VERSAFX®
FEMORAL
FIXATION
SYSTEM

Surgical Technique for Fixation of Supracondylar Fractures of the Femur
Introduction

The effective management of supracondylar femur fractures present a challenging problem to the orthopaedic surgeon. The use of a 95- or 90-degree lag screw and tube/plate provides one acceptable method of rigid internal fixation of such fractures. The 95- or 90-degree compression screw is indicated in the treatment of both intra-articular and extra-articular supracondylar femur fractures. Supracondylar femur fractures with vertical intra-articular extension through the intercondylar notch are ideal for this device as compression may be applied across the fracture site.

The Versa-Fx System provides the surgeon with the flexibility to use either the 95- or 90-degree plate and sliding compression screw for the fixation of supracondylar femur fractures.

FIGURE 1 PATIENT POSITIONING
Surgical Technique for Supracondylar Femur Fractures

Patient Positioning and Radiographic Control

After administering a general or spinal anesthesia, transfer the patient to the operating table in the supine position. If desired, place a sterile bump under the ipsilateral thigh (Figure 1). Prep and drape the affected leg using a sterile technique. Place the calf and foot in a sterile stockinette. Exclude the contralateral lower extremity from the sterile field with a U-drape. The ipsilateral iliac crest should be included in the operative field, should a bone graft be required.

It will be necessary to use image intensification or other x-ray imaging. The image intensifier should be sterile-draped and may be positioned from either the contralateral or ipsilateral side of the operating table.

Incision, Exposure and Fracture Reduction

Expose the supracondylar fracture through an anterolateral approach (Figure 2). Make a linear incision starting approximately 15 cm proximal to the patella along a line that runs from the anterior-superior iliac spine to the lateral border of the patella. Carry the incision distally to the lateral border of the patella. The exact length of the incision is determined by the extent of the fracture. Open the interval between the vastus lateralis and the rectus femoris to expose the vastus intermedius. Longitudinally incise the fibers of the vastus intermedius over the anterior aspect of the femur. Extend the dissection subperiosteally around the bone.

The exposure may be carried distally by continuing the skin incision distally along the lateral border of the patella, ending 1 cm below the joint line of the knee. Incise the lateral patellar retinaculum 1 cm from the patella. Incise the synovium to expose intra-articular fractures (Figures 3A and 3B).
As an alternative method, use a lateral approach that is posterior to the vastus lateralis. However, the anterolateral approach provides a better exposure of intra-articular fractures.

The fracture should be reduced under direct vision. Intra-articular fractures may be temporarily stabilized with cancellous interfragmentary screws or K-wires. Be careful to place these screws or K-wires anterior or posterior to the insertion site of the center of the anterior half of the femoral condyles.

Inspect the supracondylar portion of the fracture for comminution and assess the need for bone grafting. Reduce the fracture under direct vision and stabilize it with bone clamps.

**Guide Pin Placement**

Place the 95- or 90-degree template along the lateral femoral condyle and establish the appropriate angle between the guide pin and the lateral femoral cortex. The guide pin should ideally pass through the center of the anterior half of the condyles without penetrating the intercondylar notch (Figure 4). The guide pin will pass approximately parallel to the knee joint; however, small angular deviations may be necessary to ensure that the side plate lies flush against the lateral femoral cortex. If desired, temporarily place a guide pin along the anterior aspect of the distal femur running through the center of the femoral condyles and remaining superior to the notch. Use image intensification to confirm the guide pin position.

Mark the starting point for the guide pin on the lateral femoral condyle. Drill the guide pin into the condyles using image intensification for guidance. Advance the guide pin until it abuts the subchondral bone of the medial femoral condyle.

The guide pin placement for a 90-degree compression screw is similar to that for a 95-degree compression screw except that the 90-degree template is used to establish the appropriate angle between the guide pin and the lateral femoral cortex. In this case, when positioned flush against the lateral femur, the 90-degree template will direct the guide pin at approximately 5 degrees superior to the knee joint.
Determining Guide Pin Depth and Reaming and Tapping the Lag Screw Channel

Use the Guide Pin Depth Gauge to measure the length of the pin within the bone. This measurement, called the “pilot length,” is used to determine the length of the lag screw and to set the depth of the Lag Screw Reamer (Figure 5).

