Advances in Implant Technologies for Spine Surgery

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KEYWORDS

• Spine • Surgery • Implant • Prosthesis • Cage • Screw • Technology

KEY POINTS

- Three-dimensional (3D)-printed technology can create patient-specific prosthetics for spinal reconstruction and screw placement.
- Modifying interbody porosity and surface coating can improve osseous integration and reduce subsidence.
- Innovations in percutaneous pedicle screw systems have improved safety and efficiency.
- Carbon fiber-reinforced polyetheretherketone pedicle screws offer promising benefits in imaging evaluation and adjuvant treatment planning in spinal malignancies.
- Lumbar facet replacement devices offer a potential alternative to some spinal conditions traditionally considered for fusion surgeries.

INTRODUCTION

Spine implant materials continue to evolve to address the diverse needs of the multicompartment spine.[1] In only a few decades, a plethora of devices have emerged. The intervertebral disc can be replaced with interbody spacers or artificial discs, the vertebral body can be matched by cages for both structure and function, the stabilizing posterior elements can be reconstituted by the now-conventional pedicle screw and rod paradigm, just to name a few.[1] In this article, the authors discuss new developments in spine implants for both devices and materials. These advances in implant technology include three-dimensional (3D)-printed materials, expandable devices, specialized surface designs, pedicle screw techniques and construction, and novel facet replacements. The authors analyze these state-of-the-art technologies, their proposed uses, and consider future applications.

THREE-DIMENSIONAL-PRINTED TECHNOLOGY

Spine Prosthetics

Because 3D printing can be so personalized, multiple groups in recent years have evaluated its utility in complex reconstruction outcomes, particularly for en bloc resection of spinal tumors.[2–4] In patients undergoing total sacrectomies, 3D-printed prostheses have demonstrated more uniform stress distribution, lower peak stress, and better stability.[4] More recently, a small series reported on thoracolumbar tumor reconstructions using 3D-printed titanium alloy prosthetics and demonstrated proof of principle with reasonable clinical outcomes up to ~1 year follow-up.[2,3] These studies have shown a wide range of prosthesis subsidence but few cases of revision surgery. In direct comparisons between patients with 3D-printed titanium alloy and traditional titanium mesh cages, studies have noted

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non-inferiority in terms of fixation failure or subsidence and, in some cases, decreased rates of subsidence and back pain.[5,6]

SCREW APPLICATIONS

In addition to customized implants, 3D-printing has been used in preoperative planning for screw placement in terms of insertion point, path, length, and thickness of screws.[7] Such 3D-printed screw guide templates have helped further reduce instrumentation complications.[8,9]

This application has been used especially in deformity surgery to facilitate preoperative planning. In both adult degenerative scoliosis and adolescent idiopathic scoliosis, reports have detailed how preoperative 3D models have helped intraoperative screw trajectories with accurate placement within ~1 mm of optimal screw entry points and greater than 90% acceptable screw placement. Although such studies have been in small case series, comparisons to historical reports of misplaced freehand screws have been encouraging.[9,10]

Although the early findings suggest that 3D-printed patient-specific screw guides may improve the precision and safety of spinal procedures, more extensive and robust studies are required to elucidate their full potential in clinical practice.

Expandable Vertebral Body Replacement Cages

The anterior spinal column bears up to 75% of axial loading.[11] To optimize its reconstruction following corpectomy, expandable cages (**Fig. 1**A, B) have been applied in practice.[11–18]

The expandable feature of vertebral body replacement (VBR) cages has been studied for reducing subsidence, which complicates 80% of patients with anterior column reconstruction. In principle, maximizing end cap size may ameliorate loading stress and, thereby, decrease subsidence. Several reports have detailed the feasibility of using these expandable cages in a broad range of patient populations, from cervical to lumbar spine and for pathologies ranging from degenerative disease to malignancies, and confirmed improvement in standard clinical outcomes and low revision rates (eg, 1/40).[11,19] Radiographically, reports have shown greater than 90% fusion with these cages in both cervical and thoracolumbar locations, though subsidence rates up to 17% have been shown with 14-month follow-up.[13,14] As these studies had heterogeneous population, limited conclusions could be drawn. Nevertheless, the reports have indicated the feasibility of an expandable anchored titanium cage after anterior corpectomy.[15]

