

ORIGINAL RESEARCH

Utility and Precision of CT-Based Patient-Specific Instrumentation for Total Knee Arthroplasty

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ABSTRACT

Introduction: Patient-specific instrumentation has been introduced to total knee arthroplasty (TKA). This paper reports on the clinical, operative, and radiographic outcomes of CT-based TKAs.

Methods: 100 consecutive TKAs (94 patients) using CT-based patient-specific instrumentation (PSI) were performed. The planned preoperative versus the actual bony resections were compared. Pre- and postoperative Knee Society Score (KSS), range of motion (ROM), and complications were analyzed. Long-leg standing radiographs were obtained to assess alignment. Additionally, 10 randomly selected TKA patients received postoperative CT imaging for comparison.

Results: Average patient follow up was 3.9 years. At 1 year, mean KSS increased from 44.3 to 81.8, whereas KSS Functional Score improved from 59.1 to 81.8. Mean ROM was 110.5 preoperatively and 111.3 postoperatively. Two patients had a postoperative infection requiring surgery. The actual bony resections achieved during surgery strongly correlated with the preoperatively planned resections of all 6 bone fragments measured ($p < 0.001$). Average postoperative alignment measured on plain radiographs was 179.36° . The average postoperative hip-knee-ankle measured by CT was $179.9^\circ \pm 1.31^\circ$. When comparing the X-ray and CT measurements, we found only 0.09° average difference preoperatively and 0.2° postoperatively ($p < 0.001$).

Discussion: The present study demonstrates improvement in patient function and accurate and reliable postoperative alignment, thereby supporting the use of CT-based patient-specific instrumentation in TKA.

Level of Evidence: II; Prospective case series.

Keywords: Total knee arthroplasty; Patient-specific instrumentation; Arthroplasty outcomes.

INTRODUCTION

Total knee arthroplasty (TKA) is a highly successful treatment for end-stage de-

generative arthritis of the knee. In order to provide pain relief, the operative goals of neutral lower extremity mechanical axis (MA) restoration, durable implant fixation, and adequate ligament balance have remained valid for 30 years. Multiple studies have linked implant longevity to implant alignment after TKA [1-6]. To achieve these results, several alignment techniques have been developed.

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In a conventional or standard technique, intramedullary (or extramedullary) alignment rods are used to help the surgeon place cutting blocks for correct bony resections. Advantages of this technique are its ease of use, speed of application, reproducibility, and familiarity to the surgeon. However, some of the concerns reported with this technique are postoperative malalignment (increased radiographic outliers), increased blood loss, and potential for increased pulmonary fat emboli [7,8].

Another technique, computer-assisted orthopedic surgery (CAOS), was introduced in the mid-1990s. In CAOS, anatomical landmarks of the patient are registered into a computer navigation system intra-operatively. The surgeon is thus provided real-time information about surgical instrument placement, implant positioning, bony resections, and alignment. The benefit of this technique is increased accuracy of implant placement and alignment [9-13]. Complexity and surgery time, however, are increased using this technique [14,15].

Recently, patient-specific instrumentation (PSI) has been introduced to perform TKAs. PSI utilizes a preoperative X-ray and a magnetic resonance imaging (MRI) or computed tomography (CT) scan of the lower extremity to create a three-dimensional model of the patient's anatomy. This model is then used to preoperatively plan the patient's surgical bony resections for proper implant placement. Once planned, unique patient-specific resection blocks are manufactured for the surgery. The theoretical advantage is this technique facilitates accurate implant placement without adding time and complexity to the procedure. Additional potential advantages include decreased blood loss from not entering the intramedullary canal and decreased instrument burden in

the operating room. Theoretical disadvantages of this technique include exposure to CT radiation, additional expense of imaging and PSI manufacturing, and time required for block production.

Published studies utilizing MRI have not yielded acceptable outcomes, resulting in reluctance to widely adopt the technique [16,17]. There is, however, a paucity of published studies utilizing a preoperative CT scan as the imaging modality. The objective of the present study was to prospectively evaluate clinical, operative, and radiographic outcomes from 100 CT-based PCI TKAs.

MATERIALS & METHODS

Study Design

This is a prospective consecutive series of 100 TKA performed in 94 patients using CT-based PCI technology (MyKnee®, Medacta International SA; Castel San Pietro, Switzerland) (Figure 1). An Institutional Review Board (IRB) approval was obtained. Each enrolled patient provided a written informed consent to participate in the study.

