Access Pelvic Fixator™

SURGICAL TECHNIQUE

Attila Poka, MD
Director, Orthopedic Trauma Service
Grant Medical Center
Columbus, OH
The Access™ Pelvic Fixator was designed specifically for use in the management of hemodynamically unstable patients with fractures of the pelvis.

The Access™ Pelvic Fixator is intended to provide rapid stabilization of pelvic ring fractures; emphasizing speed and precision, through a simplified surgical technique with minimal componentry. The system accommodates the three dimensional shape of the iliac wing by facilitating independent bone screw placement in the anterior superior iliac spine. Each arm of the fixator provides for telescopic movement in order to match individual patient size and minimize fixator profile. Additionally, the system was designed to hinge in the coronal plane to provide for surgical access to the abdomen, as well as subsequent abdominal distension.

A stabilization bar is incorporated into the system to allow for hinging of the telescopic arms without compromising the reduction. Once the position of the fixator is defined, the hinge may be locked and the stabilization bar can be removed. To return the fixator to its original position, the stabilization bar is put back on the frame and the hinge is returned to a neutral position and locked. The telescopic arms can then be returned to their original position.
(One) Access™ Pelvic Fixator  P/N 12100
(One) Access™ Pelvic Fixator  Stabilization Bar  P/N 12145
(One) 4.8mm Drill Guide  P/N 03060
(One) 4.8mm Drill Bit Complete (240mm)  P/N 03010
(One) Trocar  P/N 03075
(Six) Soft Tissue Guides (100mm)  P/N 03090
(One) T-Wrench for Bone Screws  P/N 03125
(One) 5mm Allen Wrench  P/N 03110
(Six) Bone Screws

The following are suggested bone screw sizes; however, each patient should be evaluated pre-operatively and bone screws should be chosen based on individual patient needs. All bone screws are tapered and must not be backed out or they will lose purchase. Additional sizes are available with longer overall and thread lengths with and without trocar tips.

6/5 Cortical 180mm (overall length)  
60mm (thread length)  
P/N A60-18060

6/5 Cortical 200mm (overall length)  
50mm (thread length)  
P/NA60-20050

6/5 Cortical 220mm (overall length)  
50mm (thread length)  
P/N A60-22050

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1. Stabilization Bar
2. Anterior Connecting Bar
3. Telescoping Arms
4. Bone Screw Clamps
5. Trocar
6. Soft Tissue Guides
7. 4.8mm Drill Guide
8. 4.8mm Drill Bit
9. Cortical Bone Screws
10. T-Wrench for Bone Screws
11. 5mm Allen Wrench
Fixator Preparation

To facilitate rapid application, the bone screw clamps are dismantled from the telescoping arms using the 5mm allen wrench. The remainder of fixator components can be addressed once the bone screws have been inserted and the bone screw clamps have been applied to the screw shanks.

Design Rationale:

Anterior frames are beneficial in antero-posterior compression Types II and III, lateral compression Types II and III, vertical shear and combined mechanical pelvic instabilities. In patients with the above noted instabilities, anterior frames are applied immediately to stabilize the pelvis and reduce the incidence of hemodynamic decompensation. Associated acetabular fractures require individual consideration. For hemodynamically unstable patients presenting with an associated acetabular fracture and an intact anterior 1/3 iliac wing, an anterior frame can be applied for resuscitative purposes, until definitive fixation can be undertaken.

Surgical Technique
**SURGICAL TECHNIQUE**

1. **Drilling and Bone Screw Application**

**A** Patients are placed in the supine position and prepped and draped in routine sterile fashion. Bone screw placement is recommended using percutaneous techniques and following the principles of free-hand, independent bone screw placement. Convergent bone screw placement is paramount and care should be taken to insure accurate pin placement. This will provide the stable foundation for appropriate bone to screw interface.

**B** Two centimeters posterior to the antero-superior iliac spine, a one-centimeter transverse incision is made at a 90° angle from the iliac crest. Using the trocar and soft tissue guide, the iliac wing is located and the inner and outer tables of the hemipelvis are identified. Divide the thickness of the iliac crest into thirds, remembering that there is an overhang to the outer table of the hemipelvis. The ideal placement of the bone screw should be targeted for introduction in the inner third of the iliac crest.

