DOES PATIENT SPECIFIC TOTAL KNEE ARTHROPLASTY ADD VALUE?

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INTRODUCTION

The classic total knee arthroplasty (TKA) mechanical alignment (MA) surgical procedure aspires to consistently establish neutral limb alignment and a coronal joint line perpendicular to the mechanical axis between hip and ankle centers. Soft tissue releases are required to compensate for the non-anatomical joint line that is established. Patient specific surgical procedures restore the knee joint articulating surfaces and joint line to the individual's previous healthy condition, not necessarily a global normal that is the goal of classic TKA surgery. A patient specific restoration holds the promise of eliminating adjustments to the soft tissue envelope and restoring joint motion that is 'normal' for that individual, thereby increasing patient satisfaction.

Although a patient specific surgical procedure (PSSP) may have more philosophical appeal for many patients and surgeons alike, does the attention to individual patient details end in better outcomes or provide economic benefit? This exhibit presents a summary of surgical approaches, computational evidence and a literature review that attempts to answer this question.

EVOLUTION OF PATIENT SPECIFIC SURGERY

The classic MA surgical procedure is the standard for comparison, as it obtains good to excellent outcomes, employs simple surgical planning using inexpensive radiographic images of patient anatomy and can be performed with standard surgical instruments.

The PSSPs evolved from the classic MA methods when surgical planning was expanded from two dimensional (2D) radiographs to three dimensional (3D) computer models of patient anatomy, gathered pre-operatively by computed tomography (CT) or magnetic resonance imaging (MRI) technology. Both surgical plans are developed by overlaying 3D computer aided design (CAD) models of available sizes and shapes of stock TKA components, sizing and positioning them to the surgeon's best judgment.

For classic MA surgical plans, the components are positioned so that the distal femoral and proximal tibial bone cuts are perpendicular to the mechanical axis (blue planes in **Figure 1**).

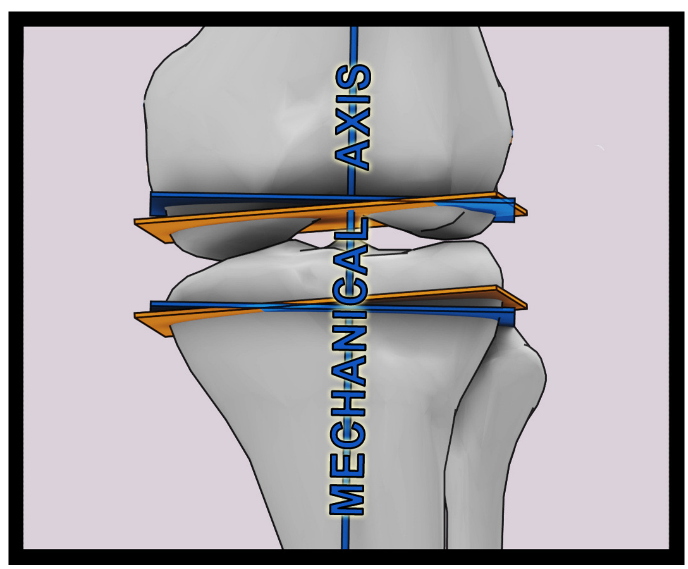

Figure 1 - *Bone resection planes for classic total knee arthroplasty (TKA) mechanical alignment (MA) surgical procedure (blue) are perpendicular to the mechanical axis between hip and ankle centers. Patient specific surgical procedure (PSSP) resection planes (orange) restore an individual patient's joint line.*

Once the surgical plan is in place in the computer, it needs to be translated to the surgical theatre. The most common method is to 3D print custom, disposable, plastic bone saw resection guides, commonly referred to as patient specific instrumentation (PSI) or more broadly, patient specific cutting guides (PSCG). The second employs a computer assisted navigation (CAN) robotic platform that senses the location of the patient's bony anatomy and guides the surgeon's cutting tools to assist in the execution of the plan. The third employs imageless CAN systems that gather patient bony geometry during surgery by repeatedly probing exposed articular surfaces to generate a 3D model of patient anatomy, allowing a surgical plan to be established and executed in place without the need for pre-operative imaging.