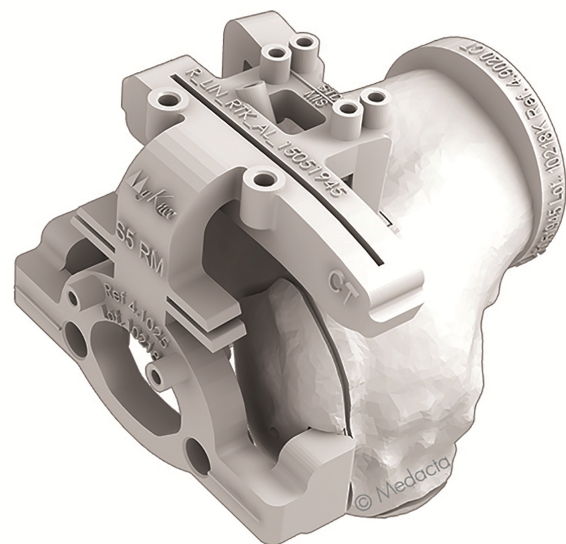


Figure 1. MyKnee® PSI cutting block developed using patient's CT bone imaging.

All patients received the same ultra-congruent kinematic implant (GMK, Medacta International SA; Switzerland) and were eligible to receive an elective TKA. Inclusion criteria mandated patients 18 years of age or older who were able to undergo a CT scan. They were required to provide written informed consent. Exclusion criteria included patients unwilling or unable to have a CT scan. Patients were not excluded due to pre-existent hardware in the knee, pacemakers, obesity, or claustrophobia.

PCI and CT Imaging

Utilization of PSI begins preoperatively with a CT scan of the lower extremity, including the hip, knee, and ankle, obtained utilizing a proprietary, standard protocol (no plain X-rays are required for surgical planning with this particular technology). The average effective dose for the CT is 3-8 mSv, depending on patient characteristics such as BMI and size. The CT scan is then sent to the reconstruction engineers who create a 3-di-

mensional reconstruction and determine the preoperative alignment of the lower extremity. Surgical planning is performed according to the surgeons' preferences (Figure 2). Once the implant position and alignment are approved by the surgeon, bone models and the blocks are manufactured using rapid-prototyping technology. This process requires 3 weeks. The senior authors' goal for implant positioning is to recreate a neutral mechanical axis (hip-knee-ankle angle of 180°), femoral rotation of 0° based on the transepicondylar axis, and a posterior tibial slope of 4.5° based on surgeon's preference.

Surgical Technique

All surgeries were performed via a medial-parapatellar or subvastus arthrotomy. No osteophytes were removed as the blocks use their positive topography for registration. Once cartilage was removed from predetermined areas to allow for bony contact, the PSI cutting block was placed on the femur and secured with smooth pins.

