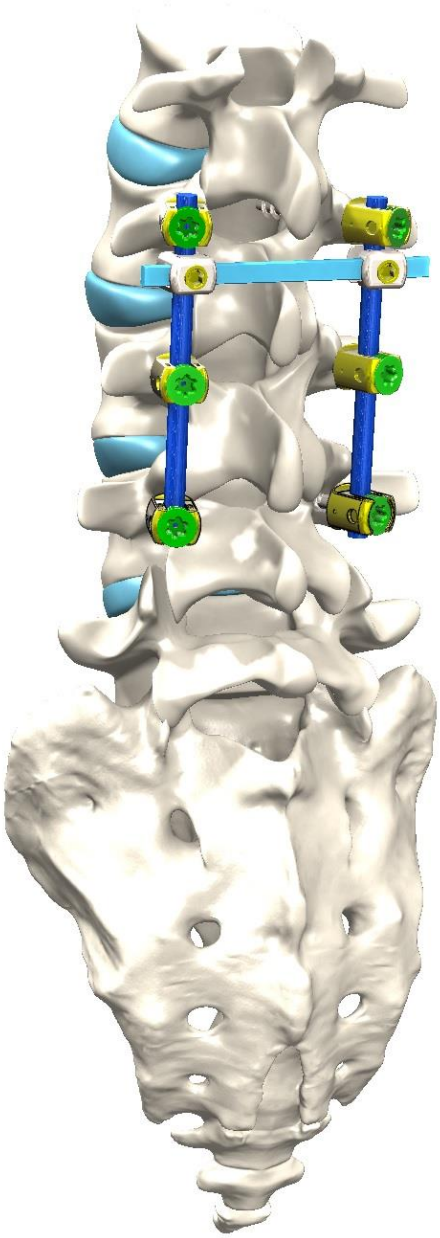
Radical Pedicle Screw™

PEDICLE SCREW SPINAL SYSTEM

SURGICAL BROCHURE



SYSTEM OVERVIEW

The Radical™ Screw Pedicle Screw System is designed to create rigid bone union (arthrodesis) between vertebral segment in the lumbar and lower thoracic vertebrae using a pedicle screw and rod construction. The system is premised on the widely accepted posterior approach, and includes an optional cross-linking mechanism for enhanced stability.

Manufactured from Titanium 6AI 4V Alloy (ref. ISO5832-3), the Radical Pedicle Screw™ offers a unique deep thread design which is predicted to provide excellent clinical results to patients with poor bone quality.

Features and Benefits

- **A wide range of implants:**

- The pedicle screw is available either with a fixed head design or with a multi-axial swivel head design;
- Radical Pedicle screws are available in both Cannulated and non-cannulated formats;
- Radical™ pedicle screws are available in fenestrated format. Fenestrated pedicle screws permit augmentation by way of injecting acrylic bone cement or BMP into the vertebral body via the lateral windows after screw placement, thereby creating early fixation whilst also stabilizing the whole construct;
- Further refinements include a multi-axial screw with an extended u-shaped head for complications related to spondylolisthesis;
- cross-linking device for improved stability;
- a wide variety of laminar hooks for the treatment of scoliosis;
- Unique design deep thread;
- The Radical™ Pedicle Screw is the culmination of long-standing partnerships and dialogue with leading specialists and engineers in the field of product design associated with corrective spinal surgery;
- Fenestrated Screw design (optional);

The Radical™ Screw Pedicle screw fusion technique could salvage a patient's quality of life, particularly for patients that suffer from advanced scoliosis or deformity where progressive pulmonary or neurologic impairment exists.