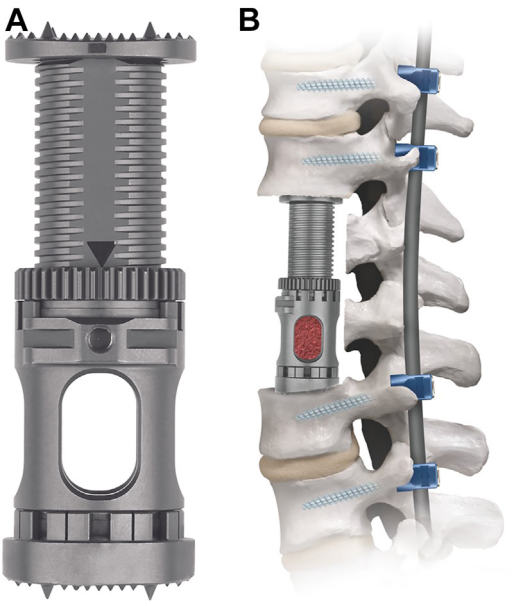

Fig. 1. Anterior view of expandable vertebral body replacement cage (*A*) and lateral view of Globus expandable VBR in thoracic spine (*B*).

One of the larger series on expandable VBR cages focused on traumatic thoracolumbar spinal fractures. After 2 years, 97.9% bony fusion and 4.2% total revision rates were reported.[16] A few other studies have also focused on specific patient populations including osteoporotic thoracolumbar fractures, post-traumatic kyphosis, and thoracolumbar metastases. In general, these reports have demonstrated good clinical outcomes, improved VAS scores, and kyphotic deformity parameters.[17–20] Interestingly, in those patients with osteoporotic thoracolumbar fractures, subgroup analyses suggested that Japanese Orthopedics Association scores were improved more in lumbar-only pathology than thoracolumbar pathology.[17] Further, in patients who underwent subaxial corpectomies, although there seemed to be low fusion rates (65.3% over 3 years), there were still improved rates of average VAS pain scores, neck disability index (NDI) scores, and Cobb angles.[20] Overall, though there are notable limitations, reports in recent years on expandable VBR cages have painted a favorable landscape for expandable VBR cages.

INTERBODY IMPLANT INNOVATIONS

Implant characteristics, including surface coating, chemistry, and topography including porosity and roughness, determine implant osteointegration and successful bony fusion. Therefore, evolving technologies have focused on optimizing all these

features together in order to enhance fusion outcomes.[21]

EXPANDABLE INTERBODY IMPLANTS

As noted above with expandable VBR cages, devices that conform in situ offer several unique advantages in the surgical setting, namely that they require a smaller corridor for access while still providing for in vivo pathology correction. In TLIFs, Lin and colleagues' meta-analysis of expandable and static cages in 1440 patients showed higher anterior disc height and foraminal height, lower Oswestry disability index scores, and nonsignificant increase in posterior disc height and lordosis for the expandable cage group.[22] Conformational meshes have emerged as another type of expandable implants. They offer the additional advantage of integrating in accordance with the patient's anatomy. Stone and colleagues reported success with a radiolucent, porous polyester mesh pouch that is compatible with minimally invasive approaches offering multiple planes for graft–device interaction, promoting osteogenesis. This device was tested in a prospective, multicenter, single-arm FDA-approved investigational device exemption (IDE) trial. The study which enrolled 102 patients reported significant reduction in VAS back pain at 6 weeks and 24 months postoperatively. Similar reductions were noted in pain radiating to lower limbs and 99% fusion rates 2 years after surgery. No adverse events solely related to the implanted device were reported.[23] Of note, however, this particular study faced limitations such as lack of a control group and limited follow-up and needs to be validated by a future randomized study.

