A Novel Decortication and Graft Delivery Technique for Minimally Invasive Spine Fusion Surgery

Anthony Russo MD[1], Travis Greenhalgh[2], Andrew Shoup[2]*

[1] Montana Orthopedics, 435 S. Crystal, Suite 400, Butte, MT 5970

*[*2] SurGenTec, 911 Clint Moore Rd, Boca Raton, FL 33487 (Corresponding Author: travis@surgentec.com)*

Abstract: Minimally invasive (MIS) lumbar fusion has become a popular alternative to traditional methods of lumbar decompression and fusion. When compared with the open technique, the minimally invasive approach can result in decreased pain and blood loss as well as a shorter length of hospitalization. However, the narrower working channel in the MIS technique increases the difficulty of decortication and bone grafting. This paper describes a novel set of instruments, the 3D GraftRasp System by SurGenTec, that physicians can use to help create an optimal environment to fuse the facet joints and lateral gutters during minimally invasive lumbar fusions. Retrospective clinical data from case reports are presented on 3 patients that underwent single level and multi-level MIS lumbar fusions utilizing the 3D GraftRasp System. The case reports show that the 3D GraftRasp System can provide a viable solution for physicians wanting to perform a minimally invasive procedure to achieve fusion while decorticating and packing bone graft around the facet joints and lateral gutters.

Study Design: Retrospective Case Reports

Keywords: Minimally Invasive, Spinal Fusion, Rasp, Bone Grafts, Decorticate, Non-union, Lumbar Fusion, Graft Delivery

AMA CPT Code: 22612 (when applicable)- Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)

I. Introduction

Lumbar spine fusion is widely considered to be the best surgical strategy for the management of different symptomatic spinal pathologies, particularly cases with degenerative disc disease, stenosis, biomechanical instability, and deformity [1]. To obtain satisfactory results, lumbar spine fusion should stabilize spinal segments to eliminate any further degenerative changes and prevent movement at affected levels. Posterolateral intertransverse fusion was the first option for lumbar fusion dating back to the early days of fusion surgeries and used as a gold standard for years. Posterolateral fusion is usually performed adjunct to pedicle screws, facet screws, cortical screws, or other means of stabilization. Prior to fixation devices and hardware, posterolateral fusions were performed stand-alone using bone graft only. The majority of physicians utilize this procedure in open cases, but not during minimally invasive (MIS) cases. The basic aim of MIS is to limit surgical incision and soft tissue damage that is usually associated with open conventional methods. MIS has the potential to achieve superior results in terms of lower postoperative back pain, intraoperative bleeding amount, decreased scar tissue formation and postoperative hospitalization period, with improved quality of life [2]. However, until now it has been a challenge for physicians to perform a posterolateral fusion procedure in a minimally invasive fashion. In traditional open lumbar fusion surgeries, bone graft is typically packed in the lateral gutters while in minimally invasive cases, this is generally neglected due to the lack of access. During these MIS cases, physicians rely solely on the disc space to fuse. When the disc space does not fully fuse, it can lead to non-union and ultimately require revision surgery. There have been many attempts to address this gap, with different techniques and systems, but reproducibility and effectiveness have been challenging to achieve.

Physicians attempting to fuse the posterolateral elements in a minimally invasive fashion currently use a cobb in attempt to remove soft tissue and decorticate the facet/transverse processes. This method hasn't been proven effective and the cobb is not designed to properly decorticate those bony elements. After decortication, the physician packs bone graft using the same incision and attempts to place it over the bony elements blindly while fighting tissue throughout. This is challenging to perform effectively because the bone graft can migrate, and it is difficult to deliver directly to the decorticated area. In an ideal situation, the graft must be placed in one continuous trail bridging the transverse processes and other lateral elements. If not placed properly the graft will migrate from the surgical site and increase the likelihood of non-union.

In the following sections, we describe the unique 3D GraftRasp System by SurGenTec and present retrospective clinical data from case reports with long-term follow-up. The case reports detail preoperative and postoperative data on three patients who underwent a lumbar MIS procedure during which the 3D System provided decortication and bone graft packing capability for the gutters.

