Reference Papers

Accuracy of a Novel Computer-assisted Guidance System for Total Knee Arthroplasty

This memo reports on the results of a computer analysis to be presented at the 2013 International Society for Computer Assisted Orthopaedic Surgery.

Introduction

Clinical outcomes for total knee arthroplasty (TKA) are especially sensitive to lower extremity alignment and implant positioning,[1] with research associating tibial bone cuts in more than 3° of residual varus with higher risk of implant failure.[1] The use of computer-assisted orthopedic surgery (CAOS) can provide an opportunity to improve overall TKA accuracy.[2]

CAOS systems fall into two broad categories: Image-based systems relying on data acquired from pre- or intra-operative imaging, and image-free systems that intra-operatively acquire anatomical landmarks to generate a bone model. From this model, surgeons can define and target implant location and orientation. Image-free systems are appealing because costly medical imaging modalities (e.g., CT, MRI) can be avoided. Due to the lack of direct imaging, achieving high functional accuracy could be more challenging for image-free CAOS techniques. Thus, the assessment of functional accuracy of image-free CAOS systems is of particular importance.

The objective of our study was to assess the accuracy of a novel image-free CAOS guidance system (Exactech GPS®, Blue Ortho®, Grenoble, France) by using synthetic leg models and a high precision 3D scan technique.

Materials and Methods

We assembled seven synthetic neutral knee inserts (MITA knee insert M-00598, Medical Models, Bristol, UK) with a commercially available artificial leg (MITA trainer leg M-00058, Medical Models, Bristol, UK). A high-precision 3D scanner (Comet L3D, Steinbichler, Plymouth, MI) was used to scan the leg components and collect pre-identified anatomical landmarks for the femur (i.e., femoral head center, distal and posterior condyles, and distal femur center) and the tibia (i.e., intercondylar eminence, medial and lateral plateaus, tibial tuberosity, and medial and lateral malleoli) prior to making cuts.

Next, procedures were performed using the Exactech GPS. The probe tracker was used to acquire the same pre-identified anatomical landmarks. After adjusting the cutting block to match targeted resections, the bone cuts were performed.

After the bone cuts were completed, the knee insert was re-scanned and the models made before and after the cuts were overlaid *(Figure 1)*. Resection parameters were calculated from the pre-identified anatomical landmarks using advanced software packages (XOV & XOR, RapidForm, Lakewood, Colo. and UG NX, Siemens PLM, Plano, Texas).

Finally, for each knee insert, the sets of data obtained from the 3D scanner were compared with those from the guidance system. Given the high accuracy of the 3D scanner (standard deviation error less than 50 μm for the dimensions of the knee insert), 3D scan measurements were used as our baseline to assess the error of the CAOS system.

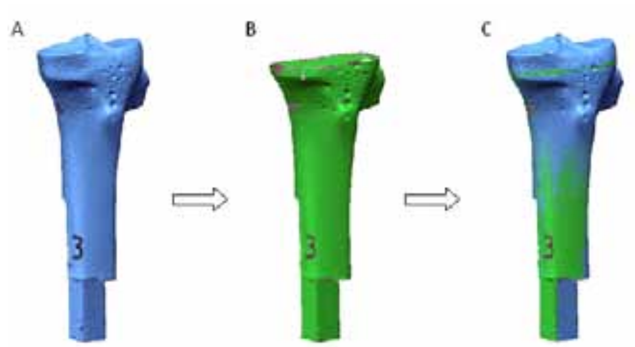

Figure 1. *Bone were 3D scanned before (A) and after (B) cut and then the two models were overlaid (C) in order to define the resections and the angles.*

Table 1. Errors of the CAOS system on resection and joint angle measurements.

Bone	Parameter	Measurement errors		
		Mean	SD	[Min, Max]
Tibia	Medial resection (mm)	0.09	0.20	[-0.30, 0.30]
	Lateral resection (mm)	0.20	0.36	[-0.30, 0.70]
	Varus/Valgus (°)*	0.03	0.39	[-0.30, 0.87]
	Slope (°)*	0.16	0.36	[-0.50, 0.50]
Femur**	Medial resection (mm)	-0.32	0.39	[-0.80, 0.20]
	Lateral resection (mm)	-0.20	0.44	[-0.80, 0.40]
	Varus/Valgus (°)*	0.51	0.42	[-0.20, 1.00]
	Flexion/Extension (°)*	0.23	0.23	[0.00, 0.60]

**Varus/Valgus: varus is signed negative, valgus is signed positive; Slope: decreased slope is signed negative, increased slope is signed positive; Flexion/Extension: Flexion is signed negative, extension is signed positive*
***Based on six bones only, as the locking pins dissociated from the synthetic bone during the preparation of femur #2*

Results

Bone resection thickness and orientation measurement errors by the CAOS system for both the tibia and femur are given in *Table I*.

