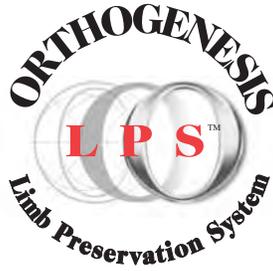


SURGICAL TECHNIQUES



Significant bone loss requiring extensive reconstruction around the hip and knee is often required following the treatment of malignant bone tumors, aggressive benign bone tumors, infection, multiple revised and failed joint replacements and massive trauma, particularly in the elderly osteoporotic patient. Limb-sparing techniques, using modular segmental endoprostheses, provide a reliable, functional reconstruction for these patients.

Due to unpredictable and difficult conditions encountered with the remaining bone, muscle and soft tissues, the prosthetic construct must perform under severe conditions. The Orthogenesis™ Limb Preservation System (LPS) is designed with these considerations in mind to allow for versatility and predictability in these difficult reconstructions.

Other limb-sparing techniques include allograft-prosthetic composites, osteoarticular allografts, intercalary allograft, resection arthrodeses, rotationplasties or resection arthroplasties. Each technique has its specific indications, advantages and disadvantages, and must be chosen based on the individual patient's functional and psychological needs and the surgeon's prior experience and training.

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INDICATIONS

The Orthogenesis Limb Preservation System is a modular implant system with a wide choice of components that can be utilized to address severe lower extremity bone loss secondary to neoplasms, infections, massive trauma or failed joint replacements.

This system is designed to offer:

- Proximal femoral replacement
- Total femur replacement
- Distal femoral replacement
- Proximal tibial replacement
- Mid-shaft femoral (intercalary) replacement

CONTRAINDICATIONS

Active sepsis is a contraindication. Treated infection, particularly as a part of a two-stage exchange protocol, with or without an interim spacer, is not a contraindication. Relative contraindications include skeletal immaturity and metabolic disorders, which may impair bone formation, distant foci of infections, which may spread to the implant site, and severe soft tissue loss resulting in poor joint mobilization.

Preoperative Planning

Reconstruction of the proximal femur due to significant bone loss can be effectively performed utilizing the Orthogenesis LPS. The following technique reviews the intended design and use of the instruments and implants for this procedure and provides a general framework. Surgeons should utilize techniques that best meet the individual needs of each patient. Consider the following recommendations for a successful outcome:

- Perform preoperative planning and radiographic analysis for every case. Use the Orthogenesis LPS templates in preoperative planning to assess the approximate resection level; position the proximal femoral body replacement and segmental component(s) (if needed) to restore leg length and offset; and determine the femoral stem extension diameter and length that could be used to provide adequate fixation and stability in the remaining host femoral diaphyseal bone. Although leg length restoration is ideal, in cases where soft-tissues are resected for oncologic purposes, extremity shortening may be necessary to allow for soft tissue closure around the prosthesis.



- Evaluate the acetabulum to decide if acetabular reconstruction should be made based on the disease process, the degree of bone loss and the necessity of either an intra- or extra-articular resection margin in oncological resections.

Exposure and Intraoperative Planning

Perform the surgical approach so that every attempt is made to preserve as much of the abductor mechanism and iliotibial band as possible while achieving a wide resection of the tumor and the biopsy tract in oncology cases. Secure closure of these structures at the end of the procedure is necessary to provide stability and improve function. First complete acetabular preparation when required, followed by femoral preparation.

There are many methods to determine resection length measurements. The following is one such method. Mark points of reference and measure between the pelvis and an area distal to the appropriate resection level as determined in preoperative planning. After proximal femur

and acetabulum exposure, mark a horizontal line on the femur 1 cm below the proposed resection level to allow for any slight cut obliquity, blade thickness and subsequent femoral resection planing. Make all marks using an osteotome, electrocautery, marking pen or methylene blue.

Rotational alignment is critical to restoring proper anteversion and maintaining hip joint stability. It can be determined using several methods.

Mark the anterior femoral cortex with a vertical line at a site distal to the resection line and perpendicular to the horizontal line previously created. The linea aspera on the femur’s posterior aspect can act as a guide to the rotational orientation of the femur.

An option is to place a Steinmann pin in the ilium, superior to the acetabular midline. Measure the distance between the Steinmann pin and the horizontal line on the femur with the leg in a neutral position with no flexion and record it prior to any bone resection (Fig. 1.1).

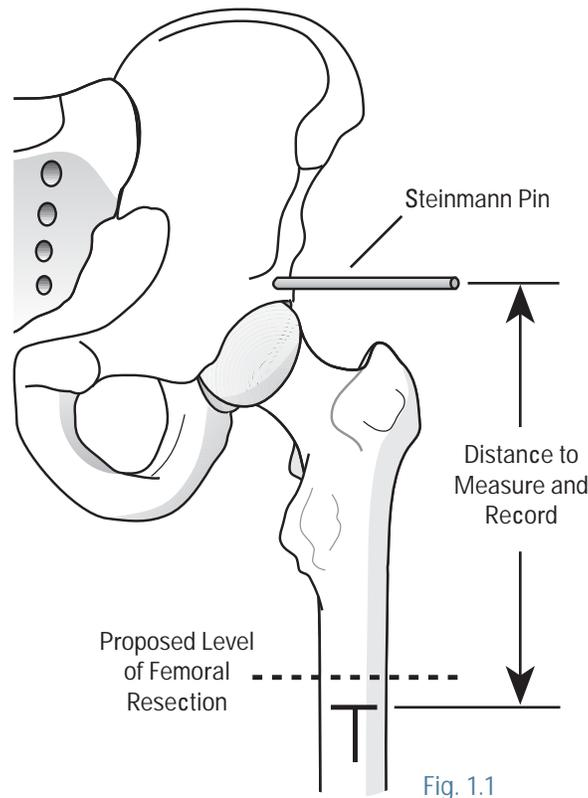


Fig. 1.1

Another method at the beginning of the procedure involves performing a secondary leg length check to verify the medial malleoli position of the operative and non-operative legs and to ensure the same relationship following trial implant insertion. The resection level should be at a level where healthy native diaphyseal bone is available for stem insertion. If performing the reconstruction for primary bone sarcoma, review the preoperative imaging studies, such as plain radiographs, CT scans and MRI of the femur to determine a safe resection level.

The minimum proximal femoral resection level is 90 mm from the center of the femoral head, using the +1.5 mm femoral head. This minimum resection level includes the 70 mm proximal femoral replacement body length plus the 20 mm stem component collar height (Fig. 1.2a). If additional replacement length is needed, the 25 mm segmental component is the shortest segment available, making 115 mm the next resection level (Fig. 1.2b).

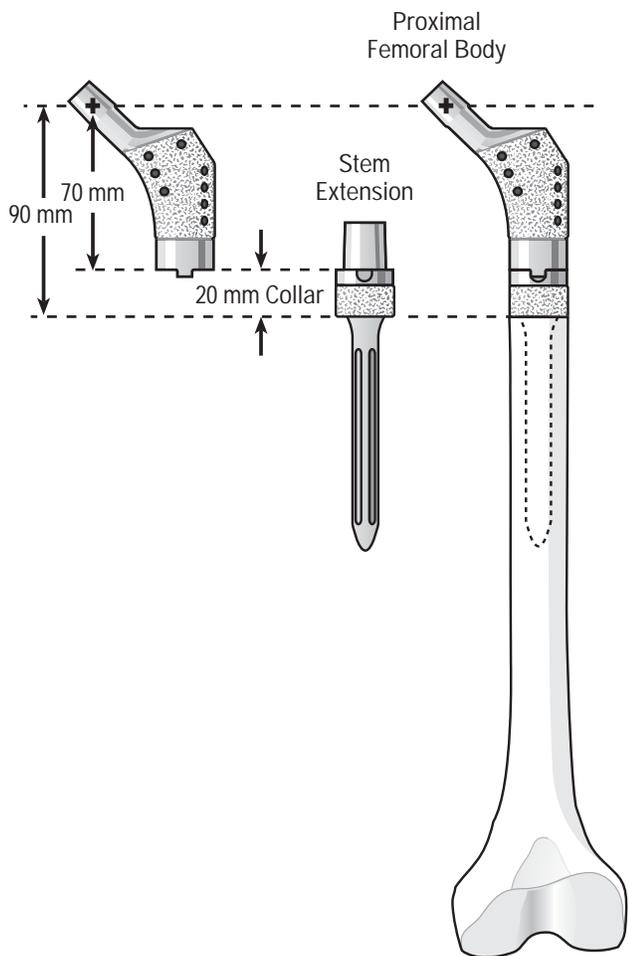


Fig. 1.2a

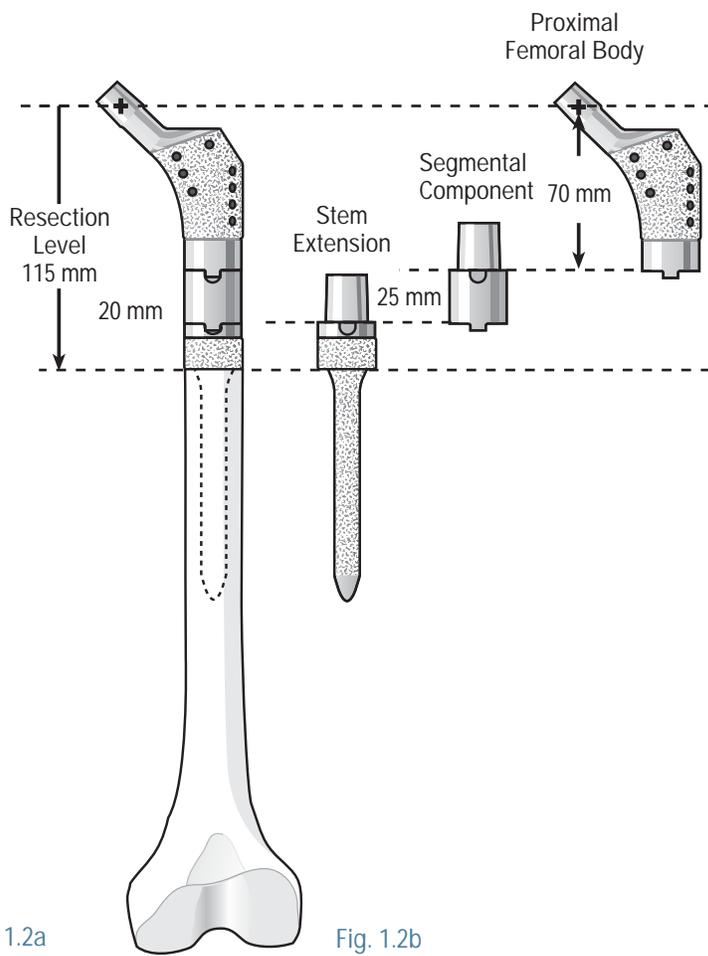


Fig. 1.2b

Segmental components are then available in 5 mm increments alone or in combination with other segmental components to adjust leg length (Fig. 1.2c). The illustration and chart to the right demonstrate the segmental component lengths available, along with the combination capabilities to replace missing gaps in 5 mm increments.

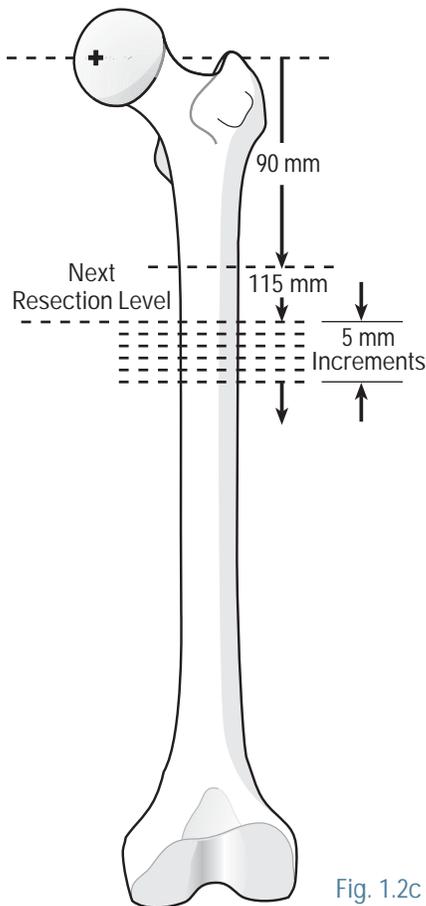
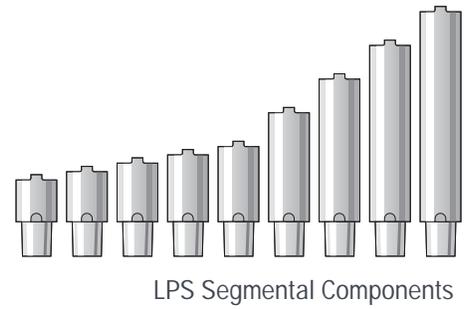


Fig. 1.2c

SEGMENTAL STACK CHART

Remaining Gap	LPS Segmental Components
25	25
30	30
35	35
40	40
45	45
50	25 + 25
55	25 + 30
60	25 + 35
65	65
70	25 + 45 or 30 + 40
75	30 + 45 or 35 + 40
80	35 + 45
85	85
90	25 + 65
95	30 + 65
100	35 + 65
105	105
110	25 + 85 or 45 + 65
115	30 + 85
120	35 + 85
125	125
130	25 + 105 or 45 + 85
135	30 + 105
140	35 + 105
145	40 + 105
150	25 + 125 or 45 + 105
155	30 + 125
160	35 + 125
165	40 + 125
170	45 + 125
175	125 + 25 + 25
180	125 + 25 + 30
190	125 + 65
195	125 + 25 + 45
200	125 + 35 + 40
205	125 + 35 + 45
210	125 + 85
215	125 + 25 + 65
220	125 + 30 + 65
225	125 + 35 + 65
230	125 + 105
235	125 + 25 + 85
240	125 + 30 + 85
245	125 + 35 + 85
250	125 + 40 + 85

Femoral Resection

Resect to healthy femoral diaphyseal bone and remove the entire proximal femur, particularly in oncology cases, so it can be measured and used later as a reference for building the trial construct (Fig. 1.3).

Femoral Medullary Canal Preparation

Following femoral resection, prepare the remaining femoral canal for the appropriate stem extension. A flexible intramedullary (IM) reamer is recommended for the bowed stem extension and a straight IM reamer is recommended for the straight stem extension.

Cemented Stem Application Options

If using a cemented stem, choose a smaller final stem than the last IM reamer used to allow for a circumferential cement mantle around the stem. For example, if a 15 mm IM reamer was the final reamer used, an 11 mm stem would provide a 2 mm cement mantle per side. Using a 12 mm stem would allow for a 1.5 mm cement mantle per side while a 13 mm stem would have a 1 mm cement mantle per side.

Do not ream the femoral canal to cortical bone for a cemented application. Leave some cancellous bone for cement interdigitation.

Porous Stem Application Options

When using a porous stem, the reaming technique utilized will depend on a number of factors such as the patient age, bone quality, curvature of the remaining femur, etc. The following are general guidelines, as the surgeon will need to choose the technique based on individual patient needs.

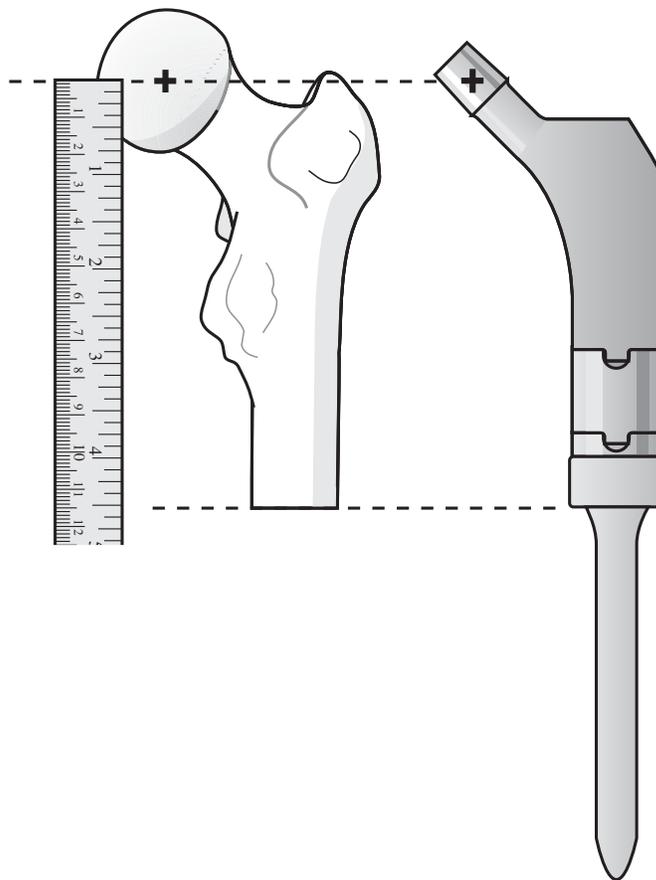


Fig. 1.3

It is recommended that a ring gauge be available. Measurement over the stem porous coating and measurement of the final selected reamer will provide the surgeon with insights based on the actual dimensions of the implant and reamer.

When using a straight porous stem, under ream by .5 mm for press-fit application using a straight reamer. If the remaining bone is fragile, consider line-to-line reaming.

When using a bowed porous stem, under reaming by .5 mm with a flexible reamer for press fit application is a technique that can be considered. Line-to-line reaming may be indicated, if needed, to allow the implant to pass through the remaining femur’s curvature or if the remaining bone is fragile (see [Implant Insertion section on pages 12-14 for additional insight](#)).

The Orthogenesis LPS stem extensions are available in 100 and 125 mm straight or 150 and 200 mm bowed lengths in cemented and porous-coated designs (see [chart at right](#)).

STEM EXTENSIONS

CEMENTED STEMS (STRAIGHT)

Description
10 mm diameter x 100 mm length
11 mm diameter x 100 mm length
12 mm diameter x 100 mm length
12 mm diameter x 125 mm length
13 mm diameter x 125 mm length
14 mm diameter x 125 mm length
15 mm diameter x 125 mm length
16 mm diameter x 125 mm length
17 mm diameter x 125 mm length

POROUS STEMS (STRAIGHT)

Description
11.5 mm diameter x 100 mm length
12.5 mm diameter x 100 mm length
13.5 mm diameter x 100 mm length
13.5 mm diameter x 125 mm length
14.5 mm diameter x 125 mm length
15.5 mm diameter x 125 mm length
16.5 mm diameter x 125 mm length
17.5 mm diameter x 125 mm length
18.5 mm diameter x 125 mm length

CEMENTED STEMS (BOWED)

Description
11 mm diameter x 150 mm length
12 mm diameter x 150 mm length
13 mm diameter x 150 mm length
14 mm diameter x 150 mm length
15 mm diameter x 150 mm length
16 mm diameter x 150 mm length
17 mm diameter x 150 mm length
11 mm diameter x 200 mm length
13 mm diameter x 200 mm length
15 mm diameter x 200 mm length
17 mm diameter x 200 mm length

POROUS STEMS (BOWED)

Description
12.5 mm diameter x 150 mm length
13.5 mm diameter x 150 mm length
14.5 mm diameter x 150 mm length
15.5 mm diameter x 150 mm length
16.5 mm diameter x 150 mm length
17.5 mm diameter x 150 mm length
18.5 mm diameter x 150 mm length
12.5 mm diameter x 200 mm length
14.5 mm diameter x 200 mm length
16.5 mm diameter x 200 mm length
18.5 mm diameter x 200 mm length

NOTE: Reference the LPS Design Guide, Cat. No. 0612-35-050, for complete ordering information.

Finish Preparation Using the Calcar Planer/Bevel Reamer

Once intramedullary reaming is completed, prepare the osteotomy surface to help assure the stem extension’s proper fit. The calcar planer/bevel reamer produces an even, perpendicular surface and is designed to cut an angled relief (bevel) in the bone to match the stem extension flare under the collar. This helps to ensure complete femoral stem extension seating on the prepared diaphyseal bone surface (Fig. 1.4).

Use the calcar planar and insert a bevel reamer with a pilot that is at least 1 mm smaller than the last IM reamer used and position it in the femoral canal. Use the appropriate adapter to attach the assembled planer and bevel reamer with pilot to a power drill reamer. The calcar planer/bevel reamer should be under power prior to planing the resection cut. This will minimize any resected bone chipping caused by the calcar planer cutting blades.

Sequential use of the bevel reamer with pilot will prepare the bevel in the remaining bone with more efficiency and precision. The following are recommendations for calcar planer/bevel reamer use with porous or cemented stems:

- For a **porous stem extension**, begin reaming with a calcar planer/bevel reamer with a pilot that is at least 1 mm less than the final IM reamer used and finish with a final bevel reamer that matches the final stem extension size. For example, if a 15.5 mm stem is the chosen implant, the final bevel reamer with a pilot will be the 15.5 mm. Note that the pilot is undersized by .5 mm from the stated size. For example a 15.5 mm pilot is 15 mm in diameter. This makes allowances for an under ream technique. If a 15 mm IM reamer was last used, the final bevel reamer with a pilot will still be 15.5 mm to match the implant.