II. Technology Description

The 3D GraftRasp System (Dilate, Decorticate and Deliver) is a novel set of instruments that allow physicians the ability to perform a true posterolateral fusion in a minimally invasive fashion. This unique technology recently received the 2020 *Orthopedics This Week* Spine Technology Award [3]. The 3D GraftRasp System was designed to ensure proper bone decortication with tactile and audible feedback while delivering bone graft directly to the surgical site. The GraftRasp (Fig. 1a & 1b) comes in a straight or curved option (Fig. 1c) depending on the anatomy and physician preference. The rasp teeth were designed to be removable and disposable to ensure that the teeth are sharp for every case. The rasp teeth are also available with different teeth patterns to fit varying physician preference.

Fig 1a: GraftRasp

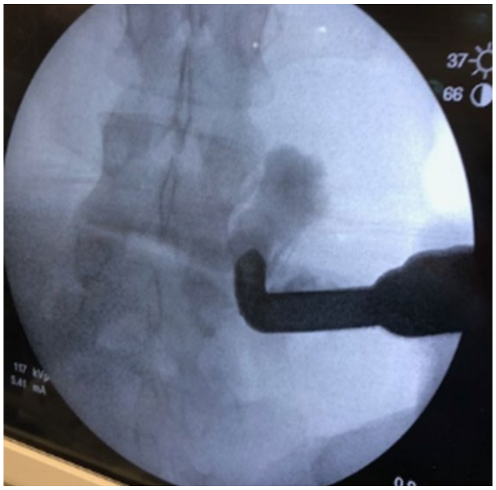

Fig 1b: GraftRasp Docked on the Transverse Process

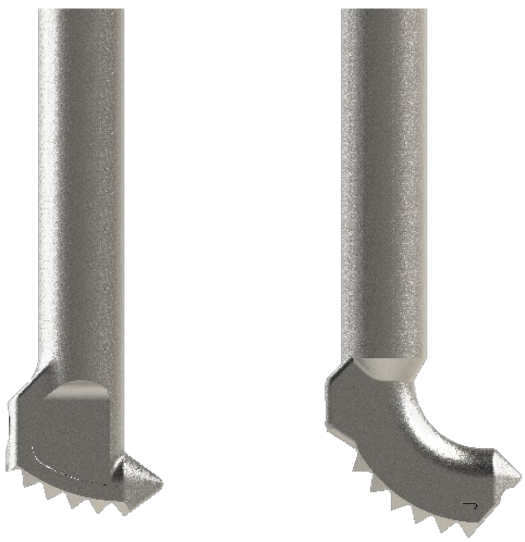

Fig 1c: Straight and Curved GraftRasp Tip

To allow for universal, quick, and accurate bone graft delivery after rasping, the 3D GraftRasp System is used in conjunction with the GraftGun Universal Graft Delivery System (Fig. 1c). The GraftGun includes a universal loading device which enables physicians to use allograft, autograft, or synthetic biologics. To save time and decrease the risk of cross contamination, physicians also have the option to use one of SurGenTec's synthetic or allograft prefilled tube options.

Fig 1c: GraftGun Universal Graft Delivery System

A unique feature of the 3D system is the ability of the physician to deliver bone graft directly through the GraftRasp, as it has a lumen that can accept the GraftGun tube. Without removing the rasp from the decortication site, the GraftGun may be actuated to deliver graft through the aperture of the rasp directly over the facet joint and in between the two transverse processes. The GraftGun is designed to deliver bone graft precisely out of the rasp aperture to the surgical location. The system works well with the custom dilation set or free-handed, depending on physician preference.

The 3D GraftRasp System is FDA cleared [4] and is the only device of its kind cleared by the FDA to allow physicians to simultaneously decorticate bone and deliver graft to an orthopedic site. The system is indicated to be used in orthopedic procedures to rasp or decorticate bone from transverse processes and/or facets, and for the delivery of hydrated allograft, autograft, or synthetic bone graft material to an orthopedic surgical site.

III. Surgical Technique Used in Clinical Cases

The physician's surgical technique below describes the use of the 3D GraftRasp system. A standard MIS-

TLIF technique was utilized during the 3 cases but is not covered in detail below.

