HISTORY OF AND COMPLICATIONS ASSOCIATED WITH PERCUTANEOUS PEDICLE SCREW FIXATION SYSTEMS

The first percutaneous pedicle screw (PPS) insertion was reported in Berlin, almost 40 years ago, albeit for an external fixator application [1]. Although a fully percutaneous system with a subcutaneous rod arrived in 1995 [2], the commercial availability of the PPS system would not occur till 2001 when Medtronic launched their SEXTANTâ system (Medtronics, Memphis, TN, USA), the use of which was reported by Foley et al. [3] in the form of case reports with its use limited to 1 or 2 level fixations for degenerative disc disease.

However, since then there have been over 40 systems that have been in use spanning four generations developed by multiple companies [4] with a wide variety of indications including spinal fractures, long constructs in scoliosis, oncology, vertebral fractures as well as spondylosis [5-10].

Although the principle of minimizing damage to soft tissue during percutaneous placement of pedicle screws was retained, each newer generation of systems attempted to improve the learning curve for surgeons, decrease intraoperative complications, lessen operative time and expand indications for PPS fixation.
The first generation instruments like Sextant system and longitude 1 and 2 had a limited ability to correct spinal slippage and had heavy, easily detachable, and complicated extender assemblies that were attached to the screw head.

The second generation instruments like VIPER (Depuy, Chester, PA, USA), Sextant Advanced (Medtronics), MANTIS (Stryker, Portage, MI, USA), and ILLICO SE (AlphaTEC Spine, Carlsbad, CA, USA) allowed powerful reduction and linkage to navigation systems. Most modern instrumentations are largely based on the designs of these systems. Systems like the Ballista (Zimmer, Westminster, CO, USA) and SpiRit (Spirit Spine, Pasadena, CA, USA) that used ratchets showed promise in that they could provide parallel compression, however, in some cases the ratchet would get stuck, leading to the gradual abandonment of ratcheted devices in PPS systems.

The third generation systems were subtle modifications of the second generation with the introduction of a tab which was introduced through the extender which allowed a decrease in weight and easy removal of the extender. They also introduced lower profile 5- to 6-mm rods with titanium alloy which meant that they could be used in long constructed for deformity correction. The Medtronic Voyager ATMAS system (Medtronics) shows advancement over its Sextant predecessor (Medtronics) with a list of features including ability to link to an O-arm navigation system (Medtronics) as well as the Mazor X robotic system (Medtronics). The Bendini spinal rod bending system (Nuvasive, San Diego, CA, USA) that complements PRECEPT (Nuvasive) and RELINE systems (Nuvasive) allows predictable and reproducible patient specific rod bending preventing high loads at the screw bone interface.

The latest generation (fourth generation) works aims to decrease operative time by allowing a guide wire free placement of pedicle screws. It therefore does away with the use of Jamshidi needles, bone tunnel creation, guidewire positioning, use of a dilator, and tapping, however as the PPS that is inserted is sharp tipped, there have been some problems in re-inserting the screw [4].

**LEARNING CURVE AND COMPLICATIONS OF PPS FIXATION**

The concept of learning curves, originally introduced in the aircraft industry in 1936 [11] and defined for the surgical community by the British Royal Infirmary inquiry [12] as recently as 2004, which in the context of surgery is defined as “the time taken and/or the number of cases required by an average surgeon to become proficient (e.g., reduce operative time, estimated blood loss, and morbidity/adverse events) to be able to perform a procedure independently with a reasonable outcome.”

The factors affecting this learning curve in minimally invasive (MIS) spine surgery have been well defined by Sharif and Afzar [13] and include surgeon proficiency, progressive training arrangements, progressive procedure advancements as well as hospital equipment and staff support. Minimally invasive spine surgery and therefore PPS may pose a challenge to surgeons in terms of limited visualization and lack of traditional landmarks and therefore MIS/PPS is said to have a shallow learning curve [14,15], meaning the proficiency of the surgeon in the procedure does not markedly increase with an increase in the number of procedures (Steep learning curves are actually better than shallow ones).