For young patients with healthy bone, ream to the pilot length to make lag screw insertion easier. In elderly patients with osteopenic bone, ream to a depth of 10 mm shorter than the pilot length to enhance screw purchase in the bone.

Use the Lag Screw Reamer with the short barrel reamer only. This will ensure that the reamer head does not cross the fracture site. The reamer is designed to countersink the lateral femoral cortex for optimal side plate placement, flush against the bone. Ream to the point where you countersink as shown in Figure 6. The depth of reaming may be checked (or affirmed) by image intensification. If the guide pin is pulled out when the reamer is extracted, use the Guide Pin Relocator to replace it.
The reamed lag screw channel may be tapped using the Cannulated Bone Tap with centering collar. Set the tap by placing the back of the collar with the desired millimeter setting read at the back in the same manner as the reamer (Figure 7). Tapping is usually not needed with osteopenic bone.

If desired, use the metal tube/plate provisionals to check the angle of fixation and the exact fit of the implant (Figure 8). Because all Versa-Fx Femoral Fixation implants are packaged presterile, use of the provisionals is preferable to opening more than one implant package if an adjustment is necessary.

Note: If the surgeon chooses not to assemble the tube/plate on the lag screw inserter, as in figures 9 and 10, use of the provisional should be done after the lag screw has been inserted.

**Determining the Lag Screw Length**

Determine the lag screw length from the "pilot length." Because a short barrel will be used, the lag screw may need to be up to 10 mm longer than the pilot length to ensure adequate overlap between the lag screw and tube/plate.
Insertion of the Implant

Assemble the T-handle onto the Lag Screw Inserter and place the selected tube/plate onto the recessed diameter of the inserter. Place the appropriate length lag screw into the driving tip of the instrument. Then place the entire assembly over the guide pin and insert it into the prepared lag screw channel (Figures 9 and 10). The T-handle of the inserter should be in the same plane as the shaft of the femur when the screw is completely inserted to the appropriate depth. After inserting the lag screw, move the tube/plate into position over the lag screw with the barrel resting in the lag screw channel. If desired, clamp the tube/plate to the shaft of the femur. At this point, there should be solid fixation of the condyles.
Attaching the Side Plate

Check to be sure that reduction of the supracondylar portion of the fracture has been accomplished. Fix the side plate to the lateral femoral cortex using 4.5 mm diameter bicortical bone screws and 6.5 mm cancellous bone screws in the two distal holes. Each hole should be sequentially drilled, measured and tapped, and the appropriate length screw should be inserted in a neutral position (Figures 11 and 12).

If necessary, place bone graft at the fracture site.

Impaction (Optional)

If you elect to impact the fracture, use the Impactor* (If bone graft will be used at the fracture site, the graft should be inserted before impaction.)

Screw the Impactor Guide into the back of the lag screw. Slide the Impactor over the guide until the plastic nose fits flush onto the plate (Figure 13). Carefully tap on the Impactor with a mallet while monitoring the degree of impaction.

*Developed in conjunction with William M. Deyerle, M.D.
Use of a compression screw is recommended in all cases to ensure adequate overlap of the screw in the tube as well as to achieve further impaction (Figure 14). However, it is important to avoid excessive force with compression or impaction because the lag screw may strip the threads in soft bone. In osteopenic patients, it may be desirable to use a lag screw with extra-wide threads in order to increase the purchase in the medial condyle. Use image intensification to examine the fracture alignment and hardware position.

After compression is achieved, the compression screw should be removed.

Final radiographs should be obtained before closing to make certain that the fracture is completely compressed and there is no gap or abnormal angulation at the fracture site.

**Wound Closure**

Irrigate the wound with antibiotic solution. Place closed suction drains in the wound and use for 48 hours postoperatively. Close the wound with interrupted absorbable sutures in muscle, fascia and subcutaneous tissues. Close the skin with staples and apply a pressure dressing.

**Postoperative Care**

Give the patient prophylactic antibiotics for 48 hours. When possible, use anti-embolism stockings and aspirin therapy to help prevent thrombo-embolism. Initiate continuous passive motion of the ipsilateral knee in the immediate postoperative period.