Once the necessary incisions and decompressions are done, the physician removed the facet joint and inserted a TLIF cage into the disc space. Pedicle screws were then inserted utilizing a percutaneous or a mini-open technique. After the pedicle screws were placed, the contralateral facet joint and lateral gutters became the focus. Intraoperative imaging was utilized to place the GraftRasp in the correct anatomical location. The GraftRasp was then used to decorticate bone around the facet joints and lateral gutter to prepare for fusion. During rasping, tactile feel and audible sound were utilized to ensure proper decortication of the bone.

Decortication using the GraftRasp was accomplished with either a percutaneous or a mini-open technique. During the percutaneous technique, the GraftRasp was inserted into the inferior pedicle screw incision and placed on the transverse process/vertebral body junction. The rasping occurs on the inferior transverse process and then moves to the superior transverse process. The GraftRasp was moved in a medial/lateral sweeping motion with rotational movement at the junction of the inferior transverse process. Subsequently, it was moved cranially along the lateral border of the facet joint and rotated to obtain appropriate decortication of the facet joint, including the superior articular process and the inferior articular process at the level being fused. The GraftRasp was then moved cranially and lateral to the junction of the superior transverse process and utilized in a medial/lateral sweeping motion with rotational movement to decorticate that junction as well. Once decortication was complete, the GraftGun was inserted into the handle of the rasp and used to deliver fiber allograft over the facet joint and between the adjacent transverse process junctions. Care was taken to deliver graft in a controlled manner between adjacent segments. Once the graft was placed, the GraftGun was removed from the rasp to ensure no bone graft was left in the lumen of the rasp. If any graft remained in the lumen, the flexible pusher was used to eject the graft.

IV. Retrospective Case Reports

Case I

A 55-year-old female presented several years of progressive back pain and 6 months of progressive L5 radiculopathy as demonstrated by radiographs (Fig 2a and Fig 2b). The patient was recalcitrant to nonoperative interventions, including oral medications and steroid injections.

Fig. 2a: Preoperative AP radiograph

Fig. 2b: Preoperative lateral radiograph

The patient's postoperative course was uneventful, and she was discharged to home in less than 24 hours with complete resolution of lower extremity symptoms. She was followed regularly as an outpatient for 24 months postoperatively. By 3 months, the patient was demonstrating significant formation of fusion mass both within the intervertebral disc space and in the lateral gutters. At the 3-month follow up, the patient felt she had nearly complete resolution of preoperative symptoms.

Images taken at 1 year (Fig. 3a and Fig. 3b) and 2 years (Fig. 4a, Fig. 4b and Fig. 4c) show complete posterolateral fusion. The scans were graded by an independent radiologist to confirm the fusion diagnosis.

Fig. 3b: CT scan at 1-year follow up (lateral view)

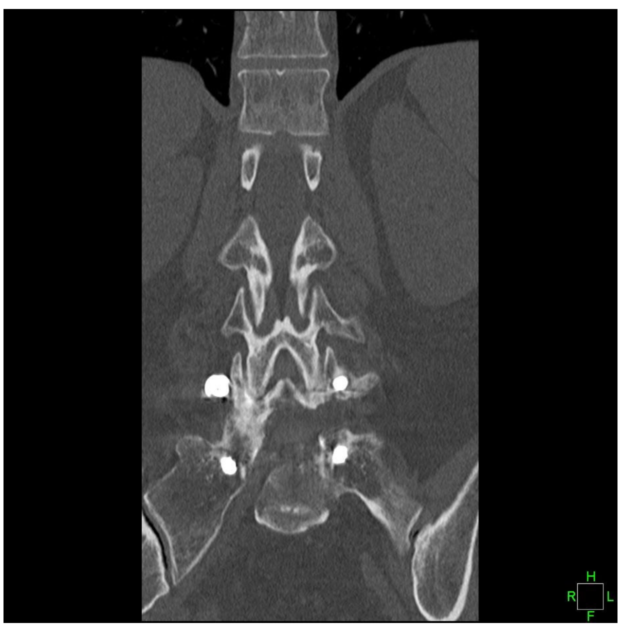

Fig. 3a: CT scan at 1-year follow up (AP view)

Fig. 4a: CT scan at 2-year follow up (AP view)

Fig. 4b: CT scan at 2-year follow up (Lateral view)

Fig. 4c: Lateral Radiograph at 2-year follow up

Case 2

A 64-year-old female presented several years of progressive back pain with lower extremity radiculopathy secondary to spondylolisthesis at L4-5 and degenerative collapse at L5-S1 (Fig. 5a and Fig. 5b). Symptoms were managed for several years with nonoperative interventions, however effectiveness of these interventions waned over 6 months prior to surgery.

