Patient-Specific Imaging and Missed Tumors: A Catastrophic Outcome

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Abstract

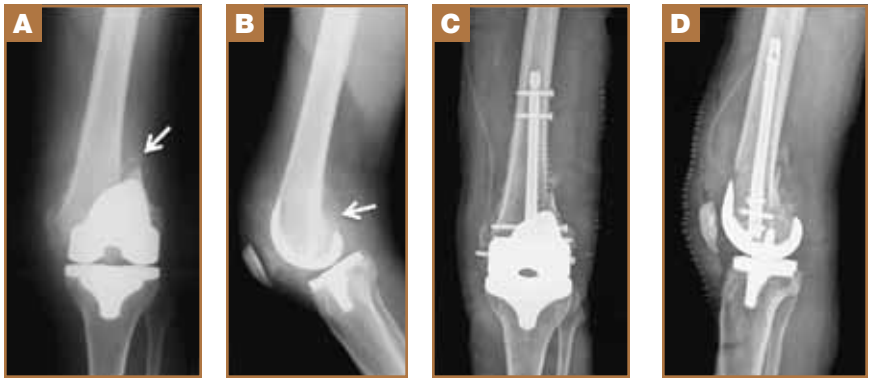
Patient-specific instrumentation (PSI) is a relatively new technology aimed at increasing the accuracy and efficiency of total knee arthroplasty (TKA). Its premise is reliant upon preoperative imaging techniques to acquire detailed measurements of a patient's distal femur and proximal tibia. Although a limited number of studies in the current literature have begun to critically evaluate this promising technology, a number of potential controversies exist. We present 2 patients with radiographic evidence of musculoskeletal neoplasms present on initial preoperative imaging that were not recognized prior to placement of patient-specific total knees. The expanding role of non-diagnostic imaging in TKA is examined, and we suggest guidelines for prevention of further devastating outcomes.

Technology in total knee arthroplasty (TKA) continues to evolve in efforts of improving patient outcomes, while at the same time minimizing healthcare costs and complication rates. The widespread success of TKAs coupled with an aging population has further created a rising demand for knee replacements.[1] As previous studies have shown restoration of a neutral mechanical axis to be paramount in achieving optimal results,[2-6] patient-specific instrumentation (PSI) is an emerging technology aimed at increasing the accuracy and precision of component alignment. Additionally, proponents argue this technology can result in shorter operative times as well as a reduction in necessary intraoperative equipment, thus allowing the surgeon improved efficiency and patient volume.

Detailed measurements of a patient's distal femur and proximal tibia are obtained preoperatively using full-length radiographs, computed tomography (CT), or magnetic resonance imaging (MRI) of the affected knee. The images are sent to the implant manufacturer where a computer–based templating program creates a patient-matched guide to determine proper bony resection, component size, alignment, and rotation. Depending on the specific implant system selected, the guide can then be used intraoperatively to either facilitate pin placement for traditional cutting blocks, or incorporate the necessary cutting slots into the guide itself. This eliminates the need for intramedullary or extramedullary alignment rods, and has been shown to reduce the surgical procedure by as many as 21 steps.[7]

While some early results of PSI are encouraging,[8-10] the requisite preoperative imaging needed to design the custom guides presents a number of potential controversies, including payment for the non-diagnostic imaging and having an 'official' read performed by a radiologist. In contrast to studies, which are obtained as part of a diagnostic workup, imaging for PSI is utilized in patients where a diagnosis (ie, osteoarthritis) has already been made and obtaining measurements for component templating is considered the primary objective.

Figure 1. Radiographs demonstrating a left periprosthetic supracondylar femur fracture with associated soft tissue mass (A, B) treated with a short retrograde intramedullary nail through the femoral component (C, D). The underlying aggressive lytic osseous neoplasm has eroded through the anterior metaphyseal cortex.



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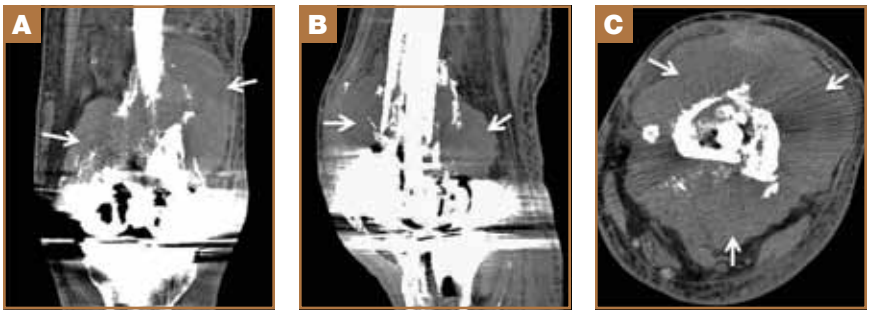

Figure 2. Computed tomography coronal (A), sagittal (B), and axial (C) images (without contrast) demonstrating a large heterogeneous soft tissue mass surrounding a pathologic supracondylar femur fracture in the setting of recent TKA.

