Effect of Electromagnetic Navigation System Assisted Percutaneous Full-endoscopic Foraminoplasty and Discectomy on Lumbar Disc Herniation: A Randomized Controlled Trial

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Research article

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Abstract

Background Electromagnetic navigation-guided technique is an exciting innovative procedure, which has been applied in neurosurgery, otolaryngology, oral and maxillofacial surgery, etc. However, no previous study of the application of electromagnetic navigation to guide endoscopic surgery of disc herniation has been reported. Here, we introduce a new technique of electromagnetic navigation system assisted percutaneous full-endoscopic lumbar foraminoplasty and discectomy and compare it to conventional TESSYS technique. Methods This is a prospective, randomized controlled trial. The observation group was treated with SEESSYS, and the control group was treated with the traditional Transforaminal Endoscopic Spinal Surgery System (TESSYS). Overall surgical time and fluoroscopy time were recorded in all cases. Outcomes of symptoms were evaluated by Visual Analog Scale (VAS) score, Oswestry Disability Index (ODI), and modified MacNab criteria (excellent, good, fair and poor). Results 34 patients (SEESSYS, 17 patients; TESSYS, 17 patients) were enrolled in this study. Both overall surgical time and working tube introduction time were significantly shorter in SEESSYS group than that in TESSYS group ($P<0.01$). The fluoroscopy time in SEESSYS group was significantly less than that in TESSYS group ($P<0.01$). Back VAS, leg VAS and ODI at each time point after surgery were not significantly different between two groups ($P > 0.05$). In both the SEESSYS and TESSYS group, there was a significant decrease in back VAS, leg VAS and ODI at each time point after surgery compared with pre-operation respectively ($P<0.01$). The excellent and good rate of SEESSYS group was 95%, which is similar to the 90% in TESSYS group. Conclusions Electromagnetic navigation system assisted percutaneous full-endoscopic foraminoplasty and discectomy may be a safe and effective method for treating lumbar disc herniation and this method has the advantages of shortening operative time and fluoroscopy time compared with conventional TESSYS technique. Trial registration The study was registered at Chinese Clinical Trail Registry on Feb 06, 2020 with the registration
number: ChiCTR2000029604. (http://www.chictr.org.cn/showproj.aspx?proj=49149)

1 Introduction

Lumbar disc herniation (LDH) is a common degenerative disc disease, with an incidence rate between 3.7% and 5.1%[1]. For LDH patients who failed in conservative treatment, surgery should be performed to relieve nerve compression.

In the past few decades, the surgical approach of lumbar discectomy has been constantly minimally invasive, from open and mini-open surgery to minimally invasive technique. In 1999, Yeung AT firstly introduced the Yeung Endoscopic Spine System (YESS) through safe triangle to complete minimally invasive disc surgery and achieved a good outcome[2]. On this foundation, Hoogland T et al. improved the tools, and introduced the concept of foraminoplasty that can be accomplished by reamers to extend maneuvering room of safe triangle, which was known as TESSYS method (transforaminal endoscopic spine system)[3–5]. Nowadays percutaneous endoscopic lumbar discectomy (PELD) is gradually becoming a new gold standard surgical procedure for LDH with the advantages of desirable satisfactory clinical outcome, less trauma, less bleeding, less postoperative pain and faster recovery[2–4, 6]. However,

the steep learning curve, which can easily lead to surgical complications by the beginners' improper operation, is still a major technical obstacle of PELD. Even for surgeons who have extensive operational experience with this technology, multiple intraoperative fluoroscopy is also needed to identify the position of the working tube for safety while excessive X-ray exposure may cause serious potential harm of radiation on the doctors and patients[7].

Electromagnetic navigation-guided technique is an exciting innovative procedure, which provides navigational assistance coupled with steer ability and movability. Now it has been applied in neurosurgery, otolaryngology, as well as oral and maxillofacial surgery[8–10]. Previous studies have showed that electromagnetic navigation could ease the surgeon’s work, reduce complications and minimizes surgery time[9, 11]. It is also used for placement of fiducial markers for stereotactic radiotherapy and accurate navigation to target lesions [12].

At present, electromagnetic navigation has just been applied in spinal surgery for pedicle screw placement[13, 14]. However, to our knowledge, no previous study of the application of electromagnetic navigation to guide endoscopic surgery of disc herniation has been reported. Here, we introduce a new technique of electromagnetic navigation system assisted percutaneous full-endoscopic lumbar foraminoplasty and discectomy, which applies a new device of I-See (Full Visualization Endoscopic System) Electromagnetic-navigation Endoscopic Spinal Surgery System (SEESSYS) to realize full-visualization of the entire surgical procedure. This article will describe the SEESSYS procedure, compare it to conventional TESSYS technique and outline the challenges of widespread implementation of this new technology.