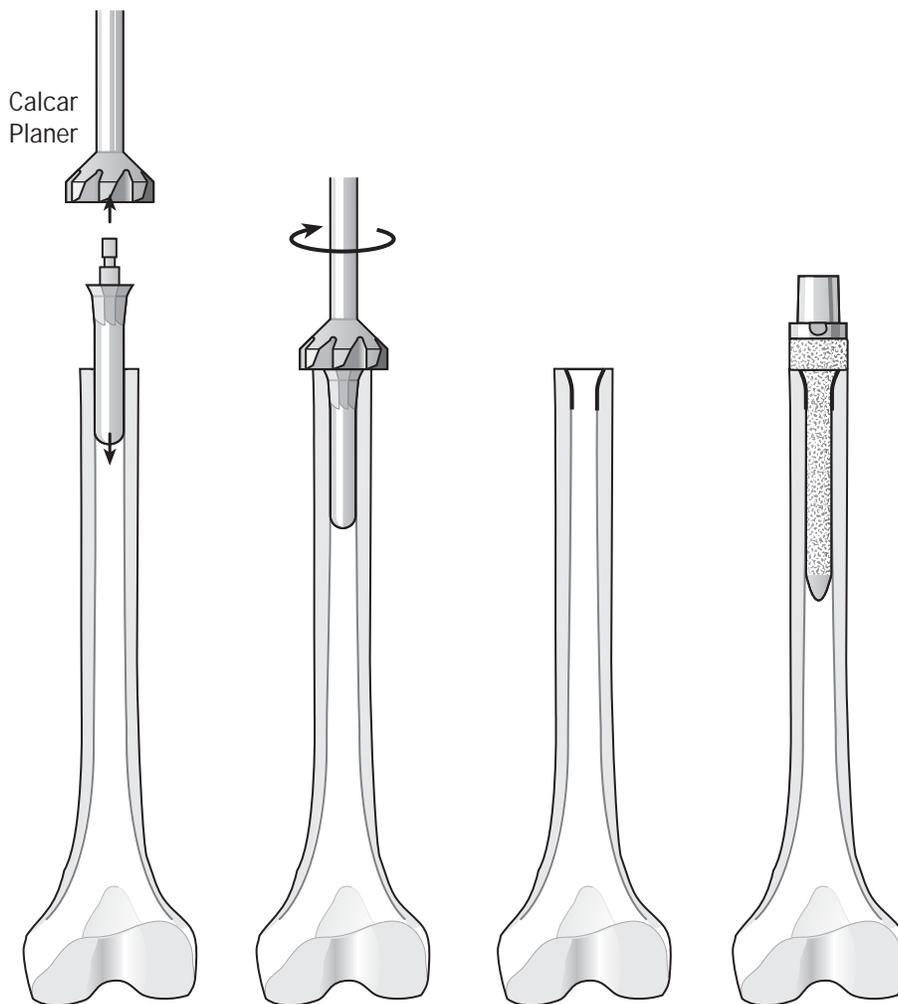


Fig. 1.4

- For a **cemented stem extension**, begin reaming with a calcar planer/bevel reamer with a pilot that is at least 1 mm less than the final IM reamer used and finish with a final bevel reamer pilot that matches the final IM reamer size used. For example, if the last IM reamer used was 15 mm, the 15 mm bevel reamer pilot will be the final bevel reamer used, irrespective of the stem size chosen, to allow for an adequate cement mantle.

Trial Reduction

Following femoral preparation for the stem extension, perform a trial reduction. Assemble the appropriate proximal femoral body, segmental component(s) (if needed) and distal stem trial that would fill the missing bone gap based on previous measurements. If the proximal femur is available in one piece, overlay the trial construct to assess the exactness of replacement.

These measurement methods, as previously discussed, provide a multitude of cross checks when evaluating the amount of bone to be replaced. The trial components are designed to snap together and match the implant component dimensions (Fig. 1.5a). The trial stem should closely match the last IM reamer or can be 1–2 mm smaller depending on the fit.

Utilize the stem trial size to provide enough stability to prevent “spinning” when performing a trial reduction. **Insert all trial constructs by hand and never impact them into the canal.** The 150 and 200 mm trial stems are bowed and need to be inserted in proper orientation to match the femur’s anterior bow. Insert the trial construct into the remaining proximal femur and use it to assess fit, leg length, offset, joint stability, soft tissue tension and range of motion (Fig. 1.5b).

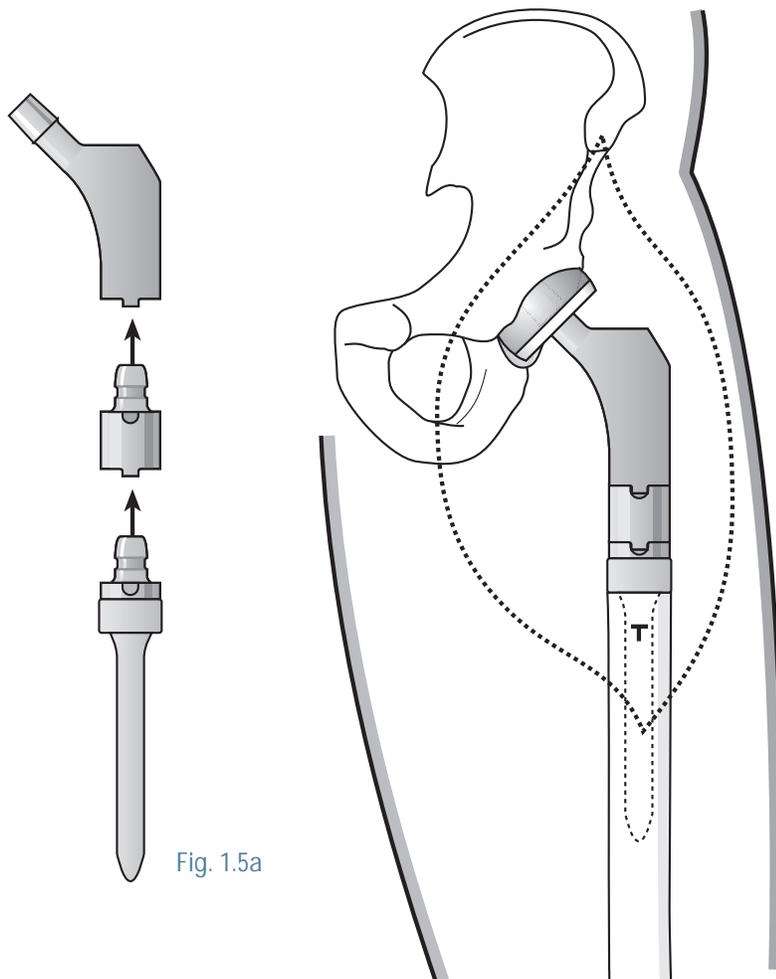


Fig. 1.5a

Fig. 1.5b

If the soft tissues are tight, the leg length is slightly long and the implant's offset is excessive, evaluate the use of a shorter trial femoral head. If the soft tissues are tight and the leg length is long, but the femoral offset is acceptable, try reducing the vertical height/leg length by adjusting the segmental trials.

If the segmental trials used are at the minimum length of 25 mm and the leg length is long, consider recutting the femoral osteotomy to adjust for the leg length discrepancy. If the femoral cut is revised, re-ream the femur distally and finish the osteotomized surface with the calcar planer/bevel reamer. If this is not done, the stem's distal end may encounter unreamed bone and an intraoperative fracture may occur. If the soft tissues are loose and the femoral offset is inadequate, try a longer femoral head.

Be aware that the ability to judge soft tissue tension is compromised when the abductor musculature attachment has not yet been reconstructed. One test for excessive soft tissue tension is to extend the hip and try flexing the knee. If the hip flexes when the knee flexes, the soft tissue tension may be excessive.

At this point, another way to intraoperatively check leg length measurement is to compare the medial malleoli. Use the trial construct to assess proper femoral anteversion. This is not difficult if a straight stem is used. In this case, use the neutral femoral body and rotate the entire construct within the femur to obtain the required femoral anteversion (usually 10 – 15 degrees).

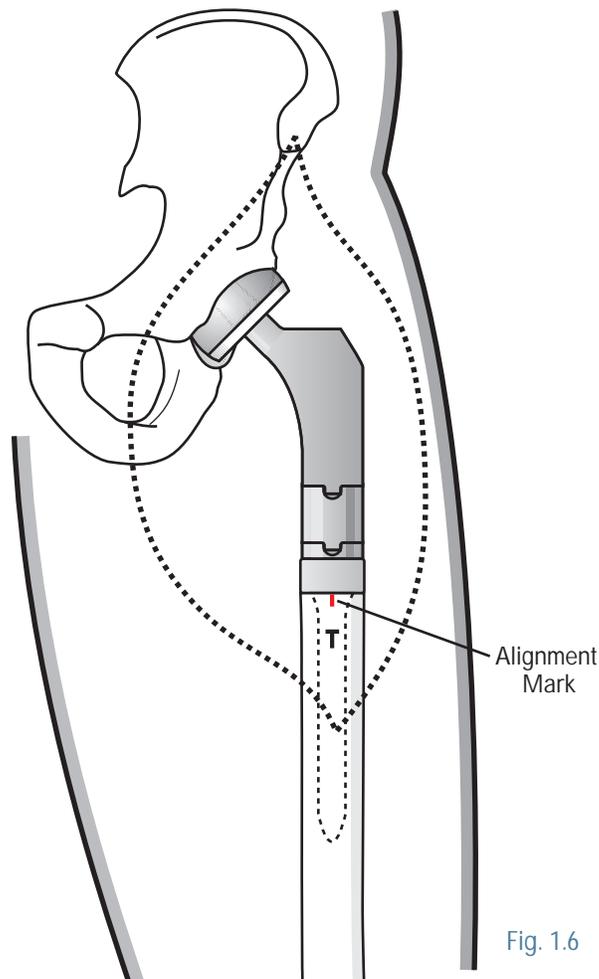


Fig. 1.6

Once proper anteversion orientation is established, use the anti-rotation slot (tab) on the trial as a reference to mark the femur (Fig. 1.6). This final mark will serve as an alignment guide when inserting the implant.

If a bowed stem is used, the surgeon has much less control over the stem's rotation within the femur. This situation is where the anteverted 15-degree proximal femoral body should be considered.

Implant Assembly

Once the trial segments have yielded a satisfactory result with the trial reduction, assemble the appropriate implant components using the implant impaction stand. This helps to stabilize the implant components for assembly and impaction.

It is important to orient the implant components along the same axis as the trial components, particularly when using a bowed stem. The implant components use a Morse-taper design for locking. Assemble the components by hand and place the impaction cap over the stem component. Then impact them together using a mallet to securely seat the tapers together (Fig. 1.7). There should be approximately a 1 mm gap between component bodies.

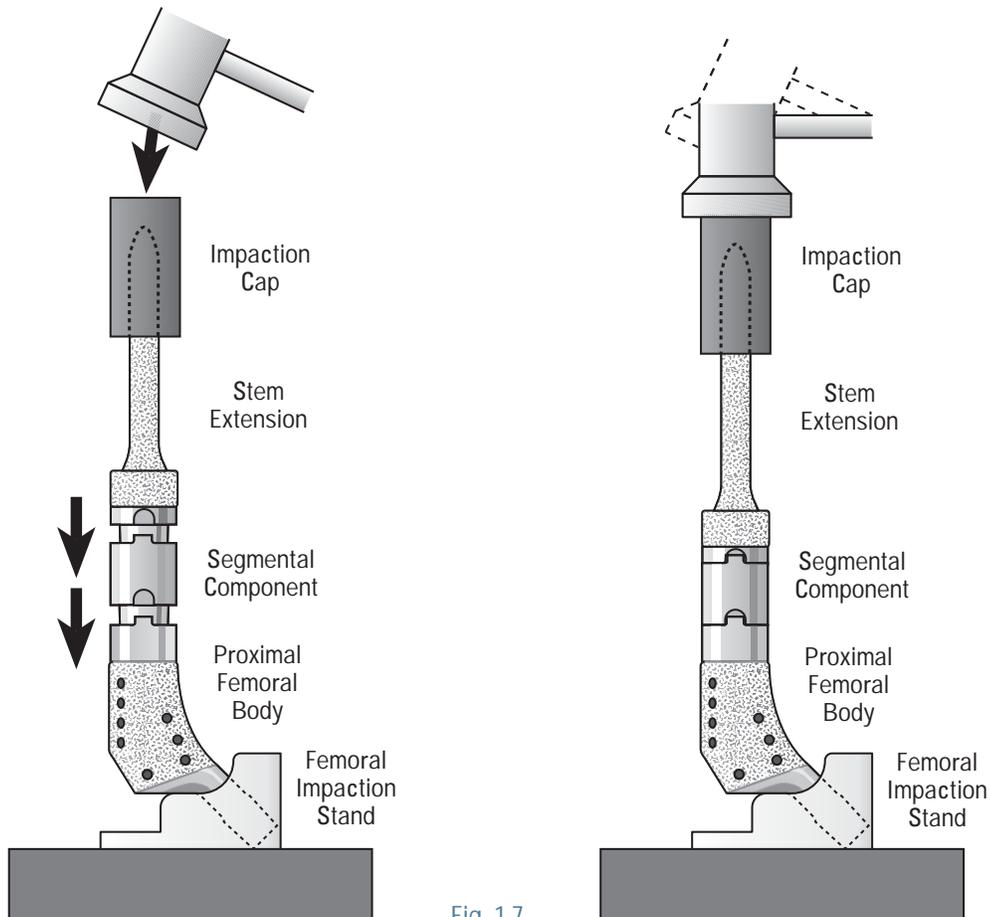


Fig. 1.7

Implant Insertion

If using SmartSet™ MV bone cement to fix the distal femoral stem extension to host bone, follow the manufacturer’s recommended procedures to mix, deliver and pressurize the bone cement.

Use the Orthogenesis LPS inserter/extractor with the version guide and with the implant construct to assist in the insertion of the implant into the femoral canal. Thread the inserter into the proximal femoral body and place the version guide around the neck of the implant (Fig. 1.8). Make certain that the inserter threads are completely seated and that no threads are showing.

To determine the implant’s proper orientation, use the alignment mark previously placed on the femur and the implant’s anti-rotation slot (tab) (Fig. 1.9). Note that the 150 and 200 mm stems are bowed and the correct bow-to-femur orientation must be accomplished.

If cement is used, remove any excess cement from around the implant collar during insertion and after final seating.

The stem extension shoulder should be flush to the femur’s cut surface (Fig 1.10). Give meticulous attention to the stem position. Failure to align the stem in proper version may result in instability.

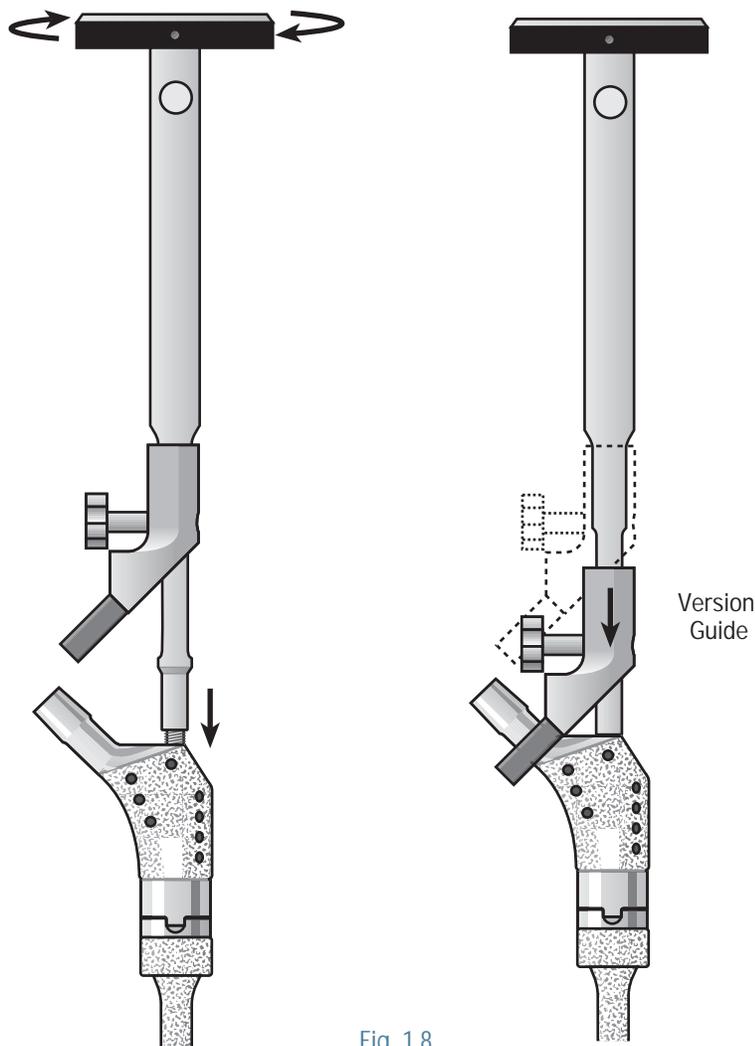


Fig. 1.8

When using a bowed porous stem, curvature of the remaining bone in comparison to the implant needs to be appraised especially for the impact of mismatch conditions. Under reaming by .5 mm with a flexible reamer is a technique that can be considered. Insertional feel and non-advancement with component impaction should be an indication to remove the construct and try to pass the same flexible reamer another four to six times and evaluate the insertional feel again. If the construct still presents with non-advancement, line-to-line reaming should be considered. The construct should then be inserted into the medullary canal and attention to insertional feel and advancement assessed again.

Placement of a “prophylactic” cerclage wire around the proximal end of the remaining diaphysis may decrease the risk of intraoperative fracture during press-fit insertion of porous stem extension particularly with fragile bone.

Should the implant construct with a porous stem not advance and become lodged in the femoral canal, there

are two methods for removal. First, try to remove the implant by using the mallet to strike the platform of the inserter to extract the construct. If this fails, disassemble the implant construct from the stem extension using the disassembly tool (see [disassembly technique on page 56 – 57](#)). The exposed porous stem extension taper is threaded. Remove the version guide from the inserter/extractor. Place the slap handle through the inserter/extractor. Completely thread the inserter/extractor into the porous stem thread. Use the slap handle to provide the extraction force to the lodged porous stem extension until it is removed from the femoral canal. An LPS extension adapter (Cat. No. 2987-72-045) is also available for use with the slap hammer and rod from the Moreland Hip Revision Instrument Set (Cat. No. 2420-30-000) when additional force is required. Evaluate the need to re-ream the canal. Reassemble the components making sure the tapers are clean and dry before assembly. Reinsert the implant construct.

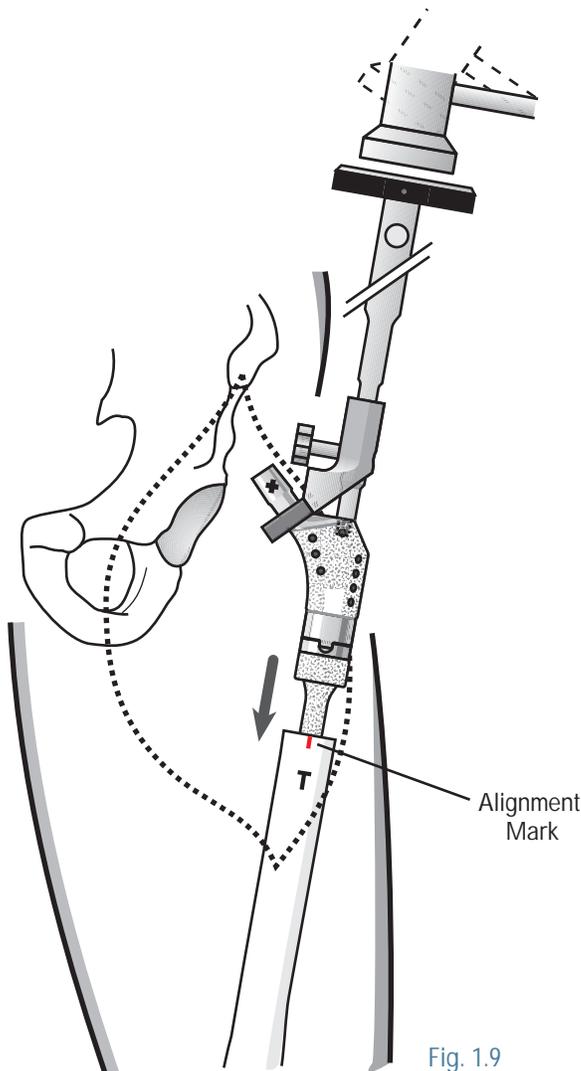


Fig. 1.9

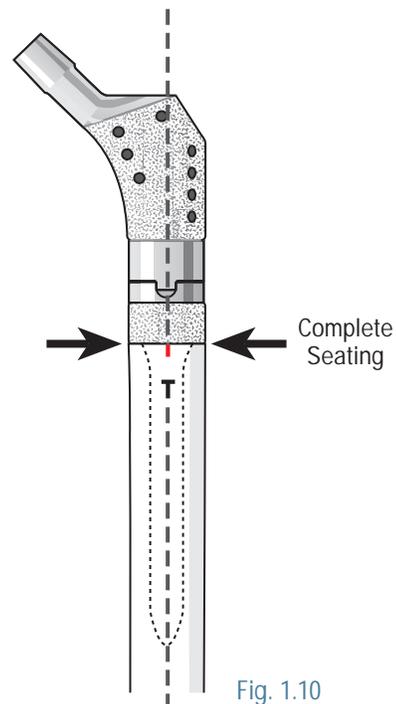


Fig. 1.10

Perform a final trial reduction with the implant to fine tune soft tissue balancing. Make alterations using either longer or shorter trial femoral heads as needed. Check leg length restoration against the initial recorded measurement (Fig. 1.11).

Closure

Soft tissue reconstruction is one of the most important aspects of this procedure. Restoration of the abductor musculature attachment is important for postoperative hip stability and gait. The proximal femoral replacement segment holes allow for soft tissue reattachment using sutures or Mersilene tape (Fig. 1.12), but the long-term stability of soft tissues using this method is uncertain. Another method is to use the suture holes to assist in securing a tenodesis between the abductor tendons and the adjacent iliotibial band.

Use the proximal femoral body replacement component to reattach the greater trochanter, when present (Fig. 1.12). This feature works by utilizing the reattachment holes provided in the proximal femoral body component. Attach the greater trochanter and abductors with either heavy sutures or Mersilene tape.

If the abductors are extensively shortened, use the proximal femoral replacement body with trochanteric build-up for reattachment (Fig. 1.13). Abductor function is significantly enhanced if at the time of initial resection the abductors and vastus lateralis are taken together in one layer and the abductors are not detached. Do this whenever possible from the oncological point of view. This is very similar to the trochanteric slide or vastus slide approaches used in revision total hip arthroplasty.

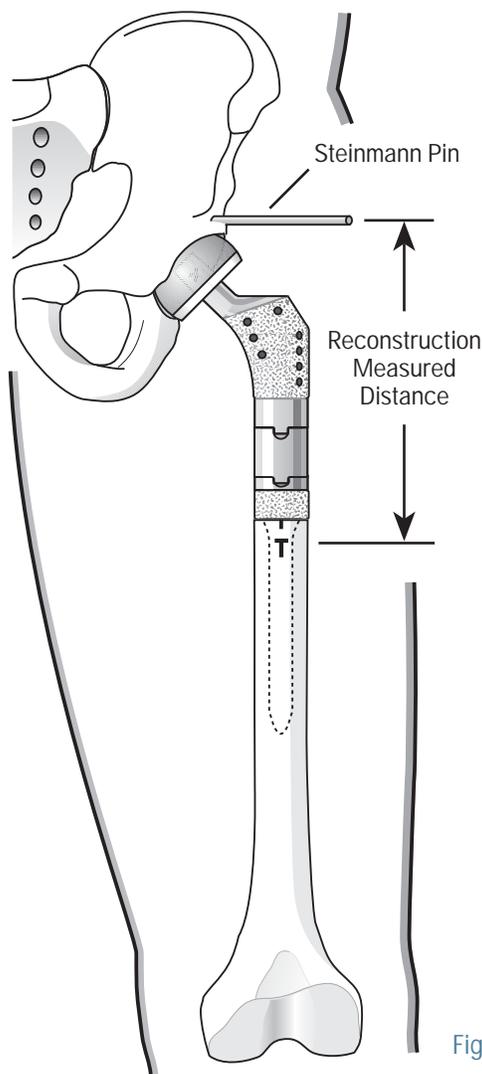


Fig. 1.11

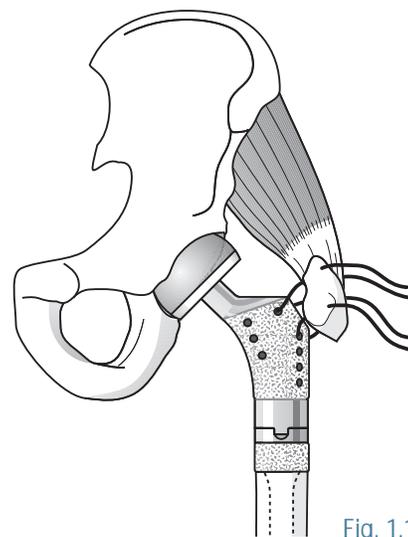


Fig. 1.12

Twist the selected femoral head implant onto the implant neck taper and then impact it with a head impactor and mallet using a sharp blow. Use the acetabular component (i.e., bipolar cup, fixed cup, cage, etc.) based on the specific patient's needs.