Porous Implants

Porous implants, by virtue of their construction and osteointegration, result in a more mechanically stable column and lower risk of fusion failure. Increased bone–device interface results in lower rates of disc subsidence and early bone fusion, as proven in canine[24] and ovine models under standardized stress settings.[25] Fogel and colleagues evaluated the potential effects of porous bodies (lattice vs solid) and endplates (microporous vs smooth) on cage stiffness and subsidence in an ovine interbody fusion model. There were 16.7% and 16.6% reduction in cage stiffness by using porous body lattice and microporous endplate, indicating that body lattice and microporous endplates characteristic can enhance early fusion through cage stiffness and stress shielding reduction. Furthermore, porous titanium cage showed the lowest stiffness and block stiffness (**Fig. 2**). Owing to stiffness reduction, and hence optimized osteointegration and potential diminished subsidence, they hypothesized that porous titanium cage may be a viable option in clinical settings.[25] In terms of subsidence, Krafft and colleagues showed that 3D-printed porous titanium intervertebral cages in lateral interbody fusions showed a subsidence rate of 6.7%, though all were clinically irrelevant and did not require revision operation.[26] Porous polyetheretherketone (PEEK) implants have been reported in multilevel anterior cervical discectomy and fusions procedures (**Fig. 3**), with data suggesting good clinical outcomes. Out of 33 patients with $\geq$3-level anterior cervical discectomy and fusion (ACDFs), two patients developed cage subsidence (6.1%) and one patient had pseudoarthrosis (3%), though overall successful fusion rate was recorded at 97%, which supersedes established rates for complex cohorts.[27]

Surface-Coated Technologies

Antimicrobial-coated orthopedic implants have already proven to be efficacious and safe in clinical use.[28] Silver (Ag), copper (Cu), and iodine (I) are candidates for coated implants, with delivery also possible through a variety of techniques.[29] Application in spinal surgery with the use of silver and hydroxyapatite surface-coated lumbar interbody cage was recently reported by Morimoto and colleagues which showed promising results.[30] In another small study comparing titanium-coated versus uncoated PEEK cage in single-level

Fig. 2. Nuvasive anterior lumbar interbody fusion (ALIF) Modulus implant.

Courtesy of NuVasive, Inc.

Fig. 3. Nuvasive porous PEEK Cohere extreme lateral interbody fusion (XLIF) implant. (*Courtesy of* NuVasive.)

posterior lumbar interbody fusion, 3-month fusion rates were 88% and quantified vertebral cancellous condensation, as an index of bone ingrowth, were significantly greater in titanium-coated cages, suggesting titanium coatings may promote solid fusion and enhance the outcomes of interbody fusions.[31]

SCREW INNOVATIONS

Minimally Invasive Spine Surgery

Minimally invasive spine surgery (MISS) has been defined by key technologies, notably percutaneous pedicle screw systems. This technique has significantly changed since its initial description in the early 1980s by Magerl and colleagues,[32] now with a currently established insertion technique of:[33]

1. X-ray imaging for localization (eg, fluoroscopy or CT scan)
2. Skin incision and blunt dissection of fascia
3. Jamshidi needle to dock at screw insertion site
4. Kirschner (K)-wire placement
5. Repeat X-ray imaging for confirmation of screw insertion site
6. Breach cortical bone using the K-wire as a guide (ie, with a cannulated awl)
7. Successive dilators
8. Tunneling or "tapping" through a pedicle
9. Cannulated screw placement over the K-wire
10. Repeat X-ray imaging for final screw confirmation

Recently, fourth-generation percutaneous pedicle screw systems have streamlined the screw insertion process further. Systems like the VIPER PRIME (DePuy Synthes Spine, Raynham, MA, USA) (**Fig. 4**A–I),[34] Voyager ATMAS (Medtronic, Memphis, TN, USA), and RELINE ONE (NuVasive, San Diego, CA, USA) (**Fig. 5**A–C) consolidate many of the above steps into a single instrument pass while using intraoperative navigation. These systems remove the need for Jamshidi needles, K-wires, dilators, tapping of cancellous bone, or multiple radiation exposures. Ultimately, these "all-in-one" instruments can abbreviate a screw insertion process to.

1. Intraoperative scan for navigation
2. Skin incision
3. Navigated placement of screwdriver system to desired insertion point
4. Screw insertion
5. Repeat intraoperative scan for hardware placement confirmation (optional)

Although the fourth-generation systems achieve this integrated approach with different mechanisms, the common factor is a single device that allows for maneuvering a screw to a desired insertion point, breaching cortical bone, and tunneling through a pedicle. Previously, each of these steps involved an exchange between the operator and assistant. However, with all-in-one instruments, a significant amount of time is saved per screw; the VIPER PRIME[35] claims a 60% reduction in screw insertion time. This has been corroborated by multiple groups and a significant reduction in operative time has been confirmed across similar systems, although studies define differently what is the time required for screw insertion.[36–38] Beyond saving time, removing the K-wire also reduces risks as it has been implicated in various complications related to displacement or bending (eg, cerebral spinal fluid [CSF] leak and retroperitoneal hematoma).[39]