2 Methods

2.1 Patient selection

This study was approved by the ethics committees of Guangdong Provincial Hospital of Chinese Medicine (Approval No. TF2018-001-1). The institutional review board approved the informed consent and protocol, which described the details of the operation, including prognosis, benefits, potential risks and remedial measures for complications. All methods were in accordance with the relevant guidelines and regulations.

Consecutive patients with clinically-symptomatic LDH undergoing percutaneous endoscopic surgery in our department from September to November 2018 were included in this study. Patients were separated into the SEESSYS group and the TESSYS group using a random number table. The inclusion criteria were 1) Typical lower extremity radiating pain, with or without low back pain; 2) Straight leg elevation test is positive, with/without muscle strength decreased or skin sensitive loss of the nerve root innervation area; 3) Magnetic Resonance Imaging (MRI) and computerized tomography (CT) scan show LDH; 4) The imaging manifestations are correspond to the symptoms and signs; 5) Age > 18 years old; 6) Informed consent to this study. The exclusion criteria were 1) Lumbar hyperextension and hyperflexion X-ray

indicate operative segmental instability; 2) Multiple lumbar disc herniations; 3) Previous surgical history of the responsible segment; 4) Concomitant tumor, tuberculosis, infection or fracture and other disease;5) The patient has psychiatric and could not complete the scale.

2.2 Surgical Tools

Electromagnetic Navigation System (Fiagon, GmbH, Germany) including magnetic field generator, MultiPad, MaperBrige, Localizer, computer mainframe and monitor, kirschner wire and IseePointer (Fig. 1.A-G). I-See (Full Visualization) Endoscopic Spine Surgical System (Joimax®, IseeU, Germany) including needle, guide rod, endoscopy, Isee-reamer with IseePointer (Fig. 1.H-K). And multifunctional plasma radiofrequency electrode system (Xi'an Surgical Medical Technology Co., Ltd., China) were used in the surgery.

2.3 Operative Technique

All operations were performed by the same surgical team. The patient is positioned in the prone position, and local anesthetic is administered.

SEESSYS Procedure. The magnetic field generator is placed near the surgical site (Fig. 2.A). After the kirschner wire is fixed in the spinous process of the adjacent vertebra, the patient localizer is put on the kirschner wire and connected to the computer mainframe (Fig. 2.B). Next, the MaperBrige is placed near the surgical section (Fig. 2.C). Anterior-posterior and lateral lumbar X-ray are measured by the C-arm and those images are transmitted to the navigation host for auto-complete registration. (Fig. 2.D and E). After that, the Multipad is connected to identify and calibrate different devices (Fig. 2.F). Then set the puncture target point (Fig. 3.B) and puncture under the guidance of electromagnetic navigation system (Fig. 3.C). After the guide wire reaches the target position, the stepwise dilatation guiding rods are inserted to expand the soft tissue and the protective sheath tube is inserted (Fig. 3.D). Precise full-visualization foraminoplasty is performed under the endoscope with the guidance of electromagnetic navigation (Fig. 3.E). After that, endoscopic nerve decompression is performed in the same way as TESSYS technique. Under electromagnetic navigation guidance, the real-time position of the endoscope and the range of decompression could be identified clearly on the monitor without any additional X-ray perspective(Fig. 3.F and G).

TESSYS Procedure. Use an 18-gauge needle to access the intervertebral foramen assisted by C-Arm radiographic monitoring. Dilate the surrounding soft tissue by guide tubes of increasing diameter. The intervertebral foramen is then stretched step-by-step by progressively larger reamers. To avoid damage to the dural sac and nerve roots, the whole process of foraminoplasty should be monitored by X-ray fluoroscopy. After the intervertebral foramen is enlarged in the Kambin's Triangle, the working channel and endoscopy is inserted. Then the nucleus pulposus protruding into the spinal canal is resected and the degenerative tissue in the disc is removed. Finally, the fiber annulus is trimmed by using a probe bipolar. Confirm that the nerve root has been completely released.

2.4 Outcome Assessment

Overall surgical time and fluoroscopy time were recorded in all cases. Outcomes of symptoms were evaluated by follow-up interviews at 1 day, 2 weeks, 3 months, 6 months and the last follow-up after surgery. Leg pain and low back pain were measured by Visual Analog Scale (VAS) score (1–10). Functional outcomes were assessed by using Oswestry Disability Index (ODI), and modified MacNab criteria (excellent, good, fair, poor) was measured at last follow-up.

