Efficacy of Transforaminal Endoscopic Spine System (TESSYS) Technique in Treating Lumbar Disc Herniation

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Background:
To compare efficacy and safety of percutaneous transforaminal endoscopic spine system (TESSYS) and traditional fenestration discectomy (FD) in treatment of lumbar disc herniation (LDH).

Material/Methods:
A total of 106 LDH patients were divided into TESSYS group (n=48) and FD group (n=58). Visual analogue scale (VAS), Oswestry disability index (ODI), Japanese Orthopedic Association (JOA), and modified MacNab criteria were used for efficacy evaluation. Post-operative responses were compared by enzyme-linked immunosorbent assay (ELISA) based on detection of serum IL-6, CRP, and CPK levels.

Results:
In the TESSYS group, compared with the FD group, we observed, shorter incision length, less blood loss, shorter hospital stay, lower hospitalization cost, shorter recovery time, lower complication rate (all \( P < 0.001 \)), and lower VAS scores of lumbago and skelalgia at 3 days and 1, 3, and 6 months postoperatively (all \( P < 0.05 \)). At 24 and 48 h postoperatively, CRP level was remarkably higher in the FD group compared to the TESSYS group (\( P < 0.001 \)). Further, comparison of IL-6 levels at 6, 12, 24, and 48 h postoperatively revealed significantly higher levels in the FD group than in the FESSYS group (all \( P < 0.001 \)).

Conclusions:
TESSYS had clinical advantages over FD and entails less trauma and quicker postoperative recovery, suggesting that TESSYS is well tolerated by patients and is a better approach than FD in surgical treatment of LDH.

MeSH Keywords:
Dienestrol • Manipulation, Orthopedic • Osteoarthritis, Spine • Pain Measurement

Full-text PDF: http://www.medscimonit.com/abstract/index/idArt/894870
Background

Lumbar disc herniation (LDH) is one of the most frequently diagnosed causes of low back pain (LBP) and is a common cause of radiculopathy. LDH presents with considerable variability in LBP among patient populations [1] but patients who have LDH will commonly present symptoms of consistent radiculopathy [2]. LDH can result from general wear and tear associated with constant sitting, squatting, or driving [3]. Epidemiological evidence indicates that axial torque/twist combined with repetitive motions of flexion-extension can result in LDH [4]. Gene mutations have also been implicated in the etiology of LDH, for example, mutations leading to altered expression of proteins such as MMP2 and THBS2 [5]. Clinical treatment of a herniated lumbar disc initially follows a conservative care regimen that includes analgesics, epidural steroid injections, and physical therapy. In a case report, Birbilis et al. presented the case of a 74-year-old man presenting with a large disc herniation at L5-S1, experiencing moderate sciatic pain, and having a positive result in the straight-leg-raising test at 30 degrees. The patient was symptom-free and the spontaneous disappearance of the herniated disc fragment was revealed 1 year later through conservative treatment with medication and physical therapy, suggesting that the disc regression could have been due to dehydration, resorption as a result of an inflammatory reaction, or retraction into the intervertebral space, and underlining the need to limit surgical treatment strictly to patients with neurological deficits and severe unremitting leg pain despite conservative measures [6]. Surgery and minimally invasive procedures are recommended for patients with severe dysfunction of the nerve root or cauda equine when conservative treatments fail to control symptoms [1,7].

Among minimally invasive techniques, the percutaneous transforaminal endoscopic spine system (TESSYS) has become a prevalent therapy for LDH [8,9]. Transforaminal endoscopic lumbar discectomy is popular because of its advanced endoscopic visualization and increased patient demands for minimally invasive procedures [10]. TESSYS, developed by Dr. Thomas Hoogland, made it possible to use foraminoplasty to operate inside the spinal canal and widen the foramen between vertebrae near the facet joint with special reamers [11]. TESSYS is a minimally invasive method for treating lumbar disc pathology compared to the traditional tube or open retractor procedures that rely on direct or microscopic visualization [12]. TESSYS has fewer postoperative complications than conservative surgery, with a mean complication rate of 2.8% [13,14]. For example, transient lower extremity dysesthesia or hypesthesia induced by irritation of nerve root, the most frequent complication of conventional operations, is relatively rare in TESSYS [11]. In addition, TESSYS technique has been reported to achieve high success rates in young and elderly patients due to its unique surgical approach and instrument design [15].

