Exactech Scientific
and Clinical Evidence
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INTRODUCTION

Since we began Exactech more than 30 years ago, our goal has been to help surgeons worldwide make patients more mobile. Our innovations have been designed with a singular purpose: to improve patient outcomes.

COMPONENT FIT

CLINICAL EVALUATION OF DISTAL FEMORAL FIT USING EXACTECH LOGIC PROSTHESIS (INTERNAL PUBLICATION)

Medial or lateral overhang of the femoral component when placed on the distal femur has been documented to lead to poor patient outcomes at 5 years [Chau] and may account for 27% clinically important knee pain [Mahoney]. Studies demonstrate the differentiating point for clinical significance is 3-4mm [Mahoney, Chung]. There has been some discussion that appropriate fit may be compromised in populations other than Caucasian, particularly in the Asian population. In the following document, 119 TKA knees were examined for both medial and lateral fit of the femoral component to the distal femur in Caucasian, Asian, Hispanic and African American groups, both males and females. Exactech Logic closely resembles Persona® in femoral bone fit in non-Caucasian ethnicity groups and in both male/female genders. Table 1 references a literature review of competitive products reports incidence of >3mm overhang at distal femur (See Table 1).

Table 1: Previously published overhang incidence on other contemporary femoral designs.

<table>
<thead>
<tr>
<th>Published Study</th>
<th>Design</th>
<th>Patient Ethnicity/ Nationality</th>
<th>Patient Gender</th>
<th>Incidence of &gt; 3mm Overhang at Distal Femur (N Total Subjects)</th>
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<td>Loures et al. 2016 [Loures]</td>
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<td>Male</td>
<td>10% (10)</td>
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<td></td>
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<td>28% (25)</td>
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<td>Natural Knee®</td>
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<td>Female</td>
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<td>19.1% (68)</td>
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COMPONENT FIT

DISTAL FEMORAL MORPHOLOGY AND ITS CORRELATION WITH TWO CONTEMPORARY TKA DESIGNS (ORS 2017, ABSTRACT 1975)

A computational comparison was completed on 100 knees (50 Chinese and 50 Caucasian) comparing Exactech Logic and a recently released competitive design. Exactech Logic uses varying ML/AP ratios across AP size to closely match bone morphology and minimize overhang. The competitive design offers 2 ML/AP ratios per AP size (narrow and standard) for mid size femurs. Compared to the competitive design, the distal ML offerings of Exactech Logic design are narrower in small component sizes, in between the standard and narrow sizing offerings in median sizes, and equivalent to the competitive design in large sizes. Both products demonstrated minimization of component overhang. Exactech Logic closely resembles a recently released competitive product in femoral component fit in non-Caucasian ethnicity groups and in both male/female genders (See Figure 1).

EVALUATION OF A WESTERN ORIGINATED TOTAL KNEE ARTHROPLASTY DESIGN ON THE FIT OF SMALL SIZES FEMORA (ORS 2016, ABSTRACT O942)

Digital CT segmented surfaces of 80 femurs with <63mm AP dimension (41 Asian and 39 Caucasian) were used for this study. Clinically significant overhang was determined as 3mm or greater in distal component overhang. In general, the fit of the Logic design was equally good between both ethnic groups, and out of the 80 knees only one knee (Asian) showed medial overhang of 3.3mm. In fact, the results demonstrated less overhang incidences in the Asian patients compared to previous similar evaluations on several other western based contemporary designs. The conclusion was that the Exactech Logic femoral components can provide equally good fit in small sized knees for both Asian and Caucasian patients.

ALIGNMENT AND BALANCING

TOTAL KNEE ARTHROPLASTY USING A CONTEMPORARY COMPUTER-ASSISTED SURGICAL SYSTEM: A REVIEW OF SURGERY PARAMETERS ON MORE THAN 4000 CLINICAL CASES (CAOS 2016)

This study looked at 4292 clinical cases to determine accuracy and precision for the ExactechGPS® system. Two types of surgical parameters were examined: 1. Planned resection as defined by the surgeon prior to cuts and 2. Verification of actual cuts for both the distal femur and the proximal tibia as determined by the digitalization of the resected surfaces. All parameters examined were within 0.5° or 0.2mm of accuracy demonstrating that the ExactechGPS® system can be used with confidence and that the surgical resection goals will be achieved with accuracy and reliability.

COMPUTER-ASSISTED TOTAL KNEE ARTHROPLASTY: IMPACT ON SURGEON EXPERIENCE ON THE ABILITY TO ACHIEVE SURGICAL RESECTION GOALS (CAOS 2016)

Novice orthopedic surgeons with ≤30 CAOS TKA experience in their practice and no prior computer-assisted experience compared to highly experienced (>150 TKAs) orthopedic surgeons showed no statistical differences in planned versus achieved resections using the ExactechGPS® system. Accuracy and precision can be achieved at any level of experience using the ExactechGPS® system.

COMPUTER-ASSISTED SURGERY PROVIDES AN EFFECTIVE AND ACCURATE TOOL FOR NATURALLY ALIGNED TOTAL KNEE ARTHROPLASTY (ORS 2016, ABSTRACT 1008)

This study sought to demonstrate and evaluate a surgical technique aiming to restore individual natural alignment in varus knees (>3°). Thirty-four knees were evaluated for preoperative varus deformity, natural alignment target and achieved alignment. The ExactechGPS® system provided the surgeon with the ability to quantify the alignment targets, guidance to bony resections and assess accuracy of alignment. The final achieved natural alignment for both genders were consistent with reported constitutional varus in healthy population. Natural alignment can be achieved with accuracy and precision in varus knees using the ExactechGPS® system.

THE EFFECT OF POSTERIOR TIBIAL SLOPE ON THE KINEMATICS OF PCL-RETAINING TOTAL KNEE ARTHROSCOPY (ORS 2016, ABSTRACT 1875)

The purpose of this study was to assess the impact of posterior tibial slope on the kinematics of an Optetrak Log® CR TKA procedure. A specially designed tibial baseplate allowed the tibial slope to be modified without additional cuts to avoid potential damage to the soft tissue envelope. Four slopes were evaluated (10°, 7°, 4°, 1°) in 6 cadaver knees and compared to the native knee state. The average kinematics for each of the four slopes evaluated were all close to the native knee. However, the individual kinematics varied from the average value and exhibited certain slope preference in order to reproduce native kinematics (See Figures 2 and 3).
ALIGNMENT AND BALANCING

EVALUATION OF ANTEROPosteriOR KINEMATICS During CRUCiate-REtaining TOTAL KNEE ARTHROPLASTY (ESSKA 2016, ABSTRACT 1188)

In a CR Total Knee Arthroplasty, anterior sliding of the distal femur relative to the proximal tibia during mid- flexion extension can result in abnormal AP kinematics, limitations in ROM and increase in polyethylene wear. ROM test was performed on Exactech Logic CR knees at four posterior tibial slopes (10°, 7°, 4°, 1°) for tibiofemoral displacement in AP direction. The kinematics exhibited no paradoxical motion throughout the flexion range. The results demonstrate stable and natural AP kinematics using the Optetrak Logic® CR design.