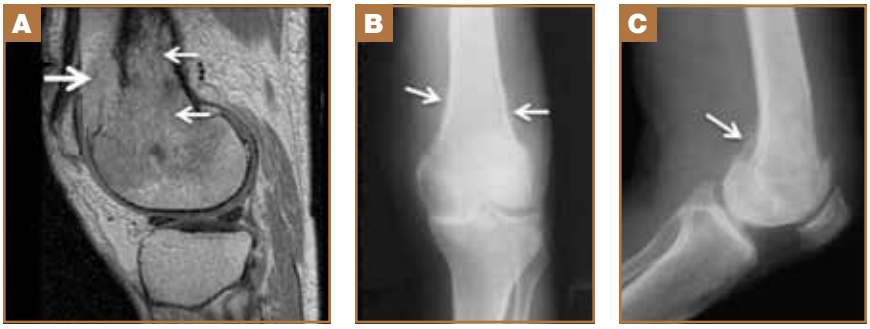

Figure 3. Preoperative sagittal fast spin-echo proton density (FSE PD) MRI (A) and radiographs (B, C) of the left knee prior to TKA showing a destructive, marrow replacing lesion of the distal femur. Marrow replacement and anterior cortical destruction can be appreciated on MRI. AP and lateral radiographs are notable for a subtle but aggressive periosteal reaction at the femoral metaphysis (B, C).

We present 2 cases in which preoperative advanced imaging demonstrated abnormalities concerning for malignancy; however, these findings were missed in both cases. The patients went on to have knee replacements, resulting in widespread contamination of the surgical field, and near immediate postoperative failure. We discuss the role of non-diagnostic imaging in TKA and PSI, and suggest guidelines for the prevention of further devastating outcomes. The patients provided written informed consent for print and electronic publication of this case report.

Case Series

Case 1

A 74-year-old male with a history of left knee osteoarthritis underwent a patient-specific TKA in June 2012 at a local community hospital. His past medical history was significant for diabetes, hypertension, and a cerebrovascular accident with residual mild left-sided weakness. He had no prior history of malignancy or other musculoskeletal abnormalities. In preparation for the procedure, a preoperative MRI was performed and sent directly to the implant manufacturer for component design. The surgery was uneventful and the patient was discharged home without complication shortly thereafter.

Two weeks postoperatively, he was participating in physical therapy when he experienced an episode of immediate left thigh pain and swelling with passive full extension. After his symptoms did not improve over the following week and he remained unable to bear weight on the affected leg, the patient presented to his surgeon for further evaluation. Radiographs demonstrated a left periprosthetic supracondylar femur fracture for which he was then treated with a short retrograde intramedullary nail through the femoral component (**Figure 1**). Once again, no intraoperative abnormalities were noted and the patient was treated with routine postoperative care.

Over the next 2 months, he continued to have significant left knee pain, swelling, and tenderness to palpation. On serial radiographs, the treating physician noted what was considered to be early periosteal callus formation with evidence of osseous nonunion. In September, the continued swelling was thought to represent hematoma formation and an aspiration was attempted. No fluid was obtained, prompting the surgeon to order a CT scan of the left lower extremity. Imaging demonstrated a large heterogeneous 9 cm x 11 cm x 11 cm soft-tissue mass with central necrosis surrounding a pathologic supracondylar femur fracture (**Figure 2**). The bone around the fracture had a moth-eaten appearance with no definite matrix appreciated, concerning for malignancy.

The patient underwent an open incisional biopsy of the lesion through an anterior suprapatellar approach in the beginning of October 2012, which confirmed the diagnosis of high–grade intramedullary osteosarcoma. Further imaging of the chest revealed multiple bilateral pulmonary nodules consistent with metastatic disease, representing a new finding compared to his initial preoperative chest x-ray from May 2012. Additionally, several small hypermetabolic lesions suspicious for malignancy were found within the brain on whole body positron emission tomography.

