Chapter 3
Superion: An Indirect Lumbar Decompression

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3.1 Introduction

Lumbar spinal stenosis (LSS) is a condition in which the spinal canal becomes narrowed from various causes such as degenerative facet arthropathy, disc degeneration, spondylolisthesis, and thickening of the ligamentum flavum [1]. These conditions can occur in combination or as a singular cause of the disease state. The most common manifestation of spinal stenosis is neurogenic claudication. Neurogenic claudication manifests itself as pain in the lower back and extremities, impaired walking, and other forms of disability in the elderly. Lumbar spinal stenosis is the most frequent indication for spinal surgery in those over 65 [2].

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As increasing numbers of people in the aging population suffer from the debilitating symptoms of LSS, great interest has focused on minimally invasive treatments.

Conservative or nonsurgical management remains the front-line approach for patients suffering from mild-to-moderate symptoms of LSS. Conservative measures include physical therapy, medications, lumbar orthotics, and epidural steroid injections. Due to the mechanical compressive nature of LSS, conservative measures often fail to provide durable long-term relief, especially as symptoms progress.

Open lumbar laminectomy has long been accepted as the standard of care for patients with severe symptoms from LSS [3]. Cauda Equina syndrome remains the only absolute indication for decompression in LSS. All other open laminectomies are performed electively to improve the quality of life for these individuals who have disabling back and leg pain and significant limitations in walking tolerance [4]. The treatment algorithm for those with mild-to-moderate LSS has been less well defined. Patients with mild-to-moderate LSS may obtain partial relief from conservative measures but remain dissatisfied with their outcomes, or they may have failed an extended course of non-surgical management but are unable or unwilling to undergo traditional laminectomy and the considerable risks it entails. Open lumbar laminectomy has been shown to be associated with postoperative complication rates ranging from 12 to 29%, depending on comorbidity status. This is particularly important since LSS is predominantly a disease of the elderly, a demographic inherently associated with higher rates of comorbidities [5].

Indirect spinal decompression via interspinous spacer is a novel technique in the management of patients with mild-to-moderate LSS. While different options exist to accomplish this procedural goal, this chapter focuses on the spacer that, via studies monitored by the Food and Drug Administration, has the highest level of evidence-based support at this time.

The Superion® IDS is a minimally-invasive spinal implant that treats LSS symptoms by limiting extension at the symptomatic level that compresses the neural elements, and is designed for percutaneous surgical placement (Fig. 3.1). The device

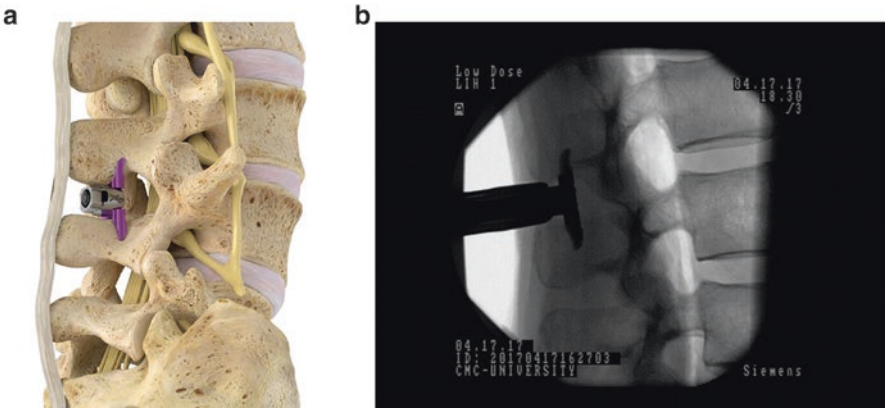

Fig. 3.1 (**a**, **b**) Superion implants

is intended to treat moderate spinal stenosis in the adult spine and can be implanted under general anesthesia, monitored anesthesia care, or local anesthesia with or without neuromonitoring.