- **Indications for use:**

The Radical™ Pedicle Screw Spinal System is intended for posterior non-cervical pedicle fixation for the following indications:

- Spondylolisthesis;
- Trauma (e.g. fracture or dislocation);
- Treatment of Spinal stenosis;
- Deformities or curvatures (scoliosis, kyphosis and lordosis);
- Reconstruction due to Tumour treatment;
- Pseudo arthrosis – in cases where solid bony union is not achieved after spinal fusion attempts;
- Revision surgery – due to failed previous fusion;

FIXED HEAD Pedicle screw





MULTI-AXIAL HEAD Pedicle screw

Radical™ Screw Pedicle Screw

- Laboratory proven design:
  Each screw is provided with a threaded cup that accommodates a 5.5mm or 6.0mm alignment rod. The rod is secured with a torx type grub screw and ring design that prevents splaying of the collar. The torx grub screw features a small protrusion which facilitates improved mechanical locking of the rod.

- Optimal head design:
  The swivel design of the multi-axial screw allows for improved screw and rod assembly once the screw has been seated in the transverse process.

- A modified Cancellous-type thread:
  The CNC machined, deep modified cancellous type thread improves the implant's pull-out strength (ref test report).

- Variable diameters and lengths:
  The screw is available in Ø6.5mm, 7.0mm, and 8.0mm, while four screw lengths are offered, measuring 35mm, 40mm, 45mm, and 50mm. (Additional sizes are available upon request.)

- Benchmark material:
  All the screw implants are manufactured from Ti 6Al 4V Eli alloy (ISO 5832-3).

- Rod design:
  The Radical™ alignment rods offer excellent fatigue strength.
  Together with Titanium's Favourable bending characteristics, the alignment rods can easily accommodate the specific lordosis of the patient.

- Mechanical testing:
  A construct of the "worst case scenario" i.e. the shortest screw with the smallest diameter, and the thinnest rod, was dynamically tested according to ASTM F1717at the CSIR's Department of Manufacturing & Materials Technology, showing no signs of deterioration after 5 million cycles. (Ref. test report no. CSIR/MFC/AME/ER/2021/0033/B)
  Further mechanical testing was done to determine pull-out strength, torsion testing, and axial rod slip tests.

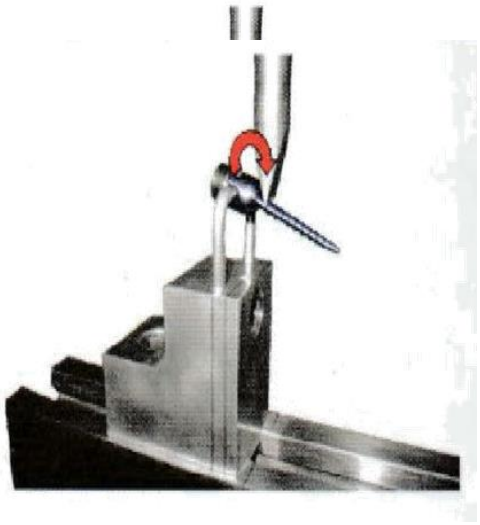
Loading configuration for pull-out strength



Loading configuration for fatigue testing



Loading configuration for torsion testing



Mechanical Properties:

	Test Avg.*
Pull-Out strength	- 7.54 kN
Torsion test	- 5.7 Nm
Axial Rod Slip Test	- 2.13 kN

*Based on independents tests performed by Council for Scientific and Industrial Research (SCIR) Manufacturing and Materials Technology Division. Full report available on request.

** ISO 5832-3 (implants for surgery – Metallic Parts – Part 3 Wrought titanium 6AL 4V

*** ISO 5832-2 (implants for surgery – Metallic materials – part 2: Unalloyed Titanium)

Warning: Excessive angulation and re-bending will compromise any metal's fatigue resistance.
An attempt should be made to maintain a smooth curve during contouring.

SYSTEM OVERVIEW

Pedicle Screws

Post-Surgery pedicle screw loosening remains a serious problem and the design of the RADICAL™ Pedicle screw is intended to assist in resolving the pedicle screw loosening crisis. Bone substitutes such as Bone Morphogenic Protein or acrylic bone cement is proposed as a suitable bone augmentation system.

Radical™ Pedicle screw – Thread design logic and related information.