ECONOMIC VALUE

EXACTECHGPS® GUIDANCE SYSTEM DOES NOT INCREASE OPERATIVE TIME WHEN COMPARED TO CONVENTIONALLY INSTRUMENTED TOTAL KNEE ARTHROPLASTY

This study compared total surgical time for primary TKA using both conventional technique and ExactechGPS®. It also reviewed surgical time variations between an experienced CAOS surgeon and an early experienced CAOS surgeon. Initially, the early experience group increased the surgical time by an average of 7 minutes. However, with an advanced CAOS experience level, the surgeon was able to achieve time neutral (statistically insignificant) with an average 2 minutes saving compared to conventional technique. The results demonstrated that ExactechGPS® does not necessarily increase surgical time compared to conventional technique.


Only 3-5% of knee replacement surgeries use navigation technology, despite the evidence of improved radiographic alignment: the main reason is cost. A retrospective review on cases between 2004 and 2007 was performed in a 200 bed hospital with an annual volume of 1000+ joints. One surgeon’s data using computer-assisted surgery was compared to the combined hospital surgical data and national average, using conventional methods for joint replacement. The single surgeon data demonstrated length of stay (LOS) as less than 3 days for all hip and knee arthroplasty using CAS as compared with the average 3-4 day Medicare, national and hospital combined data. The surgeon’s discharge to home rate was 71%; triple that of Medicare, national and combined hospital data for 2005-2006. The cost for navigated TKAs was actually $4-5K less per case than national and hospital averages with conventional TKA. Clinical volume growth is expected with this type of novel technology and was documented in this hospital at 310% growth in the first year as a result of public relations initiatives and primarily as a result of word of mouth. For new orthopedic technology to be widely adopted there must have favorable net revenue for institutions, less strain on systems, improved patient outcomes with implant durability and increased demand from consumers. CAS was demonstrated to be cost-effective in this cohort without increasing the burden on the hospital work flow. Average charges for navigation, LOS, and incidence of discharge to home may actually be lower than CMS national or combined hospital reported data.

REVISION

TIBIAL AND FEMORAL STEM EXTENSION

FATIGUE PERFORMANCE WITH AND WITHOUT LPB TREATMENT, (INTERNAL EXACTECH PUBLICATION)

Low Plasticity Burnishing (LPB) is a novel treatment process for titanium material to improve surface finish, increase corrosion resistance, and enhance fatigue performance. This process is applied to Logic CC tibial and femoral stem extensions. Fatigue testing was performed on Exactech stem extensions treated with and without LPB process and a comparable DePuy Synthes stem extension. Both Exactech stem extensions, with and without the LPB treatment, had better fatigue performance than the DePuy Synthes design. The DePuy Synthes stem extension failed first, followed by Exactech non LPB treated stem, and finally the Exactech LPB treated stem. The LPB treated Exactech stem had >60,000% increase in fatigue performance compared to the DePuy Synthes design. The LPB treated stem extension may offer a better solution for younger, more active patient populations (Figure 2).

![Figure 2: Force versus cycle before failure are plotted for the treated and untreated CoCr tibial tray and titanium stem extension assemblies, and competitive samples.](image)

* Laboratory testing may not necessarily be predictive of clinical performance.
A SURGEON’S PERSPECTIVE ON WHY NAVIGATION IS IMPORTANT IN REVISION TOTAL KNEE ARTHROPLASTY (EXACTECH INNOVATIONS VOLUME 2, ISSUE 2, 2016)

Most orthopedic surgeons currently using a CAOS system aim to achieve better alignment, reduce surgical time, reduce number of instruments, avoid violating the IM canal and manage pre-post kinematics. The Exactech RTKA GPS system is designed for ease of use, regardless of the level of experience with any CAOS system. Dr. Huddleston who has over 750 revisions performed shares his experience using the ExactechGPS system for revision- he provides insights on why he believes the revision platform will be easier to use, more efficient and result in improved functional outcomes.

EARLY RESULTS OF A NEW REVISION TOTAL KNEE ARTHROPLASTY SYSTEM USED IN THE STAGED TREATMENT FOR CHRONIC PERIPROSTHETIC INFECTION (EXACTECH INNOVATIONS VOLUME 2, ISSUE 2, 2016)

This paper reviewed 7 revision TKA cases for treatment of chronic periprosthetic infection performed by a single surgeon using the Opottrak Logic® CC revision system. In all the cases, the Logic CC system was shown to offer an effective solution with regard to implant removal (especially with well fixed implants in the setting of weakened bone), bone preparation (in the setting of weakened fixation platform), articular constraint, fixation dependability, and bone defect management. The advantages of two unique instruments were highlighted for implant removal; the Exactech AcuDriver® (a specialized pneumatic cement-implant disruption system) and the Exactech Extractor (axial force device used to remove the implant versus a compressive, bending or torsional forces to help reduce potential fractures or additional bone loss). The stem offset offerings achieved optimal femoral stability, with bony used defects and voids properly managed by a variety of cones and augment solutions. A wide selection of constraint options were used to address varying levels of collateral ligament competence. The surgeon believes that the Logic CC Revision system offers features and options that allow for the management of virtually any revision knee arthroplasty scenario.
Clinical Evaluation of Distal Femoral Fit Using Exactech Logic® Prosthesis

Yifei Dai Ph.D., Weimin Yue Ph.D., Herbert M Bertram M.D., Richard J Friedman M.D., Chul-Won Ha M.D. Ph.D., James I Huddleston M.D., Raymond P Robinson M.D., Laurent D Angibaud M.S.

Introduction

Over more than 40 years of the history of total knee arthroplasty (TKA), the treatment evolved from targeting pain relief and restoration to basic functions in the general patient population, to a surgery with comprehensive consideration of individual’s characteristics with regard to both prosthesis design and surgical techniques. Such considerations include adequate component fit, accurate balancing of the joint gaps, proper post-operative kinematics, minimized infection rates, and so on and so forth. Among these considerations, the call for adequate component fit is linked to the underlying clinical concern on the overhanging of the components. Component overhang has been shown to lead to poor patient outcomes at 5 years post-operatively [Chau], and may account for 27% of clinically relevant knee pain after TKA [Mahoney], possibly due to irritation of the knee tendons and ligaments [Dennis]. Especially in the femur, the goal of minimizing component overhang can be complicated by the other surgical targets. For example, as overhang can be avoided by undersizing the femoral component, the undersized component anteroposterior (AP) dimension can increase flexion laxity and/or result in anterior notching. Although these situations may be resolved by additional femoral resections to prepare for the undersized femur, the joint line will be inevitably elevated that can negatively impact patellofemoral kinematics, increase the incidence of instability, introduce excessive polyethylene wear, decrease knee flexion range, and cause anterior knee pain [Belleman, Yoshii, Figge, Laskin, Singerman].

Studies have identified that an overhang of 3-4mm is the differentiating point for clinical importance [Mahoney, Chung]. In a 2010 study, Mahoney et al. reported that more than 3 mm of component overhang can increase the risk of clinically important knee pain by 90% [Mahoney]. Also, a recent investigation by Chung et al concluded that more than 4mm of overhang can significantly lower the maximum flexion angle postoperatively [Chung]. These findings confirmed that proper component fit to the distal femur is critical for the success of the TKA, which emphasize the need for the continuous evaluation on the morphological fit of the current femoral component designs.

Several morphological analyses have reported varying degrees of femoral fit in several globally marketed contemporary TKA systems, ranging from none to moderate-severe overhang incidences (Table 1). Also, these studies demonstrated that within the same design, the goodness of fit can vary between both genders and different ethnicities. To compare the fit of the Exactech Optetrak Logic® design with the published data on other contemporary designs, a clinical assessment of the Logic femoral design was carried out by a collaboration between Exactech and several clinical sites. The objective of this study was to clinically assess the fit of the Logic femoral components against the anatomy from a group of multiethnic TKA patients.

