Early Results of the Triage Medical® Percutaneous Transfacet Pedicular BONE-LOK® Compression Device for Lumbar Fusion

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ABSTRACT

Study Design:

Prospective clinical and radiographic follow up of patients undergoing interbody fusion with supplemental percutaneous posterior transfacet pedicular fixation using the BONE-LOK® by Triage Medical®.

Objectives:

To prospectively assess the feasibility of a novel percutaneous posterior transfacet pedicular fixation device used for minimal invasive supplemental fixation of lumbar interbody fusions.

Summary of Background Data:

Minimally invasive surgery (MIS) has become widely used across multiple specialties, but in spine surgery, MIS techniques are still relatively young and evolving. Transfacet pedicular fixation is a percutaneous method to fix the lumbar facets while minimizing soft tissue disruption and preserving the adjacent facet joint. Multiple clinical studies show low pseudoarthrosis and reoperation rates, decreased pain scores, and few complications compared to pedicle screw fixation.

Methods:

26 consecutive patients underwent lumbar interbody fusion with supplemental percutaneous posterior transfacet pedicle screw fixation by multiple surgeons. There were 18 males and 8 females with an average age of 41.7 years (range 23 to 72 years). The average BMI was 27.9 (range 22 to 48). Diagnoses include one or two-level discogenic back pain and degenerative spondylolisthesis. Patients were followed prospectively to assess radiographic fusion rates, complications, length of surgery, estimated blood loss, incision lengths, and length of hospitalization. Demographic information was gathered and body mass index (BMI) was calculated for each patient. The primary focus was on signs of implant failure, loosening, and reoperation rates. Only patients followed for at least 6 months were included in this study.

Results:

There were no radiographic signs of implant failure or loosening. One patient had CT evidence of bilateral screws that penetrated the L5 pedicle but there was no neurologic defict. Radiographic fusion was probable in all patients. There were no radiographic signs of implant failure or loosening. The average LOS to place one device was 17.5 minutes (range 10 to 30 minutes) and 30 minutes (range 22 to 48 minutes) for two devices. The estimated blood loss attributed to device placement was less than 100 cc for each patient and the maximum incision size was less than one inch. All surgeons felt the instrumentation was easy to use and became easier with use. Each surgeon reported decreasing surgical time with experience.

Conclusions:

This novel transfacet pedicular device is safe and effective for minimal invasive supplemental fixation to lumbar interbody fusion.

Key Words:

Posterior spinal stabilization, transfacet pedicular fixation, percutaneous, MIS, minimal invasive, interbody, spinal fusion.

KEY POINTS

1. Percutaneous fixation with the Triage Medical® BONE-LOK® was effective for minimal invasive posterior supplementation for 360 degree lumbar fusion.
2. The instrumentation was technically straightforward for multiple surgeons in academic and community practice settings.

3. Single midline incision lengths were less than 2 cm even for 2-level fusions.
4. The blood loss was minimal.
5. Length of surgery decreased with experience.
6. There were no complications attributed to the device.
7. There were no reoperations.
8. There were no hardware failures.
9. The BONE-LOK® had significant cost savings over traditional pedicle screw fixation.

PRECIS

Percutaneous transfacet pedicular fixation using Triage Medical® BONE-LOK® device was safe and effective when used for minimal invasive supplemental posterior fixation for lumbar interbody fusions. There were no technique-related complications, hardware failures, or reoperations. Both academic and community practicing surgeons felt the instrumentation was straightforward and demonstrated decreased length of surgery time with experience.

INTRODUCTION

Pedicle screw fixation has been the device of choice for lumbar fusion but pedicle screw fixation is losing popularity because of complications directly or indirectly attributed to pedicle screws, pain from the wide exposure and soft tissue disruption needed to place screws, and adjacent segment degeneration possibly due to impingement of the adjacent facet complex by the pedicle screws and rods. (1-5) Although, there is increasing interest in total disc replacement (TDR) as a means to address concerns with pedicle screw-related complications, it is estimated that only about 5% of patients undergoing lumbar fusions have single level discogenic disease and would qualify for a TDR. (6-7) For many surgeons, 360 degree fusion utilizing an interbody device is still the preferred treatment method. As such, implant manufacturers have developed stand-alone anterior interbody fixation methods while others have developed percutaneous posterior pedicle screw options to limit the complications associated with traditional posterior pedicle screw fixation. Although there is a growing number of percutaneous pedicle screw options that have diminished the amount of soft tissue disruption associated with traditional pedicle screws, the techniques are still more disruptive and the cost of the devices more expensive compared to facet screw fixation. With these continued limitations facing pedicle screw fixation, there is increasing interest in transfacet pedicular fixation to allow for minimal invasive percutaneous placement posteriorly. (10-29)