Encourage the patient to sit in a chair on the first postoperative day. On the second postoperative day, begin physical therapy for nonweight-bearing ambulation training. Use serial x-rays to document healing. When appropriate, gradually increase weight bearing as healing progresses.
DESCRIPTION

The compression tube/plates of this system are used with the 8 Compression Hip Fixation System lag screws (Cat. No. 1181 series) for the internal fixation of proximal femoral fractures and of supracondylar fractures. This insert encompasses both applications, with section headings and clauses specifying Hip and Supracondylar, respectively.

Hip

The Versa-Fx compression tube/plate is a keyed device.

The compression tube/plates have an outside tube diameter of 12.2 mm; an inside diameter of 8.7 mm; short (25.4 mm) and standard (38.1 mm) tube lengths; tube/plate angles of 130°, 135°, 140°, 145°, and 150°. Plates are available with 2, 3, 4, 5, 6, 8, 10, 12, and 14 holes in regular tube length, and 4, 5, and 6 holes in short tube lengths. All screw holes accept ECT Internal Fracture Fixation bone screws with hexagonal socket heads (Cat. No. 2306) or self-tapping screws (Cat. No. 2319). The most proximal hole accepts the Magna-Fx Cannulated Screw (Cat. No. 1146 series), a 4.5 mm cortical screw, or a 6.5 mm cancellous screw. Each plate has a distal compression hole for the ECT compression device (Cat. Nos. 2365-10 or 2366-13). (Self-Compression Plate [SCP] holes are used on all standard and short barreled tube/plates.)

Supracondylar

Tube/plates with angles of 90° and 95° are used in supracondylar applications. A surgeon may also elect to use the 150° tube/plate when conditions warrant (see INDICATIONS AND USAGE). The 90° and 95° tube/plates are available with 6, 9, or 12 cortical screw holes; two cancellous screw holes are found in all supracondylar compression tube/plates. The 2332 and 2333 cancellous screws are recommended for supracondylar applications.

Lag Screws

Free-Lock compression lag screws (Cat. No. 1181 series) are self-impacting and cannulated to accommodate 3.2 mm guide wires. The screw threads are gently tapered for easy insertion and removal. Lag screws range in length from 55 to 150 mm; lag screw diameter is 12.7 mm and 15.8 mm; the shaft diameter is 8.7 mm; and thread lengths are 25.4 mm or 17.2 mm. A complete line of instrumentation to facilitate implantation and removal is available.

Material:

Tube/plate: 22-13-5 stainless steel
Provisionals: 22-13-5 stainless steel

INDICATIONS AND USAGE

Hip

The Versa-Fx Femoral Fixation System may be used for internal fixation of hip fractures, with application to intracapsular and intertrochanteric fractures, osteotomies, and arthrodeses.

Supracondylar

The Versa-Fx Femoral Fixation System may be used for the internal fixation of supracondylar fractures with displaced intra-articular fragments, with vertical intra-articular extension, and in the patient with multiple lower extremity fractures.

The reverse 150° tube/plate is indicated in both intra-articular and extra-articular supracondylar femur fractures.

WARNINGS

Note: The compression tube/plate component of the Versa-Fx System was not designed to be mated with corresponding components from the Key-Free Compression Hip Fixation System. Also, since close tolerances are important for proper functionality of this device, the tube/plate component may not be compatible with corresponding or allegedly interchangeable variations of lag screw components made by other manufacturers. Combining tube/plates from the Versa-Fx System with lag screws from other systems may lead to device failure or surgical complications.

(Note: Free-Lock Lag Screws [Cat. No. 1181 series] are used with this system.)

Preoperative procedures, knowledge of applicable surgical techniques, good reduction, proper selection, and correct placement of the implant are equally important for the successful use of all temporary internal fixation devices.

To prevent damaging the lag screw during insertion, the appropriate lag screw inserter (Cat. No. 1199-01) must be used. A damaged lag screw may no longer slide freely in the tube/plate. Misalignment of the lag screw and inserter can cause damage to the lag screw making subsequent placement of the tube/plate difficult or impossible.