Although the risk of complications in MIS decompression surgeries dropped by almost 100% after the initial 30 cases with no effect on outcomes between the initial and latter cases, the evidence for a pedicle screw fixation is not quite the same [15,16]. Silva et al. [17] in a 150 patient cohort of 1-/2-level MIS transforaminal lateral interbody fusion showed only a 50% improvement in proficiency by case 12 and 90% by case 39 with the complication rate being as high as 33% till case 12 and 20.5% till case 39. However, the ‘proficiency’ in this case was only assessed with help of mathematical models based solely on operative time. A more accurate representation of the learning curve would be through analysis of pedicle violation, interpedicular orientation etc. during initial cases of a surgeon as done by Landriel et al. [18] who found that the violation of the pedicle wall in their cohort of surgeons new to the technique was most commonly at L5 and the cause of these violation was a bad entry point in 48% cases and incorrect angulation in 52% cases. They concluded in their study that 70 PPSs needed to be placed to achieve a breakout rate as low as that of experienced surgeons, which in single level cases would be 70 cases, much higher than that reported by Silva et al. [17] However, with the use of 3rd/4th generation instruments combined with robotics, recent evidence [19] suggests that the learning curve is being shortened and accurate placement of pedicle screws would get easier earlier in the surgeons career. Use of cadaver training can also prove to be an effective tool to fight the learning curve for this procedure by placement of the first 70 screws in these spines.

**PREOPERATIVE CONSIDERATIONS AFFECTING COMPLICATION RATE**

Since, as mentioned above, the perioperative rate even late
in the learning curve may as high as 21%, identification and optimization of the independent risk factors that predispose patients to perioperative complications of PPS fixation becomes paramount [20–23].

Jenkins et al. [21] reported that an age of more than 50, obese status of a patient and preoperative diagnosis of diabetes mellitus were the only significant patient characteristics that affected complication rate. There was no bearing of the smoking status, hypertensive status, preoperative visual analogue score, American Society of Anesthesiologists physical status classification grade or Charlson Comorbidity Index on the postoperative complication rate. However, since the rate of major technique associated complications including neurological dysfunction (0%) and durotomy (0.5%) were low, the effect of these factors on major complications cannot be assessed accurately. Another study by Claus et al. [22] directly contradicts the findings above by suggesting that morbid obesity (body mass index >40 kg/m²) was not associated with either objective outcomes, postoperative complications, readmissions or adjacent segment disease. A pooled meta-analysis by Huang et al. [24] of 12 studies suggested that patient age (>65 years) and multilevel fixation were independently linked to higher major and minor complication rates, however, with no effect on objective patient reported outcomes.

Outcomes in patients compromised by these negatively associated factors will be dependent on the surgeon’s experience and it is best therefore to limit oneself to single level PPS fixation in younger, nonobese patients in early days with progression to more complex indications and multilevel fixation with increased experience.

**OPERATIVE CONSIDERATIONS**

1. **Level of Surgery**

Mody et al. [25] reported that almost 50% of surgeons admitted to performing surgery at the wrong level at some point in their career making it imperative to address this challenge of wrong level MIS surgery. The most common site of wrong level surgery was lumbar followed by cervical spine [26]. Multiple protocols have hence recommended the 3 R approach (right patient, right side and right level), Timeouts and marking the correct side to avoid wrong level and side surgery [26,27]. However, there continued to be incidence of wrong site/level of surgery with ineffectiveness of these protocols [28].

To try and battle these challenges, some authors have suggested placement of fiducial markers under computed tomography (CT) scan or fluoroscopic guidance under conscious sedation of the patient in the outpatient setting [29,30]. One must also always be aware of the anatomical variations that could lead to surgery at the wrong level as described by Shah et al. in their papers [31,32].

