

Can Plain X-Rays Generate Reliable Data for Identification and Fabrication of Custom Implants?

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INTRODUCTION

Accurate data of the dimensions of the proximal femur are available from x-rays when specific techniques are followed. Three calibrated x-rays are required: a full pelvis view which includes both hips and anterior-posterior view of the proximal two-thirds of the affected femur and a direct lateral view of the end of the proximal two-thirds of the affected hip.

Each view requires a specific magnification marker positioned at the level of the bone near the greater trochanter.

METHOD

This particular x-ray technique has been developed to facilitate custom fabrication through the X-Press™ process provided by Orthogenesis. The reproducibility of this technique cannot be attested to utilizing other fabrication processes.

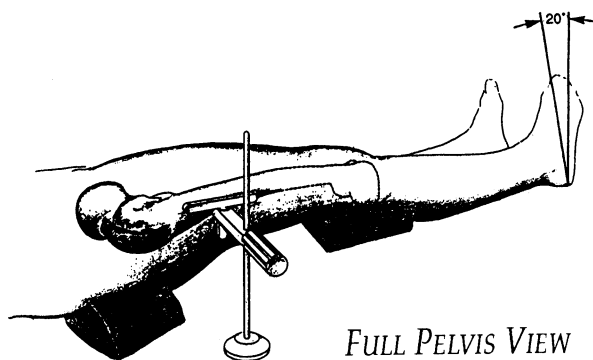
56 Custom X-Press™ titanium stems have been fabricated and implanted based on the x-ray techniques described here. Ten stems have had a HA proximal surface, 40 stems a beaded, commercially pure titanium surface, and six stems with surface geometry consisting of proximal steps with HA and distal flutes.

TECHNIQUE

Calibrated x-ray views are required for this procedure. Marking the patient's skin at the level of the greater trochanter prior to making the first x-ray simplifies location for additional needed x-rays.

FULL PELVIS VIEW

Patient Position: patient lies supine with both legs extended and the pelvis near level both with the plane of the film and in the patient's transverse plane. In most cases, patients feet are pointed internally by approximately 15-20° (less if the patient is unable



FULL PELVIS VIEW

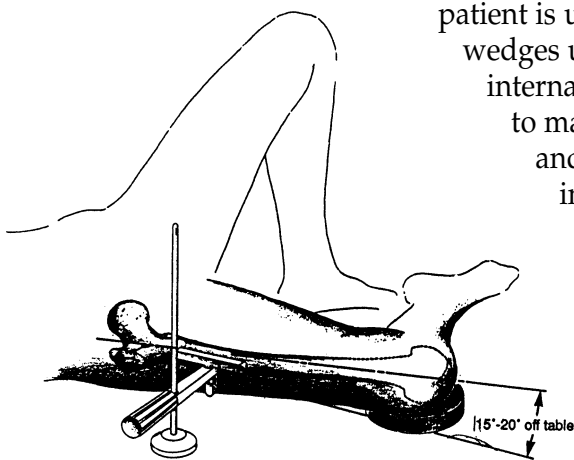
to internally rotate without excessive pain) to orient the femoral neck parallel to the film plane. The entire length of the femur must also be approximately parallel with the film plane. Wedges of foam blocks may be used under the knee to maintain the parallel orientation between the length of the femur and the plane of the film. Place the magnification marker at the level of the femur between the patient's legs as proximally as possible, insuring that it appears in the imaging area.

X-RAY CRITERIA

The entire width of the pelvis, both acetabula and both proximal femora should appear in the x-ray image. The femora should be approximately parallel to each other, and at 90° to a line connecting the two acetabula. The lesser trochanter should be invisible or nearly invisible (with less than 5 mm of exposure), as it is posterior to the femur when the femur is rotated properly. The three balls of the magnification marker should be clearly visible.

PROXIMAL FEMUR VIEW

Patient Position: Place the patient exactly as he or she was positioned for the full pelvis view. Correct internal rotation of the affected femur is critical in this view. If the



PROXIMAL FEMUR VIEW

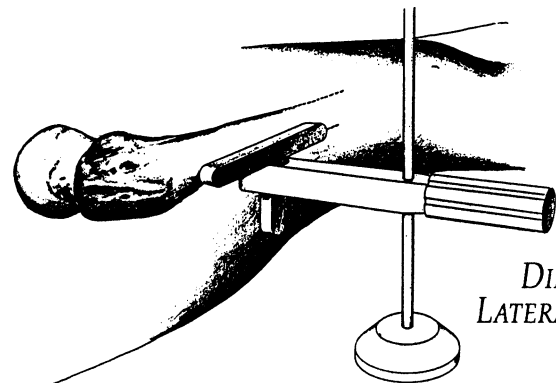
patient is unable to internally rotate without excessive pain, place foam wedges under the affected hip, raising that side of the body until 20° of internal rotation is realized. Place foam blocks or wedges under the knee to maintain the parallel orientation between the length of the femur and the table. Reposition x-ray equipment to extend the view to include the proximal two-thirds of the femur rather than the full width of the pelvis.