<table>
<thead>
<tr>
<th>Published Study</th>
<th>Design</th>
<th>Patient Ethnicity/Nationality</th>
<th>Patient Gender</th>
<th>Incidence of &gt;3mm Overhang at Distal Femur (N Total Subjects)</th>
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<tr>
<td>Loures et al. 2016</td>
<td>Scorpio®</td>
<td>Brazilian</td>
<td>Male</td>
<td>10% (11)</td>
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<td></td>
<td>Brazilian</td>
<td>Male</td>
<td></td>
<td>14% (11)</td>
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<td></td>
<td>Natural Knee®</td>
<td>Brazilian</td>
<td>Female</td>
<td>40% (11)</td>
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<td>Mahoney et al. 2010</td>
<td>NexGen® Standard</td>
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Table 1: Previously published overhang incidence on other contemporary femoral designs.

Materials and methods

TKA Surgeries

A total of 119 knees subjected to primary TKA were included in this study. The patients were recruited from multiple ethnicities, with both genders included (Table 1). Exclusion criteria were: 1) previous
Results

A summary of over-/under-hang incidences is presented in Table 2. Across genders and ethnicities, the Logic femoral component consistently minimized clinically important overhang. Only 1 knee (Asian, female, medium femoral size 3.0) out of the 119 studied had clinical important overhang slightly over 3 mm (4 mm).

Discussion

Released in 2009, Exactech Optetrak Logic design continues the successful evolution of the Exactech Optetrak knee system. Optetrak Logic allows today’s patients a greater range of motion and patella function necessary to maintain their activity and independence. The system has demonstrated excellent clinical long-term clinical results around the world [Robinson, Edwards, Ehrhardt].

One of the key reasons for the clinical success of the Logic design, as confirmed by the findings in this study, may be dedicated to the sizing of the femoral components. This multi-center implantation study on the fit of the Logic femoral components demonstrated extremely low incidence of clinically important femoral component overhang (near 0% incidence), suggesting minimal risk of soft-tissue impingement related complications with the use of this design. In addition, contrary to the common belief that the fit of western originated knee designs may be compromised in other populations, especially Asian [Yue, Chung, Loures], the Logic femoral design was shown to provide equally good fit for all 4 ethnic groups studied. In addition, although it has been reported that component fit in the female knees is inferior to that in the male knees [Loureis, Mahoney], the Logic design did not demonstrate gender-dependence in this study. A summary of published overhang incidences using various knee designs is presented in Table 3. Compared to the published studies, the low incidence of clinically important overhang in Logic was demonstrated to be comparable to the designs with the availability of gender solutions (Table 3).

Clinical assessment on the distal femoral fit of the Exactech Optetrak Logic® femoral component design demonstrated minimal (near zero) incidence of clinically important overhang in both genders and 4 ethnic groups. The data confirmed that the sizing of the Logic femoral component respects the anatomy of the distal femur, potentially minimizing the risk of TKA complications related to femoral component overhang.

Table 2. Ethnic and gender distribution of the study subjects.

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Total (N)</th>
<th>Female (N)</th>
<th>Male (N)</th>
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<tr>
<td>Caucasian</td>
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<tr>
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</tr>
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<td>Hispanic</td>
<td>10</td>
<td>4</td>
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</tr>
<tr>
<td>African American</td>
<td>15</td>
<td>12</td>
<td>3</td>
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</table>

Five senior surgeons, each from an individual surgical center, performed primary TKA surgeries using Exactech Optetrak Logic® knee prostheses on the recruited knees. The surgeries were carried out followed each individual surgeon’s standard practice, with the common target of neutral varus/valgus alignment, 0° flexion/extension, and 10 mm resection depth according to the surgical techniques of the Logic implant system (surg tech).

Distal femoral fit assessment

After sizing and implanting the femoral component, the surgeon used a gauge specifically designed by Exactech for this study to measure the medial and lateral fit (over- or under- hang) at the anteroposterior (AP) middle point of the distal resection surface (Fig 1). The difference between bony edge of the resection and the femoral component was assessed for pooled data and each gender/ethnicity. The percentage of acceptable component fit (≤ 3 mm overhang) and the incidence of clinically important overhang (> 3 mm) were assessed across the bones, and per gender/ethnicity. Statistical significance was defined as p < 0.05.

A summary of over-/under-hang incidences is presented in Table 2. Across genders and ethnicities, the Logic femoral component consistently minimized clinically important overhang. Only 1 knee (Asian, female, medium femoral size 3.0) out of the 119 studied had clinical important overhang slightly over 3 mm (4 mm).

Discussion

Released in 2009, Exactech Optetrak Logic design continues the successful evolution of the Exactech Optetrak knee system. Optetrak Logic allows today’s patients a greater range of motion and patella function necessary to maintain their activity and independence. The system has demonstrated excellent clinical long-term clinical results around the world [Robinson, Edwards, Ehrhardt].

One of the key reasons for the clinical success of the Logic design, as confirmed by the findings in this study, may be dedicated to the sizing of the femoral components. This multi-center implantation study on the fit of the Logic femoral components demonstrated extremely low incidence of clinically important femoral component overhang (near 0% incidence), suggesting minimal risk of soft-tissue impingement related complications with the use of this design. In addition, contrary to the common belief that the fit of western originated knee designs may be compromised in other populations, especially Asian [Yue, Chung, Loures], the Logic femoral design was shown to provide equally good fit for all 4 ethnic groups studied. In addition, although it has been reported that component fit in the female knees is inferior to that in the male knees [Loureis, Mahoney], the Logic design did not demonstrate gender-dependence in this study. A summary of published overhang incidences using various knee designs is presented in Table 3. Compared to the published studies, the low incidence of clinically important overhang in Logic was demonstrated to be comparable to the designs with the availability of gender solutions (Table 3).

Clinical assessment on the distal femoral fit of the Exactech Optetrak Logic® femoral component design demonstrated minimal (near zero) incidence of clinically important overhang in both genders and 4 ethnic groups. The data confirmed that the sizing of the Logic femoral component respects the anatomy of the distal femur, potentially minimizing the risk of TKA complications related to femoral component overhang.

![Figure 1. Illustration of distal femoral component fit measurement using the special gauge.](image-url)
Table 3. A) Medial and lateral fit of the femoral component for each gender. B) Medial and lateral fit of the femoral component for each ethnicity. Positive millimeter values indicate component overhang, negative millimeter values indicate component underhang.

|                      | Medial | Lateral |               |               |               |               |               |
|----------------------|--------|---------|---------------|---------------|---------------|---------------|
|                      | Female | Male    | Female        | Male          |               |               |
| Mean (mm)            | -3.4   | -5.4    | -2.2          | -1.4          |               |               |
| Standard Deviation (mm) | 2.4    | 2.4     | 2.2           | 1.9           |               |               |
| Max Overhang (mm)    | 2.0    | 0.0     | 2.0           | 4.0           |               |               |
| % Clinically Important Overhang | 0.0% | 0.0%     | 0.0%           | 1.3%           |               |               |

References

INTRODUCTION: Morphological fit of the femoral component is important for the success of total knee arthroplasty (TKA) [1]. In the distal femoral morphology, there is a difference in component shape, especially the most recently released TKA designs. The purpose of this study was to evaluate distal femoral morphology in Asian and Caucasian knees and compare to two new TKA designs.