Biomechanical data on the all-in-one screw systems, although sparse, have been promising in demonstrating at least non-inferiority. Pereira and colleagues showed no significant difference in pullout forces, fixation stiffness, or screw displacement necessary for pullout in cadaveric spines using both new and conventional systems.[40] Early clinical reports have also shown minimal complication rates. Misplacement and breach of screws have been reported at ~10%, which is comparable to current minimally-invasive spine surgery (MISS) techniques of 6% to 23% and remains improved compared with the upward of 39% breach rates in a traditional open approach.[37,38]

Carbon Fiber-Reinforced Polyetheretherketone

Modern titanium instruments are strong fixation devices that reliably immobilize the spine. However, a

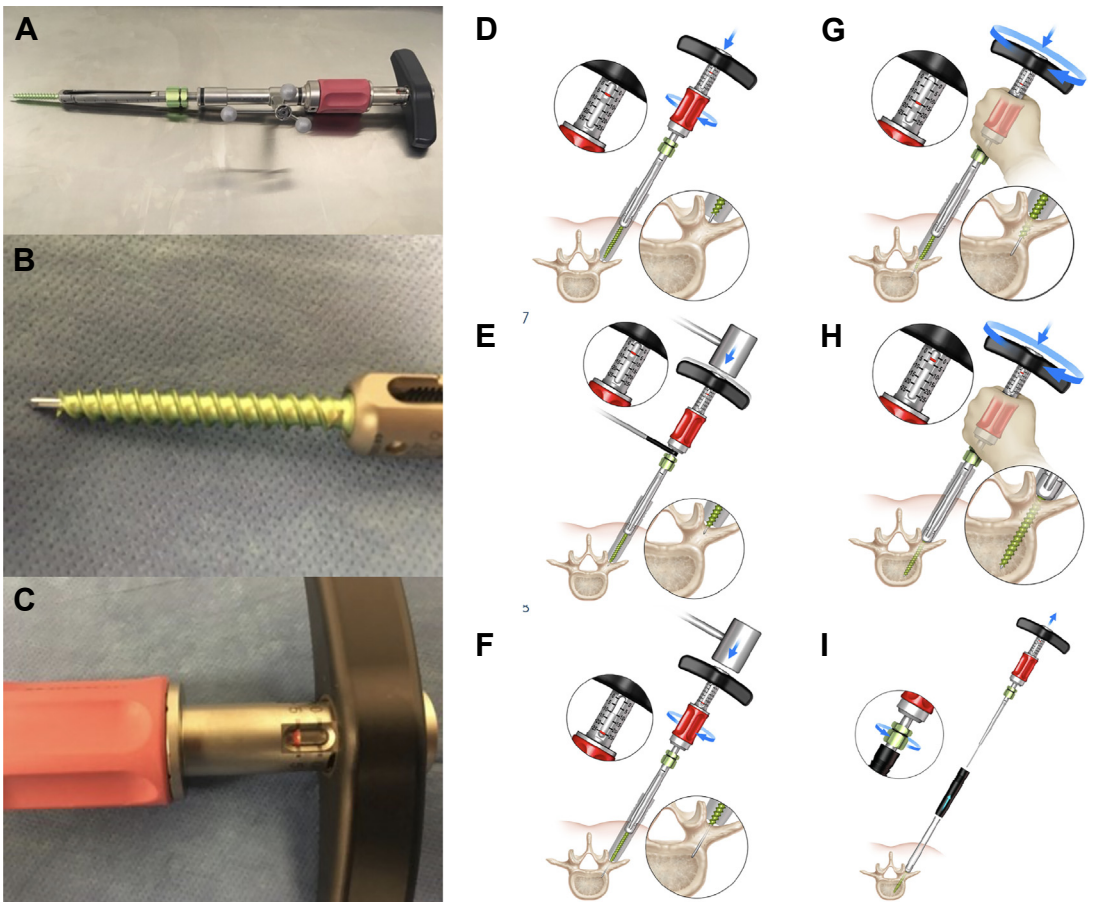

Fig. 4. (*A*) VIPER PRIME screw inserter assembled with a navigation tower. (*B*) At baseline, the stylet rests ~3 mm past the screw tip. (*C*) Expanded view of the handle with red stylet depth line. Screw insertion involves (*D*) docking at desired location and turning red handle clockwise to extend stylet past the screw tip as you (*E*) mallet the stylet into bone and through pedicle. (*F*) The depth gauge (expanded view) indicates how far the stylet is past the screw tip. (*G*) Insert screw by holding the red stylet handle still and turning the T-handle. (*H*) The red line decreases toward its baseline as the screw advances. (*I*) Turn green knob to disengage the inserter assembly from the screw.

