

Prospective Non-Randomized Comparative Clinical Outcome of Computer Assisted Total Knee Arthroplasty with and without a Minimally Invasive Approach

Chumroonkiet Leelasestaporn MD*

* Department of Orthopaedic Surgery, Bhumibol Adulyadej Hospital, Bangkok, Thailand

Objective: Compare clinical outcomes of computer assisted total knee arthroplasty using the LCS® knee implant with (CAMITKA) and without (CATKA) minimally invasive surgery.

Material and Method: The author prospectively performed 71 computer-assisted total knee arthroplasties (TKA) in group of the present study using the Ci™ navigation system in a non-randomized manner.

Results: CAMITKA subjects had a mean operation time of 105 minutes, average incision length of 9.1 cm, mean total blood loss of 541 ml, mean time to ambulation of 25.4 hours, and required approximately 10 and 18 days using walkers and canes respectively, before ambulating unaided. CATKA subjects had a mean operation time of 81 minutes, average incision length of 13.5 cm, mean total blood loss of 599 ml, mean time to ambulation of 45.4 hours, and required 17 and 27.5 days using walkers and canes respectively, before ambulating unaided. All outcome differences have statistical significances, except blood loss. Mechanical axis alignment measured from post-operative radiographic assessment showed that 2.5% of all knees were outliers and average axis deviations were 1.39° and 1.34° for CAMITKA and CATKA subjects, respectively. No complications were detected. CAMITKA is advantageous with respect to recovery time.

Conclusion: Minor surgical pitfalls were experienced with CAMITKA regarding visualization and initial registration of the navigation system. However, they may be corrected by coupling navigation with CT scan, fluoroscopy, and/or ultrasound. Additionally, accurate mechanical axis alignment shows that computer assisted surgery technology allows minimal invasive surgery in TKA because it allows visualization of areas not directly revealed without aid.

Keywords: Computer assisted surgery, CAS, Minimally invasive surgery, MIS, Total knee arthroplasty, TKA, Total knee replacement, TKR

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Alternative methods of surgery in Total Knee Arthroplasty (TKA) are becoming more prominent worldwide. Computer assisted surgery (CAS) has become a popular alternative to conventional TKA. Although it is more costly and is sometimes lengthier than traditional TKA, it has sufficient potential in reducing bone alignment errors, which makes it a feasible alternative in many cases. Since alignment is the key to overall success of arthroplasty, malalignment in TKA can lower strength and stability of the prosthetic knee component⁽¹⁾ resulting in decreased implants longevity⁽²⁻⁸⁾. Improvements in prosthesis have also

resulted in modification of the overall success of TKA. By using prosthetics designed to reduce contact stress in combination with CAS, there may be greater potential for increased achievement in TKA procedures. In addition to the aforementioned improvements, it has been suggested that incision size is associated with reductions in blood loss, tissue damage, pain, dose of painkiller, and length of hospitalizations from TKA^(9,10). Therefore, a minimally invasive surgery (MIS) technique coupled with CAS may also improve knee replacements in a variety of ways.

MIS in combination with CAS is a relatively new approach in TKA. MIS reduces the size of incision to a level previously unattainable, due to limitations in visibility of the surgeon. The coupling of MIS with CAS has removed viewing limitations by allowing surgeons access to the entire area of interest via a digitized model on a computer screen. Ideally, with this

Correspondence to:

Leelasestaporn C, Department of Orthopaedic Surgery, Bhumibol Adulyadej Hospital, Royal Thai Air force, Phaholyothin Rd, Bangken, Bangkok 10220, Thailand.
Phone: 0-2534-7366, Fax: 0-2974-6308
E-mail: chumroonkiet_1@yahoo.com

technique, the largest dimension required to implant a particular prosthesis will be the only factor in determining the minimal incision size.