METHODS: Digital femoral surface models of 50 Chinese (25M:25F) and 50 Caucasian (25M:25F) were used in this study. The anteroposterior (AP) and mediolateral (ML) dimensions were measured at the anteroposterior mid-point of the distal femur and the ML measurements of the model were compared to the ASIS measurements. The dimensional mismatch between femoral models and the distal resection were listed in Table 1, and four design offerings were selected for evaluation. The corresponding sized femoral component from the design was then placed on each resected distal femur.

RESULTS: Significant differences found between ethnicities and genders were presented in Table 1. The majority of the differences were between small sized femora. The fit between Caucasian and Chinese femora was compared, with statistical significance defined as p<0.05.

DISCUSSION: The study demonstrated femoral morphology in Asian and Caucasian knees, and demonstrated the majority of the differences exist between genders for these two ethnicities studied. The two newly released contemporary designs both have aspect ratios at the lower bound of the bone morphology, but were shown to have acceptable component overhang.

SIGNIFICANCE: Virtual analysis of 100 femora demonstrated gender and ethnic differences in distal resection morphology between Caucasian and Chinese. Two newly released contemporary femoral implants with different sizing philosophies (single and multiple ML offerings) both demonstrate minimal component overhang.

REFERENCES:

Table 1. Dimensional mismatch results between femoral components and distal resection

<table>
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<td>AP (mm)</td>
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IMAGES AND TABLES:

Table 2. Femoral component fit results for Chinese and Caucasian femora

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Figure 1. Measurement of femoral component overhang: (a) transverse cut; (b) sagittal view (purple color).
TOTAL KNEE ARTHROPLASTY USING A CONTEMPORARY COMPUTER-ASSISTED SURGICAL SYSTEM: A REVIEW OF SURGICAL PARAMETERS ON MORE THAN 4000 CLINICAL CASES

Fabrice Bertrand BS1, Yifei Dai PhD2,*, Laurent Angibaud BS2, Cyril Hamad BS3, Amaury Jung BS1, David Liu MBBS FRACS1

1 Blue Ortho, La Tronche, 38700, FR
2 Exactech Inc, Gainesville, FL, 32653, USA, yifei.dai@exactech.com
3 The Gold Coast Centre for Bone and Joint Surgery, Queensland, 4224, AU

INTRODUCTION

Computer-assisted orthopaedic surgery (CAOS) has been shown to offer increased accuracy to the bony resections compared to the conventional techniques [1] but may be dependent on the actual system used and how the algorithm for bone resections are calculated. Previous studies of CAOS have mostly focused on alignment outcomes, based on a small number of patients from selected hospital sites [1]. Several meta-analyses on the outcomes of CAOS systems, while system-dependency has been reported to influence alignment parameters [4]. To date, limited information is available to benchmark the ability of a specific CAOS system for its efficiency in achieving the intraoperative surgical goals based a large number of clinical cases. The purpose of this study is to assess the accuracy and precision of achieving surgical goals in more than 4000 cases using a specific contemporary CAOS system.

MATERIALS AND METHODS

Surgical parameters (alignment and depth of resections) were extracted from the technical logs of 4292 TKA surgeries performed between October 2012 and January 2016 using a contemporary CAOS system (ExactechGPS, Blue-Ortho, Grenoble, FR). The logs did not contain any information related to patient demographics or identity. The following surgical parameters were investigated: 1) planned resection, defined by the surgeon prior to the bone cuts. These parameters serve as inputs for the CAOS guidance; 2) Checked resection, defined as digitalization of the actual resection surfaces by manually pressing an instrumented checker onto the bony cuts. The resection of the distal femur and tibial were evaluated for the coronal and sagittal planes.

RESULTS

For the tibial resection, deviations in coronal alignment (tibial varus/valgus angle), sagittal alignment (posterior tibial slope), and resection depth were $-0.05 \pm 0.88^\circ$, $0.22 \pm 1.58^\circ$, and $0.14 \pm 1.54$ mm, respectively (Fig. 1). For the femoral resection, the deviation in coronal alignment (femoral varus/valgus angle), sagittal alignment (femoral flexion), and resection depth were $0.00 \pm 0.93^\circ$, $0.32 \pm 1.39^\circ$, and $0.05 \pm 1.33$ mm, respectively (Fig. 1).

Mediolateral gap asymmetry was $0.99 \pm 0.16$ and $1.01 \pm 0.19$ for extension and flexion, respectively. Flexion-extension gap asymmetry was $1.15 \pm 0.38$ and $1.11 \pm 0.44$ for medial compartment and lateral compartment, respectively (Fig. 2).

DISCUSSION

An instrument platform for TKA should provide assistance in bony resections that match the target with accuracy and reproducibility, as well as the ability to help properly define joint gaps when needed. This study demonstrated that the specific CAOS system used can offer accurate and precise intra-operative guidance to the surgeon in achieving his/her surgical resection goals. Numerous studies have shown that malalignment can lead to complications, such as component loosening, instability, polyethylene wear, and patellar instability [8-10]. TKA performed using conventional instruments is reported to achieve satisfactory lower limb alignment (within $\pm 3^\circ$ of varus/valgus relative to the mechanical axis) in only 70-80% of cases [3,5], which may be one of the factors contributing to 20% of patients being dissatisfied with the results of surgery [7]. This study reviewed a large number of cases spanning the application history of the specific CAOS system, providing a complete clinically relevant evaluation of its accuracy and precision in terms of bony resection. We believe surgeons can use this specific CAOS system with confidence that the surgical resection goals will be reproduced with accuracy and reliability.

REFERENCES

DISCLOSURES
LA and YD are employees of Exactech Inc; AJ, CH, and FB are employees of Blue Ortho; DL is a paid consultant of Exactech Inc.

COMPUTER-ASSISTED TOTAL KNEE ARTHROPLASTY: IMPACT OF SURGEON EXPERIENCE ON THE ABILITY TO ACHIEVE SURGICAL RESECTION GOALS
Yifei Dai PhD*, Laurent Angibaud BS1, Amaury Jung BS2, Cyril Hamad BS2, Fabrice Bertrand BS2
1*Exactech Inc, Gainesville, FL, 32653, USA, yifei.dai@exac.com
2 Blue Ortho, La Tronche, 38700, FR

INTRODUCTION
Accurate positioning of the knee prosthesis is critical for the success of total knee arthroplasty (TKA) [1]. TKAs performed using conventional instruments highly rely on surgeon’s experience and skill level. Studies have reported that only 70-80% of the TKA cases using conventional instruments can achieve satisfactory lower limb alignment (within ±3° of varus/valgus relative to the mechanical axis) [2,3], which may be one of the major contribution factors to the fact that up to 20% of patients remain dissatisfied with the results of the surgery [4]. Computer-assisted orthopaedic surgery (CAOS) has been shown to offer increased accuracy and precision to the bony resections compared to the conventional techniques [5]. As the early adopters champion the technology, reservation may exist among new CAOS users of (novice surgeons) regarding the ability of achieving the same results as the experienced surgeons can produce. To date, limited retrospective review has been done on the differences between experience users and novice user of a specific CAOS system based on a database of surgical reports. The purpose of this study was to investigate if there are immediate benefits in the accuracy and precision of achieving surgical goals for the novice surgeons, as compared to the experienced surgeons, by using a contemporary CAOS system.

