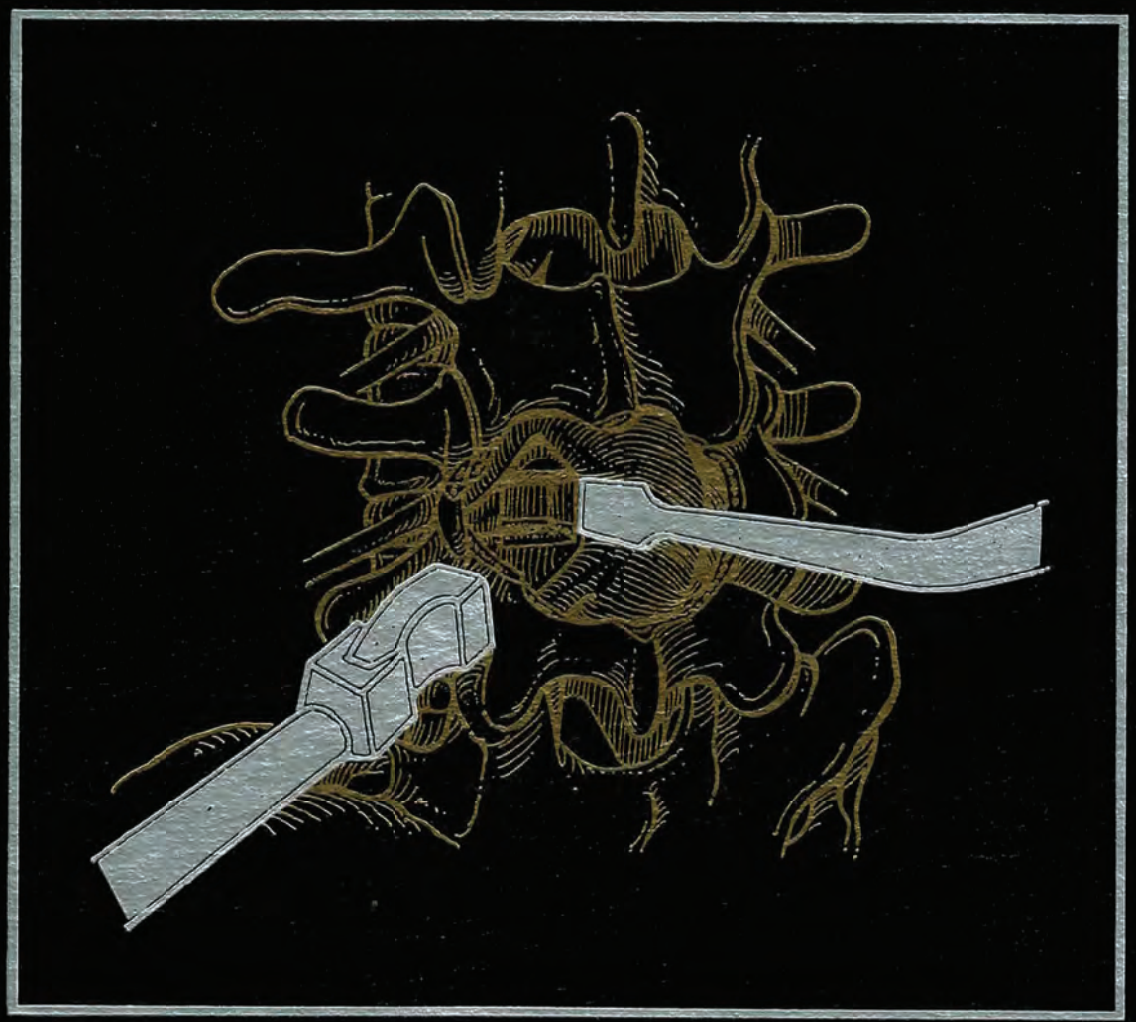
EXHIBIT 1015

LUMBAR INTERBODY FUSION TECHNIQUES

Cages, Dowels, and Grafts



Edited by

Regis W. Haid, Jr. • Mark R. McLaughlin • Richard G. Fessler

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Lumbar Interbody Fusion Techniques

Cages, Dowels, and Grafts

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CHAPTER

16 Technique for Impacted Posterior Lumbar Interbody Fusion

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The techniques for posterior lumbar interbody fusion (PLIF), including its indications, variations, and clinical success rates, have been well documented elsewhere in this book and in the literature.[1-12] Multiple implantable interbody devices, ranging from carbon fiber to titanium to machined allograft, in numerous shapes ranging from threaded dowels to hollow blocks to tapered wedges, have similarly been described. The success rates of such cylindrical devices and bone grafts have been previously documented.[11,13-18] This chapter simply describes our experience with a technique for impacted PLIF that uses a tapered block of cortical allograft bone. We believe that it is considerably easier to navigate rectangular blocks between the exiting superior and inferior nerve roots given the decreased width of the implant. Despite the decreased width of the graft, the rectangular shape preserves the distracted interbody height and the foraminal diameter while limiting root retraction. The significant distractive forces applied may be transmitted to the endplates, and the implant may be placed parallel to the long axis of the thecal sac. By minimizing the nerve root retraction necessary for graft implantation, we hope to minimize the risk of motor and sensory deficits.

The most commonly used rectangular devices include carbon fiber and titanium cages, as well as cortical allograft bone.[19,20] The use of titanium implants has been reported in a number of major European series with acceptable results.[19] We prefer to use allograft bone given its structural stability under axial compression and the fact that the modulus of elasticity of the implant is similar to that of the adjacent vertebral bodies. Not only do the impacted cortical wedges undergo osseous integration, there is no postoperative metallic artifact on imaging studies, which allows for better radiographic assessment of fusion.

Although PLIF procedures have been reported that do not employ pedicle screw fixation, we believe there is significant evidence to support the use of posterior seg-

mental fixation in increasing the rates of spinal fusion.[21] The reported success of pedicle screw fixation in other series has led us to use the technique as an adjunct to the PLIF procedure.[16,21-24] We believe that the combination of an interbody graft under compression, along with posterior segmental fixation, results in an extremely rigid construct and increased fusion rates. We have also found that patients with significant segmental instability demonstrate a more rapid improvement in their pain, which is most likely due to the immediate stability imparted by pedicle screw fixation. Although some surgeons have advocated supplemental intertransverse fusion with this PLIF technique, the potential advantage gained from the additional fusion area may not offset the increased postoperative pain associated with the muscle dissection required to expose the lateral aspects of the transverse process. In certain difficult cases, we combine an intertransverse arthrodesis with a PLIF in an attempt to increase the likelihood of a successful fusion.

TECHNIQUE

We prefer to use the Tangent PLIF system (Medtronic Sofamor Danek, Memphis, Tenn.). This system offers an array of instruments to facilitate disc removal and endplate preparation prior to placement of the machined cortical allograft bone. Additionally, the allograft bone (Regeneration Technologies, Tallahassee, Fla.) is available in multiple lengths and heights modeled to follow the fit of an intraoperative series of templates. Thus the surgeon may select a customized allograft implant without having to consume operative time fashioning a fibular graft by hand. Such engineering is designed to maximize surgical efficiency and minimize operative time.

SURGICAL TECHNIQUE

Step 1: Harvest Autologous Iliac Crest Graft. The patient is anesthetized and placed in the prone position. We typically use the Jackson spinal table or chest rolls and thigh supports to recreate the patient's normal lumbar lordotic angle. Care is taken to specifically pad all pressure points, thereby minimizing the risk of neuropraxic injury (Fig. 16-1). Through an appropriate length midline incision, we divide the subcutaneous tissues down to the level of the lumbodorsal fascia. Once the fascia is identified, a suprafacial plane is dissected laterally to expose the posterior superior iliac spine

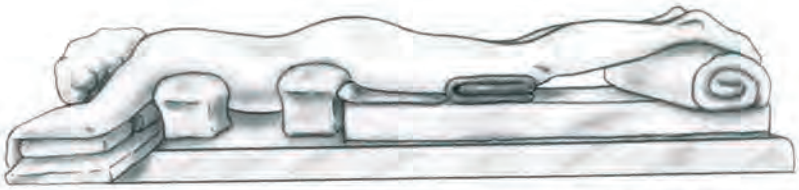

FIGURE 16-1. The patient is placed in the prone position with all appropriate pressure points padded. It is important to maintain lumbar lordosis by keeping the legs in a neutral position. We have found the Jackson table to be best suited for lumbar fusion procedures because it allows for good lordosis, leaves the abdomen in a dependent position to decrease epidural bleeding, and is ideal for use with C-arm fluoroscopy. (With permission from Medtronic Sofamor Danek.)

(PSIS). The fascia is opened over the PSIS, and this area is dissected in a subperiosteal fashion to expose the roof of the PSIS. The gluteal musculature attached to the ileum is preserved when exposing this landmark. Minimizing dissection in the region decreases discomfort at the postoperative graft site. Typically, a Hibbs or Taylor retractor is helpful in exposing the crest. A cortical window is opened in the PSIS using osteotomes, taking care to expose the cancellous bone but not to violate the anterior surface of the crest. Using a combination of bone gouges and curettes, approximately 30 ml of autologous graft is harvested. The amount of graft harvested may be tailored to the number of levels fused. The gouges are used in a rotating fashion so that the bone can be harvested by undermining the cancellous bone without violating the cortex, leaving the pelvic wing intact. The bone is then morcellized and stored for later use during the procedure. One of us (C.L.B.) prefers to use locally harvested autograft from the morcellized decompression elements. The graft site may be irrigated and packed with Gelfoam (Pharmacia, Upjohn, Kalamazoo, Mich.), waxed with bone wax, or reconstructed using methylmethacrylate bone cement or a prefabricated titanium or synthetic cement restrictor (Medtronic Sofamor Danek, Memphis, Tenn.). The fascial incision is closed in a water-tight fashion and attention is then returned to the midline incision.

