CONTENTS

• INTRODUCTION 1

• SURGICAL TECHNIQUE FOR VERTEBRAL BODY DEROTATION (VBD) 3

  En Bloc Vertebral Body Derotation (Multiple Apical Levels) 6

  Segmental Vertebral Body Derotation (Individual Vertebral Level) 9

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SURGICAL TECHNIQUE FOR VERTEBRAL BODY DEROTATION (VBD)
USING THE EXPEDİUM SPINE SYSTEM IN SCOLIOSIS

It is accepted that with the use of pedicle screws in Scoliosis correction, significant coronal plane correction can be consistently obtained. True axial plane correction can now be achieved to address the rotational deformity of the spine, ribs and chest wall. The main goal of vertebral body derotation (VBD) is to achieve rotational deformity correction, which may decrease the need for thoracoplasty. (Figure 1)

THE STEPS ARE AS FOLLOWS:

On the concave side: Insert Monoaxial, Uniplanar, or Polyaxial Screws at every level. Consider also using Polyaxial Reduction Screws at the apex of the concavity, particularly for severe curves.

On the convex side: Insert Monoaxial, Uniplanar or Polyaxial Screws into at least 3-4 convex pedicles at the apex, as well as the proximal and distal foundations.

Confirm placement of screws and check screw length with fluoroscopy or plain X-rays prior to rod insertion.
Contour the concave rod with extra kyphosis (anticipating that the rod will become flatter during the translation/reduction of the scoliosis) to pull the apical vertebrae dorsally out of chest, and correct apical lordosis. (Figure 2)

Contour the convex rod with less thoracic kyphosis to push down on the convex side of the vertebral bodies, thus displacing them anteriorly and decreasing the rib prominence. (Figure 2)

**NOTE:**

The rod’s mechanical properties will be an important factor in kyphosis restoration and derotation. The stronger rods in the EXPEDIUM portfolio (i.e., High Strength SS, Ultra High Strength SS and CoCr Alloy rods) will be more effective than the Standard SS and Ti rods in axial derotation and sagittal plane restoration, since less flattening of the rod can be expected. The rod strength, however, should be matched to the patient’s bone density.

Insert the concave rod into the pedicle screw anchors leaving the set screws loose. (Figure 3)
The rod can engage the anchors via one or both of the following:

a. Translation Maneuver: Insert the rod proximally and distally and tighten the connectors proximally and distally, leaving the rod in the correct sagittal plane.

After proximal and distal foundations are connected and locked, apical screws are translated to the rod segmentally by using reduction devices or reduction screws. (Figure 4A)

b. Rod Rotation Maneuver: Insert the rod and perform a rod rotation maneuver as in the classic CD Technique. In this case, the rod rotates from the midline scoliotic position laterally to the left. (Figure 4B)

During the 90° rotation one must have control over the convex ribs by pushing down to avoid aggravating the rib prominence.

Finally, proceed with one or both of the Vertebral Body Derotation techniques explained in the following section.
EN BLOC VERTEBRAL BODY DEROTATION (MULTIPLE APICAL LEVELS)

After the concave rod is engaged in all anchors, attach VBD instruments: EXPEDIUM Derotation Quick Sticks, Facilitators, Flex-Clip with Rotation Tube or VIPER 2 Screw Extensions, (Figure 5A-D) to apical screw heads on both concave and convex sides. (Figure 6)

A) Quick Stick  
B) Facilitator  
C) Flex-Clip with Rotation Tube  
D) VIPER 2 Screw Extension
An assistant pushes down on the convex ribs and the convex screws while the concave and convex screws are rotated in the direction that will reduce the rib prominence (counterclockwise in Figures 6 & 7). This should be done simultaneously to distribute strain and to limit loading of the bone-screw interface. The rotation of the concave screws will help decrease the torsion and will lift the concavity out of the chest. (Figures 6 & 7)

A rehearsal of this maneuver prior to rod insertion can be helpful to gain a sense of how much force is to be applied safely.
Lifting the concave side out of the chest is effectively done with the Quick Sticks locked on the TOP NOTCH feature of EXPEDIUM implants. This feature provides 360° control of the anchor point without the need for additional instrumentation.