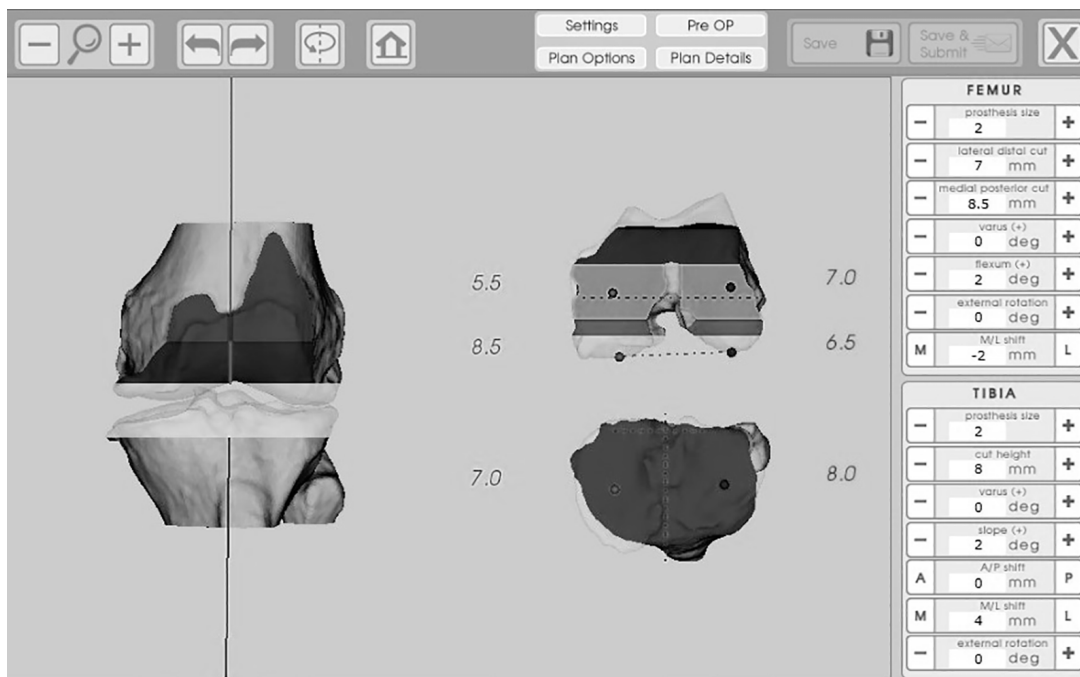


Figure 2. A computer screen image of 3-dimensional planning for bone resections for femur and tibia during CT-based PSI TKA.

Pilot holes were drilled in the distal femur setting the rotation and anterior-posterior placement of the standard 4-in-1 block. The distal resection was performed through a cutting slot on the block. The 4-in-1 block was then placed and the remaining femoral resections were performed in routine fashion. The tibial PSI resection block was registered to bone, following cartilage removal, and secured with smooth pins. Alignment, rotation, and slope were verified using a tibial drop rod and visual inspection and the proximal tibia was subsequently resected. If the PSI was deemed to be inaccurate, the surgeon abandoned it and used conventional instrumentation to complete the TKA. Final bone preparation, patella resurfacing, trial-ing, and ligament balancing were performed as is standard to all surgical techniques.

Clinical Assessment

The primary outcome of the study was to compare the planned preoperative femoral and proximal tibial resections to the intraoperative resections and pre- and postoperative alignment. Data was acquired preoperatively, intraoperatively, 6 weeks postoperatively, and annually thereafter.

Clinical outcomes included pre- and postoperative Knee Society Score (KSS), range of motion (ROM) measured with a goniometer), and complications (infection, revision, deep vein thromboses, pulmonary embolism).

Operative data included tourniquet time (TT) as an indicator of surgical efficiency, surgical room time, and complications. The thickness of actual bone resections was measured and compared to that of the planned resections from the CT scan. After the bone was resected, the overlying cartilage was removed at predetermined spots based on the preoperative planning. A cal-

iper was used to measure the thickness of the bone fragments and 1.0 mm was added to account for saw thickness. The 6 bony resections evaluated included those of the distal medial femur, distal lateral femur, posterior medial femur, posterior lateral femur, medial tibia, and lateral tibia. Successful use of blocks versus conversion to standard technique was also recorded. The accuracy of the surgical plan in determining correct implant size was recorded. The associations of planned versus actual resection measurements were assessed by a Pearson correlation coefficient. The consistency of X-ray and CT scan based hip-knee-ankle (HKA) measurements were assessed by intraclass correlation. All statistical analyses were performed using SAS V9.3 (Cary, NC) and the R statistical software (www.r-project.org).

Preoperative and 6-week postoperative long-leg standing radiographs were obtained to assess HKA alignment. The preoperative long-leg standing radiograph was obtained for study purposes, not for surgical planning. The femoral component angle (FCA) in the coronal plane, the tibial component angle (TCA), and posterior slope of the tibia were also assessed. All radiographic measurements were performed by an unbiased third party utilizing PACS software (Merge OrthoPACS). Additionally, 10 patients were randomly selected and consented to undergo a postoperative CT scan for measurement of the HKA, FCA, TCA, femoral rotation, and tibial slope via CT scan. Statistical analysis was performed to evaluate the correlation between the HKA determined preoperatively and the HKA determined postoperatively in this subgroup.

RESULTS

Ninety-four consecutive patients were en-

rolled in the study, representing 51 left and 49 right TKAs (Table 1). Six patients had staged bilateral TKAs and 1 patient had bilateral simultaneous surgery during the enrollment period. All patients approached for study participation chose to take part in the study—no patients were excluded.