Step 2: Obtain Wide Bony Exposure. After the bone graft has been harvested, the midline incision is extended deeper and the spinous processes of the appropriate surgical level are exposed. By means of a subperiosteal technique, paraspinous muscles are dissected laterally to the base of the transverse processes. The pars interarticularis is identified and dissected free of the overlying soft tissues (Fig. 16-2, *A*). The pars interarticularis is an important landmark both because it marks the region of the exiting nerve root and is helpful in determining pedicle entry site. We prefer to mark our preliminary pedicle entry sites prior to bony decompression. These sites are then reconfirmed with fluoroscopic guidance and by direct palpation of the pedicle within the canal. It is important to expose the base of the transverse process and pars interarticularis of the superior and inferior vertebra before proceeding with the decompression.

Step 3: Perform the Decompression. The spinous processes and lamina are removed to complete the decompression of the spinal canal yielding an intracanal view of the pedicles. We prefer to utilize a high-speed drill to thin the posterior elements and bone overlying the lateral recess. This minimizes blood loss during this portion of this procedure and makes bone removal easier with the Kerrison rongeur. After the decompression is performed, the bone chisel or osteotome is used to remove the medial aspect of the facet joint (Fig. 16-2, *B*). In appropriately selected patients, the spinous processes and interspinous ligament may be left intact. The decompression and access to the disc are accomplished through bilateral hemilaminectomies and medial facetectomies.

Step 4: Follow the Nerve Roots. After the decompression of the spinal canal is performed, the pedicles of the superior and inferior vertebrae can be visualized and palpated. A Woodson dissector is utilized to follow the course of the nerve laterally into the foramen, ensuring adequate decompression.

Step 5: Find the True Axilla of the Superior Nerve Root. After the foraminotomy is performed and the remaining lateral recess exposure is completed, the epidural venous plexus is coagulated and divided. The superior and inferior nerve roots must be identified, and the venous plexus of the superior nerve root must be carefully coagulat-

ed and divided as well. This tethering venous plexus must be released to expose the true axilla of the nerve root. This allows for a larger portal of entry for the interbody device and provides greater relaxation of the superior nerve root. The combination of medial facetectomy and superior nerve root release will minimize the possibility of nerve root traction injury or cerebrospinal fluid leakage.

Step 6: Place the Pedicle Screws. Some of us (M.R.M., R.W.H., and B.R.S.) prefer to place the pedicle screws before performing the PLIF. Quite simply, if a dural tear is encountered during the PLIF portion of the procedure, significant epidural bleeding may occur. The loss of spinal fluid makes the bleeding more difficult to control because of the lack of the normal static tamponade from the intact thecal sac. Occasionally the bleeding can be significant enough to prohibit placement of the interbody device. The pedicle screws may be placed by means of a freehand technique, guided imaging, or with fluoroscopic guidance.

Step 7: Perform a Generous Discectomy. Next a radical discectomy is performed after incision of the anulus (Fig. 16-2, *C*). This discectomy is performed bilaterally so

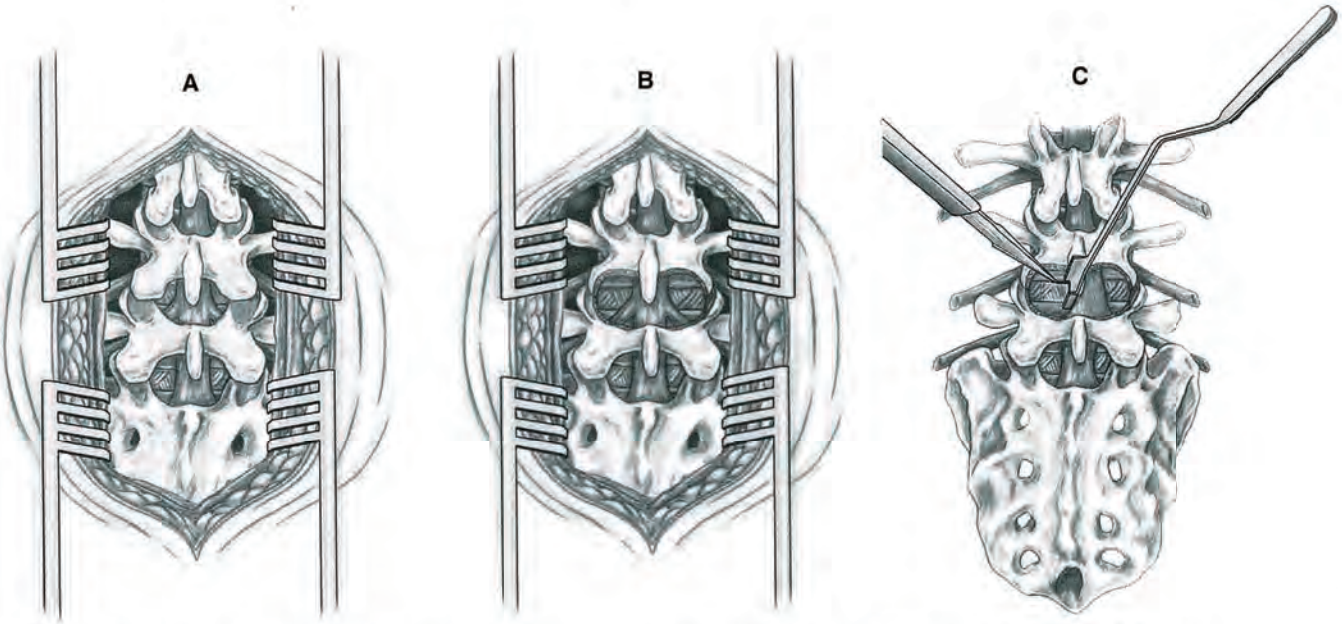

FIGURE 16-2. A, Adequate exposure includes complete exposure of the affected level with a clean dissection of the pars intra-articularis and base of the transverse processes of the proposed levels for fusion. **B,** For L4-5 PLIF, a laminectomy is performed to expose the exiting and traversing roots bilaterally. The dissection and bony removal must be adequate to allow for safe retraction of the nerve roots when the interbody graft is navigated between the nerve roots. Although not depicted in this illustration, we typically place the pedicle screws at this point in the procedure. Alternatively, pedicle screw fixation can be performed after the PLIF is completed. **C,** An annulotomy and discectomy are performed bilaterally, and soft tissue fragments are removed from the intradiscal space. This will allow for removal of extruded fragments, and will decompress the canal. A generous discectomy at this point prevents the distractor from popping out after placement. If the disc space is collapsed, an aggressive discectomy may not be possible until distraction is achieved. (With permission from Medtronic Sofamor Danek.)

Continued.

that the soft fragments within the interspace and any extruded fragments are removed. This aggressive decompression will allow for treatment of any symptomatic nerve root compression, as well as entry into the disc space for distraction. It should be noted that if there is significant disc space collapse, a complete discectomy may not be possible until adequate disc space distraction is achieved.

Step 8: Perform the PLIF. Steps 1 to 7 highlight the critical preparation required for safe placement of the interbody grafts. Once these preliminary steps are completed, the disc space is then sequentially distracted under fluoroscopic guidance until the optimal disc space height is achieved and foraminal diameter is restored. This is performed by initially inserting the smallest distractor possible (Fig. 16-2, *D*). The size of the distractors ranges from 7 to 14 mm. Once the distractor is tamped into place within the disc space, it is rotated 90 degrees to allow for distraction of the space. The T-handle is then removed, attached to the next larger sized distractor, and placed in the contralateral disc space. This is repeated using progressively larger distractors on alternating sides until the optimal disc height is obtained. The final distractor or the largest one is left within the disc space in the distracted position. The interspace may then be prepared on the contralateral side. Interspace preparation consists of three instruments: the rotating cutter, the round scraper, and the box chisel. These are designed to sequentially remove the disc material and create a channel that exposes cancellous bone to the implant.

On placing the rotating cutter, a nerve root retractor is placed with minimal retraction. Each rotating cutter has depth markings on the instrument, which can be used to assess the depth of insertion within the disc space. The rotating cutter is inserted into the disc space with the cutting blades parallel to the dural sac. If necessary, the cutter is rotated once or twice at a depth of 20 mm to remove osteophytes from the dorsal endplate. Removal of osteophytes facilitates placement of the guides and free-hand chisel. The rotating cutter is then inserted to a depth of 25 to 30 mm with the flat surface parallel to the dura. The rotating cutter, after being placed at the optimal depth as verified by C-arm fluoroscopy, is then rotated and carefully lifted out. This removes the soft tissue from the disc space (Fig. 16-2, *E*). The rotation is continued with sweeping motions with sequentially larger cutters as necessary for safe removal of the disc. This initial endplate preparation is accomplished from the lateral anulus to beneath the midline.