The fenestrated RADICAL™ Pedicle screw is designed specifically to address the post-op pedicle screw loosening crisis which is a global phenomenon;

a) In an effort to address this crisis in Spinal fusion surgery, OCI has designed the Radical™ Pedicle screw system. The name "Radical" is used simply to highlight the huge radically difference between a coarse thread and routine pedicle screw designs.

b) A drastically modified cancellous type thread (*coarse thread) was considered during the design phase, mainly because of its deeper core thread ratio. At the risk of a coarse thread introducing potential for flank shearing, mechanical tests have proven this fear to be non-existent. The increased flank dimension results in a feature for improved bone penetration. Tests have shown zero deformation of the Radical thread (post-test).

c) *Coarse threads are more resistant to stripping because of the greater flank engagement with the adjacent bone. Coarse threads install much faster as they require fewer turns per unit length, thereby reducing bone damage/interference and reducing potential bone stripping which could potentially lead to screw loosening.

d) A general overview of Pedicle screws globally, has shown Pedicle screw designs to follow a cortical type or modified cortical type thread. It is the opinion of OCI, that this type of thread design is totally lacking in the struggle to eliminate pedicle screw loosening. A closely spaced, shallow thread design and a reduced core-to-outer diameter ratio are typical of cortical screws.

e) Radical™ screw design is based upon a logic of widely spaced deep threads with an improved core to outer diameter ratio. At the proximal area the Radical screw has a double thread which is considered to improve cortical bone fixation at that extremity of the screw. The two-start feature ensures a constant pitch as the screw is threaded into the bone, thereby eliminating potential shear type damage to the bone.

Test Results – ref ASTM F543 - 17

The ultimate tensile strength of the 7mm and 8mm sample screws was 8225N (839kg.f) and 9296N (948 kg.f) respectively. The *coarse screw thread of both the 7mm and 8mm samples screws showed no flank deformation after testing.

These Laboratory tests are performed to prove the efficacy of the thread design. Pull out tests are performed in conformance with ASTM-F543-17 ("Standard specifications and Test methods for Metallic Bone screws").

a) A favourable factor in the design of the Radical™ Pedicle screw is the increase in surface area when compared with other Pedicle screws currently being sold in the marketplace.

b) Using Solid Works software the Radical™ pedicle screw shows a surface area of ±1850 sq mm vs the surface area of a well-designed thread to be ±1050sq mm. This represents a 75% increase of screw surface to bone which increases the opportunity for bony on-growth.

SURGICAL OVERVIEW

1.1 The point of insertion of the lumbar pedicle screw is usually the base of the transverse process. The exact point of entry can be determined by intersecting a transverse line through the middle of the transverse pro-cess and a vertical line through the middle of the transverse process and a vertical line through the facet joint. Using a sharp pedicle punch the cortex is breached at the determined point of entry. (Refer to fig. 1.)

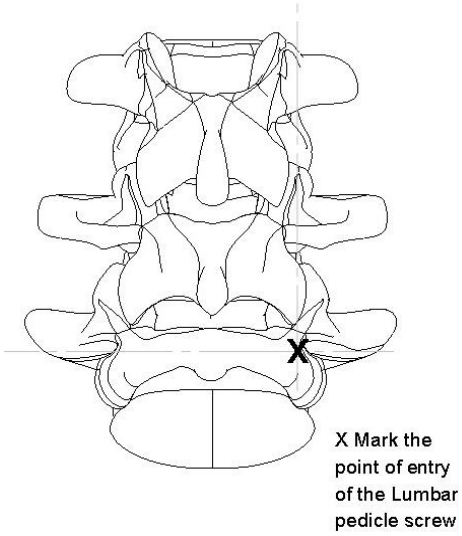


Fig.1

1.2 The pedicle probe is then used with a gentle rotary movement to negotiate the pedicle. When using the pedicle probe, it is recommended that both hands be used in order to avoid any sudden plunge. The angle of the pedicle will converge, depending on the lumbar vertebra. This convergent angle will vary as follows;

