Clin Orthop Relat Res (2016) 474:40–46
DOI 10.1007/s11999-015-4216-y

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

SYMPOSIUM: 2015 KNEE SOCIETY PROCEEDINGS

The Mark Coventry Award

Custom Cutting Guides Do Not Improve Total Knee Arthroplasty Clinical Outcomes at 2 Years Followup

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Published online: 25 February 2015

Abstract

Background Custom cutting guides (CCGs; sometimes called patient-specific instrumentation [PSI]) in total knee arthroplasty (TKA) use preoperative three-dimensional imaging to fabricate cutting blocks specific to a patient's native anatomy.

Questions/purposes The purposes of this study were to determine if CCGs (1) improve clinical outcomes as measured by UCLA activity, SF-12, and Oxford knee scores; and (2) coronal mechanical alignment versus standard alignment guides.

Methods This was a retrospective cohort study of patients undergoing primary TKA using the same cruciate-retaining, cemented TKA system between January 2009 and April 2012. Patients were included if they were candidates for a unilateral, cruciate-retaining TKA and met other prespecified criteria; patients were allowed to self-select either an MRI-based CCG procedure or standard TKA. Ninety-seven of 120 (80.8%) patients in the standard and 104 of 124 (83.9%, $p = 0.5$) in the CCG cohort with a minimum of 1-year followup were available for analysis. The first 95 patients in the standard (mean followup, 3 years; range, 1–4 years) and CCG (mean followup, 2 years; range, 1–4 years) cohorts were compared. The alignment goal for all TKAs was a hip-knee-ankle (HKA) angle of 0°. UCLA, SF-12, and Oxford knee scores were collected preoperatively and at each patient's most recent followup visit. Postoperative, rotationally controlled coronal scout CT scans were used to measure HKA alignment. Independent-sample t-tests and chi-square tests were used

One of the authors (DN) has received fees from OrthAlign, Inc (Aliso Viejo, CA, USA), outside the submitted work. One of the authors (RMN) has received personal fees from Biocomposites (Staffordshire, UK), personal fees from Cardinal Health (Dublin, OH, USA), grants and personal fees from DePuy, A Johnson & Johnson Company (Warsaw, IN, USA), grants and personal fees from Smith & Nephew (Memphis, TN, USA), grants and personal fees from Wright Medical Technology, Inc (Memphis, TN, USA), personal fees from Medtronic (Minneapolis, MN, USA), personal fees from CardioMEMS (St Paul, MN, USA), personal fees from Integra Sciences (Plainsboro, NJ, USA), grants from Biomet (Warsaw, IN, USA), grants from Stryker (Mahwah, NJ, USA), and grants from Medical Compression Systems, Inc (Tel Aviv, Israel) outside the submitted work. One of the authors (RLB) has received grants, personal fees, and other from Stryker (Mahwah, NJ, USA), grants from Biomet (Warsaw, IN, USA), grants from Medical Compression Systems, Inc (Tel Aviv, Israel), grants from the National Institutes of Health (National Institute of Arthritis and Musculoskeletal and Skin Diseases and National Institute of Child Health and Human Development), grants from Smith & Nephew (Memphis, TN, USA), grants from Wright Medical Technology (Memphis, TN, USA), other from The McGraw-Hill Companies, Inc (Columbus, OH, USA), and other from Wolters Kluwer Health-Lippincott Williams & Wilkins (Philadelphia, PA, USA), outside the submitted work.
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Each author certifies that this institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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for comparisons with a p value ≤ 0.05 considered significant.

Results At the most recent followup, no differences were present between the two cohorts for range of motion (114° ± 14° in CCG versus 115° ± 15° in standard, p = 0.7), UCLA (6 ± 2 in CCG versus 6 ± 2 in standard, p = 0.7), SF-12 physical (44 ± 12 in CCG versus 41 ± 12 in standard, p = 0.07), or Oxford knee scores (39 ± 9 in CCG versus 37 ± 10 in standard, p = 0.1). No differences were present for the incremental improvement in the UCLA (1 ± 4 in CCG versus 1 ± 3 in standard, p = 0.5), SF-12 physical (12 ± 20 in CCG versus 11 ± 21, p = 0.8), or Oxford knee scores (16 ± 9 in CCG versus 19 ± 10 in standard, p = 0.1) from preoperatively to postoperatively. There was no difference in the percentage of outliers for alignment (23% in standard versus 31% in CCG with HKA outside of 0° ± 3°; p = 0.2) between the two cohorts.