Postoperatively, the patient spent two nights in the hospital and upon discharge had complete resolution of radicular symptoms. Back pain steadily improved over the following year. Patient reported no significant back or leg symptoms at 6 months. CT scans taken at 1 year (Fig. 6a and Fig. 6b) and 2 years (Fig. 7a and Fig. 7b) show complete posterolateral fusion as graded by an independent radiologist.

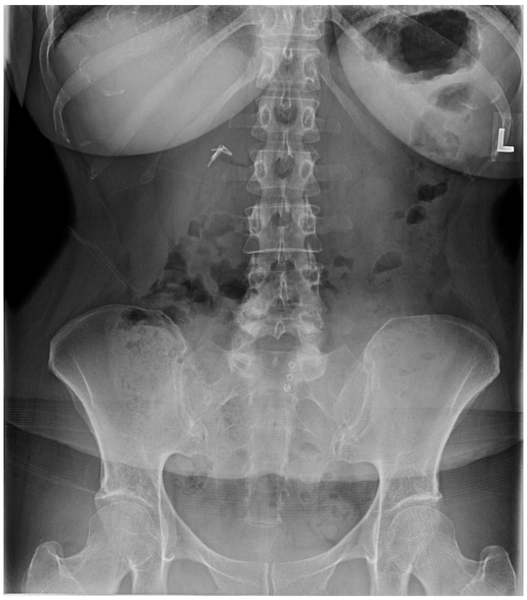

Fig. 5a: Preoperative radiograph (AP view)

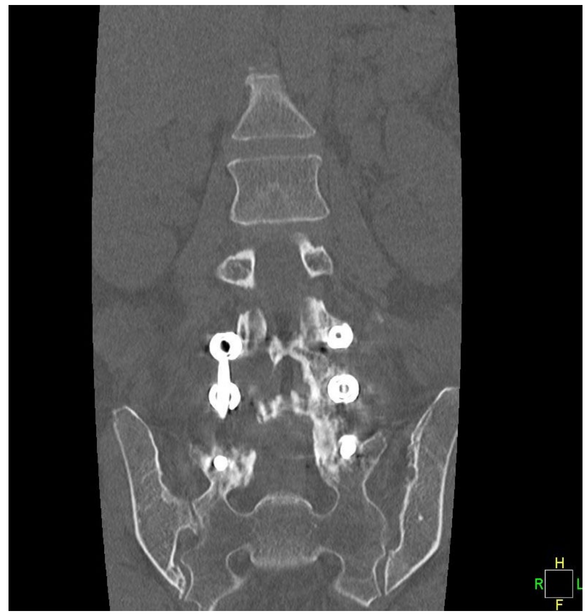

Fig. 6a: CT scan at 1-year follow up (AP view)

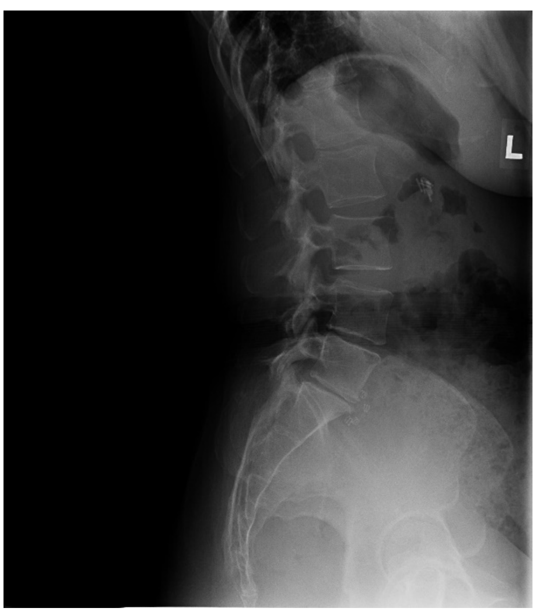

Fig. 5b: Preoperative radiograph (lateral view)