This will provide a better mechanism for bone screw purchase and limit the potential for having the screw penetrate the inner or outer tables of the pelvic wing. If an open technique is used, inserting a blunt k-wire along the inner table will help identify the orientation of the shape and contour of the pelvic wing. This will insure bone screw placement parallel to the inner table. Additionally, use of palpation will help direct bone screw placement.

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Using the trocar and soft tissue guide, the iliac wing is located and the inner and outer tables of the hemi-pelvis are identified.

The ideal placement of the bone screw should be targeted for introduction in the inner third of the iliac crest.
Once the position of the bone screw has been identified, the soft tissue guide is tapped with a mallet to secure positioning. A 4.8mm drill guide and drill bit are inserted into the soft tissue guide. The drill is aimed toward the greater trochanter. Drilling is commenced, allowing for approximately 1cm of penetration into the cortex. Over-drilling beyond one centimeter is not recommended and should be avoided. Once the cortex has been opened, the drill bit and drill guide are removed and gentle pressure is maintained on the soft tissue guide to prevent losing the predrilled hole.

The appropriate 6/5 cortical bone screw is inserted into the soft tissue guide allowing the screw threads to draw the bone screw deeper into the pilot hole between the inner and outer tables of the iliac wing.

Repeat steps 1A-D for insertion of remaining bone screws. Fixator stability and bone screw interface may be optimized with three bone screws in each hemipelvis. Individual patient considerations and clinical condition will dictate the number and position of bone screws. Three bone screws are recommended for patients with osteopenia.
2 Bone Screw Clamp Application

Using a 5mm Allen wrench, the bone screw clamp is detached from the telescoping arm by loosening the telescoping set screw. Once the fixator clamp is removed, all locking components on the clamp are loosened to allow free excursion of the components and to facilitate clamp to bone screw application.

The bone screw clamp is applied to the shanks of the bone screws, leaving approximately 5 to 6 centimeters for subsequent bone screw hygiene. Using the same 5mm wrench, the bone screw clamp fittings are definitively locked to the shanks of the bone screws.

The T-wrench may be applied to the shanks of the bone screws while tightening the clamp fittings to provide an additional measure of counter torque. This will prevent unnecessary stressing of the bone screw interface during the tightening procedure. Repeat bone screw clamp application on the contralateral hemipelvis.

Loosening all locking components on the bone screw clamp to allow free excursion of the components to facilitate clamp to bone screw application.
Applying the bone screw clamp to the shanks of bone screws, leaving approximately 5 to 6 centimeters for subsequent bone screw hygiene.

Using the 5mm allen wrench, the bone screw clamp fittings are definitively locked to the shanks of the bone screws. The large ball joint should remain loose.
Once the bone screw clamps have been secured to the shanks of the bone screws, the telescoping fixator arms and anterior connecting bar are re-attached. Using the 5mm allen wrench, the telescoping arms are inserted into the stem of the bone screw clamp. Lock the telescoping set screw.

Providing reduction is achieved by loosening the bar locking screws on the anterior portion of the fixator. Surgeons are encouraged to apply a compressive force across the pelvic ring by pushing against the greater trochanter. It is not recommended to push against the bone screw clamps or the telescoping arms of the device. This will increase forces on the pin to bone interface. This can cause the bone screws to break out and potentially increase or exacerbate posterior instability. Pushing from the greater trochanter will provide an even compressive force across the pelvic ring. Once adequate compression has been achieved, the bar locking screws are definitively tightened. The ball joints are then positioned in a plane that is perpendicular to the long axis of the body and locked.
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The ball joints are then positioned in a plane that is perpendicular to the long axis of the body and locked.
Hinging The Fixator

Depending on the surgical needs of the patient, the fixator may be hinged cephalad or caudal to gain surgical or radiographic access. This will allow for greater access to the abdomen or pelvis and account for abdominal distention.

