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Is continuous locking suture with braided suture sufficient for arthrotomy repair in the conventional TKR? A randomized controlled trial study

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ABSTRACT

Introduction: Medial-parapatellar-arthrotomy is the standard approach for total knee replacement(TKR). No studies have clarified the outcomes as quadriceps-strength-recovery (QS) and safety of Continuous-locking-suture-technique(CLS) for the arthrotomy-repair.
Methods: Patients were randomly assigned into a CLS($n = 40$) and an interrupted-horizontal-mattress(IHM, $n = 40$). QS, visual-analog-scale(VAS), modified-timed-up-and-go(TUGT) test, Western-Ontario-and McMasters-Universities-Osteoarthritis-Index[WOMAC] and Knee-Society-Score[KSS] were followed for 6 months'.
Results: A significantly-shorter capsular-closure-time in CLS(233 ± 40 VS 388 ± 47 sec)($p < 0.0001$). There were insignificant difference in QS, VAS, TUGT, WOMAC and KSS during the 6-month follow-up period($p > 0.05$ all). No wound complications were found.
Conclusion: CLS with braided-suture is safe and effective as demonstrated a recovery of the QS and knee function outcome comparable to IHM.
Trial registration: This study was registered in Thai Clinical Trials Registry on December 2015 (https://www.clinicaltrials.in.th). The registration number was TCTR20151208003.

1. Introduction

Total knee replacement (TKR) through a medial parapatellar arthrotomy is considered a gold standard and remains one of the most popular TKR approaches due to the excellent exposure to the knee joint with the relatively easy and safe surgical technique.[1] However, the major drawback of this approach is the dissection of the quadriceps tendon, resulting in a slower recovery compared to the minimally invasive or quadriceps-sparing approach.[2,3] Previous studies showed that the quadriceps weakness after TKR could persist over a significant period, such as 6 months postoperatively,[4] and the muscle may not return to the strength level of the contralateral limb even after 1 year.[5,6] Therefore, efficient arthrotomy repair for the quadriceps and the extensor mechanisms after the medial parapatellar approach, which allows for early rehabilitation focused on the quadriceps strength (QS), is an important key to improving the outcomes after TKR.

Traditionally, the standard technique for arthrotomy repair involves using an interrupted suture with multiple knots with a large-size absorbable braided suture due to the high tensile strength for suture breakage. However, this suture technique is time-consuming and usually creates uneven tension.[7] As an improvement over the interrupted technique, an innovated barbed knotless suture has recently been introduced for the continuous running suture technique, and it has a demonstrated ability to facilitate comparatively faster wound closure time, superior watertight closure, and potentially minor cost reduction.[8–10,] Notably, though, a few studies have reported an association between the barbed suture and some postoperative complications, such

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List of abbreviations

TKR	Total knee replacement
QS	Quadriceps strength
CLS	Continuous locking suture
IHM	Interrupt horizontal mattress
N-QS	Normalized quadriceps strength
OL-QS	Operative leg quadriceps strength compared with contralateral QS
VAS	Visual analog pain scale
TUGT	Modified time up and go test
WOMAC	Western Ontario and McMasters Universities Osteoarthritis Index
KSS	Knee society score
RCT	Randomized control trial
BMI	Body mass index
NSAIDs	Nonsteroidal anti-inflammatory drugs
ROM	Range of motion
FC	Flexion contracture
PRC	Packed red cell
HHD	Hand-held dynamometer
GFR	Glomerular infiltration rate
INR	international normalized ratio
OA	Osteoarthritis

as surgical site infection,[11] extensor mechanism repair failure,[12] and possible higher risk of reoperation.[13] To the best of our knowledge, the evidence for the optimal wound closure has not been clearly developed,[14] and the data related to the postoperative outcomes after using other simple suture techniques, such as continuous locking suture (CLS) with braided suture for arthrotomy repair in TKR, has never been published. Therefore, this study aimed to compare the outcome after arthrotomy repair in conventional TKR between the CLS and the standard interrupted suture, in terms of the QS and functional recovery.

2. Materials and methods

The study was approved by the ethical clearance committee of the authors' institution (Protocol ID: 12-57-10, in accordance with the ethical standards in the 1964 Declaration of Helsinki, and registered in the Thai Clinical Trials Registry (https://www.clinicaltrials.in.th). Written informed consent was obtained from all patients before enrollment.

