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# Laparoscopic Assisted Fusion of the Lumbosacral Spine: A Biomechanical and Histologic Analysis of the Open Versus Laparoscopic Technique in an Animal Model

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# Laparoscopic Assisted Fusion of the Lumbosacral Spine: A Biomechanical and Histologic Analysis of the Open Versus Laparoscopic Technique in an Animal Model

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animal model; biomechanical testing; fusion; laparoscopy; lumbosacral spine; swine

## Abstract:

Study Design. An animal model for laparoscopic lumbosacral fusion.

Objectives. To compare the biomechanical and histologic results of open to laparoscopic lumbosacral discectomy and fusion in an animal model.

Background Data. Early clinical reports of laparoscopic lumbosacral fusions are encouraging, but animal experiments have not been reported.

Methods. Ten pigs (50-80 kg) were divided into two groups. Group 1 underwent an open anterior lumbosacral discectomy and fusion at L7-S1 using autologous bone graft and a titanium MOSS (DePuy Motech) cage. Group 2 was identical to Group 1 except that a laparoscopic technique was used. The animals were killed at 3 months, and the lumbosacral spines were harvested for biomechanical and histologic testing.

Results. Estimated blood loss and average length of operation, respectively, for the two groups were: Group 1, 50 mL, 2 hours 50 minutes; and Group 2, 40 mL, 3 hours 40 minutes. There were no perioperative or postoperative complications in either group. Motion analysis results showed less motion in lateral bending, flexion, and extension than in the intact specimen in both groups. Tensile testing showed that the stiffness was significantly greater in the open group than in the laparoscopic group ($P < 0.004$). Histologic examination showed a less extensive discectomy and less bone growth in the implant in the laparoscopic group. Inadequate decortication of end-plates occurred in two animals who underwent laparoscopy.

Conclusions. Although lumbosacral discectomy and implant insertion can be performed using the laparoscopic technique, the construct may not have the same biomechanical strength as that attained with the open procedure. Laparoscopic-assisted lumbosacral fusion surgery requires additional investigation before it is widely used in clinical situations.

Endoscopic techniques for minimally invasive surgery have been widely used in the general, urologic, gynecologic, and thoracic communities for several years. This has led to a decrease in postoperative pain and length of hospital stay, more rapid return to work, and a decrease in the overall costs associated with many procedures.[1-3,7,10] Since its introduction in the late 1980s, laparoscopic cholecystectomy has rapidly become the standard of care for gallbladder disease that requires surgery.[7]

Recently, there has been interest within the spinal community to apply endoscopic techniques anteriorly to the thoracolumbar spine. In 1991, Obenchain[8] was the first to report the laparoscopic removal of a lumbar disc. This was followed by the report of a series of 21 cases in 1994.[9] Regan et al[11] reported their early experience with video assisted thoracotomy in a variety of thoracic spine procedures with encouraging results. In 1995, Mathews et al[5] reported the preliminary results of five patients after laparoscopic anterior uninstrumented interbody fusion with a minimum of 6 months of follow-up. Initial results based on clinical outcome and plain flexion-extension radiographic evaluation were favorable. Zucherman et al[14] reported their results with a custom designed laparoscopic delivery system and "BAK" fusion cages in their first 17 patients, with an average follow-up of 8 months. The group thought the technique described was effective and offered advantages when compared with more commonly used procedures for lumbosacral fusions. In addition, there has been a prospective multicenter report of the complications associated with 100 consecutive anterior thoracolumbar spinal procedures performed with endoscopy.[6] There were no permanent iatrogenic neurologic injuries or deep spinal infections in this group of patients undergoing a variety of spinal procedures from biopsy to vertebral corpectomy.

Despite a growing number of reports of the clinical results of spinal endoscopic procedures, there have been relatively few animal studies comparing its efficacy to that of more conventional techniques. The purpose of this experiment was to evaluate the technique of laparoscopic surgery to perform an anterior lumbosacral discectomy and interbody fusion, and to compare the biomechanical and histologic results of the open and laparoscopic techniques.