Fenestration discectomy (FD) is indicated primarily for treating LDH; it has several advantages, including short operation time, simple surgical procedure, fast postoperative recovery, markedly lower surgery cost, and preservation of mobility of the operation segments [16]. The purpose of the present study was to further investigate the efficacy and safety of TESSYS compared to FD in treatment of LDH.

Material and Methods

Ethics statement

The study was carried out with the approval of the Institutional Review Board of the First Affiliated Hospital of Nanchang University. Written informed consents were obtained from eligible patients and the study was designed to conform to the Declaration of Helsinki.

Subjects and study design

Between January 2009 to January 2012, 106 LDH patients were admitted to the Department of Orthopaedic Surgery, the First Affiliated Hospital of Nanchang University. From this patient pool, study subjects were randomly enrolled into the present study. The diagnosis of LDH was confirmed by clinical symptoms, lateral X-ray, and MRI examination. Based on different surgery approaches, LDH patients were divided into 2 groups: the TESSYS group and the FD group. In the TESSYS group there were 26 males and 22 females; average age was 39.5 years (range, 22–58 years); average duration was 15.5 months (range, 5 months–6 years); and average follow-up time was 16.7 months (range, 12–25 months). Clinical features were: 9 patients with central herniation, 26 with paramedian herniation, and 15 with foraminal herniation; and within the LDH patients in the TESSYS group, 5 occurred at L3-4, 31 at L4-5, and 13 at L5-S1. In the FD group there were 31 males and 27 females; average age was 42.8 years (range, 27–61 years); average duration was 22.3 months (range, 6 days–7 years); and average follow-up time was 17.3 months (range 12.5–23.5 months). The FD group had 18 patients with central herniation, 15 with paramedian herniation, and 15 with foraminal herniation; and within the LDH patients in the FD group, 5 occurred at L3-4, 34 at L4-5, and 19 at L5-S1. Patient exclusion criteria were: (1) LDH associated with other diseases, including neuropathy, incretion, metabolic diseases, any diseases related to heart, lung, liver, or kidney, or acute/chronic inflammation; (2) multi-level disc herniation; (3) infection of spine, tumor, discitis, or vertebral tuberculosis; (4) recurrent intervertebral disc herniation; and (5) lumbar instability or spondylolisthesis at more than 2 levels.
TESSYS procedures

Patients were arranged in lateral position with the affected side upwards, and coxa and knee bent. Using C-arm X-ray devices, the herniated disc was verified and the direction and site of puncture was marked. After being sterilized and draped, patients were given local infiltration anesthesia using lidocaine (1%) preoperatively. The procedure was performed with posterolateral approach. When the spinal needle reached the intervertebral disc through the foramen intervertebrale, acidic coeruleum methylenum (1 ml) was injected to stain the degenerated nuclear tissue (Figure 1). The amount of contrast agent was carefully controlled to avoid dye leaking to the canalis spinalis via fractured annulus fibrosus (AF). Prior to removing the spinal needle, a guide wire was inserted through the spinal needle, and then a 0.8 cm skin incision was made along the guide wire, followed by sequential dilatation of the tract, which could then make way for a working cannula. The position for the working channel was visualized and finalized under the C-arm. Then, the foramen intervertebrale was washed with continuous normal saline under an endoscope. After identification of the structures, the blue-stained degenerated nucleus pulposus (NP) was then removed using various grasping forceps and assisted by use of a microscope. After the nerve root decompression was performed, the working cannula was retracted and the skin was stitched.

FD surgery

Patients were positioned in prone position with the abdomen free, and epidural anesthesia was given with 15–18 mL of 1.5% plain lidocaine through a catheter. A 4-cm posterior midline incision was made. The sacrospinal muscle was separated along the lateral margin of the acantha and lamina after subcutaneous tissue and aponeurotic fascia were cut open. With the upper and lower lamina and zygaphyseal joints exposed, fenestration was performed by resecting partial lamina using bayonet tissue forceps and then a flavectomy was carried out to expose the dural sac and nerve root. A nerve root retractor was used for medial retraction of the spinal dura mater and nerve root and then the herniated intervertebral disc tissue was exposed. The ligamenta longitudinale posterius and AF were incised using a microknife. The herniated NP and remaining degenerated NP within the intervertebral disk were removed using an NP clamp. The canalis spinalis and nerve root canals were examined and the nerve root was loosed. The wound was washed after complete hemostasia and a drainage tube was kept in place. Finally, the incision was sutured.