3.2 Indications

Indirect Decompression System indications:

- Neurogenic intermittent claudication (NIC) secondary to lumbar spinal stenosis (LSS) presenting with leg and/or buttock pain that is relieved with flexion
- Moderately to severely impaired physical function
- Diagnosis of LSS defined as narrowing among the central, lateral, and/or foraminal spinal canal
- Radiographic confirmation of moderate LSS, as 25–50% reduction in canal area vs. adjacent level(s)
- Symptomatic with history of conservative management ≥6 months
- Male or female that is skeletally mature
- May be implanted at up to two adjacent levels from L1-L5

Indirect Decompression System contraindications:

- Unremitting buttock and/or leg pain in any spinal position that is not relieved with forward flexion
- Axial low back pain
- Spondylolisthesis or degenerative spondylolisthesis >grade 1.0
- Significant dynamic instability of the lumbar spine defined as ≥3 mm translation or ≥5° angulation on flexion/extension
- Significant scoliotic changes defined as lateral curvature >10° at level of intended treatment
- Sustained pathologic fracture of the vertebrae or multiple fracture of the vertebrae and/or hips
- Baastrup's disease (kissing spine syndrome): adjacent spinous processes in close approximation secondary to spine degeneration
- An allergy to titanium or titanium alloy
- Spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ, such as:
  - Instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1 (on a scale of 1–4)
  - An ankylosed segment at the affected level(s)
  - Fracture of the spinous process, pars interarticularis, or laminae (unilateral or bilateral)
  - Scoliosis (Cobb angle >10°)

- Cauda equina syndrome defined as neural compression causing neurogenic bladder or bowel dysfunction
- Diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or equivalent method) in the spine or hip that is more than 2.5 S.D. below the mean of adult normal
- Active systemic infection, or infection localized to the site of implantation
- Prior fusion or decompression procedure at the index level
- Morbid obesity defined as a body mass index (BMI) of greater than 40

3.3 Relative Contraindications

- Severe spinal stenosis with neurologic deficit
- More than two levels of symptomatic lumbar spinal stenosis
- Prior lumbar surgery at affected levels
- Paget's disease or vertebral metastases

Spinous process fractures can occur with Superion® IDS implantation. Potential predictors for spinous process fractures include:

- Thin, or "gracile" spinous processes: if a spinous process is unusually thin, or measures less than 20 mm in superior-inferior dimension, the likelihood of a postoperative spinous process fracture may be increased.
- "Kissing" spinous processes: is the spinous processes are in very close approximation, or are in contact (i.e., "kissing"), increased difficulty may be experienced in placement of the Cannula. Where spinous processes do not "open up" in flexion, the likelihood of a spinous process fracture may be increased (Fig. 3.2).

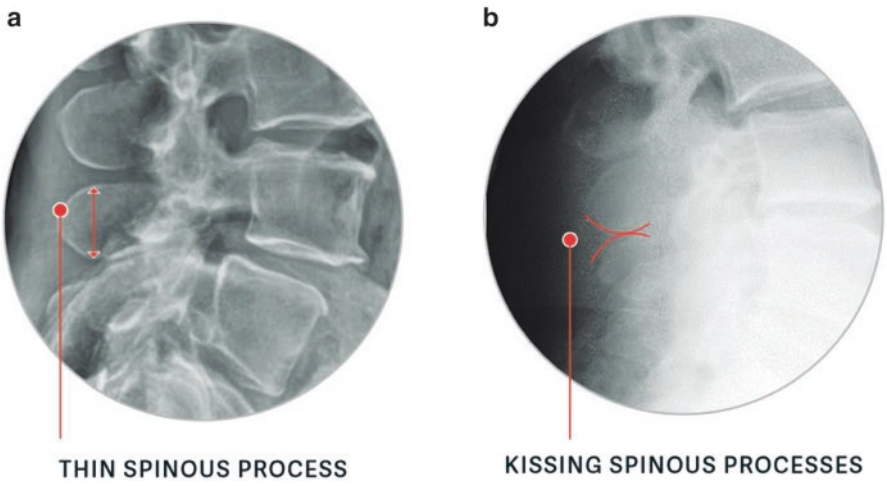

Fig. 3.2 (**a**) Thin spinous process. (**b**) "Kissing spine"

- If the Superion® Implant is placed in a "shallow" or more dorsal position, the likelihood of a postoperative spinous process fracture may increase by a factor >4. To reduce the potential for postoperative fracture, be certain to locate the implant body sufficiently anterior, and confirm implant position in lateral view of fluoroscopy.