## Materials and Methods

Ten male pigs (50-80 kg) were divided into two groups. Group 1 underwent an open anterior lumbosacral discectomy and fusion at the lumbosacral junction using autologous bone graft and a metal implant. Group 2 was identical to Group 1 except that a laparoscopic technique was used. The pig model allowed for the performance of both the open and endoscopic procedures without extensive modifications in the technique or the use of specially modified instruments. A modified MOSS cage (DePuy Motech, Warsaw, IN) that could be inserted laparoscopically under compression in the lumbosacral intervertebral space was used for both the open and laparoscopic procedures. All animals were made *nil per os* the day preceding surgery. On the morning of surgery, they were premedicated with telazol (Midwest Veterinary Supply, Madison, WI) 6 mg/kg and xylazine 2.2 mg/kg administered intramuscularly. Anesthesia was maintained with halothane 1-1.5% through a breathing circuit after intubation. Balanced electrolyte fluids were administered intravenously throughout the procedure. The animals were given cephazolin 1 g IM preoperatively. An oral gastric tube was placed to decompress the stomach.

All pigs were placed initially in a left lateral recumbent position. The left posterior iliac crest was prepared and draped in the usual fashion, and bone graft was harvested through a vertical incision overlying the posterior iliac crest. After adequate hemostasis, copious irrigation, and wound closure, the animal was placed in the supine position with the lower extremities tied to the end of the table. The abdomen was prepared and draped in the usual sterile fashion and the animal placed in the Trendelenburg position.

For the open procedure a vertical midline incision was made from the umbilicus to just above the pubis. The abdomen was entered in the midline and the bowel retracted cranially using a moist laparotomy pad and a malleable retractor. Foley catheter cannulation of the bladder was not possible, so the bladder was drained using an 18-gauge needle, intravenous extension tubing, and suction. The lumbosacral junction was identified. The posterior peritoneum overlying the lumbosacral disc was incised vertically, the sacral artery and vein identified, ligated with hemoclips, and transected. Additional exposure of the disc space was performed with kitners, which were used to sweep the parietal peritoneum laterally. Exposure was maintained and the vessels protected with malleable retractors. The anterior annulus was excised using a 15 blade. Curettes were used to evacuate the disc space of disc material. A lamina spreader was used to distract the intervertebral space to expose the posterior margin of the disc space to allow for additional evacuation of disc material posteriorly. A high-speed burr was used to expose the bleeding subchondral bone of the adjacent end-plates. The intervertebral space was sized and an implant was packed with cancellous bone, inserted into the disc space, and rotated into position so that it was placed under compression. Cancellous bone was packed around the implant. The wound was copiously irrigated. The peritoneum was closed with 2-0 vicryl. The abdominal fascia was closed with 0 ticron. The subcutaneous tissues were closed with 2-0 vicryl, and the skin was closed with 3-0 nylon. Anteroposterior and lateral radiographs were taken to document the implant position. The animals were awakened from anesthesia, extubated, and their oral gastric tube was removed. Prophylactic antibiotic administration was continued for 48 hours, and the animals received 72 hours of buprenorphine 0.01 mg/kg IM twice a day. Diet was advanced gradually to a regular diet during a period of 24 hours.

For the laparoscopic procedure, bone graft harvesting was identical to that used in the open procedure. After bone graft harvesting, the animal was placed in the Trendelenburg position and prepared and draped in the usual fashion. The abdominal cavity was insufflated using a Veress needle to 15 mm Hg. A standard five-portal laparoscopic approach as described by McAfee[12] was established. A laparoscopic Babcock was inserted through the left midaxillary line portal and the bladder grasped. An 18-gauge spinal needle was placed percutaneously to drain the bladder of urine. A laparoscopic hernia stapler used to secure the emptied bladder to the right abdominal wall away from the lumbosacral junction. Anterior exposure of the lumbosacral junction proceeded in a standard fashion, as described by McAfee.[12] Vessels were retracted and protected, and the location for the working portal was determined using lateral C-arm control and a percutaneously placed Steinmann pin. The working portal was placed directly opposite the disc space. Disc excision proceeded using laparoscopic curettes, osteotomes, and rongeurs. The exposed end-plates were taken down to bleeding subchondral bone using a high-speed burr. The disc space was sized in a fashion identical to that used in the open procedure. The appropriate implant was packed with cancellous bone and placed under compression in the disc space in a manner identical to that used in the open procedure, and the disc space was packed with cancellous bone. The position of the implant was confirmed fluoroscopically. The surgical site was irrigated, the hernia staple removed from the bladder, and the retractors and portals removed after assessment for iatrogenic visceral injuries and intra-abdominal bleeding. The fascia was closed with 0 vicryl sutures, the subcutaneous tissues were closed with 2-0 vicryl sutures, and the skin was closed with interrupted 3-0 nylon sutures. Anteroposterior and lateral radiographs were taken immediately

after surgery to document the position of the implant. The animals received the same postoperative care as did those that underwent the open procedure.