Percutaneous facet screw fixation has been shown to limit the surgical exposure, soft tissue disruption, incision size, length of surgery, estimated blood loss, perioperative pain, and pseudoarthrosis and reoperation rates compared to traditional pedicle screws. (8-9) Multiple biomechanical (10-16) and clinical studies (16-29) have justified facet screw fixation as a technique that provides stable fixation comparable to pedicle screw fixation both short and long term. Pseudoarthrosis rates vary from 2% to 9% with greater than 90% good to excellent clinical outcomes.

In 1948, King described placing a screw directly across the facet joint. (27) This was the first documented report of a facet screw. Boucher, in 1959, described placing a longer screw starting on the lamina just medial to the inferior facet and directed through the pedicle. (28) In 1986, Magerl used an even longer screw directed across the base of the spinous process, through the laminar, and across the facets. (29) All three methods fixate the facets and avoid injury to the adjacent facet above the fused segment, which may decrease the incidence of adjacent segment disease. A novel cannulated transfacet pedicular device has been developed to improve on the ease of applying facet screw minimally invasively with a built-in mechanism to apply graded compression across the facet joint. The device is cannulated to allow percutaneous insertion using guide wires. A double helical thread design along with the ability for axial compression increases the biomechanical stability. (14) The purpose of this study was to report the early clinical results of this transfacet pedicular device as a minimal invasive percutaneous posterior fixation option to supplement lumbar interbody fusion in patients with discogenic back pain.

METHODS

Since may 2004, eight surgeons performed anterior interbody fusions supplemented posteriorly with a percutaneous 4.5mm transfacet pedicular compression fixation device (Figure 1A) (BONE-LOK® Transfacet Pedicular Fixation System, Triage Medical®, Inc. 13700 Alton Parkway, Suite 160, Irvine, CA 92618) in 26 consecutive patients. There were 18 males and 8 females with an average age of 41.7 years (range 23 to 72 years). The average BMI was 27.9 (range 22 to 48). The device is based on Triage Medical® patented CLASP® (Compression Locking Anchor with Secondary Purchase) technology platform. (Figure 1B) The Teleport™ access system allows percutaneous BONE-LOK® placement. (Figure 1C-D) The anterior lumbar interbody device was packed with either

Figure 1A. The Triage Medical® BONE-LOK®.

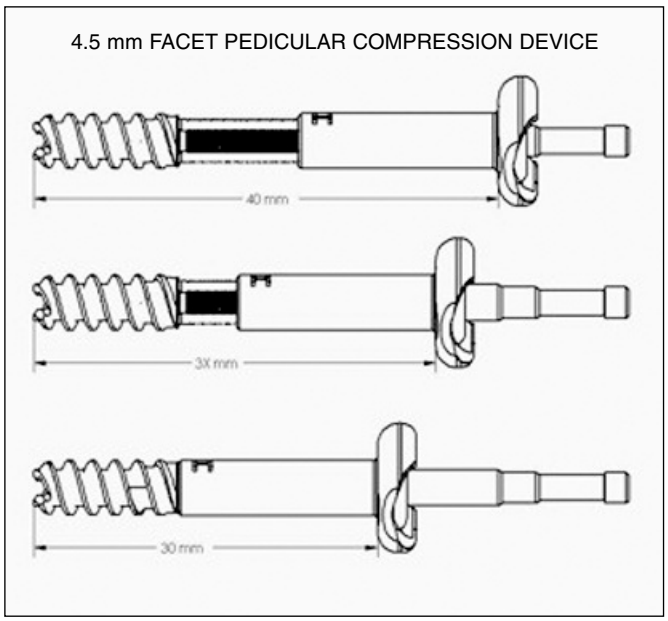

Figure 1B. Graded changes in the length of the device.