Conclusions At a mean followup of greater than 2 years, CCGs fail to demonstrate any advantages in validated knee outcome measure scores or coronal alignment as measured by CT scan versus the use of standard instrumentation in TKA. The clinical benefit of CCGs must be proven before continued implementation of this technology.

Level of Evidence Level III, retrospective controlled study.

Introduction

Despite the clinical success of TKA, concerns remain regarding the ability of surgeons to achieve their intraoperative goals for overall hip-knee-ankle (HKA) and component alignment. The most commonly used method of setting coronal component alignment in TKA is an extramedullary tibial and an intramedullary femoral alignment guide, but this method has shown a limited degree of accuracy [2, 3, 5, 21, 30]. Although computer-assisted surgical techniques have consistently demonstrated improved alignment accuracy versus standard guides [3, 13, 16, 19, 27, 32], the increased capital costs, operative times, learning curve, and unproven functional benefits associated with their use have limited their widespread acceptance [9].

A recent modification in surgical technique in TKA has been the introduction of custom cutting guides (CCGs; sometimes called patient-specific instrumentation [PSI]) in which preoperative three-dimensional (3-D) imaging is used to manufacture cutting blocks specific to a patient's native anatomy. Numerous potential benefits of CCGs exist compared with both standard and computer-assisted surgical instrumentation, including their ease of use; a decrease in operative times and instrument trays; the ability to preoperatively plan for component size, alignment, and position; and an improvement in postoperative alignment versus the use of standard alignment methods [4, 18, 23]. However, to date the majority of reports have not confirmed these proposed benefits [6, 11, 33, 37, 39, 41].

Prior studies on the use of CCGs in TKA have predominantly focused on the avoidance of outliers in overall and component alignment in the coronal plane. Although studies comparing postoperative alignment with the use of CCGs versus standard instrumentation have been contradictory [11, 20, 23–25, 36, 40], a systematic review of Level I and Level II studies concluded that CCGs did not improve coronal alignment in TKA [31]. Similarly, reports focusing on clinical outcomes with the use of CCGs versus standard instrumentation have failed to demonstrate consistent improvements in several functional outcome measures such as the Knee Society score, SF-12 score, or Knee Osteoarthritis Outcome Score [37, 40, 41]. Although these reports were helpful in studying the use of CCGs, they possessed numerous limitations including the presence of small cohort sizes (less than 50 patients per group) and short followup postoperatively (less than 7 months) [37, 40, 41]. Whether these findings remain true in assessments of larger cohorts with longer followup has not been established. Given that in 2012, over 82,000 TKAs worldwide were performed using CCGs, larger studies and longer followup evaluating their functional and radiographic outcomes are warranted [35].

Therefore, this study was conducted to assess whether CCGs with the use of preoperative 3-D MRI would demonstrate improved (1) clinical outcomes as measured by Oxford Knee, SF-12, and UCLA Activity Scores; and (2) coronal mechanical alignment as measured by postoperative CT at a mean of 2 years postoperatively.