2. **Positioning**

Appropriate positioning includes attention to maintenance of physiological curvatures, confirmation of smooth C-arm transition from the anteroposterior (AP) to the lateral positions and appropriate visualization of the target pedicles and avoidance of double imaging on the superior end plate of the vertebral body in AP position and double pedicle/posterior wall image in the lateral position [33]. Markings can be made on the operating room floor after patient positioning to guide the C-arm technician to the correct position of the C-arm unit if it has to be moved between AP and lateral positions in case of a machine with a narrow radius of curvature.

3. **Skin Incisions**

Although fairly straightforward for single level fixations, when attempting a multilevel fixation, incisions that are linearly arranged (in a straight line) prove to be helpful during rod insertion [34]. The incision lines for percutaneous placement in obese individuals should be more lateral by about 2 cm in the lumbar spine than they would be for a nonobese patient. This allows for decreased manipulation and tension over the skin and soft tissues [35]. For each screw incision, some authors recommend the use of 1% lidocaine with adrenaline to inhibit the nociceptive pathway and decrease bleeding [33].

4. **Jamshidi Needle/Guide Wire Insertion**

Jamshidi needles are used to carve out the trajectory in the pedicles, however, changing this trajectory can prove to be challenging with a straight needle and hence a beveled tip is preferred with allows subtle changes in trajectory [33]. Landriel et al. [33] also recommend the use of short and long handled Jamshedi needles in alternating spine segments to prevent obstruction of the surgeon’s hand when changing trajectory. They also recommend that if a wrong path has been created by one Jamshedi needle with failed attempts to correct it, the needle in the wrong path can be kept there and a different Jamshedi needle should be used to create a new trajectory.

The technique of guide wire insertion for PPS has been well
illustrated by Mobbs et al. [34] in their technical paper. Complications of guide wire insertion ranges from 0.4% to 14.8% [36]. Types of complications can include K-wire fractures, cerebrospinal fluid (CSF) leaks [37], to infection [38], fractures of facets [39], bladder or visceral injuries, cardiac tamponade, retroperitoneal hematoma, etc. [36,40].

The guide wire can occasionally breach the anterior cortex when tapping or inserting the screw. This can lead to devastating complications. Mobbs et al. [40] divided this breach into minor (<5 mm), moderate (5–25 mm), and major (>25 mm). With a minor breach, the sympathetic chain (and its functions of ejaculation, temperature sensation and perspiration are under threat). A moderate breach risks injury to the major vessels (and associated risk of aneurysms, pseudoaneurysms, and retroperitoneal hematomas) and a major breach risks injury to the bowel and viscera. And therefore, it is important to prevent the anterior breach of the guide wire. These injuries can occur either due to fracture of guide wire and eventual migration or direct injury through a breached guide wire [36]. These complications are more often seen in both osteoporotic and obese patients [41] and are associated with increased operative time and intraoperative conversions from MIS to open procedures [42].

Therefore, surgeons should be cautious when inserted taps or screws over guide wires that a wide variation in the angle of insertion of the guide wire and the tap/screw can result in inadvertent migration or fracture of the guide wire [43]. Anterior breach can be prevented by sequential lateral images on fluoroscopy as the tap and screws are advanced on top of the guide wire and making sure that the guide wire does not penetrate beyond anterior one-third of the body [33]. The wire should be removed once the screw tip has entered the vertebral body.

Unintentional K-wire removal is often seen when removing the Jamshedi needle or the tap. This can be prevented by using a K wire, the end of which is long enough to be visualized at all times. It has been recommended that in cases of inadvertent removal of K wire, reininsertion through a free hand technique should be avoided as it is associated with high risk of dural injury [33]. Reapproach to the pedicle with placement of Jamshedi needle under fluoroscopic guidance should be done in these cases.

