tubular retractor systems.

through complete removal of the contralateral ligamentum flavum around the facet joint and partial removal of the contralateral superior articular process. Some clinicians prefer to insert 2 cages rather than 1 cage. By using the biportal endoscopic approach, it is possible to insert 2 PLIF cages via a unilateral biportal endoscopic approach.

Two types of endoscopic lumbar interbody fusion surgeries can be used, depending on the surgical approaches (Fig. 8, Table 1). The first is the trans-Kambin approach (Fig. 8A),[6,7,13,19] and the other is a posterolateral approach (Fig. 8B).[2,4,11] The trans-Kambin endoscopic TLIF procedure was performed via Kambin's triangle, like fully endoscopic transforaminal lumbar discectomy. Endplate preparation and cage insertion were performed via Kambin's triangle.[6] The posterolateral approach is similar to MIS TLIF surgery. The posterolateral endoscopic TLIF approach is based on MIS TLIF (Fig. 8B).[5,11,18] Direct decompressive procedures, including ipsilateral laminotomy and total facetectomy, were performed in the posterolateral endoscopic TLIF approach. Although endoscopic TLIF through the trans-Kambin approach is less invasive than the posterolateral approach, the disadvantage of the trans-Kambin approach is exiting nerve root injury. Previous studies reported the frequency of exiting nerve irritation or injury from 0% to 22% in the trans-Kambin approach in uniportal endoscopic TLIF.[7,19] Since a cage is inserted through Kambin's triangle, there might be a high possibility of exiting nerve root injury during insertion. Direct decompression and endplate preparation may also be limited in the trans-Kambin approach.

In contrast, the posterolateral approach might have a lower possibility of exiting nerve root injury during cage insertion. Before cage insertion, full neural decompression procedures were performed. Enough space for cage insertion was made

Table 1. Comparison of 2 types of endoscopic TLIF

Variable	Trans-Kambin approach	Posterolateral approach
Bone work	Ipsilateral superior articular process (Foraminoplasty)	Ipsilateral superior articular process and inferior articular process Ipsilateral lamina
Direct decompression		
Ipsilateral	Possible	Possible
Contralateral	Impossible	Possible
Indirect decompression	Possible	Possible
Endplate preparation	Direct sighted under endoscopic view	Direct sighted under endoscopic view
Cage insertion	One cage	One or 2 cages
Exiting nerve root injury	Slightly higher than the posterolateral approach	A little
Similar surgical approach	Transforaminal endoscopic discectomy	Minimally invasive TLIF

TLIF, transforaminal lumbar interbody fusion (trans-Kambin approach versus posterolateral approach).

Table 2. Summary of publications of biportal endoscopic lumbar interbody fusion

Study	Publication year	Study design	Cases	Follow-up (mo), mean ± SD	Clinical outcomes	Perioperative complications
Heo et al.[5]	2017	Cases series	69 Cases	13.5 ± 7.1	Improvement of VAS and ODI	Dura tear (2), hematoma (3)
Kim and Choi[18]	2018	Cases series	14 Cases		Improvement of VAS	L5 root palsy (1), dura tear (1)
Heo et al.[4]	2019	Cases control study	23 Cases (biportal), 45 cases (microscopic)	13.4 ± 2.5	Improvement of VAS and ODI	Hematoma (1)
Park et al.[11]	2019	Cases control study	71 Cases (biportal), 70 cases (conventional)	17.1 ± 4.9	Improvement of VAS and ODI	Dura tear (3), infection (1) Hematoma (1)
Ahn et al.[2]	2019	Systemic review	-	-	-	-

SD, standard deviation; VAS, visual analog scale; ODI, Oswestry Disability Index.

through facetectomy and laminectomy. We could also achieve complete direct decompression of the central canal and nerve roots, like in MIS TLIF. We could place the cages safely during biportal endoscopic TLIF.[5] This posterolateral approach was available in biportal or uniportal endoscopic systems.[5]

Five articles on biportal endoscopic fusion surgeries have been published (Table 2).[2,4,5,11,18] Two articles reported the technique and preliminary clinical results. These 2 articles focused on the technical aspect of biportal endoscopic TLIF.[5,18] Additionally, early favorable clinical outcomes were presented. Another 2 articles presented comparative studies of biportal endoscopic TLIF with conventional PLIF or TLIF surgeries.[4,11] Compared to conventional fusion surgeries or MIS fusion surgeries, the benefits of biportal endoscopic fusion were less blood loss and postoperative pain. These advantages of biportal endoscopic TLIF may lead to early recovery and early return to work after surgery. Moreover, the combination of biportal endoscopic fusion surgery with enhanced recovery after surgery programs might reduce complications and shorten hospital stays after surgery.[4] However, biportal endoscopic fusion surgeries were more difficult than conventional open surgery or microscopic surgery with a tubular retractor. A comparison of operation time may offer clues to the technical difficulty. The operation time for biportal endoscopic fusion surgeries was longer than that for conventional PLIF and TLIF surgeries.[4,11] Moreover, there were complications related to biportal endoscopic TLIF. Durotomy, postoperative epidural hematoma, infections, and nerve root palsy have been reported in previously published articles (Table 2).[2,4,5,11,18] Although the reported complications related to biportal endoscopic TLIF were mainly minor, endoscopic fusion procedures are very difficult and have the possibility of major complications. Incomplete surgery may be another problem of endoscopic fusion surgeries. Therefore, we strongly recommend that endoscopic fusion surgeries should

be tried after extensive experience with endoscopic surgeries, such as endoscopic decompression and endoscopic discectomy using uniportal or biportal endoscopy.

