

Accuracy of A CAOS Enhanced Mechanical Instrument System for Total Knee Arthroplasty

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Abstract

This study investigated the accuracy of a novel CAOS enhanced mechanical instrument system for TKA, and its sensitivity to surgeon's experience level. Resection errors in varus/valgus alignment were assessed across senior, fellow, and resident surgeon groups, and compared between CAOS guided resections and resections performed with conventional instruments. The findings demonstrated that regardless of surgeon experience level, the CAOS enhanced mechanical instrumentation significantly reduced alignment errors compared to conventional instrumentation, along with substantial increases in the prevalence of optimal resections.

1 Introduction

Accurate positioning of the knee prosthesis is critical for the success of total knee arthroplasty (TKA) [1]. However, only 70-80% of the conventional TKA cases can achieve satisfactory lower limb alignment (within $\pm 3^\circ$ of varus/valgus relative to the mechanical axis) [2,3], which may be one of the contributing factors to the fact that up to 20% of patients remain dissatisfied after the surgery [4].

Computer-assisted orthopaedic surgery (CAOS) offers increased accuracy and precision to the bony resections compared to the conventional techniques [5]. Despite the proven benefits provided by CAOS technology, one of the drawbacks for its adoption by the surgeons may be the inconvenience of switching from conventional instruments to CAOS-specific instruments. Recently a novel system has been introduced to enhance conventional mechanical instruments with CAOS technology. The purpose of this study was to investigate alignment accuracy achieved by surgeons with varying TKA experience levels using the CAOS enhanced mechanical instrument system.

2 Materials and Methods

Two senior surgeons, two fellow surgeons, and four orthopedic residents participated in this study using knee models (MITA knee insert, Medical Models, Bristol, UK). First, each senior and fellow surgeon performed distal femoral and proximal tibial resections (6 knees) using a conventional instrument system. For the residents, each surgeon performed the same resections on 3 knees. The same resection activities were repeated on a matching set of knee models with the addition of the CAOS enhancement (ExactechGPS[®] TKA Plus, Blue-Ortho, Gieres, FR). The target for the coronal alignment of both resections was set to be 0° varus/valgus relative to mechanical axis.

The knee models were scanned and digitized (Comet L3D, Steinbichler, Plymouth, MI, USA; Verify64 & DesignX 64, Geomagic, Lakewood, CO, USA; and Unigraphics NX version 7.5, Siemens PLM Software, Plano, TX, USA) at the pre- and post- resections stages. On the intact bone surface, a set of virtual landmarks were annotated to establish the anatomical reference. After registration of the pre- and post- resection digital surfaces, the anatomical reference systems were re-created on the resected bone. The varus/valgus alignment (*achieved alignment*) was measured.

Alignment accuracy in each resection was defined as the signed and unsigned angular deviation between the alignment target (0° varus/valgus) and the *achieved alignment*. The unsigned differences represent the magnitude of resection errors. The signed differences however, identify any bias of the alignment error with a tendency towards more varus or valgus. Accuracy in varus/valgus alignment was compared between senior, fellow, and resident surgeons. The percentages of cases with optimal resection (less than 2° alignment deviation, without clinically alter the joint mechanics [2]) were compared between CAOS enhanced cases and conventionally instrumented cases, as well as between senior, fellow, and resident surgeons. Statistical significance was defined as $p < 0.05$.

3 Results

Compared to the cases performed with the conventional instrument system, those using the CAOS-enhanced instrument system exhibited improved varus/valgus alignment accuracy (Fig. 1). Impact from a surgeon's TKA experience level was found in the conventionally instrumented tibial resections. Specifically, the senior surgeons had less tibial varus/valgus alignment errors (both signed and unsigned) than those from the fellow and the resident surgeons (p values ≤ 0.017), while no significant difference was found between surgeon groups for femoral varus/valgus alignment (n.s.). In contrast, under CAOS guidance, all surgeon groups achieved on average $\leq 1^\circ$ accuracy (signed or unsigned) in both femur and tibial varus/valgus alignment (Fig. 1). Significantly higher percentages of optimal varus/valgus alignment were found in the CAOS resections compared to the conventionally instrumented resections (Table 1). All cases performed with CAOS guidance achieved optimal alignment, except for tibial resections from the fellow surgeon group (92%) (Table 1).