The remaining soft tissue and cartilaginous endplate are removed using the round scraper (Fig. 16-2, *F*). Gentle scraping or curettage of the soft tissue with small repetitive motions in an anterior to posterior direction will best prepare the endplate. The goal of this step is to roughen the surface of the endplate to optimize graft incorporation. This step removes any residual soft tissue on the endplate and promotes contact between the interdiscal bone graft and the bleeding endplate to optimize graft incorporation.

The size of the cutting chisel for preparation of the endplate may be determined by preoperative planning or by comparison to the height restored by the interspace distractor. A template overlay can be placed on the radiographic image at the adjacent level and can often help determine graft size. The cutting chisel size should be approximately 1 to 2 mm larger than the distractor size.

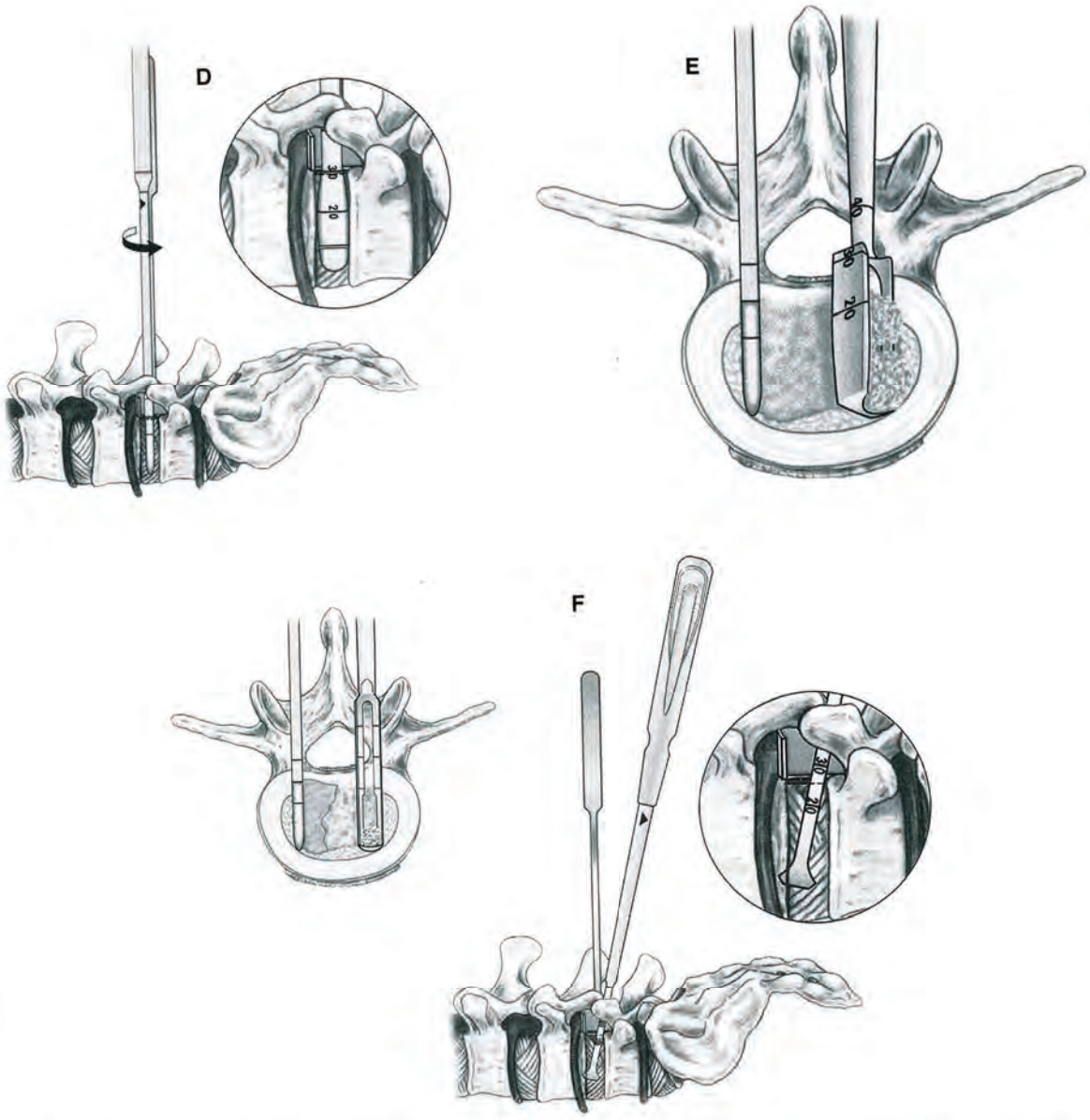

FIGURE 16-2, cont'd. D, The disc space is then sequentially distracted until the original disc height is restored. This is achieved by initially inserting a small distractor with an attached T-handle with the flat surface parallel to the endplate. The T-handle is then rotated 90 degrees to distract the collapsed space. Then, on the contralateral side, a slightly larger distractor is placed and similarly rotated. Each side is then alternately distracted until the desired disc height is achieved. **E,** Once the desired distraction is achieved, one distractor is left in place while the contralateral side is prepared. On the opposite side, the rotating cutter is then inserted and rotated to remove residual disc material and create a channel in the dorsal-most endplate. **F,** The remaining soft tissue and cartilaginous endplate coverings are removed from the endplate using the round scraper. By means of short stroking motions, curettage of the soft tissue adherent to the endplate is performed starting medially and progressively moving laterally until both the caudal and cephalad endplates are denuded of soft tissue. This step will optimize graft incorporation. (With permission from Medtronic Sofamor Danek.)

Continued.

With the dura gently retracted, the guiding tongs of the cutting chisel may be seated into the disc space (Fig. 16-2, *G*). With the use of C-arm fluoroscopic guidance to determine the trajectory, the chisel is impacted into the disc space to a maximum depth of 30 mm. This depth may vary depending on the specific patient and the vertebral body being instrumented.

The cutting blades remove the residual osteophytes and complete the debridement of the endplate. The chisel serves to parallel the endplates and essentially create a channel, which is the optimal bed to receive the impacted Tangent wedge. Fluoroscopic images should be checked frequently during the chisel step to avoid asymmetrical resection of either the superior or inferior endplate.

After impacting the cutting chisel up to the desired depth, the slap hammer is attached to the chisel handle and rotated 90 degrees. The chisel is removed with a repeated gentle upward stroke. After the cutting chisel is removed, a disc distractor 1 mm larger than the anticipated wedge size is then prepared and placed into the prepared disc space and rotated 90 degrees to maintain the disc space height. The distractor from the opposite side is then removed. Insertion of the Tangent wedge is not recommended until preparation of the entire disc space has been completed.

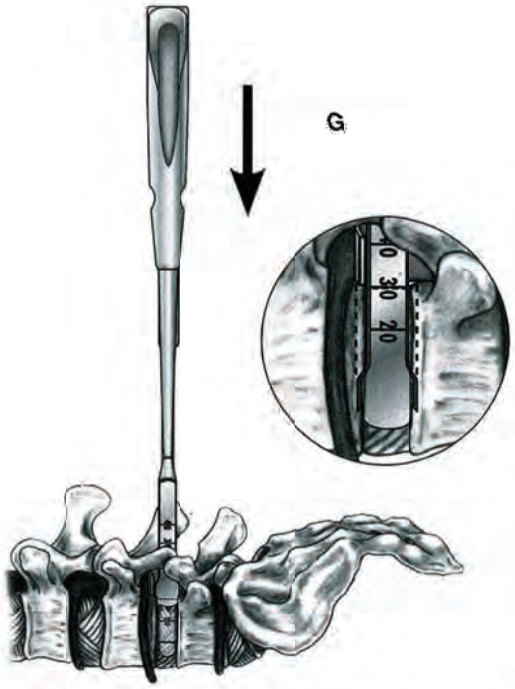

FIGURE 16-2, cont'd. G, Final endplate preparation is performed with the use of the cutting chisel. The dura is retracted and the tongues of the cutting chisel are seated into the disc space. Under fluoroscopic guidance, the chisel is impacted into the disc space to a maximum depth of 30 mm. The cutting blades remove residual osteophytes and complete the debridement of the endplate in a parallel path, creating an optimal bed to receive the Tangent wedge. (With permission from Medtronic Sofamor Danek.)

Continued.

After endplate preparation is completed on the initial side, the distractor is inserted to maintain the disc space height and the contralateral side is prepared in a similar stepwise fashion. Once endplate preparation is complete, the wedge height and length should be determined and appropriate grafts chosen and prepared. The wedge height is again determined by the preoperative template provided or the cutting chisel (8 mm, 10 mm, or 12 mm). The length of the Tangent wedge is determined by evaluation of preoperative radiographs and the templating process as well as by intraoperative fluoroscopy.

The appropriate-sized Tangent wedge is firmly attached to the inserter with a threaded trocar (Figs. 16-2, *H* and *I*). The wedge is then gently impacted into the disc space at the appropriate angle until the implant is countersunk approximately 3 to 4 mm.