The last article was a review article about endoscopic TLIF, including biportal as well as uniportal endoscopic systems.[2] There were only short-term clinical outcomes of endoscopic TLIF and no randomized case-control studies of endoscopic lumbar fusions. Consequently, this review article was not able to conclude the advantages and superiority of endoscopic TLIF.[2]

Compared with MIS TLIF, biportal endoscopic approaches may afford better endplate preparation. We could insert an endoscope into the intervertebral disc space during endplate preparation. It was possible to precisely demonstrate the condition of the endplate via endoscopy. The cartilaginous endplate was separated and removed from the osseous endplate under a magnified endoscopic view.[4] General instruments used for endplate preparation, such as an angled curette, box designed curette, and angled pituitary forceps, were available to perform complete endplate preparation under endoscopic guidance. Thirty-degree endoscopy and angled instruments may be useful for contralateral disc removal and endplate preparation. Endoscopy-guided endplate preparation may prevent osseous endplate injury during endplate preparation and subsidence of a cage. One of the important purposes of lumbar fusion surgery is the restoration of segmental lordosis. Since the biportal endoscopic TLIF technique achieved complete facetectomy and could accommodate the insertion of a large TLIF cage, this biportal endoscopic approach might be as good as MIS TLIF in restoring segmental lordosis.

Biportal endoscopic TLIF exhibited similarity with MIS TLIF with a tubular retractor and has several advantages of endoscopic approaches. However, a long-term follow-up study and randomized case-control studies should be performed.

CONCLUSION

Herein, we present the technique and literature review of biportal endoscopic TLIF. Biportal endoscopic TLIF might have the advantages of MIS fusion surgeries as well as those of the endoscopic approach. Direct decompression, endoscopically guided endplate preparation, and the insertion of large cages may be the merits of biportal endoscopic lumbar fusion procedures. To reveal the efficacy and clinical usefulness of the biportal technique, long-term blinded, randomized case-control studies are needed.

POINTS OF THE SURGICAL TECHNIQUE

1. In the biportal endoscopic TLIF technique, direct decompression was first performed via unilateral laminotomy with bilateral decompression.
2. The inferior articular process, as well as the superior articular process, was removed for safe insertion of a large cage.
3. The cartilaginous endplate should be completely removed from the osseous endplate for interbody fusion under a magnified, clear endoscopic view. It was possible to demonstrate endplate conditions during the endplate preparation procedure via endoscopy.
4. A large volume of fusion materials, including auto-bone, allo-bone, and demineralization bone matrix, should be inserted via a funnel before insertion of the cage.
5. The release of the medial part of the contralateral facet joint may be helpful for disc space distraction and the reduction of spondylolisthesis.
6. Percutaneous pedicle screw insertion was subsequently performed after the interbody fusion procedures.

CONFLICT OF INTEREST

The authors have nothing to disclose.

SUPPLEMENTARY MATERIALS

Supplementary video clip 1-3 can be found via https://doi.org/10.14245/ns.2040178.089.v.1, https://doi.org/10.14245/ns.2040178.089.v.2, and https://doi.org/10.14245/ns.2040178.089.v.3.

Supplementary video clip 1. Left-sided biportal endoscopic TLIF with the insertion of one TLIF cage. Video clip 2. Left-sided biportal endoscopic TLIF with the insertion of 2 PLIF cages. Video clip 3, the author's interview and overall surgical procedures.

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The Spine Journal 21 (2021) 2066–2077

Clinical Study

Minimally invasive transforaminal lumbar interbody fusion using the biportal endoscopic techniques versus microscopic tubular technique

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Received 14 March 2021; revised 13 June 2021; accepted 14 June 2021

Abstract

BACKGROUND CONTEXT: Minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) with microscopic tubular technique is an established surgical procedure with several potential advantages, including decreased surgical-related morbidity, reduced length of hospital stay, and accelerated early rehabilitation. A recently introduced biportal endoscopic technique for spine surgery presents familiar surgical anatomy and can be conducted using a conventional approach with a minimal footprint; it is also applicable to TLIF.
PURPOSE: To compare the clinical and radiological outcomes of biportal endoscopic technique transforaminal lumbar interbody fusion (BE-TLIF) and microscopic tubular technique transforaminal lumbar interbody (MT-TLIF) in patients with single- or two-segment lumbar spinal stenosis with or without spondylolisthesis.
STUDY DESIGN: A retrospective cohort study.
PATIENT SAMPLE: One hundred two participants with neurogenic intermittent claudication or lumbar radiculopathy with single- or two-level lumbar spinal stenosis with or without spondylolisthesis.
OUTCOME MEASURES: Clinical outcomes were assessed using the visual analog scale (VAS) score for the back and leg pain, Oswestry Disability Index (ODI), and the Short Form-36 health survey Questionnaire (SF-36). Demographic data, operative data (total operation time, estimated blood loss, amount of surgical drain, postoperative transfusion, and length of hospital stay), and laboratory results (plasma hemoglobin, serum creatine phosphokinase, and C-reactive protein) were also evaluated. The fusion rate was assessed using the Bridwell interbody fusion grading system. Postoperative complications were also noted.
METHODS: Patients were divided into two groups: group A (BE-TLIF) and group B (MT-TLIF). The clinical outcomes, including VAS-Back and VAS-Leg, ODI, and SF-36 scores, were evaluated at 1 month, 6 months, and 1 year after surgery. Differences in demographics, operative data, and the laboratory and radiological results were assessed between the two groups. The fusion rate was assessed using standard standing lumbar radiographs and computed tomography scans conducted 1 year after surgery.
RESULTS: Seventy-nine patients were analyzed in this study, 47 from group A and 32 from group B. Demographic and operative data were comparable for both the groups. The VAS-Back and SF-36 scores were more significantly improved in group A than in group B at 1 month after surgery. However, there were no significant differences between groups for the mean VAS-Back, VAS-Leg, ODI, and SF-36 scores at 1year after the surgery. Although the total operation time was significantly longer in group A, the estimated blood loss and the amount of surgical drainage was significantly higher in group B ($p < .001$). There were no between-group differences for the fusion rate and postoperative complications.
CONCLUSION: Both BE-TLIF and MT-TLIF provided equivalent and favorable clinical outcomes and fusion rates. Further large-scale, randomized, controlled trials with long-term follow-ups are warranted.