The mean error of the CAOS system was less than 0.35 mm for bone resection measurements, and less than 0.6° for joint angle measurements. Even considering the ranges of the errors, it was no more than 1mm for all bone resection measurements and no more than 1° for all joint angle measurements. The low variability is also reflected by the small SD values. The errors were smaller on the tibia than on the femur.

Discussion

To our knowledge, this is the first study to use a high-resolution 3D scanner to assess the accuracy of surgical cuts associated with use of an image-free CAOS system. The non-contact measurement feature of the scanner was appropriate for measuring fragile objects such as the synthetic foam of the knee insert that are difficult to use with conventional measuring machines featuring tactile measuring heads.

The study demonstrated that the evaluated image-free CAOS system was able to achieve both high accuracy (small mean errors) and high precision (small error variability) when making femoral and tibial bone resections during computer-assisted TKA.

Determining precise landmarks using CAOS for TKA has been shown to be of critical importance.[3] For this reason, the insert anatomical landmarks used by the scanner and guidance system were carefully identified and prepared to ensure consistency.
It should be noted that the "gold standard" measurement we used in this study (high precision 3D scan and reverse engineering modeling) also has potential of errors. Modeling errors could occur during the idealization of resection surfaces from the scanned model (which may not be perfectly flat). In order to minimize this effect, the operator used a similar area as the one checked by the guidance system and established the simulated plan through three points of contact.

In conclusion, this study demonstrates a high level of in-vitro accuracy of the Exactech GPS.

References

1. **Ritter MA, Faris PM, Keating EM, Meding JB.** Postoperative alignment of total knee replacement: its effect on survival. Clin Orthop Relat Res. 1994; 299:153-156
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Evaluation of the Alignment Discrepancies During Total Knee Arthroplasty Using an Image-free Computer-assisted Guidance System

This memo reports on the results of a computer analysis to be presented at the 2013 International Society for Computer Assisted Orthopaedic Surgery.

Introduction

Clinical outcomes of total knee arthroplasty (TKA) are especially sensitive to lower extremity alignment and implant positioning, with research associating tibial bone cuts in more than 3° of residual varus with higher risk of implant failure.[1] From pre-operative planning to final implant cementation, TKA preparation is defined by a succession of many individual steps, each presenting potential sources of error that can result in devices being implanted out of the desired range of alignment.

The objective of our study was to evaluate alignment discrepancy occurring during different steps associated with TKA using a novel image-free CAOS guidance system. (Exactech GPS®, Blue Ortho®, Grenoble, France)

Materials and Methods

We assembled seven synthetic neutral knee inserts (MITA knee insert M-00598, Medical Models, Bristol, UK) with a commercially available artificial leg (MITA trainer leg M-00058, Medical Models, Bristol, UK).

A pre-surgical profile was established to define resection parameters for the proximal tibial and distal femoral cuts *(Figure 1A)*. The proximal tibial cut was defined by the resection level off a medial plateau reference point, the varus/valgus alignment and the slope angle. The lateral resection was therefore an output and not reported. A similar rationale applies to the medial resection of the distal femoral cut.

First, Exactech GPS was used to acquire the pre-identified landmarks. Next, the cutting block was adjusted to match the resection targets and fixed to the bone using locking pins. Bone cuts were performed, and finally, the actual cuts were checked. Data from the guidance system were collected at three separate steps: (1) cutting block adjusted but not pinned to the bone *(Figure 1B)*, (2) cutting block adjusted and pinned to the bone *(Figure 1C)* and (3) after the cuts were checked *(Figure 1D)*. These data were then compared to the resection target parameters to track potential dispersions occurring during the process.

