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Comparison of Customized Cutting Block and Conventional Cutting Instrument in Total Knee Arthroplasty: A Randomized Controlled Trial

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ABSTRACT

Background: Customized cutting block (CCB) was designed to ensure the accurate alignment of knee prostheses during total knee arthroplasty. Given the paucity of CCB efficacy data, we compare CCB with conventional cutting guide using a randomized controlled trial.
Methods: One hundred eight osteoarthritic knee patients underwent total knee arthroplasty by one experienced surgeon were randomized to receive CCB (n = 54) or conventional cutting instrument (CCI) surgery (n = 54). The primary outcomes were limb alignment, prostheses position, and operative time. The secondary outcomes were hemodynamic alteration after surgery, functional outcomes (modified Western Ontario and McMaster University Osteoarthritis Index) and range of motion at 2 years after surgery.
Results: Mean hip-knee-ankle angle in the CCB group was 179.4° ± 1.8° vs 179.1° ± 2.4° in the CCI group, Δ = 0 (95% confidence interval [CI] −0.6 to 1.1, *P* = .55). Mean operative time was faster in the CCB arm: 93 ± 12 vs 104 ± 12 minutes, Δ = 11 (95% CI −16.7 to −7.2, *P* < .0001). There were no differences in hemodynamic parameters, mean blood loss (446 [CCB] vs 514 mL [CCI], Δ = −68 [95% CI −138 to 31 mL, *P* = .21]), postoperative hemoglobin changes, incidence of hypotension (systolic <90 mm Hg), oliguria, and rates of blood transfusion. Functional outcomes and range of motion were also similar.
Conclusion: There was no improvement in alignment, hemodynamic changes, blood loss, and knee functional outcomes. CCB reduced surgical time by 11 minutes in our population. CCB cost-effectiveness should be further investigated.

The customized cutting block (CCB) has been developed to help surgeons perform total knee arthroplasty (TKA) with more accurate alignment of the prosthesis, decrease intraoperative decision making, and reduce operative time [1].

The innovation of CCB is that it shifts most part of decision making to preoperative step instead of intraoperative step. CCB produces a 3-dimensional image of the knee joint to produce the cutting blocks specific to each patient's anatomy, using either magnetic resonance imaging (MRI) or computed tomography (CT), depending on the manufacturer's recommendation. In this way, the optimal implant size and alignment can be mapped onto a virtual knee, reviewed and modified by the surgeons.

Customized cutting instruments have been reported to have several advantages, including more accurate coronal alignment, fewer outliers, no penetration into the intramedullary (IM) canal, less use of operative resources, and decreased surgical time. These features might also reduce hospital costs [2–9]. By contrast, several disadvantages have recently been reported and include the preoperative scheduling of imaging, waiting for the manufacturing of the CCB, the need for training, no improvement in coronal alignment, higher rates of misalignment, similar operative time, and higher cost [10–16].

To date, most reported studies have been small cohort studies, retrospective and nonrandomized studies comparing outcomes of CCB vs conventional instruments [3,9,17–19]. Moreover, each study

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used a unique technical protocol of preoperative imaging data acquisition and CCB manufacturing which makes comparison between studies challenging.

Given the paucity of data, we conducted a randomized trial to compare the outcomes of primary TKA performed with CCB and conventional cutting instrument (CCI).

Patients and Methods

This study was designed as a single center, prospective, randomized controlled trial conducted at Thammasat University Hospital between October 2012 and May 2014. The institutional ethics review board approved this study. The study protocol was registered in clinicaltrials.gov (NCT02128464). All patients provided written informed consent.

The inclusion criteria were: (1) patients with a diagnosis of osteoarthritis or rheumatoid arthritis of the knee who qualified for TKA surgery (painful and disabled knee joint with involvement of one or more compartments), (2) no contraindication for a preoperative MRI, (3) willing to wait approximately 4 weeks for surgery, and (4) giving written informed consent. The exclusion criteria included: (1) previous ipsilateral hip or ankle replacement, (2) previous osteotomy with metallic hardware (this would interfere with the accurate interpretation of the MRI), and (3) previous ipsilateral tibial or femoral fractures.

