INTRODUCTION

Ancillary fixation in knee arthroplasty has traditionally been used for early fixation of cementless tibial implants to prevent micro-motion and in turn facilitate bone ingrowth and long-term fixation. Cemented TKA and UKA remain the gold standard in primary knee replacement, with the thickness of the cement mantle contributing to implant position and long-term integrity of fixation. New technologies and surgical methods have increased the precision of bone resection and implant positioning, which increases the likelihood of the implant functioning as designed by the manufacturer and implanted by the surgeon. This, coupled with improved imaging, patient-specific design, and precision bone resection techniques provides the opportunity to increase the precision and clinical success of knee arthroplasty. The purpose of this study was to assess the surgical technique, integrity of screw fixation, and precision of tibial and femoral component positions for the cemented Bodycad Unicompartmental Knee System relative to the pre-operative surgical plan, the scientific literature, and Bodycad laboratory data.
MATERIALS AND METHODS

Several tests were performed on the Bodycad Unicompartmental Knee System (BUKS) using cadaver knees and Sawbones models (Pacific Research Laboratories) to assess: (1) the effect of screw fixation on initial cemented fixation, (2) position of the femoral component due to screw fixation, (3) the strength of fixation of the femoral component, (4) 3D mapping of screw trajectory for mal-engagement and normal- and mal-positions, (5) the potential for screw back-out and, (6) cement thickness.

Instruments and implants were manufactured by Bodycad. Cadaver knees and sawbones models were prepared for surgery using the standard Bodycad surgical technique. Cadaver specimens were sourced from the University of Sherbrooke Medical Centre, Sherbrooke, Canada. The 3D scanner used for cadaver surgeries was the TRIOS scanner (3Shape), precision of 4.5±0.9 μm and accuracy of 6.9±0.9 μm. The 3D scanner used for evaluation of screw trajectory and implant position in Sawbones models was the ATOS II Triple Scan with GOM-LIFT 890. CloudCompare software was used for evaluating implant position. Fatigue and strength testing were performed with an ADMET axial-torsion testing machine.

Screw trajectory, femoral component position and fixation, and screw retention [Ref 1]: 3D bone models with 20 pcf Sawbones inserts were prepared for testing. The position of the femoral component and the trajectory of the screws were measured with the 3D scanning system before and after cemented fixation with screws (1) aligned, (2) not engaged, and (3) mal-aligned, as shown in Figure 1. The strength of fixation was measured by axial pull off at a rate of 50 mm/min. Micro motion testing of fixation of the femoral component and screw was performed with 6 to 60 Nm torque for simulated chair-rise motion for 250,000 cycles for worst case fixation (no cement) per the method of Schultz [9]. Micro motion of the femoral implant and screw were monitored throughout testing with a video capture system.

![Normal Screw Alignment](image1)
![Worst Case Engagement](image2)
![Worst Case Trajectory](image3)

Figure 01: Screw positions shown with the instrument used intra operatively for screw alignment
Assessment of implant position accuracy: Femoral and tibial implant position were assessed using ten (10) cadaver legs. The study was divided in four steps. (1) Planning and personalization of the BUKS for each cadaver knee following the Bodycad design and manufacturing procedure, (2) The BUKS was implanted per the surgical technique at the University of Laval (Quebec City, Canada) by three orthopedic surgeons, Étienne Belzile, MD, Michèle Angers MD, and Martin Bédard MD. During surgery, the cut validator instrument was used to confirm the accuracy of the tibial cut (intra op accuracy of +/- 0.5 mm), (3) 3D scanning of the specimen immediately after surgery via surgically enlarged access, and (4) Comparison of the planned position of the prosthesis with the resulting 3D scans (accuracy measurement).

RESULTS AND DISCUSSION

Evaluation of the Bodycad surgical technique showed insertion of the screw to enhance cemented fixation of the femoral and tibial components by reliably and repeatedly extruding excess cement at the margins of the interface between the bone model and implant, a decrease in potential gaps and excess cement between the implant and bone, and uniformity of cement thickness of 0.9 mm (Figure 2). The same tests on Sawbones showed that insertion of the screw resulted in the position of femoral implant to be closer to plan. Evaluation of all possible screw trajectories showed worst-case alignment to negligibly shift the femoral component from the planned position. The results of pull off testing of the femoral component with screw fixation measured a mean maximum load of 708±68N with a displacement at break of 8.7 ±1.8 mm. Bone cement dominated the retention force of the femoral component (as expected).