In addition, using the EXPEDIUM Derotation Frame and/or Alignment Fork multiple Quick Sticks can be linked together and rotated in unison. (Figure 8)

**NOTE:**

Some surgeons believe that the VBD maneuver with both rods in place minimizes the loss of rotational correction that occurs from spine “spring back” when inserting and rotating one rod at a time. In this case, follow the same steps described above but with both rods already implanted.

Tighten the set screws on the concave rod holding this position. (Figure 9A)

Implant the convex rod and tighten the set screws on the convex side. (Figure 9B)
SEGMENTAL VERTEBRAL BODY DEROTATION (INDIVIDUAL VERTEBRAL LEVEL)

Segmental Vertebral Body Derotation can be done as the sole derotation maneuver or in addition to the En Bloc maneuver described before.

Implant both rods and capture them with the set screws. Most set screws should be left loose since lengthening of the spine is expected at each level that will be segmentally derotated. Only the set screws in the distal neutral vertebra should be tightened (e.g., L1 in Figure 10A).

Attach two Quick Sticks in the distal segment to lock the bottom neutral vertebra (Figures 10A, B). Then attach Quick Sticks in the next proximal 1-2 vertebrae. The Quick Sticks on the distal vertebra must be held by an assistant to provide counter-rotation force.
Derotate each proximal vertebral body to achieve a neutral position in reference to the neutral distal vertebra (Figure 11A, B). After derotation of each segment, the set screws are tightened. Repeat this process, moving along towards the apex.

Complete neutral derotation may not be achieved at the apex relative to its torsion in the axial plane during the first pass. Repeating the derotation maneuvers at some levels can be helpful due to viscoelastic relaxation of the spine. Care must be taken not to loosen the bone-screw interface while performing the maneuver.

The EXPEDIUM Derotation Quick Sticks, Facilitators, Flex-Clip with Rotation Tube or VIPER 2 Screw Extensions, are all effective in this step of Segmental Derotation. (Figure 5A-D)

In addition, using the EXPEDIUM Derotation Frame, Quick Sticks in the same vertebral level can be linked together and rotated in unison. (Figure 10B)

Repeat the derotation for each segment, until all vertebral levels nearly match the neutrally rotated distal vertebra.

During Segmental Spinal Derotation, segmental compression (convexity) and/or distraction (concavity) may be simultaneously applied to effect maximal correction, just before the set screws are tightened.
Additional coronal correction can be achieved with the use of EXPEDIUM Coronal In-situ Benders. In-situ contouring is more easily achieved when using standard SS rods than when using High and Ultra Strength Rods. (Figure 12)
INDICATIONS

The EXPEDITUM Spine System is intended to provide immobilization and stabilization of spinal implants in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDITUM Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion in skeletally mature patients.

CONTRAINDICATIONS

Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.

Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system. Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient’s occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

WARNINGS, PRECAUTIONS, AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, etc., which come into contact with other metal objects, must be made from like or compatible metals.

4. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:
   A. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.
   B. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.
   C. A condition of sensitivity, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
   D. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
   E. Foreign body sensitivity. The surgeon is advised that no prostatic test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.
   F. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

PRECAUTIONS

1. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. Reuse can compromise device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.

2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

3. CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING. If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid fracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

4. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient’s ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

5. CORRECT PLACEMENT OF ANTERIOR SPINAL IMPLANT. Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurologic damage with the use of this product. Serious or fatal hemorhage may occur if the great vessels are entrapped or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants or if pulsatile erosion of the vessels occurs because of close apposition of the implants.
Limited Warranty and Disclaimer: DePuy Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.

To order, call DePuy Spine Customer Service (1-800-227-6633).

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