For sample size calculation, mean and standard deviation of limb alignment in the previous study was 179° and 2.8° [20]. We expected to detect a difference of limb alignment >1.5° [6], with power of 80% and a 2-sided alpha level of 0.05. Therefore, 108 knees were recruited to this study with assuming a dropout rate approximately 10%. A randomization list was computer-generated using block of 4 randomization. Each randomization card was placed in sealed, opaque envelope that was opened by a study nurse after enrollment to reveal the surgical assignment either CCB or CCI. Patient disposition during the study was shown in the trial profile (Fig. 1). There were no differences in the preoperative parameters between the 2 groups (Table 1). The mean age of the patients in the CCB group was 72 ± 7 years (range 59-87 years; 12 men and 42 women). The mean age of the patients in the CCI group was 72 ± 8 years (range 61-89 years; 15 men and 39 women).

CCB Preoperative and Intraoperative Procedures

Aside from the cutting instrumentation, all other aspects of perioperative management were the same between the 2 groups and followed a standardized protocol.

The VISIONAIRE system (Smith & Nephew, Memphis, TN) was used. Patients underwent a preoperative knee MRI and a 3-feet standing knee radiograph, that included the hip and ankle joints, as per the VISIONAIRE protocol. These data were sent to Smith & Nephew Company, which digitally constructed the 3-dimension models of the tibial and femoral cutting blocks. The digital models and prosthetic templates were uploaded onto the software planner, reviewed (including component alignments in multiple planes), modified, as needed, and approved by N. Tammachote. Lastly, the manufacturer produced CCBs and sent them back to our institution in a sterile package.

The CCBs were used in accordance with the manufacturer's instructions. These blocks were carefully positioned over the articular surfaces, holes were drilled and pins were placed into holes. The distal femoral pinholes were drilled to determine the proper position of the 4-in-1 femoral cutting block. Distal femoral bone cut and proximal tibial bone cut were performed through cutting slots of the customized block. Vernier calipers were used to measure the thickness of each cut in millimeters.

CCI Preoperative and Intraoperative Procedures

Preoperative templating was carefully performed using the long-leg radiograph to consider prosthetic positioning and sizing.

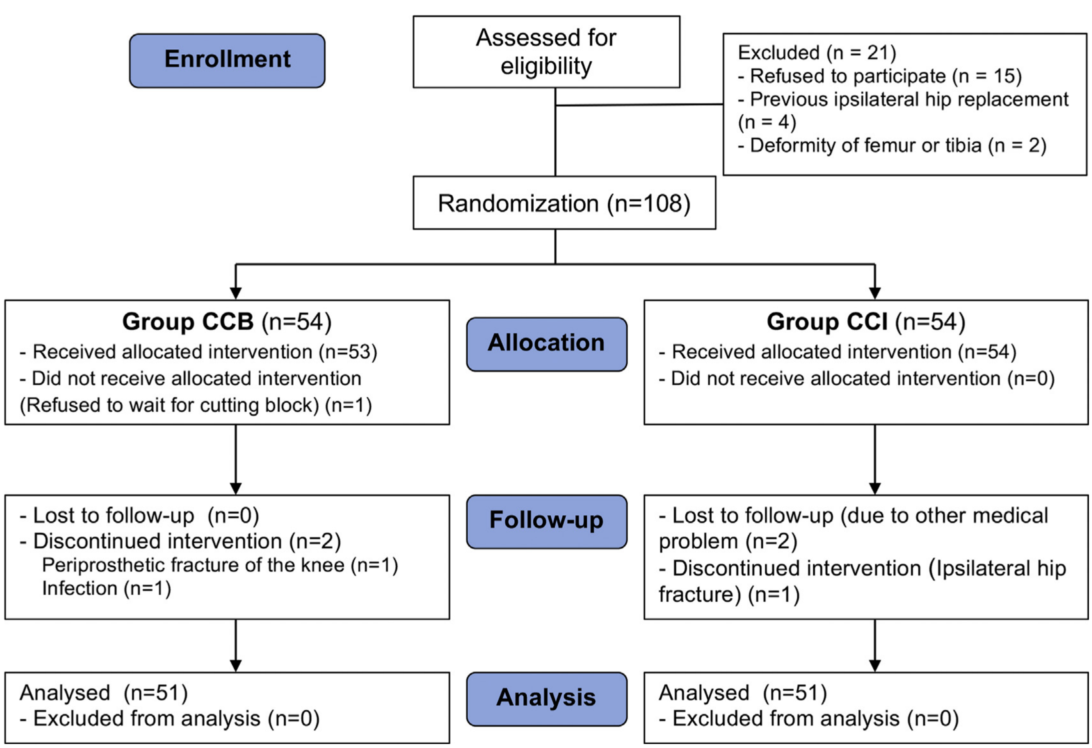

Fig. 1. Diagram shows flowchart of this study. CCB, customized cutting block; CCI, conventional cutting instrument.