Patients and Methods

This was a retrospective study that queried a prospectively maintained database of patients undergoing primary TKA using the same cruciate-retaining, cemented total knee system (Vanguard™; Biomet Inc, Warsaw, IN, USA) between January 2009 and April 2012 at a single institution. Two fellowship-trained orthopaedic surgeons (RMN, RLB) specializing in joint reconstruction enrolled patients into both the CCG and standard cohorts. Before initiation of the study, institutional review board approval was obtained. Inclusion criteria were patients deemed candidates for a unilateral cruciate-retaining TKA. Exclusion criteria were patients with a prior open knee surgery requiring hardware placement or a flexion contracture of greater than 20°, which could potentially affect the accuracy of the preoperative MRI and cutting guide fabrication. It was hypothesized that a flexion contracture of greater than 20°,

as determined by a preoperative clinical examination, could make accurate anatomic landmarking based on a supine MRI examination more difficult for cutting guide fabrication. In addition, patients with a distal femoral or proximal tibial defect requiring a metal or allograft augment or the use of either femoral or tibial stem extensions were excluded because their use would affect the interpretation of radiographic alignment achieved using each surgical technique. Patients indicated for a cruciate-substituting design based on ligamentous instability or severities of coronal or sagittal plane deformity (based on the surgeon's discretion) were also excluded to maintain implant conformity between the two cohorts. Patella resurfacing is not routinely performed in most patients undergoing TKA at our institution; thus, patients receiving patella resurfacing were also excluded to improve consistency in the surgical technique between the two cohorts. Patients with a contraindication to obtaining a MRI scan, including those with a pacemaker or prior metal clips associated with brain or eye surgery, were also excluded.

All eligible patients were offered the option of receiving a preoperative MRI and TKA with CCGs, and each patient self-selected for either the CCG or standard cohort. The operating surgeon performed all patient counseling regarding surgical technique. The key differences between the CCG and standard surgical techniques were explained to each patient. Patients were informed that the standard surgical technique (intramedullary femoral and extramedullary tibial alignment guide) is the traditional and most commonly used method to make femoral and tibial resections and assist with aligning the lower extremity in the frontal plane. Patients were then explained that CCGs have recently been developed in which a preoperative MR image is used to fabricate guides that fit onto each patient's specific anatomy, which are used to assist with performing the distal femur and proximal tibia resections. They were counseled that potential benefits included a more accurate resection alignment and shorter intraoperative time, but it was emphasized that clinical results proving these benefits were limited given the recent introduction of this technique. All further patient questions were answered by the surgeon with the intent of remaining impartial toward each surgical technique. Patients self-selecting for the CCG cohort were willing to have a MRI for image processing, fabrication, and delivery of the CCG system. In this system (Signature™; Biomet Inc), select MR images are performed of the HKA, from which a preoperative 3-D image of the knee is generated. The optimal size, position, and alignment of the implants are templated and, once approved by the surgeon, rapid prototyping technology is used to fabricate the single-use CCGs. There were no instances in which the default parameters given by the templating software were altered before cutting guide fabrication. Intraoperatively, the CCGs are then used to perform the distal femoral and proximal tibial resections. Femoral rotation is set as two holes are drilled at the distal femoral condyles through the CCG based on preoperative templating and sizing, after which the standard cutting block is placed to perform anterior, posterior, and chamfer resections. The alignment goal for all TKAs in this study was a HKA angle of 0° with the femoral and tibial components aligned perpendicular to the mechanical axis. Ninety-seven of 120 (80.8%) patients in the standard and 104 of 124 (83.9%, $p = 0.5$) in the CCG cohort with a minimum of 1-year followup were available for analysis. There were no instances in which intraoperatively CCGs were abandoned and standard instrumentation was used. The first 95 patients in the standard (mean followup, 3 years; range, 1–4 years) and CCG (mean followup, 2 years; range, 1–4 years) cohorts who were not lost to followup were compared. Ninety percent of patients included for analysis were operated on by one surgeon, whereas 10% were operated on by the second surgeon. All patients adhered to our institution's perioperative protocol including rapid mobilization beginning the day of surgery, antibiotic prophylaxis within 1 hour of surgery initiation, and the use of chemical thromboprophylaxis and mechanical compression devices. Patients in the standard and CCG cohorts were similar for age, gender, and body mass index. In addition, no differences were appreciated in the operative side (Table 1). There were no differences in tourniquet time or overall time of the procedure from incision to skin closure (Table 1). Patients were seen or contacted for clinical followup at 2 weeks, 6 weeks, 6 months, 1 year, and 2 years postoperatively. UCLA [42], SF-12 [38], and Oxford knee scores [15] were compared between the two cohorts both preoperatively and at their most recent followup visit. Patients in the CCG cohort had increased UCLA, SF-12 physical component, and Oxford knee scores preoperatively ($p = 0.001$ to 0.03; Table 2).