MATERIALS AND METHODS
Two groups of surgeons were randomly selected from a record retaining database for the TKA surgeries performed between October 2012 and January 2016 using a contemporary CAOS system (ExactechGPS, Blue-Ortho, Grenoble, FR). The records did not pertain any information related to the patients. The first group (novice users) included 7 surgeons, who had no navigation experience prior to the adoption of the CAOS system studied and performed equal or less than 20 CAOS TKAs in their practice. To investigate the intra-group variation in the novice group, the “novice group” was further divided into established surgeons with extensive experience in conventional TKA (novice-senior group), and junior surgeons who were less experienced (novice-junior group). The second group contained 6 surgeons (experiences users), each used the CAOS system for more than 150 TKAs. All the surgeries from the first group were included in the study, annotated as the “novice group” (86 cases). The most recent 20 cases from each surgeon in the second group were collected as the “experienced group” (120 cases). The following surgical parameters were investigated in both groups: 1) planned resection, resection goals defined by the surgeon prior to the bone cuts; 2) checked resection, digitization of the realized resection surfaces, obtained by manually pressing an instrumented checker onto the bony cuts. Due to that anterior, posterior and facet cuts of the femur were all based on the distal resection, only the distal resection was evaluated for the femur.
Deviations in the resection parameters were quantified for both tibia and femur (planned vs checked). The results were compared within the novice group (novice-senior vs novice-junior), as well as between the novice and experience groups (ANOVA). In addition, knees with optimal resection (<2°/mm in deviation, as greater differences may clinically alter the joint mechanics [6]) and acceptable resection (<3°/mm in deviation, as commonly adopted in the existing studies [2,3]) were identified. Statistical significance was defined as p<0.05.

RESULTS
A summary of the deviations between the planned and achieved resections for is presented in Table 1. No statistical differences were found between the senior and the junior surgeons in the novice group. Similarly, no differences were found between the experienced group and novice group, except for that the cases in the novice group tended to resect slightly more bone in the tibia (p < 0.01), and had slightly larger standard deviations compared to the experienced group. The experienced and novice groups had comparable, high percentages of the knees in both the optimal and acceptable categories (Fig 1).

DISCUSSION
This study demonstrated that regardless of the surgeon’s experience with TKA in general, new adoption of the CAOS system investigated can immediately benefit the accuracy and precision of the bony resections at a comparable level with experience CAOS users. Although significant difference was found between novice and experienced groups in tibial resection depth, the difference in was too small to be clinically relevant (difference in means = 0.57mm). The CAOS system offers substantial reduction of the outliers compared to TKAs performed with conventional instruments [4]. The findings aligned with a smaller scope study including multiple CAOS systems [7].

REFERENCES

DISCLOSURES
LA and YD are employees of Exactech Inc; AJ, CH, and FB are employees of Blue Ortho.
The use of computer-assisted surgery (CAS) in total knee arthroplasty (TKA) has been shown to improve patient-specific alignment and functional outcomes. However, achieving the ideal alignment can be challenging, especially in patients with pre-existing anatomical variations.

**Introduction**

Casale et al. [1] reported that even with CAS, postoperative alignment in TKA can vary significantly, with some cases showing alignment deviations of up to 20°. This highlights the importance of developing effective surgical techniques to improve alignment accuracy.

**Methods**

The study included a retrospective analysis of patient data from a prospective study involving 50 patients who underwent TKA with CAS. Patients were divided into two groups: those with pre-existing varus deformity and those with neutral alignment.

**Results**

- **Varus Deformity Group**
  - Average preoperative alignment: 15° varus
  -术后平均对线：15° varus
  - Successful restoration of neutral alignment in 80% of cases
- **Neutral Alignment Group**
  - Average preoperative alignment: 0°
  -术后平均对线：0°
  - Successful restoration of neutral alignment in 90% of cases

**Discussion**

The study demonstrated that CAS can be an effective tool for improving postoperative alignment in TKA, especially in patients with pre-existing deformities. However, continued research is needed to improve alignment accuracy and patient satisfaction.

**References**

Evaluation of Anteroposterior Kinematics during Cruciate-Retaining Total Knee Arthroplasty

Yifei Dai1, Laurent Angibaud2, Jean-Yves Jenny3, Michael B Cross4, Arnaud Jury4, Cyril Hamad5

1Exactech Inc, Gainesville, FL, USA, 2Hôpitaux Universitaires de Strasbourg, Illkirch, FR, 3Hospital for Special Surgery, New York, NY, USA, 4Blue Ortho, La Tronche, FR

Disclosures: Laurent Angibaud and Yifei Dai (1,4 Exactech Inc), Michael B Cross (1,3B,5-Smith and Nephew PLC, 3B-Exactech Inc, LinkBio Corp, Intelligent Surgical Inc), Jean-Yves Jenny (1-Aesculap Inc, 3B-FH Orthopedics Inc, Exactech Inc), Arnaud Jury and Cyril Hamad (3A Blue Ortho)

Introduction

Paradoxical motion, characterized as non-physiological anterior sliding of the distal femur relative to the proximal tibia, is a unique phenomenon in the anteroposterior (AP) kinematics of cruciate-retaining total knee arthroplasty (CR TKA) that is prevalent in as many as 83% of the CR TKA knees. Besides altering normal AP knee kinematics, this undesirable motion can limit postoperative range of motion, increase wear of the polyethylene insert, and elevate strain in the surrounding soft tissues. Although postoperative tibiofemoral AP displacement has been evaluated in various CR designs, the evaluations were based on kinematic testing of a single component placement on each knee specimen. Surgical parameters, such as the reconstructed posterior tibial slope (PTS), were usually overlooked during the evaluation. The purpose of this study was to investigate the AP kinematics of a CR TKA design with variations in PTS.

Materials and Methods

CR TKAs were performed on six cadaveric knees (fresh frozen, non-arthritic, PCL presumably intact) using a CAOS system. The implanted tibial baseplate was specifically designed with a mechanism to precisely and easily modify the PTS without potential damages to the soft-tissue envelope. After implantation at each of the 4 PTSs (10°, 7°, 4°, and 1°), knee kinematics was measured by the CAOS system through passive range of motion (ROM) tests. Each measurement was performed with a closed arthroscopy (patella reduced in the trochlea groove) and repeated 3 times. The AP displacement of the medial and lateral contact locations between the femoral component condyles and the tibial component were tracked referencing the center of the proximal tibia. The average AP displacements was evaluated from 0° to 90° flexion to identify any paradoxical motion and compared between PTSs. Statistical analysis of the data was performed by sampling at every 5° from 20° to 90° of flexion, with significance defined as p < 0.05.

Results

No paradoxical sliding was observed for all 4 PTSs (Fig. 1). Across the 0° to 90° flexion range, all 4 PTSs exhibited a physiological rollback pattern. No significant differences were found between the 4 PTS groups in both medial (p ≥ 0.40) and lateral (p ≥ 0.38) AP displacement.

Discussion

This study utilized a CAOS system to quantitatively evaluate the AP kinematics of a CR TKA design. Compared to other designs that were reported to have paradoxical motion, the data demonstrated that regardless of the PTS selected for the CR TKA, the design investigated exhibits physiological and non-paradoxical AP motion during mid-flexion. This method can be expanded to various surgical parameters to investigate their impact on the TKA kinematics.

ExactechGPS Guidance System Does Not Increase Operative Time When Compared to Conventionally Instrumented Total Knee Arthroplasty

Pasquale Petrera MD; Xeve Silver MS; Laurent Angibaud BS

Introduction

Computer assisted orthopedic surgery (CAOS) improves implant alignment in TKA [1,2]. However, one perceived drawback for its application is the increased surgical time compared to the use of standard mechanical instrumentation. This study compared the time efficiency between a next generation CAOS system (ExactechGPS®, Blue-Ortho, Grenoble, FR) and conventional instrumentations, and assessed the impact of surgeon experience on the efficiency.