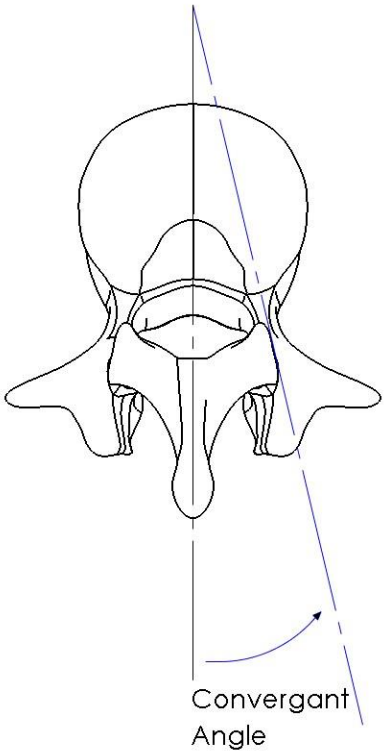


Fig. 2

1.3 The positioning of the screw's point of entry can be checked radiographically using the left and right pedicle markers as reference. (Refer to fig. 3.) lt is imperative that the line of entry is perpendicular to the vertebral body. (Refer to fig. 4.)

1.4 Once the positioning of the screw hole has been checked, the pedicle is further bored with a pedicle curette. The pedicle will now accept the pedicle screw. Prior to screw insertion, decortication of the transverse process is suggested.

- Decortication is advised on the outer aspect of the facet joint of the most cranial screw.

1.5 The multi-axial screw is inserted with the multi-axial driver. An open screwdriver may be used to align the u-shaped tulip screw heads. (Refer to fig. 5.) When inserting the screws, commence from a cranial to a caudal direction.

Note: Care should be taken with the screw placement so as to avoid tendency to place the L5 screw too laterally. This will obviate unnecessary and difficult rod bending.