The animals were killed at 3 months after surgery using Beuthanasia D (Midwest Veterinary Supply) 0.2 ml/kg IV. Extraneous soft tissue and transverse processes were removed. Anteroposterior radiographs were obtained to asses implant position at the time of sacrifice. The lumbar spines (L6-S1) were harvested. The L6 vertebra and the sacrum were used to attach the loading and base frames, respectively. Three markers reflecting infrared light were rigidly attached to each of L7 and the base frame. The prepared specimens were mounted on a specially designed loading frame and loaded to a maximum of 3.0 Nm in six directions: flexion, extension, right and left lateral bending, and right and left axial rotations. The spatial locations of reflecting markers in response to the applied load were measured and recorded using a three-dimensional motion measuring system consisting of 3 VICON cameras (Oxford, England) and a Micro-Vax 3100 workstation (DEC, Maynard, MA). The resulting spatial data were transformed in three rotations (flexion/extension, Rx; axial rotations, Ry; and lateral bending, Rz) and in three translations (Tx, Ty, and Tz) of the L7 vertebra with respect to the base frame. Motion data were used for the quantitative assessment for fusion. The translational and rotational motion data for each group were statistically compared using analysis of variance with Tukey's mean comparison. Finally, an MTS system was used for tensile testing to collect load and displacement data. A linear regression analysis was performed to determine the slope (stiffness). Data were compared to five intact specimens and analyzed using analysis of variance with Tukey's mean comparison.

After biomechanical testing, the specimens were fixed in 70% ethyl alcohol. After sufficient time had passed to effect fixation, a high resolution (no magnification) radiograph was made of the specimen using a Faxitron radiograph unit (Kristalloflex-2, Siemens, New York, NY) and Ektascan EM-1 high resolution film (Kodak, Rochester, NY). This was used to guide the pathologist in trimming the specimen. The specimens were trimmed in the following manner: The superior half of L7 was removed, the inferior half of S1 was removed, and all tissues posterior to the anterior part of the spinal canal were removed. Finally, all spinal levels were bisected in the coronal plane (through the center of the implant using the radiographs to determine the location and angle) to produce anterior and posterior halves. These halves were labeled and processed by sequential dehydration in alcohols, cleared in xylene, and embedded in graded catalyzed methyl methacrylate (Osteobed, Polysciences Inc., Warrington, PA). The blocks were sectioned with a diamond saw (Buehler Isomet, Lake Bluff, IL) to an approximate thickness of 100 to 300 μm. Approximately five to eight sections were made in the coronal plane of the explant. The thickness of the sections was measured with a metric micrometer to determine the exposure time. Differential staining using the Multiple stain (a trichrome stain) was used to permit histologic differentiation of bone, soft tissue, cartilage, and nuclei. A blinded examiner evaluated the slides for end-plate decortication, presence and extent of fusion (criterion was a bony bridge between the two vertebral bodies), the quality and quantity of bone in the implant and in contact with the implant, and the extent of bone ingrowth into the fusion cage device.

After qualitative analysis was performed, quantitative histomorphometry was performed using an image analysis system (Image Pro-Plus Imaging Software version 1.2 on a 486 personal

computer). The system was calibrated using a transparent ruler captured in the same plane as the histologic section. Measurements were made of the total width of the intervertebral disc and the width of the area destroyed during the discectomy from right to left on at least four of the coronal sections (two anterior and two posterior) for each animal to measure the extent of the discectomy. After the code to treatment was broken, statistical comparisons for percent discectomy were made between groups.

## Results

The average estimated blood loss for the group undergoing the open technique was 50 mL (range, 50-100 mL), and duration of the operation was 2 hours 50 minutes (range, 1 hour 50 minutes-3 hours 30 minutes). For the laparoscopic group, the average blood loss was 40 mL (range, 40-220 mL), and the duration of the operation was 3 hours 40 minutes (range, 3 hours 10 minutes-4 hours 50 minutes). There were no intraoperative or post-operative complications in either group. There was no implant migration noted in either group during the course of the study (Figure 1, A and B). Motion analysis results showed less motion in lateral bending, flexion, and extension as compared with that of the intact specimen in both groups (Figure 2). However, tensile testing showed that the stiffness was significantly greater ($P < 0.004$) in Group 1 than in Group 2 (Figure 3).