Keywords: Biportal endoscopic technique; Microscopic tubular technique; Minimally invasive surgery; Transforaminal lumbar interbody fusion; Lumbar spinal stenosis; Neurogenic intermittent claudication; Lumbosacral radiculopathy

FDA device/drug status: Approved (Titanium porous interbody cage (Tiporous; Conduit EIT cellular titanium cage, De PuySynthes, MA, USA); percutaneous pedicle screw system (ANAXTM 5.5 MIS spinal system, U&I Corporation, Gyeonggi, Korea)

Author disclosures: ***MSK:*** Nothing to disclose. ***KHY:*** Nothing to disclose. ***JYC:*** Nothing to disclose. ***DHH:*** Nothing to disclose. ***HJC:*** Nothing to disclose. ***HJP:*** Nothing to disclose.

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https://doi.org/10.1016/j.spinee.2021.06.013
1529-9430/

Introduction

Minimally invasive transforaminal lumbar interbody fusion (MIS-TLIF) with the microscopic tubular technique (MT) uses a muscle splitting approach with paramedian incisions and a tubular retractor system to minimize the paravertebral musculature injury, blood loss, postoperative pain, opioid consumption, and to improve the mobilization, recovery, and the length of hospital stay during the immediate postoperative period. It possesses equivalent fusion rates and long-term functional outcomes compared to the conventional posterior lumbar interbody fusion (PLIF) and TLIF [1–6]. Microscopic tubular technique transforaminal lumbar interbody fusion (MT-TLIF) requires a high degree of dependence on tubular retractor systems, leading to a challenge for achieving sufficient neural decompression and interbody grafting due to the limited surgical visualization and a risk of a significantly increased radiation exposure [7]. A few studies reported that MT-TLIF resulted in a relatively long operation time, increased revision and readmission rates, increased hardware-related complications, and a higher incidence of nerve root injury, which may be associated with the deep learning curve [8,9].

A recently introduced biportal endoscopy (BE)-assisted technique for spine surgery separates the viewing and working channels and allows for continuous fluid irrigation through two independent surgical ports, in contrast to the uniportal endoscopic spine surgery. Using two independent transmuscular tracts as viewing and working portals results in free movement of the surgical view and dynamic handling of surgical instruments, allowing for a relatively short learning curve [10,11]. BE can be used for all MIS spinal decompression procedures, such as unilateral laminotomy for lumbar discectomy, unilateral laminotomy for bilateral decompression, and unilateral foraminotomy for decompression, all of which have demonstrated good clinical efficacy [12]. Furthermore, BE can be applied to lumbar interbody fusion surgery [13–15].

In prospective clinical trials, BE-assisted decompressive laminectomy is comparable to conventional microscopic decompressive laminectomy in long-term outcomes of up to 2-years, with advantages that include decreased postoperative pain and opioid consumption and earlier rehabilitation [16–19]. These advantages by BE could be useful for lumbar interbody fusion surgery; however, there is a lack of clinical evidence for BE-assisted transforaminal lumbar interbody fusion (BE-TLIF). The purpose of this study was to compare the clinical and radiological outcomes of BE-TLIF with MT-TLIF after at least 1 year.

Material and methods

Study design and patient population

This retrospective cohort study of prospectively collected data was conducted on 102 consecutive patients who underwent BE-TLIF (57 patients) and MT-TLIF (45 patients) between March 2018 and July 2019. Written informed consent was obtained from all patients.

The inclusion criteria were as follows: 1) Patients aged between 40 and 80 years who had undergone single- or two-segment MIS-TLIF, and had radiating pain in the lower extremities (visual analog scale [VAS] score ≥4) and/or neurogenic intermittent claudication and 2) Definite lumbar spinal stenosis with or without low-grade degenerative spondylolisthesis (grade ≤2), low-grade isthmic spondylolisthesis (grade ≤2), and segmental instability (anterior translation [>3 mm] and/or increasing segmental sagittal motion [>15°]) on plain standing radiographs and magnetic resonance imaging (MRI). The exclusion criteria were having high-grade degenerative and isthmic spondylolisthesis (grade >2), advanced adult spinal deformity (coronal Cobb's angle >25°), other spinal diseases (eg, spine infection, ankylosing spondylitis, other inflammatory spondylitis, spinal tumor, spinal trauma, or neurologic disorders), cognitive and psychological disorders (eg, Alzheimer dementia, intellectual disability, or drug abuse), and other disorders that the surgeon considered inappropriate for participation in the study. During the study, there were 10 follow-up losses in Group A and 11 in Group B. In addition, one patient in Group B who died from pneumonia and another patient in Group B had an osteoporotic verterbral compression fracture were excluded from the study. Therefore, 23 of the initially included 102 patients were excluded,

and the study was conducted with 47 patients and 65 segments in Group A, and 32 patients and 43 segments in Group B (Fig. 1).