Figure 1C. The Teleport™ used for minimally invasive access to the facets.

demineralized bone matrix (DBM) or bone morphogenic protein-2 (BMP) as Infuse (Medtronic Sofamor Danek, Memphis, TN). Each patient underwent anterior and posterior fixation on the same day. No navigation system was used to aid with device placement. Four of the seven surgeons were in an academic institutions and three were in a private community practice. For this report, only patients with a minimum of six month followup were included for review. Patient charts and postoperative plain radiographs and CT scans were reviewed to document demographic data, BMI, diagnoses, incision size, length of surgery, estimated blood loss, technique-related complications, hardware failure, reoperation rates, and pseudoarthrosis.

Inclusion criteria were patients with one or two-level discogenic low back pain with no spondylolisthesis or scoliosis. Anterior lumbar fusion was performed with either femoral ring allograft, PEEK, or metal. The interbody devices were placed direct anteriorly in 13 patients, Posterolaterally through a TLIF approach in 9 patients, laterally through the XLIF approach in one, and caudal to cephalad between the anus and sacrum to place the TRANS1 device in three patients. The ALIFs were placed at L3-S1 in 8 males and 5 females, The TLIFs at L4-S1 in 2 females and 7 males, the TRANS1 devices at L5-S1 in three males, and the XLIF devices at L3-4 and L4-5 in a female. ALIFs were placed at L4-5 alone in four patients, L5-S1 alone in four patients, at L3-5 in one patient and at L4-S1 in four patients. TLIFs were placed at L4-5 in one patient, at L5-S1 in five patients, and at L4-S1 in three patients. All nine patients who had TLIFs had unilateral facet devices and pedicle screws on the contralateral side. Only one patient who had an ALIF, placed at L5-S1, had unilateral facet device placed. Therefore a total of 69 transfacet pedicular BONE-LOK® devices were placed between L3-S1. There were eighteen single and eleven two-level cases.

TECHNIQUE

Transfacet pedicular fixation followed the technique described by Boucher. (28) **Even though the devices can be inserted using a "mini open" technique the following percutaneous approach is the preferred method.**

Step 1 – Percutaneous Approach

This is our recommended approach to limit soft tissues disruption. No incision is made until after the entry point (step 2) and trajectory (step 3) have been established.

Step 2 - Entry Point

The Entry point is the location on the posterior elements at which the BONE-LOK® device is to be placed. This point is determined by landmarks best identified with a series of Lateral and AP fluoroscopy images.

The Cephalad/Caudal entry point is located using the transition of the pars and inferior articular process, which is in

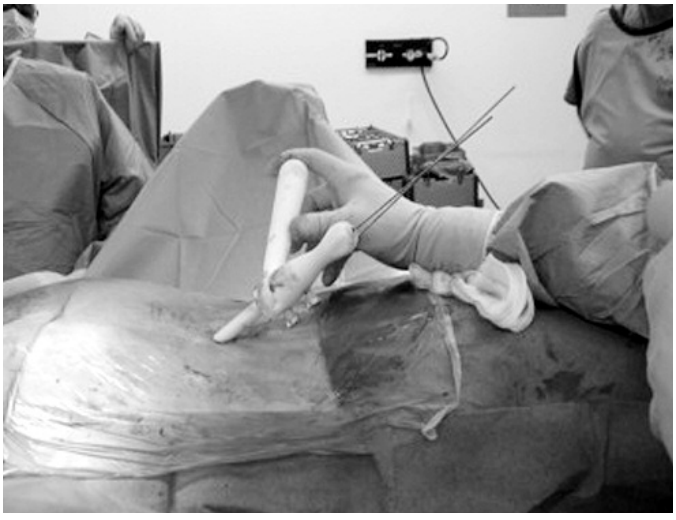

Figure 1D. The Teleport™ being used for access during surgery.

line with the inferior endplate of the superior vertebral body. The Medial/Lateral starting point would be lateral to the junction of the Lamina and the Inferior Articular Process. (Figure 2)

