INTRODUCTION

Computer-assisted orthopaedic surgery (CAOS) has been proven to help minimise human error during total knee arthroplasty (TKA) by improving the accuracy, reliability and reproducibility during the placement of the knee prosthesis [1,2]. Evaluations of CAOS systems generally overlooked the intrinsic accuracy of the systems themselves, and have been largely focused on the final implant position and alignment in the reconstructed knee [2,3]. Although accuracy at the system-level has been assessed [4], the study method was system-specific, required a custom test bench, and the results were clinically irrelevant. As such, clinical interpolation/comparison of the results across CAOS systems or multiple studies is challenging. This study quantified and compared the system-level accuracy in the intraoperative measurements of resection alignment between two CAOS systems.

MATERIALS AND METHODS

Computer-assisted TKAs were performed on 10 neutral leg assemblies (MITA knee insert and trainer leg, Medial Models, Bristol, UK) using System I (5 legs, ExactechGPS®, Blue-Ortho, Grenoble, FR) and System II (5 legs, globally established manufacturer). Preoperatively, a set of anatomical landmarks were annotated on the inserts by small dimples created by a metal probe. The surgeries then referenced the defined anatomical landmarks. Post bone cut, the alignment parameters were collected by the CAOS systems (CAOS measured alignment). The pre- and post-operative leg surfaces were scanned, digitized, and registered (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). The alignment parameters were measured virtually, referencing the same pre-defined anatomical landmarks (baseline). The signed and unsigned measurement errors between the baseline and CAOS measured alignment were compared between the two CAOS systems with significance defined as p<0.05. The unsigned differences represent the magnitude of measurement errors generated by the CAOS system. The signed differences however, identify any bias of the measurement error, such as a tendency of resecting towards more varus (or valgus), higher flexion (or extension), or an increased (or reduced) posterior slope.

RESULTS

The measurement errors are presented in Table 1. Compared to System I, System II had a higher unsigned error magnitude in the measurements of tibial varus/valgus alignment and posterior slope (p≤0.01), and lower magnitude in the measurement of femoral varus/valgus alignment (p=0.03). System II exhibited higher error bias towards tibial varus alignment (up to 2.59°), more posterior slope (up to 1.61°), and more femoral hyper extension (up to 1.6°) than System I (p<0.01). The mean signed and unsigned errors were generally less than 1°, with the exception of System II in the measurement of tibial varus/valgus alignment (signed and unsigned mean errors=1.93°).
DISCUSSION

This study demonstrated that there exists system-dependent bias and variability associated with intraoperative measurements of alignment parameters during TKA. The results showed that System I generally had lower variability and less bias in the resection alignment measurements than System II. The majority of the differences, although significant, were clinically irrelevant (<1° in means). Notably, System II was shown to produce on average ~2° measurement errors in tibial varus/valgus alignment biased towards varus.

Intra-operative measurement of surgical resection parameters during imageless computer-assisted TKA surgery is a critical step, in which a surgeon directly relies on the real-time data obtained by the optical trackers to prepare the bony resections and check the final realized cuts. As pointed out previously, the “smart” user interface of CAOS systems may cause overlooking of the underlying system-level errors [4]. Clinical-level accuracy in alignment outcomes has been shown to be system-dependent [5], this study further suggested there are differences in system-level accuracy between CAOS systems.

REFERENCES


DISCLOSURES

Yifei Dai and Laurent Angibaud are current employees of Exactech Inc.

Barton Harris is a paid surgeon consultant of Exactech Inc.
Table 1. A) Signed and B) unsigned errors in the measurements of resection alignment, generated from the two CAOS systems investigated.

<table>
<thead>
<tr>
<th>Bone</th>
<th>Alignment (°)</th>
<th>System I</th>
<th>System II</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean [Min, Max]</td>
<td>SD</td>
<td>Mean [Min, Max]</td>
</tr>
<tr>
<td>Tibia</td>
<td>Varus/Valgus</td>
<td>0.42 [-0.08, 1.2]</td>
<td>0.52</td>
</tr>
<tr>
<td></td>
<td>Posterior Slope</td>
<td>0.11 [-0.21, 0.56]</td>
<td>0.32</td>
</tr>
<tr>
<td>Femur</td>
<td>Varus/Valgus</td>
<td>0.80 [-0.22, 1.59]</td>
<td>0.68</td>
</tr>
<tr>
<td></td>
<td>Flexion/Extension</td>
<td>0.30 [0.13, 0.40]</td>
<td>0.47</td>
</tr>
</tbody>
</table>

Figure 1. Significant differences (*) found between the two CAOS systems investigated in the A) signed and B) unsigned measurement errors.