All operations were performed by two spine surgeons (MSK and HJP) with more than 1 year of experience in biportal endoscopic spine surgery and 5 years of experience in microscopic spine surgery. The choice of technique was based on the surgeon's preference and experience. There was no specific contraindication or exclusion in selecting either surgical technique. This study was approved by the Institutional Review Board (IRB approval No: 2020-07-018) of XXX.

Surgical procedure

MT-TLIF was performed using surgical microscopic visualization under a tubular retractor system (METRx system; Medtronic Sofamor Danek, Memphis, TN, USA) or Insight Access Tube set (DePuy Synthes Spine; Reynham, MA, USA). BE-TLIF was performed using a general arthroscopic surgical system (4-mm, 0°, or 30°; ConMed Linvatec, Largo, FL, USA) using an automated pressure-controlled pump system (10 K Fluid System, ConMed Linvatec). All surgeries were implanted in a banana-shaped curved, titanium porous (Ti-porous; Conduit EIT cellular titanium cage, DePuy Synthes, West Chester, PA, USA) interbody cage using a unilateral approach. In addition, mixtures of autogenous local bone and demineralized bone matrix were grafted into the disc space, and bilateral posterior instrumentation was performed using a percutaneous pedicle screw system with a compression/distraction rack device (ANAX 5.5 MIS spinal system, U&I Corporation, Gyeonggi, Korea).

Under general endotracheal anesthesia, all patients were placed in a knee-flexed prone position on the operating table over a radiolucent Wilson frame. Before surgical prepping, the C-arm fluoroscopic anteroposterior and lateral images were obtained to ensure that the pedicles and endplates could be adequately imaged prior to the surgery. After making a surgical incision and setting the tubular retractor system, the surgical process for MT-TLIF was performed according to Schwender et al. [20].

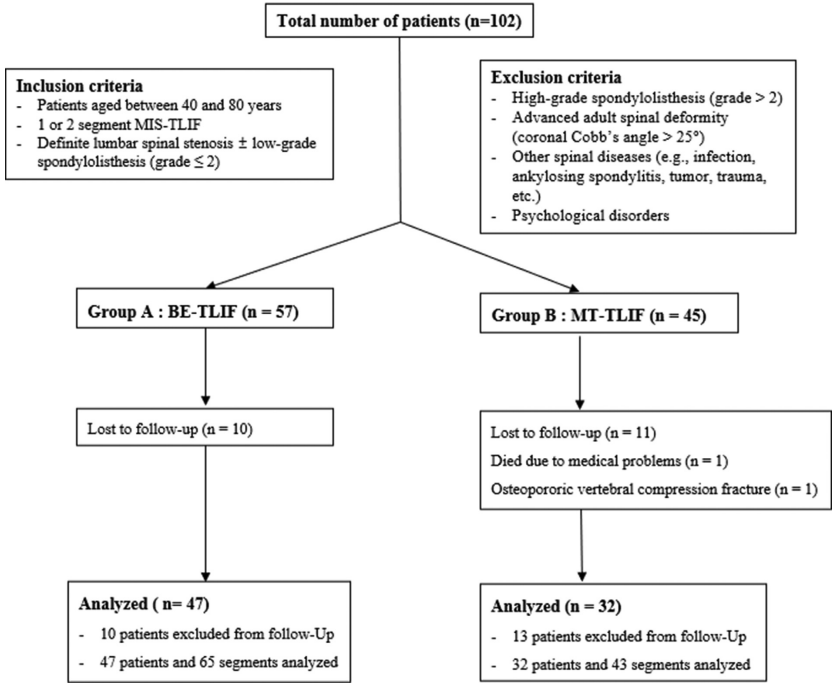

Fig. 1. Flowchart of patient inclusion. MIS-TLIF, minimally invasive transforaminal lumbar interbody fusion; BE-TLIF, biportal endoscopic technique transforaminal lumbar interbody fusion; MT-TLIF, microscopic tubular technique transforaminal lumbar interbody fusion.

For BE-TLIF, two 1-cm long vertical skin incisions were placed right outside the lateral pedicular line of the target segment. These two independent surgical ports were referred to as the P(R) and P(L) ports. In addition, another 0.7 cm long transverse skin incision was made at the point where the intervertebral disc meets with the medial pedicular margin and is referred to as the quarterback (Q) port (Fig. 2). Through each surgical port, the soft tissues were gently peeled from the vertebral isthmus, lamina, and facet joint using a small periosteal elevator. A 4 mm, 0° endoscope was inserted through the P(L) port and the surgical instruments through the P(R) port; this could be reversed following the surgeon's preferences. An automated pressure-controlled pump system was connected to the endoscope and set to a pressure of 30−35 mmHg during the surgery. While maintaining continuous fluid irrigation through each surgical port, an arthroscopic tissue shaver was used for tissue dissection and a bipolar radiofrequency thermo-controlled ablator (bRFA) was used for tissue cauterization and vascular coagulation.

After endoscopic visualization of the ipsilateral inferior and superior articular processes of the facet joint and the upper and lower vertebral lamina, bilateral laminotomy was performed using a diamond high-speed drill and chisel until the boundary of the ligamentum flavum was attached to the bilateral upper and lower lamina, and the facet joint was identified. We carefully performed en-block flavectomy and further neural decompression to identify the contralateral exiting nerve root and the bilateral transversing nerve roots. Subsequently, the inferior and superior articular processes were resected and the lateral extension of the ligamentum flavum was removed exposing the ipsilateral exiting nerve root and Kambin's triangle (Fig. 3, Supplementary Video 1).