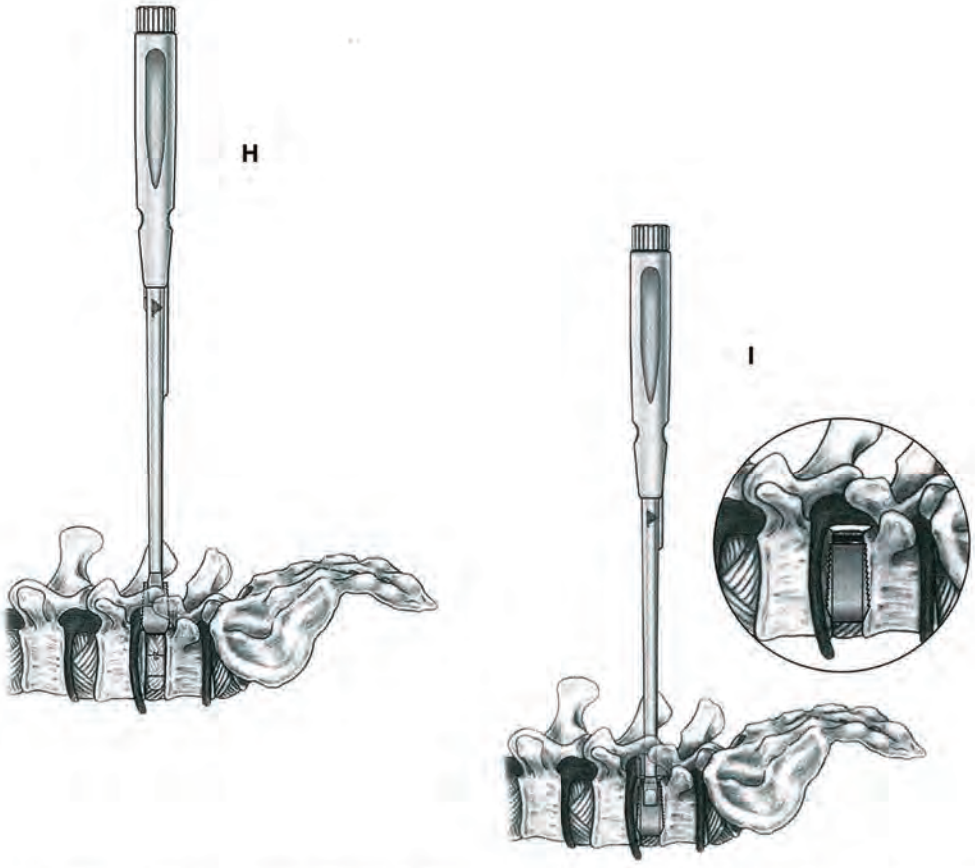

FIGURE 16-2, cont'd. H and **I,** The appropriate Tangent wedge is then firmly attached to the inserter with the threaded trocar. The wedge is then gently impacted into the disc space until it is 3 to 4 mm below the posterior margin of the vertebral body. It is important to aim the wedge down the channel that was created by the cutting chisel. (With permission from Medtronic Sofamor Danek.)

Continued.

Step 9: Autograft Placement. Once the Tangent wedge has been inserted on the contralateral side, the disc distractor is removed from the ipsilateral side, and morcellized autograft (harvested earlier) is packed into the prepared disc space beneath the midline structures. Sufficient cancellous bone may be swept medially using the 7 mm distractor to adequately fill all of the residual intradiscal space (Fig. 16-2, *J*). The second Tangent wedge may then be inserted into the disc space along the previously prepared channel. Once it is seated and the inserter is removed, any residual space between the wedge and the anulus may be filled with the remaining autograft cancellous bone (Fig. 16-2, *K*).

Step 10: Supplemental Segmental Internal Fixation. After the initial wedge placement, the extradural space and foramina are probed to ensure adequate decompression of the neural elements. To facilitate satisfactory immobilization of the grafted interspace, segmental internal fixation is applied using a standard technique. Autograft bone may be placed posteriorly over the facets and medial transverse processes to complete the grafting procedure.

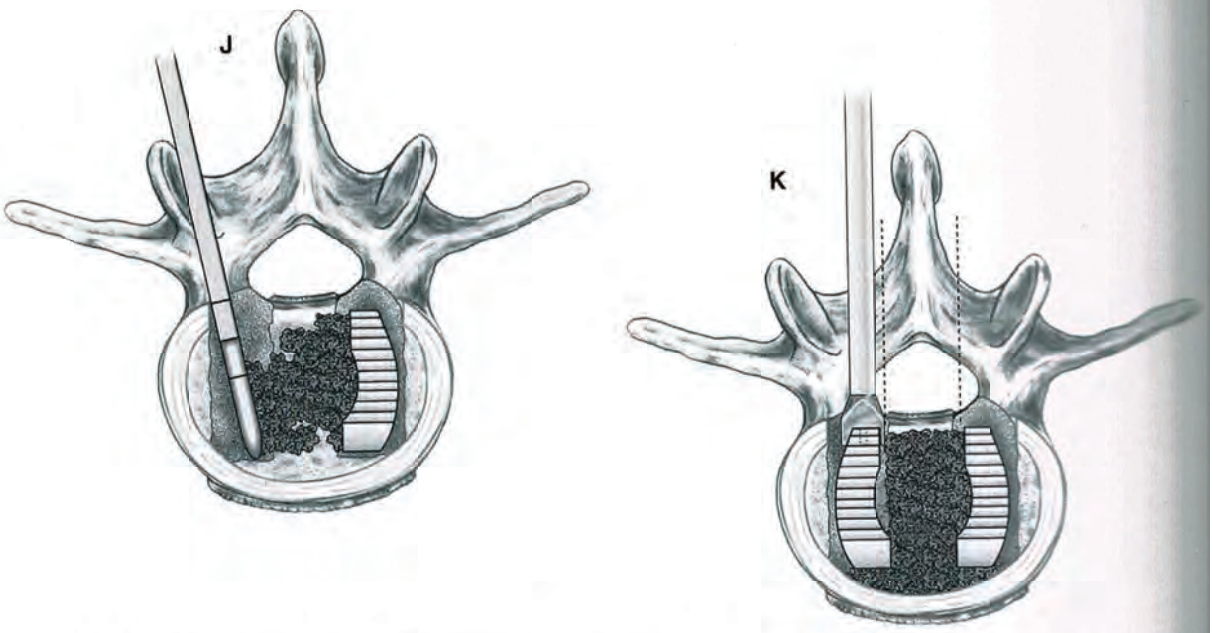

FIGURE 16-2, cont'd. J, Once the Tangent wedge has been inserted on the contralateral side, the disc distractor is removed from the original side. Morcellized autograft is then packed into the prepared disc space beneath the midline structures. The graft is then swept against the impacted wedge using a small disc distractor to fill the space between the Tangent wedge and the endplate preparation site for the second Tangent wedge. **K,** Similar to *E* to *I*, the contralateral endplates are prepared using the rotating cutter, round scraper, and cutting chisel. The second Tangent wedge is then inserted into the disc space along the previously prepared track. Once the grafts are properly seated, segmental fixation is applied using a standard technique. The facets and medial transverse processes are decorticated, and autograft is placed posterolaterally. (With permission from Medtronic Sofamor Danek.)

RESULTS

Because of the variation in results reported by recent studies, it is difficult to assess outcome data supporting the technique of lumbar interbody fusion.[25] In selected populations, PLIF appears to demonstrate increased fusion rates when compared to posterolateral fusion in similar populations.

On reviewing the PLIF series from both Emory and Wake Forest Medical Centers, in which titanium cages were used without supplemental pedicle screw fixation, we identified a 91% stability rate (as defined by absence of movement on flexion/extension radiographs).[26,27] A fusion rate could not be determined for this series because we believe that the radiographic artifact created by the cages obviates any certainty as to the occurrence of fusion, despite the use of CT reconstructions. Our results were therefore simply reported as "stability" rates. We were able to obtain a 100% stability rate when we supplemented the metallic cages with pedicle screw fixation. Combining both the stand-alone PLIF series and the PLIF series that used supplemental posterior fixation, we found our incidence of transient nerve root injury to be as high as 10%. In both series we identified a rate of permanent motor or sensory deficit, presumably caused by retraction, of 5%. Similarly, the rate of cerebrospinal fluid leakage was 9%. Although both complication rates were consistent with other published reports, we believed that they were unacceptably high. During the past 4½ years, we have switched almost exclusively to the use of the Tangent impacted PLIF technique with rectangular cortical bone wedges. We have subsequently performed this procedure in more than 300 patients. Preliminary follow-up of this series of patients has demonstrated stability rates that compare well with the cage/pedicle screw series, whereas the complication rate for patients sustaining nerve root injury was less than 1% and cerebrospinal fluid leakage 1%. We believe that the introduction of such rectangular devices has decreased nerve root retraction injuries and significantly reduced the morbidity of this operation, while maintaining exceptional fusion rates.

CONCLUSION

Surgical treatment of degenerative lumbar disease has undergone incredible advances in the past 20 years. The specific development of interbody techniques for the treatment of degenerative disease, particularly involving the lumbar spine, has revolutionized spine surgery. As we continue to search for new materials to use as interbody implants, two principles become readily apparent. First, the shape of the implant must allow for minimal disruption and injury of the existing structures. Second, any material used must have characteristics that make it better than allograft, which in our minds appears to be the standard.

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CHAPTER

18 Ray Cages

Duncan Q. McBride, M.D., and J. Patrick Johnson, M.D.