Table 1. Study Patients and TKAs.

Variable	Number
Total Patients	94
Male	34
Female	60
Total TKAs	100
Left	51
Right	49

Ninety-seven (97%) knees had a diagnosis of osteoarthritis and 3 (3%) had post-traumatic arthritis. The average BMI was 31.5 and average age was 64.5 (range 41–90). Two patients died due to unrelated causes and 6 patients were lost to follow-up. The remaining patients had an average follow up of 3.9 years (range 3.5–4.4 years). Average KSS improved from 44.3 to 81.8 while

KSS Function Score improved from 59.1 to 81.8 at latest follow up. Average ROM arc of the patients was 110.5 (range 0–130) preoperatively and improved to 111.3 (range 0–130) postoperatively. Two patients had a postoperative infection requiring irrigation and debridement. There were no thromboembolic complications and no revisions in study patients. No patient required a manipulation under anesthesia for postoperative stiffness.

Average TT (skin incision to final implant placement) was 31.3 minutes (range 16–51 minutes). No intraoperative complications occurred nor were there any cases of abandoning the PSI blocks for standard technique.

The actual resections achieved during surgery were strongly correlated to the planned resections of the distal medial ($r=0.67$; $p<0.001$) and distal lateral femoral condyles ($r=0.84$; $p<0.001$) (Table 2). Similarly, there was a strong correlation between the actual resections of the posterior medial ($r=0.78$; $p<0.001$) and posterior lateral ($r=0.79$; $p<0.001$) femoral condyles and the planned cuts. For the tibial cuts, there was a strong correlation between the

Table 2. Preoperatively Planned versus Actual Bony Resections for TKAs.

	Planned mean (mm)	Actual mean (mm)	Correlation (CI)	P Value
Femoral Resections				
Distal Medial	8.9±0.9	8.7±1.2	0.67 (0.55,0.77)	<0.001
Distal Lateral	6.7±1.9	7.2±1.8	0.84 (0.77,0.89)	<0.001
Posterior Medial	8.9±1.5	8.3±1.6	0.78 (0.69,0.85)	<0.001
Posterior Lateral	6.8±1.7	6.2±1.6	0.79 (0.70,0.85)	<0.001
Tibial Resections				
Medial	6.3±1.7	6.4±1.5	0.78 (0.69,0.85)	<0.001
Lateral	8.2±0.9	8.3±1.1	0.66 (0.53,0.76)	<0.001

actual medial ($r=0.78$; $p<0.001$) and lateral ($r=0.79$; $p<0.001$) resections compared to the planned tibial resections. The planned size of implant was utilized in 86% of femoral implants and 89% of tibial implants. Implant choice was changed at the surgeons' discretion intraoperatively.

Sixty patients had preoperative varus deformities with HKA average of 174.7° (range 167 – 179.5°). Fourteen patients had

preoperative valgus deformities averaging 184.4° (range 180.5 – 190°). Twenty-six patients were neutral. Average postoperative alignment was 179.4° (range 175 – 186°). Alignment was $180\pm 3^\circ$ in 94% of patients postoperatively. More specifically, alignment was $180\pm 2^\circ$ in 73% and $180\pm 1^\circ$ in 49% of patients. There were only 6 outliers with maximal postoperative angulation of 6° from neutral (Figure 3).

Post-Operative Alignment

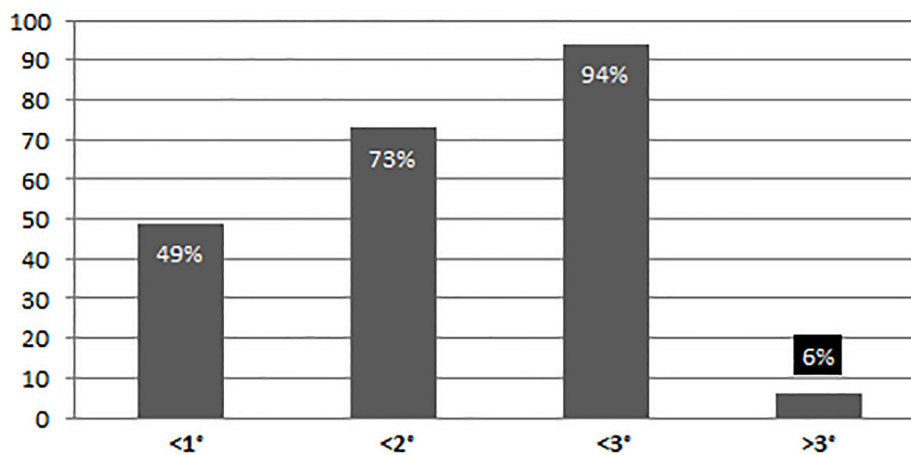


Figure 3. Postoperative alignment in CT-based PSI TKA patients.