Complete the operation with a multi-layer soft tissue closure over drains. Meticulous closure is important to minimize the possibility of postoperative hematoma formation, which is possible with large dissection. Use the standard closure over drains and soft tissue reattachment procedures.

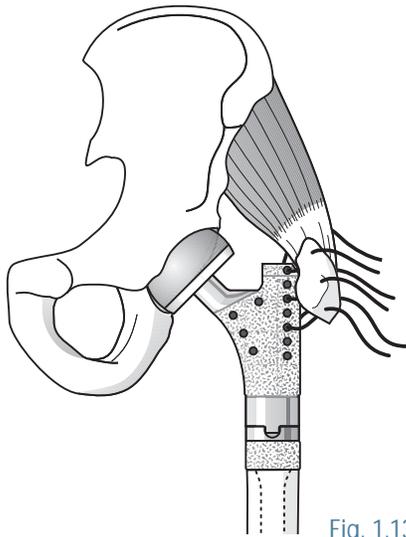


Fig. 1.13

POSTOPERATIVE CARE

Individualize postoperative care, as many of these procedures involve extensive dissections.

The patient's activity and weight-bearing status will depend on the extent of the surgery, the individual patient's needs and the implant's fixation type. The weight-bearing status is generally full weight bearing with cemented stems. With cementless stems, individualize the weight-bearing status based on patient's needs. However, it is suggested for patients not on chemotherapy to adhere to toe-touch weight bearing for at least six weeks. For patients on chemotherapy, 12 weeks is suggested.

Preoperative Planning

The Orthogenesis LPS can be used to replace the entire femur. The following technique reviews the intended design and use of the instruments and implants for this procedure and provides a general framework. Utilize techniques that best meet the needs of each case, since each is unique and has specific challenges. Consider the following recommendations for a successful outcome:

- Using preoperative templating, use the full lower extremity radiographs to help determine the length of femur to be replaced by the prosthesis and **if there are any special needs in reconstructing the acetabulum and proximal tibia.**
- The minimum Orthogenesis LPS total femoral construct when using the X-small LPS distal femoral component is 185 mm, which includes the proximal femoral body (70 mm), total segmental (55 mm) and distal femoral (60 mm) components. The minimum Orthogenesis LPS total femoral construct is 175 mm which includes the proximal femoral body (70 mm), total segmental component (55 mm) and distal femoral (50 mm) component. Use an additional segmental component(s) to replace missing femoral bone (Fig. 2.1).

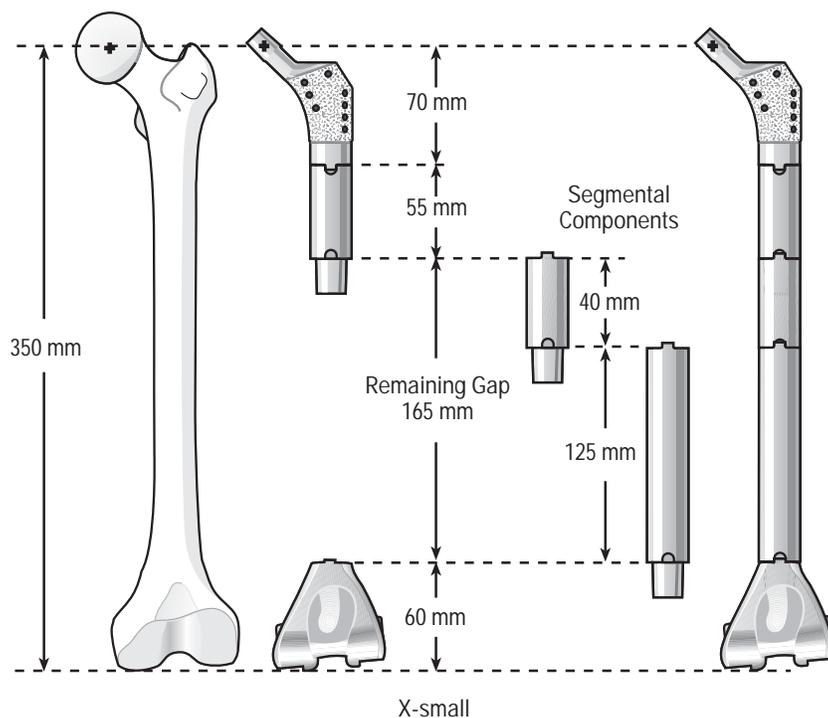


Fig. 2.1

Exposure and Intraoperative Planning

Use the surgical approach based upon the surgeon's preoperative plan and exposure preference. During the reconstruction, take care to avoid stretch injury to the neurovascular structures in this extensive procedure. Perform the acetabular reconstruction as required. A bipolar cup can be considered for stability, particularly for oncologic use.

If using a fixed acetabular component, consider using a large femoral head (36 mm), a constrained liner or a tripolar construct (if available) for stability.

Leg length measurement is very important for a successful surgical outcome. An example of one measurement method utilizes a horizontal line made 1 cm below the proposed tibial resection level using an osteotome, electrocautery, marking pen or methylene blue.

Place a Steinmann pin in the ilium, superior to the acetabulum midline. Extend the limb and measure the distance between the pin and marked horizontal line on the tibia and record the length prior to any resection (Fig. 2.2). It is important to measure the knee in full extension. Avoid measurement with the knee in flexion for consistency of measurement results. Remove the Steinmann pin and mark the hole with a cautery or marker pen so the Steinmann pin location can be found and reinserted later during the trial reduction process.

Excise the femur according to standard oncologic principles for a neoplasm or as dictated by the underlying pathology, such as post infection, end-stage revision arthroplasty, etc.

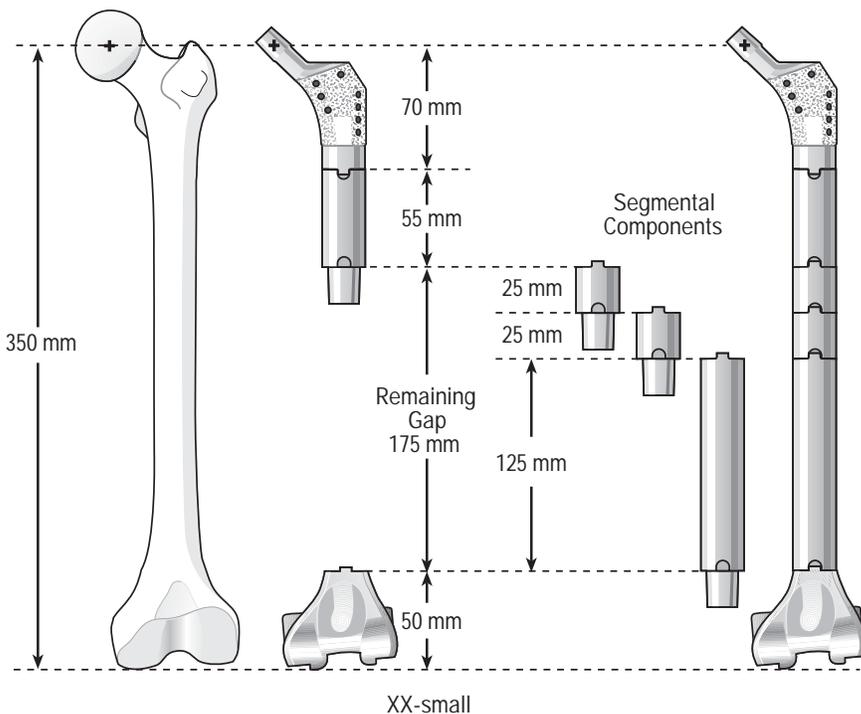


Fig. 2.1 cont.

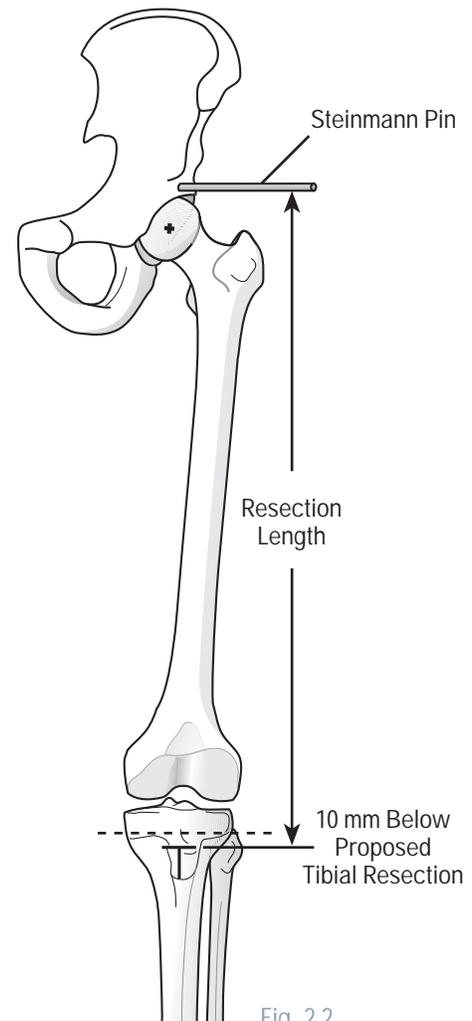


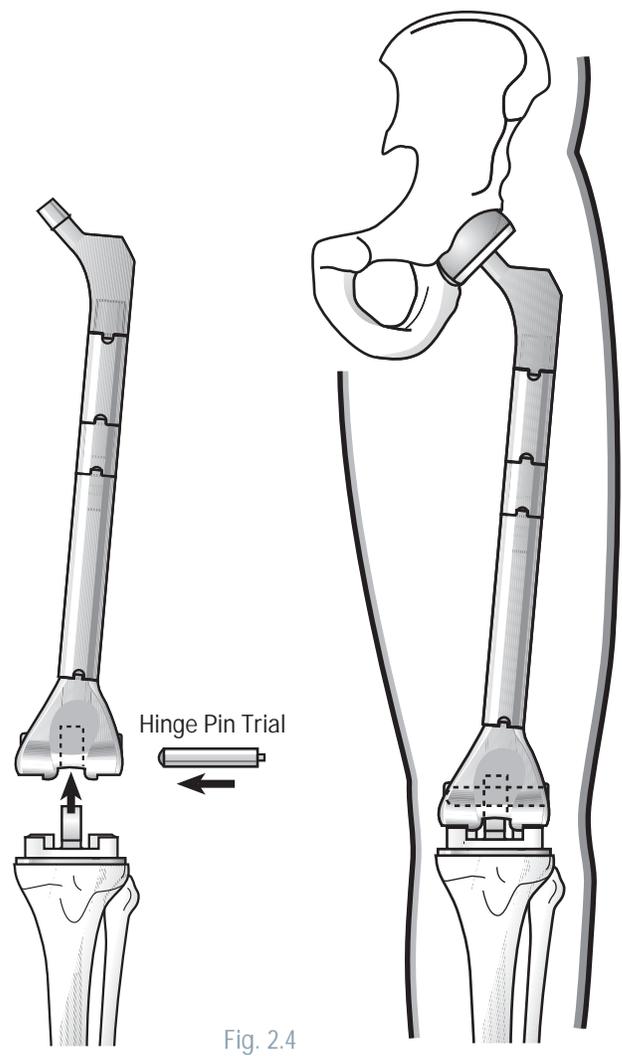
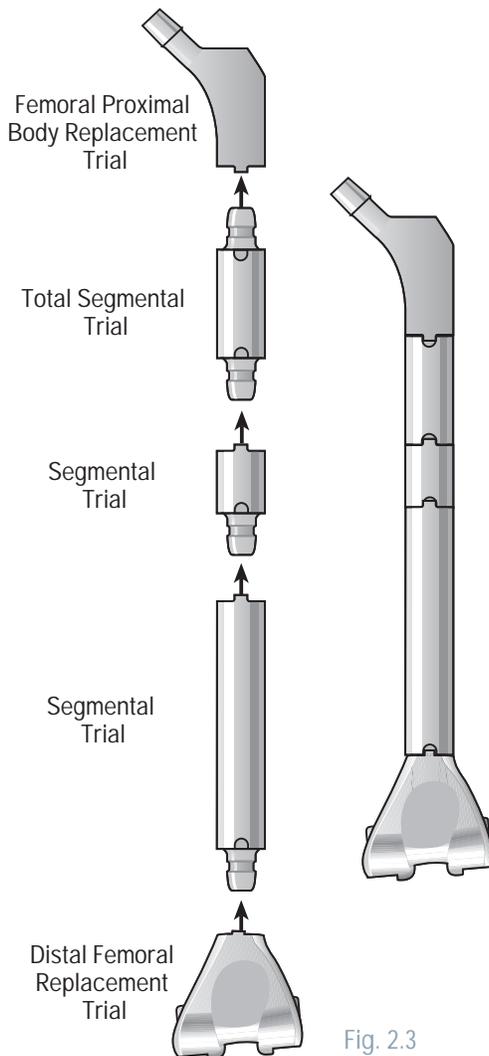
Fig. 2.2

Tibial Preparation

Prepare the proximal tibia. This can be done with intra-medullary or extramedullary instrumentation that is available with the Mobile Bearing Tibial (M.B.T.) revision knee system, S-ROM® knee system or other tibial cutting guides. The remainder of the tibial preparation follows the technique for the M.B.T. Revision Tibial Tray or S-ROM Tibial Tray, depending upon the system being used.

When using the S-ROM tibial tray, only use the S-ROM hinged tibial insert bearing. When using the M.B.T. revision tibial tray, only use the Orthogenesis LPS hinged tibial insert bearing. Use only the LPS extra-small hinged tibial insert bearing sizes to match the Orthogenesis LPS extra-small Distal Femoral Replacement component. It is recommended the extra-extra small tibial insert be used with the extra-extra small LPS Distal Femoral Replacement components.

Resurface the patella using a dome patella replacement, such as the S-ROM or Sigma dome patella component.



Trial Reduction

Assemble the total femur trial components for an initial trial reduction to check for the correct approximation of the femoral replacement. The trial construct consists of a proximal femoral body, total segmental, segmental and distal replacement trial components (Fig. 2.3).

Perform trial reduction after assembling the Orthogenesis LPS trial and tibial trial components (Fig. 2.4). Use the proximal femoral body trial with 15 degree built-in anteversion to evaluate the proper total femoral replacement version.

Insert the Steinmann pin into the previously drilled hole in the ilium. Check the femur's length against the measurement recorded prior to the resection. Make femoral length changes by changing the segmental trial lengths, which offer 5 mm increment capability. Compare the knee joint line to the opposite side for proper height. The joint line is determined by the level of femoral component. Assess proper anteversion (Fig. 2.5), offset and stability.

Make fine adjustments to leg length and femoral offset using the range of different femoral head lengths. Use varying tibial insert polyethylene heights to provide joint stability and to adjust leg length.

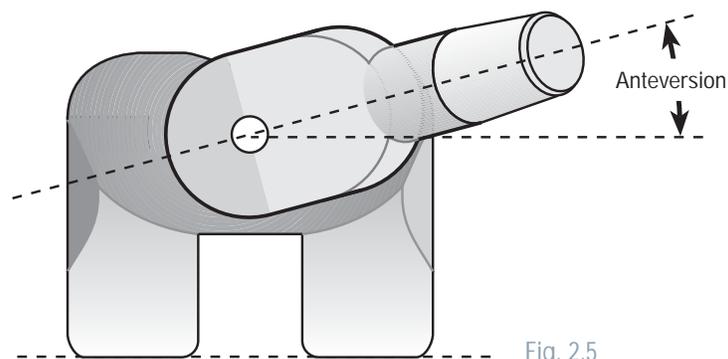


Fig. 2.5

Implant Assembly

After trial reduction, assemble the implants using the implant holder stand on the back table. The implant component alignment should duplicate the trial component's orientation so that femoral anteversion and proper femoral/tibial construct alignment is correct. Place the distal femoral replacement component on the distal femoral impaction stand.

Stack the component tapers to assemble the total femoral and segmental components and the proximal femoral body replacement component. Use the impaction cap to impact down on the proximal femoral replacement body to impact the tapers together (Fig. 2.6). There should be approximately a 1 mm gap between the component bodies.

Implant Insertion

If using SmartSet MV bone cement, mix and deliver according to the manufacturer's recommendation. Impact and hold the tibial tray component until the cement is cured. When using the press-fit stem with the S-ROM tibial tray, it should not be cemented. Only apply cement to the cut tibia surface.

Place the total femur implant construct into the remaining femoral soft tissue envelope. Reduce the Orthogenesis LPS femoral replacement into the chosen acetabular and tibial components. Trial femoral heads and trial tibial inserts can be evaluated to make assessments in choosing final implant sizes.

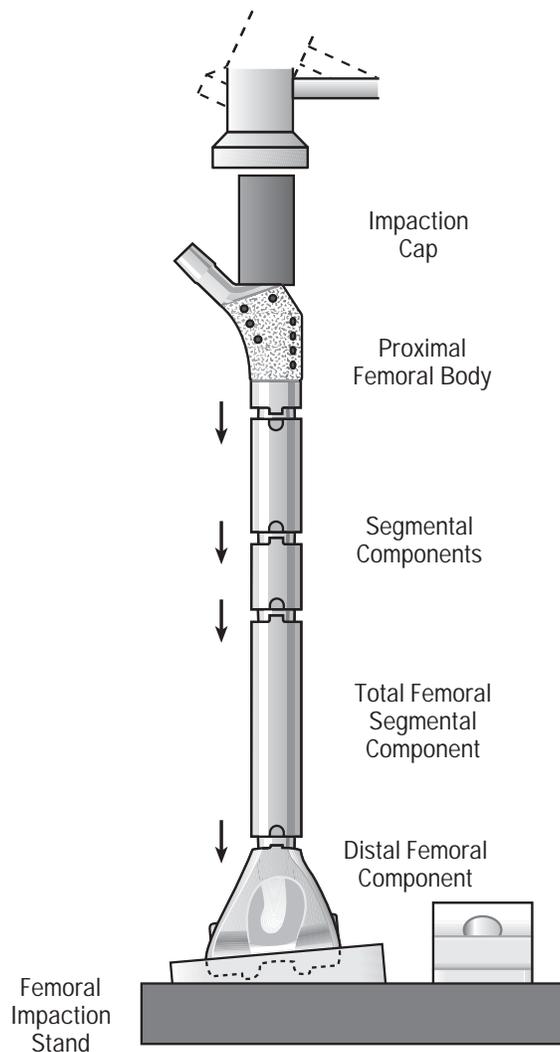


Fig. 2.6

Once the final trial reduction is accomplished, connect the total femur construct to the hinged tibial insert bearing using the locking pin, which is passed through the Orthogenesis LPS distal femoral replacement component and the bushings of the hinged tibial insert bearing (Fig. 2.7).

One method that can be used to secure the locking pin uses manual pressure to push the locking pin through until it “clicks” and locks into place.

Another method uses forceps to squeeze the locking pin while pushing the pin until it is completely seated in the square cut-out in the Orthogenesis LPS distal femoral component. Pressure is released from the forceps. Ensure the pin is securely locked, push the locking pin from the opposite side of insertion and confirm that it is captured and locked.

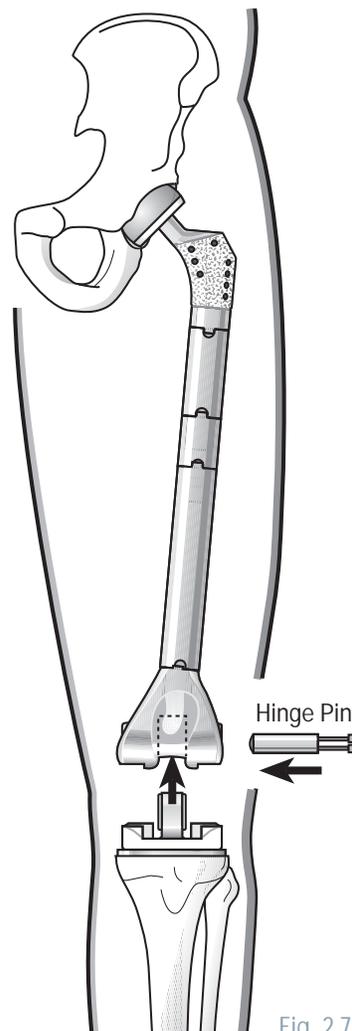


Fig. 2.7

Once the total prosthesis is positioned in vivo, perform the final leg length and offset checks with a trial femoral head (Fig. 2.8). Remove the trial femoral head, twist the selected femoral head into the proximal femoral body taper and impact it with a mallet blow. Reduce the Orthogenesis LPS femoral replacement into the acetabular component.

Closure

With the components securely in place, soft tissue closure is important to successful procedure completion. If the hip capsule is present, place a purse-string suture around the residual capsule and secure it over the bipolar or acetabular component chosen.

Use the proximal femoral body replacement component to reattach the greater trochanter when present. This feature works by utilizing the reattachment holes provided in the proximal femoral body component. Attach the greater trochanter and abductor with either a heavy suture or Mersilene tape. If the abductors are extensively shortened, use the proximal femoral replacement body with the trochanteric build-up for reattachment.

If possible, suture the gluteus medius muscle to the lateral femoral muscles and then fasten the fascia lata to the proximal femoral replacement component holes. This assists in securing the gluteus musculature until scar tissue is formed with the surrounding soft tissue protecting against early subluxation.