Preceding 2004, TKA in Thailand was performed via the conventional method. Use of computer-assisted total knee arthroplasty (CATKA) was introduced in Thailand in July 2004. Shortly thereafter, the addition of a MIS component emerged. Although both are relatively new procedures, they are becoming more widely available and preferable by some surgeons, as well as patients. In the present study, the authors aimed to compare clinical outcomes of CATKA and computer-assisted TKA with MIS (CAMITKA).

Material and Method

The author prospectively performed 71 TKA procedures in each arm of the present study. Subjects' allocation into the control and experimental group was non-randomized and based on subjects' preference after being thoroughly informed of the pros and cons of both alternatives. CATKA surgeries from the present study occurred between August 2004 and March 2007, while CAMITKA surgeries took place between January 2005 and July 2007. All subjects were receiving treatment for diagnosed osteoarthritis (OA). All implants from the present study used the DePuy Low Contact Stress (LCS® Knee) mobile bearing system (cemented), and surgeries were all performed through use of Ci™ Software (DePuy International Ltd). Software operation was done by two pins fixation at the tibia and one pin fixation at the femur, followed by a registration sequence. Anteroposterior view of the knee radiographs (scanograms) as well as the corresponding digital photographs for each subject was taken post-operatively by an independent knee replacement surgeon, who had not taken part in any operation in the present study. After digital images of scanograms were taken, the files were loaded into AutoCAD® 2005 and mechanical axis measurements were calculated. Any deviation in alignment greater than 3° (either varus or valgus) was considered to be an outlier.

The authors termed 'minimally-invasive' to be a surgical technique whereby a routinely shorter skin incision was made. The author consistently used the mid-vastus approach throughout the present study. The authors' also defined 'ambulation' as the point at which a study subject was able to begin walking independently with the aid of a walker, a cane, or unaided. For the present study, the authors did not

include post-operative pain or range of motion (ROM) as other studies⁽²⁾.

Independent proportion ratios were tested statistically to compare the ratios of male to female, left to right knees, and varus to valgus knees (post-operatively) between the study groups. A z-ratio was calculated from the difference between the independent proportions; and a 2-tailed probability value (P) was generated to determine likelihood of significance among the ratios of the two study groups. Non-parametric Chi-square (χ^2) statistical tests were utilized for analysis of outlier occurrence (frequency). A trend test was performed and an R^2 value was generated using Pearson's Product. T-tests were used for all other statistical significance testing. Statistical significance was declared for a calculated p-value at or below the 0.05 level.

Results

The average age at the time of surgery was 65.9 years and 67.6 years for the CAMITKA and CATKA groups respectively (Table 1). A Student's t-test demonstrated no significant difference in average age at the time of surgery between the two groups ($p = 0.1786$). The average age from the present study was in agreement with other TKA studies in recent years^(1-7,2,11,12). The proportion of female to male patients was somewhat higher in the CATKA group, although both groups were predominately comprised of female patients. The subjects consisted of 60 females and 11 males vs. 57 females and six males within the CAMITKA and CATKA groups, respectively (Table 1). Testing for significance between the two independent proportions (2-tailed) indicated rather weak probability that no significant differences existed in female to male ratios within the CAMITKA and CATKA subjects ($z\text{-ratio} = -1.036$, $p = 0.3002$). However, both groups from the present study are comparable with current similar studies in terms of exhibiting a higher female to male ratio^(1,2,5,7,9,10). With CAMITKA patients, there were 44 right knees and 27 left knees that underwent surgery, while there were 31 right knees and 32 left knees among CATKA patients (Table 1). The two independent proportions for left to right knee ratios among CAMITKA and CATKA groups demonstrated a low probability that no significant differences existed between them ($z\text{-ratio} = 1.486$, $p = 0.1373$).