2.5 Statistical Analysis

Statistical analyses were performed with SPSS 18.0 (SPSS, Inc., Chicago, Illinois, USA). Continuous variables were expressed as mean ± standard deviation (SD). The Shapiro-Wilk test was used to check the normality of data. Differences in age, BMI, symptom duration, operation time and fluoroscopy time between two groups were tested using an independent two-sample t-test and chi-square test was used to test for differences in the distribution of categorical variables. Data such as VAS and ODI were analyzed using a two-way analysis of variance (ANOVA) with repeated measures to evaluate change over time (Preoperative, Post-Op 1 day, Post-Op 2 week, Post-Op 3 month, Post-Op 6 month and Last follow-up) and group (SEESSYS and TESSYS). Statistical significance was defined when the probability value was less than 0.05.

3 Results

3.1 Patient Characteristics

A total of 34 patients (SEESSYS, 17 patients; TESSYS, 17 patients) were enrolled in this study. The Shapiro-Wilk test revealed normality of all data ($P > 0.05$). Baseline demographics were not significantly different ($P > 0.05$) between two groups (Table 1). The mean follow-up period was 12.2 months (range from 11 to 13 months).

3.2 Operation time and fluoroscopy time

Overall surgical time included the time to set up the navigation device in SEESSYS group, which is about 5 minutes, including the time of device connection, images transmission and registration. Nonetheless, both overall surgical time and working tube introduction time were significantly shorter in SEESSYS group than that in TESSYS group ($P < 0.01$). What's even more remarkable is that the fluoroscopy time in SEESSYS group was significantly less than that in TESSYS group ($P < 0.01$) (Table 2).

3.3 Back VAS scores

The results of the two-way ANOVA on back VAS showed a significant interaction between groups and time, $F(5,80) = 0.383$, $P < 0.05$. The preoperative back VAS were not significantly different between two groups, $F(1,16) = 1.662$, $P > 0.05$. Back VAS at Post-Op 1 day, Post-Op 2 week, Post-Op 3 month, Post-Op 6 month and Last follow-up were also not significantly different between two groups ($F = 1.362$, $P > 0.05$;

F= 0.086, P > 0.05; F= 0.212, P > 0.05; F = 0.086, P > 0.05; F = 0.027, P > 0.05, respectively). In both the SEESSYS and TESSYS group, there was a significant decrease in back VAS ($p < 0.01$ and $p < 0.01$, respectively) at Post-Op 1 day, Post-Op 2 week, Post-Op 3 month, Post-Op 6 month and Last follow-up compared with pre-operation (Table 3).

3.4 Leg VAS scores

The results of the two-way ANOVA on leg VAS showed a significant interaction between groups and time, $F(5,80) = 91.481$, $P < 0.05$. The preoperative back VAS were not significantly different between two groups, $F(1,16) = 0.459$, $P > 0.05$. Leg VAS at Post-Op 1 day, Post-Op 2 week, Post-Op 3 month, Post-Op 6 month and Last follow-up were also not significantly different between two groups (F= 2.759, P > 0.05; F= 2.085, P > 0.05; F= 0.274, P > 0.05; F = 0.073, P > 0.05; F = 0.019, P > 0.05, respectively). In both the SEESSYS and TESSYS group, there was a significant decrease in leg VAS ($p < 0.01$ and $p < 0.01$, respectively) at Post-Op 1 day, Post-Op 2 week, Post-Op 3 month, Post-Op 6 month and Last follow-up compared with pre-operation (Table 3).

3.5 Oswestry Disability Index

The results of the two-way ANOVA on ODI showed a significant interaction between groups and time, $F(5,80) = 438.349$, $P < 0.05$. The preoperative ODI were not significantly different between two groups, $F(1,16) = 0.236$, $P > 0.05$. ODI at Post-Op 1 day, Post-Op 2 week, Post-Op 3 month, Post-Op 6 month and Last follow-up were also not significantly different between two groups (F= 0.000, P > 0.05; F= 0.274, P > 0.05; F= 0.731, P > 0.05; F = 2.485, P > 0.05; F = 3.347, P > 0.05, respectively). In both the SEESSYS and TESSYS group, there was a significant decrease in ODI ($p < 0.01$ and $p < 0.01$, respectively) at Post-Op 1 day, Post-Op 2 week, Post-Op 3 month, Post-Op 6 month and Last follow-up compared with pre-operation (Table 3).