A bent guide wire should be removed immediately by levering it on the tap handle and removing it gently without sharp blows on the tap or screw Fourth generation guide-wireless screws will also be helpful in preventing these complications. Any suspicion of major vascular injury has to be treated with abandonment of procedure and urgent CT angiography with a vascular consult for further assessment.

### 5. Screw Insertion

Some unique challenges have been described and some helpful tips have been suggested by Mobbs et al. [34] that would be useful for PPS fixation including:

1. Changing the direction of screw placement following initial cannulation of pedicle by a Jamshedi needle with the help of an undersized tap placed on a K wire. Using the tap to lever and change the direction to a more appropriate trajectory can be done, but one must be aware of the aforementioned risks of K-wire fractures

2. Placing of the S1 screw in a more inferior starting position to prevent the impingement of percutaneous retraction sleeves of L5 and S1 on each other.

3. Abandoning the PPS system for an open approach with a high-speed drill in case of sclerotic pedicles would prevent much frustration to the surgeon.

The issues relating to screw misplacement have already been mentioned and should be kept in mind especially during placement of the first 70 screws by a surgeon. Zhao et al. [44] highlighted that lack of anatomical markers is a major factor for malposition of screws. They also recommended that in cases of CSF leakage, merely readjusting the position of pedicle screw could yield satisfactory results with open revision surgery with dura mater exploration and repair reserved for patients whose leakage is not alleviated post-operatively.

Poor fracture reduction can be prevented by adequate preoperative fracture type assessment and use of middle pedicle screws as forward driving points to for a strong string force for reduction and correction of kyphosis [45]. It has also been shown that single axis pedicle screws are more effective than polyaxial screws for fracture reduction [46].

### 6. Rod Insertion

Although quite straightforward for single segments, insertion of rods in multi-segment constructs can be challenging as removing rods after placement in PPS systems is difficult and therefore, a number of questions need to be answered before this step. As mentioned by Mobbs et al. [34], these questions should relate to the length of rod, appropriate bending of the rod, direction of insertion of rod and need of additional incision for insertion of rod. Mobbs et al. [34] recommended that length between retraction sleeves can prove to be an adequate
guide to rod length. To ensure easy passage of bent rods, the heights of the pedicle screws should be kept at an equal length throughout the construct and the rod should be introduced from that side of the construct where the pedicle screw is closest to the skin. However, Landriel et al. [33] suggest placement of rod from caudal to cephalad in kyphosis and cephalad to caudal in lordosis. They also recommended to lower the rod slowly and as parallel to the spine as possible to allow screw extenders to adopt their own angle. They also recommended to adjust the screws halfway in the construct and the superior and inferior distal screws would be last to be adjusted. They noted that alignment of the screw extender by force could lead to its breakage from the screw head and advised to lower all screw extenders simultaneously and progressively to reduce force in screw extender unions.

Although it is recommended to prevent un-evenness of screw heads in the lateral projection, a high-grade spondylolisthesis at L5–S1 may prevent this and cause intraoperative complications. This can be tackled, as mentioned by Landriel et al. [33] by use of an interbody cage to initially reduce the listhesis and if the indented alignment persists, a longer screw should be used in L5 to allow matching of the height of the screw heads.

New techniques of computer assisted rod bending system have shown to avoid screw pull out and loosening postoperatively and can be used to minimize such complications [47].

7. Placement of Inner

If the screw extender detaches from the screw head while placing the inner, a wider incision can be taken, soft tissue retracted and the inner can be placed under direct vision after confirming the rod has passed through it.

CONCLUSION

Minimally Invasive Approach to pedicle screw placement has its fair share of complications and identification of factors that cause and utilization of techniques that prevent these should be actively sought by the surgeon. Although challenging in the initial phase of a surgeon’s career, appropriate patient selection and adherence to guidelines can help with desired outcomes.

NOTES

Conflicts of Interest

The authors have nothing to disclose.

Funding/Support

This study received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

ORCID

Neel Anand  https://orcid.org/0000-0003-4565-6612

REFERENCES