Step 3 - Trajectory

The same series of Lateral and AP fluoroscopy images are used to determine the trajectory of the K-wire that guides the BONE-LOK® device into place. This is done by placing the wire through the skin until an appropriate endpoint is reached, while the fluoroscopy images are being taken. (Figure 3-4)

Step 4 - Guide Wire

1. Once the entry point and initial trajectory have been determined, the start point (at the skin's surface) is marked.
2. The K-Wire (or Access Needle - surgeon preference) is inserted into the patient at the start point along the previously determined trajectory. The wire is advanced until the tip is at the entry point. The wire may need to be backed off and repositioned to insure that the trajectory will enter the pedicle and end near the superior endplate of the inferior vertebral body. The entry point and trajectory are confirmed with a series of Fluoroscopy images. (Figure 3-4)
3. At this point the K-wire is tapped into the superior articular process. The Access Needle is passed over the K-Wire, with the bevel facing up, and tapped into the superior articular process. Once the Access Needle is inserted, the K-Wire is then driven across the facet joint and into the pedicle.
4. Then an incision is made in the skin and fascia just large enough for the chosen Teleport™ access system.
5. The appropriate procedure for the selected Teleport™ access system is followed to allow access to the bone.

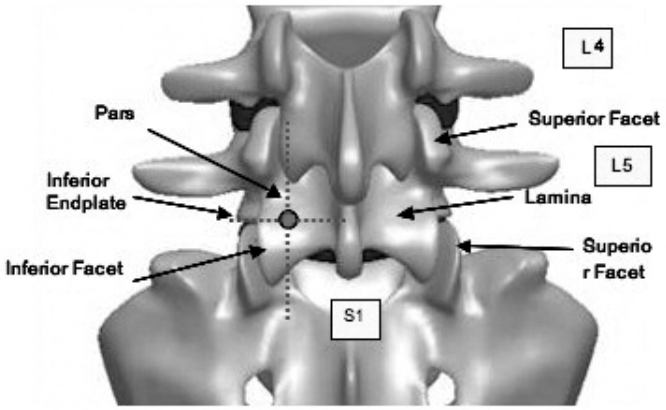

Figure 2. Entry Point.

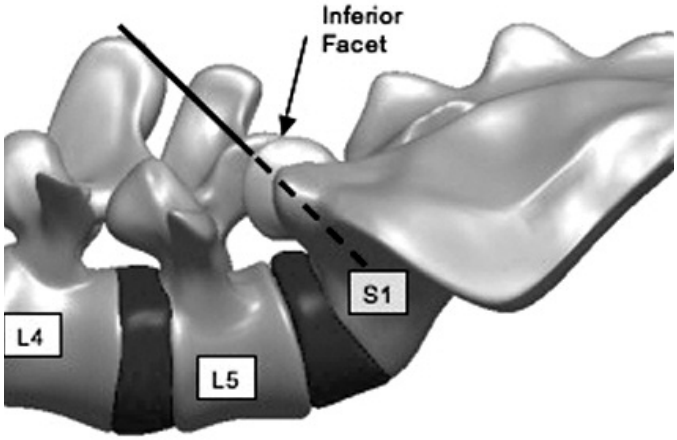

Figure 3A. Lateral view trajectory.

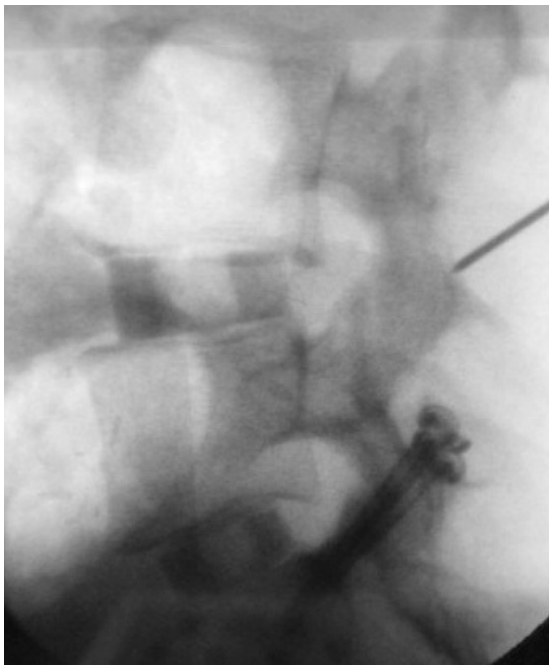

Figure 3B. Lateral trajectory on fluoroscopy view.