Annulotomy was performed using an Indian knife, the serial disc reamers were inserted into the disc and the nuclear fragmentectomy was performed. The cartilaginous endplate was carefully removed using a small-head angled curette and bRFA [21]. A serial trial implant was used to determine the height of the intervertebral disc with minimal endplate injury and the real implant size. Graft materials were placed in the anterior disc space through a funnel and a banana-shaped interbody cage was placed in the intervertebral space. During this stage, the dura and traversing root can be protected by inserting a dural retractor into the Q portal. Once the cage was inserted at a suitable depth, the interbody cage was reposed using the cage impactor so that it was parallel to the sagittal and coronal planes within the intervertebral disc (Fig. 4, Supplementary Video 2). Finally, we confirmed whether the cage position crossed the midline of the intervertebral disc and whether it was aligned in the sagittal and coronal planes. After hemostasis was achieved, a surgical drain tube was inserted into the Q port. The endoscopic equipment was removed from the surgical field and bilateral percutaneous pedicle screw fixation was performed using conventional methods through the previous incision (Fig. 5).

Postoperative protocol

Neurological evaluations were performed in the recovery room immediately following the surgery. The patients were monitored for 24 hours after the surgery for any complications. Postoperative MRI examination was performed 2 days after the surgery. All patients were encouraged to ambulate on postoperative day 1. For postoperative pain control, we employed automatic intravenous patient-controlled analgesia with 1 mL of continuous infusion and 1 mL of bolus infusion with a 15-minute lockout interval, combined with 25 μg/kg fentanyl, 0.3 mg Ramosetron, and saline until postoperative day 2. Additional tramadol injection was used for pain control upon request by the patients (VAS score>5). After the patient-controlled analgesia was removed, patients were administered a transdermal 5 mg buprenorphine patch (NORSPAN patch, Mundipharma Korea Ltd., Seoul, Korea) at 4 weeks after surgery.

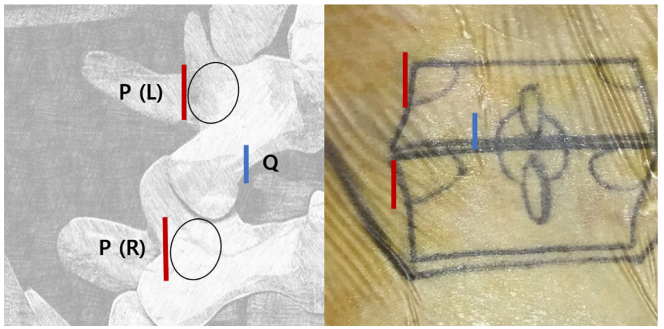

Fig. 2. P (R) and P (L) ports were placed right outside the lateral pedicular line of the target segment. Q port was placed where the intervertebral disc meets with the medial pedicular margin.

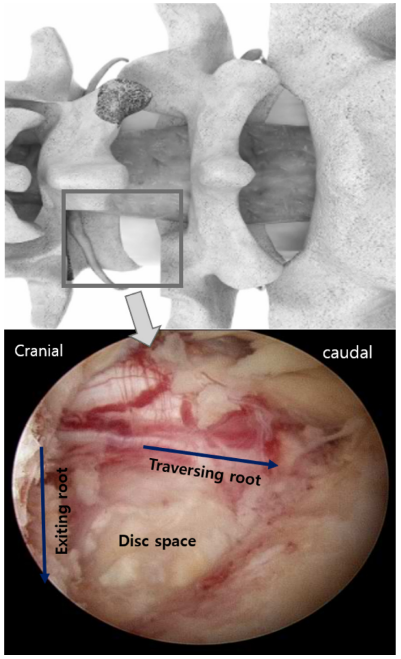

Fig. 3. Endoscopic image of Kambin's triangle. The inferior and superior articular processes were subsequently resected, and the lateral extension of the ligamentum flavum was removed.

Outcomes and measurements

Baseline demographic data were collected, including age, sex, height, weight, body mass index, bone marrow density, and American Society of Anesthesiologist physical status classification score. The clinical outcomes included the VAS score for the axial back (VAS-Back) and leg pain (VAS-Leg), Oswestry Disability Index (ODI), and Short Form-36 health survey Questionnaire in Spine Surgery (SF-36), at baseline and at 1, 6, and 12 months after the surgery. Radiologic measurements, including disc height, segmental sagittal Cobb angle, and lumbar lordotic angle were evaluated through standard standing lateral radiographs at baseline and at 1, 6, and 12 months after the surgery. At 1 year after surgery, plain standing radiographs and computed tomography (CT) scans were performed and the fusion rate was assessed following the Bridwell interbody fusion grading system. Two blinded independent observers measured the spinal fusion grade. For patients included in the final follow-up examination, clinical outcome measurements and postoperative 1-year CT scans were performed.

Operative data including the total operation time (from skin incision to skin closure), estimated blood loss, amount of surgical drain, postoperative transfusion, and hospitalization duration (duration of hospital stay after the operation) were recorded. In addition, kinetics of plasma hemoglobin, serum creatine phosphokinase (CPK), and C-reactive protein (CRP) were measured at baseline and at 1, 3, and 7 days after surgery. Perioperative complications were defined as intraoperative or postoperative complications within 4 weeks after surgery. Late complications were defined as complications from 4 weeks to the final follow-up examination. Recurrent pain was defined as recurrent axial back and/or leg pain with a VAS score of ≥4 during the follow-up period.