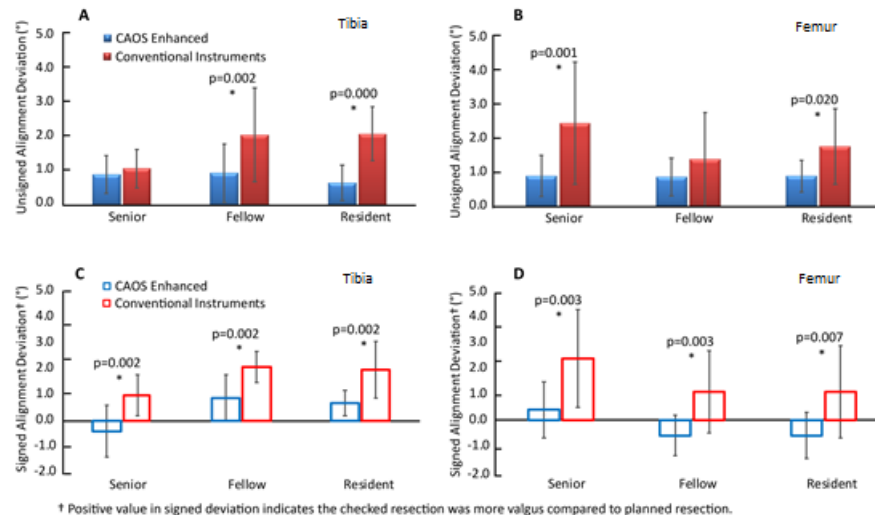


Figure 1. Unsigned alignment deviation in A) tibia and B) femur. Signed alignment deviations in C) tibia and C) femur. Significances found between CAOS and conventional resections were marked with p values.

Optimal Resection (<2° Deviation)	Senior	Fellow	Resident
Tibia			
Conventional	92% (11/12)	33% (4/12)	50% (6/12)
CAOS Enhanced	100% (12/12)	92% (11/12)	100 (12/12)
P	1.000	0.009	0.014
Femur			
Conventional	42% (5/12)	67% (8/12)	58% (7/12)
CAOS Enhanced	100% (12/12)	100% (12/12)	100% (12/12)
P	0.005	0.093	0.037

Table 1. Comparison of percentage of optimal resection between CAOS and conventionally instrumented resections.

4 Discussion

This study showed significant improvement in coronal alignment accuracy when a CAOS-enhanced mechanical instrument system is used, compared to conventional instrument system. The result reported that surgeons with varying experience level can achieve high accuracy in the varus/valgus alignment using the CAOS guidance provided based on a conventional instrument system. Furthermore, substantial improvement (8%-59%) in the percentage of optimal resection was observed in the CAOS guided resections, compared to the conventional cases.

Though based on conventional mechanical instrument and being streamlined compared to its matching “full-size” system (ExactechGPS®, Blue-Ortho, Gieres, FR), the CAOS system investigated was demonstrated to offer comparable accuracy [9] and the same robustness to surgeon TKA experience level [10]. The system investigated may provide an uncomplicated solution to add the benefit of CAOS

guidance [3] to the conventional instrumentation without major disruption in the surgical tools the surgeons are already familiar with.

5 References

- [1] Fehring TK, Odum et al. Early failures in total knee arthroplasty. *Clin Orthop Relat Res.* 2001;(392):315-8.
- [2] Ensini A, et al. Alignments and clinical results in conventional and navigated total knee arthroplasty. *Clin Orthop Relat Res.* 2007;457:156-62.
- [3] Hetaimish BM, et al. Meta-analysis of navigation vs conventional total knee arthroplasty. *J Arthroplasty.* 2012;27(6):1177-82.
- [4] Scott CE, et al. Predicting dissatisfaction following total knee replacement: a prospective study of 1217 patients. *J Bone Joint Surg Br.* 2010;92(9):1253–8.
- [5] Sparmann M, et al. Positioning of total knee arthroplasty with and without navigation support: a prospective, randomised study. *J Bone Joint Surg Br.* 2003;85(6):830-5.
- [6] Walker PS, Meere PA, Bell CP. Effects of surgical variables in balancing of total knee replacements using an instrumented tibial trial. *Knee.* 2014;21(1):156-61.
- [7] Jeffery RS, Morris RW, Denham RA. Coronal alignment after total knee replacement. *J Bone Joint Surg Br.* 1991;73(5):709-14.
- [8] Wasielewski RC, Galante JO, Leighty RM, et al. Wear patterns on retrieved polyethylene tibial inserts and their relationship to technical considerations during total knee arthroplasty. *Clin Orthop Relat Res.* 1994;299:31–43.
- [9] Angibaud LD, Dai Y, Liebelt RA, et al. Evaluation of the Accuracy and Precision of a Next Generation Computer-Assisted Surgical System. *Clinics in Orthopedic Surgery.* 2015;7(2):225-33.
- [10] Dai Y, Angibaud L, Jung A, et al. Computer-assisted total knee arthroplasty: impact of surgeon experience on the ability to achieve surgical resection goals. *Bone Joint J.* 2017;99-B(SUPP 3), 90.