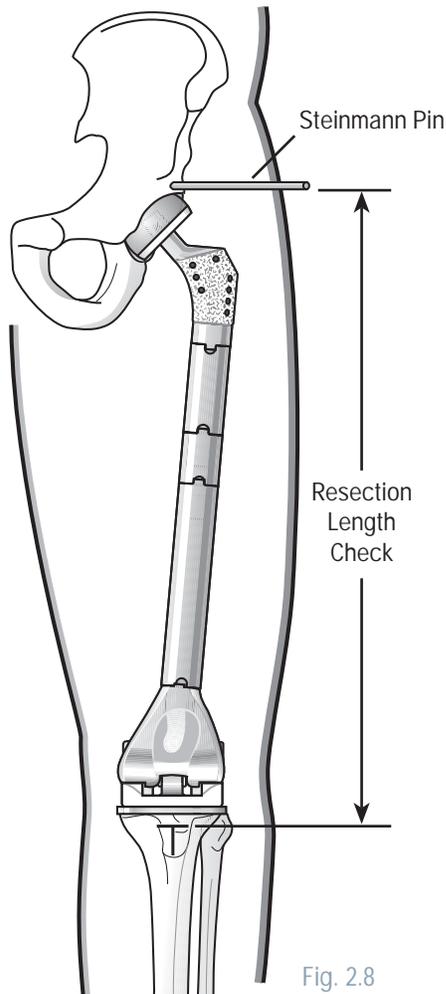


Fig. 2.8

Suture the iliopsoas muscle, if desired, to the holes in the medial aspect of the proximal femoral body replacement component. Reattach the vastus lateralis to the intermuscular septum, the fascia lata and knee joint capsule, if present. The rotating knee hinge allows for 6 degrees of hyperextension to 110 degrees of flexion.

If, due to grossly inadequate soft-tissue integrity, knee flexion beyond 90 degrees causes luxation of the hinged insert bearing out of the tibial component base, the patient must have a knee brace postoperatively to limit flexion to 90 degrees. In such cases, consider closing the wound with the knee in full extension. Close the knee joint and skin in layers after inserting a suction drain.

POSTOPERATIVE CARE

Individualize postoperative care.

These procedures involve extensive dissections with the placement of large drains.

Weight-bearing protocol depends on the acetabular reconstruction and soft tissue stability.

Preoperative Planning

Use the Orthogenesis LPS to efficiently perform distal femur reconstruction due to significant bone loss. The following technique reviews the intended design and use of the instruments and implants for this procedure and provides a general framework. Utilize techniques that best meet the needs of each case, since each case is unique and with its own challenges. Consider the following recommendations for a successful outcome:

- Perform preoperative planning and radiographic analysis for every case. Use the Orthogenesis LPS templates for preoperative planning to assess the approximate resection level; position of the distal femoral replacement and segmental component(s) (if needed) to restore the joint line; and determine the diameter and length of the femoral stem extension that could be used to provide adequate fixation and stability in the remaining host femoral diaphyseal bone.
- Evaluate the tibia to assess any deficiencies or abnormalities that may be present and to choose the implant system used to reconstruct the tibia.

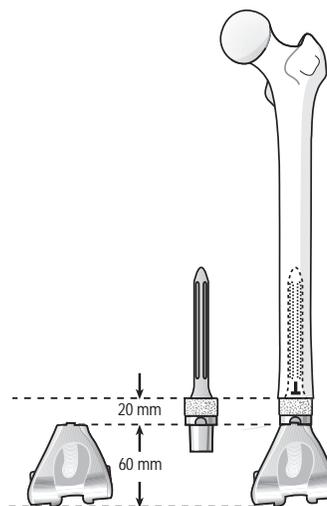
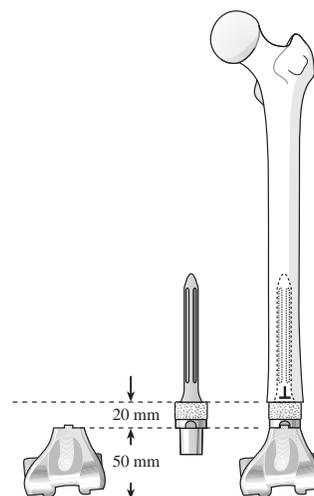


Fig. 3.1a



Exposure

Use a surgical approach that best achieves the exposure needed for extensive removal of bone in the distal femur and proximal tibial areas. Leg length measurement and alignment are important checks to be done prior to any bone resection. During surgery, take care to avoid stretch injury to the neurovascular structures. If performing the reconstruction for primary bone sarcoma, the preoperative imaging studies, such as plain radiographs, CT scans and MRI of the femur, must be reviewed to determine a safe resection level.

Intraoperative Planning

The minimum distal femoral resection level is 80 mm when using the X-small distal femoral replacement component. The minimum distal femoral resection is 70 mm when the XX-small distal femoral replacement component is used. This minimum resection level includes the distal femoral replacement component lengths of 50 mm and 60 mm plus the 20 mm stem component collar height (Fig. 3.1a).

Additional replacement length is usually needed. The 25 mm segmental component is the shortest segment available, making the 105 mm the next resection level (Fig. 3.1b). Segmental components are then available in 5 mm increments alone or in combination with other segmental components to adjust leg length (Fig. 3.1b,c). The chart on page 28 demonstrates the segmental component lengths available along with the combination capabilities to replace missing gaps in 5 mm increments.

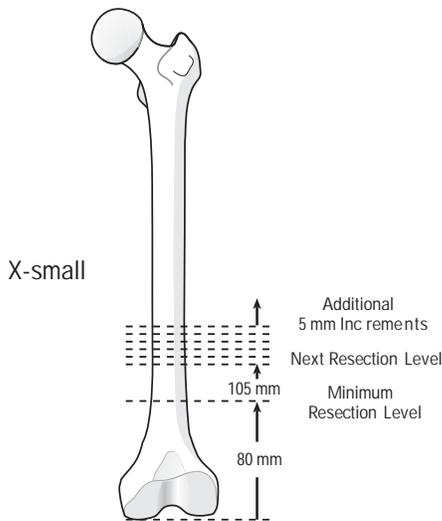


Fig. 3.1b

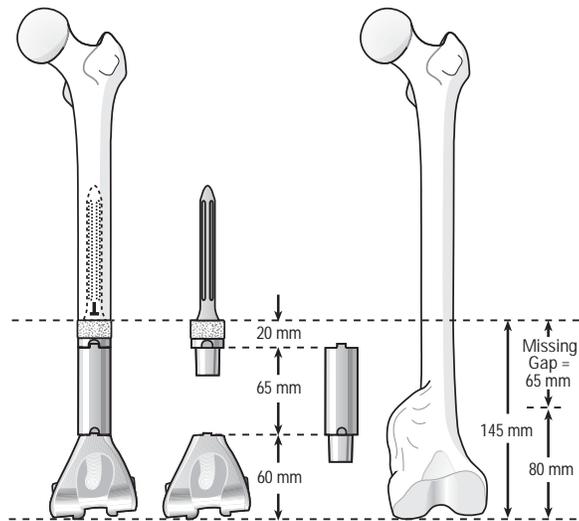
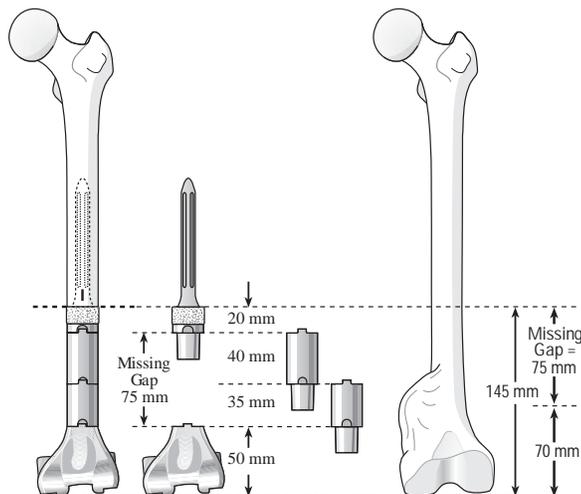
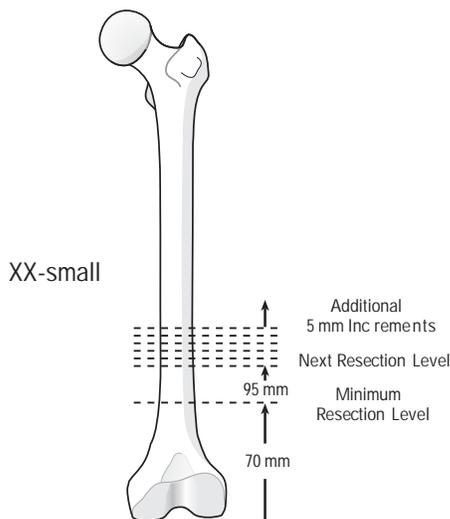


Fig. 3.1c



After achieving distal femur and proximal tibia exposure, mark the proposed distal femoral resection level with the extremity fully extended in a reproducible position. Avoid measurement with the knee in flexion for consistency of measurement results. Make a horizontal line on the femur 1 cm above the proposed resection level as a reference for use in leg length measurement. Then mark a perpendicular vertical line on the anterior cortex midline in line with the femoral trochlear groove. This mark serves as a reference for correct femoral prosthesis rotational alignment.

Make another horizontal line 1 cm below the proposed resection level on the tibia for use as a reference in leg length measurement. These marks can be made with electrocautery, osteotome, marking pen or methylene blue (Fig. 3.2). Record this measurement prior to any resection and use for future reference in the case.

Another measurement that is useful is the distance from the natural joint line to the horizontal line marked on the femur. This is a very useful reference when re-establishing the level of the joint line.

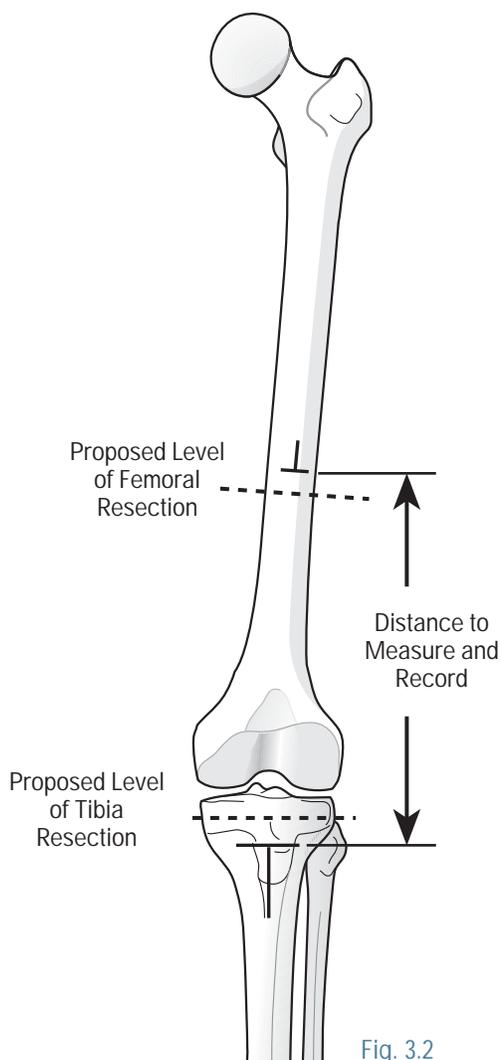


Fig. 3.2

Tibial Preparation

Prepare the proximal tibia. This can be done with intramedullary or extramedullary instrumentation that is available with the M.B.T. revision knee system, the S-ROM knee system or other tibial cutting guides. The remainder of the tibial preparation follows the technique for the M.B.T. revision tibial tray or the S-ROM tibial tray, depending upon the system being used.

When using the S-ROM tibial tray, only use the S-ROM hinged tibial insert bearing. When using the M.B.T. revision tibial tray, only use the Orthogenesis LPS hinged tibial insert bearing. Use only the LPS extra-small hinged tibial insert bearing sizes to match the Orthogenesis LPS Distal Femoral Replacement component extra-small. It is recommended that the extra-extra small LPS hinged tibial insert bearing be used with the extra-extra small LPS Distal Femoral Replacement component.

Distal Femoral Resection

When a distal femoral tumor resection is required, excise the tumor and affected soft tissue prior to any tibial bone resection, except in the case of an extra-articular resection. In this case, it is technically easier to osteotomize or resect the patella first, then cut the tibia and finally cut the femur. Once the bone and soft tissue resection have been performed, prepare the remaining host femur. All distal femoral resections need to be to the level of healthy, femoral diaphyseal bone.

Femoral Medullary Canal Preparation

Following femoral resection, prepare the remaining femoral canal for the appropriate stem extension. A flexible IM reamer is recommended for the bowed stem extension and a straight IM reamer is recommended for the straight stem extension.

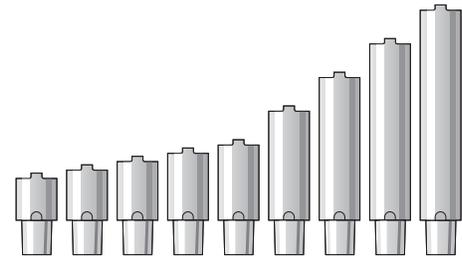
Cemented Stem Application Options

If using a cemented stem, choose a final stem that is smaller than the last reamer used to allow for a circumferential cement mantle around the stem. For example, if a 15 mm IM reamer was last used, an 11 mm stem would have a 2 mm cement mantle per side.

Do not ream the femoral canal to cortical bone for a cemented application. Leave some cancellous bone for cement interdigitation.

Porous Stem Application Options

When using a porous stem, the reaming technique utilized will depend on a number of factors such as the patient age, bone quality, curvature of the remaining femur, etc. The following are general guidelines, as the surgeon will need to choose the technique based on individual patient needs. It is recommended that a ring gauge be available. Measurement over the stem porous coating and a measurement of the final selected reamer will provide the surgeon with insights based on the actual dimensions of the implant and reamer.



LPS Segmental Components

SEGMENTAL STACK CHART

Remaining Gap	LPS Segmental Components
25	25
30	30
35	35
40	40
45	45
50	25 + 25
55	25 + 30
60	25 + 35
65	65
70	25 + 45 or 30 + 40
75	30 + 45 or 35 + 40
80	35 + 45
85	85
90	25 + 65
95	30 + 65
100	35 + 65
105	105
110	25 + 85 or 45 + 65
115	30 + 85
120	35 + 85
125	125
130	25 + 105 or 45 + 85
135	30 + 105
140	35 + 105
145	40 + 105
150	25 + 125 or 45 + 105
155	30 + 125
160	35 + 125
165	40 + 125
170	45 + 125
175	125 + 25 + 25
180	125 + 25 + 30
185	125 + 25 + 35
190	125 + 65
195	125 + 25 + 45
200	125 + 35 + 40
205	125 + 35 + 45
210	125 + 85
215	125 + 25 + 65
220	125 + 30 + 65
225	125 + 35 + 65
230	125 + 105
235	125 + 25 + 85
240	125 + 30 + 85
245	125 + 35 + 85
250	125 + 40 + 85

When using a straight porous stem, under ream by .5 mm for press-fit application using a straight reamer. If the remaining bone is fragile, consider line-to-line reaming.

When using a bowed porous stem, under reaming by .5 mm with a flexible reamer for press fit application is a technique that can be considered. Line-to-line reaming may be indicated if needed to allow the implant to pass through the remaining femur's curvature or if the remaining bone is fragile (see **Implant Insertion section on pages 32-34 for additional insight**).

The Orthogenesis LPS stem extensions are available in 100 and 125 mm straight or 150 and 200 mm bowed lengths in cemented and porous-coated styles (see **chart on page 29**).

Finish Preparation Using the Calcar Planer/Bevel Reamer

Once reaming is completed, prepare the osteotomy surface to help assure the stem's proper fit. The calcar planer/bevel reamer produces an even cut surface and an angled relief (bevel) in the bone to match the stem extension flare under the collar. This helps to ensure complete stem extension seating on the prepared diaphyseal bone surface.

Use a calcar planer and insert a bevel reamer with a pilot that is at least 1 mm smaller than the last IM reamer used (Fig. 3.3) and insert it into the femoral canal. Sequential use of the bevel reamer with the pilots prepares the bevel in the

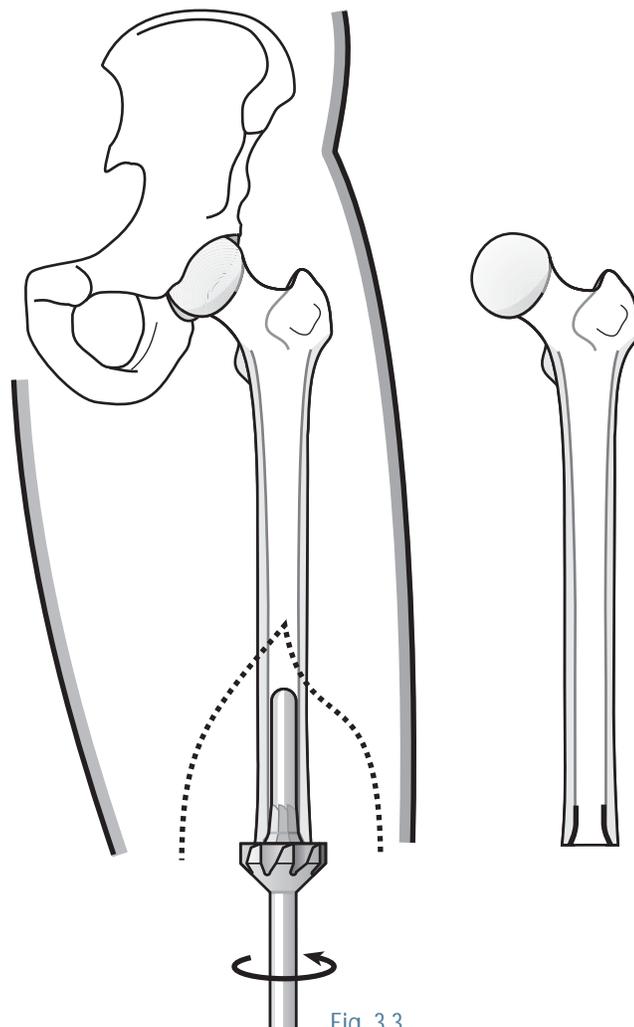


Fig. 3.3

remaining bone with more efficiency and precision. Attach the assembled planer and bevel reamer with a pilot to a power drill reamer using the appropriate adapter. The calcar planer/bevel reamer should be under power prior to planing the resection cut. This will minimize any resected bone chipping by the calcar planer cutting blades. The following are recommendations for the calcar planer/bevel reamer for use with cemented or porous stems:

- For a porous stem extension, begin reaming with a calcar planer/bevel reamer with pilot that is at least 1 mm less than the final IM reamer used and finish with a **final bevel reamer that matches the final stem extension size**. For example, if a 15.5 mm stem is the chosen implant, the final bevel reamer with a pilot will be the 15.5 mm. Note, the pilot is undersized by .5 mm from the stated size. For example a 15.5 mm pilot is 15 mm in diameter. This makes allowances for an under ream technique. If a 15 mm IM reamer was last used, the final bevel reamer with a pilot will still be 15.5 mm to match the implant.
- For a cemented stem extension, begin reaming with a calcar planer/bevel reamer with a pilot that is at least 1 mm less than the final IM reamer used and finish with a **final bevel reamer pilot that matches the final IM reamer size**. For example, if the last IM reamer used was 15 mm, the 15 mm bevel reamer pilot will be the final bevel reamer used irrespective of the stem size chosen to allow for an adequate cement mantle.

Resurface the patella using a domed patella replacement such as the S-ROM or Sigma dome patella component.

Trial Reduction

Following the femur’s preparation for the stem extension, perform a trial reduction. Replace the missing bone from the distal femoral resection to the contemplated joint line level. Utilizing this measurement, assemble the appropriate distal femoral replacement component, segmental component(s) and distal femoral stem trials that would fill the missing bone gap (see chart on page 27).

STEM EXTENSIONS

CEMENTED STEMS (STRAIGHT)

Description
10 mm diameter x 100 mm length
11 mm diameter x 100 mm length
12 mm diameter x 100 mm length
12 mm diameter x 125 mm length
13 mm diameter x 125 mm length
14 mm diameter x 125 mm length
15 mm diameter x 125 mm length
16 mm diameter x 125 mm length
17 mm diameter x 125 mm length

POROUS STEMS (STRAIGHT)

Description
11.5 mm diameter x 100 mm length
12.5 mm diameter x 100 mm length
13.5 mm diameter x 100 mm length
13.5 mm diameter x 125 mm length
14.5 mm diameter x 125 mm length
15.5 mm diameter x 125 mm length
16.5 mm diameter x 125 mm length
17.5 mm diameter x 125 mm length
18.5 mm diameter x 125 mm length

CEMENTED STEMS (BOWED)

Description
11 mm diameter x 150 mm length
12 mm diameter x 150 mm length
13 mm diameter x 150 mm length
14 mm diameter x 150 mm length
15 mm diameter x 150 mm length
16 mm diameter x 150 mm length
17 mm diameter x 150 mm length
11 mm diameter x 200 mm length
13 mm diameter x 200 mm length
15 mm diameter x 200 mm length
17 mm diameter x 200 mm length

POROUS STEMS (BOWED)

Description
12.5 mm diameter x 150 mm length
13.5 mm diameter x 150 mm length
14.5 mm diameter x 150 mm length
15.5 mm diameter x 150 mm length
16.5 mm diameter x 150 mm length
17.5 mm diameter x 150 mm length
18.5 mm diameter x 150 mm length
12.5 mm diameter x 200 mm length
14.5 mm diameter x 200 mm length
16.5 mm diameter x 200 mm length
18.5 mm diameter x 200 mm length

NOTE: Reference the LPS Design Guide, Cat. No. 0612-35-050, for complete ordering information.

If the distal femur is available in one piece, an alternate method is to measure the resected bone from the osteotomy to the end of the condyles. Then assemble the trial components and from the joint line to the resection line, evaluate the match of the trial to the resected bone (Fig. 3.4). The trial components are designed to snap together and match the implant component dimensions (Fig. 3.5a). Utilize the stem trial size to provide enough stability to prevent “spinning” when performing a trial reduction.

The trial stem should closely match the last IM reamer used or it can be 1 – 2 mm smaller depending on fit. **Insert trial constructs by hand. Never impact them into the canal.**

The 150 and 200 mm trial stems are bowed and need to be inserted in proper orientation to match the femur’s anterior bow. Insert the trial construct into the remaining distal femur and use it to assess fit, leg length, joint line, joint stability, soft tissue tension and range of motion (Fig. 3.5b).

If the soft tissues are tight and are adversely affecting the range of motion, consider soft tissue releases. However, if the leg has been excessively lengthened, reducing leg length will correct the problem. The leg length can be adjusted with the segmental trials, which allows for 5 mm increments of correction.