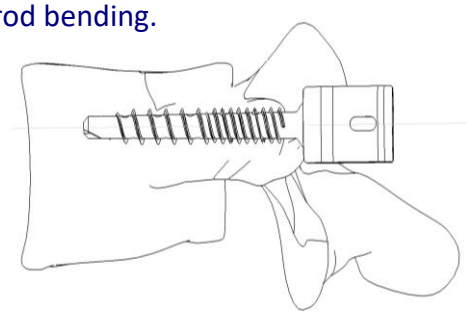


Fig. 5
Screw head is Vertically Aligned

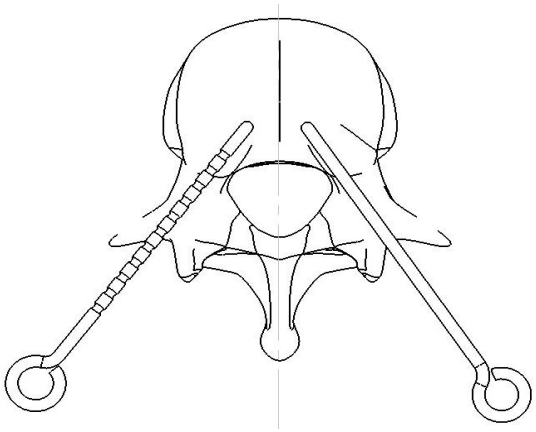


Fig. 3

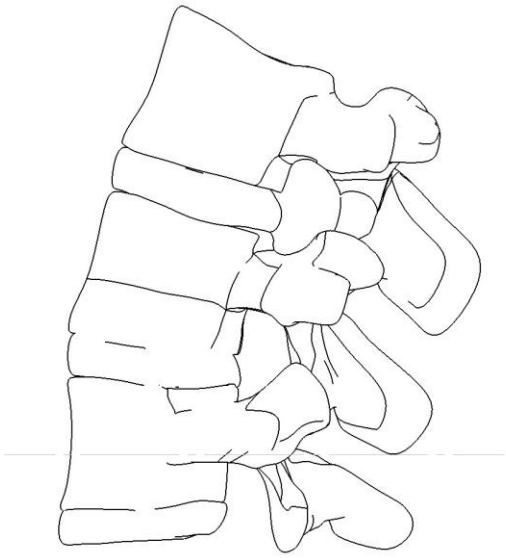
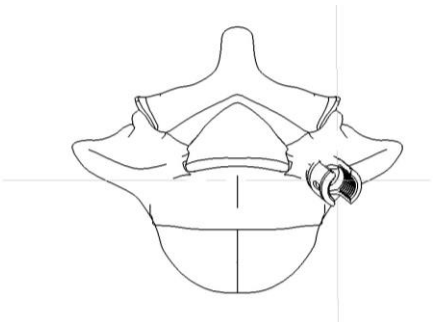


Fig. 4
Dotted line indicates perpendicular line of entry

- 0 -10° for L1 and L2,
- 15° for L3 and L4 and
- 20° for L5 vertebra. (Refer to fig. 2.)



N.B. The correct feel of the pedicle should require minimal force and a sudden plunge often signifies that the cortex has been breached. The length of the required pedicle screw can be determined by using a depth gauge

SYSTEM OVERVIEW

2. Sacral Screw Insertion

2.1 The sacral screw is introduced in the same manner as the lumbar screw, but the point of introduction is 1mm distal to the superior articular facet of the sacrum and 1mm laterally. (Refer to fig. 6a & 6b.) The pedicle probe is introduced in a 20° medial direction and superiorly in order to breach the end-plate of the sacrum. (Refer to fig. 7.)

2.2 If the bone is poor (osteoporotic), or the anticipated screw-bone strength is in any way compromised, the sacral end-plate should be breached by means of the blunt collared sacral-punch. Alternatively, careful drilling with a drill bit is recommended. This will permit the tip of the screw to engage the cortical bone and significantly improve the pull-out strength.
The fenestrated screw with acrylic bone cement is recommended for use in patients that have poor bone quality and/or Osteoporotic bone.

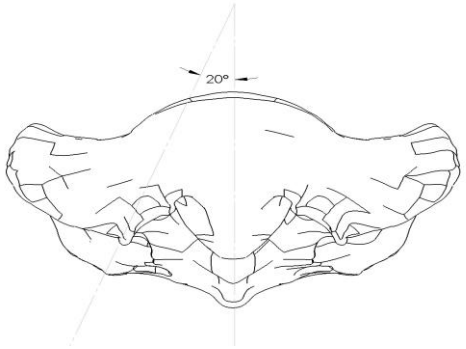


Fig.7
Screw is inserted in a convergent direction

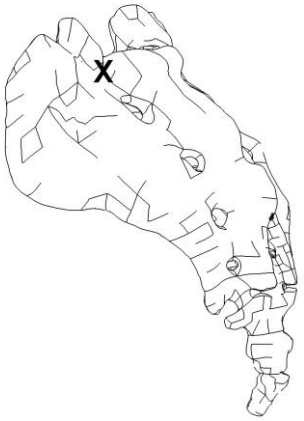


Fig. 6a
The Pedicle probe is directed into the superior end plate of S.1

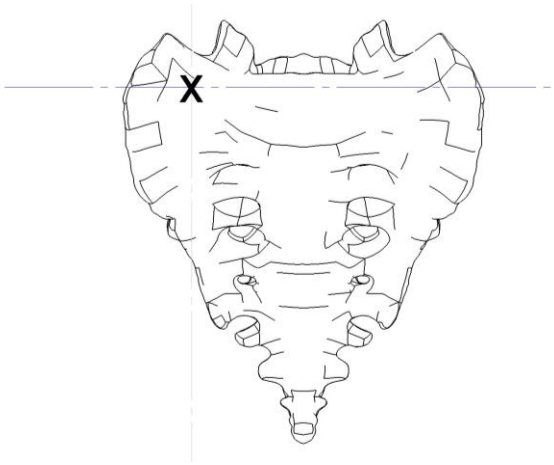


Fig. 6b
X marks the point of entry of the sacral pedicle screw. Patients with poor bone quality (see Radical™ fenestrated screw technique information para 3.3 and 3.4 below).