Step 5 - Two in one Drill

The supplied cannulated drill is designed to be passed over the K-wire. The drill can be connected through an AO style quick connect, or a Jacobs chuck, as long as they are fully cannulated. The drill is passed over the K-wire and advanced under power until the depth limiting feature contacts the bone. This is confirmed through fluoroscopy.

Step 6 - Tap

The cannulated tap is connected to the provided cannulated ratcheting handle by an AO style quick connect. The tap is driven into the bone until the tip reaches the appropriate depth, which should be verified by fluoroscopy.

Step 7 - Device Placement

The device is loaded onto the driver and is passed over the K-wire. The anti compression clip is removed and the device is advanced to, and then into, the bone; this should be accompanied by a series of fluoroscopy images to insure proper depth.

Step 8 - Compression

After the proper position of the distal tip has been established, the driver is removed and the compression device is passed over the K-wire and over the Pull-Pin. The amount of compression is determined by fluoroscopy and tactile feedback.

Step 9 - Pull Pin Removal

Once the appropriate compression has been achieved, the Pull-Pin must be removed. The Pull-Pin Remover is placed over the K-wire and down to the Device. The Pull-Pin Remover is turned in a "clockwise" direction while applying light downward force. Typically it will take no more than 4 full turns for the threads to release, at which point the Pull-Pin Remover can be removed from the site.

Step 10 - Remove K-wire

Remove K-wire. Devices are intended to be used bilaterally (Figure 5), so the procedure should be repeated for the other

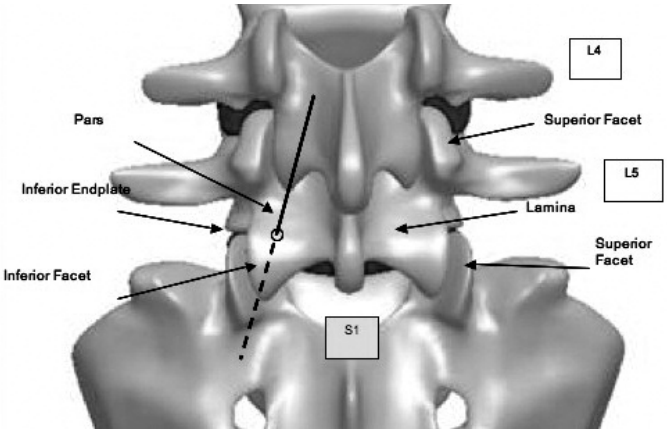

Figure 4A. AP view trajectory.

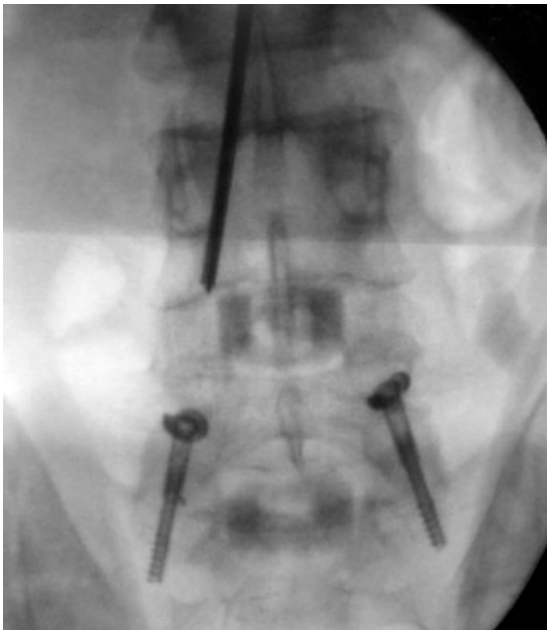

Figure 4B. AP trajectory on fluoroscopy view.