Postoperative management

For the TESSYS group, patients were given antibiotic for 1~3 days to prevent infection. Anti-inflammation and dehydration protocols were implemented by giving mannitol and dexamethasone for 3 days; after complete bed recovery for 3 h, patients were allowed out-of-bed activity with assistance.
of a girdle brace. Patients were discharged from the hospital after 3–6 days with straight leg raising exercise training to avoid adhesion of the nerve root. Patients were allowed to perform moderate lumbar and dorsal extensor exercises after 1 month. For patients in the FD group, hormone therapy, neurotrophic drugs, and drugs that ameliorate microcirculation were given. The drainage tube was removed when the drainage volume was less than 50 mL/24 h. With the help of a girdle brace, patients walked as appropriate 3–5 days after the surgery. Lumbar and back muscle exercises were recommended 2 weeks after the surgery and patients were asked to wear the girdle brace for 1 month and to avoid strenuous activities for 3 months.

**Treatment efficacy assessment**

Clinical data, such as time of surgery, the length of incision, volume of bleeding during surgery, and hospitalization time, were recorded. Postoperative follow-up was done by physicians who did not participate in the surgery. The evaluation of osphyalgia and skelalgia condition at 1 day before the surgery and at 3 days, 1 month, 3 months, 6 months, and 12 months after the surgery were performed with the visual analogue scale (VAS) [17]. For the assessment of lumbar function, we used the Oswestry disability index (ODI) and the Japanese Orthopaedic Association (JOA) back pain evaluation questionnaire [18,19]. Clinical response was evaluated using modified MacNab criteria at the last follow-up [20]. Patients received a lateral X-ray of lumbar vertebra 6 months after the surgery. The sagittal lordosis of lumbar vertebrae was presented using lumbar lordosis (LL). Cobb method was used for measuring: tangents were drawn on the superior endplate of L1 and S1 on the lateral X-ray film of lumbar vertebra, respectively. The intersection angle of lines perpendicular to the 2 tangents was the angle of the L1 and S1 (Figure 2). The ratio of the distance among vertebrae (d) and the superior vertebrae (D) (d/D) was measured to assess the change in height of the target intervertebral space. Frymoyer-Pope method was utilized for measuring the height of the intervertebral space: the average value of the front distance between 2 vertebrae and the posterior distance between the 2 vertebrae by Frymoyer-Pope method.
Enzyme-linked immunosorbent assay (ELISA) for serum IL-6, CRP, and CPK levels

Peripheral venous blood samples (5 ml) were collected in sterile tubes on the 1st morning after patients were admitted to the hospital. Additional samples in the series were collected at 1, 6, 12, and 24 h after the surgery. Within 2 h of collection, blood samples were centrifuged at 3000 r/min for 15 min at room temperature, and serum was separated and placed in sterile freezing tubes and stored at −20°C for further use. ELISA Kit ( Innocent Company, Shenzhen) was used for detection of serum IL-6, CRP, and CPK following the manufacturer’s protocol.

Statistical analysis

Data are presented as means ± standard deviation (SD). The 2-sample t test was used to inspect measurement data and the chi-square test was performed for data categories. Comparisons between groups were performed by either t test (with homogeneity of variance) or rank test (with heterogeneity of variance). SPSS18.0 software (SPSS Inc., Chicago, IL, USA) was used for data analysis. Statistical significance was set at P value less than 0.05.