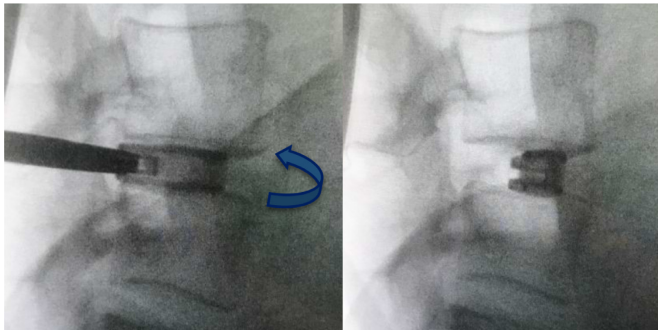

Fig. 4. The cage was inserted at a suitable depth and reposed the interbody cage using the cage impactor so as to be parallel to the sagittal and coronal plane within the intervertebral disc.

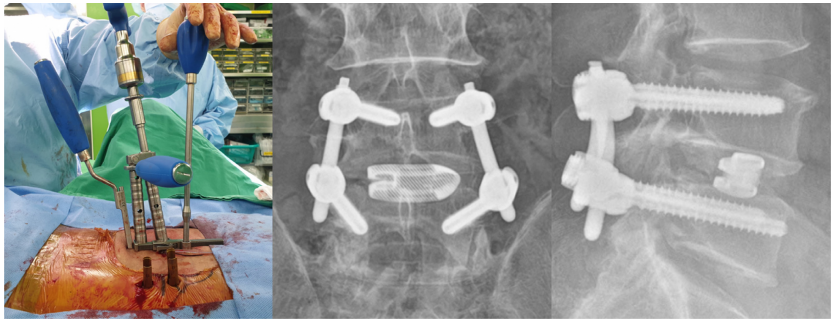

Fig. 5. Bilateral percutaneous pedicle screw fixation was performed using the conventional methods through the previous incision.

Statistical analysis

Patients were divided into Groups A (BE-TLIF) and B (MT-TLIF). Independent t-test (two groups) or ANOVA (>two groups) were used for comparing the normal continuous variables between the two groups. Non-normal continuous variables were analyzed using the Kruskal–Wallis test. Operative data and perioperative complications were analyzed using Fisher's exact test. A p-value ≤.05 was considered statistically significant. All statistical analyses were performed using SPSS (IBM Corp., Armonk, NY, USA).

Results

Data of 79 patients (47 and 32 in Groups A and B, respectively) were analyzed in this study. The mean age of patients was 66.87 ± 10.41 and 66.38 ± 9.45 years in Groups A and B, respectively. There was no significant difference in the preoperative diagnosis and fusion level between the two groups. Demographics were comparable in both groups and are summarized in Table 1. The mean follow-up period was 15.01 ± 2.53 months (Table 1).

Clinical outcomes

For both groups, all clinical parameters of the VAS-Back, VAS-Leg, ODI, and SF-36 scores improved significantly over the baseline value from 4 weeks onwards after surgery, which lasted until the final follow-up examination (p < .05); there was no significant difference between groups for the mean VAS-Back, VAS-Leg, ODI, and SF-36 scores at baseline and at 6 and 12 months after the surgery. However, the VAS-Back and SF-36 scores improved more significantly in Group A than in Group B at 4 weeks after the surgery. (Fig. 6)

Radiological outcomes and spinal fusion rate

There was no difference in the radiologic parameters before and after surgery between the two groups for the segment disc height, segmental sagittal Cobb angle, and lumbar lordotic angle. The spinal fusion status was evaluated following the Bridwell grading system: Group A consisted of eight, 10, four, and zero cases of grades I, II, III, and IV, respectively, whereas Group B comprised 14, 24, five, and zero cases of grades I, II, III, and IV, respectively. In the Bridwell grading system, when grades I and II were defined as spinal fusion, there were no significant differences in the fusion rates between the two groups (81.8% and 88.4%, respectively; p = .63; Table 2). The interobserver reliability of the spinal fusion grade had intraclass correlation coefficients of 0.96 (95% confidence interval [CI], 0.94–0.98).

Operative data, laboratory outcomes, and complications

The total operation time was significantly longer in Group A (170.46 ± 34.81 minute) than in Group B (135.70 ± 42.88 minute; p < .001). However, the mean estimated blood loss and mean amount of surgical drainage was significantly higher in Group B (395.31 ± 180.36 mL; 225.81 ± 101.40 mL) than in Group A (185.74 ± 172.51 mL, p < .001; 163.81 ± 121.04 mL, p = .016). On postoperative day 1, the decrease in the hemoglobin levels compared to the baseline was significantly different in Group B (−2.32 ± 0.99) than in group A (−0.88 ± 0.81; p < .001). However, no differences were observed for the mean hospitalization duration and mean amount of transfusion (Table 3).

The serum CPK and CRP kinetics demonstrated a characteristic increase-and-decrease pattern. In both groups, the CPK levels reached a maximum level on postoperative day 1 (CPK_1) and returned to a normal range on postoperative day 7 (CPK_7). Group B had significantly higher CPK_1 levels (p = .048). The CRP levels reached a maximum level on postoperative day 2 (CRP_2) and returned to a normal range in the second week after surgery (CRP_{14}). The CRP_1 levels were significantly higher in Group B than in Group A (p = .033). The mean CRP_2 values were 3.92 ± 1.87 in

Table 1
Comparison of demographic data between the two groups

		Group A (n = 47)	Group B (n = 32)	P-value
Age (years)		66.87 ± 10.41	66.38 ± 9.45	0.826
Sex (Male: Female)		17: 30	17: 15	0.207
BMI (m/Kg^2)		25.32 ± 3.15	26.23 ± 3.26	0.223
BMD (T-score)		−1.58 ±1.14	−1.46 ± 1.54	0.718
Fusion level (%)	1	29 (61.7)	21 (65.6)	0.907
	2	18 (38.3)	11 (34.4)	
Operation level (%)	L2-3	4 (6.2)	1 (2.3)	0.448
	L3-4	7 (10.8)	9 (20.9)	
	L4-5	34 (52.3)	22 (51.2)	
	L5-S1	20 (30.8)	11 (25.6)	
Cage height (mm)		11.25 ± 1.38	11.14 ± 1.01	0.645
Follow up months		14.5 ± 2.3	15.78 ± 3.16	0.376

BMI, body mass index; *BMD*, bone mineral density.
Note: Values are presented as mean ± standard deviation. Statistical significance was set at $p < 0.05$.

