VISIONAIRE™ Technology Patient-Specific Fit: A Comparison of Imaging Modalities

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Summary
Several diagnostic imaging modalities were evaluated for producing the VISIONAIRE™ Patient Matched total knee arthroplasty (TKA) cutting blocks (Smith & Nephew, Inc., Memphis, TN, USA) including magnetic resonance imaging (MRI), computed tomography (CT), and CT arthrogram. Ultimately, the VISIONAIRE MRI pre-operative imaging protocol has been shown to provide accurate replication of bone and cartilage anatomy that is required for patient-specific instruments. The accuracy of fit on the femur and tibia achieved with VISIONAIRE cutting blocks is due to the anatomic detail available in MRI scans, which are used in the manufacture of each unique cutting block. This level of anatomical replication in TKA is unattainable with other imaging modalities.

Introduction
Patient-specific cutting blocks are an emerging technology for use in total knee arthroplasty (TKA). These cutting blocks are generated through the processing of diagnostic imaging data, which enables the creation of a three-dimensional representation of a patient’s unique anatomy that can be used to manufacture disposable surgical instrumentation. While the concept of various patient-specific systems is the same, there can be significant differences in design methodology. A specific example is the imaging modality that collects the anatomic landmarks used in block generation.

The success of patient matched TKA depends upon the accuracy with which instrumentation matches the patient’s anatomy. During design evaluation of VISIONAIRE Patient Matched cutting blocks (Smith & Nephew, Inc., Memphis, TN, USA), specific anatomical locations were carefully defined to ensure optimal contact and instrument stability. These are areas in which the majority of ambiguous patient anatomy or severe deformity is avoided. The landmark areas for the femur are the anterior sulcus, the distal sulcus, and the distal condyles. For the tibia, the landmark areas are the anterior medial ledge and the proximal medial and lateral condylar plateaus. Failure to accurately capture the overall surface of the femur and tibia results in sub-optimal cutting block fit, which can adversely affect clinical outcome of the case. In evaluating different imaging modalities, it is important to understand the strengths and weaknesses of each and how they relate to cutting block fit.
Strengths and Weaknesses of CT

Computed tomography (CT) is known for being able to produce high resolution diagnostic images, particularly with respect to the imaging of bone [1]. The anatomical features shown in a CT image are dependent upon the radio density of the object, measured in Hounsfield units (HU), which represent the ability of a material to attenuate the passage of radio waves relative to water. While the density of bone (400 HU) allows for easy differentiation from the surrounding soft tissue, the radio wave attenuation produced by cartilage is close to that of water (0 HU), meaning that there is no way to differentiate cartilage from the synovial fluid. Segmentation of cartilage and bone are important in producing a cutting block which closely fits the anatomy of the patient. Therefore, an inability to adequately differentiate between the soft tissues of the knee joint could result in sub-optimal fit, unless the operating physician wants to remove surface cartilage prior to placement of the cutting block.

In a study measuring the accuracy of CT imaging during patient matched TKA, an ovine model was used to assess the quality of the resulting 3D anatomic rendering [2]. While the study described a high level of accuracy for CT segmentation, the model focused only on recreation of the surface of the bones and did not demonstrate how modeling could be adequately adjusted to account for cartilage. Even if this had been addressed, in an ovine model the average thickness of articular cartilage is estimated to be around 0.4-0.5mm, whereas in human knees, this range increases significantly to 2.2-2.5mm [3]. Not being able to accurately measure the thickness of articular cartilage could introduce a significant source of error in determining optimal fit of a cutting block, especially when considering that cartilage thickness can be markedly different between patients suffering from osteoarthritis [4].

One CT modality that is effective for exposing the fluid/cartilage boundary is CT arthrography, which requires that a contrast agent, typically an iodinated contrast, be injected into the joint. Unfortunately, iodine allergies, procedure pain, and the expense of having a physician and/or radiologist present for this procedure makes CT arthrography an undesirable modality compared to alternatives, such as magnetic resonance imaging (MRI).

A final consideration with respect to CT is the level of radiation delivered to the patient during imaging. While traditional CT imaging represents less than 5% of all imaging procedures, it can account for up to 40% of cumulative radiation exposure from diagnostic imaging [5]. CT has been highlighted for having a shorter imaging duration than MRI, which may act to minimize the risk of movement artifacts. However, there is still the risk of their occurrence and the need to repeat CT imaging, which does increase radiation dose to the patient. This is not a concern with alternative modalities, such as MRI. Therefore, while CT is associated with lower scan times and increased resolution of the tibia and femur, these benefits are off-set by radiation risk and the inability to accurately render articular cartilage. The latter is critically important in producing the unique interface required for a patient matched cutting block.

VISIONAIRE™ MRI-Based Cutting Block

VISIONAIRE Patient Matched cutting blocks are created based upon MRI imaging data, a modality capable of capturing and creating bone models that accurately represents a surface made up of bone and cartilage (Figure 1). MRI has been shown to have a high level of accuracy when combined with a robust image

Figure 1: MRI image clearly identifying the bone and cartilage (left), as compared to a CT image which does not differentiate the soft tissues (right)

Figure 2: VISIONAIRE® Patient Matched cutting block conforming closely to patient bone and soft tissue
processing protocol [6]. Cadaveric studies were utilized during the VISIONAIRE™ design process to optimize anatomical fit of the blocks. Specifically, multiple processing protocols and modalities were evaluated and scrutinized by three orthopaedic surgeons [7, 8]. Each machine that generates an MRI image used in the production of VISIONAIRE cutting blocks is certified using a specially designed phantom. Moreover, pre-defined settings for each MRI machine are submitted prior to the first case to ensure that the imaging outputs have no distortion and use consistent magnification with the highest possible image resolution. This combination of consistent, high quality imaging and robust data processing facilitates the manufacture of cutting blocks that closely fit the anatomy of the patient (Figure 2).

VISIONAIRE cutting blocks produced with the MRI imaging methodology have been successfully utilized in over 20,000 procedures worldwide. Furthermore, VISIONAIRE Patient Matched cutting blocks have demonstrated an ability to more closely reconstitute the mechanical axis of the patient, as well as reduce operative time and post-operative length of stay, as compared to traditional TKA instrumentation [9]. This clearly demonstrates that MRI is an effective modality with which to generate accurate patient matched cutting blocks.

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