The mean mechanical axis deviation was 1.39° for the CAMITKA subjects and 1.34° for the CATKA group (Table 2). This small difference had no statistical significance ($p = 0.8264$). A comparison of outlier

Table 1. Pre-operative demographic data for CAMITKA and CATKA

	CAMITKA (n = 71)	CATKA (n = 63)	Proportion (P)	p-value
Mean age (yrs)	65.9	67.6	-	0.1786
Male (%)	11 (15.5%)	6 (9.52%)		
Female (%)	60 (84.5%)	57 (90.48%)	0.3002	-
Left knees (%)	27 (38.0%)	32 (50.8%)		
Right knees (%)	44 (62.0%)	31 (49.2%)	0.1373	-

Table 2. Post-operative results of CAMITKA versus CATKA

Post-operative means	CAMITKA	CATKA	p-value
Operation time (min)	104.80	80.60	<0.001
Blood loss (ml)	540.50	599.40	0.1796
Incision length (cm)	9.12	13.50	<0.001
Mechanical axis deviation (degrees)	1.39	1.34	0.8264
Axis alignment outliers (%)	2.50	2.50	0.7518
Blood drain time (hr:min)	16:51	35:33	<0.001
Time required to begin walking* (hr:min)	25:27	45:25	<0.001
Duration of using a walker (days)	9.62	16.80	0.004
Duration of using a cane (days)	16.20	27.50	0.035
Duration of hospitalization (days)	5.45	5.24	0.7179

* Walking with either the aid of a walker or a cane

frequency between the two groups (via Chi-square test) yielded similar results. Post-operatively for each group, only one outlier occurred (2.50%) among the 40 randomly measured mechanical axis (Table 2). Frequency of outliers among CAMITKA and CATKA subjects revealed no statistical significance ($p = 0.7518$). The sole outliers had deviations of 3.45° (valgus) and 4.60° (varus) for CAMITKA and CATKA subject groups,

respectively. Overall, the distribution of mechanical axis alignments was rather uniform (Fig. 1). In addition, a time trend was generated to see if there were any differences among alignment improvements (Fig. 2). The Pearson's R^2 value for both groups expressed improvements in mechanical axis alignments over time, but not in a range sufficient to deem either group statistical significant (CATKA $R^2 = 0.1568$, CAMITKA $R^2 = 0.0908$).

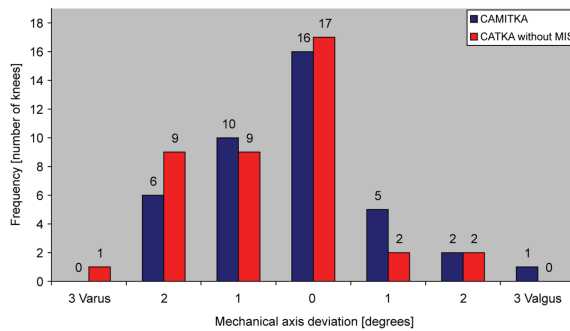


Fig. 1 Distribution of mechanical axis deviation (in degrees varus or valgus) for CATKA versus CAMITKA

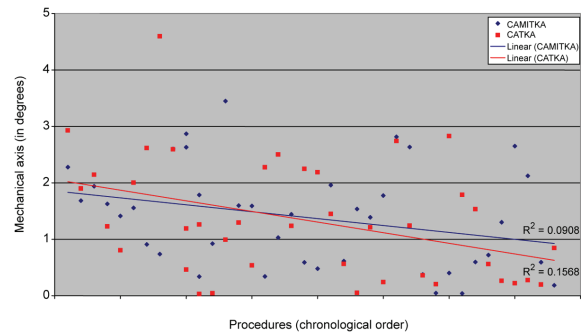


Fig. 2 Trend of mechanical axis alignment for CATKA & CAMITKA procedures (in chronological order by date of operation)

The ratio of varus to valgus oriented knees (post-operatively) was considerably higher within the CATKA group (3.44 to 1) than for CAMITKA subjects (0.739 to 1). For CATKA subjects, percentages were 77.5% varus and 22.5% valgus. Conversely, in the CAMITKA subjects, varus knees accounted for only 42.5% versus 57.5% being in valgus orientation. These two independent proportions suggests a very low probability that no difference exists in varus to valgus ratios between the two groups (z-ratio = -1.91, $p = 0.0561$). An average incision length of 9.12 cm was measured post-operatively on the CAMITKA patients. As expected, this was significantly shorter than the 13.5 cm average incision length among CATKA subjects ($p < 0.001$).