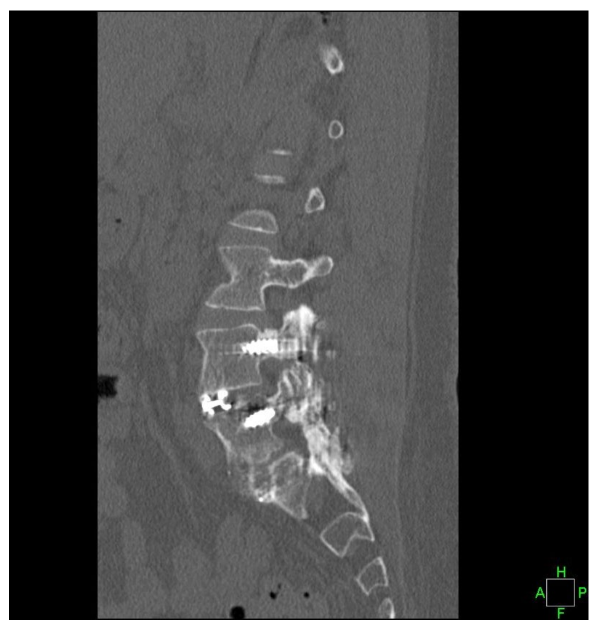

Fig. 6b: CT scan at 1-year follow up (lateral view)

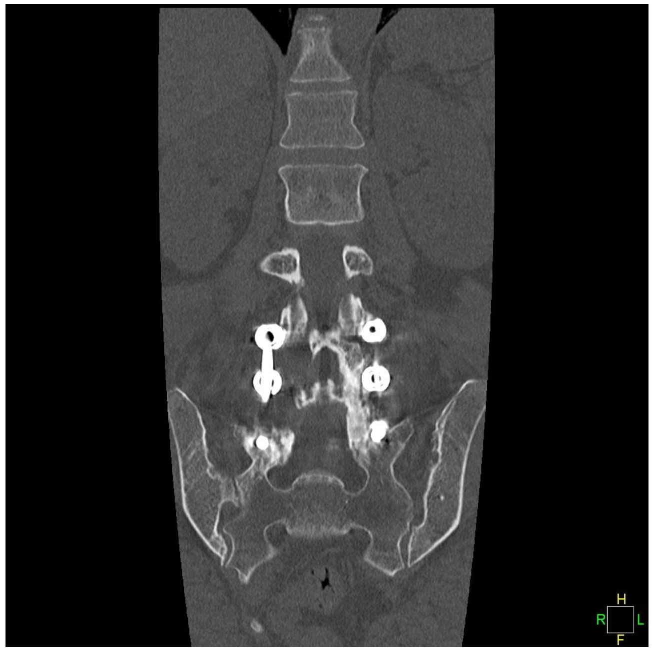

Fig. 7a: CT scan at 2-year follow up (AP view)

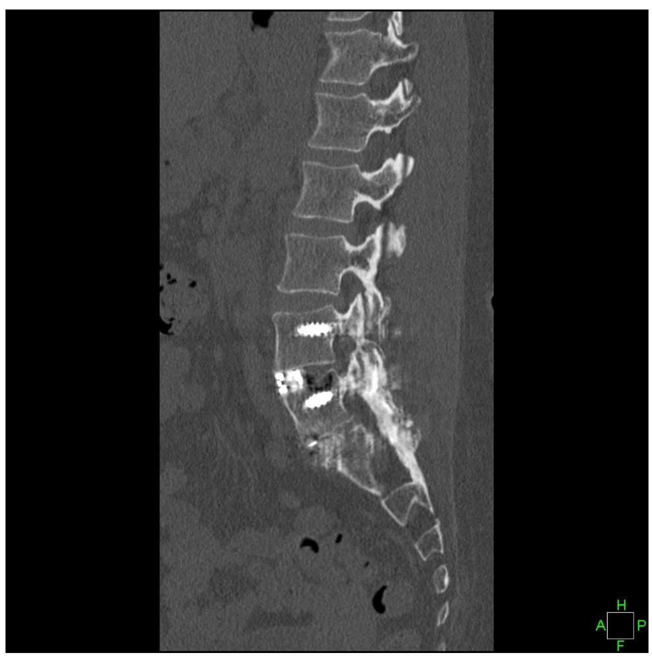

Fig. 7b: CT scan at 2-year follow up (Lateral view)