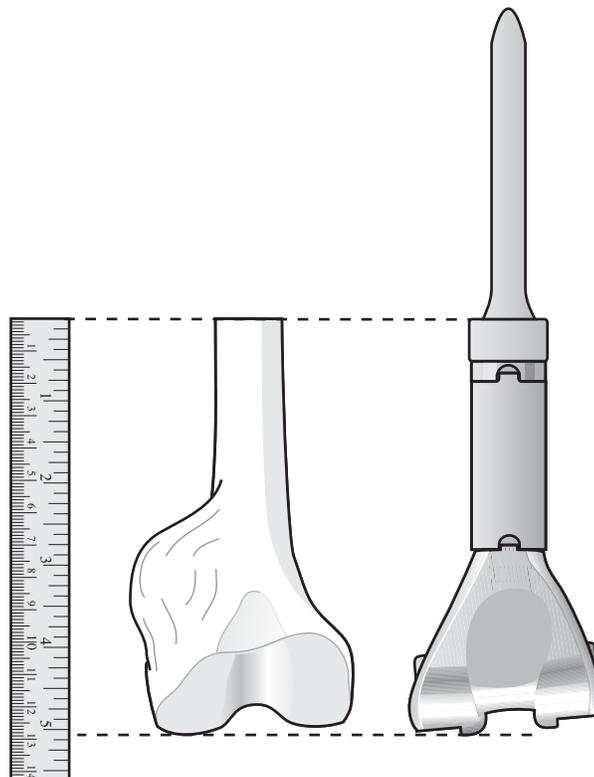


Fig. 3.4

Compare the knee joint line to the opposite side for proper height. The joint line is determined by the level of the femoral component. If the segmental trials used are at the minimum length of 25 mm and the joint line is too far distal, consider recutting the femoral osteotomy to adjust for the discrepancy. If the femoral cut is revised, re-ream the femur more proximally and finish the osteotomized surface with a calcar planer/bevel reamer. The stem's distal end may encounter unreamed bone and an intraoperative fracture may occur if re-reaming is not done.

Varying the hinged tibial insert trial heights can affect leg length. Use the trial construct to assess proper component rotational orientation. **Once proper orientation is established, use the anti-rotation slot (tab) on the trial as a reference to mark the femur.** This mark serves as an alignment guide when inserting the final implant (Fig. 3.5b).

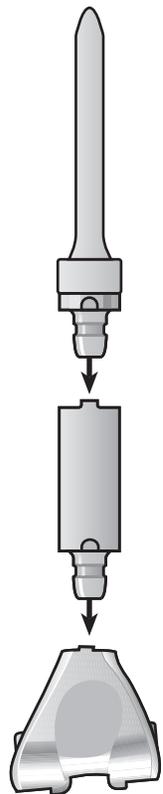


Fig. 3.5a

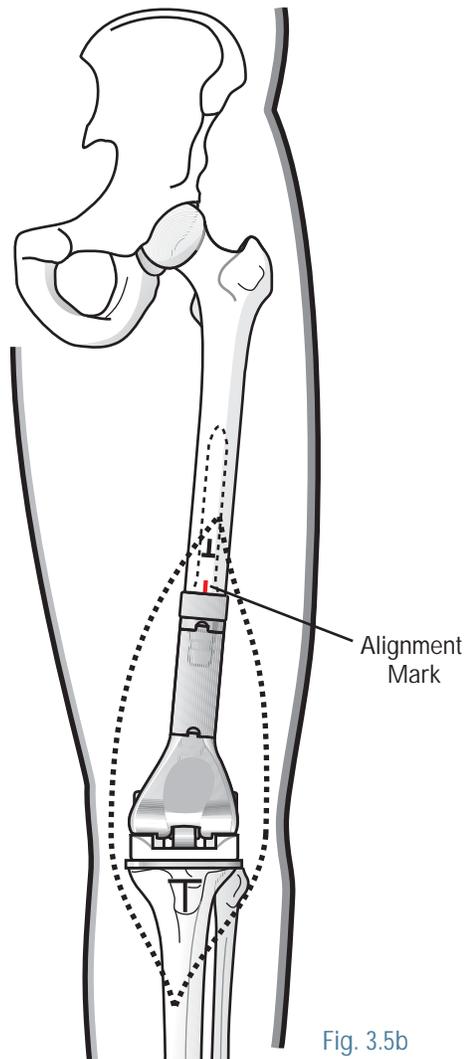


Fig. 3.5b

Implant Assembly

Once the trial segments yield a satisfactory result with the trial reduction, assemble the appropriate implant components. Use the implant impacting stand to help stabilize the implant components for assembly and impaction. It is important to orient the implant components along the same axis as the trial components. The implant components use a Morse-taper design for locking. Assemble the implant components by hand and place the impaction cap over the stem component. Then impact the components together using a mallet to securely seat the tapers together (Fig. 3.6). There should be approximately a 1 mm gap between the component bodies.

Implant Insertion

If using Endurance bone cement to fix the distal femoral stem extension to host bone, follow the manufacturer’s recommended procedures to mix, deliver and pressurize the bone cement.

Use the distal femoral impactor with the implant construct to assist in the insertion of the implant into the femoral canal. The distal femoral impactor mates with the distal femoral replacement component. Use a mallet to impact the assembled construct (Fig. 3.7).

Use the alignment mark previously placed on the femur and the implant’s anti-rotation slot for proper implant orientation. Note that the 150 and 200 mm stems are bowed and the correct bow-to-femur orientation must be accomplished.

If using the porous stem, impact the construct in place using a mallet to strike the inserter and align the anti-rotation tab with a mark on the femur for proper alignment (Fig. 3.8). Insert a cemented stem and align as noted above. Remove excess bone cement from around the implant collar.

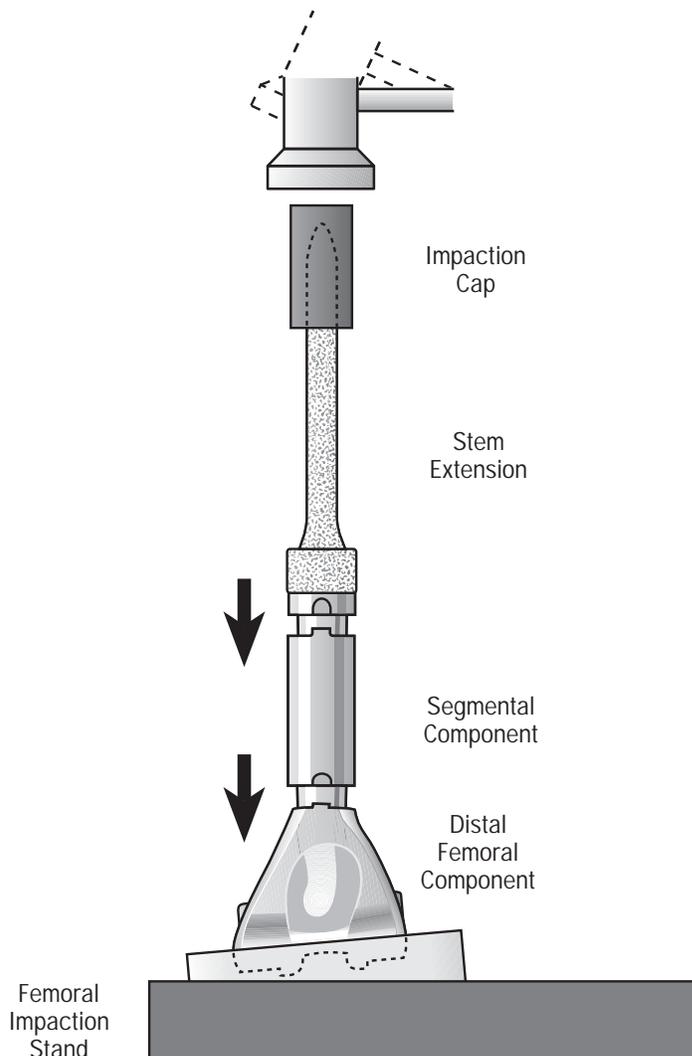


Fig. 3.6

When using a bowed porous stem, curvature of the remaining bone in comparison to the implant needs to be appraised especially for the impact of mismatch conditions. Under reaming by .5 mm with a flexible reamer is a technique that can be considered. Insertional feel and non-advancement with component impaction should be an indication to remove the construct and try to pass the same flexible reamer another four to six times and evaluate the insertional feel again. If the construct still presents with non-advancement, line-to-line reaming should be considered. The construct should then be inserted into the medullary canal and attention to insertional feel and advancement assessed again.

Placement of a “prophylactic” cerclage wire around the proximal end of the remaining diaphysis may decrease the risk of intraoperative fracture during press-fit insertion of a porous stem extension particularly with fragile bone.

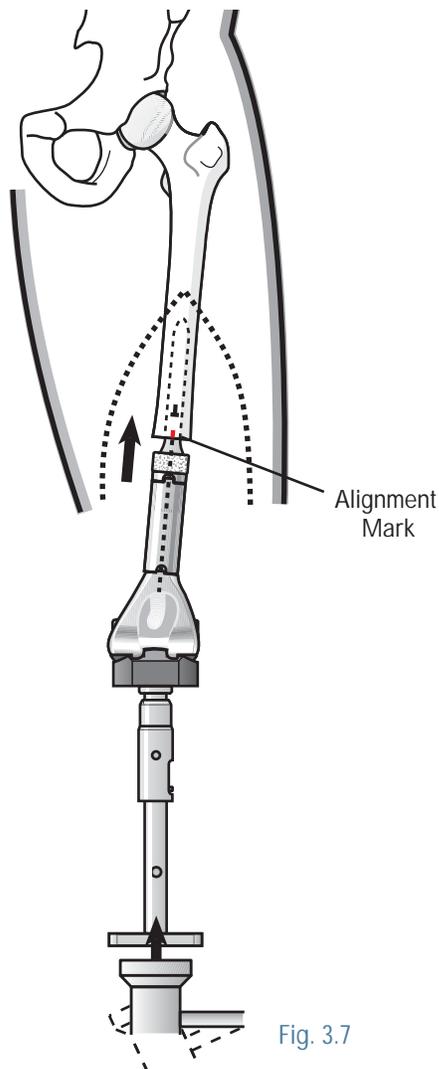


Fig. 3.7

Should the implant construct with a porous stem not advance and become lodged in the femoral canal, there is a technique for removal. Disassemble the implant construct from the stem extension using the disassembly tool (see [disassembly technique on page 56 – 57](#)). The exposed porous stem extension taper is threaded. Place the slap handle through the inserter/extractor. Completely thread the inserter/extractor into the porous stem thread. Use the slap handle to provide the extraction force to the lodged porous stem extension until it is removed from the femur. Make sure the tapers are clean and dry before assembly. Reinsert the implant construct after re-reaming.

The stem extension shoulder should be flush to the femur’s cut surface when using either the cemented or porous stem extension (Fig. 3.8). Give meticulous attention to the distal femoral component’s rotation. If it is internally rotated, patellar instability will result.

Perform a final trial reduction. Evaluate stability and leg length adjustments by using the trial-hinged tibial-bearing trials prior to choosing the final implant component.

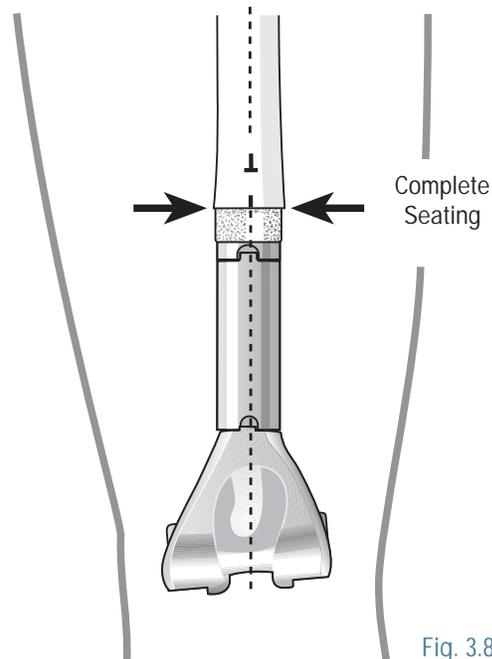


Fig. 3.8

Use the locking pin to mate the distal femur component to the tibial bearing through the hinged tibial insert bearing. Pass the locking pin through the Orthogenesis LPS distal femoral replacement component and the hinged tibial insert-bearing bushings (Fig. 3.9a,b).

One method to secure the locking pin uses manual pressure to push the locking pin through until it “clicks” and locks into place. Another method uses forceps to squeeze the locking pin while pushing the pin until it is completely seated in the square cut-out in the Orthogenesis LPS distal femoral component. Once the pin is seated, release the pressure from the forceps. To ensure the pin is securely locked, push the lock pin from the opposite side of insertion and confirm that it is captured and locked.

Closure

If knee flexion beyond 90 degrees causes luxation of the hinged insert bearing out of the base of the tibial component, this could be due to grossly inadequate soft tissue integrity. In that situation, the patient must have a knee brace postoperatively to limit flexion to 90 degrees. In such cases, consider closing the wound with the knee in full extension. One of the most important aspects of this procedure is the soft tissue reconstruction, which is done based on individual patient needs. Soft tissue closure should completely cover the prosthesis.

In oncologic applications when soft tissues are resected to achieve a wide bone tumor margin, the amount of remaining soft tissue coverage is reduced. In this case, remaining musculature mobilization may be necessary to achieve proper soft tissue coverage around the prosthesis.

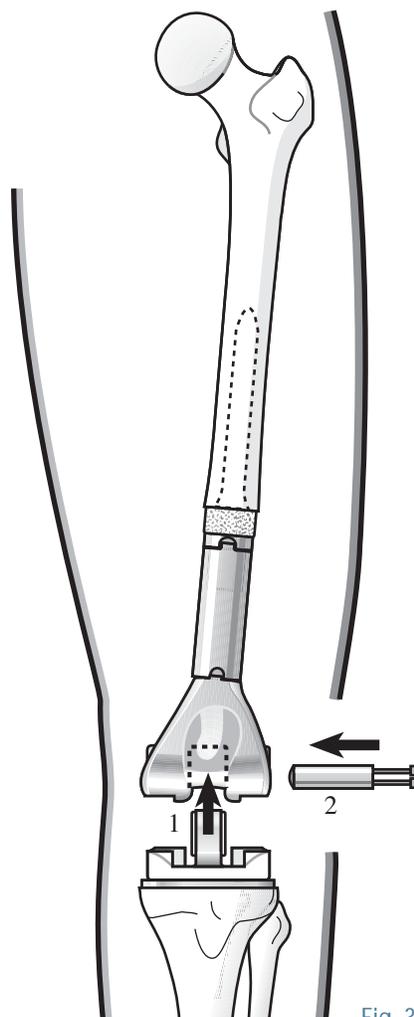


Fig. 3.9a

Perform wound closure in multiple layers to minimize hematoma formation. Perform meticulous wound closure to minimize wound complications that may preclude immediate physical therapy or other adjuvant oncologic treatments, such as radiation therapy or chemotherapy.

Occasionally, if there is significant soft tissue fibrosis (e.g. from prior surgery, trauma, irradiation, etc.), then extremity shortening may be necessary to minimize soft tissue tension and allow wound closure without undue tension. Typically the wound is closed over large bore drains to minimize hematoma collection.



Fig. 3.9b

POSTOPERATIVE CARE

Individualize postoperative care.

Many of these procedures involve extensive dissections. The patient's activity and weight-bearing status will depend on the extent of the surgery, the individual patient's needs and the implant's fixation type.

The weight-bearing status with cemented stems is generally full.

With cementless stems, the weight-bearing status can be individualized based on the patient's needs.

However, it is suggested for patients not on chemotherapy to adhere to toe-touch weight bearing for eight weeks. For patients on chemotherapy, 12 weeks is suggested.

Preoperative Planning

Use the Orthogenesis LPS to efficiently perform the proximal tibia reconstruction due to significant bone loss. The following technique reviews the intended design and use of the instruments and implants for this procedure and provides a general framework. Utilize techniques that best meet the needs of each case, since each is unique and has specific challenges. Consider the following recommendations for a successful outcome:

- Perform preoperative planning and radiographic analysis for every case. Use the Orthogenesis LPS templates for preoperative planning to assess the following: approximate resection level; joint line; the proximal tibial replacement position and segmental component (if needed) to restore leg length; and the diameter and length of the tibial stem extension that could be used (to provide adequate fixation and stability in the remaining host tibial diaphyseal bone).
- Evaluate the femur to confirm establishment of the knee joint line and assess any abnormalities or deficiencies that may exist. Use the S-ROM **hinged** femoral component with the Orthogenesis LPS proximal tibial replacement component.

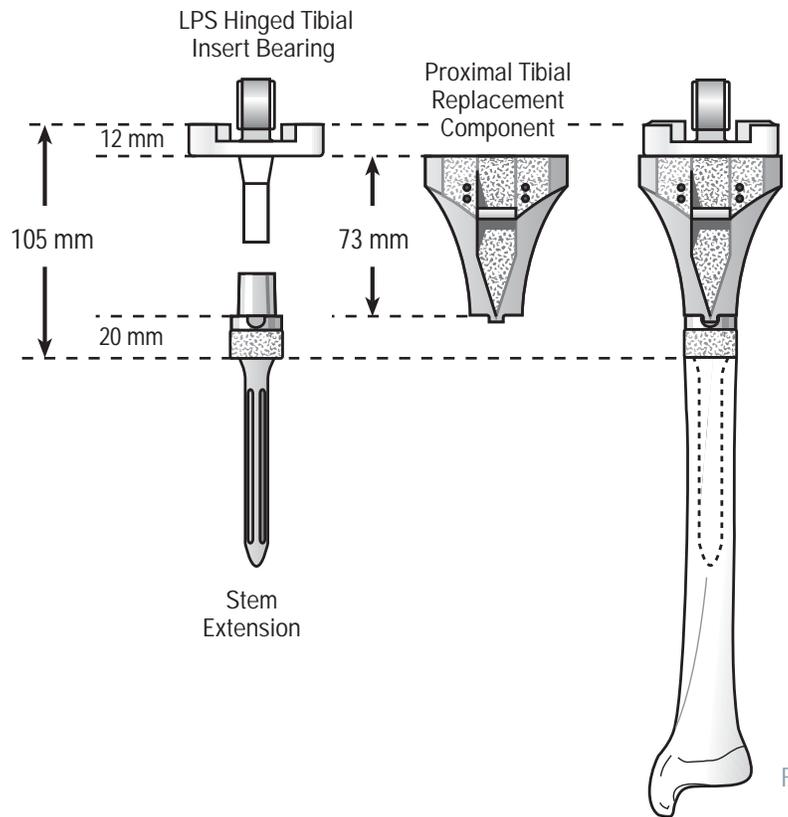


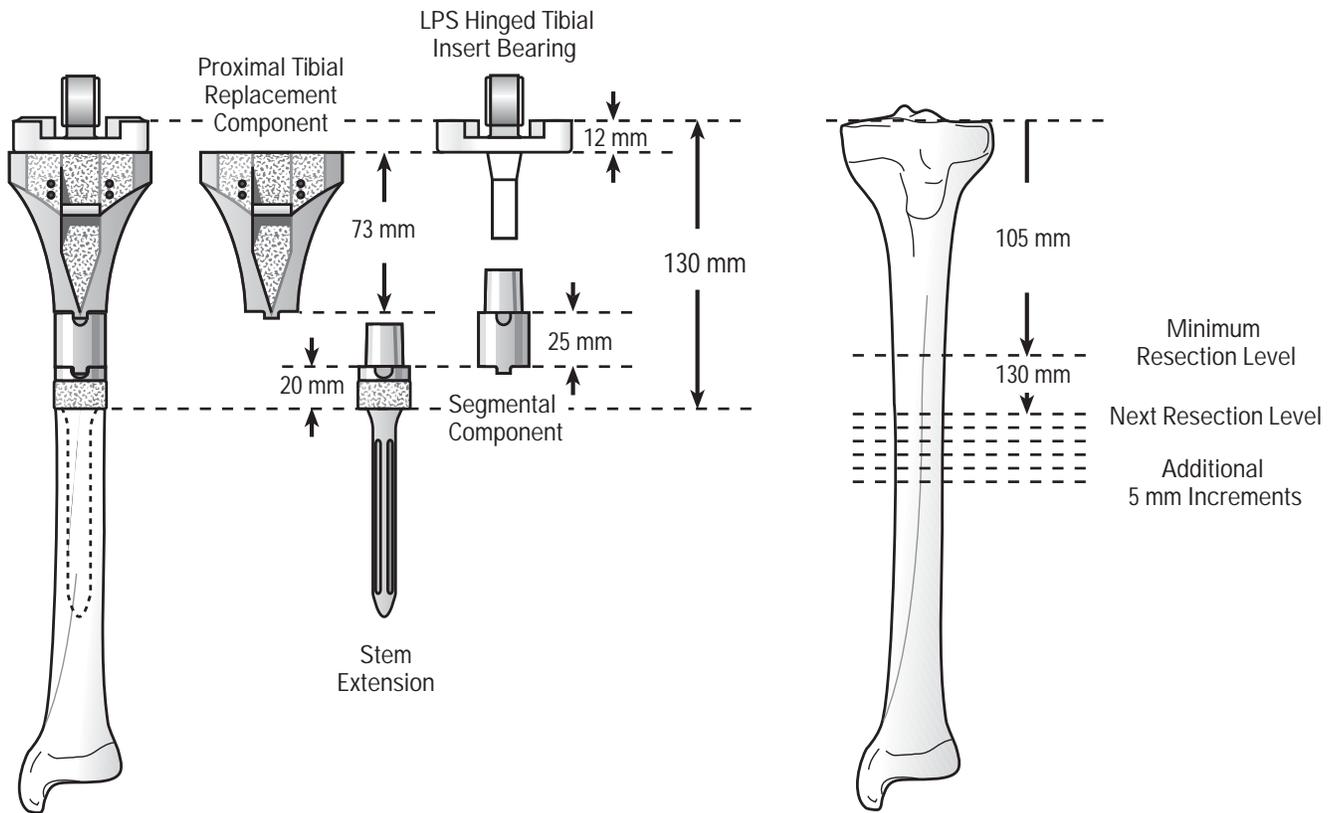
Fig. 4.1

Exposure and Intraoperative Planning

Use a surgical approach that best achieves the exposure needed for extensive bone removal in the proximal tibial and distal femoral areas. It is important to check leg length measurement and alignment prior to any bone resection. During surgery, take care to avoid stretch injury to the neurovascular structures. If performing the reconstruction for primary bone sarcoma, review the preoperative imaging studies, such as plain radiographs, CT scans and MRI of the tibia to determine a safe resection level.