persistent problem has been the imaging artifact caused by the metal, which restricts postoperative MRI and CT evaluation.[41] The thermoplastic polymer PEEK helped address this problem as PEEK systems are radiolucent and have been commonly used in cervical spine surgery.[42] However, their semirigid design limits long-term fusion because they permit continued micromovements.[43] In recent years, integrating carbon fiber into the PEEK matrix has generated a rigid and radiolucent material for screw designs and instrumentation.

In biomechanical studies, carbon fiber-reinforced PEEK (CFR PEEK) is equivalent to titanium constructs in both biocompatibility and biomechanical properties.[41] Studies across CFR PEEK systems have shown similar properties compared with known titanium constructs for mean bending yield load, fatigue from cyclic axial compression, and pullout strength.[44,45] The benefits of CFR PEEK have mostly focused on their potential in oncology patients. Presumably, radiolucent constructs (**Fig. 6**A–C) facilitate imaging evaluation and increased accuracy for radiotherapy planning in the short term and more easily detect local recurrence in the long term. However, few studies have objectively evaluated the benefits of CFR PEEK in postoperative radiation planning. Müller and colleagues compared radiation planning accuracy on five patients with CFR PEEK screws and five with standard titanium alloy screws and found that CFR PEEK allowed for a reduced standard deviation in target volume measurements.[46] By extension, CFR PEEK systems allowed for more accurate and precise postoperative radiation planning.

Intraoperatively, retrospective series show low complications with CFR PEEK including 1 of 34

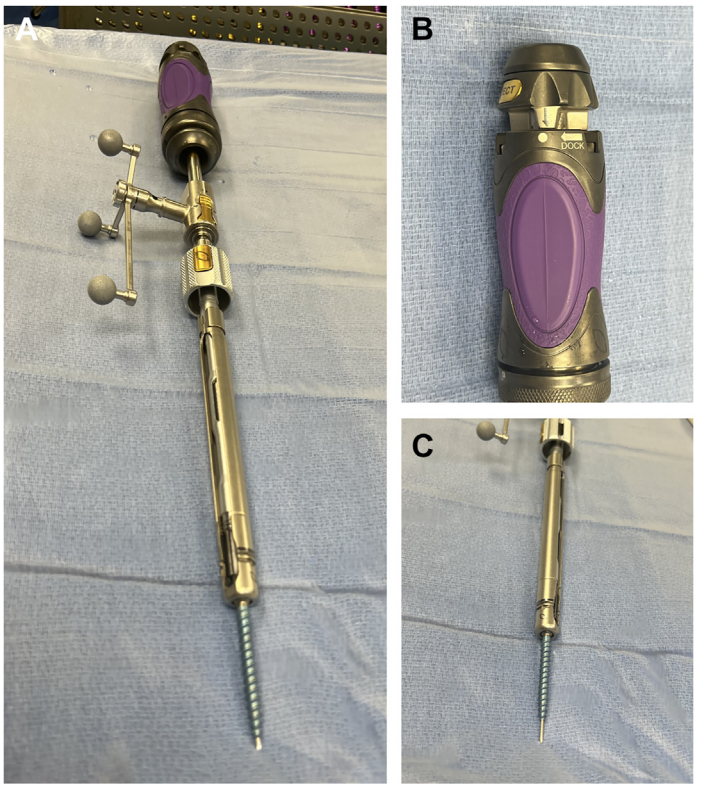

Fig. 5. (*A*) Nuvasive RELINE ONE all-in-one cannulated pedicle screws with extended tabs. The awl-tipped vector enables docking and breaching of cortical bone. The vector is then extended further (*B*) by rotation and advancement of the handle cap to guide the screw in its determined trajectory (*C*).

cases and 1 of 69 cases having a fractured screw during insertion.[47,48] A recent systematic review on CFR PEEK for primary and metastatic spine tumor patients showed similar operative outcomes compared with titanium implants.[49] Pedicle screw fractures occurred in 1.7% of CFR PEEK cases and 2.4% of titanium constructs. Reoperation occurred in 5.7% of CFR PEEK systems and 4.8% of titanium constructs. Multiple groups are actively collecting long-term oncologic outcomes, but current limited cumulative data have shown an overall local recurrence rate of 13.0% more than 13.5 months average follow-up.