Implantation of the Ray threaded fusion cage (TFC) is a simple and effective method to fuse the lumbar spine. The technique of insertion is uncomplicated and accessible to spine surgeons who are accustomed to standard discectomy or posterior lumbar interbody fusion (PLIF) approaches. The anatomy of the approach for inserting the cages is familiar to surgeons who have performed these techniques, because the exposure is the same as for a standard laminectomy with expanded facetectomy and foraminotomy. In addition, the instrumentation is very uncomplicated with only four tools needed to insert the cages, which come in two lengths and four widths, 12 to 18 mm. The TFC itself is a very well-conceived device, which has deep threads to hold the cage in place, approximately 70% bone-to-bone surface area on the edges that face the vertebral bodies (Fig. 18-1), and excellent elasticity and load-sharing that assist bone graft fusion in accordance with Wolff's law.[1]

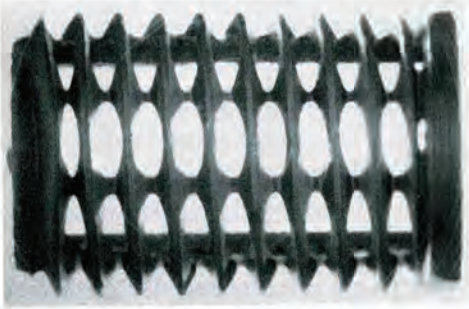

FIGURE 18-1. Enlarged image of the Ray TFC photographed through the aspect that faces the vertebral bodies. The design of the cage permits approximately 70% open space on the bone contact surface through which fusion ingrowth occurs.

INDICATIONS

The Ray TFC is appropriate for posterior lumbar spinal fusion in patients with degenerative disc disease (DDD) or spondylolisthesis grade I. The cage is recommended for use in up to two adjacent levels. Such a procedure is indicated for patients with lumbar spine instability or segmental failure characterized by intractable, severe mechanical low back pain—that is, pain which increases with sitting, standing, and walking, and is improved by reclining or laying flat.

Imaging characteristics consistent with DDD are low signal on T2-weighted sagittal MRI indicating dehydration of the disc. The disc is typically collapsed in its rostrocaudal aspect. Bony endplate changes, characterized by increased signal in the marrow adjacent to the degenerated disc, are frequently seen and are known as modic changes. With significant disc collapse, the neural foramina may be narrowed on the lateral sagittal images with the superior facet impinging on the exiting nerve root. On axial views, a widening of the space between the articular surfaces of the facets may be seen. Plain x-ray films in flexion and extension may demonstrate excess motion indicative of instability. In spondylolisthesis, Ray TFC insertion is indicated in patients with grade I as well as grade II deformity that can easily be reduced to grade I. This is due to the requirement for sufficient endplate surface area on both vertebral bodies to accommodate the length of the cage.

Prior to fusion surgery, conservative management should be attempted for approximately 6 months in most patients. Aggressive conservative management should include physical therapy with muscle strengthening, aquatic therapy, or swimming to exercise the lower back and stomach muscles in a horizontal and buoyant environment, and weight loss where appropriate. Patients should avoid sitting whenever possible, which obviously poses a problem in everyday living. Reclining, with the weight of the head and shoulders resting back and the knees elevated, is the preferred posture for relaxation. Bracing with a hard or well-crafted semirigid orthotic device is a helpful adjunct.

Patients are candidates for surgery when they have achieved insufficient relief of low back pain with such conservative management. Positive indicators for success of the fusion to relieve the back pain include severity of the image changes and response to bracing. In our experience, relief of low back pain after facet joint block injections, indicating "shearing force" on that segment, correlates well with pain relief after a fusion. Discography may be needed if a diagnostic dilemma exists regarding the disc as a pain generator, or where multiple degenerative discs are present. Concordant pain and disruption of the disc on injection of contrast material into the nucleus are indicators that the disc is the source of the patient's mechanical low back pain, and that fusion will likely achieve relief of pain. Negative indicators include secondary gain (e.g., financial, legal, disability, and family issues), advanced age, severe osteoporosis, and severe psychological problems. Smoking does not appear to reduce the fusion percentage with the Ray TFC technique. Some surgeons require that patients undergo psychological testing prior to fusion surgery.

Many patients have severe DDD after laminectomy and discectomy, chymopapain injection, or other discectomy techniques. Reoperation is more difficult when the Ray

TFC is used because of adherence of the epidural scar to the root and the disc space. This will add to the operative time because of the tedious dissection, and it can limit the retraction of the root. This also increases the risk of injury to the root because of the adherence.

In patients with very severe DDD or instability, some surgeons may wish to use a combination PLIF with cages and posterior lumbar fusion with a pedicle screw construct. This achieves a posterior 360-degree fusion. This is a controversial technique because some believe it is similar to "wearing a belt and suspenders," whereas others believe that the immediate anterior and posterior rigid fixation is a more stable construct than either alone.

Determining Cage Size

Some surgeons wish to estimate the size of the Ray TFC they will use during the surgery by analyzing the preoperative images. Axial MRI or CT scans with a centimeter scale can be used to measure the anteroposterior diameter of the vertebral body in question. This measurement helps to determine whether a long or short Ray TFC is most appropriate. In a patient with a vertebral body of at least 3 cm, a long (26 mm) cage can be used. If the anteroposterior diameter of the vertebral body is less than 3 cm, the shorter (21 mm) cage length must be used. This is so that there is approximately 3 mm of vertebral body on either end of the cage. The width of the cage is determined by the distance from the midline to the pedicle, and this is best established intraoperatively. Preprinted templates that can be used with the MRI or CT scans are also available. The basic principle is that the largest cage possible is inserted in order to achieve maximum stabilization of the segment and to increase the surface area of the fusion.

POSTERIOR LUMBAR INTERBODY FUSION TECHNIQUE

Insertion of the Ray TFC is performed through a typical posterior approach. Exposure of the transverse processes is not required. The most unique aspect of this exposure is the relatively large amount of facetectomy that is required to achieve insertion of the maximum cage width.

Unless the spinous process has been removed at a prior surgery, this bony stricture and the supraspinous and intraspinous ligaments are left intact. These elements provide a posterior tension band that helps hold the segment and puts a compressive force on the cage to help with the fusion. A laminectomy is performed medially to the midline and superiorly to the superior edge of the ligamentum flavum. Bilateral wide laminectomies are performed with preservation of the pars interarticularis on the superior vertebra. The ligamentum flavum is removed and extensive facetectomy is performed. The facetectomy needs to be wide enough to fully unroof the exiting nerve root at that level. The exiting nerve root is typically found under the extreme lateral edge of the ligamentum flavum, which follows the root out to the edge of the foramen. The surgeon must visualize the exiting root crossing the lateral edge of the disc in the foramen. Exposure of the upper and lower pedicles is thus performed. At this time, a discectomy is typically performed in the customary fashion with retraction of the tra-

versing root. The discectomy is followed out to the medial edge of the pedicle (Fig. 18-2, *A*). The traversing and exiting nerve roots are then retracted using the specially designed nerve root and ganglion retractors provided in the Ray TFC instrument tray (Fig. 18-2, *B*). When the midline structures have been left intact, the dural retractor is bent and inserted under the interspinous ligament, and the surgical assistant's hand is brought toward the midline, which retracts the traversing root and dural sac to the midline. Simultaneously, the slightly narrower ganglion retractor is placed medial to the exiting root and retracted laterally parallel to the disc (Fig. 18-2, *C*). In cases where the spinous processes have been removed, care must be taken not to retract the traversing root past the midline.

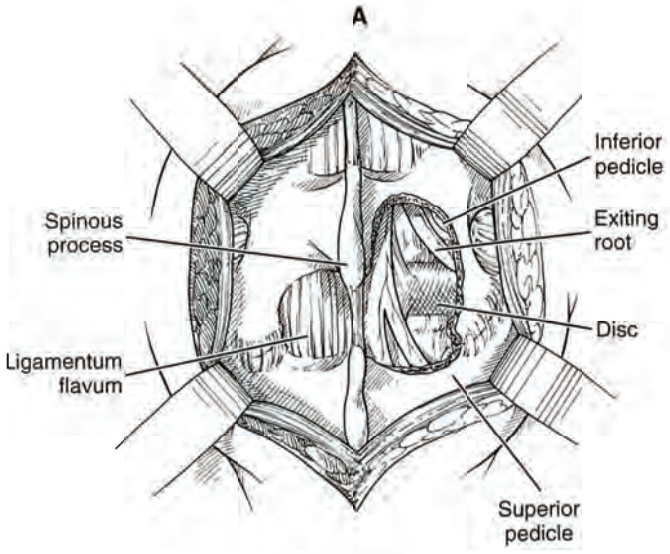

FIGURE 18-2. A, Exposure necessary to place the Ray TFC. The exiting root is seen as it crosses the disc, and the pedicles above and below are seen in the surgical field. **B,** The nerve root and ganglion retractors are provided for safe retraction of the exiting and traversing roots. **C,** Axial view through the surgical site demonstrating the orientation of the medial retractor on the exiting root and dural sac. Note that the retractor has been bent to fit under the spinous process to prevent the dura from being retracted past the midline. This retractor has also been bent again above the skin to remove the assistant's hand from the surgeon's view. The lateral retractor protects the exiting root as it crosses the disc. The blades of the Taylor drill guide are fitted between the curved retractor ends.