The minimum proximal tibial resection level is 105 mm with a 12 mm hinged insert bearing. This minimum resection level includes the 73 mm proximal tibial replacement component length plus the 12 mm hinged insert-bearing plus the 20 mm stem component collar height. If additional replacement length is needed, the 25 mm segmental component is the shortest segment available making the 130 mm the next level of resection (see Fig. 4.1).

Segmental components are then available in 5 mm increments alone or in combination with other segmental components to adjust leg length.



After achieving proximal tibia and distal femur exposure, mark the proposed tibial resection level with the extremity fully extended in a reproducible position. Avoid knee flexion for consistency of measurement results. Mark a horizontal line on the tibia 1 cm below the proposed resection level as a reference for use in leg length measurement and make a perpendicular vertical mark on the anterior crest of the tibia.

Mark another horizontal line on the femur, above the level of the femoral component and in line with the trochlear groove. Make these marks with electrocautery, osteotome, marking pen or methylene blue (Fig. 4.2). Record this measurement prior to any resection and use for future reference in the procedure.

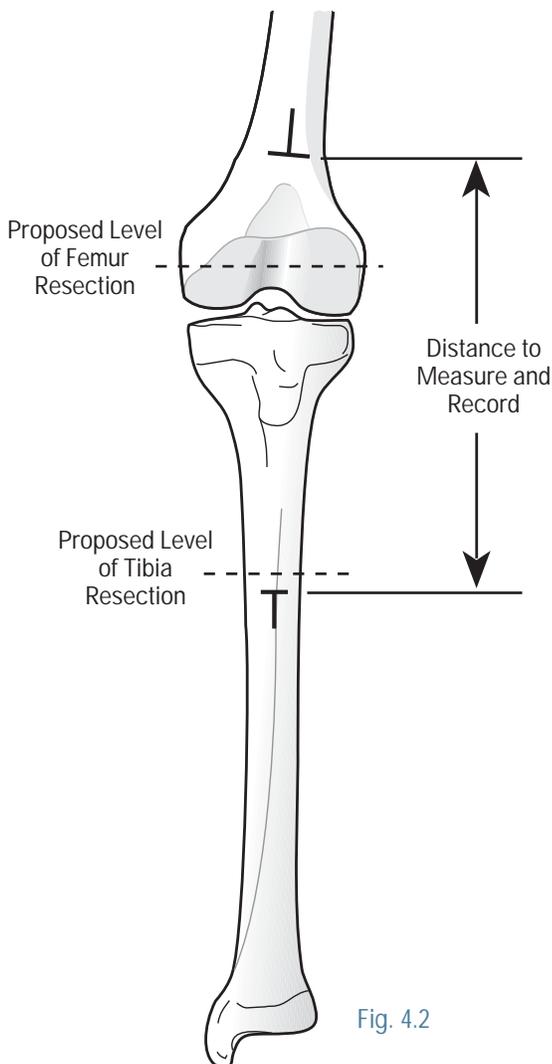


Fig. 4.2

Tibial Resection

When a proximal tibial tumor resection is required, excise the tumor and affected soft tissue prior to any femoral bone resection. The tibia is then resected to healthy, diaphyseal bone.

Femoral Preparation

Follow the technique for implanting the S-ROM hinged femoral component and prepare the distal femur for the S-ROM hinged femoral component. It is mandatory to use the S-ROM femoral sleeve and stem components due to the high torsional stresses from soft-tissue loss.

Tibial Medullary Canal Preparation

Following the distal femoral preparation, ream the remaining tibial canal for the stem extension. The straight stems are recommended for use in the tibia. The straight IM reamer is recommended for the straight stem extension.

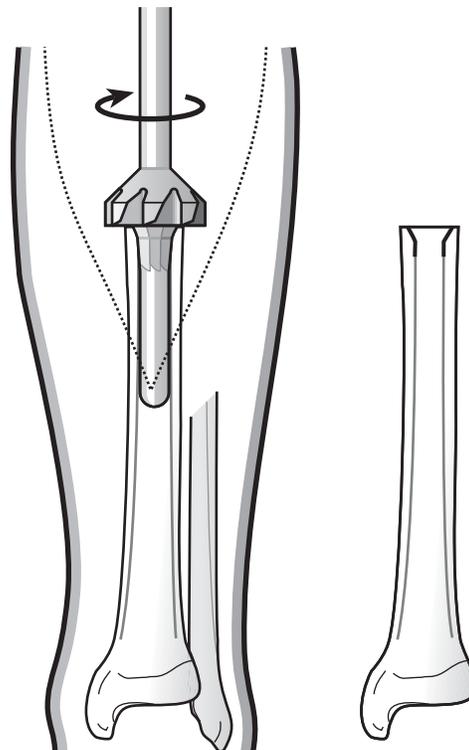


Fig. 4.3

If using a cemented stem, choose the final stem that is smaller than the last reamer used to allow for a circumferential cement mantle around the stem. For example, if a 15 mm IM reamer was last used, an 11 mm stem would have a 2 mm cement mantle per side. If a 13 mm stem were used, there would be a 1 mm cement mantle per side.

Do not ream the tibial canal to the cortical bone for a cemented application. Leave some cancellous bone for cement interdigitation.

When using a porous-coated stem extension, under ream by .5 mm for a straight stem press fit application. If the remaining bone is fragile, consider line-to-line reaming.

The Orthogenesis LPS stem extensions are available in 100 and 125 mm straight lengths in cemented and porous-coated styles for tibial use. The table to the right reviews the stem extensions that are available with Orthogenesis LPS.

Finish Preparation Using the Calcar Planer/Bevel Reamer

Once reaming is completed, prepare the tibial resection osteotomy surface to help assure proper stem extension fit. The calcar planer/bevel reamer produces an even cut surface and is designed to cut an angled relief (bevel) in the bone to match the stem extension flare under the collar. This helps to assure complete femoral stem extension seating on the prepared diaphyseal bone surface.

Use the calcar planer/bevel reamer with pilot that is at least 1 mm smaller than the last IM reamer used (Fig. 4.3) and insert it into the femoral canal. Sequential use of the bevel reamer with the pilots will prepare the bevel in the remaining bone with more efficiency and precision. Attach the assembled planer and bevel reamer with the pilot to a power drill reamer using the appropriate adapter. The calcar planer/bevel reamer should be under power prior to planing the resection cut.

STEM EXTENSIONS

CEMENTED STEMS (STRAIGHT)

Description
10 mm diameter x 100 mm length
11 mm diameter x 100 mm length
12 mm diameter x 100 mm length
12 mm diameter x 125 mm length
13 mm diameter x 125 mm length
14 mm diameter x 125 mm length
15 mm diameter x 125 mm length
16 mm diameter x 125 mm length
17 mm diameter x 125 mm length

POROUS STEMS (STRAIGHT)

Description
11.5 mm diameter x 100 mm length
12.5 mm diameter x 100 mm length
13.5 mm diameter x 100 mm length
13.5 mm diameter x 125 mm length
14.5 mm diameter x 125 mm length
15.5 mm diameter x 125 mm length
16.5 mm diameter x 125 mm length
17.5 mm diameter x 125 mm length
18.5 mm diameter x 125 mm length

CEMENTED STEMS (BOWED)

Description
11 mm diameter x 150 mm length
12 mm diameter x 150 mm length
13 mm diameter x 150 mm length
14 mm diameter x 150 mm length
15 mm diameter x 150 mm length
16 mm diameter x 150 mm length
17 mm diameter x 150 mm length
11 mm diameter x 200 mm length
13 mm diameter x 200 mm length
15 mm diameter x 200 mm length
17 mm diameter x 200 mm length

POROUS STEMS (BOWED)

Description
12.5 mm diameter x 150 mm length
13.5 mm diameter x 150 mm length
14.5 mm diameter x 150 mm length
15.5 mm diameter x 150 mm length
16.5 mm diameter x 150 mm length
17.5 mm diameter x 150 mm length
18.5 mm diameter x 150 mm length
12.5 mm diameter x 200 mm length
14.5 mm diameter x 200 mm length
16.5 mm diameter x 200 mm length
18.5 mm diameter x 200 mm length

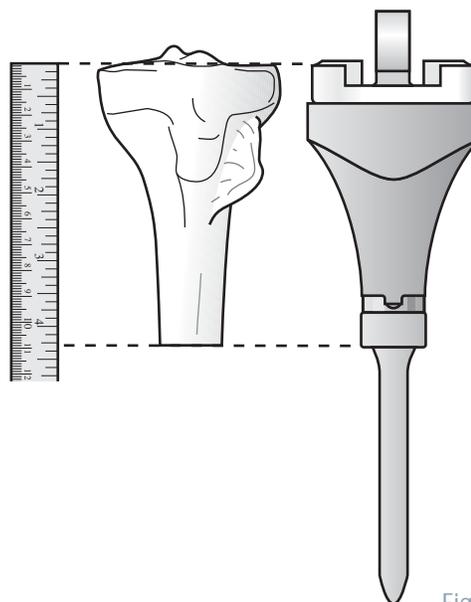
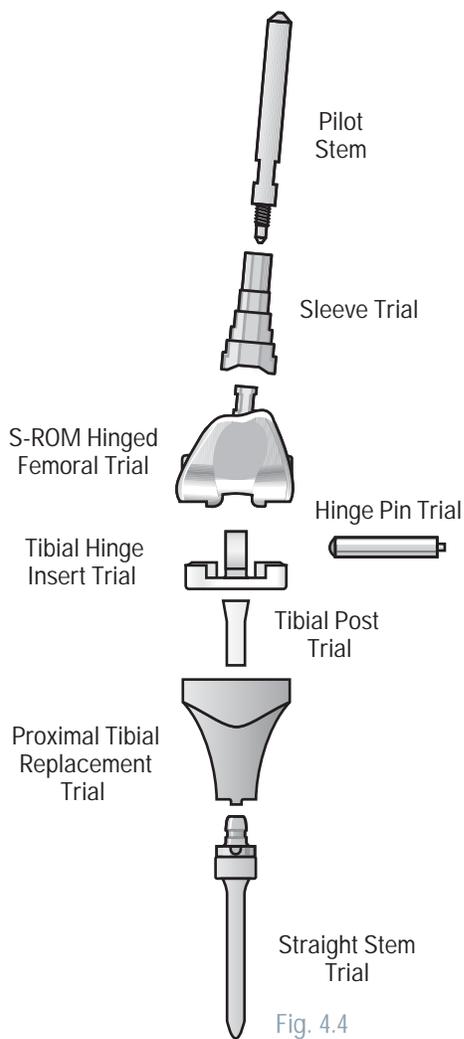
NOTE: Reference the LPS Design Guide, Cat. No. 0612-35-050, for complete ordering information.

This will minimize any resected bone chipping caused by the calcar planer cutting blades. The following are recommendations for using the calcar planer/bevel reamer with cemented or porous stems:

- For a porous stem extension, begin reaming with a calcar planer/bevel reamer with a pilot that is at least 1 mm less than the final IM reamer used and finish with a **final bevel reamer that matches the final stem extension size**. For example, if a 15.5 mm stem is the chosen implant, the final bevel reamer with a pilot will be the 15.5 mm. Note the pilot is undersized by .5 mm from the stated size. For example a 15.5 mm pilot is 15 mm in diameter. This makes allowances for an under reaming technique. If a 15 mm IM reamer was last used, the final bevel reamer with a pilot will still be 15.5 mm to match the implant.

- For a cemented stem extension, begin reaming with a calcar planer/bevel reamer with a pilot that is at least 1 mm less than the final IM reamer used and finish with a **final bevel reamer pilot that matches the final IM reamer size**. For example, if the last IM reamer used was 15 mm, the 15 mm bevel reamer pilot will be the final bevel reamer used irrespective of the stem size chosen to allow for an adequate cement mantle.

Resurface the patella using a domed patella replacement, such as the S-ROM or Sigma dome patella component.



Trial Reduction

Following the tibia preparation for the stem extension, perform a trial reduction. Measure the gap from the distal tibial resection to the level of the contemplated joint line. Check leg length restoration using the marks made previously on the femur and tibia. Utilizing this measurement, assemble the tibial replacement component, segmental component (if needed) and distal stem trials that would fill the gap of missing bone (Fig. 4.4). If the proximal tibia is available in one piece, an alternate method is to measure the resected bone. Assemble the trial components, and from the joint line to the resection line, evaluate the match of the trial to the resected bone (Fig. 4.5).

The trial components are designed to snap together and match the implant component dimensions. Utilize the stem trial size to provide enough stability to prevent “spinning” when performing a trial reduction.

The trial stem size should closely match the size of the last reamer and it can be 1 – 2 mm smaller than the last IM reamer used depending on the fit. **Insert all trial constructs by hand and never impact them into the canal.** Insert the Orthogenesis LPS trial construct into the remaining proximal tibia and mate with the trial S-ROM femoral hinged trial construct to assess fit, leg length, joint line, joint stability, soft tissue tension and range of motion (Fig. 4.6).

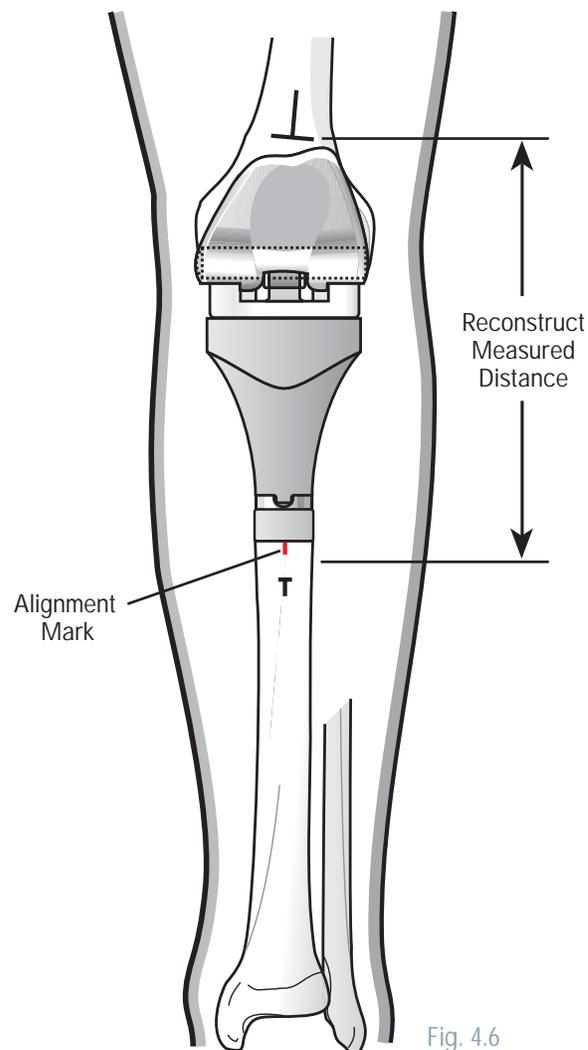


Fig. 4.6

Varying the hinged insert-bearing trials and/or segmental trials, if used, can help fine tune leg length adjustments. Use the trial construct to assess proper component rotational orientation. **Once proper orientation is established, use the anti-rotation slot (tab) on the trial to mark the tibia (Fig. 4.6).** This mark serves as an alignment guide when inserting the implant.

Implant Assembly

Once the trial segments yield a satisfactory result with the trial reduction, assemble the appropriate implant components. The implant components use a Morse-taper design for locking. Assemble them by hand with the tibial component plateau placed on top of a clean, sterile cloth or positioned on the S-ROM tibial assembly stand with the stem pointing towards the ceiling.

Assemble the implant components and place the impactation cap over the stem extension. Then use a mallet to securely seat the tapers together (Fig. 4.7). There should be approximately a 1 mm gap between the component bodies.

Implant Insertion

If using Endurance bone cement to secure the distal femoral stem extension to host bone, follow the manufacturer’s recommended procedures to mix, deliver and pressurize the bone cement.

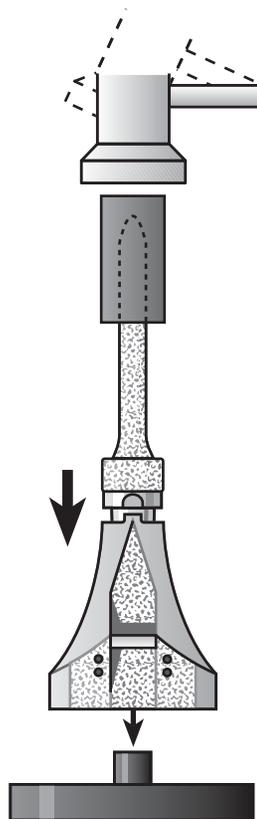


Fig. 4.7

Use the S-ROM tibial impactor to insert the implant construct. Orientate the implant's anti-rotation slot with the alignment mark previously placed on the tibia. If using the porous stem, impact the construct in place using a mallet to strike the inserter and align the anti-rotation tab with mark on the femur for proper alignment (Fig. 4.8a). Placement of a "prophylactic" cerclage wire around the proximal end of the remaining diaphysis may decrease the risk of an intra-operative fracture during press-fit insertion of a porous stem extension, particularly with fragile bone. Insert a cemented stem construct and align as noted above. Remove the excess bone cement from around the implant collar.

The stem extension shoulder should be flush to the tibia's cut surface when using either the cemented or porous stem extension (Fig. 4.8b). Give meticulous attention to the stem's position. Failure to align the stem in proper rotation may result in patellar instability.

Perform a final trial reduction. Make leg length adjustments and check joint stability by using the trial-hinged tibial bearing trials prior to choosing the final implant component.

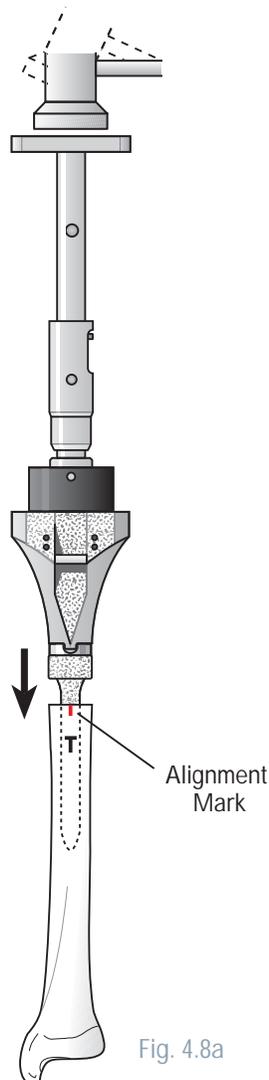


Fig. 4.8a

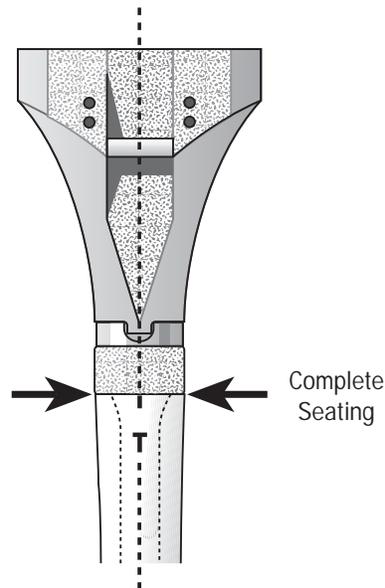


Fig. 4.8b

Use the locking pin to mate the distal femoral component to the Orthogenesis LPS tibial bearing through the hinged tibial insert bearing. Pass the locking pin through S-ROM hinged femoral component and the Orthogenesis LPS hinged tibial insert-bearing bushings (Fig. 4.9). It is important to note that the Orthogenesis LPS hinged tibial insert bearing chosen must match the S-ROM hinged femoral component. For example, if a small S-ROM hinged femoral component size is used, then the corresponding Orthogenesis LPS hinged tibial insert must be a small size component.

One method to secure the locking pin uses manual pressure to push the locking pin through until it “clicks” and locks into place. Another method uses forceps to squeeze the locking pin while pushing the pin until it is completely seated in the square cut-out in the Orthogenesis LPS distal femoral component. After the pin is seated, pressure is released from the forceps.

To ensure the pin is securely locked, push the lock pin from the opposite side of insertion and assess that it is captured and locked.

Closure

One of the most important aspects of this procedure is the soft tissue reconstruction. Attach the patellar tendon to the implant with heavy sutures or Mersilene tape. In order to further secure the patellar tendon, raise the medial or lateral or bilateral gastrocnemius flaps and suture them to the patellar tendon and the surrounding soft tissues.

The gastrocnemius flap(s) also fills the defect left by the biopsy tract excision and covers the implant. Use a split-thickness skin graft over the exposed muscle flap at the biopsy track excision site.

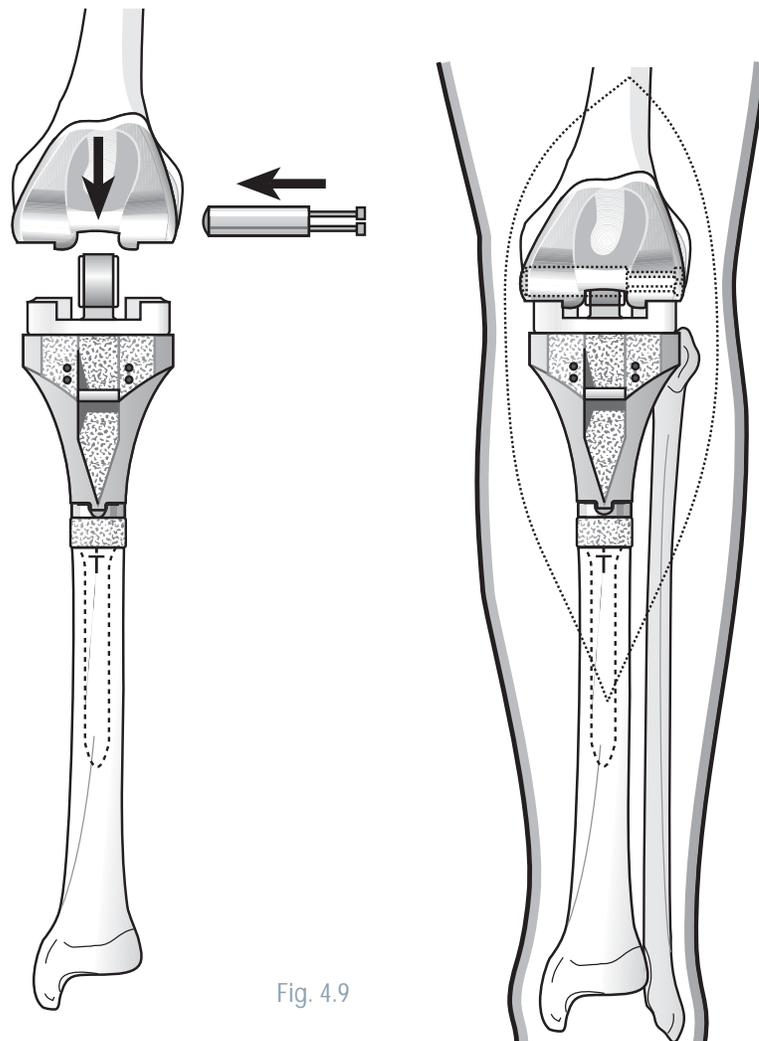


Fig. 4.9

If, due to grossly inadequate soft tissue integrity, flexion beyond 90 degrees causes luxation of the hinged insert bearing out of the base of the tibial component, the patient must have a knee brace postoperatively to limit flexion to 90 degrees. In such cases consider closing the wound with the knee in full extension.

