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The accuracy of component alignment in custom cutting blocks compared with conventional total knee arthroplasty instrumentation: Prospective control trial

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ABSTRACT

Background: The purpose of this study was to assess whether custom cutting blocks improve accuracy of component alignment compared to conventional TKA instrumentation.
Methods: Eighty primary TKA patients were enrolled in an open-label randomized prospective clinical trial and were divided into two groups, 40 custom cutting blocks and 40 conventional TKA instrumentations. The primary outcome was prosthetic alignment with respect to mechanical axis and epicondylar axis. Secondary outcomes included operative time, 24-hour postoperative blood loss and hemoglobin at discharged.
Results: There were no statistical significant differences in the postoperative mechanical axis between the custom cutting blocks group and conventional TKA group, (95% vs. 87.5% within 3° of neutral mechanical alignment, $p = 0.192$). The average rotational alignment was statistically significantly different in the custom cutting blocks group (1.0° ± 0.6° vs. 1.6° ± 1.8° external rotation from epicondylar axis, $p < 0.001$). There were statistical significant differences in operation time between custom cutting blocks group and conventional group, skin to skin [57.5 ± 2.3 min vs. 62.1 ± 1.5, $p < 0.001$]. We found an improvement in group 1 compared with group 2 regarding the proportion of patients with postoperative blood loss within 24 h.
Conclusions: Custom cutting blocks technique was a surgical procedure which provided better accuracy in rotational alignment but no statistical differences in mechanical axis, less operative time and reduced blood loss than the conventional TKA instrumentation in the majority of patients.

1. Introduction

Prosthetic malalignment affects patient satisfaction and implant survival [1–4]. The postoperative alignment outlier, the mechanical axis that exceeds ±3 varus/valgus deviation, has been associated with abnormal stress, deterioration of the prosthesis and aseptic loosening [5,6]. In addition, an improper component rotation has demonstrated some complications including patellofemoral problems such as diffuse and anterior knee pain and inferior tibiofemoral ligamentous balancing [7–9]. As a result of these problems, the development of surgical techniques, such as navigation and robotics, has been taken. However, their applications were limited by cost and complexity [31–34].

Even though custom cutting blocks technique is a relative new concept in TKA. Preoperative three-dimensional computer tomography (3D-CT) images are imported by the software to determine sizing. Alignment and bone resection are planned in accordance with the standard parameters. The cutting blocks are designed and then constructed to fit the patient's individual articular deformity. So this new technique is a potential improvement of component accuracy and elimination of the alignment outliers.

With regard to the previous literatures, they have reported several mixed results. One pilot study cited alignment error in a small case series ($n = 4$) [10]. On the other hand, the others showed the positive preliminary operative results [11–13]. The purpose of this study was to assess whether the custom cutting blocks improve accuracy of component alignment in terms of coronal and rotational alignment as compared to the conventional TKA instrumentation.

2. Materials and methods

This study has been approved by our institutional review board. Consent to participate in this research was obtained for all patients. Eighty consecutive patients (70 women and 10 men) treated from August 2011 to August 2012, were included in this open-label randomized prospective control study. The criteria for inclusion in this study were as follows: patients who underwent primary total knee arthroplasty at Phramongkutklao Hospital and suited for implantation using the custom cutting blocks: no femoral nails/bone plates that extend into the knee, i.e. within 8 cm of joint line; no metal device that could cause CT scatter about the knee and no deformities greater than 15° of fixed varus, valgus or flexion contracture. The patients with previous ipsilateral distal femoral or high tibial osteotomies, ankylosis of the hip joint on the side to be treated, inflammatory arthritis and previous patellectomy were excluded. All eighty primary TKA patients were assigned to one of the two