2.1. Study population

This study was conducted as a single-center, double-blinded prospective randomized control trial (RCT) in a medical university hospital. From June 2016 to July 2017, 100 potentially eligible patients, who were scheduled for primary TKR with a single high-volume arthroplasty surgeon (SW), were screened and recruited. The inclusion criteria were patients who 1) were diagnosed as advanced primary knee osteoarthritis, 2) were aged between 55 and 85 years old, 3) had a body mass index (BMI) lower than 35 kg/m^2, and 4) could follow the study's protocol and had given their informed consent. The exclusion criteria were patients who 1) had inflammatory polyarthritis, such as rheumatoid arthritis and gouty arthritis, 2) had a previous surgery on the operated leg, 3) had severe deformity or bone loss requiring augmentation (either metal augmentation or bone graft augmentation) or constrain type prosthesis, and 4) had another concomitant lower extremity disorder or neuromuscular disorder.

2.2. Subject allocation and randomization

The randomization was generated by STATA 12.0 software (Stata Corp, College Station, Texas, USA), with a block size of 4, and further concealed with sealed envelopes. The allocation was revealed intraoperatively before the arthrotomy repair (after prosthesis insertion) by a research assistant who did not participate in the outcome assessment. All patients were allocated into one of two groups: the CLS group or the interrupted horizontal mattress (IHM) group.

2.3. Surgical procedure

All operations were performed by a single surgeon (SW). The surgical approach was the medial parapatellar approach with measured resection technique. The fixed-bearing and posterior cruciate-substituted prosthesis design was implanted in all patients. Patellar resurfacing was done in all cases, and the implants were all fixed with cement. The pneumatic tourniquet was inflated with pressure equal to 150 mmHg above the patient's systolic blood pressure and deflated after wound closure. Multimodal cocktail periarticular injection with the standard regimen was injected into the posterior knee capsule and the surrounding soft tissue around the knee joint, as previously described by Tammachote et al.,[15] before the final implant insertion. The drain tube was applied before closing the joint capsule. The arthrotomy repair was performed in a 30° knee flexion[8] and using only 1-0 Vicryl (Ethicon, Cincinnati, OH, USA). To guarantee the anatomical arthrotomy repair and prevent quadriceps impairment due to the capsular laxity, two key-stitch interrupted sutures were made at the superomedial and inferomedial aspect of the patellar, as shown in Fig. 1A. In the IHM group, the joint capsule was closed with the IHM suture technique, tying at least 4 throws per knot,[16] along the entire arthrotomy wound with approximately 10 mm of separation between stitches (Fig. 1B). Regarding the CLS group, the suture was started at the most proximal part of the quadriceps cut and then was run down in a continuous locking fashion to the end of the incised joint capsule. To prevent the suture breakage from the increased tension during knee flexion, two additional secure knots—using the CLS free loop itself—were tied at the beginning and the end of capsular curved edge along the patella border (Fig. 1C). The subcutaneous layer was closed with the interrupted suture using 2-0 Vicryl (Ethicon, Cincinnati, OH, USA). The skin was closed with the interrupted vertical mattress suture using 3-0 Ethilon® (Ethicon, Cincinnati, OH, USA). After wound closure, the intra-articular tranexamic application was applied through the drain tube, and the drain was clamped for 2 h, as described by Sa-ngasoongsong et al.[17]

2.4. Postoperative protocol

Postoperative care and rehabilitation program followed the same protocol used by the research assistant who did not participate in the statistical analysis. The perioperative pain management included intravenous patient-controlled analgesia morphine and intravenous NSAIDs for the first 48 h, followed by oral tramadol and NSAIDs as required if the patient had a 10-point pain visual analog scale (VAS) higher than 3. All patients were instructed to sit at the bedside and start to perform passive range-of-motion (ROM) exercises within 12 h after operation. On the second day, patients were allowed to ambulate with weight bearing as tolerated with gait aids. All patients were discharged within 5 days post-surgery. A home-based postoperative rehabilitation program was given, including passive ROM exercises, isometric quadriceps exercises in the knee extension position, and walking with gait aids at least 20 min twice a day. After 6 weeks postoperatively, the gait-aid discontinuation and stair climbing were allowed.