3.6 Modified MacNab criteria

The excellent and good rate of SEESSYS group was 95% (excellent in 15 patients, good in 4 patients, fair in 1 patients), which is similar to the 90% in TESSYS group (excellent in 15 patients, good in 3 patients, fair in 1 patient, poor in 1 patient).

3.7 Perioperative Complications

The safety is assessed by observing perioperative complications. In the TESSYS group, there was a young patient who had postoperative hyperesthesia, presenting with severe radiating pain of the right lower extremity, which was even more severe than preoperative symptoms. No residual or recurrent disc was found in the postoperative MRI. As a result, he received conservative treatments such as

methylprednisolone, mannitol and mecobalamin. After two weeks, his pain and numbness gradually subsided.

In addition, there were no serious complications such as nerve and blood vessel injury or cerebrospinal fluid leakage in both groups. No wound hematoma, infection and other perioperative complications were found.

4 Discussion

There are two key issues to be addressed to complete PELD. One is to place working tube accurately to the target lesion, the other is to relieve the nerve roots completely from compression without new complications. On account of the complex anatomy of intraspinal canal and the extremely limited room for maneuver, however, there is a high risk of damage to nerves and blood vessels if not handled properly[15].

Some studies have already indicated that, despite the benefits of this minimally invasive technique are outstanding, the learning curve of TESSYS is steep[15–17]. For beginners, it's not so easy to get the working tube into the spinal canal precisely through the safe triangle. Even for surgeons who are already proficient in this procedure, it also needs to be performed with the assistance of multiple X-ray photography to ensure safety. Intraoperative X-ray guided puncture and catheterization is the most commonly used method in current clinical practice. In addition, although with higher image resolution and more accurate localization, CT navigational assistance is also with much greater radiation, which has been also reported in the endoscopic surgery [18, 19]. Radiation damage caused by massive X-rays to patients and doctors is noteworthy, and in fact it has gradually gained attention[20]. Giuseppe reported that there is an increase in the risk of tumours in orthopaedic surgeons exposed to routine radiation [21]. Moreover, neither the CT nor X-ray guided surgical procedure can display the instrument position in real-time, and the process of catheterization is blind operation, which depends on the skill level of the surgeon. Therefore, some new technologies have been introduced in recent years, such as intraoperative ultrasonic monitoring and guidance[22, 23]. Though the ultrasound navigation has contributed to reduce radiation injury, its accuracy is still questionable because ultrasonic perspective is susceptible to bone and air interference. What is more serious is that its blind-spot could bring unpredictable noxious stimulus to nerves and blood vessels. Although the technique combining CT and ultrasonographic imaging can even provide real-time image data, it has not been popularized in the clinic.

Electromagnetic navigation system generates a magnetic field and then uses it to transmit and receive electromagnetic signals to determine the spatial position of the target. The basic principle is to use the magnetic field of known spatial distribution to realize the positioning of objects in the magnetic field according to the data obtained by the sensor[24, 25]. Through the intraoperative real-time positioning system, the position of the surgical instrument in the field is accurately positioned. The operator can observe the actual position of the instruments by referring to the horizontal, coronal and sagittal three-dimensional images displayed on the computer monitor, which can be more accurate[8, 9, 11, 12, 24].

Using electromagnetic navigation in percutaneous full-endoscopic surgery, surgeons can observe the farthest safe position that surgical tools can reach at real time, and maximally remove the lesion to make the decompression effect more thorough.

This study evaluated the clinical outcome, operation and fluoroscopy time of SEESSYS technique compared with the conventional TESSYS approach. The central finding of the study is that in terms of reducing intraoperative radiation exposure, the SEESSYS technique was obviously superior to the TESSYS technique. Besides, although there was no significant difference in clinical efficacy evaluation between the two groups, the overall surgical time and working tube insertion time of the SEESSYS group were shorter than that of the contrast group.

Commitment to quality in every step of the procedure by combining electromagnetic navigation guidance and I-See (Full Visualization) endoscopic system produces highly accurate and safe results. In comparison with optic navigation, electromagnetic navigation reduces fluoroscopy time from X-ray radiation and offers better convenience.

Although the application value of electromagnetic navigation technology in the field of spinal surgery has been reflected, the navigation system cannot replace the surgeon's mastery of anatomical knowledge and surgical training. In fact, it is just a means for assisting doctors to complete precise catheterization and decompression faster and more safely. In addition, to prevent the indication deviation caused by the movement of the patient's position during the operation, the surgeon should verify the accuracy of the navigation system at any time, and once the deviation is found, it should be re-registered immediately. The main limitation of this feasibility study is its small sample size. Therefore, larger-scale studies are needed to corroborate these findings and extend them to a wider population.