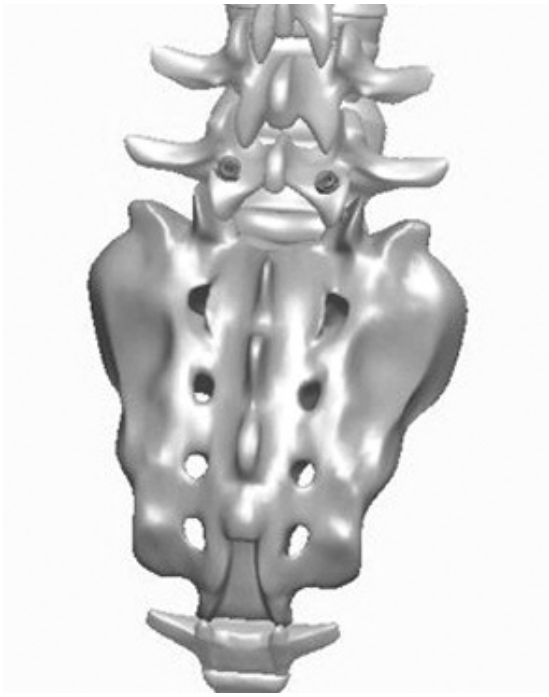

Figure 5A. Bilateral fixation.

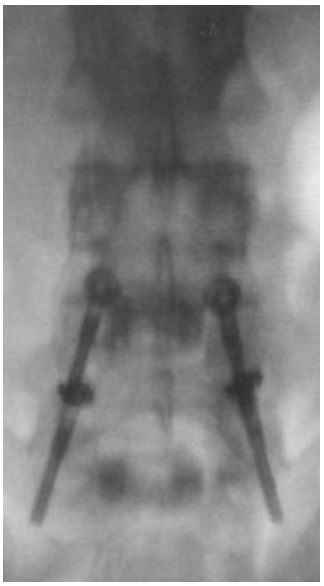

Figure 5B. AP view of bilateral Two-level lumbar fixation.

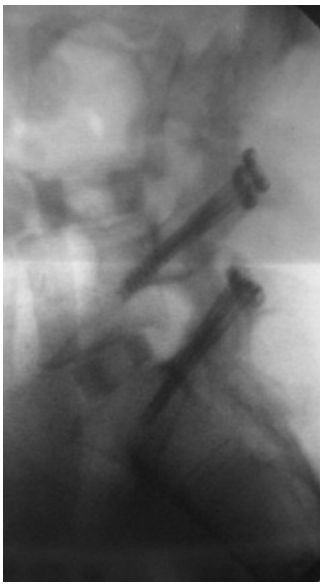

Figure 5C. lateral view of bilateral Two-level lumbar fixation.

facet at that level as well. Once both devices are placed, and it's been verified that both Pull-Pins and both K-wires have been removed; a standard closing procedure is utilized for the small incision. (Figure 6)

RESULTS

There were no radiographic signs of implant failure or loosening. Only one technique-related complication occurred in a patient who had CT scan evidence of penetration of the L5 pedicle. There was no neurologic deficit. Radiographic fusion was probable in all patients. The average LOS to place one device was 17.5 minutes (range 10 to 30 minutes) and 30 minutes (range 22 to 48 minutes) for two devices. The estimated blood loss attributed to implant placement was less than 100 cc for each patient. All surgeons felt the instrumentation was easy to use and became easier with use. Each surgeon reported decreasing surgical time with experience.

DISCUSSION

Many clinical and biomechanical studies have substantiated the use of facet fixation in the lumbar spine. Best and Sasso (8-9), reported a significant improvement in VAS scores, decrease in blood loss, decrease in operative time, and reoperation rates in patients who had facet fixation versus pedicle screw fixation to supplement an anterior interbody fusion device. Stonecipher (22) reported on 35 patients treated with posterior lumbar interbody fusion (PLIF) with facet fixation, with successful fusions and satisfactory outcomes in 34 patients. Margulies (23) reported on 57 patients undergoing single level and two level posterolateral fusions. Overall, good to excellent results were found in 50 patients (88%). El Masry (24) reported on 38 patients undergoing posterolateral fusion with Boucher screw fixation. All patients had a successful fusion and 89% had good to excellent results. Recently, Ferrara et al.(12) performed a mechanical comparison of Boucher screw fixation to pedicle screw fixation. For both short-term and long-term cyclic testing, facet screw fixation was comparable to pedicle screw fixation. Kim et al., (15) assessed interbody fixation of L4-L5 lumbar motion segments from sixteen cadaveric human spines that were tested in cyclic flexion/extension, lateral bending, and torsion following supplemental insertion of either transfacet pedicular fixation devices or 5.5mm pedicle screw instrumentation. A load cell was used to measure the compressive forces on the anterior column during testing. Motion segment stiffness and anterior column compression were analyzed. The transfacet pedicular device demonstrated a statistically similar stiffness and statistically similar anterior column load profile when compared to the pedicle screw system for each testing direction. The authors concluded that the device provided adequate stability for use in single level arthrodesis.