2.5. Data collection and outcomes measurement

Demographic data—including age, gender, BMI, comorbid disease,

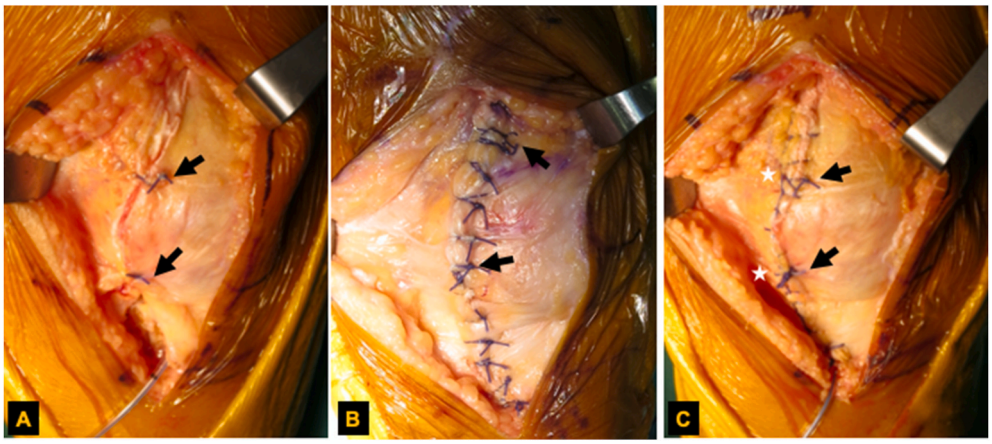

Fig. 1. The illustrations show the arthrotomy repair surgical techniques in both groups. (A) Initially, two key-stitch interrupted sutures (black arrow) were performed at the superomedial and inferomedial of the patellar border. (B) In the IHM group, the arthrotomy repair was done with only interrupted horizontal mattress suture. (C) In the CLS group, the continuous locking sutures were performed with two secure knots (white star).

preoperative laboratory value, knee osteoarthritis grading according to Ahlbäck classification,[18] preoperative deformity, preoperative knee motion and flexion contracture (FC) angle, preoperative knee function as Western Ontario and McMasters Universities Osteoarthritis Index (WOMAC) knee score and Knee Society Score (KSS) were recorded. Intraoperative data and perioperative information—such as length of quadriceps cut, capsular closure time, operative time, length of surgical wound, and number of total packed red cell (PRC) transfusions—were collected. The capsular closure time was defined as the duration for the arthrotomy repair between the most proximal suture and the most distal suture, excluding the time for the initial key-stitch interrupted sutures.

Postoperative QS-related outcomes comprised the peak isometric QS, 10-point VAS, and modified timed up and go test (TUGT) at 2 weeks, 6 weeks, 3 months, and 6 months postoperatively. The isometric QS was measured by using a digital hand-held dynamometer (HHD) (Micro-FET2™, Hoggan Health Industries, Draper, UT, USA) with a standard knee extensor measurement protocol (measuring patients in sitting position with full thigh support and 30° knee flexion, applying the HHD at the distal third of tibia, and instructing the patients to progressively increase their effort to the maximal QS level for at least 5 s).[19] The protocol included 3 trials with a minimal 30-s rest period between each contraction. The primary outcome was the peak isometric QS, which was assessed via two methods: 1) normalized quadriceps strength (N-QS) defined by the peak isometric QS divided by the patient's BMI, and 2) operative leg quadriceps strength (OL-QS) compared with contralateral leg QS and reported as a percentage. The modified TUGT was defined as the time spent from chair raise and walk with or without gait aids for 3 m, which mirrored the definition in our previous study.[20] The knee functional outcomes, such as the WOMAC knee score and KSS, were collected at 6 weeks, 3 months, and 6 months postoperatively. The postoperative complication related to the suture technique as wound dehiscence, prepatellar hematoma, and wound infection. All outcomes were collected by the author (KC) who was not involved in the randomization.

2.6. Statistical analysis and sample size calculation

Medcalc software version 15.8 was used to analyse the data. Normally distributed continuous data were presented as mean and standard deviation and compared with Student t-test, while non-normally distributed continuous data were presented as median and interquartile range. Categorical data were presented as proportion of cases and compared with Fisher's exact test or the chi-square test as appropriate. The repeated-measurement analysis of variance was used to determine the statistical difference in the QS recovery, VAS, modified TUGT, WOMAC, and KSS during the postoperative period. Intention-to-treat analysis was performed. A significance difference was considered if the two-sided p-value was less than 0.05.