A significant difference in the average operation times between each group was apparent. The MIS technique performed on CAMITKA patients required an average of 104.8 minutes. In contrast, CATKA procedures required an average of 80.6 minutes ($p < 0.001$). This difference should get smaller as time progresses and as the MIS technique is performed more frequently (Table 2).

Average blood loss and blood draining time both favored CAMITKA patients, although the former was not considerably different. The average total blood loss for CAMITKA subjects was 540.5 ml versus a slightly higher average of 599.4 ml for those in the CATKA group. In terms of post-operative time required for blood draining, significant differences were seen between the two groups. CAMITKA patients required post-operative blood draining for an average of 16.51 hours, while patients from the CATKA procedure group needed an average of 35.33 hours of draining time ($p < 0.001$).

Difference in time required to begin ambulation was also highly significant. The average post-operative time duration for CAMITKA patients to begin walking (by walker or cane) was 25.27 hours versus an average time duration requirement of 45.25 hours for CATKA subjects ($p < 0.001$). In addition, subjects showed a noticeable difference in the average time spent using a walker and a cane, during post-operative rehabilitation. The CAMITKA subjects required an average of 9.62 days using a walker, while the CATKA patients necessitated an average of 16.8 days ($p = 0.004$). The average CAMITKA patient spent 16.2 days using the aid of a cane versus an average of 27.5 days was required for CATKA patients ($p = 0.035$). The CAMITKA group had two subjects that required the use of a cane for 60 days (well over 4 standard deviations above the

mean). These two cases were consequently eliminated from the statistical analysis calculations. Without adjustments for bias, the average duration of using a cane among CAMITKA subjects was 17.9 days opposed to 27.5 days required for CATKA patients, on average ($p = 0.0727$). Here it can be seen that without adjusting, it becomes a borderline case of statistical significance. However, with or without adjustments, a clear difference is worth noting.

Average post-operative hospitalization was not very different. CAMITKA subjects had an average post-operative hospitalization of 5.45 days, while those in the CATKA group stayed an average of 5.24 days post-operatively. The CAMITKA group had two subjects requiring 39 days (4 standard deviations above the mean) and one subject requiring 30 days (more than 3 standard deviations above the mean) for post-operative hospitalization. Thus, those three subjects were omitted from the statistical analysis. However, without adjustments, the average post-operative hospitalization for CAMITKA patients was 6.76 days vs. an average of 5.24 days for CATKA patients ($p = 0.1086$). Regardless of scenario, adjusting for bias made no significant difference between the two groups.

Discussion

CAS in TKA can offer better precision via a higher accuracy in mechanical axis alignment. Accurate limb orientation ensures a higher potential to establish equilibrium among the soft tissues, thus enhancing the durability of the prosthesis. Although this may not guarantee patients' fulfillment of post-operative results, and patients may need pre-operative counseling; good alignment can maximize the functional capability of the knee⁽¹³⁾. The authors believed that perhaps the combination of CAS navigation and a MIS approach could generate good results.

From the results observed in the present study, we can conclude several important observations. Although it has been reported in previous studies^(14,15), it is worth mentioning that complications were neither detected nor reported by neither the physician nor patients from the present study. The authors did not witness a difference in the post-operative mechanical axis alignments or the number of outliers between the two groups, but the authors have noted a similar trend of alignment improvements over time among both groups (Fig. 2). In contrast to mechanical axis results, the mean operation times between the two study groups were significantly different. This difference has been

reported in previous studies^(12,16). In other studies, a difference in average operation time with CAMITKA was not observed⁽¹¹⁾. However, the average operation time for the present subjects was considerably longer than in the Dalury and Dennis study⁽¹²⁾. The longer operation times required for CAMITKA procedures will most likely decrease as more operations occur and the surgeon becomes more comfortable with using a MIS technique in combination with CAS.