Case 3

A 46-year-old female presented with progressive back pain and recurrent radicular symptoms secondary to multiple L5-S1 disc herniations (Fig. 8a and Fig. 8b). Nonoperative interventions were not successful.

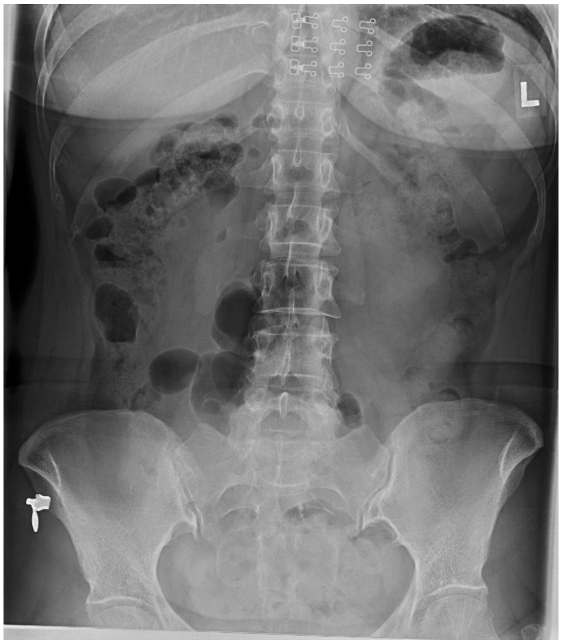

Fig. 8a: Preoperative radiograph (AP view)

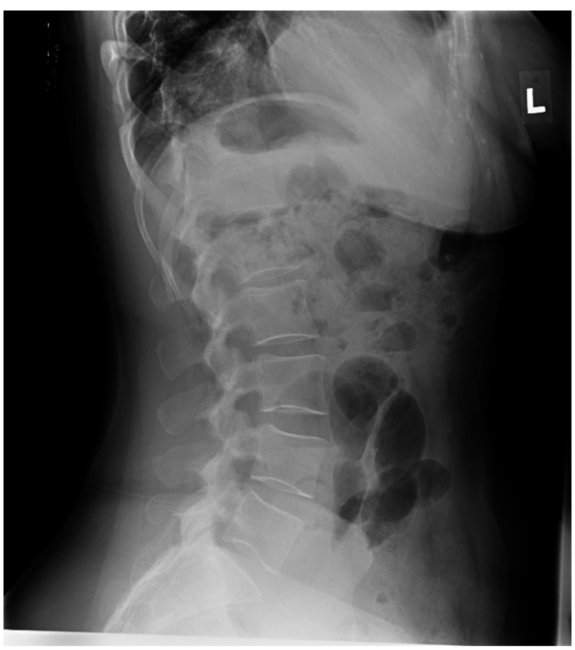

Fig. 8b: Preoperative radiograph (lateral view)

The patient's postoperative course was uneventful, and she spent less than 24 hours in the hospital postoperatively. The patient experienced complete resolution of lower extremity symptoms after surgery. At 6-month follow-up, the patient reported no residual symptoms other than some mild back discomfort. CT scans taken at 1 year (Fig. 9a and 9b) and 2 years (Fig. 10a and Fig. 10b) show complete posterolateral fusion as graded by an independent radiologist.