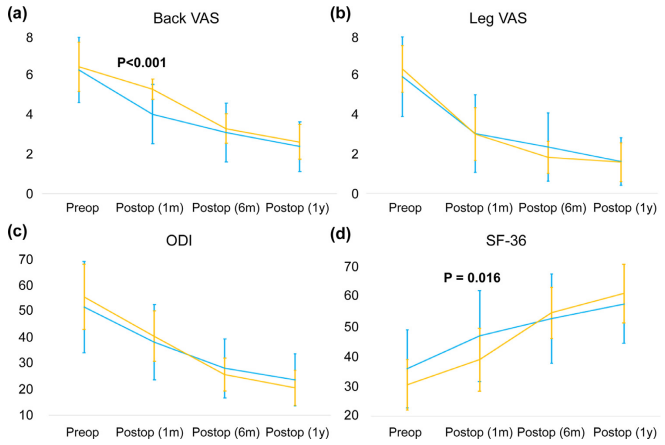

Fig. 6. Clinical outcomes between two groups. Blue line: Group A; Yellow line: Group B. A) VAS-Back. B) VAS-Leg. C) ODI. D) SF-36. In both groups, all clinical parameters improved significantly over the baseline value from 4 weeks after surgery, which lasted until the final follow-up examination ($p < 0.05$). VAS-Back and SF-36 were significantly improved in Group A than in Group B at 4 weeks after surgery. VAS, visual analog scale; ODI, Oswestry Disability Index.

Group A and 8.43 ± 1.29 in Group B; however, no significant difference was observed between the two groups (p = .172) (Fig. 7).

One, two, and three cases of incomplete neural decompression, epidural hematoma, and incidental dural tear, respectively, occurred in Group A. All but one patient who had incomplete neural decompression recovered without a secondary surgery. Two, one, one, and one cases of incomplete neural decompression, epidural hematoma, incidental durotomy, and surgical-site infection, respectively, occurred in Group B. No major complications, such as surgery-related death, thromboembolic events, atelectasis, pneumonia, surgical-site infection, stroke, and neurological damage were observed. There were no between-group differences regarding the complications (Table 4).

Discussion

In this retrospective cohort study, we demonstrated that BE-TLIF delivered comparable clinical outcomes and spinal fusion rates to MT-TLIF at 12 months after the surgery. The VAS-Back and SF-36 scores improved significantly with BE-TLIF in the fourth week after surgery. Although BE-TLIF requires a longer operation time than MT-TLIF, it involves less perioperative blood loss. BE-TLIF results in reduced lower back pain and improved quality of life during

Table 2
Comparison of radiologic outcomes between the two groups

		Group A (n = 65 seg)	Group B (n = 43 seg)	P-value
Preop disc height (mm)		8.39 ± 2.70	7.82 ± 2.49	0.266
Preop op level sagittal angle (°)		8.36 ± 4.22	7.66 ± 3.78	0.371
Preop lumbar lordosis (°)		32.27 ± 13.31	32.10 ± 10.74	0.943
Postop disc height (mm)		10.30 ± 1.90	10.27 ± 3.09	0.949
Postop op level sagittal angle (°)		7.67 ± 4.45	8.11 ± 3.64	0.577
Postop lumbar lordosis (°)		34.35 ± 12.59	37.46 ± 10.88	0.182
*Disc height (mm)		1.94 ± 3.09	2.36 ± 3.98	0.561
*Op level sagittal angle (°)		0.31 ± 5.52	0.75 ± 4.63	0.342
*Lumbar lordosis (°)		2.48 ± 11.94	5.36 ± 7.59	0.141
Fusion (%)†	Yes (1,2)	57 (87.7)	38 (88.4)	0.473
	No (3,4)	8 (12.3)	5 (11.6)	
Fusion grade (%)†	1	24 (36.9)	14 (32.6)	0.630
	2	33 (50.8)	24 (55.8)	
	3	8 (12.3)	5 (11.6)	
	4	0 (0)	0 (0)	

Note: Values are presented as mean ± standard deviation. Statistical significance was set at $p < 0.05$.
* Difference between pre- and postoperative values.
† Bridwell interbody fusion grading system: Grade I is defined as a fusion with remodeling and trabeculae present; Grade II is an intact graft with incomplete remodeling and no lucency present; Grade III is an intact graft with potential lucency at the cranial or caudal end; Grade IV is absent fusion with collapse/resorption of the graft.

Table 3
Comparison of surgical technique related outcomes between the two groups

		Group A (n=47)	Group B (n=32)	P-value
Preop Hb (g/dL)		13.09 ± 1.47	13.23 ± 1.59	0.691
Postop Hb (g/dL)		12.22 ± 1.60	10.92 ± 1.69	0.001*
Hb (△)		−0.88 ± 0.81	−2.32 ± 0.99	< 0.001*
Postop Hemovac drain (mL)		163.81 ± 121.04	225.81 ± 101.40	0.016*
Op time (minutes)		170.46 ± 34.81	135.70 ± 42.88	< 0.001*
Hospital day		14.53 ± 4.14	12.59 ± 4.54	0.058
EBL (mL)		185.74 ± 172.51	395.31 ± 180.36	< 0.001*
Transfusion (%)	0	43 (91.5)	27 (84.4)	0.614
	1	3 (6.4)	4 (12.5)	
	2	1 (2.1)	1 (3.1)	

Hb: Hemoglobin; *EBL*: Estimated blood loss.
Values are presented as mean ± standard deviation. Statistical significance was set at $P < 0.05$.
* $P < 0.05$.