Despite its promise, common limitations to CFR PEEK systems have been recognized.[48] Current products cannot be bent to suit individual anatomy intraoperatively and available pre-bent options may not suit every individual case. Ultimately, it is unclear whether the presumed increase in postoperative imaging accuracy and higher chance of detecting local recurrence generates a significant clinical impact on oncology patient outcomes. Recent commentary on CFR PEEK systems pointed out how the continued evolution of targeted therapies and immunotherapies in oncology are what will really affect these patients' outcomes.[50] However, for spine tumors that continue to have limited systemic options and still rely on en bloc surgical therapy, such as primary chordoma and chondrosarcoma tumors, CFR PEEK systems may substantially impact their postoperative course. In part due to this unclear effect on outcomes and also from the considerable increase in costs, CFR PEEK systems have not yet been widely adopted.

Facet Replacement Devices

Lumbar facet arthroplasty (LFA), using facet replacement devices (FRD), has been proposed as a method for achieving dynamic spinal stabilization. Although several FRD systems have emerged for LFA, including the Anatomic Facet Replacement System (Facet Solutions Inc, acquired by Globus Medical) and the Total Facet Arthroplasty System (TFAS) (Archus Orthopedics, acquired by Globus Medical), the Total Posterior Spine System (TOPS) (Premia Spine) is the only such device with FDA approval thus far (FDA PMA number P220002).[51]

The TOPS consists of a motion implant and four pedicle screws (**Fig. 7**A, B). The motion implant is defined as two titanium endplates connected by a polyurethane chamber. This chamber houses titanium and polycarbonate urethane articulating

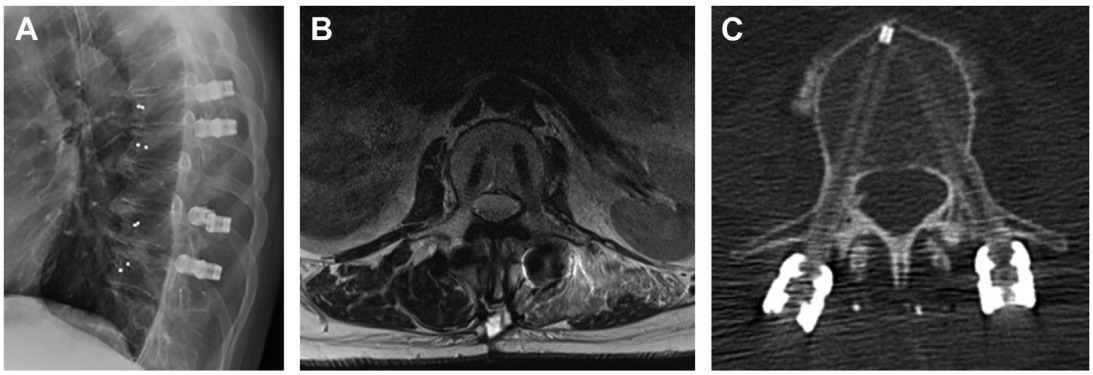

Fig. 6. (*A*) Sagittal X-ray of thoracolumbar CFR PEEK instrumentation (icotec ag, Altstätten, Switzerland) demonstrating their radiolucent screw shafts. Postoperative MRI (*B*) and CT (*C*) demonstrating reduced imaging artifact. (Image B, *Courtesy of* prof. Ehab Shiban, department of neurosurgery, university hospital of Augsburg, Germany.)