5 Conclusions

In summary, electromagnetic navigation provides accurate guidance for percutaneous spinal endoscopy, displaying the anatomical position of the surgical instrument in real time. This technique could help the spine surgeon to remove the lesions to the greatest extent and probably reduce the occurrence of surgical complications, which has great clinical application value. Moreover, this system can reduce fluoroscopy time to doctors and patients. At the moment they are preliminary results with this technique, but obviously the results are encouraging. We believe that the combination of electromagnetic navigation system and endoscopic technology, SEESSYS technology, will further expand the accuracy, safety and efficiency of percutaneous endoscopic surgery.

Declarations

Ethics approval and consent to participate

This study was approved by the ethics committees of Guangdong Provincial Hospital of Chinese Medicine (Approval No. TF2018-001-1). Written informed consent was obtained from individual or

guardian participants.

Consent for publication

Not applicable

Availability of data and materials

All data generated or analysed during this study are included in this published article.

Abbreviations And Acronyms

SEESSYS: I-See (Full Visualization Endoscopic System) Electromagnetic-navigation Endoscopic Spinal Surgery System

YESS: Yeung Endoscopic Spine System

TESSYS: transforaminal endoscopic surgical system

PELD: Percutaneous endoscopic lumbar discectomy

LDH: lumbar disc herniation

MRI: Magnetic Resonance Imaging

CT: computerized tomography

BMI: body mass index

VAS: Visual Analog Scale

ODI: Oswestry Disability Index

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Competing interests

The authors declare that they have no competing interests

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Authors' contributions

Yong-Jin Li and Bo-Lai Chen designed the study and performed the surgery. Yong-Peng Lin, Si-Yuan Rao and Bin-De Zhao wrote the paper. Tao Wen, Li Zhou,b, Guo-Yi Su, Yan-Xin Du reviewed and edited the manuscript. All authors read and approved the final manuscript.

Acknowledgments

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Tables

Table 1. Patient Demographics of the SEESSYS and TESSYS Groups

	SEESSYS group	TESSYS group
Age (years)	50.7610.02	47.8216.68
Sex (male/female)	8/9	11/6
BMI*(kg/m2)	23.762.75	25.412.79
Symptom duration (months)	8.415.75	9.186.13
Level		
L1-2	1	0
L2-3	1	1
L3-4	2	2
L4-5	10	10
L5-S1	3	4

* BMI, body mass index

Table 2. Differences in operation time and fluoroscopy time between SEESSYS and TESSYS Groups

	SEESSYS group	TESSYS group	P Value
Overall surgical time (minutes)	52.9412.88	76.3516.03	0.000
working tube introduction (minutes)	13.592.89	28.415.33	0.000
Decompression (minutes)	39.3513.61	47.9415.10	0.091
Fluoroscopy Time (seconds)	3.652.52	47.359.26	0.000
Postoperative Hospital stay (days)	1.470.62	1.530.62	0.785

Table 3. Comparison of Clinical Outcomes in the SEESSYS and TESSYS Groups

	SEESSYS group	TESSYS group	P Value
VAS of leg pain			
Preoperative	6.590.87	6.410.86	0.059
Post-Op 1st day	1.530.51*	2.121.49*	0.135
Post-Op 2nd week	1.290.59*	1.710.99*	0.149
Post-Op 3rd month	0.820.73*	0.940.66*	0.625
Post-Op 6th month	0.760.66*	0.710.69*	0.801
Last follow-up	0.260.44*	0.290.43*	0.845
VAS of low back pain			
Preoperative	3.290.69	3.530.62	0.303
Post-Op 1st day	1.350.61*	1.590.51*	0.229
Post-Op 2nd week	0.470.66*	0.530.52*	0.741
Post-Op 3rd month	0.590.62*	0.710.69*	0.603
Post-Op 6th month	0.410.51*	0.350.49*	0.734
Last follow-up	0.560.49*	0.530.62*	0.880
ODI			
Preoperative	63.886.91	62.597.27	0.598
Post-Op 1st day	17.763.15*	16.473.50*	0.266
Post-Op 2nd week	13.412.12*	13.062.36*	0.650
Post-Op 3rd month	11.411.69*	10.882.06*	0.419
Post-Op 6th month	9.711.93*	10.651.73*	0.414
Last follow-up	8.941.02*	9.531.28*	0.150

VAS, Visual Analog Scale; ODI, Oswestry Disability Index; Post-Op, postoperative.