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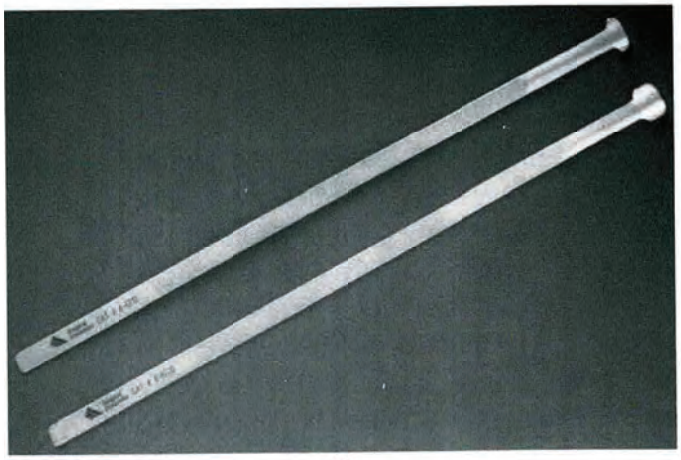
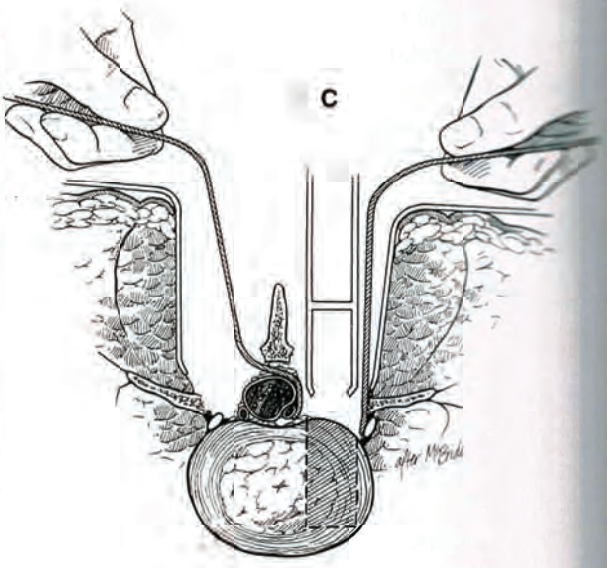




The contours of the retractors are designed to accommodate the circular Tang drill guide or the vertebral spacer. Both of these instruments are provided in four sizes corresponding to the four diameters of the cages (Fig. 18-2, *D* and *E*). The diameter of the cage that is ultimately inserted is determined by the maximum size of the spacer or drill guide that can be placed between the retractors. Thus the size of the cage is determined by the distance from the midline to the medial pedicle (see Fig. 18-2, *B*). Some surgeons may wish to use the vertebral spacer on the first exposed side to determine the size of the drill guide used on the opposite side. Regardless of whether the Tang retractor or the spacer is placed first, the initial insertion into the disc space begins to achieve distraction of the disc space. The blades of the Tang drill guide are tapered and blunt, so that they enter the empty disc space and push the vertebral bodies apart.

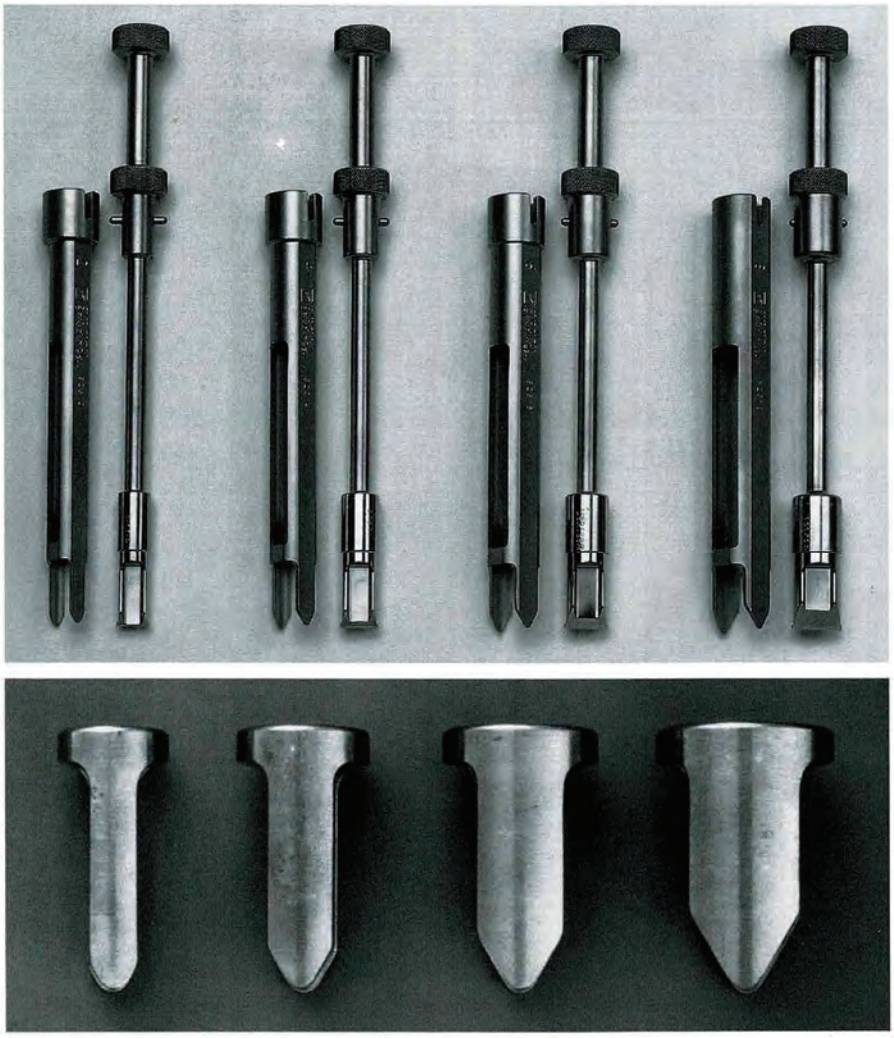
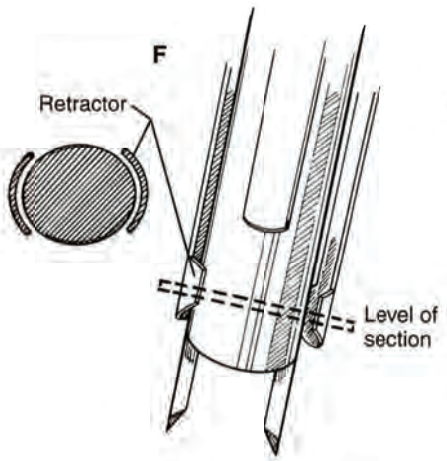


FIGURE 18-2, cont'd. D, Four sizes of Tang drill guide are available in the tray. These range from 12 to 18 mm. **E,** Corresponding sizes of vertebral spacers. *Continued.*

Insertion of the Tang blades into the disc, with the concurrent protection of the nerve roots while the blades are inserted into the disc space, is the most technically demanding and highest risk step of this operation. Direct visualization of the roots must be possible, as well as direct visualization of the insertion of the blade (Fig. 18-2, *F*). The Tang blades must not be in contact with the dura, and the initial tapping of the device must be performed gently. The surgeon must be aware if there is any reflex leg movement on tapping of the instrument. If this does occur, the orientation of the retractors and Tang blades must be checked to ensure that there is no direct impact on the nerve root. Occasionally, one of the roots will peek in around the edge of the root retractor and can be trapped under the circular edge of the Tang drill guide as it comes down onto the anterior aspect of the spinal canal. If this occurs, a freer or other fine dissector can be used to pull the root back out of the way of the drill guide or spacer.

When the spacer is used, it is inserted directly and unscrewed from its handle (Fig. 18-2, *G* and *H*). This technique will ensure that the disc space does not loosen on insertion of the opposite-sided cage. When the Tang retractor blades are used, the retractor



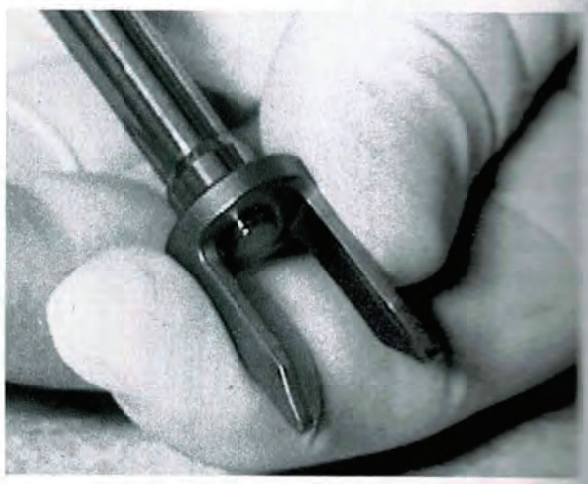


FIGURE 18-2, cont'd. F, Insertion of the Tang blades between the curved contours of the retractors protecting the roots. **G,** The vertebral spacer is attached to its handle with a screw mount. **H,** Lateral fluoroscopic image with vertebral spacer in correct orientation parallel to the disc space.

Continued.

is positioned and an end cap is placed on the end before impacting the device with the mallet (Fig. 18-2, *I* and *J*). The trajectory of the Tang blades on the drill guide or the spacer is confirmed using lateral fluoroscopy. The blades should be inserted parallel to the midaxis of the disc on the lateral view (Fig. 18-2, *K*). The instrument is driven into the disc space such that it rests flush with the anterior aspect of the spinal canal abutting the posterior longitudinal ligament. When the Tang retractor/drill guide is appropriately inserted, the neural elements in the spinal canal are protected from the drill itself. The Tang retractor is inserted so that the larger opening of the shaft, which is the working port, is facing inferiorly (Fig. 18-2, *L*). This allows the surgeon to insert instruments into the disc space to remove pieces of disc material, to suction blood, and so forth.