3.4 Risks and Complications

Inherent risks and complications are those associated with any other surgical procedure, including:

- Anesthesia-related complications
- Blood loss, blood vessel damage, and hematoma
- Phlebitis or deep vein thrombosis, pulmonary embolism
- Blood transfusion related complications
- Cardiovascular and pulmonary complications
- Injury to muscle, soft tissue, or nerves
- Fever or infection, pneumonia
- Wound seroma, drainage, or delayed Healing
- Discomfort and rehabilitation associated with surgery
- Stroke or death

Risks associated with lumbar spine implants and associated instruments include:

- Sensitivity or allergy to the implant material
- Failure of the device and/or procedure to improve symptoms and/or function
- Pain and discomfort at the operative site secondary to presence of implants
- Implant malposition or incorrect orientation or cam lobes fracture
- Spinous process fracture
- Production of wear debris which may damage soft tissues including muscles or nerves
- Formation of hypertrophic scar tissue at implant site
- Migration or dislodgement of the implant from the original position, losing the effectiveness or causing damage to adjacent bone, soft tissues, or nerves
- Loosening, fatigue, deformation, breakage or disassembly of the implant, which may require another operation to remove the implant

Risks associated with lumbar spine surgery include:

- Damage to nerve roots to the spinal cord causing partial or complete sensory or motor loss
- Loss of bladder and/or bowel functions
- Dural leaks and tears in the tissue surrounding and protecting the spinal cord
- Instruments used during surgery may break or malfunction, which may cause damage to the operative site or adjacent structures
- New or worsened back or leg pain
- Surgery at the incorrect location or level

3.5 The Superion Implants

The implants are made of biocompatible strong titanium, with a high ratio of contact area to implant size, and contoured cam lobes correspond to spinous process anatomy (Fig. 3.3).

Equipment kit (Fig. 3.4): The Superion kit contains sharp and notched tip dilator 1, a main dilator 2, interspinous gauge, an inserter, a driver, a mallet, a radiolucent handle, a ring forceps and a self-retaining retractor.

Fig. 3.3 Superion implants available in five color-coded sizes (8, 10, 12, 14, and 16 mm)

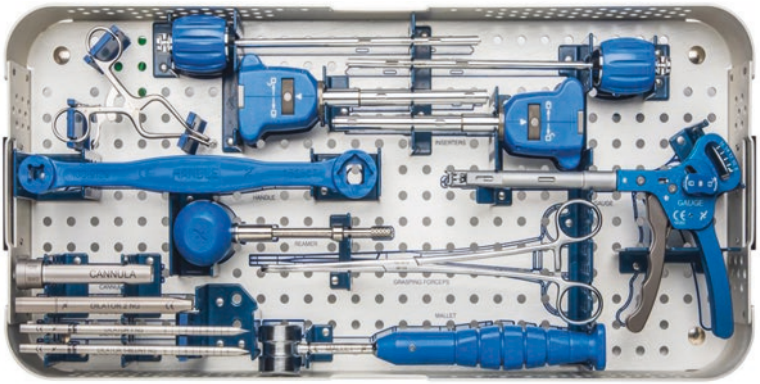

Fig. 3.4 The Superion instrument tray

3.6 Surgical Procedural Steps

3.6.1 Patient Positioning

Place the patient in prone position on a fluoroscopic table over a Wilson frame to ensure adequate flexion of lumbar spine, and to separate spinous processes to facilitate introduction of dilators. Follow the usual operating room discipline, wear appropriate surgical attire, and maintain strict sterile conditions to perform the procedure (Fig. 3.5).

3.6.2 Placement of Incision

Identify correct level and confirm midline and axial position in AP and lateral position. Make a 12–15 mm vertical incision at the operative level to expose superior spinous ligament (SSL). Confirm midline scalpel position under fluoroscopy before the incision (Fig. 3.6).