Results

Comparison of surgery-related indicators

Our data collected show significantly shorter incision length, less blood loss, shorter hospital stay, lower cost of hospitalization, and shorter recovery time in the TESSYS group compared to the FD group (all P<0.01). No significant differences were found between the 2 groups when surgery time and return-to-work rates were compared (both P>0.05). The procedure-related complication rate for the TESSYS group and FD group were 6.3% (3/48) and 20.7% (12/58), respectively, showing a notably lower rate in the TESSYS group (P<0.01). Three patients developed temporary postoperative limb paresthesia, including hyperalgnesia and/or numbness, in both groups. The symptom was ultimately resolved at 1-month follow-up, following conservative treatment. In the FD group, dural laceration occurred in 2 patients and was managed by intraoperative dural repair and postoperative conservative treatment, with removal of the drainage tube when significant drainage fluid had disappeared. Limb weakness occurred in 4 patients but they regained strength to preoperative levels within 6 months after conservative treatment. Acute urinary retention was encountered in 4 patients and urinary function was restored after local massage and intermittent catheter opening. There were no reports of nerve root injury in either group (Table 1).

Comparison of clinical efficacy

VAS, JOA, ODI score, and LL were measured to compare the clinical efficacy of the TESSYS group and FD group. There was no significant difference in preoperative VAS score for osphalgia and skelalgia, JOA score and ODI score for lumbar function, or LL for sagittal lordosis of lumbar vertebra between the TESSYS group and FD group (all P>0.05). The VAS, JOA, and ODI score in both groups were significantly improved postoperatively (all P<0.01). The postoperative VAS score of the TESSYS group at 3 days, 1 month, 3 months, and 6 months after the surgery was significantly lower than that in the FD group at the corresponding time period (all P<0.05). However, no significant differences in VAS score at 12 months after the surgery was between the 2 groups (P>0.05). As for postoperative JOA and ODI score, no notable difference was found between the 2 groups at each corresponding follow-up time point (all P>0.05) (Table 2). Based on the modified MacNab, at the end of the follow-up, 95.84% of the patients in the TESSYS group and 94.82% of patients in the FD group were classified as excellent or good, with no significant differences between the 2 groups (P>0.05). Some patients were reexamined by MRI post-surgery and showed significant regression or disappearance of disc herniation (figure 4).

Change in lumbar stability

To study the lumbar stability in the TESSYS group and FD group, Cobb angle and ratio of d/D were measured. The preoperative and postoperative Cobb angle showed no evident change in the FD group (25.38±6.89° vs. 24.48±6.08°, t=0.774, P>0.05), but in the TESSYS group, postoperative Cobb angle was reduced significantly as compared with preoperative Cobb angle (23.36±6.54° vs. 26.81±7.19°, t=4.769, P<0.01). No obvious differences were found in the d/D, which was measured for changes in height of target intervertebral space in the 2 groups before and after the surgery (P>0.05).

Comparison of serum CRP, CPK, and IL-6 levels

There was no statistical difference in serum CRP level between the 2 groups preoperatively and at 1, 6, and 12 h after surgery (all P>0.05). However, at 24 and 48 h after surgery, CRP levels were remarkably higher in the FD group than in the TESSYS group (P<0.001) (Table 3). Although CPK levels increased observably in both groups at 1, 6, 12, and 48 h after surgery, the increases in CPK level in the FD group were significantly higher when compared to the TESSYS group (P<0.001) (Table 4). The differences in IL-6 levels between the 2 groups were not significant immediately following surgery (P>0.05). However, at 6, 12, 24, and 48 h after surgery, the difference in IL-6 levels between the 2 groups became notable, with IL-6 levels increasing significantly faster in the FD group (all P<0.001) (Table 5).
Our research data suggests that both TESSYS and FD are effective in LDH treatment. However, we also uncovered significant benefits to TESSYS over those observed for FD. TESSYS proved to be minimally invasive, with lower post-operative burden and rapid recovery under the strict control of operation indication. Due to high demand for less traumatic surgical procedures, minimally invasive spine operation procedures have been commonly used in recent years. Compared with traditional open or tube retractor surgery, TESSYS was significantly superior in many factors. First, the temporary complication rates of TESSYS are low, as measured by persistent sensory deficits (1%), dysesthesias (10%), and dural tears (0.3%), compared to traditional fenestration discectomy (FD) conducted under general anesthesia [21,22]. Moreover, TESSYS was reported to be a safe and effective treatment for LDH owing to minimal iatrogenic damage to the nerve root because of inherent features of the procedure, such as targeted posterolateral access, broadening the foramen, and more intelligent instrumentation to increase...
the distance between the needle and the nerve root [12, 23]. Furthermore, the stability of ligamentum flavum and intracranial capsule structures was maintained during the TESSYS procedure by microscopic or direct visualization to manage the extruded disc fragment, causing less scar formation [11]. TESSYS also was clearly associated with good clinical outcomes, high quality of life, shorter hospitalization, and high satisfaction rate due to lack of rebarbative scar tissue on the skin [15].