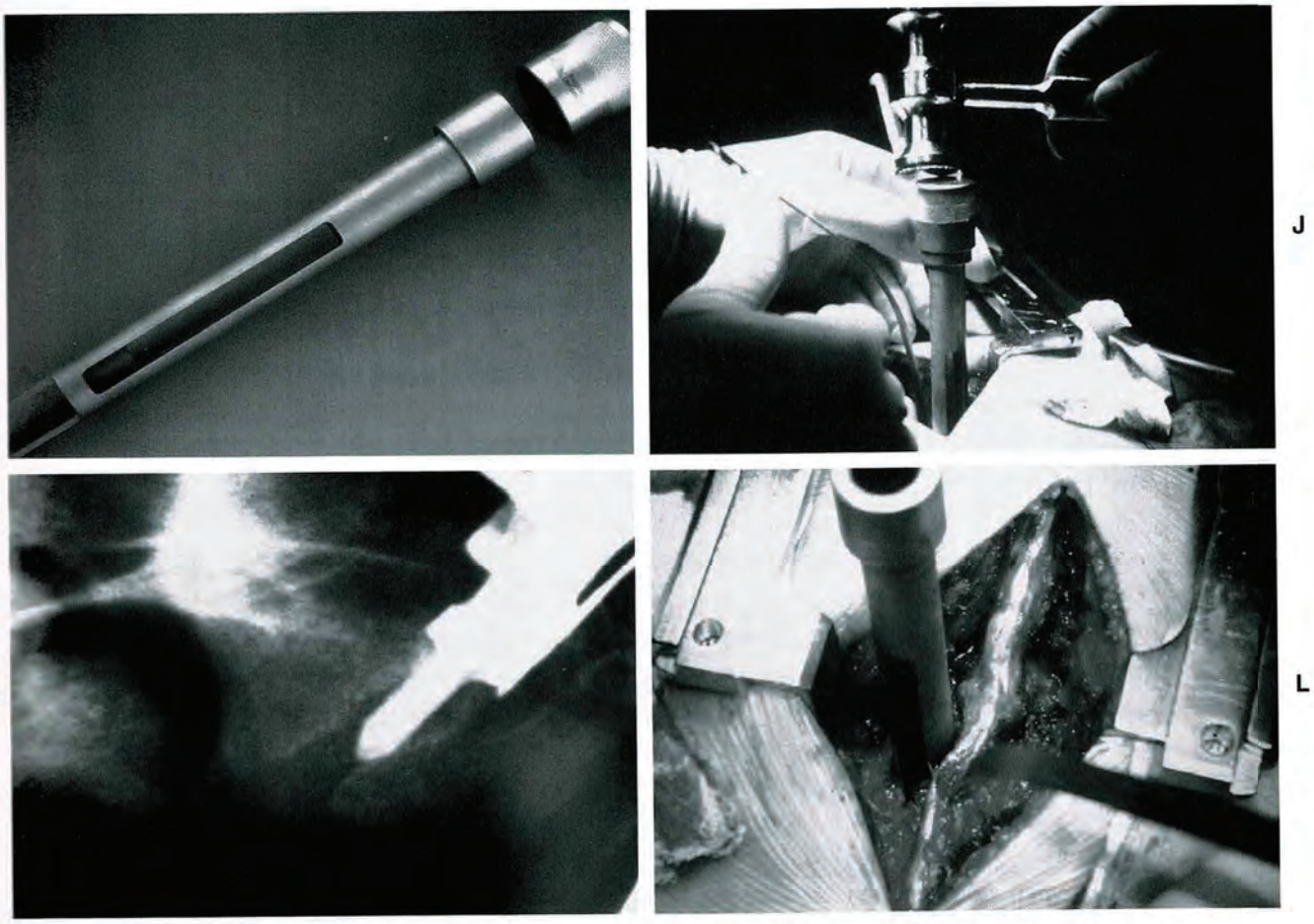


FIGURE 18-2, cont'd. I, The Tang drill guide with the end cap. **J,** Tapping of the Tang drill guide end cap with a mallet. **K,** Lateral fluoroscopic image of the Tang retractor inserted at its maximum depth. Note that the bottom of the circular portion of the drill guide is flush with the posterior longitudinal ligament. The orientation of the Tang blades in this case is slightly inferior to the midaxis of the disc on this lateral view. **L,** The Tang drill guide in place with the larger opening facing inferiorly. Note the medial retractor bending under the midline structures from the opposite side.

Continued.

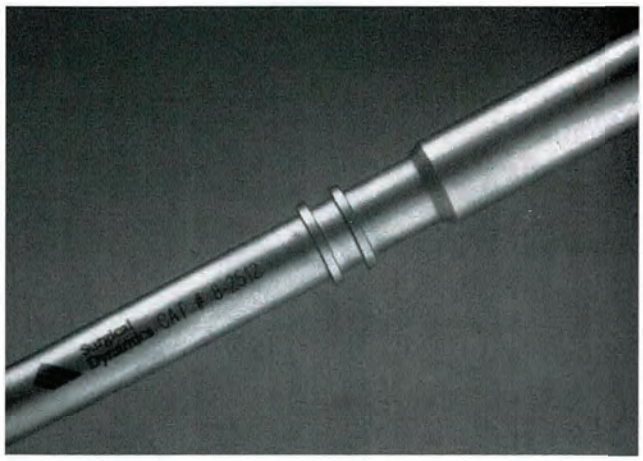
Then the appropriate-sized four-fluted drill is chosen and inserted into the universal T-handle, which attaches to all of the insertion instruments (Fig. 18-2, *M*). The drill has double-locking positive stops to ensure that it is inserted at the appropriate depth for either the 21 or 26 mm cage length. The drilling is performed under fluoroscopic guidance to visualize purchase into both the superior and inferior vertebral bodies. Also, the depth of the drilling is confirmed by means of the fluoroscope. The drill should be inserted to approximately 3 mm from the anterior aspect of the disc space. In our experience, direct visualization of the drill depth is preferable to any preoperative estimate of the appropriate cage length.

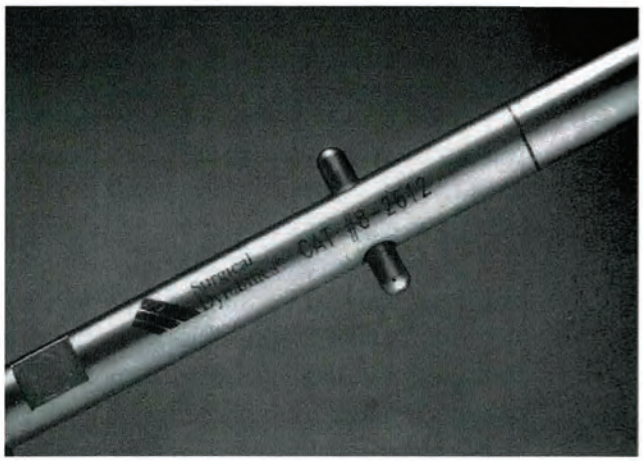
After the drill hole has been made and the drill removed, the stray bits of disc in the disc space may be removed through the working port using a pituitary rongeur. The threads are then cut into the drilled hole in the vertebral endplates using the vertebral bone tap of the appropriate diameter. The tap is slightly wider than the drill and achieves a sharp cut in the bone by use of a steady downward force in a clockwise motion. There are ridges on the tap, which indicate the depth appropriate for the 21 or 26 mm cages (Fig. 18-2, *N*). Again, the depth of the tapping should be followed by means of fluoroscopy and should equal the depth of the original drilling. The tap is removed in a counterclockwise direction to preserve the threads, and the threads are then palpated using a Woodsen elevator or the curved end cap remover provided with the Ray TFC instrumentation. The surgeon should be able to palpate the grooves of the threads in the superior and inferior endplates through the working port in the Tang retractor. If the threads in the endplates are thought to be inadequate, insertion of a larger cage must be performed.

Once the vertebral endplates are successfully tapped, a cage of appropriate length and width is selected and opened from its sterile packaging. Because of the wide variety of possibilities, cages of numerous diameters and lengths should be available in the operating room, so that the appropriate size can be chosen at this point. Each package contains a pair of equal-sized cages that are capped on the distal end with a polypropylene end cap. The package also contains proximal end caps, which are to be inserted after the cages are packed with bone. The cages are attached to the cage insertion instrument. They are then driven into the tapped opening with a steady downward clockwise motion, and the depth and trajectory are double-checked by means of fluoroscopy. Care is taken not to overinsert the cages beyond the drilled depth, as the final turns will strip the threads in the bone. The cage insertion instrument is marked with a laser-etched line to indicate the same depth as the raised ridge on the tap. Also, the cage insertion instrument has a pin indicator that must be aligned in the cephalocaudal direction when the cage is fully inserted, so that the reinforced edges of the cage face the disc and the open sides of the cage face the bone (Fig. 18-2, *O* and *P*). These relationships are also checked with fluoroscopy (Fig. 18-2, *Q*). The diameter of the cage is slightly wider than that of the tap, and this achieves an added degree of vertebral distraction and ensures tight purchase of the cage within the vertebrae.