Method

Surgical time was retrospectively reviewed on sixty-three primary TKAs performed by a board-certified orthopedic surgeon (PP) usingOptetrak Logic PS knee system (Exactech, Gainesville, FL) grouped as 1) Group I (control): 21 TKAs using conventional mechanical instruments; 2) Group II: 21 TKAs performed with early experiences using ExactechGPS; and 3) Group III: 21 TKAs performed with advanced experiences using ExactechGPS. Patient condition (age, BMI, gender, etc.), surgical technique (excluding the use of the guidance system), and post-operative guidelines were similar across the three groups. No cases were lost and no patient had any intra-operative complications. Surgical time was compared across the three groups (significance defined as p<0.05).

Results

A summary of the surgical time is presented in Table 1. Compared to the TKAs using conventional mechanical instruments, the average surgical time for the TKAs performed with early ExactechGPS experiences was 7 minutes longer. However, with advanced ExactechGPS experience, the average surgical time decreased to 2 minutes less than the time required by using conventional mechanical instruments. Furthermore, TKAs with advanced ExactechGPS experience exhibited the least variability (standard deviation) among the three groups. None of the differences were significant (p>0.20).

Discussion

The results demonstrated that with ExactechGPS, there was no significant difference in TKA surgical time compared to the conventional instrumentation. Nevertheless, once the initial learning curve is reached, the guidance system generally decreases the surgery time compared to conventional mechanical instrumentation.

In contrast to data reported on traditional navigation systems [3-5], the comparable (with conventional mechanical instrumentation) efficiency reported in this study may be contributed to the unique features of the ExactechGPS system compared to traditional CAOS technologies, such as indication for use inside the sterile field, blood occlusion-resistant tracker design, customizable operative technique according to
the surgeon’s preference, and overall compact and reduced number of instruments. The system may provide an advantageous solution for reducing surgical cost and improving clinical outcomes.

References

<table>
<thead>
<tr>
<th>Group</th>
<th>I (Control)</th>
<th>II</th>
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<tr>
<td>Surgical Technique</td>
<td>Conventional Instrumentation</td>
<td>Early Experience ExactechGPS®</td>
<td>Advance Experience ExactechGPS®</td>
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<td>Surgical Time (Minutes, Mean ± SD)</td>
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<td>97 ± 13.9</td>
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<tr>
<td>Range (Minutes, Min - Max)</td>
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<td>79 - 131</td>
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<tr>
<td>P-value (Compared to Group I)</td>
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Table 1. Surgical time for each TKA group.
Tibial and femoral stem extension fatigue performance with and without LPB treatment.

Background

Modular total knee arthroplasty (TKA) systems today provide surgical flexibility that allows a surgeon to optimize implant configurations for a variety of patients in order to restore knee function and stability. As the demands for implant performance increase from an ever broadening patient demographic, advanced materials and manufacturing techniques may hold the key towards the development of implants with greater long term efficacy and patient satisfaction. Towards this end, Exactech has sought novel methods to improve the fatigue performance of tibial and femoral stem extensions used in its newest revision system, Logic CC.

Low Plasticity Burnishing (LPB) is a process by which a smooth free-rolling spherical ball is moved across a metallic surface under a sufficiently high force to induce plastic deformation, thereby creating a compressive outer layer of residual stress. Initially used in aerospace, LPB processing has been shown to significantly improve surface finish, improve fatigue strength through the retardation of fatigue crack nucleation, and reduce susceptibility to corrosion in titanium. For these reasons, LPB was investigated as a technology that would further improve from the existing tibial and femoral stem extension fatigue performance. To this end, an extreme loading scenario under lab testing environment was used to compare the fatigue performance and endurance limit of tibial stem extensions with and without LPB processing.

Question/Purposes

Will LPB technology applied to tibial and femoral stem extensions provide an improvement in fatigue performance that will meet the growing demands of an ever evolving revision TKA patient cohort?

Methods

Two configurations of the same Exactech design were chosen to evaluate the effect of LPB on stem extension fatigue performance; consisting of a LPB treated and untreated titanium (Ti) stem extension paired with cobalt chromium (CoCr) tibial tray. Five samples were tested of each configuration, with each sample receiving an individual test load magnitude, respectively (Table 1). Each test was set up by constraining the tibial tray to the base of the load frame, with load applied at a distance of 4.65 cm, measured from the bottom surface of the tibial tray (Figure 1).

A competitive design configuration with identical modular locking mechanisms, consisted of Ti tibial stem extension without LPB treatment and Ti tibial tray, was tested to compare with the fatigue performance of the two Exactech design configurations.

The forces were adapted from a previous stem extension fatigue test and were expected to encompass cycle to failure values between 10 million and 1,000. Force was applied sinusoidally at a frequency of 3Hz. All tests were discontinued if 10 million cycles (Mc) had been reached or taper junction failure occurred. Failure was indicated by relative rotation between the stem extension and tibial tray, cracking at the taper junction, or inability of the stem extension to resist loading.

Results

LPB Untreated Samples: CoCr Tray – Ti Stem Extension

Cycles-to-failure for each test sample are provided in Figure 2 and Table 2. All samples except Sample 5, which underwent the highest loading magnitude, had fracture sites located within the stem extension-tibial tray junction (Figure 3). Sample 5 fractured approximately 15mm from the distal surface of the tibial tray (Figure 4), the cause could not be determined.

Table 1. Details of the five loading magnitudes.

<table>
<thead>
<tr>
<th>Sample #</th>
<th>Peak Cyclic Load (N)</th>
<th>Amplitude (N)</th>
<th>Peak Moment (Nm)</th>
<th>Peak Force (N)</th>
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<tr>
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<td>n/a</td>
<td>226,679</td>
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† Sample did not fail.

Table 2. Fatigue performance for individual test specimens.

<table>
<thead>
<tr>
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<th>Peak Cyclic Load (N)</th>
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<th>Exactech-LPB</th>
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<tr>
<td>1</td>
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<tr>
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<td>2002</td>
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† Sample did not fail.

Sample 5 was not tested as Sample 2 was evaluated at a higher load and successfully completed 10 Mc.

LPB Treated Samples: CoCr Tray – Ti Stem Extension

The sample tested at the second to lowest loading magnitude (peak cyclic force of 2002 N) reached the required 10 Mc without failing. For this reason, it was unnecessary to test a sample at the lowest load, as its cycle count was expected to exceed 10 Mc as well. Cycles-to-failure for each tested sample are reported in Figure 2 and Table 2. All failed samples fractured at the stem extension, with the fracture initiated within the stem extension-tibial tray junction (Figure 3).

Competitive Samples: Ti Tray – Ti Stem Extension, LPB Untreated

Samples (N=2) immediately failed at the lowest force magnitude; therefore it was not necessary to evaluate additional samples at the higher loading magnitudes. Cycles-to-failure for the competitive samples are reported in Figure 2 and Table 2. Both samples fractured at the stem extension, with the fracture initiated within the stem extension-tibial tray junction. Previous results have indicated that a Ti-Ti junction has better fatigue performance than an otherwise identical CoCr-Ti junction. The results herein contradicted the initial prediction that the competitive samples would outperform the untreated CoCr-Ti test samples.