Perform wound closure in multiple layers to minimize hematoma formation. Perform meticulous wound closure to minimize the wound complications that may preclude immediate physical therapy or other adjuvant oncologic treatments, such as radiation therapy and chemotherapy.

Typically close the wound over large bore drains to minimize hematoma collection.

POSTOPERATIVE CARE

Individualize postoperative care.

Many of these procedures involve extensive dissections. The patient's activity and weight-bearing status will depend on the extent of the surgery, the individual patient's needs and the implant's fixation type. In general, motion is not allowed for 8 to 12 weeks to allow for extensor mechanism healing and to minimize postoperative extensor lag.

The weight-bearing status is generally full with cemented stems. With cementless stems, the weight-bearing status can be individualized based on the patient's needs. However, it is suggested for patients not on chemotherapy to adhere to toe-touch weight bearing for eight weeks. For patients on chemotherapy, 12 weeks is suggested.

Preoperative Planning

Intercalary resection and reconstruction is a less common procedure; however, the Orthogenesis LPS allows for such reconstructions when necessary. The indications for the implant's use include soft tissue sarcomas that have invaded bone, mid-shaft locations for primary bone sarcomas, selected mid-shaft femoral metastatic lesions and selected non-union of the femur's mid-shaft. Contraindications include active sepsis and situations where insufficient remaining bone is present to support the reconstruction.

Other treatment options for these problems include use of segmental allografts fixed by intramedullary rodding or plate and screws, filling the defect with bone cement and supplemental fixation by IM rodding or plate and screw fixation and amputation.

The advantages of using the Orthogenesis LPS for intercalary reconstruction compared to other options includes the ability for immediate weight bearing and no reliance upon host bone for allograft healing for long-term durability. This healing may be compromised because of postoperative adjuvant treatment such as radiation therapy or chemotherapy.

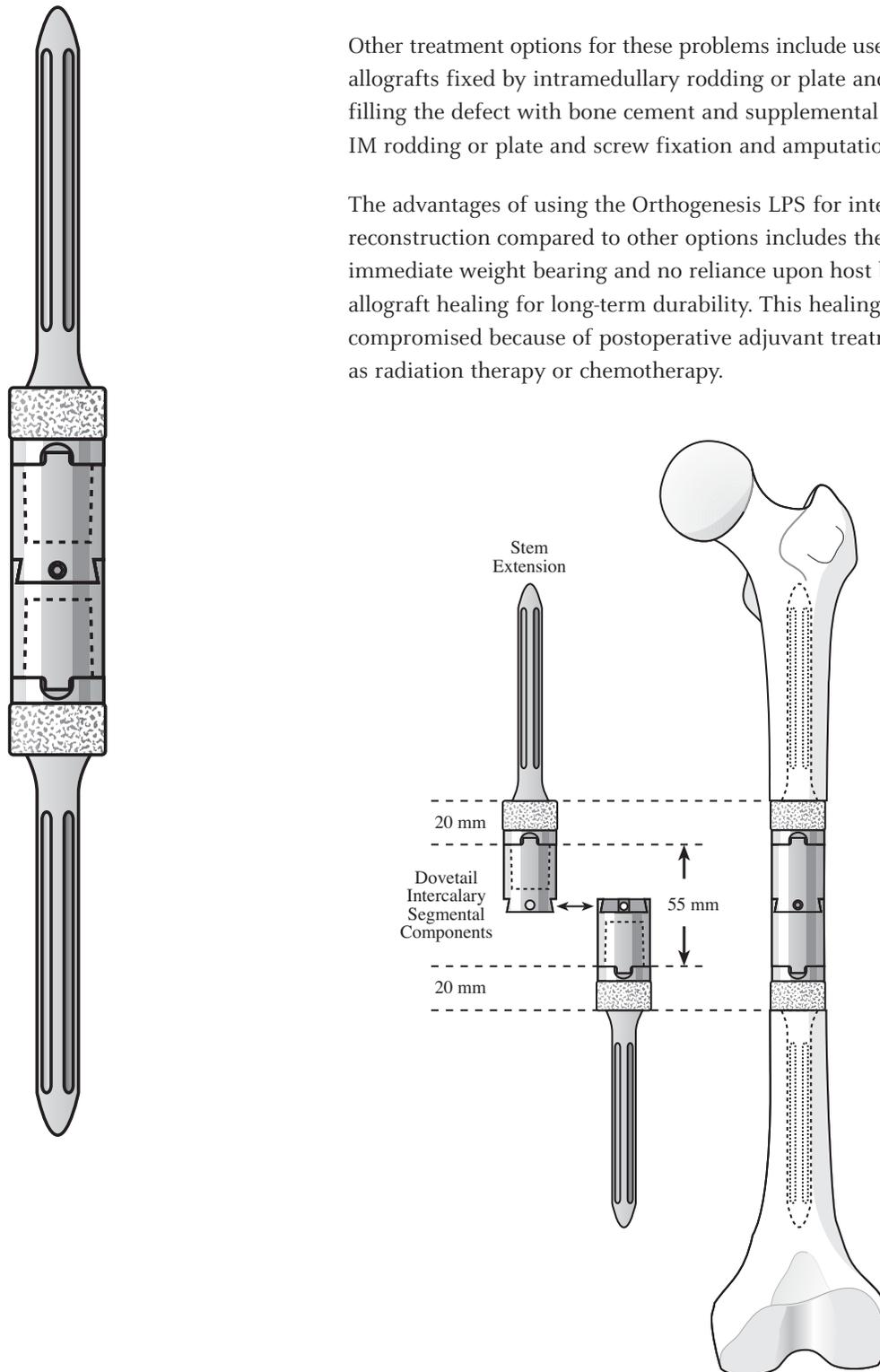


Fig. 5.1a

The system is modular and comprised of two medullary stems in the proximal and distal femur joined by Morse-taper locking with a two-piece intercalary (female/female) segmental component. If necessary, segmental segments can be added between the stems that adjust for resection length differences to restore leg lengths.

The following technique reviews the intended design and use of the instruments and implants for this procedure and provides a general framework. Use techniques that best meet the needs of each case, since each case is unique and with its own challenges. Consider the following recommendations for a successful outcome:

- Perform preoperative planning and radiographic analysis for every case. Use the Orthogenesis LPS templates for preoperative planning to assess the approximate resection levels, use of a segmental component (if needed) to restore leg length and the diameter and length of the femoral extension stems that are used to provide adequate fixation and stability in the remaining host femoral diaphyseal bone.

Exposure and Intraoperative Planning

Use a surgical approach that best achieves the exposure needed for bone resection. It is important to check leg length measurements and alignment prior to any bone resection. Take care during surgery to avoid stretch injury to the neurovascular structures. Use the preoperative imaging studies such as plain radiographs, CT scans and MRI to determine the resection levels.

The minimum intercalary femoral resection amount is 95 mm. This minimum resection level includes the 55 mm intercalary segment component length, plus the two 20 mm stem collar heights (Fig. 5.1a). If additional replacement length is needed, the 25 mm segmental component is the shortest segment available, making the 120 mm the next level of resection (Fig. 5.1b). Segmental components are then available in 5 mm increments alone or in combination with other segmental components to adjust leg length.

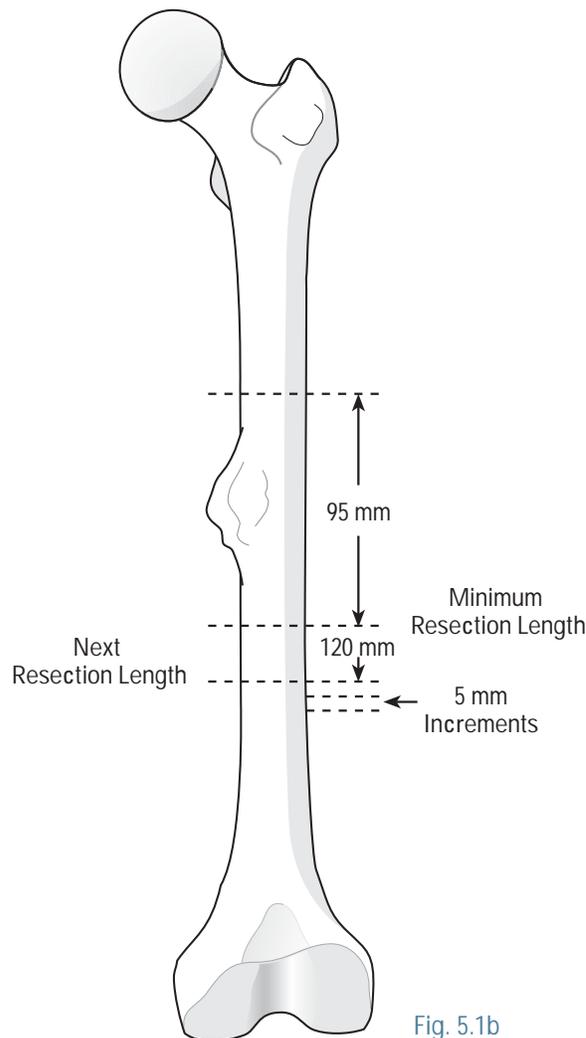


Fig. 5.1b

After exposing the femur, mark horizontal lines on the femur 1 cm above and below the anticipated resection levels to allow for a measurement to recreate leg lengths. Record this measurement prior to any resection and use it for future reference in the case (Fig. 5.2).

In order to restore proper rotational orientation after reconstruction, make vertical lines perpendicular to the horizontal lines to indicate the femur's anterior surface. Make these using an osteotome, electrocautery, marking pen or methylene blue.

Femoral Shaft Resections

Following tumor resection, create the proximal and distal osteotomies using an oscillating saw.

Once the bone and soft tissue resection has been performed, prepare the remaining host femur.

Femoral Medullary Canal Preparation

Ream the remaining femoral canals for the stem extension (Fig. 5.3). A straight IM reamer is recommended for the straight stem extension.

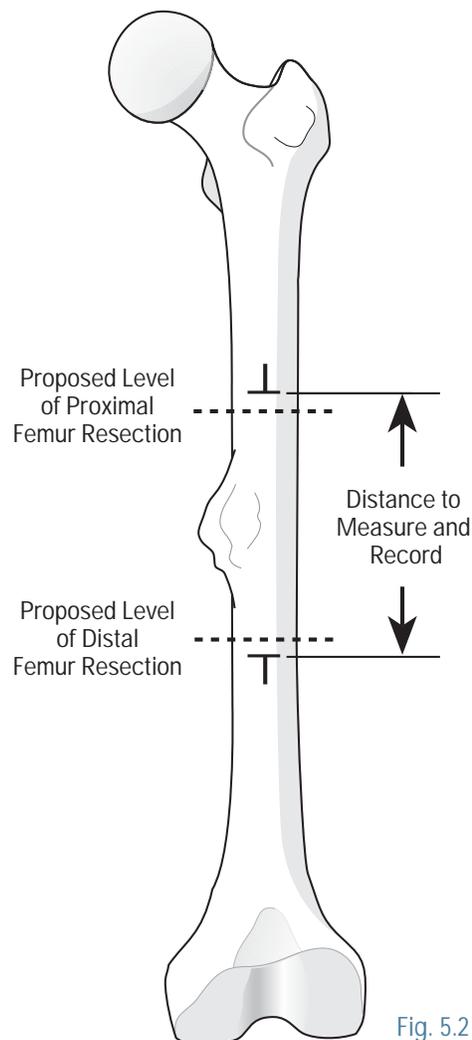


Fig. 5.2

Cemented Stem Application Options

If using a cemented stem, which is commonly the case in oncology use, choose a final stem that is smaller than the last reamer used to allow for a circumferential cement mantle around the stem. For example, if a 15 mm IM reamer was used last, an 11 mm stem would have a 2 mm cement mantle per side.

Do not ream the femoral canal to cortical bone for cemented application. Leave some cancellous bone for cement interdigitation.

Porous Stem Application Options

When using a porous-coated straight stem extension, under ream by .5 mm for press-fit application of the straight stems. If the remaining bone is fragile, consider line-to-line reaming.

Do not use a cementless application in patients with marked osteopenia or who are deemed to be at risk for an intraoperative fracture. Placement of a “prophylactic” cerclage wire around the proximal end of the remaining diaphysis may decrease the risk of intraoperative fracture during insertion of the press-fit stems or with fragile bone.

The Orthogenesis LPS stem straight stem extensions are available in 100 and 125 mm lengths with a range of diameters in 1 mm increments (see chart on page 52).

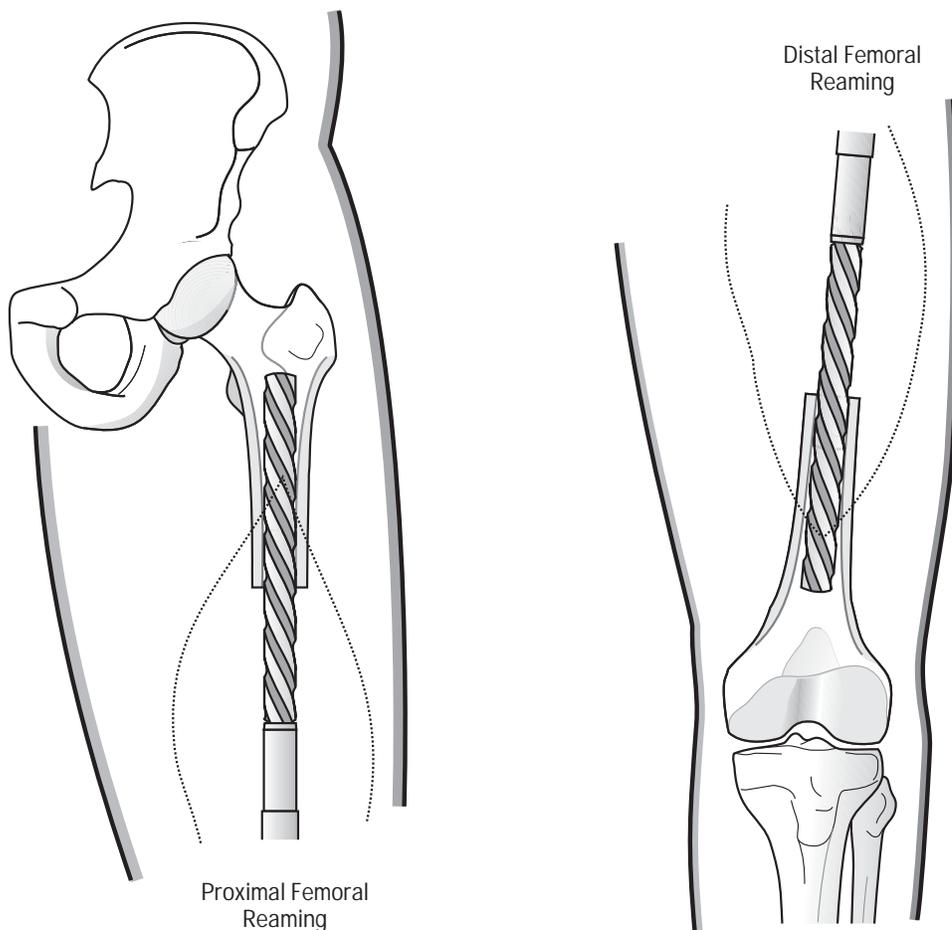


Fig. 5.3

Finish Preparation Using the Calcar Planer/Bevel Reamer

Once reaming is completed, prepare the resection to help assure proper stem extension fit. The calcar planer/bevel reamer produces an even cut surface and an angled relief (bevel) in the bone to match the stem extension flare under the collar. This helps to assure complete stem extension seating on the prepared diaphyseal bone surface.

Choose a calcar planer and insert a bevel reamer with a pilot that is at least 1 mm smaller than the last IM reamer used (Fig. 5.4) and insert it into the femoral canal. Sequential use of the bevel reamer with the pilots will prepare the bevel in the remaining bone with more efficiency and precision.

Attach the assembled planer and bevel reamer with a pilot to a power drill reamer using the appropriate adapter. The calcar planer/bevel reamer should be under power prior to planing the resection cut. This will minimize any resected

bone chipping caused by the calcar planer cutting blades. The following are recommendations using the calcar planer/bevel reamer with cemented or porous stems:

- For a porous stem extension, begin reaming with a calcar planer/bevel reamer with pilot that is at least 1 mm less than the final chosen implant and finish with a **final bevel reamer pilot that matches the final stem extension size**. For example, if a 15.5 mm stem is the chosen implant, the final bevel reamer with a pilot will be the 15.5 mm. Note, the pilot is undersized by .5 mm from the stated size. For example, a 15.5 mm pilot is 15 mm in diameter. This makes allowances for an under ream technique. If a 15 mm IM reamer was last used, the final bevel reamer with a pilot will still be 15.5 mm to match the implant.

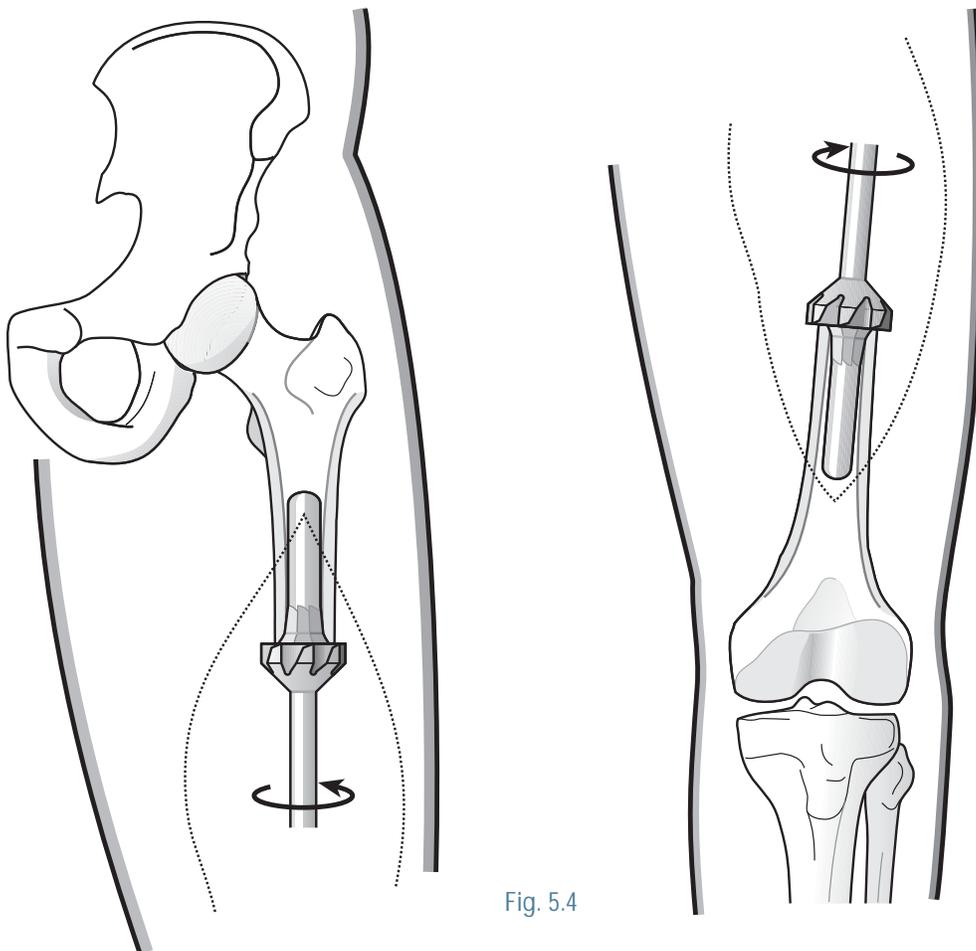


Fig. 5.4

- For a cemented stem extension, begin reaming with a calcar planer/bevel reamer with a pilot that is at least 1 mm less than the final IM reamer used and finish with a **final bevel reamer pilot that matches the final IM reamer size**. For example, if the last IM reamer used was 15 mm, the 15 mm bevel reamer pilot will be the final bevel reamer used irrespective of the stem size chosen to allow for an adequate cement mantle.

Trial Reduction

Following the femur preparation for the stem extensions, perform a trial reduction. Utilizing the preosteotomy measurement, assemble the appropriate diameter trial stem extensions, intercalary segmental trial and segmental component, if needed, that would fill the missing bone gap. An alternate measurement method is to use the resected femoral length to match total trial component length (Fig. 5.5).

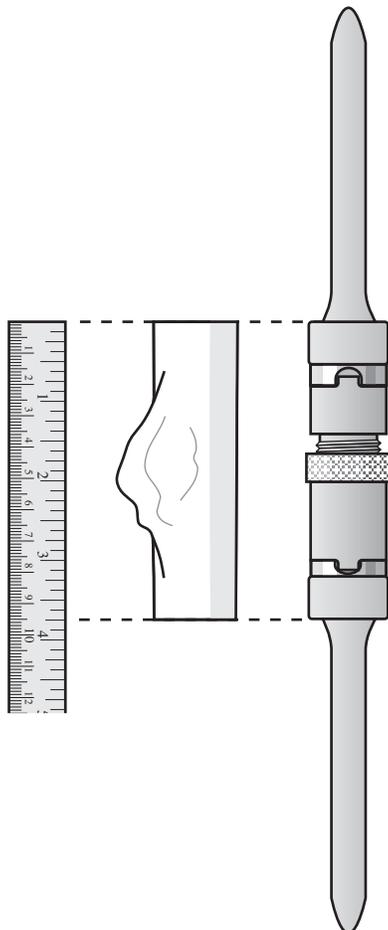


Fig. 5.5

STEM EXTENSIONS

CEMENTED STEMS (STRAIGHT)

Description
10 mm diameter x 100 mm length
11 mm diameter x 100 mm length
12 mm diameter x 100 mm length
12 mm diameter x 125 mm length
13 mm diameter x 125 mm length
14 mm diameter x 125 mm length
15 mm diameter x 125 mm length
16 mm diameter x 125 mm length
17 mm diameter x 125 mm length

POROUS STEMS (STRAIGHT)

Description
11.5 mm diameter x 100 mm length
12.5 mm diameter x 100 mm length
13.5 mm diameter x 100 mm length
13.5 mm diameter x 125 mm length
14.5 mm diameter x 125 mm length
15.5 mm diameter x 125 mm length
16.5 mm diameter x 125 mm length
17.5 mm diameter x 125 mm length
18.5 mm diameter x 125 mm length

CEMENTED STEMS (BOWED)

Description
11 mm diameter x 150 mm length
12 mm diameter x 150 mm length
13 mm diameter x 150 mm length
14 mm diameter x 150 mm length
15 mm diameter x 150 mm length
16 mm diameter x 150 mm length
17 mm diameter x 150 mm length
11 mm diameter x 200 mm length
13 mm diameter x 200 mm length
15 mm diameter x 200 mm length
17 mm diameter x 200 mm length

POROUS STEMS (BOWED)

Description
12.5 mm diameter x 150 mm length
13.5 mm diameter x 150 mm length
14.5 mm diameter x 150 mm length
15.5 mm diameter x 150 mm length
16.5 mm diameter x 150 mm length
17.5 mm diameter x 150 mm length
18.5 mm diameter x 150 mm length
12.5 mm diameter x 200 mm length
14.5 mm diameter x 200 mm length
16.5 mm diameter x 200 mm length
18.5 mm diameter x 200 mm length

NOTE: Reference the LPS Design Guide, Cat. No. 0612-35-050, for complete ordering information.