*Compared with preoperative, $P < 0.01$.

Figures

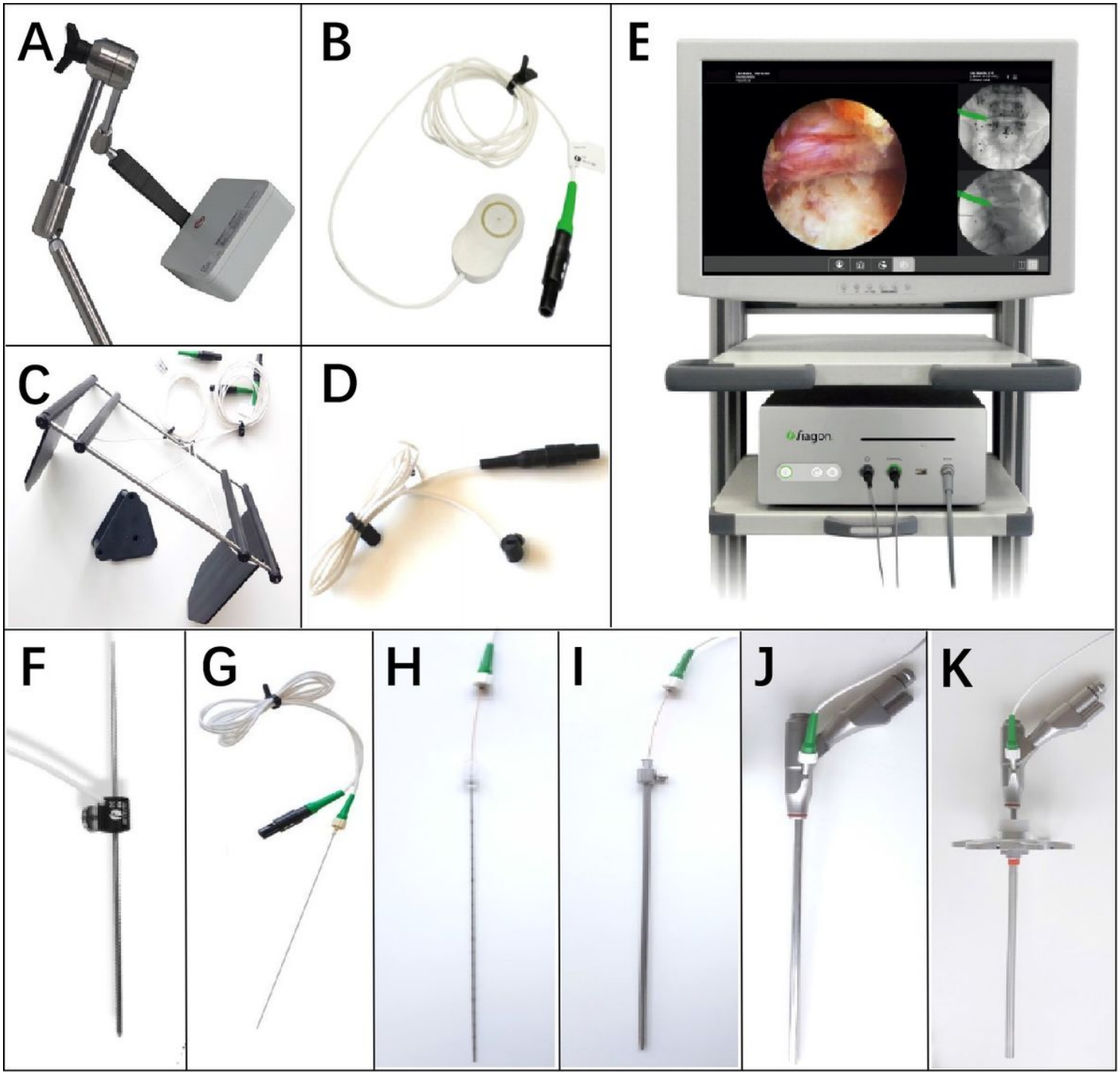

Figure 1

Equipments of TESSYS-Isee Electromagnetic Navigation Endoscopic Spinal Surgery System (SEESSYS). A) Magnetic field generator. B) MultiPad. C) MaperBrige. D) Localizer. E) computer mainframe and monitor. F) kirschner wire is used to connect localizer. G) IseePointer is a navigation probe instrument for image-guided surgery. H) Needle with IseePointer. I) Guide rod with IseePointer. J) Endoscopy with IseePointer. K) IseeReamer with IseePointer.