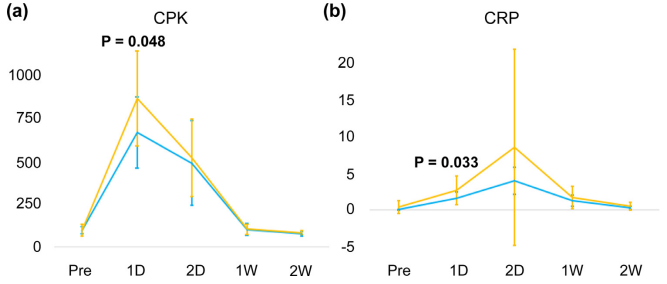

Fig. 7. Laboratory outcomes between two groups. Blue line: Group A; Yellow line: Group B. A) CPK. B) CRP. In both groups, the kinetics of serum CPK and CRP showed a characteristic increase-and-decrease pattern. CPK and CRP were significantly inferior in Group A than in Group B at 1 day after surgery. CPK, creatine phosphokinase; CRP, C-reactive protein.

serum CRP was 8.10 in Group B and >3.89 in Group A; however, this difference was not statistically significant. These findings indicated that the biportal endoscopic technique in transforaminal lumbar interbody fusion produces less inevitable systemic inflammatory response and less iatrogenic muscle injury, which is associated with less postoperative pain and higher quality of life in the early postoperative period. Therefore, the biportal endoscopic technique is a unique and reasonable technique for transforaminal lumbar interbody fusion because it is less invasive and is able to enhance functional recovery.

The fact that wash-out of graft material and osteogenic progenitors, such as hematoma, at the fusion bed may negatively affect spinal fusion because of continuous fluid irrigation is a great concern. However, previous study on transforaminal lumbar interbody fusion assisted with biportal endoscopic technique have reported an acceptable spinal fusion rate of >80%, in line with our findings [13]. Especially, the fusion rate at 12 months after surgery confirmed the non-inferiority of BE-TLIF compared to MT-TLIF. To increase the contact surface between the graft and the vertebral body and the chance of successful spinal fusion, a substantial proportion of disc materials should be removed without any vertebral endplate damage. Thus, the biportal endoscopic technique can provide a clean and magnified real-time surgical visualization, allowing for complete visual inspection of all the fusion beds. Continuous fluid irrigation may prevent the accumulation of heat energy that can cause thermal necrosis of the vertebral bone and endplate, induced by using a power drill and electrocautery. Additionally, Aryan et al. conducted a comparative study on the endplate preparation of lumbar interbody fusion using the conventional method and bRFA; they reported significantly less cage subsidence in the bRFA groups [21]. For endoscopic lumbar interbody fusion, although there is still no clear evidence, complete visual inspection of endplate trabecular bone, dispersion of thermal energy by continuous fluid irrigation, and endplate preparation using bRFA may potentially increase the chances of successful interbody spinal fusion.

This study had several limitations. First, we included a small sample size and a short follow-up period (>12 months). Second, assessment related to changes in the cross-sectional area of the paravertebral muscle through postoperative MRI examination, as an evaluation of muscle damage, was not conducted. Finally, there was heterogeneity in the type and length of conservative treatment, such as oral medication, physical therapy, and selective nerve root block. The strength of this study was that it evaluated various clinical indices, such as the VAS score for pain measure, ODI for the functional outcome, SF-36 for patient satisfaction, and laboratory biomarkers to determine the feasibility and effectiveness of BE-TLIF. However, because of the technical heterogeneity between the BE technique and microscopic tubular technique, sufficient learning curves are required, and considering the available literature, it is recommended to take 60 cases of biportal endoscopic spine surgery and challenge the BE-TLIF [39,40]. A prospective randomized controlled trial with longer follow-up periods and a larger sample size is required for additional assessment of biportal endoscopic transforaminal lumbar interbody fusion.

Conclusions

In this study, BE-TLIF and MT-TLIF provided equivalent and favorable clinical outcomes and fusion rates. Further large-scale, randomized, controlled trials with long-term follow-up periods are warranted.

Declaration of competing interests

The authors declare that they have no competing interests.

Acknowledgments

We would like to thank Editage (www.editage.co.kr) for English language editing. This research was supported by Hallym University Research Fund 2019 (HURF-2019-43).

Supplementary materials

Supplementary material associated with this article can be found in the online version at https://doi.org/10.1016/j.spinee.2021.06.013.

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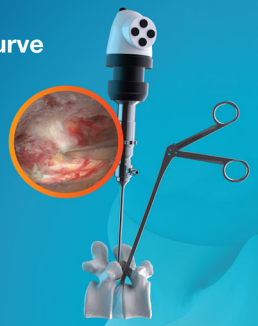

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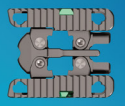

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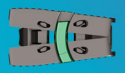
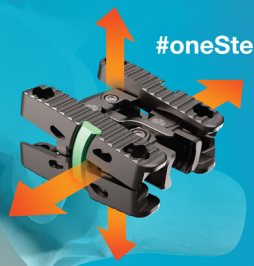


#trueLordosis™
8° 12° 15°

#oneStepExpansion



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