To allow for hinging capabilities on patients with unstable posterior ligaments, the stabilization bar must be applied to the frame prior to loosening any locking screws. The stabilization bar, when applied, will allow for telescopic movement of the fixator arms while maintaining rigid fixation between the ball joints. This will prevent shifting of the hemipelvis during the hinging process.

**Surgical Note:**
- The bar locking screws should remain definitively tightened throughout the hinging process.
- The telescoping arms of the fixator must be parallel when hinging the fixator.
- The hinges of the telescoping arms must be parallel to allow hinging.

**Hinging Cephalad**
The stabilization bar is applied to the inferior side of the fixator frame using a 5mm allen wrench. To adjust length of the stabilization bar, unlock the anterior bolt on the bar and manipulate until desired length is achieved. Once achieved, lock the anterior bolt.

The telescoping arm bolt is loosened with a 5mm allen wrench on both sides of the frame. Pulling on the anterior connecting bar will allow the frame to telescope.

Once the frame has traveled to its endpoint, the fixator hinge will be exposed. Loosening this hinge 1/4 turn will allow a free moving hinge. Position the hinge in the desired location and lock the hinge in place. The stabilization bar can be removed once the hinge is locked.
**Hinging Caudal**

The stabilization bar is applied to the superior side of the fixator frame using a 5mm allen wrench. To adjust length of the stabilization bar, unlock the anterior bolt on the bar and manipulate until desired length is achieved. Once achieved, lock the anterior bolt.

The telescoping arm bolt is loosened with a 5mm allen wrench on both sides of the frame. Pulling on the anterior connecting bar will allow the frame to telescope.

Once the frame has traveled to its endpoint, the fixator hinge will be exposed. Loosening this hinge 1/4 turn will allow a free moving hinge.

Position the hinge in desired location and lock the hinge in place. The stabilization bar can be removed once the hinge is locked.

**Reconfiguring Fixator to Original Position**

To reconfigure the frame to its original position, the stabilization bar must be reapplied.

The telescoping arms can be returned to the original position by unlocking the telescoping arm bolt, sliding the arm back towards the bone screw clamp and re-locking the telescoping arm bolt in a definitive position.

The stabilization bar can then be removed for the duration of treatment, or until otherwise needed.

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A. Adjusting Stabilization Bar length.
B. Locking Stabilization Bar onto frame.
C. Loosen Telescoping Arm Bolt on both sides of the frame to allow telescopic movement.
D. 1/4 turn will allow a free moving hinge.
E. Hinge must be locked prior to removal of Stabilization Bar.
SUGGESTED SCREW SITE CARE

Dry sterile gauze is wrapped around the shanks of the bone screws to prevent pistoning of the soft tissues on the bone screws. A solution of 2% hydrogen peroxide and sterile water should be used on the pin sites until the wounds have healed and sutures are removed. The patients are then instructed to shower on a daily basis using an antibacterial soap and water as a means for routine bone screw hygiene. Screw sites should be monitored during subsequent clinic visits. All fixator fittings should be evaluated for tightness during subsequent clinic visits.

STERILIZATION

The DynaFix® Access™ Pelvic Fixator components and instrumentation are provided non-sterile and must be sterilized prior to use. All packaging materials must be removed prior to sterilization. All fixator fittings should be sterilized in a loosened state such that connected components may move freely. The following steam sterilization parameters are recommended:

- CYCLE: Vacuum
- TEMPERATURE: 270˚ F
- TIME: 4 Minutes
- NOTE: Allow for cooling

Individuals or hospitals not using the recommended method, temperature and time are advised to validate alternative methods or cycles using an approved method or standard.

INDICATIONS

The EBI X FIX® DynaFix® Access™ Pelvic Fixator is a unilateral fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation and other bone conditions amenable to treatment by use of external fixation modality.

Caution: Federal Law (U.S.A.) restricts this device to sale by or on the order of a physician.

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicels) of the cervical, thoracic, or lumbar spine.

See package insert for full prescribing information.

To reorder, call:
(800) 526-2579
(800) EBI X FIX
Fax (800) 524-0457

EBI, as the manufacturer of this device, and their surgical consultants, do not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and utilizing the appropriate techniques for implanting the device in each individual patient. EBI and their surgical consultants are not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.