Attention is then turned to the opposite side where the steps are repeated. If a spacer has been used, it is first removed and replaced by the Tang retractor, exercising the same extreme caution as with the initial insertion.

Once the cages are placed in a satisfactory position with good purchase in the bone, they are then packed with autologous bone graft. The manufacturer recommends using





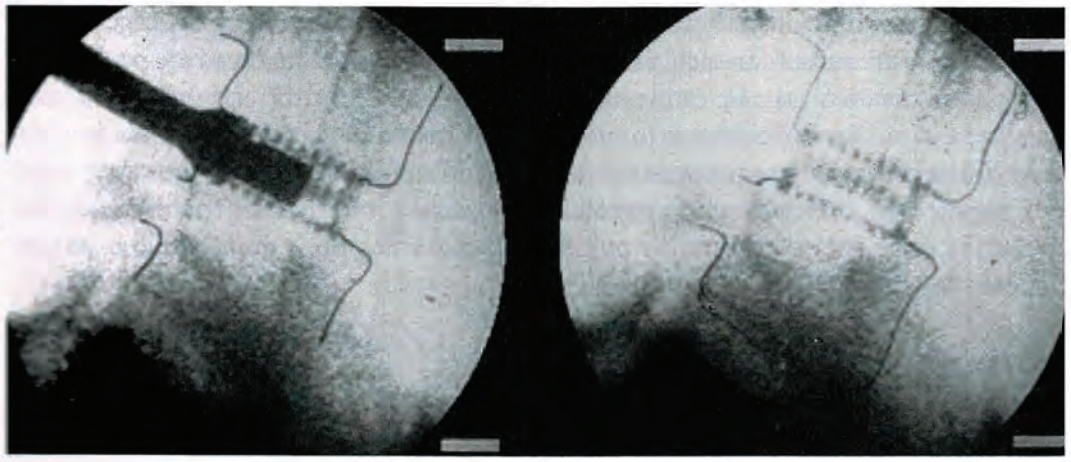


FIGURE 18-2, cont'd. M, The T-handle, which attaches to all of the drills and drivers in the Ray TFC set. **N,** The ridges on the tap indicate the drilling depth of 21 or 26 mm corresponding to the stops on the drill. **O,** The appropriate diameter and length of Ray TFC is inserted into the end of the cage driver. These are easily separated by a simple distraction force. **P,** The handle of the cage driver has an etched line that corresponds to the appropriate depth as it aligns with the top of the Tang drill guide. The bar through the cage driver is oriented in a cephalocaudad position on completion of the insertion to ensure that the buttressed aspect of the cage aligns with the disc and the open aspect of the cage aligns with the bone. **Q,** Negative fluoroscopic images of the insertion of a Ray TFC in the disc space. The alignment is parallel to the disc, and there is purchase in the bone above and below. In addition, the buttressed sides of the cage face laterally. *Continued*

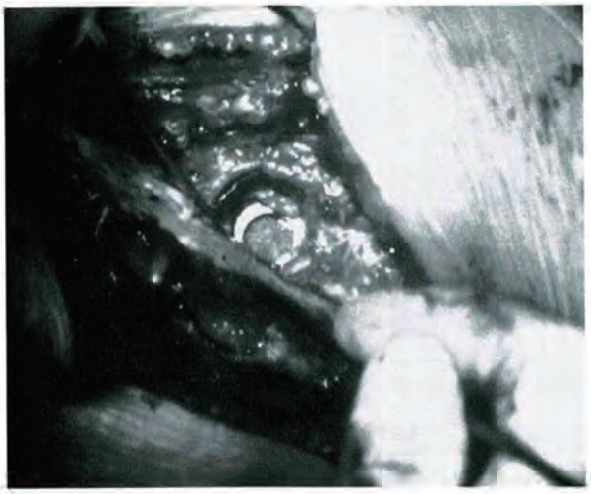


FIGURE 18-2, cont'd. R, Surgeon's view of the Ray TFC in the depths of the wound after the morcellized bone graft has been packed to the top of the cage.

iliac crest bone graft, but we and others[2] have had success with the use of morcellized local lumbar bone only. When local bone graft is to be used, we recommend that the bone graft be decorticated with the drill before removal of the lamina and facet in order to increase the cancellous/cortical ratio. The cages are packed very tightly using either the instrument provided or a cage insertion tool that is one size smaller than the cage itself. The cage is packed so that there is no empty space in the cage, and so that the bone might extrude out through the open spaces facing the vertebral bodies (Fig. 18-2, *R*). The amount of bone graft material required depends on the size of the cage. For example, 8 ml is required for each pair of 14 × 21 mm cages. The cages are packed to a depression just under the lip of the cage. This leaves space for the end cap to be placed on the proximal end of the cage to seal the graft inside. The end cap is placed on the cage with a gentle downward pressure, and a distinct snap is felt when the cap is properly engaged. Any remaining bone graft can be packed into the disc space, usually between the cages. Another option would be to place some bone graft lateral to the remaining facet joint after decortication.

PROBLEMS AND COMPLICATIONS

The most frequent intraoperative complications in the clinical trial[3] were dural tears in 9.3%, improper device placement in 4.2%, bleeding in 2.1%, and nerve root injury in 0.8%.[2] Postoperative complications included persistent pain in 11%, which dropped to 3% in 2 years, and neurologic deficit in 4.7%, which improved to 2.5% in 2 years. The overall success rate in the clinical trial was 92% for fusion and 76% for pain control. The overall success rate was deemed to be 64%. At the 2-year time point, younger patients and nonsmokers had lower levels of pain and higher levels of function. Older patients with L5-S1 involvement had higher levels of pain and lower functional scores than older patients with other levels of involvement. Patients with lower baseline function scores had lower outcome scores in general.

Certain problems can be anticipated with insertion of Ray TFC devices. In patients with a conjoined nerve root or spondylolisthesis, the exiting nerve root may be horizontal and parallel to the disc space, rather than taper around the pedicle in the customary fashion. This poses a significant problem in placement of the cage, as the root must be carefully retracted laterally. This situation may require drilling the pedicle or insertion of a smaller cage. In the circumstance of significant spondylolisthesis, the posterior lip of the endplate that projects posteriorly should typically be removed, so that the circular edge of the Tang drill guide can be inserted flush with the more anteriorly positioned body. This will ensure enough overlap of the bones to allow good purchase of the cage between the bodies. In certain circumstances, the circular edge of the Tang cannot be driven flush with the vertebral body because of the anatomy of the inferior pedicle. If the Tang blade is slightly lateral to the medial edge of the pedicle, the pedicle may prevent the circular edge of the Tang retractor from reaching the appropriate depth. In this circumstance, the drill must be used to shave off the pedicle. If the lamina is inadequately removed, a similar situation can occur with the superior edge of the Tang tube. This is particularly true in the insertion of a cage at L5-S1, where a significant extension of the lumbosacral laminectomy may be required to achieve the angle of the disc, which requires that the retractor be placed lower along the plane of the spine. Additionally, the superior pedicle may need to be drilled in circumstances where the exiting root is compressed against the superior pedicle and is impinged upon with insertion of the Tang blades. Careful drilling of the superior pedicle may achieve sufficient relaxation of the root, so that retraction can be more safely performed.

Complications are often related to root stretching on placement of the Tang drill guide. This can lead to neurologic deficits including numbness, weakness, and hyperesthesia. Dural tearing is also a significant risk. These types of complications are more likely to occur with reoperation. Malplacement of tile cage is encountered in situations where the dura is retracted past the midline in the initial cage placement. With this medial malplacement of the first cage, the medial Tang blade can be inserted directly into the cage when attempting to place the second device. In that circumstance, the surgeon must then attempt to place the second cage further lateral, which requires drilling of both pedicles. In this situation, a spacer may help after exposure of the first side to prevent this problem.

ANTERIOR PLACEMENT

Many of the previously described complications and problems can be avoided by using an anterior insertion technique for the Ray TFC. This surgical approach is appropriate for patients without problems in the spinal canal such as disc herniation or nerve root entrapment that would require a posterior decompression. Patients with radiculopathy due to neural foraminal narrowing alone are candidates for an anterior approach because of the significant amount of distraction achieved with the use of this technique. There is a double-barrel Tang drill guide available that is centered in the midline. It is best to confirm midline placement with anteroposterior fluoroscopy. In these cases, a thorough anterior discectomy is recommended to prevent disc material from being pushed posteriorly into the canal by the cage. As with posterior placement, the placement of the Tang retractor, as well as the drilling, tapping, and insertion, are followed

with lateral fluoroscopy. In general, larger cages can be placed anteriorly because there are no neural elements to work around. At L5-S1, it is recommended that the cages be placed fairly posteriorly in the vertebral body because of the wedge shape of the disc in most patients. More posteriorly, the cage will have better purchase. With at least 50% of the cage within the bone posteriorly, the cage will fuse. Because the cages are larger, and because the iliac crest is less voluminous anteriorly, the patient's bone graft may need to be augmented with Grafton putty or banked bone if two levels are fused anteriorly. Anterior placement carries with it its own set of complications, which are well described in earlier chapters. These include bleeding, retrograde ejaculation in males, and malplacement of the cage laterally, which has the potential to create radiculopathy if the cage is in the neural foramen. Endoscopic instruments for anterior placement are also available.

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