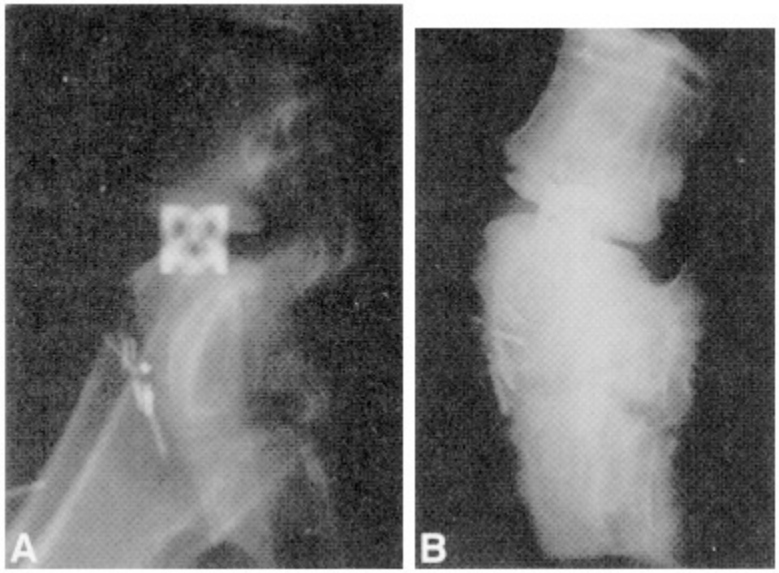


Figure 1

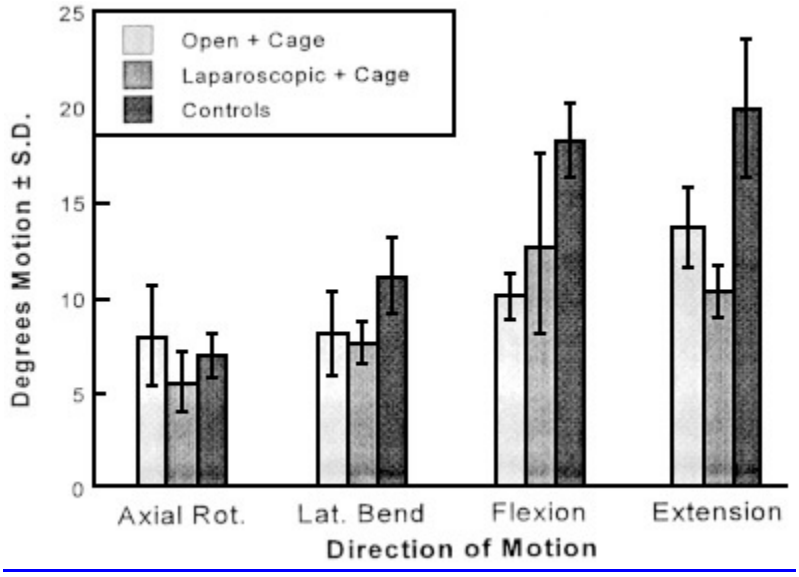


Figure 2

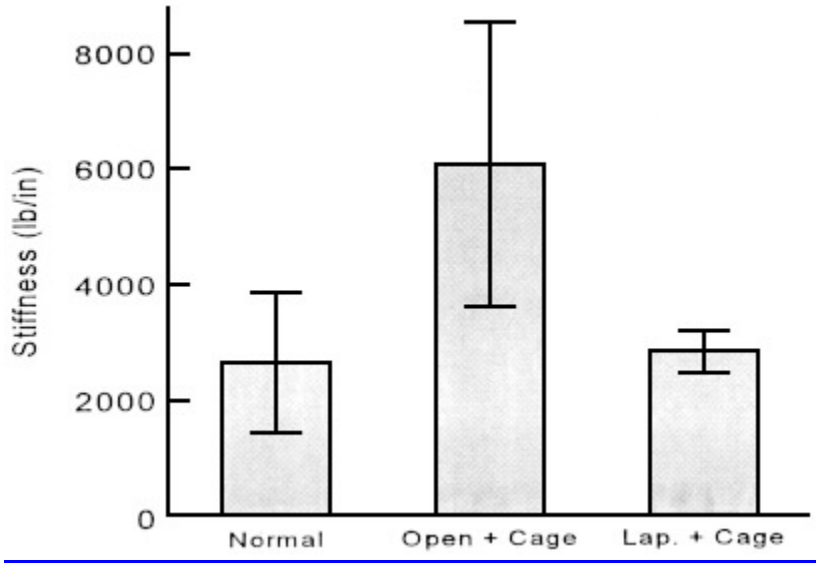


Figure 3

Histologic examination of the surgically treated segments by a blinded observer revealed that no animals in either group had bony bridging across the disc space at the time of death. However, there were distinct differences in the extent of discectomy, adequacy of end-plate decortication, and bone growth into the implant noted between the two groups. In the group that underwent the open technique, there was a greater percentage of disc removed during the discectomy than in the group that underwent the closed procedure (Figure 4). All five end-plates were decorticated in the open group, whereas two of the five animals in the laparoscopic group had no decortication of one end-plate. All of the animals in the open group

had readily apparent bone growth into the ends of the implant, and four of the five specimens demonstrated bone growth into the perforated sides of the implant (Figure 5). Two of the five animals in the laparoscopic group had bone growth into the ends of the implant similar to that of the open group, and the remaining three had minimal bone growth into the ends of the implant (Figure 6). Only one of the five specimens had bone growth into the sides.