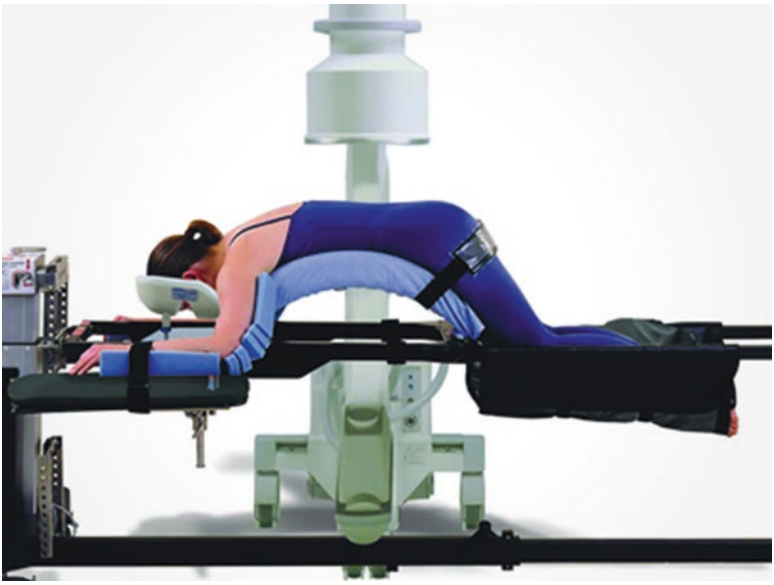

Fig. 3.5 Patient position on Wilson frame for spinal surgery

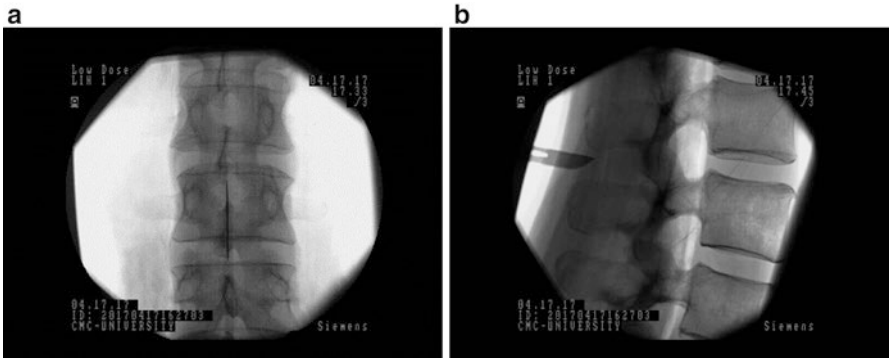

Fig. 3.6 (**a**, **b**) Confirm the position of scalpel before placing the incision

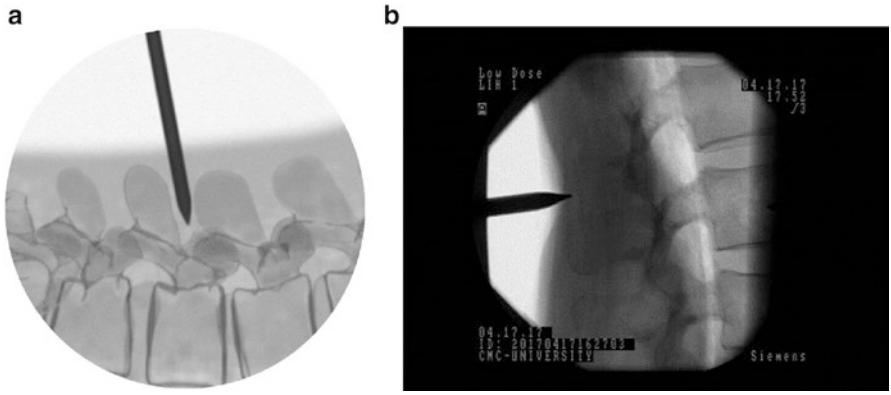

Fig. 3.7 (**a**, **b**) Insertion of dilator 1

3.6.3 Insertion of Sequential Dilators 1 and 2

Insert sharp tip dilator and advance it under lateral fluoroscopic guidance just ventral to SSL. Then using mallet, advance it up to posterior aspect of spino-laminar junction. Insert larger dilator 2 over dilator 1. Align dilator channels with superior and inferior spinous processes. Remove dilator 1, and advance dilator 2 by using radiolucent handle and mallet (Fig. 3.7).