The sample size was calculated using the data from our pilot study with 15 patients (the mean N-QS was 7.7 ± 2.8 N/kg-m^2). Assuming a 25% difference in N-QS after the CLS with a type I error rate as 0.05 and power of 0.8, the necessary sample size was 35 patients in each group.

3. Results

3.1. General characteristic data of study population

Of the 100 eligible patients, 14 patients did not meet the inclusion criteria, while 4 patients refused to consent. Therefore, a total of 80 patients were randomly enrolled in the CLS and IHM groups. At the 6-month postoperative period, 3 patients in the CLS group and 2 patients in the IHM group were lost to follow up (Fig. 2). Table 1 demonstrates the patients' demographic data, whereas Table 2 shows the intraoperative and perioperative data in both groups. The CLS group did not have any significant differences in the demographic and perioperative data compared to the IHM group ($p > 0.05$ all), except the significantly shorter capsular closure time (233 ± 40 sec vs. 388 ± 47 sec, respectively, $p < 0.0001$).

3.2. Quadriceps strength and VAS during exercise

Table 3 shows the postoperative QS outcomes. There was no significant difference in the preoperative QS in both groups; the CLS group had a median of 6.6 N/kg-m^2 and 85% in the preoperative N-QS and OL-QS vs. 6.7 N/kg-m^2 and 72% for the IHM group ($p > 0.05$ all). After the TKR, both groups demonstrated a significant decrease in both N-QS and OL-QS at 2 weeks postoperatively ($p < 0.0001$ both) and then experienced the return of QS recovery to the preoperative level within 6 weeks postoperatively (Fig. 3). Additionally, at 6 months postoperatively, the IHM group showed a significant increase in both N-QS and OL-QS compared to the preoperative level ($p < 0.05$ both). However, there was no significant difference in the N-QS and OL-QS between both groups within the 6-month postoperative period ($p = 0.89$ and 0.55, respectively).

The preoperative VAS during exercise did not significantly differ between both groups with the mean VAS of 5.5 ± 1.3 in the CLS group and 5.1 ± 1.2 in the IHM group ($p = 0.12$). Both the CLS and IHM groups showed a significant decrease in the mean postoperative VAS during exercise after 2 weeks, compared with the preoperative value ($p < 0.05$ all). Nevertheless, no significant difference in VAS during exercise was

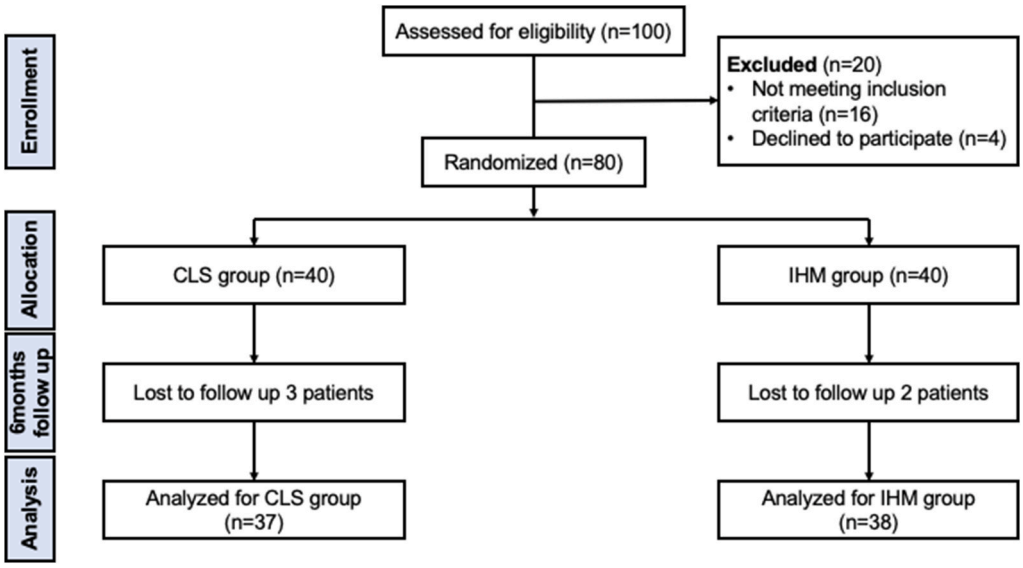

Fig. 2. The flow diagram shows how the number of patients included in this study were enrolled, randomized and allocated, followed up with, and analyzed. CLS = continuous locking suture. IHM = interrupted horizontal mattress.