Our study indicates that patient satisfaction in both groups was over 94% at the final follow-up. The VAS of the 2 groups had obvious improvement compared to VAS before surgery; however, there were no significant differences at 12 months after the operation. In addition, the JOA and ODI scores in the 2 groups also improved but were not statistically significant during the same follow-up period. In this study, the amount of bleeding in TESSYS was significantly lower than that of FD.

Table 3. Comparison of preoperative and postoperative C-reactive protein (CRP) level between transforaminal endoscopic spine system and fenestration discectomy group (±s).

<table>
<thead>
<tr>
<th></th>
<th>FD</th>
<th>TESSYS</th>
<th>F value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-op</td>
<td>0.17±0.10</td>
<td>0.15±0.07</td>
<td>0.498</td>
<td>0.490</td>
</tr>
<tr>
<td>Post-op (1 h)</td>
<td>0.22±0.09</td>
<td>0.16±0.07</td>
<td>2.526</td>
<td>0.129</td>
</tr>
<tr>
<td>Post-op (6 h)</td>
<td>0.28±0.09</td>
<td>0.21±0.05</td>
<td>4.828</td>
<td>0.053</td>
</tr>
<tr>
<td>Post-op (12 h)</td>
<td>0.29±0.11</td>
<td>0.26±0.06</td>
<td>1.035</td>
<td>0.322</td>
</tr>
<tr>
<td>Post-op (24 h)</td>
<td>1.84±0.74</td>
<td>0.18±0.09</td>
<td>48.966</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Post-op (48 h)</td>
<td>2.61±0.93</td>
<td>0.10±0.04</td>
<td>73.089</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>F value</td>
<td></td>
<td>43.29</td>
<td></td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>P value</td>
<td></td>
<td>21.52</td>
<td></td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

TESSYS – transforaminal endoscopic spine system; FD – fenestration discectomy; pre-op – pre-operation; post-op – post-operation; * main effects between groups (F=119.53, P<0.001), main effects among different time (F=43.086, P<0.001); * interaction effects (F=48.483, P<0.001).

Figure 4. Axial images of preoperative MRI examination (A) showing significant regression of disc herniation and axial images of postoperative MRI examination (B) showing significant disappearance of disc herniation.
and patients who had undergone TESSYS stopped bleeding more completely. Additionally, the direct visualization of the target in TESSYS could have contributed to the decreased fibration of canalis spinalis as well as the effects on cavum epidurale and nerve root, while the adhesion of cavum epidurale and nerve root may cause the postoperative leg pain.

Traditionally, minimally invasive techniques for surgical discectomy have been defined as smaller incisions, tubular retractors, microscopically assisted tissue dissection, and conservative removal of only extruded or sequestered nucleus pulposus with preservation of the annulus. The first truly minimally invasive technique was chymopapain dissolution of the nucleus pulposus, and other percutaneous techniques followed; however, none were as efficacious as the gold standard of microlumbar discectomy until endoscopically visualized methods evolved to allow visualized mechanical discectomy through the foramen. In experienced hands, such a technique is as effective as microlumbar discectomy and results in less surgical morbidity for herniation that is appropriate for this minimally invasive endoscopic surgical portal that completely avoids traumatizing the normal anatomy of the dorsal musculature and ligamentous structures, supplying a novel therapeutic direction for LDH in the future.