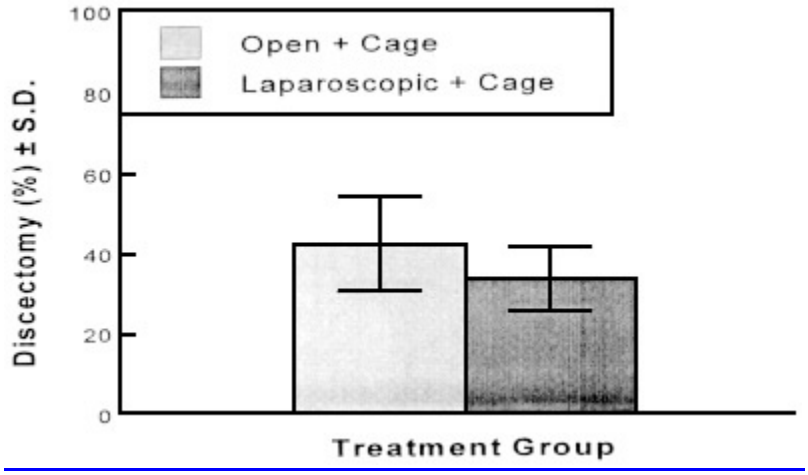


Figure 4

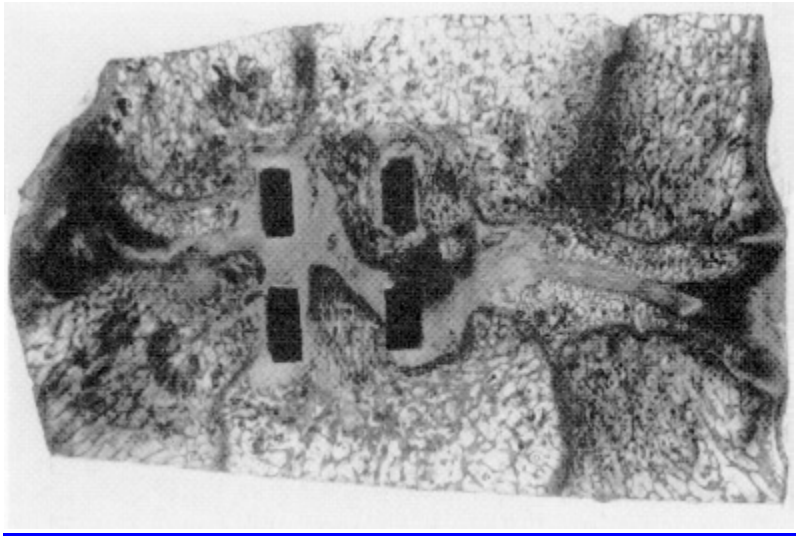

Figure 5

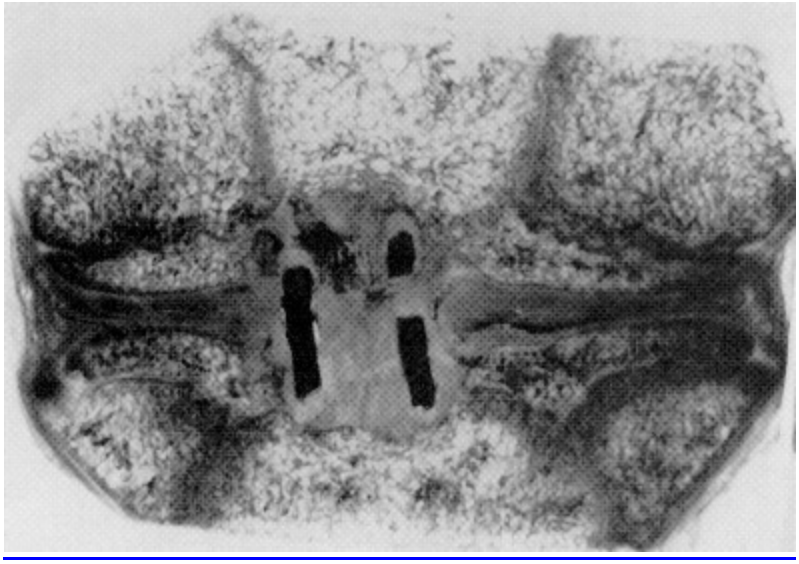

Figure 6

## Discussion

There are no published reports comparing the results of an open lumbosacral fusion with those of a laparoscopic lumbosacral fusion using an animal model. Although the fusion rate and biomechanical environment of the lumbosacral junction in an animal model is different from that of humans,[4] such a study seemed worthwhile because it would allow comparison of the two techniques using biomechanical and histologic analysis that is not possible in clinical studies. A pig model was chosen because it is an accepted model for laparoscopic surgery that is commonly used in general surgery and spine surgery laparoscopic instructional laboratories. This model requires minimal modification of the instruments and technique required to perform the surgery. However, the pig disc space is smaller than that in a human and requires a smaller implant and insertion of a single implant. Most human studies have involved the use of paired implants when feasible but also have suggested that a single implant may be used if there are anatomic variations that limit exposure.[12]

The purpose of this study was to compare the open and laparoscopic techniques with a minimum of confounding variables. An implant system that could be inserted both laparoscopically and open under compression by implant rotation using the same instrumentation and technique was chosen to minimize variables related to implant insertion that could affect outcome. Although the implant system used does not offer the same stability at the lumbosacral junction as do other commercially available threaded systems, it is similar to other techniques of laparoscopic fusion described in the literature.[13] This study demonstrated that discectomy and implant insertion at the lumbosacral junction can be safely performed using a laparoscopic technique. There were no complications encountered in either the open or laparoscopic groups. The average operative time was 50 minutes longer in the laparoscopic group and required fluoroscopy to perform. There were no device migrations or

dislocations in either group during the 3-month study period. These findings are comparable with those of published reports of the clinical results of laparoscopic lumbosacral fusions.