All patients received postoperative coronal scout CT scans of the HKA with the extremities rotated into a neutral position to standardize the measurements using a previously described method [26]. The HKA axis, which is the angle formed between the mechanical axis of the femur (the line connecting the center of the femoral head with the center of the knee) and the mechanical axis of the tibia (the line connecting the center of the ankle mortise to the center of the knee), was measured in all patients with a targeted postoperative HKA alignment of $0° \pm 3°$. For convention, a negative value corresponded with a valgus alignment.

A post hoc power analysis was conducted to assess the research question that there would be no difference in clinical outcomes between the CCG and standard cohorts at a mean of 2 years postoperatively. It was determined that a sample size of 95 patients in each cohort would provide

Table 1. Preoperative demographics and operative details

Demographics and operative details	Standard cohort (n = 95)	Custom cutting guide cohort (n = 95)	p value
Age at surgery (years)	64 ± 7	62 ± 7	0.5
Body mass index at surgery (kg/m^2)	34 ± 7	32 ± 6	0.2
Gender			
Male	39	41	0.7
Female	56	54	
Operative side			
Right	52	51	0.9
Left	43	44	
Total operative time (minutes)	92 ± 15	91 ± 18	0.8
Tourniquet time (minutes)	59 ± 13	60 ± 15	0.8

Values are mean ± SD.

Table 2. Preoperative function and activity scores

Clinical outcome score	Standard cohort (n = 95)	Custom cutting guide cohort (n = 95)	p value
UCLA score	4 ± 2	5 ± 2	0.03
SF-12 score			
Physical component	28 ± 9	33 ± 9	0.001
Mental component	53 ± 12	54 ± 10	0.4
Oxford knee score	19 ± 7	23 ± 7	0.001

Values are mean ± SD.

appropriate power (beta level = 0.80, alpha level = 0.05) to detect a four-point difference in the Oxford knee score at the most recent followup visit. A five-point difference in the Oxford knee score has been reported to be a minimal clinically important difference; thus, our study was adequately powered to detect this difference [12]. Independent-sample t-tests were used to assess group differences in continuous variables and chi-square tests were used to assess categorical variables. A p value of < 0.05 was considered statistically significant. All statistical analyses were performed using SPSS for Windows, Version 22 (SPSS, Inc, Chicago, IL, USA).

Results

At the most recent followup, there were no differences present between the two cohorts for ROM or any of the outcomes scores evaluated. There were no differences present between the two cohorts for ROM (114° ± 14° in CCG versus 115° ± 15° in standard; mean difference, −1°; 95% confidence interval [CI] −5 to 3; p = 0.7), UCLA (6 ± 2 in CCG versus 6 ± 2 in standard; mean difference, 0; 95% CI, −0.6 to 0.6; p = 0.7), SF-12 physical (44 ± 12 in CCG versus 41 ± 12 in standard; mean difference, 3; 95%, CI −0.4 to 6; p = 0.07), or Oxford knee scores (39 ± 9 in CCG versus 37 ± 10 in standard; p = 0.1) (Table 3). No differences were present for the incremental improvement in the UCLA (1 ± 4 in CCG versus 1 ± 3 in standard; mean difference, 0; 95% CI, −1 to 1; p = 0.5), SF-12 physical (12 ± 20 in CCG versus 11 ± 21; mean difference, 1; 95% CI, −5 to 7; p = 0.8), or Oxford knee scores (16 ± 9 in CCG versus 19 ± 10 in standard; mean difference, 2, 95% CI, −0.4 to 5; p = 0.1) from preoperatively to postoperatively (Table 4).