Figure 1. Photograph demonstrating the test setup. The tibial tray potted in polymethyl-methacrylate was fixed within a vise while a force was cyclically applied perpendicular to the long axis of the stem extension 4.65cm from the most distal point of the tibial tray.
Figure 2. Force versus cycles before failure are plotted for the treated and untreated CoCr tibial tray and titanium stem extension assemblies, and competitive samples.

Figure 3. Representative images of a failed stem extension. Fracture initiation occurs at the top, which was the location of highest tensile stress.

Figure 4. Photograph of unusual point of failure for Sample 5. This failure mode only occurred at the highest load in the series and was not reproduced on other tests. The remaining samples failed in the manner shown in Figure 3.

Figure 5. Photograph of the competitive stem extension samples and tibial tray.

Conclusions
The results suggest that LPB surface treatment substantially improves the fatigue performance of the CoCr tibial tray and stem extension configuration investigated. This may suggest that under extreme loading conditions, such that the stem extension experiences high transverse forces relative to the tibial tray, a stem treated with LPB would be less prone to fracture over an untreated counterpart.

In summary, LPB treatment has demonstrated an improvement of the fatigue performance of modular stem-taper constructs in Logic CC design, which may better address the increased demand by a younger, more active patient population.

References


A SURGEON’S PERSPECTIVE ON WHY NAVIGATION IS IMPORTANT IN REVISION TOTAL KNEE ARTHROPLASTY

James Huddleston, MD
Stanford University Medical Center

Navigation, or computer-assisted surgery, has been around for many years. Many of us have had experience with at least one of the major systems on the market. Most recently, I have been using ExactechGPS® for my primary TKA procedures. Personally, I have had great success with the system and believe that my patients have benefited accordingly. So when Exactech asked me to be a part of the team to design their new revision knee system, Optetrak Logic® CC, and they informed me that it included an opportunity to develop the first-of-its-kind application to use the ExactechGPS system for revision procedures (rTKA), I was intrigued and ultimately decided to accept the opportunity.

In my career as an orthopedic surgeon, I have performed 750 revision TKAs using most of the major revision knee systems on the market. The majority of these systems had room for improvement. I knew there was an opportunity to create a state-of-the-art system that uses computer-assisted surgery to achieve optimal outcomes in the revision setting. Before I began to think through inputs on how the revision platform for ExactechGPS could be beneficial to surgeons and patients, I knew that it would be helpful to review data on how computer-assisted surgery is being used in the primary knee setting.

During this journey, I realized that most orthopedic surgeons use computer-assisted surgery to achieve better alignment, to be faster in the O.R., to have an overall more efficient with improved functional outcomes. •

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REFERENCES


INTERNAL INNOVATIONS | A CLINICAL EXCHANGE ON ADVANCES IN ORTHOPAEDICS

EARLY RESULTS OF A NEW REVISION TOTAL KNEE ARTHROPLASTY SYSTEM USED IN THE STAGED TREATMENT FOR CHRONIC PERIPROSTHETIC INFECTION

Daniel C. Allison, MD
Cedars-Sinai Medical Center

INTRODUCTION
Periprosthetic infection is a devastating complication that complicates approximately 1 percent of primary total knee arthroplasties (TKA).1 In chronic cases, the condition often requires implant removal with subsequent delayed reimplantation, to offer the best chance at remission of infection.2 Extensive bone loss often occurs in these settings, as a consequence of the infection itself, the removal of implants, the initial debridement, from erosions caused by an unstable cement spacer, or combinations thereof.3 In addition to bone deficiencies, soft tissue compromise and loss also frequently complicates these conditions, for similar reasons. To minimize and address the bone and soft tissue deficits at the time of reimplantation in these challenging cases, a robust, versatile, and complete instrument and implant system remains an essential part of the revision knee surgeon’s arsenal.

We report the early results of a small case series of a new condylar constrained revision total knee replacement system (Optetrak Logic CC, Exactech, Inc. [Gainesville, FL]) used in the staged treatment of chronic periprosthetic infection. The system contains advances on both the instrument and implant sides, which may be beneficial in these difficult cases.

MATERIALS AND METHODS
The first seven periprosthetic infection cases using the new Optetrak Logic CC system performed by a single surgeon (Daniel C. Allison, MD) were retrospectively reviewed. All cases involved the treatment of chronic periprosthetic infection, as diagnosed by MSIS criteria.1 All cases were initially treated with implant removal, debridement, and articulating antibiotic cement spacer placement. In one case, the patient was referred with a previous antibiotic spacer placed by another surgeon, with persistent periprosthetic infection and severe instability (Case 2). In another case, the antibiotic cement spacer was placed three years previously at an outside hospital (Case 4). In the remainder of cases, the initial implant removal and antibiotic spacer placement was performed by the final treating surgeon (Daniel C. Allison, MD). The decision to proceed with total knee arthroplasty reimplantation was based on clinical examination, serum ESR / CRP values, joint aspiration cell count, intraoperative gross examination, and intraoperative frozen section sampling. In all cases, low dose antibiotic (1gm vancomycin, 12 gm tobramycin per 40 gm PMMA) cement was used during reimplantation. Early clinical and radiographic results were collected, and mean follow up was 14 weeks from reimplantation (range 4-17 weeks). There were no unplanned readmissions or surgeries within 30 days, and all cases sustained remission of infection during the follow up period.

CASE REPORTS

CASE 1
A 57-year-old African American female with persistent right total knee arthroplasty fibrosis, treated with previous open lysis of adhesions and tibial insert exchange at an outside hospital, presented with persistent pain and severe stiffness. Intraoperative frozen section revealed >10 WBC per high power field (HPF) in > 5 HPFs. At the time of implant removal, no specialized extraction instrumentation was used, and iatrogenic, complete, displaced fracture of the posteromedial tibial plateau occurred. The condition was immediately treated with titanium plate fixation, followed by articulating antibiotic spacer placement, and the patient’s weight bearing was limited (Figure 1A, 1B). The fracture healed, remission of infection was achieved, and the patient underwent reimplantation with the Optetrak Logic CC revision system (Figure 1C, 1D). At 27 weeks follow up, she remains free of infection, is ambulating without assistive devices, and knee motion ranges from 15° to 100° (a 65° improvement in arc of motion compared to preoperatively).
CASE 2
An 81 year-old morbidly obese Caucasian female with multiple medical problems was referred by a colleague for persistent methicillin sensitive S. Aureus right knee periprosthetic infection, along with severe instability and extensor mechanism dysfunction, status post previous implant removal and articulating antibiotic spacer placement (Figure 2A, 2B). The patient was taken to surgery for repeat debridement, antibiotic spacer exchange, and extensor mechanism reconstruction (Figure 2C, 2D). After a postoperative course of IV antibiotics, remission of infection was confirmed, and she underwent reimplantation, using extensive augmentation on the tibial and femoral sides (Figure 2E, 2F). Her severe instability was managed with soft tissue balancing and use of the condylar constrained design. At 24 weeks follow up, she has no pain or instability, with 0 – 100° of knee flexion / extension, actively and passively.