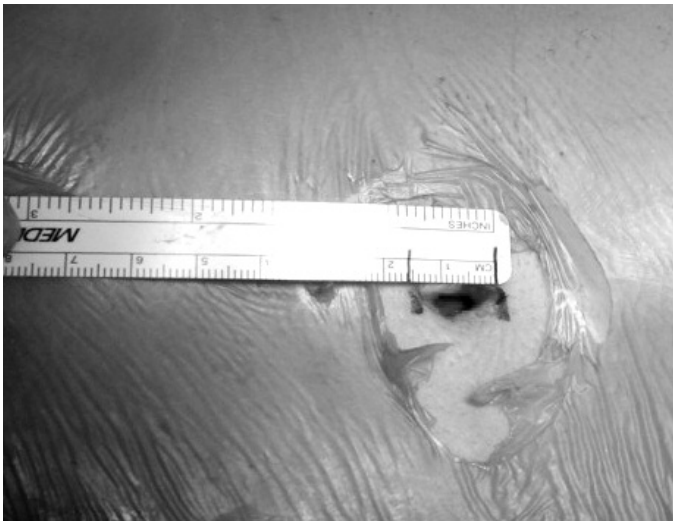

Figure 6. A 15mm incision used for two-level lumbar fixation.

These studies demonstrate evidence for the feasibility and the advantages of minimal invasive facet fixation over more open and disruptive posterior pedicle screw fixation techniques. A histologic and enzymatic analysis of back muscle injury after posterior lumbar surgery led Kawaguchi et al., (30) to conclude that post surgical morbidity is directly proportional to the extent of surgical dissection and trauma. The benefits of minimally invasive lumbar surgery (31-32) and the use of facet screw fixation as a minimally invasive fusion option are evident but it is unclear why facet fixation has not gained more surgical popularity. (10-29)

One possibility is that the technique requires significant precision in terms of screw position and screw length. The transfacet pedicular system used in this study addresses this issue by utilizing a cannulated system allowing insertion over a guide wire. The precise length of the device is adjustable in-situ allowing for precise placement of the implant tip. At that stage, if further facet compression is desirable, a ratchet-gun mechanism allows the surgeon to compress the facets without danger of advancing the device tip. The slight modification to the original Boucher (28) technique also allows the surgeon to obtain thread purchase in the pedicle of the inferior vertebral body. Although the transfacet pedicular device was utilized as a bilateral procedure, the options for its use are broader and include unilateral fixation to supplement percutaneous rod and screw fixation on the contralateral side during minimally invasive posterior interbody fusion. (32) Other options include transfacet fixation in the posterior cervical spine as an alternative to lateral mass fixation. (33)

In conclusion, numerous clinical and biomechanical studies have substantiated the effectiveness of transfacet screw fixation for lumbar fusion. The early results in this report demonstrated

that percutaneous transfacet pedicular fixation using Triage Medical® BONE-LOK® device was safe and effective as a minimal invasive supplemental posterior fixation for lumbar interbody fusion. There were no technique-related complications, hardware failures, or reoperations. Both academic and community practicing surgeons felt the instrumentation was straightforward and demonstrated decreased length of surgery time with experience. Longer term follow up and increased use of this device will provide further information that will hopefully popularize transfacet pedicular devices as the technique of choice for supplemental fixation for interbody lumbar fusion.

INDICATION FOR USE

The intended use of the 4.5mm BONE-LOK® Spinal Fixation device is as a transfacet pedicular device for bilateral facet fixation, and can be used with or without bone graft, at a single level or multiple levels, in the lumbar spine (from L1 through S1).

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