He was then referred to our institution for further evaluation. A review of the initial preoperative left knee MRI performed in May 2012 confirmed a destructive marrow-replacing lesion with loss of a portion of the anterior cortex present within the distal femur prior to placement of the patient-specific TKA (**Figure 3**).

Case 2

In September 2012, an active 86-year-old male underwent a left patient-specific TKA secondary to osteoarthritis at an outside hospital. His past medical history was significant for lympho-

plasmacytic lymphoma (Waldenstrom's macroglobulinemia) and transitional epithelial bladder cell carcinoma, which was diagnosed in 2007 and subsequently treated with systemic chemotherapy, including rituximab and chlorambucil. Following treatment, there was no evidence of recurrent disease on surveillance CT scans of his chest, abdomen, and pelvis. Additionally, his most recent immunoglobulin levels and cystoscopy 1 year prior in 2011 were both found to be normal. At baseline, he was active in his community and living independently.

In preparation for his knee replacement, a preoperative left knee MRI was performed and sent to the device manufacturer for component design. At the time of surgery, a mini mid-vastus approach was utilized, and a fracture of the medial epicondyle was found intraoperatively. This was felt to be stable and secured with a transosseous suture. A review of the operative report was otherwise unremarkable for any other abnormal findings. One week following surgery, the patient had continued pain and swelling in his left leg, prompting an ultrasound to rule out deep vein thrombosis. Although no deep vein thrombosis was found, a 7.4 cm hypoechoic, heterogenous mass located about the medial distal femur was visualized and felt to represent hematoma.

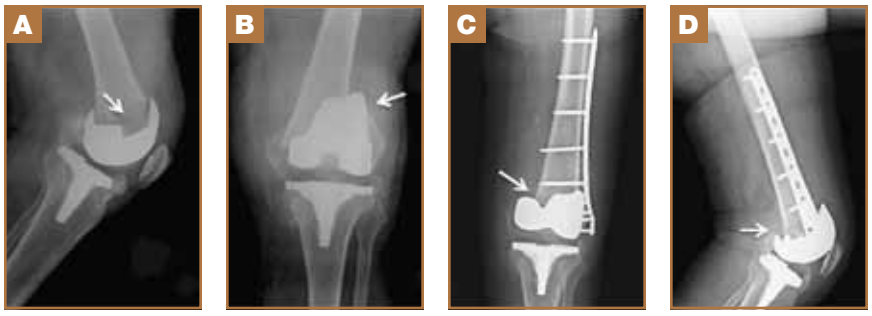

Figure 4. Periprosthetic supracondylar femur fracture (A, B) that underwent fixation with a 9-hole LISS plate. Shortly following surgery, there was near immediate loss of fixation (C, D).

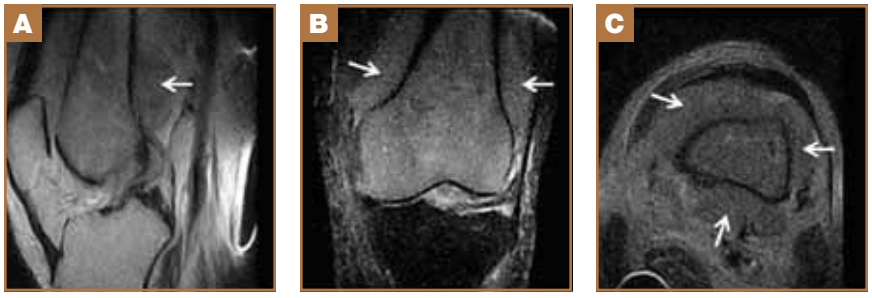

Figure 5. Preoperative left knee sagittal fast spin-echo T2-weighted (FSE T2W) MRI (A), coronal STIR (B), and axial FSE T2W (C) MRI images demonstrating a large marrow replacing lesion within the distal femur with cortical thinning and a circumferential soft tissue mass. Notice how normal fatty marrow looses signal on the STIR sequence while tumor remains pathologically bright.

Three weeks postoperatively, the patient was recovering in a rehabilitation center when his left leg buckled, causing him to fall. He experienced immediate pain and was unable to bear weight. Radiographs demonstrated a comminuted distal femur periprosthetic fracture with a displaced medial epicondyle fragment. He underwent open reduction and internal fixation of his distal femur through dual incisions medially and laterally with application of a lateral 9-hole stainless steel less invasive stabilization system (LISS) plate (Synthes Inc, West Chester, Pennsylvania). There were no complications or abnormalities noted in the operative report. However, subsequent radiographic and clinical evaluations demonstrated near immediate loss of fixation and significant hardware failure (**Figure 4**).