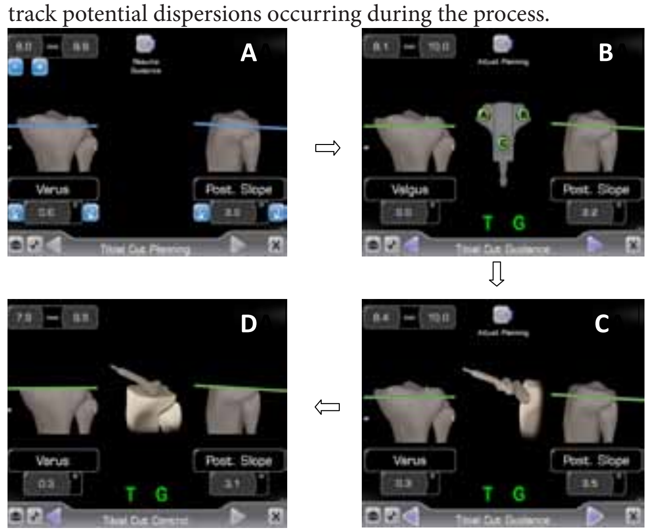

Figure 1: *Alignment acquisition sequence starting from target planning (A), cutting block adjustment (B), attachment of the cutting block to the bone (C), making bone cut and final checks (D)*

Results

Resection and rotational measurement data for both the tibia and femur along the study are given in *Table I (on back)*.

For all measurement data, the dispersions were limited as the difference in bone resection thickness and angular measurement along the process were less than 1mm and 1°, respectively.

For each studied parameter, the mean value was nominal, demonstrating that the distribution was well centered. This being said, there was a consistent derive of the distal femoral in extension (up to 0.9°) along the preparation, resulting in lower than expected resection of the distal femur (up to 0.9 mm).

Discussion

Few studies present possible causes for errors when using CAOS for TKA. Notably, Bathis et al. evaluated cutting errors as the difference between the primary cutting block position and the resulting resection plane. As a result, errors due to a malpositioning

Table I: Differences in data between the sequences

Bone	Parameter	Adjusted vs. targeted			Attached vs. targeted			Checked vs. targeted		
		Mean	SD	[Min, Max]	Mean	SD	[Min, Max]	Mean	SD	[Min, Max]
Tibia	Medial resection thickness (mm)	-0.03	0.10	[-0.20, 0.10]	0.00	0.24	[-0.30, 0.40]	-0.19	0.19	[-0.50, 0.10]
	Varus/Valgus (°)*	-0.09	0.07	[-0.20, 0.00]	-0.16	0.32	[-0.40, 0.30]	-0.10	0.22	[-0.30, 0.20]
	Slope(°)*	0.04	0.08	[0.00, 0.20]	-0.04	0.36	[-0.40, 0.50]	-0.09	0.11	[-0.20, 0.10]
Femur**	Lateral resection thickness (mm)	0.08	0.18	[-0.10, 0.40]	-0.20	0.19	[-0.40, 0.10]	-0.58	0.31	[-0.90, -0.10]
	Varus/Valgus(°)*	0.05	0.10	[-0.10, 0.20]	0.18	0.19	[-0.10, 0.40]	-0.08	0.48	[-0.90, 0.60]
	Flexion/ Extension(°)*	-0.03	0.10	[-0.20, 0.10]	0.28	0.13	[0.10, 0.40]	0.62	0.33	[0.00, 0.90]

**Varus/Valgus: varus is signed negative, valgus is signed positive; Slope: decreased slope is signed negative, increased slope is signed positive; Flexion/Extension: Flexion is signed negative, extension is signed positive*

***Based on six bones only, as the locking pins dissociated from the synthetic bone during the preparation of femur #2*

of the guide jig itself were not described.[2] In other words, they weren't able to directly differentiate the degree to which the deviation of the resection plane is the effect of inadequate fixation of the cutting block itself or the result of the sawing procedure. Based on 50 patients, they reported mean errors of 1.4°±1.3° and 1.0°±1.0° for the femoral and tibial flexion/extension, respectively.

Based on our study, we found that, in general, the dispersions at each step seem random and there was no apparent accumulating trend from step 1B to 1D. The only parameter associated with a trend was the flexion/extension of the distal femoral cut. First, there was a slight dispersion in extension from step 1B to 1C; which can be due to the offset weight of the tracker acting on the adjustable instrumentation during the pinning step. Secondly, there was, also, a consistent dispersion in extension from step 1C to step 1D; which is perceived as resulting from the skiving of the saw during the cut process. One limitation of our study is that we didn't evaluate the steps after the preparation of the bone cuts. Catani et al. stated that alignment deviations are also caused by the cementation and impaction of the implants.[3]

The evaluated image-free computer-assisted guidance system did not exhibit substantial alignment dispersions during each step of the procedure, which reflected the robustness of the system and the surgical technique.

References

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