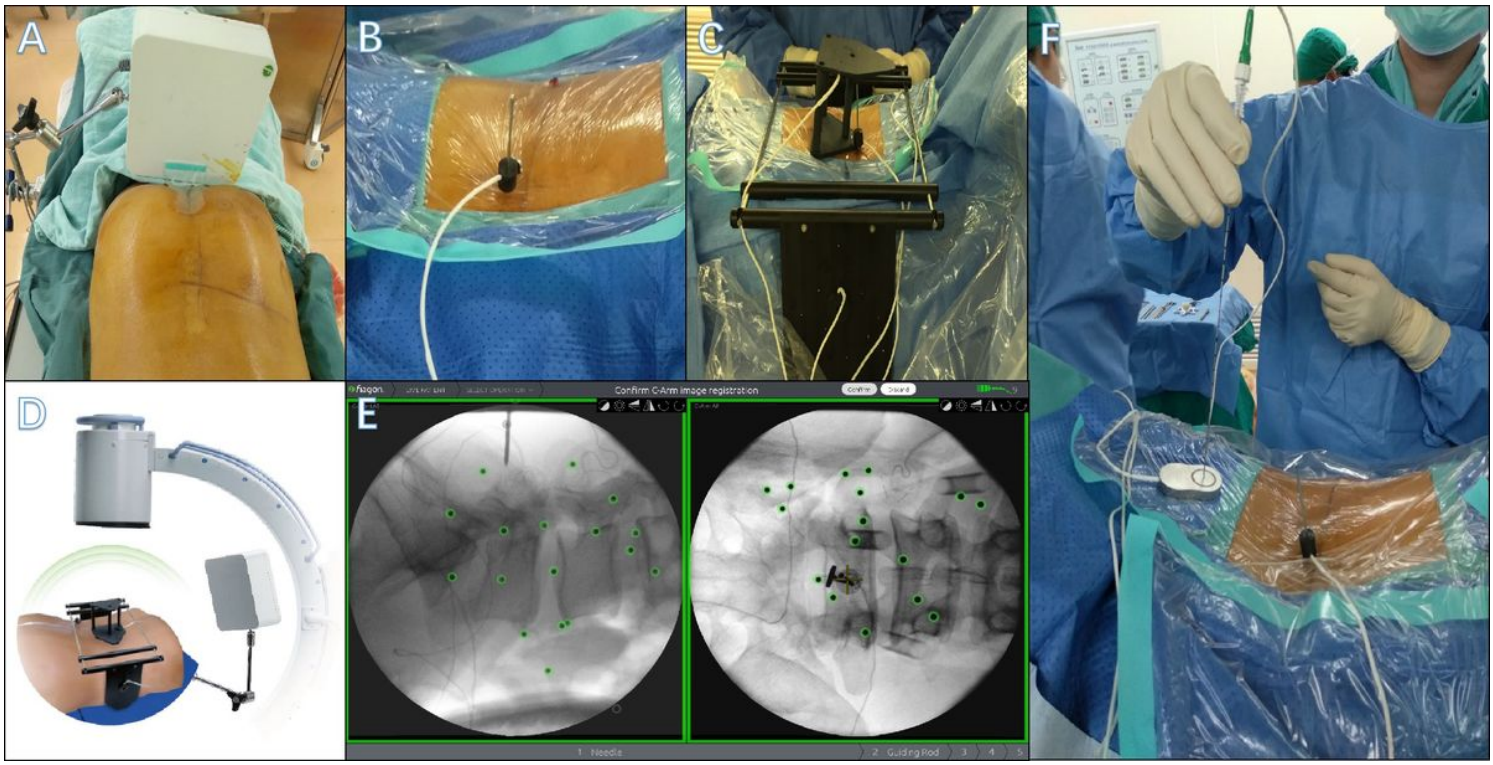

Figure 2

Surgical procedure of SEESSYS. A) Fix the magnetic field generator to the frame near the surgical site. B) Fix the kirschner wire on the adjacent spinous process of the surgical segment and connect the localizer. C) Place the MaperBrige smoothly near the surgical section. D) Positive side perspective and transfer the C-arm image to the navigation host. E) Auto-complete registration. F) The magnetic navigation function can be used after the surgical instruments are paired on the MultiPad.