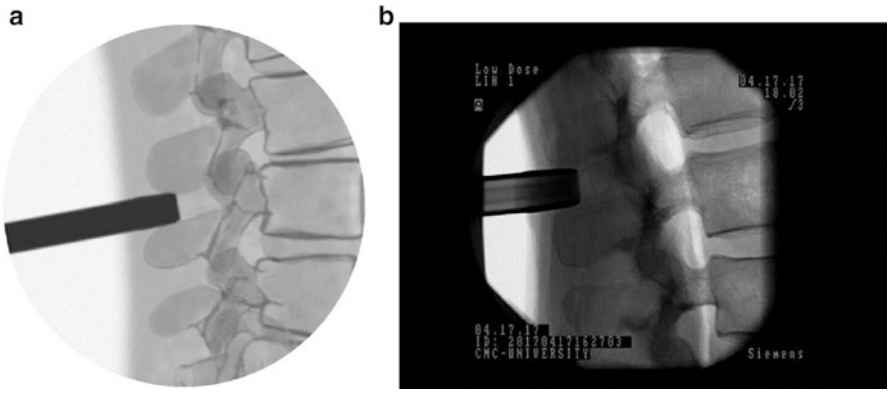

Fig. 3.8 (**a**, **b**) Insertion of cannula

3.6.4 Insertion of Cannula

Ensure the dilator 2 channels are aligned with superior and inferior spinous processes, insert the cannula over dilator 2, and advance it anterior to SSL under lateral fluoroscopy. Confirm the placement of cannula in midline in AP view and 2–5 mm anterior to SSL in lateral view (Fig. 3.8).

3.6.5 Placement of Interspinous Gauge

Insert the interspinous gauge through the cannula with handle directed laterally, and advance it until the shaft is flush with the proximal end of the cannula. Advance the gauge in lateral view to confirm the depth, with dorsal tip contacting spinolaminar junction of superior spinous process (Fig. 3.9).

3.6.6 Measuring Appropriate Size of the Implant

After optimal gauge positioning under live fluoroscopy, actuate the trigger until resistance is encountered at the distal tip, and lock the interspinous gauge. Note the measurement at the proximal end of the gauge handle corresponding to 8, 10, 12, 14, and 16 (Fig. 3.10).

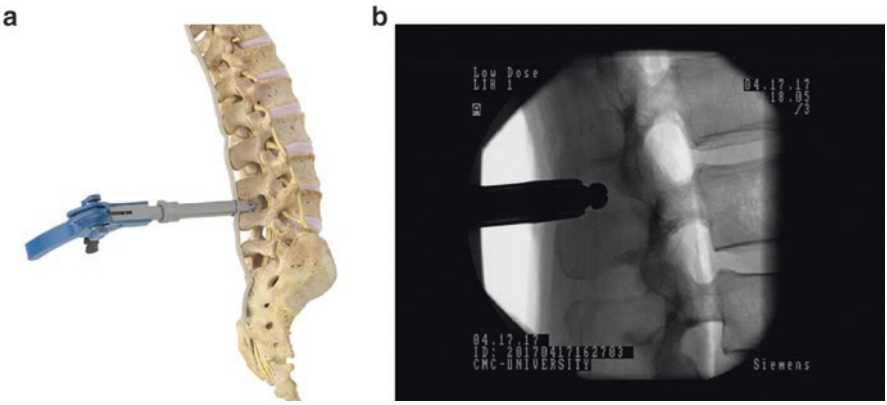

Fig. 3.9 (**a**, **b**) Placement of interspinous gauge

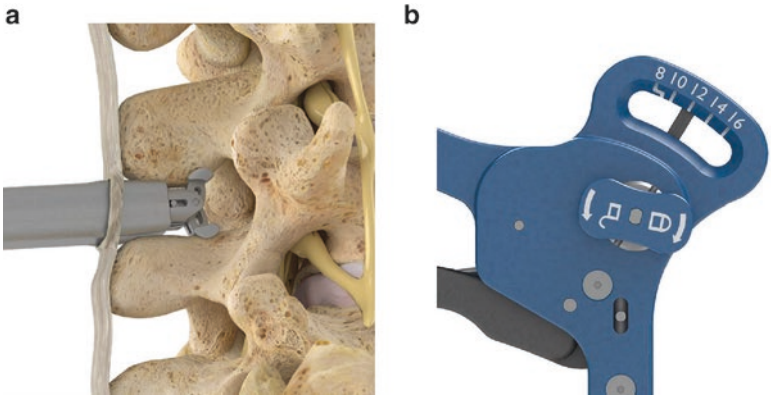

Fig. 3.10 (**a**, **b**) Measuring appropriate size of the implant

3.6.7 Loading of Properly Sized Implant

Ensure the inserter dial to unlocked position. Align the corresponding arrows on body of implant and the distal end of the inserter. Turn the inserter dial to finger-tight locked position. Place the driver inside the inserter and rotate until seats into the implant and is flush with proximal end of inserter (Fig. 3.11).