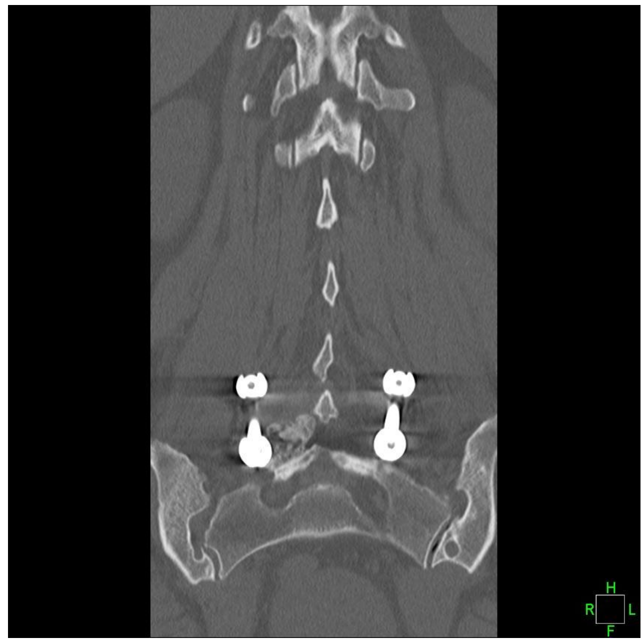

Fig. 9a: CT scan at 1-year follow up (AP view)

Fig. 9b: CT scan at 1-year follow up (lateral view)

Fig. 10a: CT scan at 2-year follow up (AP view)

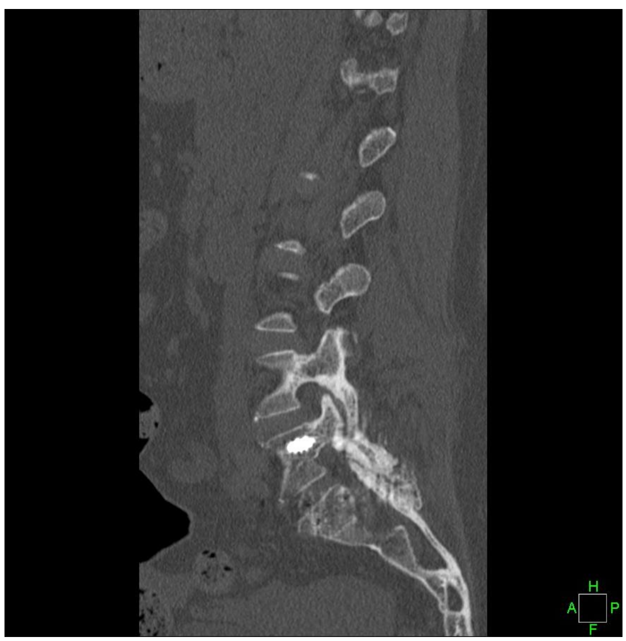

Fig. 10b: CT scan at 2-year follow up (lateral view)

V. Results

Three patients, from 46 to 64 years, that underwent single level and multilevel minimally invasive transforaminal lumbar fusions using the 3D GraftRasp System from SurGenTec were reported in this study. All three patients were released from the hospital within 24 to 48 hours with little to no pain and discomfort. Postoperative imaging was used to assess fusion using x-rays and CT scans. Independent radiologists graded all three patients fused at 1 year and 2 years. This retrospective study provides evidence that successful posterolateral fusion can be achieved in a minimally invasive fashion using the SurGenTec 3D system.

VI. Discussion

Decortication and subsequent graft packing of the posterolateral gutters has long been considered an essential ingredient of successful fusion outcomes. Decortication produces a bleeding bone surface that allows for increased availability of autologous mesenchymal stem cells and growth factors at the fusion site [5]. Coupled with the mechanical stability provided by the implant and the availability of sufficient bone graft, decortication provides an optimal environment for bone growth and subsequent fusion.

Unfortunately, the ability to properly decorticate and pack sufficient bone graft has been a challenge in MIS cases due to the lack of access. A gap has existed in the technology available to MIS physicians to prepare the surgical site and deliver graft that would compare favorably from a satisfactory technique standpoint to their open lumbar fusion counterparts.

The patented 3D GraftRasp System was designed by SurGenTec to specifically address this gap and provide MIS physicians a multifunctional tool that they currently lack to maximize the chances of successful outcomes. The long-term data presented from the retrospective case reports illustrates that the unique ability of the 3D GraftRasp System to decorticate and deliver graft to the posterolateral gutters in an MIS setting sets up favorable conditions for achieving successful long-term fusion.

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