2.3 Should the superior end-plate of the sacrum prove difficult to engage, the anterior sacral cortex can be breached in a similar manner. Screws have been introduced with up to 5mm protruding anterior to the sacrum. No ill effects have been documented.

2.4 lt is imperative that these screws be directed medially to ensure the success of this approach.

2.5 The surgeon is advised that holding the drill with both hands will avoid the possibility of a sudden uncontrolled plunging motion through the anterior cortex of the sacrum.

SYSTEM OVERVIEW

3. APPLICATION OF BONE HARVEST

3.1 A rigid pedicle screw and rod fixation assembly serves only as a temporary "bridge" to allow associated bone to fuse.

3.2 In order to ensure optimum fusion, cancellous bone should be added to the vertebral region. Bone harvested from the iliac crest may be applied to the decorticated areas prior to rod insertion.

3.3 Use of the Radical™ fenestrated pedicle screw will include the use of BMP and/or Acrylic bone cement to be applied via a specially designed cement/BMP feeder injection systems.

3.4 For further detail relating to the Radical™ injection system, please refer to the correct injection instruction leaflet available from any authorised distributor of the Radical™ system.

3.5 Alternatively the instruction can be viewed on the OCI website
decorticated areas prior to rod insertion. Acrylic bone cement to be applied via a specially designed cement/BMP feeder injection systems.

www.ortho-centric.com

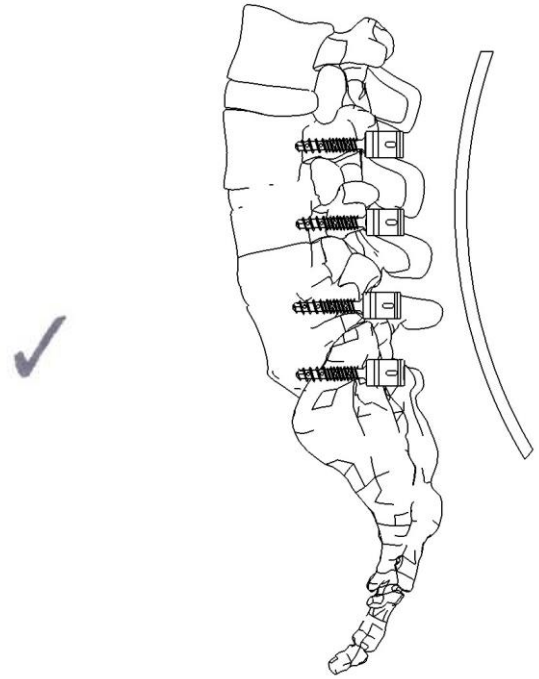
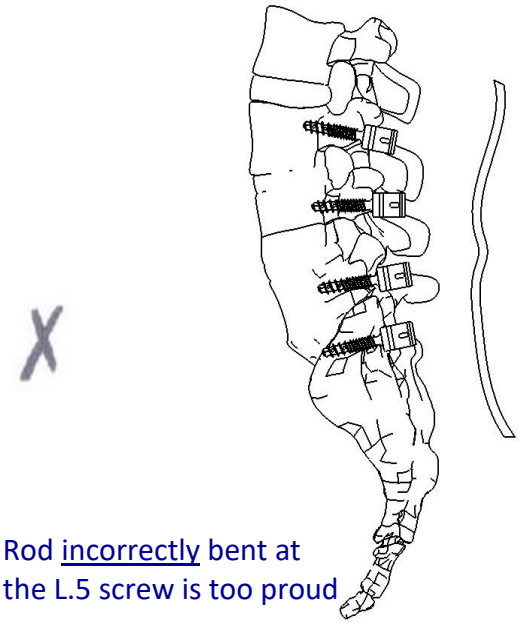


Fig.8
Rod has correct uniform bend with L.5 screw seated at correct depth



Rod incorrectly bent at the L.5 screw is too proud

4. ROD BENDING AND INSERTION

N.B.
Pre-bent alignment rods are provided with the Radical™ system which **may** eliminate the rod bending exercise.