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groups (1:1), group 1was treated by using the custom cutting blocks (TruMatch™ Personalized Solutions; DePuy, Warsaw, Ind.) while group 2 was treated by using the conventional instrumentation (Sigma™ High Performance Instrument; DePuy, Warsaw, Ind.). A medial parapatellar approach was performed in all cases. The posterior stabilized cemented total knee system (PFC Sigma; DePuy, Warsaw, Ind.) was implanted as well as patellar resurfacing was performed in all cases. In group 1, each patient had preoperative 3D CT images imported by proprietary software to plan for bone resections. The default settings for the femoral preparation were perpendicular to the mechanical axis and the femoral rotation was set parallel to transepicondylar axis. The distal femoral cut was set at 9 mm thickness for the patients who had flexion contracture less than 5°and 10 mm for the patients who had flexion contracture more than 5°. The default settings for the tibial preparation were perpendicular to the mechanical axis with 3°posterior slope. This software then shape matched the femoral and tibial components to construct the disposable cutting blocks that fit the patient's unique articular deformity (Figs. 1, 2). The waiting time from starting the CT scan to receiving the cutting block is 3 months but two cases have to repeat CT scan due to inadequate information.

In group 1, the first tibial cut was performed as a routine followed by the femoral bone cut. Before the process of chamfer bone cut, we measured the size of the femoral component by using a jig of conventional instrumentation to compare with the preoperative sizing. In group 2, the proximal tibia was prepared with an extramedullary guide perpendicular to the mechanical axis and 3° posterior slope. An intramedullary femoral guide was used to perform a 6° valgus resection cut of distal femur and set external rotated 3° relative to posterior condyle of femur. One surgeon performed all of the TKAs for groups 1 and 2. All patients had the same operative setup, wound closure and postoperative care. The operative times were recorded and divided into three periods: [1] skin to final bone cut, from the time of skin incision to the final bone cut, [2] skin to insert, from the time of skin incision to the time that the polyethylene insert was completely positioned and [3] skin to skin, from the time of skin incision to the time of final staple. We also collected 24-hour postoperative blood loss, total blood loss (the differences between hemoglobin at preoperative period and hemoglobin at discharged) and hemoglobin at discharged. All patients received a CT scan of the knee and a weight bearing film of hip–knee–ankle at 6 weeks postoperatively and evaluated by two hip & knee fellows who did not know the procedures. Inter observer reliability was analyzed by interclass correlation coefficient. The measurement used to determine component coronal alignment was the mechanical axis, from the center

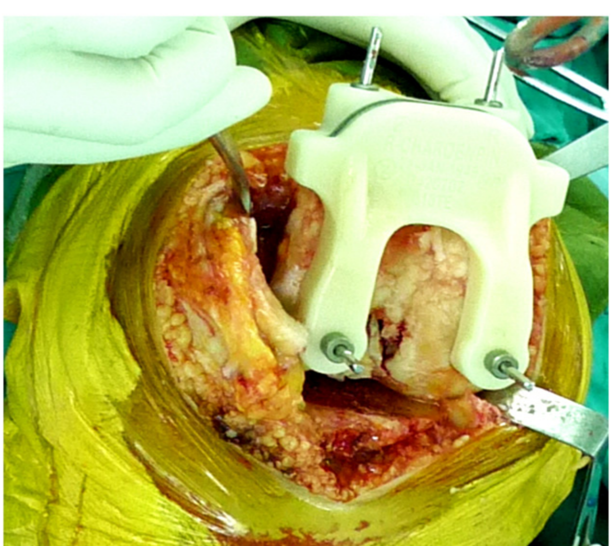

Fig. 1. Intraoperative positioning of femoral custom cutting block.

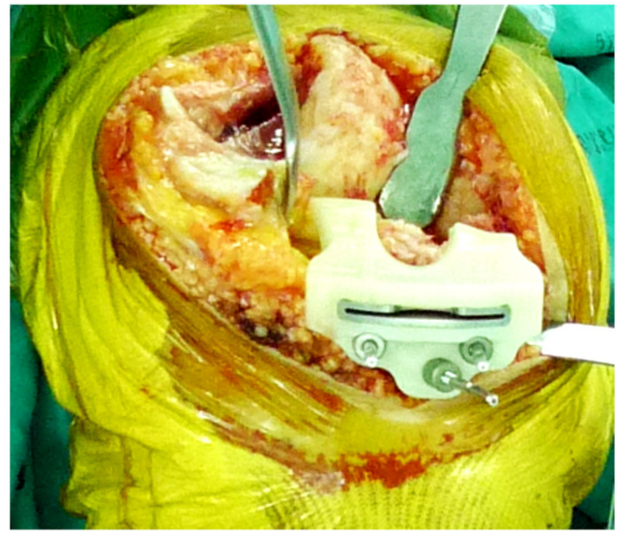

Fig. 2. Intraoperative positioning of tibial custom cutting block.