The FCA measured 89.6° (range 81 – 100°). There was 1 case reported with femoral notching. The TCA measured 86.6° (range 77 – 91°).

Ten patients underwent a postoperative CT scan for HKA verification. Preoperatively, the average HKA by CT scan was 177.0° (range 169.2 – 185.4°). The average postoperative HKA was 179.9° (range, 176.9 – 180.9°) with a standard deviation of 1.3° . The planned femoral varus/valgus alignment and femoral rotation were 0° based on the mechanical axis and transepicondylar axis, respectively. The actual average femoral alignment was 0.9° varus (sd 1.0°) and the average rotation was 1.1° (sd 0.6°). The planned tibial varus/valgus align-

ment was 0.0° and the planned tibial slope was 4.5° . Actual average alignment was 1.0° varus (sd 2.0°) and average tibial slope was 4.3° (sd 2.2°).

The pre- and postoperative CT scans were used to evaluate the agreement between the HKAs measured with radiographs and with CT (Table 3). The difference between the average HKA obtained by X-ray and by CT was 0.09° . The intraclass correlation using paired data between the preoperative X-ray HKA and the CT scan HKA was 0.999 ($p<0.001$) showing strong consistency between the preoperative X-ray and CT measurements. The intraclass correlation of the postoperative X-ray HKA and CT scan HKA was 0.78 ($p=0.0016$), again demonstrating

consistency between the X-ray and CT measurements.

DISCUSSION

PSI technology has been introduced by multiple manufactures using many image acquisition modalities. Two models of alignment were initially used during the introduction

of this technology—kinematic axis and mechanical axis.

The kinematic axis model (OtisMed, Stryker; Kalamazoo, MI, USA) was designed to restore the kinematic axis, or pre-arthritis alignment of the limb. In this technique, a MRI of the knee is used to develop PSI cutting blocks and no assessment of HKA is performed. Multiple studies were done

Table 3. HKA for 10 Patients with Pre- and Postoperative CT Scans.

	Value	P Value
Preoperative X-ray HKA	177.1°	
Preoperative CT scan HKA	177.01°	
Difference	-0.09°	
ICC (95%CI)	0.999 (0.996,1)	p<0.001
Postoperative X-ray HKA	180.1°	
Postoperative CT scan HKA	179.9°	
Difference	-0.2°	
ICC (95%CI)	0.78 (0.36,0.94)	p=0.0016

HKA, hip-knee-angle; ICC, interclass correlation; CI, confidence interval.

to report early outcomes with this technique [16,18-20]. Despite conflicting results, these studies cite a high number of intra-operative errors, alignment outliers, and early failures and the system has since been removed from the market.

All other systems are based on the mechanical axis model for alignment. Visionaire PSI (Smith & Nephew; Memphis, TN, USA) utilizes a MRI of the knee combined with a long-leg standing X-ray to determine alignment for surgical planning. Conteduca reported a small series of patients utilizing intraoperative navigation for validation of the Visionaire system [21]. Errors were noted in both coronal and sagittal alignment necessitating recuts. In contrast, Noble found significant improvement of HKA with

the Visionaire system compared to conventional instrumentation [22]. Reductions in hospital stay, operative time, incision length, and instrument tray usage were also noted. Despite these results, there is concern about the utilization of the long-standing X-ray for preoperative planning. Multiple studies have shown that these X-rays are prone to error due to rotation and flexion of the extremity [23]. Achieving neutral rotation and full extension is near impossible in the preoperative arthritic patient when performing a long-standing X-ray. In contrast, a CT scan can control for rotation of the extremity negating any potential error caused by flexion/rotation of an extremity.