components and a woven PEEK ribbon. Following a standard midline posterior approach, four pedicle screws are placed at the cranial and caudal levels, followed by placement of the TOPS motion implant.[52] Coric and colleagues published findings from the prospective, randomized TOPS FDA IDE trial for one-level symptomatic lumbar stenosis with grade 1 degenerative spondylolisthesis. A greater percentage of patients in the TOPS group (85%) met a composite outcome at 24 months than in the transforaminal lumbar interbody fusion (TLIF) group (64%).[53] This work followed initial results from the investigational arm reported by Pinter and colleagues.[54] An important limitation of this work is the relatively short follow-up for the outcome of adjacent segment disease. Small, prospective studies suggest clinical improvement, maintained range of motion, and low rates of reoperation at 5[55] and 11 years.[56]

The Anatomic Facet Replacement System (AFRS) also uses traditional pedicle screw fixation, which is then connected by a cross-link at the caudal aspect of the construct. AFRS consists of PEEK, titanium alloys, cobalt chromium alloy, commercially pure titanium, and hydroxyapatite.[57] An FDA IDE trial (NCT00401518) comparing AFRS with posterior lumbar fusion (PLF) for spinal stenosis was initiated in 2006 and completed in 2017, though the final results have not been published. Preliminary trial results suggest that similar clinical improvements and reoperation rates at between AFRS and PLF at 2 and 4 years.[58] Of note, there has been a case report ($N = 2$) describing cobalt allergies (a key component of the implant "metal on metal" motion preservation design) with local tissue reaction and return of neurologic symptoms requiring revision to traditional titanium PLF.[59]

The TFAS is composed of a rostral "L"-shaped stems anchored to a caudal motion-preserving system. TFAS is anchored via straight stems passing into the vertebral body via a traditional pedicle screw trajectory. The straight stems are secured using polymethyl methacrylate cement.[60,61] Clinical evidence for TFAS is limited. A small series ($N = 14$) was reported in 2014 with a mean follow-up of 3.7 years and revealed consistent improvement in clinical outcomes and preserved motion on dynamic radiographs.[62] An FDA IDE trial (NCT00418197) was initiated in 2005 to compare TFAS with PLF, but not completed. Preliminary results (TFAS, $N = 96$; PLF, $N = 8$) suggest that the device may yield comparable clinical improvements compared with PLF.[63] Importantly, a case

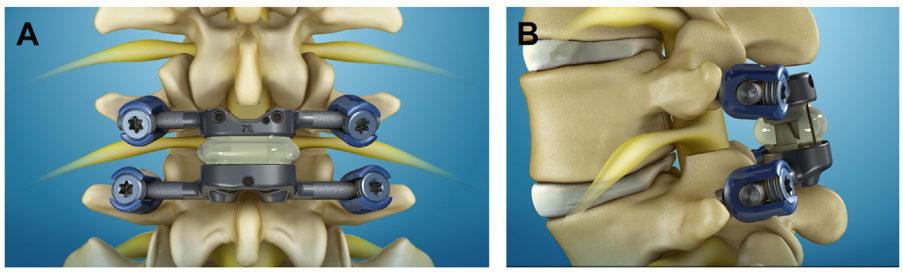

Fig. 7. Anterior-posterior (*A*) and lateral (*B*) illustrations of Total Posterior Spine System.

report (N = 2) described breakage of the stems requiring revision interbody fusion.[64]

Although FRDs offer a motion-preserving option to traditional fusion for degenerative spinal pathology, further research is required. Initial clinical results suggest that these devices can provide clinical improvements in pain and disability, though it is difficult to determine if improvements are attributable to decompression of neural elements. Long-term studies are required to thoroughly understand the impact of FRDs on adjacent segment disease.

SUMMARY

Spine implants are becoming increasingly diversified. Taking inspiration from other industries, 3D modeling of the spinal column has helped meet the custom needs of individual patients as both en bloc replacements and pedicle screw designs. Intraoperative tailoring of devices, a common need in the operating room, has led to expandable versions of cages and interbody spacers. The implant surface has been scrutinized as collaborations with other surgical fields have found certain compounds with antimicrobial and fusion-promoting properties. These partnerships have also changed the composition of implants themselves, with carbon-fiber reinforced compounds representing a hopeful addition to the spine oncology arsenal. Techniques with existing implants have also advanced, with minimally invasive "all-in-one" pedicle screws streamlining instrumentation steps in the operating room. Finally, new treatment paradigms continue to emerge, including facet replacement devices that may help treat degenerative spine pathology in a new light.

DISCLOSURE

Louis Chang: Nuvasive consultant educator, sponsored principal investigator.

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