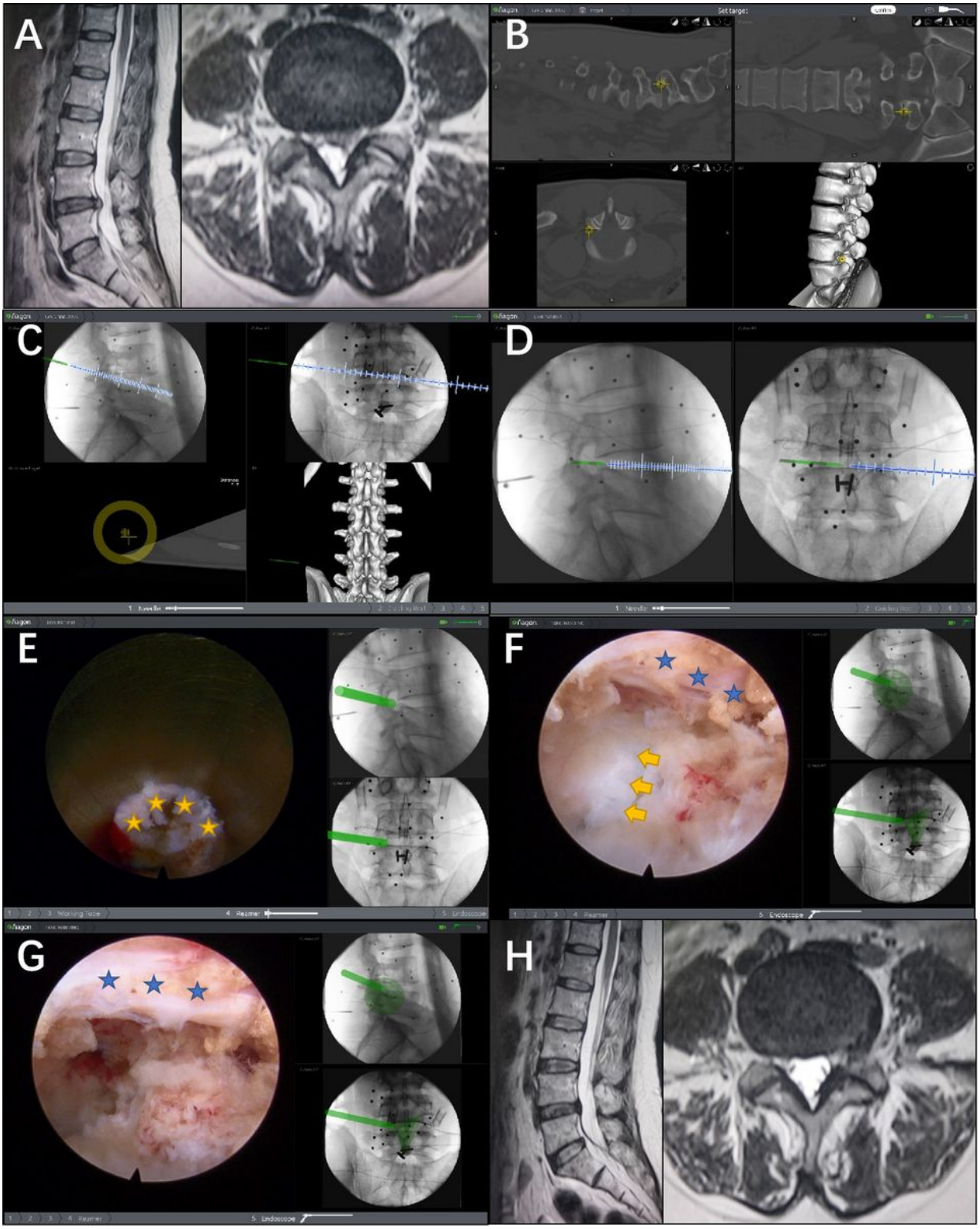

Figure 3

A 45-year-old woman with low back pain and radiating pain of her left lower lime for 2 years, aggravated for 3 months. She was treated with SEESSYS because of conservative treatment with no efficiency. A) Pre-operative MRI suggested that the L4-5 disc herniation. B) Set the surgical target locating on the L5 superior articular process. C) Observe and adjust the direction of the needle in real time under the guidance of electromagnetic navigation. D) The position of the guide rod can be observed when the

expansion guide rod is placed. E) Under the guidance of electromagnetic navigation, the position of the reamar can be observed in real time. Unlike the traditional TESSYS, the whole process foraminoplasty of SEESSYS is visualized under the endoscope. Superior articular process (the yellow star) is clearly identified under endoscopy. F) The depth of the surgical instruments into the spinal canal can also be observed in real time. L5 nerve root (the blue star) and the herniated disc (the yellow arrow). G) The herniated disc is removed and nerve root (blue stars) is relieve completely. H) Post-operative MRI at 6 months.