There were no differences between the two cohorts for postoperative alignment. The mean postoperative HKA alignment was −1° ± 2° in the standard cohort versus −2° ± 3° in the CCG cohort ($p < 0.001$). However, no difference was seen in the percentage of TKAs with a HKA alignment outside of 0° ± 3° between the two groups (23% of standard versus 31% of CCG; p = 0.2). Of the outliers, in the standard cohort 41% were in valgus and 59% were in varus, whereas in the CCG cohort 67% were in valgus and 33% were in varus.

Discussion

Although the potential benefits of CCG technology for TKA have not been consistently demonstrated, the implementation of CCGs has spread rapidly [35]. Currently, seven implant manufacturers in the United States have FDA clearance and offer CCG technology [22]. Most reports have focused on the avoidance of alignment outliers and the potential cost-effectiveness of this technology, demonstrating mixed results [6, 14, 23–25, 33–35, 39]. With regard to component and overall alignment, studies have failed to consistently demonstrate an improved accuracy with the use of CCGs versus standard

Table 3. Comparison of postoperative clinical outcomes between the two cohorts at the most recent followup examination

Clinical outcome score	Standard cohort (n = 95)	Custom cutting guide cohort (n = 95)	p value
ROM (degrees)	115 ± 15	114 ± 14	0.7
UCLA score	6 ± 2	6 ± 2	0.7
SF-12 score			
Physical component	41 ± 12	44 ± 12	0.07
Mental component	53 ± 12	54 ± 10	0.7
Oxford knee score	37 ± 10	39 ± 9	0.1

Values are mean ± SD.

Table 4. Comparison of the incremental difference between preoperative and postoperative clinical outcomes scores for the standard and custom cutting guide cohorts

Clinical outcome score	Standard cohort (n = 95)	Custom cutting guide cohort (n = 95)	p value
UCLA score	1 ± 3	1 ± 4	0.5
SF-12 score			
Physical component	11 ± 21	12 ± 20	0.8
Mental component	1 ± 20	1 ± 21	0.9
Oxford knee score	19 ± 10	16 ± 9	0.1

Values are mean ± SD.

instrumentation [6, 11, 18, 24, 40]. Furthermore, the cost-effectiveness of this technology has not been proven, because the potentially decreased operative times and instrument trays required might not offset the additional costs of preoperative imaging and CCG fabrication [6, 33, 39]. To date, small cohorts and short followup have limited studies assessing the actual clinical outcomes of CCGs. In the present study, we found no differences between the two cohorts in ROM, clinical outcome scores, or alignment outliers at a mean 2-year followup interval.

This study had several limitations that are important to recognize when interpreting our data. First, although the sizes of the cohorts in this study were larger than previously published results of clinical outcomes with the use of CCGs, the relative sizes still remain small. Thus, slight differences in functional outcomes between the two cohorts may not have been recognized. Also, although greater than 80% followup was achieved in both cohorts, given the limited cohort sizes, it would have been ideal to achieve an even higher percentage of followup. In addition, the impact of the extremely positive or negative outliers in function would have a greater impact with smaller cohorts, leading to increases in the SDs of the clinical outcome scores and perhaps masking true differences between the two groups. However, the SDs of the clinical outcomes scores seen in both cohorts are consistent with previously published reports after TKA [7, 15, 38, 42]. In addition, given the relatively recent implementation of this technology and the desire to have a mean of 2 years followup, we were limited by the total number of surgical procedures performed using CCGs. Second, randomization was not performed in this study. Thus, numerous potentially confounding variables such as variances in soft tissue deformity and patient expectations may not be accounted for. Allowing patients to self-select their instrumentation introduces the potential for participation bias, because patients in the CCG cohort may have had higher demands and expectations postoperatively, thus affecting their clinical outcome scores. In addition, although the manner in which these surgical techniques have been described to the patient has been outlined previously, the manner in which these patients were counseled by the surgeon could affect both patient expectations and their overall outcome. However, although differences were present in the preoperative clinical scores, the incremental improvement from preoperatively to postoperatively was not different between the two cohorts, and no differences were seen in the absolute postoperative scores between the two cohorts, indicating lack of a demonstrable clinical benefit with the use of CCGs. Lastly, inclusion criteria for this study were relatively strict, thus limiting the potential generalizability of this study.