Systemic wound response measurements in our study revealed that TESSYS caused less damage to local muscle tissues than FD TESSYS.

| Pre-op | FD 64.28±4.69 | 78.03±7.17 | 25.762 | <0.001 |
| Post-op (1 h) | 139.87±14.15 | 77.04±8.17 | 147.800 | <0.001 |
| Post-op (6 h) | 220.54±23.49 | 105.05±17.23 | 157.106 | <0.001 |
| Post-op (12 h) | 298.11±26.03 | 121.82±22.03 | 267.294 | <0.001 |
| Post-op (24 h) | 270.87±43.50 | 123.56±13.08 | 105.149 | <0.001 |
| Post-op (48 h) | 185.5±21.06 | 102.41±14.68 | 104.762 | <0.001 |

**Table 4.** Comparison of preoperative and postoperative interleukin-6 (IL-6) between transforaminal endoscopic spine system and fenestration discectomy group (±s).

**Table 5.** Comparison of preoperative and postoperative creatine phosphokinase (CPK) level between transforaminal endoscopic spine system and fenestration discectomy group (±s).

| Pre-op | FD 0.25±0.04 | 0.25±0.05 | 0.002 | 0.963 |
| Post-op (1 h) | 0.30±0.02 | 0.33±0.05 | 2.948 | 0.111 |
| Post-op (6 h) | 0.87±0.05 | 0.26±0.05 | 60.736 | <0.001 |
| Post-op (12 h) | 0.93±0.12 | 0.22±0.07 | 248.296 | <0.001 |
| Post-op (24 h) | 0.98±0.09 | 0.26±0.05 | 408.912 | <0.001 |
| Post-op (48 h) | 1.07±0.10 | 0.25±0.06 | 460.738 | <0.001 |

**Table 4.** Comparison of preoperative and postoperative interleukin-6 (IL-6) between transforaminal endoscopic spine system and fenestration discectomy group (±s).

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| Post-op (1 h) | 0.30±0.02 | 0.33±0.05 | 2.948 | 0.111 |
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**Table 5.** Comparison of preoperative and postoperative creatine phosphokinase (CPK) level between transforaminal endoscopic spine system and fenestration discectomy group (±s).
that of the open surgery, implying that patients tolerate TESSYS well and that TESSYS may be a more effective approach for treating LDH. CRP levels signify nonspecific response to tissue injury, and serum CRP is an acute-phase protein produced by hepatic synthesis [24]. Serum CRP only exits in minute quantities in healthy people, and its concentration increases rapidly in inflammation and tissue injury, and is used as an effective index to distinguish bacterial infection and virus infection [25]. CRP increases rapidly and exponentially in settings such as acute inflammation, tissue injury, myocardial infarction, surgical trauma, and radiation injury [26]. CPK is an important intracellular enzyme expressed by various tissues and cell types [27]. CPK is rarely found outside cells under normal circumstances when muscle cell membranes are intact and undamaged [28,29]. Mechanical and hypoxic ischemic injury can cause damage to the muscle cell membrane and promote release of CPK, thus increasing serum CPK activity for endocrine release into the blood [30]. Therefore, CPK is a good serum indicator for muscle damage [31]. By contrast, IL-6 is an important inflammatory cytokine in the cytokine network [32]. It can activate neutrophils and increase the production of inflammatory mediators after trauma, further promoting systemic inflammatory response syndrome after trauma. IL-6 can also promote the release of soluble TNF receptor and IL-1 receptor 2 and decrease the function of TNF-a and IL-1, mediating anti-inflammatory effects [33,34]. Compared to CRP, IL-6 is a more sensitive inflammation marker [35]. Surgery is a trauma for the body and it can cause local tissue damage and lead to systematic stress response [36]. The degree and duration of postoperative stress responses reflects the impact of the surgical procedure on the body. Therefore we used CRP, CPK, and IL-6 as our main parameters to measure postoperative responses [37].

Several limitations of our study should be mentioned. TESSYS is not suitable for patients with lumbar spinal stenosis, lumbar instability, or intervertebral space stenosis. TESSYS is highly effective in a narrow set of patients and, therefore, traditional surgical procedures are still very valuable in the clinic. As lifestyles and physical activities change in society, we will need to periodically reassess our options to effectively treat LDH.

Conclusions

In summary, our study provides evidence that both TESSYS and FD are effective in the treatment of LDH, but TESSYS has the advantages of less trauma and faster postoperative recovery. TESSYS caused less damage to local muscle tissues and elicited significantly lower systemic wound response compared to that of open surgery, suggesting that a subset of patients might derive significant benefits from opting for TESSYS.

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Competing interests

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