CASE 3
A 52 year-old male presented one-year status post left total knee arthroplasty with persistent left knee pain, drainage, and inability to bear weight (Figure 3A, 3B). The diagnosis of chronic periprosthetic infection was confirmed, and the patient was taken to surgery. Removal of femoral and tibial components was facilitated with a specialized Exactech extraction device (Figure 3C, 3D), and an articulating antibiotic spacer was placed. Intra-operative cultures grew Enterococcus sp. After six weeks of IV antibiotic therapy, remission of infection was achieved, and the patient was taken for uneventful reimplantation (Figure 3E, 3F). A posterior stabilized constrained (PSC) insert was used, given the patient’s competent collateral ligaments. At 13 weeks follow up, the patient is well healed, free of infection, ambulates without assistive devices, with range of motion from 0 – 110°.
CASE 4
This patient is a 57 year-old male with a history of incomplete spinal cord injury resulting in partial hemiparesis of his right lower extremity. The patient underwent prior total knee arthroplasty, which became infected, and was treated with implant removal and articulating antibiotic cement spacer placement at an outside hospital three years prior to consultation. He presented to our clinic for reimplantation, complaining of knee instability and pain (Figure 4A, 4B). Infection workup was negative, and the patient was taken for complex reimplantation, with a kinematic rotating hinged knee prosthesis as a back up implant option, given the extensive bone and soft tissue loss in the setting of weakened dynamic stabilizers. Intra-operatively, accommodation of bone defects, as well as achievement of balance and stability, was accomplished with the Optetrak Logic CC system (Figure 4C, 4D), and hinged knee replacement was not necessary. At 12 weeks follow up, the patient is well healed, ambulatory with no pain, with range of motion from 0 – 100°, actively and passively.

CASE 5
A 73 year-old male S/P total knee arthroplasty presented with persistent pain, swelling, and drainage (Figures 5A, 5B). Evaluation revealed methicillin resistant S. Aureus infection, and the patient was taken to surgery. His implants were very well fixed, and safe removal was facilitated with the Exactech Acu-Driver® pneumatic device to disrupt the cement-bone interface, followed by the Exactech extraction instrumentation for removal (Figures 5C, 5D). The implants were removed with relative ease and minimal bone loss (Figures 5E, 5F). After remission of infection was confirmed, the patient underwent reimplantation (Figures 5G, 5H). A PSC insert was used, since the patient’s collateral ligaments afforded natural articular stability. At nine weeks follow up, he is well healed, with no evidence of infection, and a 0 -100° arc of motion.
CASE 6
A 71 year-old female presented to our service status post implant removal and antibiotic spacer placement with gastrocnemius rotational flap coverage at an outside hospital, with loss of patellar tendon at time of initial debridement, as well as failure of her original flap (Figures 6A, 6B). We took the patient for repeat debridement with articulating antibiotic spacer exchange with reconstruction of the patellar tendon with allogenic collagen matrix, followed by free latissimus dorsi flap coverage by the plastic surgery service (Figure 6C). After her IV antibiotic course, remission of infection was achieved, and the patient was taken back to surgery for reimplantation. Intraoperative examination revealed that her extensor mechanism remained intact (Figures 6D, 6E). At six weeks follow up, she is well healed with no evidence of infection, with an intact extensor mechanism, and ambulating with a front wheeled walker.

Figure 6.

CASE 7
An 80 year-old male on chronic high dose anticoagulation therapy presented with chronic periprosthetic infection, secondary to Morganella morganii. The patient was treated with implant removal and antibiotic spacer placement (Figures 7A, 7B) followed by staged reimplantation (Figures 7C, 7D). At the time of reimplantation, gastrocnemius rotational flap coverage was performed by the orthopedic service, in order to augment attenuated anteromedial soft tissues. At four weeks follow up, the patient is well healed, with no evidence of infection, and ambulatory with a front wheeled walker.
DISCUSSION

The treatment of chronic periprosthetic infection of the knee can be challenging, especially with regard to the extensive bone loss and soft tissue compromise that occurs in these cases. Having the optimal equipment with regard to implant removal (especially with well fixed implants in the setting of weakened bone), bone preparation (in the setting of loss of landmarks and weakened fixation platform), articular constraint, fixation dependability, and bone defect management is essential. The new Exactech Optetrak Logic CC system may offer benefits in this regard when compared to older implant systems.

With regard to extraction, Case 1 was used with no specialized extraction devices, and in the hands of the author, medial tibial condylar fracture occurred. Though this healed with plate fixation, the fracture could have caused a more complicated treatment course. In the subsequent cases, a specialized pneumatic cement-implant disruption system (AcuDriver) and extraction device (Exactech extractor) were used, which allow for safe disruption of the bone implant interface, facilitated by the application of axial forces to remove the implant, instead of compressive, bending, or torsional forces, which may predispose bone loss or fracture upon extraction. Since this extraction instrumentation has been used, and implant removal has been achieved with relative ease, with very minimal bone loss and no further bone compromise, in all cases.

With regard to bone preparation, the intramedullary and extramedullary fixation options for cutting guides on both the femoral and tibial sides, provide the significant stability necessary to achieve accurate bone cuts. The low profile and anatomic nature of the cutting blocks and associated instrumentation allow their placement to be facilitated with minimal additional soft tissue dissection. These factors prove very important in the setting of periprosthetic infection management, where bone integrity is often compromised, and preservation of the soft tissue envelope is essential.

With regard to fixation stability and management of bone loss, implant options are essential in achieving a durable long term construct. For example, in Case 7, to achieve optimal femoral stability from both the stem and the distal femoral interface, the 4 mm stem offset function was used, allowing for optimal stem fixation, while conforming well to the patient’s natural distal femoral geometry, which proved to be altered from previous surgery (Figures 7C, 7D). Tibial cones prove to be important adjuvants to make up for the central tibial defects that inevitably occur in revision surgery, allowing for the achievement of stability, even with the use of shorter stems (Figures, 6D, 6E, 7C, 7D). Extensive distal femoral augmentation options allow for management of concomitant distal femoral and posterior femoral bone loss, achieving secure geometric stability, even in severe cases (Figures 2E, 2F, 4C, 4D).

With regard to managing constraint, the standard condylar constrained (CC) allows for articular stability to +/- 1.5° of varus/valgus constraint, and +/- 2° of rotational constraint, as is standard with most revision knee systems, and is very appropriate in the setting of collateral ligament incompetence. A differentiating feature of the Optetrak Logic CC system is the ability to use a PSC tibial insert, which provides +/- 3° of varus/valgus and +/- 4° of rotational constraint. The system even allows for use of the standard posterior stabilized insert, which provides the least amount of constraint possible in the revision setting. A convenient intra-operative insert trialing system allows for easy determination if the less constrained options are appropriate. In Case 3 and Case 5, because of excellent soft tissue stability and competent collateral ligaments, the less constrained (PSC) insert was chosen. This option to reduce constraint in the event of collateral ligament competence could be very important with regard to optimizing implant longevity, and decreasing unnecessary stresses on the bone – implant interface.

CONCLUSION

The challenges associated with treatment of chronic periprosthetic infection with regard to bone loss and soft tissue compromise offer an ideal model to test the performance and ability of a revision total knee replacement system, which can then be readily applied to less complicated cases. From the extraction instrumentation, to the bone preparation instrumentation, to augmentation and fixation options, to varying levels of constraint, the new Optetrak Logic CC system maintains the ideal of simplicity and ease of use, while still providing extensive features and options that allow for the management of virtually any revision knee arthroplasty scenario.

See additional case reports with Optetrak Logic CC on page 36.

REFERENCES

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For additional device information, refer to the Exactech Knee System—Instructions for Use for a device description, indications, contraindications, precautions and warnings. For further product information, please contact Customer Service, Exactech, Inc., 2320 NW 66th Court, Gainesville, Florida 32653-1630, USA. (352) 377-1140, (800) 392-2832 or FAX (352) 378-2617.

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