Figure 02: Example of evaluation of fixation technique and position of the BUKS femoral component
The results of fatigue testing (250,000 cycles) the BUKS femoral implant under worst case conditions (no cement, unassisted rising from chair, max-torque about the knee [9]) showed negligible difference in micro motion (6 to 23 μm) with and without the screw, and no change in screw position. This result is attributed to the inherent stability of the box geometry of the femur, precision of manufacture of the patient-matched Bodycad UKS femoral component, and accuracy of the Bodycad surgical technique. These results indicate that there are no adverse effects of femoral screw fixation for the cemented BUKS, while demonstrating two benefits: (1) Enhancement of cement fixation by minimizing gaps and excess cement and insuring uniform 0.9 mm thickness, and (2) Insuring the that pre-operative target and post-operative position are reliably close to the surgical plan.

The accuracy of tibial baseplate positioning after implantation in Sawbones models showed the final position of the tibial component deviated from the planned position by approximately 0.59 mm (average maximum observed deviation) in the superior-inferior axis, and maximum observed singular value of 2.08 mm [5]. The error measured in the Bodycad study are lower than that noted by Karia et al. 2013. [5] for Sawbones models prepared for UKA with the Mako system. The accuracy of femoral component positioning after implantation showed the final position of the femoral component deviated from the planned position by approximately 0.26 mm (average maximum deviation) in the superior-inferior axis, which is comparable (lower deviation) to Smith et al. [8] (1.17 mm in the superior-inferior axis) for Sawbones models prepared by the Blue Belt Navio system. Examples of the mapping 3D deviation analyses are presented in Figure 3a and 3b for the femoral and tibial components. The tibiofemoral surface showed minimal position deviation.
The results of the ten cadaver surgeries with the BUKS showed the average maximum 3D position deviation relative to plan of the femoral component was 1.07 mm and 0.79 mm for the tibial component (Figure 4). The average deviations (Root Mean Square) of angular displacement for the tibial component was 1.27° for the Flexion/Extension angle deviation, 1.38° Varus/Valgus angle deviation, and 3.32° Internal/External rotation angle deviation. For the femoral component, the average RMS deviation was 2.48°

Figure 03-b: Positional deviation mapping for the tibial component

Flexion/Extension, 3.15° Varus/Valgus angle deviation, and 1.85° Internal/External rotation angle deviation, which compares favorably to implant positioning accuracy data reported for studies performed using real bones and improvement versus newer technologies such as robotic assisted surgery and computer assisted navigation.
The results of positional accuracy described here for the Bodycad UKS are similar to published studies in the literature. For example, Smith et al. [8] studied the accuracy of the Blue Belt Navio technology in Sawbones models, wherein they measured a position-deviation of the implant of up to 1.17 mm when compared to the planned position, and angular errors of up to 1.52° and 0.56 mm (root mean square, RMS) for the femoral implant and up to 1.32° and 0.5 mm for the tibial implant. Bathis et al. [10] compared a robotic cutting technique with a standard cutting approach (oscillating, powered saw) and reported the variability in angle of cut to be 3 degrees in varus/valgus compared to the planned implant position. Based on Hamlin et al. [11], it is possible to extrapolate and conclude that a 3-degree variance in angle can result in 2 to 3 mm of positional variance.

In the context of a clinical trial (in vivo study), Cobb et al. [6] reported surgical RMS errors of 3.4° and 1.8 mm using the Acrobat robot assist system, and Dunbar et al. [7] reported surgical RMS errors of 3.0° and 1.6 mm using Mako robotic technique. Cobb also reported surgical RMS errors of 6.3° and 2.6 mm using conventional methods. The measured implant positions obtained for the Bodycad system for trials with cadavers and Sawbones are closer to plan than those reported by Cobb et al. [6] and Dunbar et al. [7], and significantly better than the accuracy associated with oscillating saws.
CONCLUSIONS

Screw fixation of the BUKS femoral component was shown to:
- enhance initial cemented fixation,
- more accurately position the implants relative to the surgical plan,
- augment cemented femoral fixation, and
- not affect the potential for micro motion, which in turn greatly reduces the probability of fatigue failure and back-out of the screw, while insuring uniform 0.9 mm thickness of cement. Worst-case fatigue testing showed the femoral screw to remain fixed in original position. The cadaver surgeries showed the position of the BUKS femoral and tibial components to be similar or closer to plan than current robotic and contemporary assisted surgery methods, and superior to bone resection with an oscillating saw.

REFERENCES