The above 3D methods can be also employed to obtain a PSSP outcome, the difference is in the surgical planning. The goal of a PSSP is to restore an individual patient's knee articulating surfaces and joint line to their pre-diseased condition, minimizing the adjustment of the soft tissue envelope. The articulating surfaces of the patient's 3D anatomy model are adjusted to an estimate of their healthy locations to achieve this goal. During planning, 3D CAD models of stock TKA components are positioned so the articulating surfaces best fit the reconstructed healthy anatomy, consequently restoring the natural joint line. Once positioned, the patient specific cutting planes (orange planes in **Figure 1**) are calculated for their TKA components and PSCG or CAN robot methods translate the patient specific plan to the operating theater.

Notably, only one manufacturer[1] creates metal and polymer TKA components that are unique for each patient. Articulating surfaces match the reconstructed healthy patient anatomy and bone implant interface surfaces remain in the classic mechanical alignment bony resection planes. This allows a PSSP articulation result with a classic MA surgical procedure.

Another PSSP of increasing interest is kinematically aligned (KA) TKA[2]. This surgical technique circles back to the technical simplicity of the classic TKA, as planning is done with 2D radiographs and is performed with standard surgical instruments. However, the mechanical axis is not considered, only the patient's exposed articulating surfaces are used as references during surgery. The end result meets the PSSP goals of restoring an individual patient's articulating surfaces and knee joint line to their pre-diseased condition.

TKA Procedure	Planning Image	TKA Components	Plan Translation
Classic, 2D, MA	Radiograph	Stock	Standard Instruments
3D, MA or PSSP, Guides	CT or MRI	Stock	PSCG
3D, MA or PSSP, Robotic, Pre-operative image	CT or MRI	Stock	CAN
3D, MA or PSSP, Robotic, Intra-operative probe	Intra-operative Probe	Stock	CAN
3D, MA, Custom TKA components	CT or MRI	Custom	PSCG
Kinematic Alignment, 2D, PSSP, calipers	Radiograph	Stock	Standard Instruments

Table 1 - *Total knee arthroplasty (TKA) surgical procedure summary. Both classic mechanical alignment (MA) and patient specific surgical procedures (PSSPs) can employ surgical planning images with radiographs or three dimensional (3D) models of patient anatomy using computed tomography (CT) or magnetic resonance imaging (MRI). Almost all methods position stock TKA components and do not manufacture unique, custom components from patient anatomy. The 3D surgical plans for MA procedures position components perpendicular to the mechanical axis, PSSPs match component articulating surfaces to reconstructed healthy patient anatomy. Surgical plans made in a computer are translated to the surgical theater using either 3D printed, patient specific cutting guides (PSCG) or computer aided navigation (CAN) robotic platforms. Kinematic alignment is similar to classic MA, but restores patient anatomy.*

COMPARISON

Classic mechanical alignment (MA) and the patient specific method of PSCG kinematic alignment (KA) total knee arthroplasty were compared using virtual knee simulator software, (**Figure 2**).

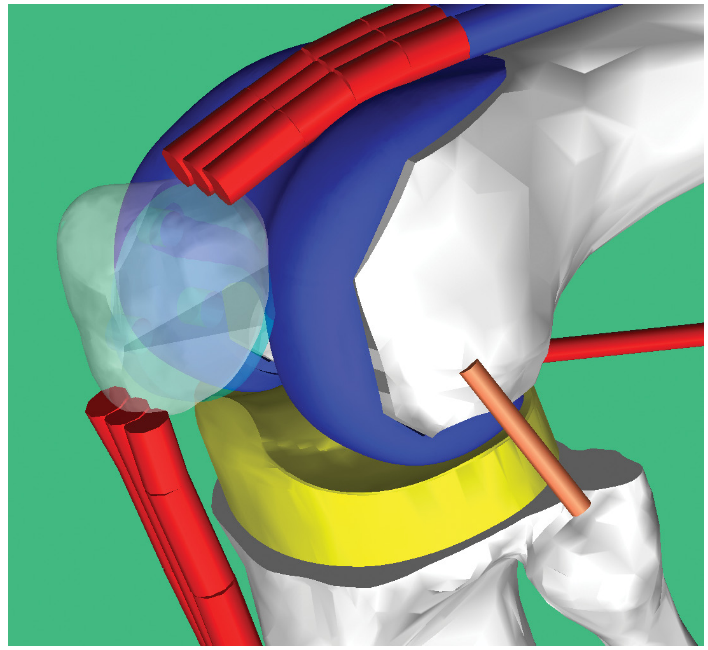

Figure 2 - *KneeSIM, a dynamic, validated, computational musculoskeletal modeling system.*