The trial stem should closely match the last IM reamer or it can be 1–2 mm smaller than the last IM reamer used. Utilize the stem trial size to provide enough stability to prevent “spinning” when performing trial reduction. **Insert all trial stems by hand and never impact them into the canal.** The intercalary trial should be unscrewed so that it is in two pieces. Each intercalary trial is then attached to each stem trial. The matching dovetails of the intercalary trials are slid into each other and the knurled locking ring is turned clockwise to lock the trial construct together (see fig 5.6). Alignment and limb restoration length are assessed. Once a satisfactory trial reduction is completed, mark the proximal distal femur in line with the anti-rotation slots. These marks are important to provide a reference for alignment when inserting the implanted stems in the femur.

If the soft tissues are excessively tight and the limb is lengthened, consider soft tissue releases, additional resection and/or varying the segmental trial (if used) to address this situation. If the limb length is short and needs to be lengthened, consider use of a segmental trial. Additional resection may be necessary if the segmental trial was not used previously and its use is greater than the amount of shortening. If any additional bone is resected, it is recommended that the femoral canal be reamed further distally and proximally followed by finishing preparation using the calcar planer/bevel reamer.

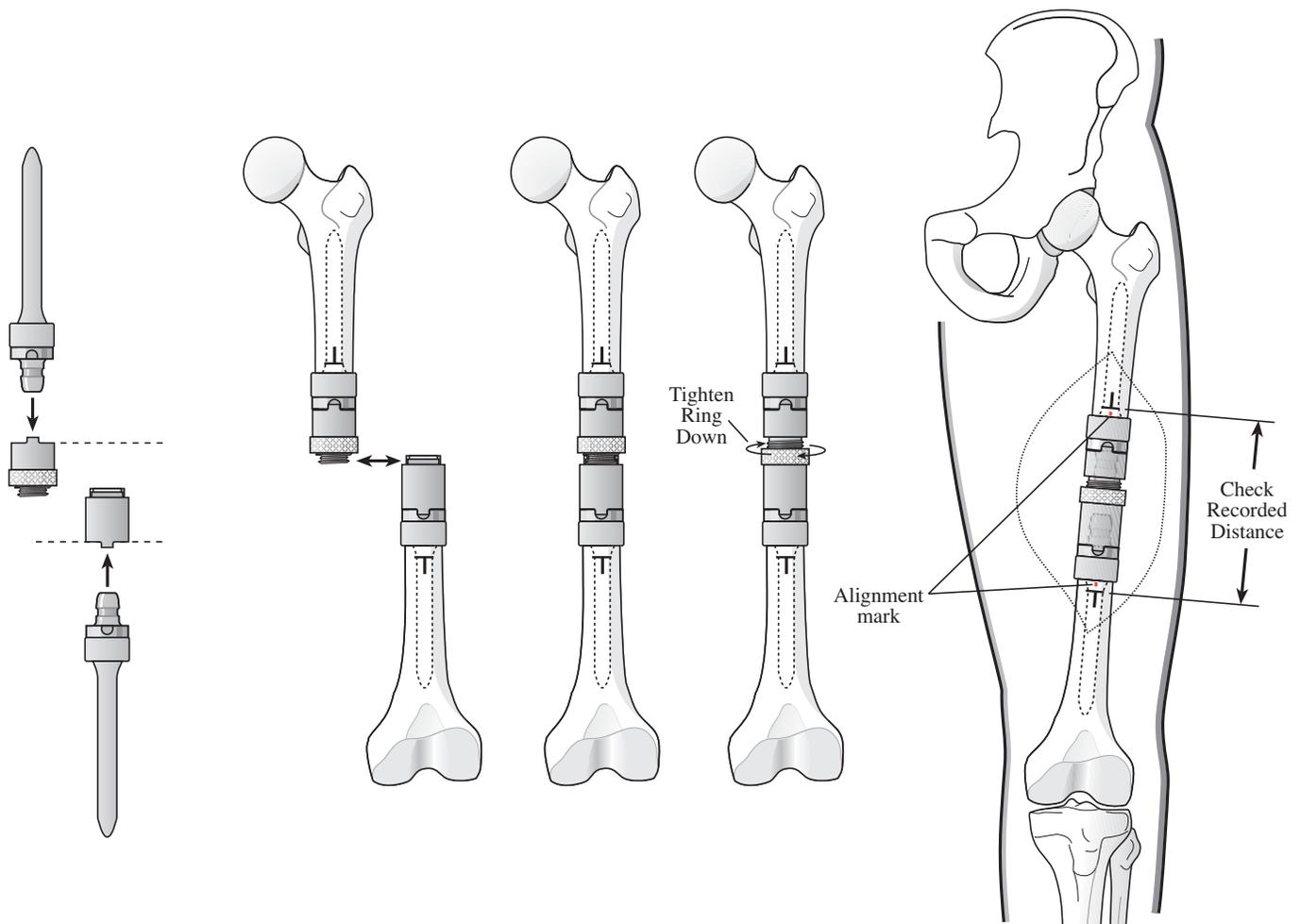


Fig. 5.6

Use the trial construct to mark proper rotational orientation of the components. To establish rotational alignment, center the anti-rotation slot (tab) on the femur's anterior aspect and mark the femur proximally and distally. These marks will serve as alignment guides on either side of the femur when inserting the stems to align the limb so that it is in the correct rotation after being coupled together through the intercalary segmental component (Fig. 5.6).

Implant Assembly and Insertion

After successful trial reduction, implant assembly and implantation can proceed.

On the back table, impact the male taper of each stem with the female taper of each dovetail intercalary component. Assemble the intercalary segment by hand with the selected stem and place the intercalary component on a sterile cloth on the back table with the stem pointing towards the ceiling. Place the impaction cap over the stem and use a mallet to impact the component tapers together with multiple blows to securely seat the components (see fig. 5.7). Repeat this procedure with the other selected stem and intercalary component.

If using Endurance bone cement to secure the femoral stems to the host bone, follow the manufacturer's recommended procedures to mix, deliver and pressurize the bone cement into the femoral canal openings.

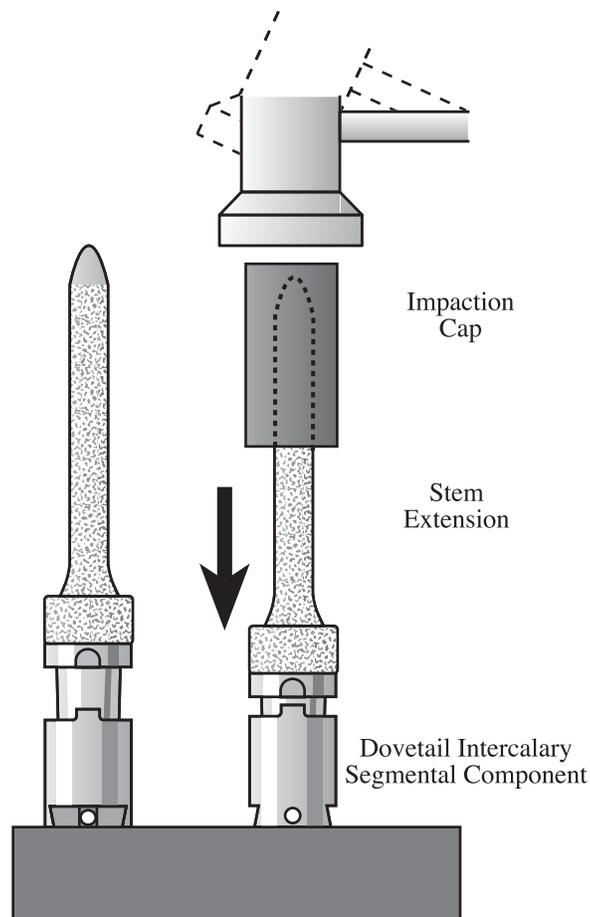


Fig. 5.7

Insert the stem/intercalary construct into the distal end of the femur, aligning the anti-rotation slot of the stem with the mark previously made on the anterior surface of the femur. Clean any cement from around the stem collar and bone junction. Hold the stem until the bone cement hardens. Align the second stem/intercalary construct made previously, and insert it into the femur's proximal end and hold it until the bone cement hardens. Again, remove excess cement from the stem collar and bone junction. Once both stem constructs are securely cemented in place, slide the two dovetail components of the intercalary device together (see fig. 5.8). Secure the components by inserting the locking pin into the threaded through hole (from either side) and tighten by turning the allen wrench (included with the device) in a clockwise direction until completely tightened (see fig. 5.9).

Closure

One of the most important aspects of this procedure is the soft tissue reconstruction. Soft tissue closure should completely cover the prosthesis. In oncologic applications, when soft tissues are resected to achieve a wide bone tumor margin, the amount of remaining soft tissue coverage is reduced. In this case, remaining musculature mobilization may be necessary to achieve proper soft tissue coverage around the prosthesis.

Perform wound closure in multiple layers to minimize hematoma formation. Perform meticulous wound closure to minimize wound complications that may preclude immediate physical therapy or other adjuvant oncologic treatments, such as radiation therapy or chemotherapy. On occasion, if there is significant soft-tissue fibrosis (e.g. from prior

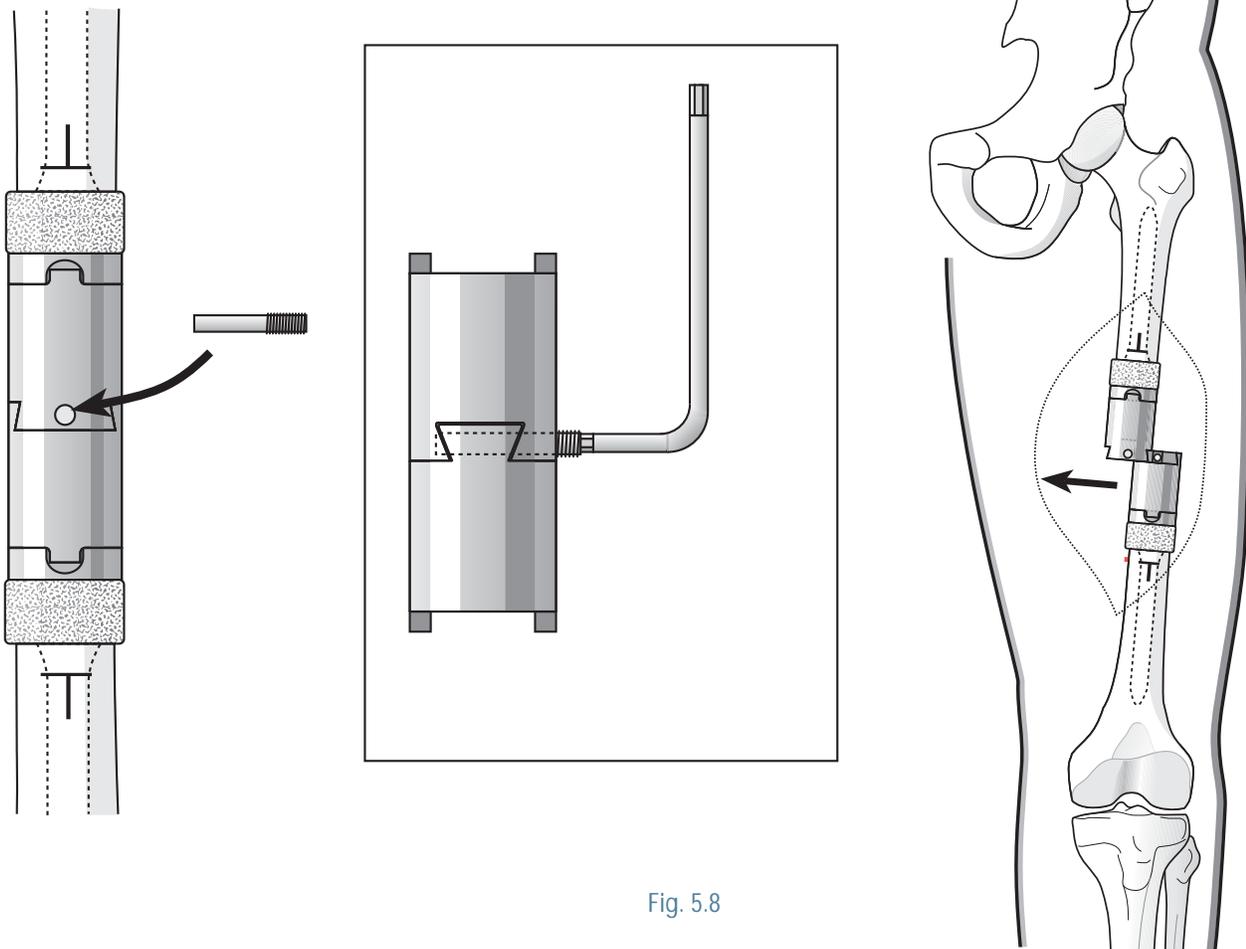


Fig. 5.8

surgery, trauma, irradiation, etc.) then extremity shortening may be necessary to minimize soft tissue tension and allow wound closure without undue tension. Typically close the wound over large bore drains to minimize hematoma collection.

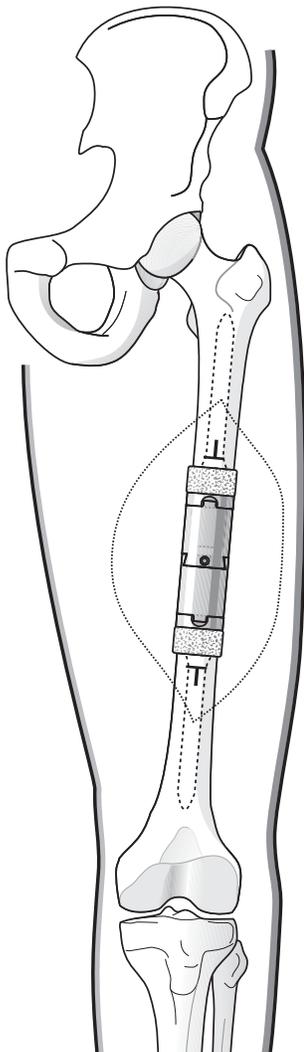


Fig. 5.9

POSTOPERATIVE CARE

Individualize postoperative care.

Many of these procedures involve extensive dissections. The patient's activity and weight-bearing status will depend on the extent of the surgery, the individual patient's needs and the implant's type of fixation.

The weight-bearing status is generally full with cemented stems. With cementless stems, individualize the weight-bearing status based on the patient. However it is suggested for patients not on chemotherapy to adhere to the toe-touch weight bearing for eight weeks. For patients on chemotherapy, 12 weeks is suggested.

TECHNIQUE TO DISASSEMBLE IMPLANT TAPERS

Although the Orthogenesis LPS is designed for secure implant taper locking, it is possible to disassemble the tapers if needed. The disassembly tool is designed to separate the tapers quickly and efficiently.

The disassembly tool's jaws are aligned with the implant's anti-rotation slots. It is critical to match the disassembly instrument's "half-moon" shape with the implant anti-rotation slot's "half-moon" shape. Once aligned, squeeze the disassembly tool's handle and push down quickly on the disassembly tool (**Fig. 6.1a**). The rotational force generated in the anti-rotation slots will produce adequate force to disassemble the taper junction (**Fig. 6.1b**).

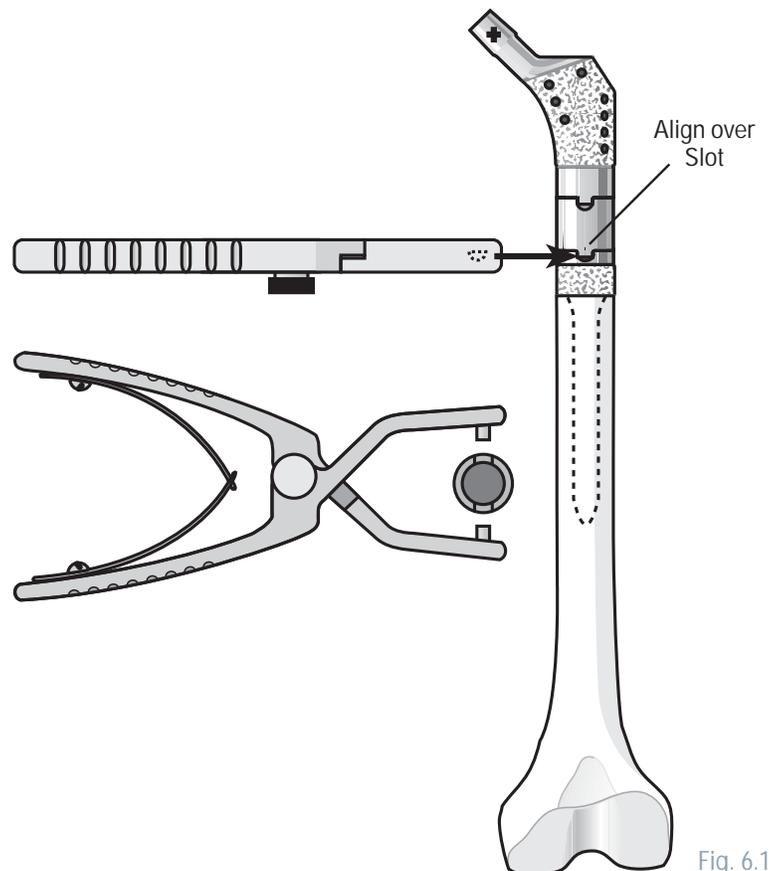


Fig. 6.1a

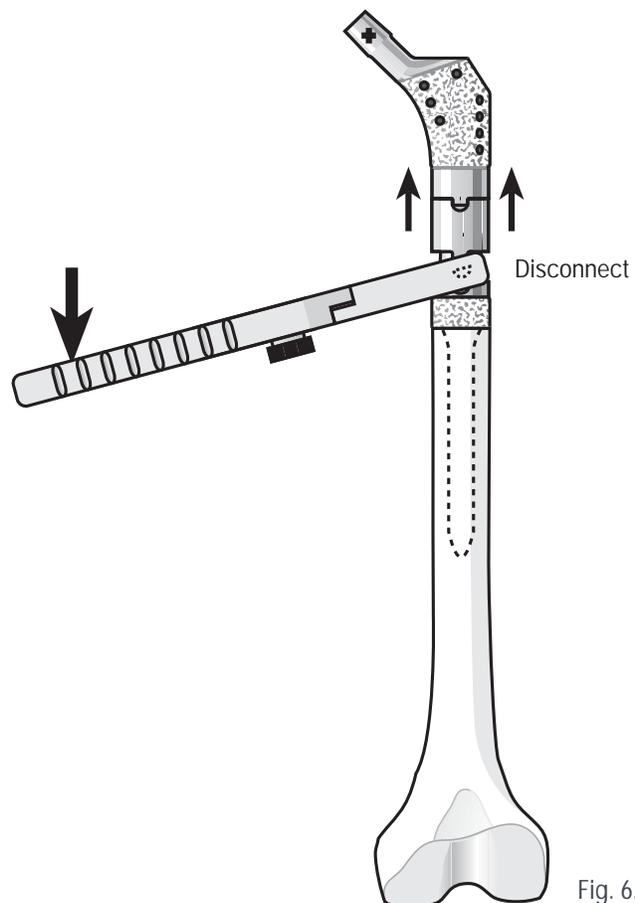


Fig. 6.1b

IMPORTANT

This essential product information sheet does not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information.

INDICATIONS:

The Orthogenesis LPS is intended for use in replacement of the mid-shaft portion of the femur, proximal, distal and/or total femur, and proximal tibia, especially in cases that require extensive resection and replacement. Specific diagnostic indications for use include:

- malignant tumors (e.g., osteosarcomas, chondrosarcomas, giant cell tumors, bone tumors) requiring extensive resection and replacement;
- patient conditions of noninflammatory degenerative joint disease (NIDJD), e.g. avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis, requiring extensive resection and replacement;
- revision for failed previous prosthesis cases requiring extensive resection and replacement;
- severe trauma requiring extensive resection and replacement.

The Orthogenesis LPS is also intended for use in bone loss post-infection, where the surgeon has elected to excise the bone and replacement is required.

The distal femoral and tibial components, tibial stems and non-porous coated femoral stems are intended for cemented use only.

CONTRAINDICATIONS:

1. Active local or systemic infection.
2. Loss of bone or musculature, osteoporosis, neuromuscular compromise or vascular deficiency in the affected limb in sufficient degree to render the procedure unjustifiable (e.g., absence of musculoligamentous supporting structures, joint neuropathy).

NOTE: Diabetes, at present, has not been established as a contraindication. However, because of the increased risk for complications such as infection, slow wound-healing, etc., the physician should carefully consider the advisability of knee replacement in the severely diabetic patient.

WARNINGS AND PRECAUTIONS:

Components labeled for "Cemented Use Only" are to be implanted only with bone cement. The following conditions tend to impose severe loading on the affected extremity thereby placing the patient at higher risk of failure of the prosthesis: obesity or excessive patient weight, manual labor, active sports participation, high levels of patient activity, likelihood of falls, alcohol or drug addiction, tumors of the supporting bone structures, other disabilities, as appropriate.

ADVERSE EVENTS:

The following are the most frequent adverse events after a prosthetic implant surgery: change in position of the components, loosening, bending, cracking, fracture, deformation or wear of one or more of the components, infection, tissue reaction to implant materials or wear debris; pain, dislocation, subluxation, flexion contracture, decreased range of motion, lengthening or shortening of leg caused by improper positioning or possible loss of limb if complications occur, looseness or wear of components; fractures of the femur or tibia, Cardiovascular disorders and thromboembolic disease.

For more information about the Orthogenesis Limb Preservation System, visit our web site at www.jnjgateway.com/orthogenesis.



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