of femoral head to the center of talus. The accepted normal value for the mechanical axis was $\pm 3°$ varus/valgus deviation. Whereas the rotational alignment was the epicondylar axis, connecting the lateral epicondylar prominence and the medial epicondylar sulcus, based on the technique described by Berger et al. [9,14,15]. We measured the sagittal alignment of femoral component from lateral view by using the anatomical axis defined as a line connecting the middle point of the femoral axis 15 cm proximal from the femoral intercondylar fossa and the middle point of the femoral axis 5 cm proximal from the femoral intercondylar fossa as described by Nakahara et al. [35], the femoral component should be perpendicular to this axis. The posterior slope of tibial component was also assessed. Pearson chi-square test, t-test, Fisher exact test and Mann–Whitney U test were used to compare baseline characteristics between the groups. The analysis was performed with SPSS software.

3. Results

There was no significant difference in the mean age of patients [69.7 ± 5.5 years (range, 58–81 years) vs. 69.3 ± 5.5 years (range, 58–82 years), p = 0.7] and BMI [25.0 ± 2.4 kg/m^2 (range 18.9–30.1 kg/m^2) vs. 25.0 ± 2.1 kg/m^2 (range, 20.1–29.4 kg/m^2), p = 0.992]. No adverse intraoperative events were seen with the use of custom cutting blocks. There were statistical significant differences in operative time between the custom cutting blocks group and the conventional group, skin to final bone cut (17.3 ± 2.3 min (range 15–25 min) vs. 20.3 ± 1.4 min (range 18–23 min), p < 0.001), skin to final inserted prosthesis (38.2 ± 4.2 min (range 30–50 min) vs. 41.3 ± 1.5 min (range 38–45 min), p < 0.001) and skin to skin (57.5 ± 2.3 min (range 54–65 min) vs. 62.1 ± 1.5 (range 60-64 min), p < 0.001) (Table 1). The size of planned femoral component matched the implanted component in 38 of the 40 knees, whereas the smaller femoral component was used in the custom block due to need increase in flexion gap. The size of planned tibial component alignment matched the implant component in 36 of the 40 knees, the smaller tibial component was used in three cases and the larger tibial component was used in the other. In the custom cutting blocks group, we measured femoral component size by using a jig compared with preoperative sizing, the results were 45% of increased size, 40% of the same size and 15% of decreased size. There were no statistical significant differences in the postoperative mechanical axis between the custom cutting blocks group [95% within 3° of neutral mechanical alignment (mean valgus 0.5° ± 1.5°, range varus 3.5° to valgus 3.5°)] and the conventional TKA group [87.5% within 3° of neutral mechanical alignment (mean valgus 0.9° ± 2.0°, range varus 4° to valgus 4°)], p = 0.192 (Fig. 3). The average femoral rotational alignment was statistically significantly different in the custom cutting blocks group (1.0° ± 0.6° vs. 1.6° ± 1.8° external rotation from epicondylar axis, p < 0.001) (Fig. 4). The average sagittal alignment of femoral component was not significant (1.91° ± 1.06° vs. 2.60° ± 1.68°, p = 0.078). The mean slope of tibial component was statistically significantly different in the custom cutting blocks group (posterior slope 2.8° ± 0.79° vs. 3.93° ± 1.28°, p = 0.008). Interclass correlation coefficient was 0.981, 0.964–0.990 (95% CI), p-value < 0.001. We found an improvement in group 1 compared with group 2 regarding the proportion of patients with postoperative blood loss within 24 h (294.3 ± 34.4 cm^3 vs. 311.8 ± 13.4 cm^3, p < 0.001). However, hemoglobin at discharged and total blood loss were not statistically significantly different, (10.5 ± 1.2 g/dl vs. 10.1 ± 0.9 g/dl, p = 0.153) and (1.7 ± 1.4 g/dl vs. 2.7 ± 1.1 g/dl, p = 0.064) respectively. In the custom cutting blocks group, the accuracy of their instrumentation was also assessed by measuring the thickness of the bone in which resected in