Fig. 3.11 (**a**, **b**) Loading of properly sized implant

3.6.8 Deployment of the Implant

Place the inserter and driver into the cannula, then align the arrow, pointing cephalad. Deploy the implant by turning the driver clockwise and assess the position under AP and lateral fluoroscopy. Do not force to deploy implant if you encounter resistance, but reposition and redeploy. Under AP fluoroscopy, the cam lobes should be capturing the superior and inferior spinous processes. Under lateral fluoroscopy, confirm the implant is not too far anterior to superior and inferior lamina. Reposition the redeploy if the implant is too far ventral or too far dorsal to spinolaminar junction. After confirming appropriate placement, continue rotating the driver until cam lobes are completely deployed (Fig. 3.12).

3.6.9 Confirmation of Final Position of Implant

It is crucial that the superior cam lobes rest ventrally against superior lamina confirmed under lateral view. If the implant is too far dorsally, will increase the likelihood of spinous process fracture by a factor of >4. In the final position, the superior and inferior spinous processes should be contained within the cam lobes in AP view, and should be positioned ventrally contacting the spinolaminar junction in lateral view (Figs. 3.13 and 3.14).

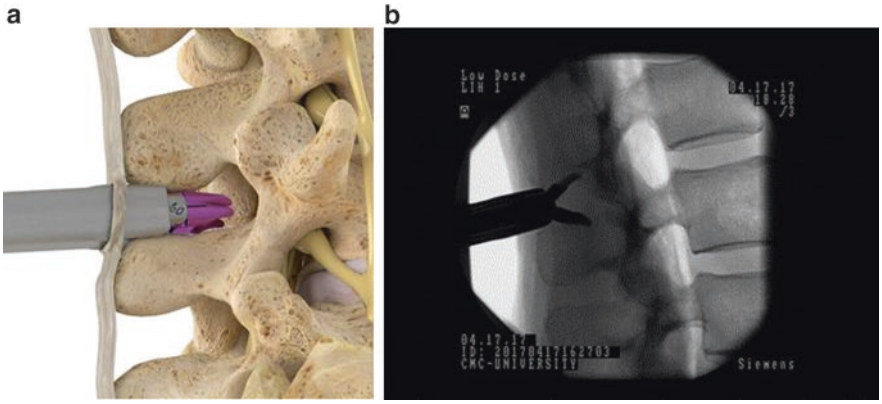

Fig. 3.12 (**a**, **b**) Deployment of the implant

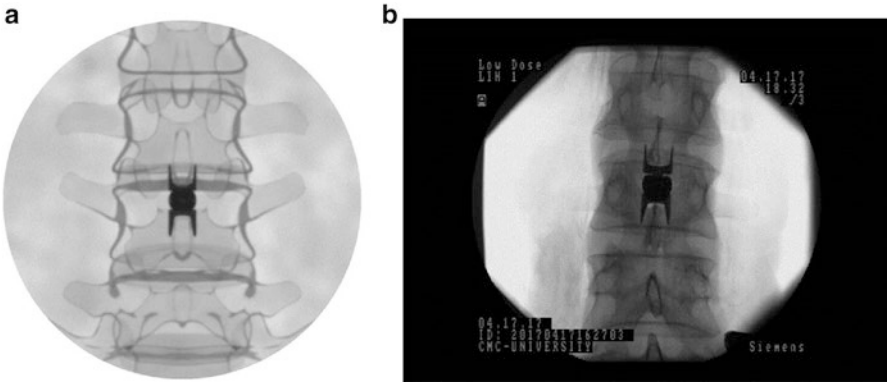

Fig. 3.13 (**a**, **b**) Final position of implant in AP view

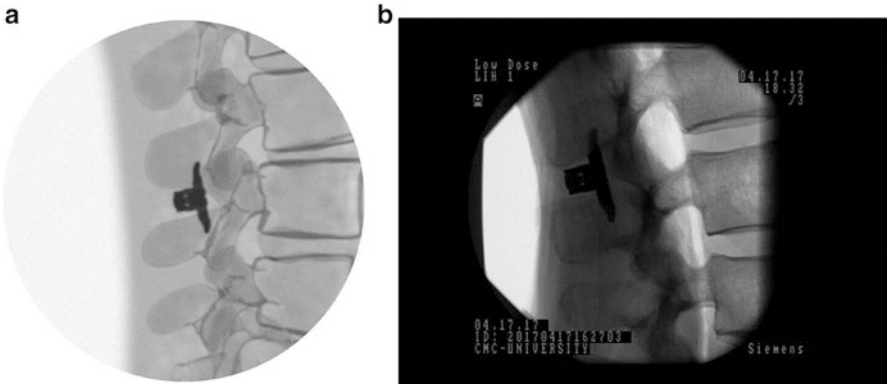

Fig. 3.14 (**a**, **b**) Final position of implant in lateral view

Removal of instruments and incision closure: Remove driver first, and then turn the inserter dial to unlock position and remove inserter. Remove the cannula and close the incision in usual fashion.

