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Bony Resection Outliers: Insights from 10,144 Clinical Cases using A Contemporary Computer-Assisted Total Knee Arthroplasty System

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Abstract

This study accessed the alignment outliers of intraoperatively measured bony resection during total knee arthroplasty on 10,144 cases performed using a modern CAOS system. The impacts from geographic regions, surgeon's adoption of the technology (learning or proficient phases), and historical progression of the CAOS application (software versions) were evaluated. The comprehensive analysis demonstrated that the CAOS system is a robust and accurate solution to assist the surgeons to achieve his/her surgical resection goals across its application history.

1 Introduction

Coronal malalignment of the implants, a result of technical errors during bony preparation in total knee arthroplasty (TKA), is among the leading etiologies of failed TKA [1]. Computer-assisted orthopedic system (CAOS) has been a proven technology to consistency improve implant alignment during compared to conventional instrumentation. Numerous studies on the CAOS TKA have been published on postoperative implant alignment [2,3]. However, the studies generally overlooked potential differences between 1) the detailed algorithms and technologies used across CAOS systems, 2) progression of the design of CAOS application such as updates and improvements, 3) the specific adoption phases of the CAOS system, and 4) patient characteristics and surgeons' surgical styles/philosophies across global geographic regions.

A standard assessment of a CAOS system for its performance is unquestionably difficult. It is almost impossible to initiate clinical studies that encompass the clinical cases performed by a CAOS system with the consideration of sufficient sample size for stratified analyses. Nowadays, modern advanced cloud-based data infrastructure allows archiving of technical performance during bony preparation, providing possibilities to comprehensively assess the alignment results of a CAOS system across its

users, geographic regions and history of its application. This study aimed to comprehensively assess the accuracy of the bony resection during the entire TKA application history of a modern CAOS system. Specifically, coronal alignment outliers in the bony resection were assessed with the factors of geographic regions, surgeon's adoption of the technology (learning or proficient phases), and historical progression of the CAOS application (software versions).

2 Materials and Methods

Cloud-based archives of the technical logs of all CAOS TKA cases performed using a modern CAOS system. All logs were stored as de-identified surgery reports without containing records of patient information of any sort. Similarly, all surgeons were de-identified with only their geographic information available. The following surgical parameters were extracted: 1) planned resection: the resection parameters determined by the surgeon prior to the bone cuts. These parameters reflected the surgeon's resection targets for the CAOS guidance; 2) checked resection, digitalization of the actual bony resection surfaces, checked by the surgeon by manually pressing an instrumented checker onto the bony cuts. Due to that anterior, posterior and chamfer cuts of the femur were all corresponded to the distal resection, only the distal resection was evaluated for the femur.

The coronal alignment error was calculated as the deviation between planned and checked resections for both tibia and femur. Outliers were identified as resections with more than 2° of coronal alignment error in the pooled group, and in the subgroups defined in Table 1. Comparisons were performed between cases from subgroups under the categories of geographic regions, surgeon's adoption of the technology (learning or proficient phases), and historical progression of the CAOS application (software versions). Statistical differences were identified between subgroups with p values < 0.05.

3 Results

A total of 10,144 CAOS TKA cases were reviewed from December 2010 to August 2018. The overall acceptable rates were 97.9% in the tibial proximal resection, and 97.2% in the femoral distal resection. The alignment results exhibited excellent accuracy and precision with more than 94% of acceptable resections in any given sub-group (Fig 1). Comparisons within each category demonstrated that the percentage of acceptable resections improved further in the proficient phase (tibia 98.4%, femur 97.9%) compared to the already high rates in the learning phase (tibial 96.0%, femur 94.7%). Furthermore, the updates of the CAOS application offered consistent further improvement in the percentage of acceptable resections, with similar results found in both tibial and femoral resections.

4 Discussion

Numerous studies have shown that malalignment can lead to various complications, such as component loosening and instability, polyethylene wear, and patellar dislocation [4-6]. It has been reported that conventional TKA can only achieve satisfactory coronal alignment (error within ± 3°) in only 60% to 80% of the cases [7-9]. In contrast, the CAOS system investigated was shown to consistently offer substantially reduction of unacceptable resections across global geographic regions and adoption phases, and improve even further through the updates and improvements of its software application overtime.

This big data study assessing the outlier rate of a specific CAOS system across all its application history considering factors that may influence the performance of the bony resections. All, not just

selective, users, geographic regions, software versions were included in the study, making this analysis an objective, comprehensive, and complete review of the performance of the system.

Table 1. Factors investigated for their impact on % acceptable resections.

Factors	Definition of Categories	Number of Categories
Geographic Regions	APAC: Japan, Australia, Korea, Singapore, India EU: France, Switzerland, United Kingdom, Italy, Spain USA	3
Adoption Phases	Learning: combined cases #1-15 from each surgeon Proficient: combined cases after #15 from each surgeon	2
Software Application	Software versions	6

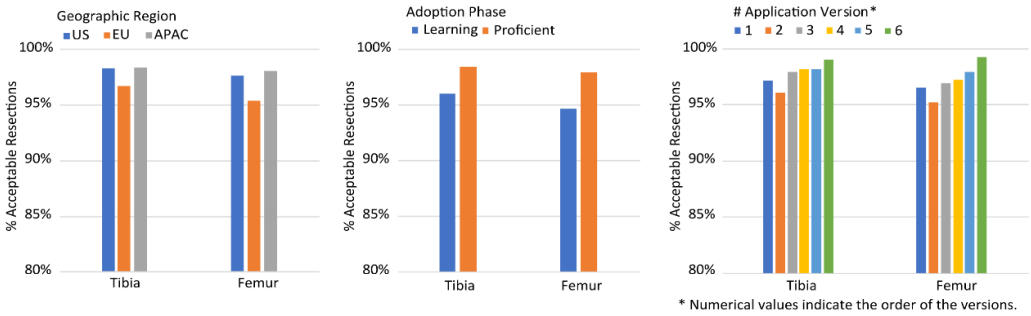

Figure 1. Alignment outliers in subgroups under each category.

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