To our knowledge, clinical outcomes after the use of CCGs in TKA have only been reported at less than 1 year postoperatively and have been limited by small cohorts of

patients [29, 37, 40, 41]. Recently, Woolson et al. [40] reported the results of a randomized clinical trial of 22 TKAs performed using a CT-based CCG system (TruMatch; DePuy Inc, Warsaw, IN, USA) versus 26 TKAs with standard instruments. They found no differences in Knee Society scores (KSS) or component alignment at a minimum of 6 months followup. Pietsch et al. [29] completed a randomized clinical trial of 40 TKAs performed with standard instrumentation versus 40 TKAs with PSI (Zimmer Inc, Warsaw, IN, USA) and similarly found no difference in the KSS at 3 months postoperatively [29]. In a retrospective review of 31 TKAs performed using a MRI-based CCG system (Visionaire; Smith & Nephew Inc, Memphis, TN, USA) versus 31 matched TKAs performed using standard instrumentation, Vundelinckx et al. [37] reported no differences in the visual analog scale, Lysholm knee, or Knee Injury and Osteoarthritis Outcome (KOOS) scores between the two cohorts at 7 months postoperatively. Lastly, Abdel et al. [1] performed a randomized controlled trial of 20 TKAs performed using a MRI-based CCG system (Materialise®, Leuven, Belgium) and 20 TKAs performed using standard instrumentation to assess early patient-reported and gait analysis outcomes. They found no difference in the new KSS, KOOS, SF-12, or 3-D gait parameters assessed at 3 months postoperatively between the two cohorts, but noted their results could not predict the presence of additional variances that could emerge at an intermediate followup period [1]. Thus, our study had larger cohorts with longer followup and corroborated these prior reports because no improvements in functional outcomes were seen with the use of CCGs at a mean followup of greater than 2 years.

Our study supports prior studies demonstrating CCGs to confer no additional benefit in achieving a neutral mechanical alignment postoperatively [10, 17, 28, 41]. Again, although prior reports to this regard are mixed [23, 24], CCGs do not consistently demonstrate a radiological advantage. However, this study solely focused on measurement of alignment in the coronal plane and not sagittal or rotational alignment as has been previously reported [40]. Because CCGs could potentially confer an advantage with regard to rotational and sagittal alignment, these additional radiographic parameters must continue to be investigated.

Finally, one of the proposed advantages of CCGs not realized in our study was an improvement in surgical time. Supporters of CCGs note improved surgical efficiency and subsequent cost-efficiency as potential advantages, yet prior Level I studies assessing these outcomes have been mixed [10, 17, 24]. Although Noble et al. [24] noted a decrease in operative times with the use of CCGs by 7 minutes, Hamilton et al. [17] found the use of traditional instrumentation to be shorter than CCGs by 4 minutes. In addition, the results of several Level II and Level II studies have also been mixed to this regard [6, 8, 11, 25]. No difference in either tourniquet time or total operative time was seen in our study. This was likely the case because the surgeons enrolling patients in this study had a high level of experience with the use of standard instrumentation and were able to perform the surgeries efficiently. Occasionally, seating of the CCGs was difficult, and thus surgeons took an increased amount of time to confirm that the blocks were seated correctly. Furthermore, a prior cost-analysis study showed any potential savings in operating room efficiency would be greatly outweighed by the current cost of the preoperative MRI and cutting guide fabrication (approximately USD 1500) [6]. Thus, because no difference in surgical times nor radiologic outcomes was noted in our study, the potential financial benefits of improved surgical efficiency and accuracy may not be realized with the use of CCGs [33, 39].

In conclusion, at a mean followup of greater than 2 years, we were unable to demonstrate an improvement in clinical outcomes, radiologic outcomes, or surgical efficiency with the use of CCGs versus standard instrumentation in TKA. Although it is important to note that only one specific CCG system was used in this study and thus the generalizability of our findings may not apply to other systems, in the absence of proven clinical or radiological advantages, the continued implementation of this technology must be questioned.

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