3.7 Clinical Pearls Superion

- Patient selection is critical for the success of this procedure. Neurogenic (arising from the nervous system) claudication (leg pain, heaviness, or weakness with walking) and relief with flexion are the most important clinical presentations.
- Up to two levels can be performed in the lumbar spine (excluding L5-S1).
- One must review the patient's imaging (MRI, CT, X-rays) to look for any contraindication to performing the procedure. Examples include Baastrup's disease (kissing spine syndrome), which may make the procedure technically impossible, and thin or gracile spinous processes that may make a spinous process fracture more likely.
- Patient positioning for the procedure with exaggerated lumbar flexion is important to maximize the interspinous space at the targeted level(s). Consider use of a Wilson frame or similar for positioning.
- A Body Mass Index (BMI) less than 35 is ideal. BMI greater than 35 can be done, but the most important factor is adequate visualization of the spinal structures in a lateral fluoroscopic view. If this view is negatively impacted by body habitus the procedure is relatively contraindicated.
- Only advance the cannulas in a lateral fluoroscopic view. To avoid injury to the dura, never advance the cannulas past the intralaminar junction.
- The initial angle of approach is critical between the superior and inferior targeted spinous process. Frequent AP and lateral x-rays are used to slowly guide the sequential dilating cannulas to the correct location with the correct trajectory. Care should be taken to avoid placing these cannulas obliquely off to the side of midline, as this makes the ultimate deployment of the Superion device difficult. It is important to ensure that your incision through the interspinous ligament is in midline and sufficiently deep and large enough to accommodate the dilator.
- Once the Superion device is fully deployed, ensure that it is in a deep anterior position adjacent to the lamina. If the device is more posterior, it increases the likelihood of a spinous process fracture.
- Best Practices for sterility and preventative precautions similar to those for a spinal cord stimulation implant should be used to prevent infection, as this an implant. For example, limit room traffic, double gloving, pre-op antibiotics, wound irrigation, full closure of the wound, and post-op antibiotics.

3.8 Evidence for Superion Therapy: Investigational Device Exemption (IDE) Pivotal Trial

A prospective, multicenter (29 sites), randomized controlled FDA-IDE pivotal trial of 391 patients compared Superion interspinous spacers (N = 190) to the control X-STOP spacer group (N = 201) [6]. Two years' results were published in *Spine* and the primary endpoints were met showing the Superion group was noninferior to the X-STOP spacer group. The predominant patient complaint of leg pain secondary to moderate LSS with intermittent neurogenic claudication was decreased in severity by 70% in both groups as indicated by mean visual analogue scores (VAS). The following was achieved in 2 years: Mean VAS scores demonstrated 77% pain relief for leg pain and 68% pain for back pain for both groups. Oswestry Disability Index (ODI) showed clinical results with a greater than 15%-point improvement in 65% of the patients [1]. Unfortunately, in 2015, the control comparator X-STOP became no longer commercially available in the United States. From the same clinical IDE study, Superion 4-year clinical data was published in *World Neurosurgery* [7]. The study indicated sustained relief of leg pain (78% VAS), back pain (66% VAS), and ODI 62% when compared to baseline [2]. At the time of this chapter completion, the Superion 5-year clinical data was recently accepted in the peer-reviewed journal *Clinical Interventions in the Aging* with similar sustained clinical results for leg and back VAS scores and ODI when compared to baseline.

In summary, the use of interspinous spacers is an option for minimizing the invasiveness of surgical treatment of Lumbar Spinal Stenosis. Proper patient selection, careful attention to procedural detail, and appropriate follow-up in the post-procedural period are each essential steps to an optimal outcome. This evidence-based treatment is an important part of the treatment algorithm, and the minimally invasive nature of the procedure is helpful in reducing risks to patients.

Acknowledgment *All images courtesy of Vertiflex Inc. (Carlsbad, CA, USA); www.vertiflexspine.com*

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