At this point, the patient was referred to our institution for further evaluation. A review of the initial preoperative left knee MRI from July 2012 demonstrated a large marrow-replacing lesion within the distal femur that was hypointense on T1 and hyperintense on T2 sequences. Marked cortical thinning of the entire distal femur was present, as well as a circumferential soft tissue mass extending from the superior pole of the patella proximally beyond the boundaries of the imaging field (**Figure 5**).

Discussion

PSI represents a promising technology aimed to improve accuracy, precision, and operative efficiency in TKA. Although further randomized controlled trials are currently ongoing to better assess clinical outcomes,[11] the implementation of any new technologies presents healthcare providers with additional and often unforeseen challenges. One such challenge associated with PSI is the need for advanced preoperative imaging, resulting in significant cost and resource utilization to our healthcare system. In some cases, improper or inadequate evaluation of this non-diagnostic imaging can result in devastating consequences, as demonstrated by the 2 cases above. A review of the literature found no prior studies that have examined the role of non-diagnostic imaging in patient-specific TKA.

Preoperative imaging performed for component templating differs from traditional studies in that it is not intended to be diagnostic in purpose. Instead, a diagnosis such as osteoarthritis has already been established, and without proper protocols in place, these studies may not be critically evaluated by the ordering physician. Furthermore, if the study is sent directly to the implant manufacturer, it may circumvent evaluation by the institution's radiology department. In an ideal scenario, all images would be followed-up by the ordering physician, however, these cases demonstrate this is not always performed.

Although MRI is increasingly used for surgical planning and stereotactic guidance for orthopedic procedures, a PubMed search revealed no published protocols describing the review of these limited studies for unexpected findings. On review of 601 asymptomatic patients and 132 patients with knee osteoarthritis who underwent at least 1 limited knee MRI scan for research purposes, Grainger and colleagues[12] found that 2.3% of healthy participants and 2.3% of patients with osteoarthritis had imaging findings which warranted further investigation to exclude malignancy. This call-back population included 4 subjects with marrow replacement requiring work-up and 1 subject who was found to have myeloma.[12] While this is not a large percentage, it is certainly significant.

Most surgical planning studies are only a single sequence in a single plane as opposed to the typical mutiplanar, multisequence diagnostic musculoskeletal MRI protocols. As an example, Smith and Nephew requires a single 2D turbo spin-echo pulse sequence in the sagittal plane as a planning study for its Visionaire Patient Matched Instrumentation system. While not the most sensitive sequence for detection of marrow replacement,[13] most marrow lesions will be detectable on this sequence. On a 1.5 T Philips Achieva Scanner (Philips Healthcare, Andover, MA), this protocol takes a mere 7.09 seconds to complete, which is less than 25% of the time of a diagnostic MRI examination of the knee. An experienced radiologist can review this sequence for unexpected findings beyond those of osteoarthritis (ie, marrow lesions, aneurysms, soft tissue masses, pathologic fractures, atypical synovitis) in less than 1 minute. Thus, the burden on the interpreting physician is minimal.

From a cost standpoint, adding cross sectional planning scans to a procedure will necessarily increase cost, both in the initial scan obtained and in costs associated with further characterization and follow-up of incidental lesions. However, limited scan time for planning studies warrants limited technical billing codes. Given that the review of these images be targeted to unexpected findings, limited professional fees are appropriate as well. Work-up of incidental findings may be more costly.

While there may be a small cost associated with formal review of these planning images, the price associated with bypassing any assessment and missing malignant disease is far greater. We submit that it is in the patient's best interest for all imaging, including limited planning scans, to be reviewed formally by either a radiologist or appropriately trained ordering physician to ensure that lesions incidental to the purpose of the scan are not missed.

PSI continues to evolve in the orthopedic surgeons' pursuit of improved outcomes in TKA. These cases represent a cautious reminder of the potentially damaging results that can occur with improper evaluation or utilization of this novel technology. Establishing protocols to ensure these images are reviewed by the treating physician and/or radiologist prior to the procedure is absolute in preventing complications such as these.

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An accompanying commentary by Wilfred C. G. Peh, MD, is available online. See, "Patient-Specific Imaging and Missed Tumors: A Catastrophic Outcome."

This paper will be judged for the Resident Writer's Award.