Other MRI based PSI technologies utilize the mechanical axis by acquiring the

hip, knee, and ankle view. Signature (Biomet) has been most extensively reported in the literature for this technology. Ng et al. retrospectively reviewed the results of 569 Biomet PSI cases and compared them to 155 TKAs using conventional instrumentation [7]. They found similar postoperative alignment between the groups, but fewer outliers in the Biomet PSI group. Nunley et al. has published 2 studies utilizing Signature. In the first study the authors evaluated the cost of Signature PSI vs. standard instrumentation and found that Signature PSI only reduced overall operative time by 12 minutes. They concluded that the cost of PSI was not justified [24]. In a second study the authors found no difference between alignment of TKA using conventional instruments (CI) vs. Signature PSI. They conclude that future studies will have to show clinical or patient satisfaction improvement before routine use of PSI is justified [19]. Finally, Stronach et al. reported modification of the surgical plan intraoperatively in 77% of femurs and 53% of tibias. They found the block did not register securely in 12% of femurs and 5% of tibias [25]. They cautioned against the routine use of PSI blocks without further data.

There is a paucity of published literature on CT-based PSI. Koch et al. reported a postoperative HKA of 180.1° in 291 cases with a 12.4% outlier rate. Furthermore, they reported that this rate compared to their experience with CAOS and was better than their experience with conventional instrumentation [23]. Likewise, our results showed a neutral postoperative alignment and low outlier rate of 6%.

The preoperative CT reconstruction can accurately predict the intra-operative resection depths as demonstrated here. All 6 bony resections measured to within 1 mm of the predicted value in the aggregate of our

series. To our knowledge, this is the latest study to verify planned PSI resections with actual intra-operative bone resections.

The opportunity to perform pre- and postoperative CT scans allowed for detailed analysis of the implants. It is well known that long-standing X-rays are subject to error due to potential flexion and rotation of the leg during the image acquisition [26]. However, the CT scanner allows for the unique opportunity to study the limb in a neutral fashion, thus eliminating these potential errors.

The restoration of mechanical axis to an average value 179.9° as measured by CT scans demonstrates the effectiveness of the blocks. Furthermore, accuracy of implantation is reflected by the restoration of the average femoral component angle within 1° , the average femoral rotation within 1.1° , average tibial component angle within 1° , and average tibial slope within 0.2° . This demonstrates that accurate preoperative planning can be achieved with the CT-based blocks.

Furthermore, we found that our preoperative HKA measured by long-standing X-ray is quite accurate as well. For example, when comparing our preoperative alignment by X-ray versus CT, we found only 0.09° average difference between them. Postoperatively, we continued to show very similar results showing X-ray HKA measurement of 180.1° versus CT measurement of 179.9° . We are pleased to see the correlation of our long-standing X-ray HKA and CT HKA, especially given postoperative CT scans are not routinely performed in follow-up.

This study only examines a CT algorithm for 1 manufacturer. Just as in MRI-based PSI, different algorithms undoubtedly exist and we do not believe that these results will necessarily be reflected in other CT PSI systems.

Disadvantages of CT-based PSI include increased radiation exposure prior to surgery. Notably, the average annual background radiation exposure in America is 6.2 mSv while the radiation exposure from a CT used for the PSI is 3-8 mSv [27]. Further studies are needed to determine the risk associated with these levels of radiation exposure. Acquisition of CT image and production of the blocks adds to the cost of procedure. How these compare to the capital investment of a conventional instrumentation set for TKA remains to be analyzed.

Limitations of this study should be acknowledged. The study only follows a prospective cohort of TKA patients and is not compared to another technique in a randomized fashion. Also the cohort analyzed by postoperative CT scan was a small fraction of the overall study population. We minimized this weakness by performing these CT scans in a randomized fashion as performing them in all 100 patients was not financially feasible.

CONCLUSIONS

The present study demonstrates improvement in patient function and accurate and reliable postoperative alignment. Consequently, we routinely support the use of CT-based PSI in TKA. Additional studies are required to assess implant durability in longer follow-up, as well as comparison to other CT-based PSI systems.

Disclosure

The Principal Investigator of this study is the Medical Director for Medacta USA. He also serves as a consultant providing education, advisory, and design services to the company. He receives royalties for certain

products for which he helped design. The MyKnee product, which is the subject of this investigation, is one of those products. The Principal Investigator does not have any equity interest in Medacta.

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