Additionally soft aluminium "Trial" rods are provided on the set which may be bent as desired, to act as an example "test Piece" that will indicate the required rod curvature. Extreme Care should be taken not to use the "Trial" test rod in the final construct.

4.1 Bending of the alignment rod is achieved with the three-lever rod bender.
Care should be taken to bend the rod smoothly so that the correct curvature is attained. This will ensure the required lumbar lordosis.

4.2 This procedure is the most difficult to manoeuvre in top loading fixation, as it requires a measure of three-dimensional visualisation while bending the rod. Kinks and repeated bending may cause stress risers and increase the chances of rod breakage. The "Trial" rod may be used to assist in this process.

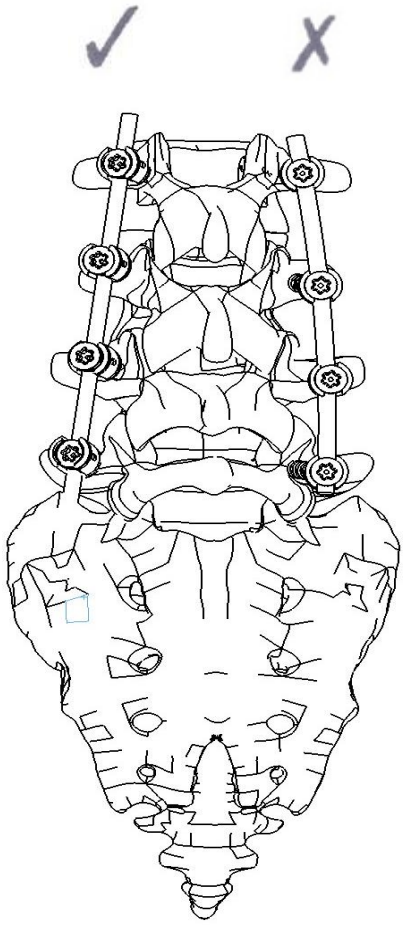


Fig.9
Usually the screw depth of L5 may have to be adjusted to ensure a uniform curvature. (Refer to fig. 8.)

Benefits

The use of multi-axial screws offers a significant benefit: They are designed to accommodate directional issues including slight vertebral misalignment between the screws.

SYSTEM OVERVIEW

5. Alignment Rod Insertion

5.1 The rod is gripped with the rod holder and top loaded into the open ends of the u-shaped screw heads. The rod pusher allows some force to be exerted onto the rod, which, together with the light tapping action of a mallet, will allow the rod to seat properly.

Note: Care should be taken to keep the screw placement in a straight line. Figure 9 illustrates the ideal placement of the rod and screw assembly once in situ.

5.2 Once seated, the rod should be loosely secured with the collars and grub screws. The rods may then be systematically tightened and the rod secured. lt is essential at this stage to ensure that the assembly has not been compromised by, for instance, cross-threading of the collar and grub screw assembly. ln most instances the grub screw will strip first and, if checked timeously, this component alone need be replaced.

5.3 Once the rods have been secured, the pedicle screw distractor/compressor is used to correct minor tilt deformities (if present) in the fusion area.

5.4 Final tightening should not be undertaken alone. A surgical assistant is required to hold the seated rod with an anti-torque device (instrument no.11 - Allen Key Driver 5mm and L-Wrench) while the surgeon does the final tightening.

5.5 This L-Wrench will afford the appropriate counter pressure and also diminish the chances of the screw breaking out of the pedicle during final tightening.

5.6 The rods may then be systematically tightened and the rod secured. lt is essential at this stage to ensure that the assembly has not been compromised by, for instance, cross-threading of the collar and grub screw assembly. ln most instances the grub screw will strip first and, if checked timeously, this component alone need be replaced.