X-RAY CRITERIA

The view should include the entire affected acetabulum and the proximal two-thirds of the femur. The lesser trochanter must be invisible or nearly invisible (with less than 5 mm of exposure), as it is hidden by the internal rotated femur. The three balls of the magnification marker should be clearly visible.

DIRECT LATERAL VIEW

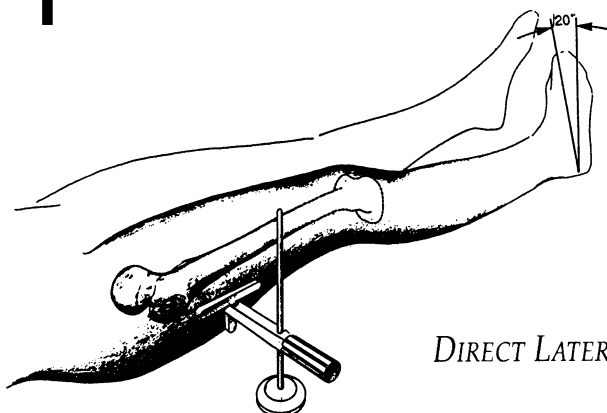
Patient Position: Patient lies supine. The patient's unaffected leg is flexed and the foot is placed flat on the x-ray table. The affected leg is flexed and externally rotated so that the ankle touches the surface of the table. Place foam blocks under the knee to maintain an angle of 20° between the length of the femur and the table. If the patient is unable to flex and externally rotate without pain, place foam wedges or blocks under the unaffected hip, rotating the entire pelvis until the knee is lowered into position. A sandbag may be used to steady the knee against the foam. Place the magnification marker at the level of the femur against the rotated anterior surface of the patient's leg. Orient the x-ray equipment to include the acetabulum and the proximal two-thirds of the femur.



DIRECT LATERAL VIEW

X-RAY CRITERIA

The view should again include the entire acetabulum and the proximal two-thirds of the femur on the affected side. The lesser trochanter should be clearly visible protruding from the posterior side of the rotated femur. The three balls of the magnification marker should be clearly visible.



DIRECT LATERAL VIEW

INDICATIONS: *Routine cementless primary and many non-complicated revision cases.*

POSSIBLE CONTRA INDICATIONS

Extreme bony defects and abnormalities might require more detailed imaging of the hip, i.e. MR1.

SURGICAL TECHNIQUE

With the patient placed in a true lateral position, a standard posteriolateral incision is made. Routing soft tissue dissection is carried out. A subcapital osteotomy is made corresponding to preoperative templating. The cut through the femoral neck is an oblique angle to match the implant neck-stem transition geometry. The trochanteric fossa is identified and perforated with a punch or intramedullary initiator. To open up the proximal femur that will allow the initial cylindrical reamers to pass directly down into the isthmus of femoral canal in a neutral orientation.

Distal reaming is carried out in half millimeter increments and when the appropriate cortical chatter is encountered, and intraoperative cortical chatter is encountered, an intraoperative x-ray is taken with the distal reamer in place. This is done to ensure that we are indeed in a neutral position and we have achieved proximal canal filling. (Note: it is better to take in intraoperative x-ray while it is still possible to correct for malalignment and/or undersizing as opposed to waiting for a postoperative view.

The initial custom broach, designed for this implant only is introduced pushing its lateral border in the direction of the greater trochanter. The initial broach is removed, and the final broach is introduced in the same manner.

Final broach designed specifically for this implant only prepares the canal to accept the implant and is intended for use during the trial reduction. Often an AP x-ray is taken to assess the position of the broach.

Upon complete insertion of the broach, there should be no rotary instability, A trial reduction is carried out to determine proper neck length and joint stability.

After removal of the trial broach, lavage is carried out on the proximal femur with antibiotic solution and final insertion of the custom implant.

Postoperative x-rays will demonstrate some areas of cancellous bone between cortex and prosthesis. A six-week postoperative x-ray should be taken in the same position as the original preop to assess fit and fill measurements of the device. (Note: initial post op done in recovery room will have the patient in a slightly different position as compared to the preoperative x-rays taken. This can result in some differences in calculations of fit and fill measurements.

POSTOPERATIVE RESULTS

56 stems have been done to date with follow up between three months and one year average being six months. Ten stems have had a HA coating, 40 stems a porous beaded coating, and six stems a surface geometry consisting of proximal steps with HA and distal flutes. Short term comparison reveals no difference between x-ray image and/or clinical results. There has been no anterior thigh pain and no subsidence seen to date.

One stem was not used due to an intraoperative decision which evaluated the bone quality to be too osteoporotic and a standard cemented stem was used in its place.

Certainly long term clinical follow up is necessary to make any definitive statements. However, early clinical comparison to other cementless devices used by this surgeon have found the X-Press™ Custom technique to offer improved pain relief with no revision to date and no ending revisions anticipated in the near future. Long term follow up will demonstrate if there is any clinical difference between different surface coatings. At this point all three surface geometries appear to be equal.