As expected, the authors saw a sufficiently reportable difference in the average incision length among our two subject groups. From review of the literature, several other studies have also noticed significant differences in the average incision lengths when MIS is performed^(9,11,12). A shorter incision (along with avoiding patella eversion) will likely result in a shorter time requirement for the patient to begin ambulation. Results from the present study suggests that a shorter incision length, less blood loss (although not significant in the present study) and less post-operative blood draining time may have a correlation with the time required for a patient to begin walking (with a walker or cane). Evidence of this can be seen when the authors divide the present study into three equal groups of subjects and view the average time required to begin ambulation in chronological order (Fig. 3), although the authors also acknowledge an improvement over time among CATKA subjects.

The authors found statistical significance for the average times spent with a walking aid during post-operative rehabilitation, with shorter average times among CAMITKA patients. The importance of these and whether they are truly correlated with the type of surgical procedure is subject to both interpretation and opinion. It can be argued that a difference in these times supports the use of a MIS

technique. However, it can also be justifiably viewed with a bit of objective caution. There may be other factors involved that truly determine the length of time an average patient spends with a walker or cane. One such argument is that a psychological component is involved. Some patients may or may not have irrational expectations pre-operatively and it is important they know what they can and cannot expect from their surgery. Some patients seem to develop a psychological dependence on either a cane or walker at some point during their rehabilitation, thus skewing the statistical figures involved. Therefore, whether the type of operation affects the amount of time a patient spends in rehabilitation with a cane or walker is probably dependent upon a case-by-case basis. In terms of the average post-operative hospitalization times, there was no significant difference between the two groups, whether using a MIS technique or not.

Despite the fact that clinical results indicate good bone alignment, the author experienced a few surgical pitfalls with CAMITKA procedures. The primary problems were related to visualization and initial registration of the navigation system software. The navigation software sometimes inaccurately estimated the implant size and rotational alignment. In addition, the lateral side, Whiteside lines, and lateral epicondyle of the affected knees were routinely difficult to visualize. The author believes that the difficulties in initial registration can be remedied by coupling navigation with a CT scan, fluoroscopy, and/or ultrasound. Nevertheless, there is room for technological improvement with the navigation system software, especially in regard to the initial registration steps.

From the current results, it can be concluded that the use of MIS in combination with CAS navigation greatly reduces the recovery time, particularly the time required to begin ambulation. Shorter incision length and less tissue damage can be an additional aid in shortening the recovery period. In addition, CAS is relatively new and has the potential for many improvements that can prove beneficial to both patients and physicians. Although these options are more costly, a cost-benefit analysis would be beneficial at some point. A further consideration of post-operative ROM comparisons among patients could also be of interest in the future. Furthermore, long-term patient outcomes should be followed and reported in order to fully determine the degree of improvements that have transpired in TKA procedures.

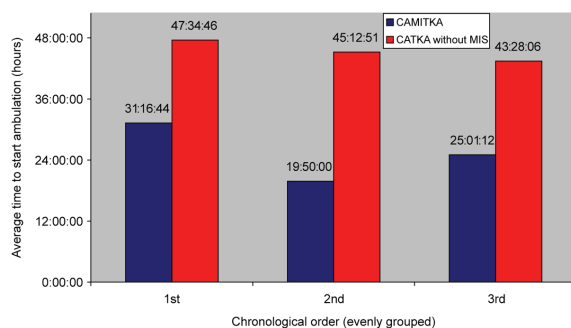


Fig. 3 Average post-operative time required to begin walking (with the aid of a walker or cane)

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Potential conflicts of interest

None.