Postmortem biomechanical testing and histologic examination demonstrated significant differences between the two groups that would not be readily apparent on short-term clinical follow-up. The group that underwent the open procedure had better scores on tensile testing than did the group that underwent the laparoscopic procedure. This difference was statistically significant ($P < 0.004$).

Distinct differences also were found between the histologic results of the two groups. A more complete discectomy was performed in the open *versus* the laparoscopic group. Decortication of the end-plates was successfully performed in all of the animals in the open group, whereas this was not adequately performed in two of the animals in the laparoscopic group. There was more bone found growing through and around the implants inserted with the open technique than in those inserted with the laparoscopic group. Although this was not objectively quantified, this observed histologic difference was supported by the better results of the open group on tensile testing.

Despite its limitations, this study highlights some of the potential shortcomings of the early clinical reports of laparoscopic lumbosacral fusion. These studies have involved a small number of patients with short-term follow-up of less than 2 years. Satisfaction with the procedure is based on a low incidence of procedure- and device-related complications, short-term clinical outcome, and patient satisfaction, rather than on histologic or biomechanical comparison of the same technique performed in the open manner *versus* laparoscopically. Based solely on the criteria used in many of the published clinical studies, the group that underwent laparoscopy could be considered successful outcomes, yet based on the postmortem histologic and biomechanical analysis, the outcomes were clearly inferior to those of the group that underwent the open procedure. The limited, short-term clinical and experimental data available on the efficacy of instrumented laparoscopic lumbosacral fusions, as well as the technical nuances and long learning curve associated with the procedure, warrant continued caution in promoting the widespread use of this technique until larger clinical studies with long-term follow-up and additional animal studies can prove its efficacy.

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