Neither the lag screw threads nor the tube/plate barrel should bridge a fracture line. If either occurs, compression of the fracture fragments will be compromised.

When this device is used in the management of unstable intertrochanteric or subtrochanteric fractures, it is important that no less than six ECT-type bone screws be placed through both cortices of the intact shaft of the femur distal to the fracture site. Use of bone grafts on the medial side opposite the plate may be required for secure fixation of subtrochanteric and supracondylar fractures. Unstable intertrochanteric fractures may need a medial displacement osteotomy in conjunction with fixation by the Versa-Fx Femoral Fixation System. External support should be required and crutches used by the patient as the device is not intended to withstand full weight bearing.

The patient treated with this device must have careful postoperative supervision until firm bone union is achieved, including detailed written instructions on the use and limitations of this device. If protected or partial weight bearing is recommended or required prior to firm union, the patient must be warned that breakage or bending of the device are complications which could occur as a result of weight bearing or muscular activity. These complications may necessitate surgical revision. An active patient or a debilitated patient who cannot properly utilize supportive devices (such as crutches) must be particularly warned about these dangers.

Internal fixation devices are designed to stabilize the fracture site during the normal healing process. After healing occurs, these devices serve no functional purpose and therefore should be removed. In most cases, removal is indicated because these implants are not intended to transfer or support forces developed during normal activities. If the device is not removed, any of the following complications may occur: corrosion, with localized tissue reaction or pain; migration, resulting in injury to soft tissue, visceral organs, or joints; risk of additional injury from postoperative trauma; breakage, which could make removal impractical or difficult; pain, discomfort, or abnormal sensations which may occur due to presence of the device; possible increased risk of infection; and bone loss due to stress shielding.

The physician must advise patient of these considerations and of the potential of subsequent surgical intervention.

Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure. Implant removal must be followed by adequate postoperative management to avoid refracture.
PRECAUTIONS

If metal screws, wire, bands, or other metallic devices are to be used together with the temporary internal device selected for this treatment, all such devices must be manufactured from a stainless steel alloy that will not cause galvanic corrosion or other metallic reaction. Laboratory tests have shown that screw fabricated from Zimmer Certified Stainless Steel can be used with the Versa-Fx Compression Tube/Plate.

A temporary internal fixation device must never be reused.

Because of the increased strength of 22-13-5 stainless steel, an Anvil Assembly (Cat. No. 1180-95) and an Anvil Base (Cat. No. 1180-96) must be used with an ECT Bending Press (Cat. No. 2371-30) to contour Versa-Fx tube/plates. Such contouring must be gradual. Under no circumstances should the tube/plate be sharply bent, reverse bent, bent at a screw hole, notched, or scratched because such treatment can critically weaken the device.

ADVERSE EFFECTS

Loosening, breakage, or bending of the device can occur. Loss of fixation, malunion, nonunion, and infection have been reported with use of sliding compression screw-plate combinations. Screw cut-out through the femoral head can occur, although this adverse effect is usually associated with osteoporotic bone.

Cancer, allergic reactions, metallosis, osteolysis, and other adverse tissue responses can be caused by the utilization of orthopaedic implants and prostheses. There are a variety of metals, polymers, chemicals, and other materials utilized with orthopaedic implants which have been known to cause cancer and other adverse bodily tissue reactions. Cancer can metastasize from the soft tissue sites (lung, breast, digestive system, and others) to bone, including areas adjacent to implants, or it can be seeded to these locations during operative and diagnostic procedures (such as biopsies). Paget’s disease has been reported to progress to cancer; patients suffering from this disease who are candidates for implantation procedures in the affected areas should be warned accordingly.

In addition, any factor that causes chronic damage to tissues may be oncogenic. These risks and possible complications must be discussed with and explained to the patient in addition to the obvious risk that all orthopaedic implants may fail.

STERILITY

The tube/plates are provided sterile by prior exposure to a minimum of 2.5 Mrad gamma irradiation. Opened but unused fixation components can be resterilized using accepted procedures for steam autoclaving or ethylene oxide. No aeration is needed for solid metal items.

Custom products of the type may be provided nonsterile. They can be sterilized using either of the above methods.