KneeSIM, a dynamic, validated musculoskeletal modeling system[3] was utilized in this study, providing a computational modeling environment of the left leg of a nominal sized patient. Solid models of the Triathlon CR component geometries were arranged in the joint space to reflect a successful virtual surgery employing MA, then repeated for KA. All model parameters were held the same except for TKA component positions. The KA femoral component used in this study was 6 degrees more flexed, 3 degrees more valgus and 4 degrees more internally rotated than the MA femoral component. The tibial insert followed the femoral component, 3 degrees more varus and 4 degrees more internally rotated[4]. The definition of walking gait established by the International Organization for Standardization (ISO) [5] was applied. The activity cycle was propelled by quadriceps and hamstring muscle forces and constrained by TKA component articulation and soft tissue envelope, including an intact posterior cruciate ligament.

The resulting component motions, articulations, and contact forces were recorded for the second cycle of activity (after steady state had been achieved) for both MA and KA models. The study used measures of component motions and patella tracking (that are associated with patient satisfaction), and contact forces and articular wear paths (associated with implant longevity) as comparison metrics. All were found to be functionally the same for both surgical procedures.

Although the medial and lateral contact forces varied between MA and KA during the loaded stance phase of walking gait, there was no discernible trend to determine if one was different than the other. Lateral compartment liftoff nearly occurred before toe off for the MA results and did occur at toe off for the KA results. Patella contact and shear forces were very similar for both cases. The study was repeated with another more conforming TKA design, and although performance was different than the Triathlon CR, the metrics for patient satisfaction and implant longevity were also found functionally equivalent for both MA and KA surgical procedures.

DISCUSSION

Computational models provide clarity in complex environments, as many parameters may be held constant while only a select few are changed to test their effect. Patient variables were held constant in this study, allowing the effect of varying the surgical procedure from the MA to KA to be understood. The KneeSIM models could discern differences between MA and KA surgical procedures, however, the component positions were not different enough to effect outcomes associated with patient satisfaction or implant longevity for two contemporary TKA designs. This result may encourage or discourage an orthopaedic surgeon from pursuing this KA surgical procedure depending on their goals and temperament. If there is no difference between the classic MA and KA, perhaps there is nothing to be gained by using such, or perhaps there is nothing to be lost.

Systematic reviews are available in the peer-reviewed literature comparing the execution of a 3D MA surgical plan using robotic platforms or patient specific cutting guides (PSCG) to the classic 2D MA surgical procedure. One meta-analysis found that robotic TKA surgeries positioned components closer to plan, but found no differences in patient range of motion[6]. Peer reviewed comparisons of PSSPs that utilize computer assisted navigation (CAN) techniques were not found, however a systematic review comparing 3D MA surgical procedures to classic 2D MA found the strength of evidence across four TKA studies to be low to very low, and found no difference in patient outcomes[7].

PSCGs are only patient specific in the sense that they fit to an individual's bony anatomy to register their position during surgery. Most PSCGs are actually designed to execute a classic MA surgery, although they can just as easily transfer a patient specific plan to the surgical theater[8,9]. A very large meta-analysis suggests that MA PSCG surgeries offer no benefits over classic TKA surgical methods[10]. However, another meta-analysis study comparing KA PSCG to classic MA procedures found that there is no additional risk of revision for loosening when using KA PSCG procedures and clinical outcomes are more favorable than classic MA[11].

In evaluating emerging technologies, the economics of their employ must be weighed against continuous improvement in patient outcome to maintain or improve the quality of patient care. Economic considerations inclusive of hospital length of stay and post-operative re-admission rates, were shown to be no different, however, operating room time was reduced by 15 minutes for KA procedures[12]. While reports indicate equivalent or improved functional outcomes for KA, no differences in revision rates were found[11,13]. When reviewing CAN techniques, one should balance the capital expenditure with the cost savings associated with avoiding complications resulting in re-admission[6,14]. Custom built TKA components have reported significantly lower transfusion rates, fewer adverse event rates, and were less likely to be discharged to a rehabilitation facility without increased hospital expense [15].

CONCLUSION

Although patient specific surgical procedures (PSSPs) summarized in **Table 1** may have more philosophical appeal for many patients, surgeons and manufacturers, this overview of computational evaluation of contemporary designs as well as the peer-reviewed literature does not clearly support that improved patient satisfaction following TKA is realized.

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