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การศึกษาเปรียบเทียบผลทางคลินิกของการผ่าตัดเปลี่ยนข้อเข่าเทียมแบบไปข้างหน้าโดยใช้คอมพิวเตอร์นำร่องด้วยเทคนิคการผ่าตัดแบบมาตรฐานและการผ่าตัดแบบแผลเล็กโดยไม่มีการสู่ม

จารย์เกียรติ ลีลเศรษฐพร

วัตถุประสงค์: การศึกษานี้มีจุดประสงค์ที่จะนำผลของการผ่าตัดเปลี่ยนข้อเข่าเทียมชนิด LCS โดยใช้คอมพิวเตอร์ร่วมกับเทคนิคการผ่าตัดแบบแผลเล็ก (CAMITKA) มาเปรียบเทียบกับวิธีการผ่าตัดประเภทเดียวกัน โดยไม่ได้ใช้การผ่าตัดแบบแผลเล็ก (CATKA) ผู้นิพนธ์ได้ทำการศึกษาแบบไปข้างหน้าโดยไม่มีการสู่ม

วัสดุและวิธีการ: ผู้นิพนธ์ได้ทำการผ่าตัดเปลี่ยนข้อเข่าเทียมโดยใช้ระบบนำร่อง Ci™ กับผู้ป่วย 71 ราย ต่อกลุ่มศึกษา
ผลการศึกษา: กลุ่ม CAMITKA มีระยะเวลาในการผ่าตัดเฉลี่ย 105 นาที, ความยาวแผลเฉลี่ย 9.1 ซม., ปริมาณเลือดที่สูญเสียทั้งหมดเฉลี่ย 541 มล., ระยะเวลาในการฟื้นตัวก่อนเริ่มเดินเฉลี่ย 25.4 ซม., และต้องใช้เวลาเดินด้วยเครื่องช่วยเดินชนิด 4 ขาเฉลี่ย 10 วันและไม่เท่า 18 วันก่อนที่จะสามารถเดินได้โดยไม่ต้องใช้อุปกรณ์ช่วย กลุ่ม CATKA มีระยะเวลาในการผ่าตัดเฉลี่ย 81 นาที, ความยาวแผลเฉลี่ย 13.5 ซม., ปริมาณเลือดที่สูญเสียทั้งหมดเฉลี่ย 599 มล., ระยะเวลาในการฟื้นตัวก่อนเริ่มเดินเฉลี่ย 45.4 ซม., และต้องใช้เวลาเดินด้วยเครื่องช่วยเดินชนิด 4 ขาเฉลี่ย 17 วันและไม่เท่า 27.5 วัน ก่อนที่จะสามารถเดินได้โดยไม่ต้องใช้อุปกรณ์ช่วย ตัวแปรทั้งหมดที่กล่าวมาข้างต้น (ยกเว้นปริมาณเลือดที่สูญเสียทั้งหมด) ของทั้งสองกลุ่มการรักษามีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ การวัด mechanical axis alignment โดยวัดจากฟิล์มหลังการผ่าตัด แสดงให้เห็นว่ามีข้อเข่าจำนวน 2.5 เปอร์เซนต์ที่คลาดเคลื่อนกว่าค่ามาตรฐาน กลุ่ม CAMITKA มีความคลาดเคลื่อนเฉลี่ยอยู่ที่ 1.39 องศา และกลุ่ม CATKA มีความคลาดเคลื่อนอยู่ที่ 1.34 องศา ไม่มีการตรวจพบภาวะแทรกซ้อน CAMITKA มีข้อดีที่ระยะเวลาในการพักฟื้น แต่ก็มีควมลำบากในการใช้อยู่ตรงขั้นตอนการ visualization และ initial registration ของระบบนำร่อง

สรุป: อย่างไรก็ตามความลำบากนี้ก็อาจขจัดไปได้โดยการใช้ CT scan, fluoroscopy และ ultrasound นอกจากนี้แล้ว mechanical axis alignment ที่แม่นยำแสดงให้เห็นว่าเทคโนโลยีการผ่าตัดโดยใช้คอมพิวเตอร์ช่วยทำให้การผ่าตัดแบบแผลเล็กในการผ่าตัดเปลี่ยนข้อเข่าเทียมเป็นไปได้ด้วยการทำให้ผู้ทำการผ่าตัดสามารถมองเห็นพื้นที่ที่ไม่สามารถมองเห็นได้โดยไม่ต้องใช้เครื่องมือช่วย