Table 1
Demographic data.

Demographic data	CLS group (n = 40)	IHM group (n = 40)	*p*-value
Age, yr [a]	69.4 (7.2)	72.1 (8.7)	0.15
Gender (male/female)	34/6	34/6	1.00
BMI, kg/m^2 [a]	27.8 (4.3)	27.2 (4.5)	0.55
Comorbidities, number of patients			
Hypertension	32	28	0.44
Diabetes	11	5	0.09
Cardiovascular	8	6	0.77
Chronic kidney disease	3	5	0.71
Preoperative laboratory values [a]			
Hemoglobin, g/dL	12.7 (1.0)	12.7 (1.4)	0.82
Platelet, x1000/mm^3	240 (55)	243 (51)	0.82
GFR, mL/min	73.1 (17.4)	73.7 (18.5)	0.90
Albumin, g/dL	37.4 (1.9)	38.0 (2.9)	0.31
INR	0.96 (0.05)	0.96 (0.05)	0.79
OA grading by Ahlbäck classification, number of patients			
1	5	6	0.35
2	28	22	
3	7	12	
Preoperative deformity (varus/valgus)	39/1	39/1	1.00
Preoperative ROM, degree [b]	124 (114–131)	120 (114–130)	0.77
Preoperative FC, degree [b]	0 (0–6)	0 (0–10)	0.30

CLS = continuous locking suture; IHM = interrupted horizontal mattress; BMI = body mass index; GFR = glomerular infiltration rate; INR = international normalized ratio; OA = osteoarthritis; ROM = range of motion; FC = flexion contracture.

[a] Value presented as mean (standard deviation) and calculated with unpaired *t*-test.

[b] Value presented as median (interquartile range) and calculated with Mann-Whitney *U* test.

found between both groups (p = 0.47) (Fig. 4).

3.3. Functional outcomes and post-operative complications

Preoperatively, there was a non-significant longer duration of the modified TUGT in the CLS group compared to those in IHM group, with the median modified TUGT of 10.1 and 8.6 s (p = 0.12), respectively. Both groups experienced a significantly slower duration in the modified TUGT at 2 weeks postoperatively (p < 0.05 both). The CLS group

Table 2
Perioperative data.

	CLS group (n = 40)	IHM group (n = 40)	*p*-value
Length of quadriceps cut, cm [a]	4.9 (0.8)	5.2 (0.7)	0.12
Capsular closure time, sec [a]	233 (40)	388 (47)	<0.0001*
Operative time, min [a]	80 (9)	79 (9)	0.41
Wound length, cm [a]	11.9 (0.8)	11.8 (1.0)	0.53
PRC transfusion, number of patients	3	5	0.71

CLS = continuous locking suture; IHM = interrupted horizontal mattress; PRC = packed red cell.

* Significant difference with p-value < 0.05.

[a] Values presented as mean (standard deviation).

Table 3
Quadriceps strength.

	CLS group (n = 37)	IHM group (n = 38)	*p*-value[a]	*p*-value[b]
Normalized quadriceps strength, N/kg-m2				
Preoperative [d]	6.6 (5.1–9.0)	6.7 (4.7–7.8)	0.55	0.89
2 weeks [c]	4.5 (1.5)	4.7 (2.3)	0.72	
6 weeks [c]	7.2 (2.6)	7.2 (2.4)	0.96	
3 months [c]	7.8 (2.7)	7.5 (2.2)	0.64	
6 months [d]	7.9 (6.2–9.1)	8.0 (6.7–10.2)	0.46	
Quadriceps strength compared with contralateral side, %				
Preoperative [d]	85 (70–104)	72 (61–99)	0.21	0.55
2 weeks [c]	59 (25)	57 (26)	0.83	
6 weeks [c]	90 (29)	88 (29)	0.79	
3 months [c]	96 (24)	92 (25)	0.45	
6 months [d]	98 (82–112)	98 (88–110)	0.63	

QS = quadriceps strength; CLS = continuous locking suture; IHM = interrupted horizontal mattress.

[a] p-value between groups in each follow-up period.

[b] p-value between groups calculated with repeated-measure ANOVA.

[c] Value presented as mean (standard deviation) and calculated with unpaired *t*-test.

[d] Value presented as median (interquartile range) and calculated with Man-Whitney *U* test.

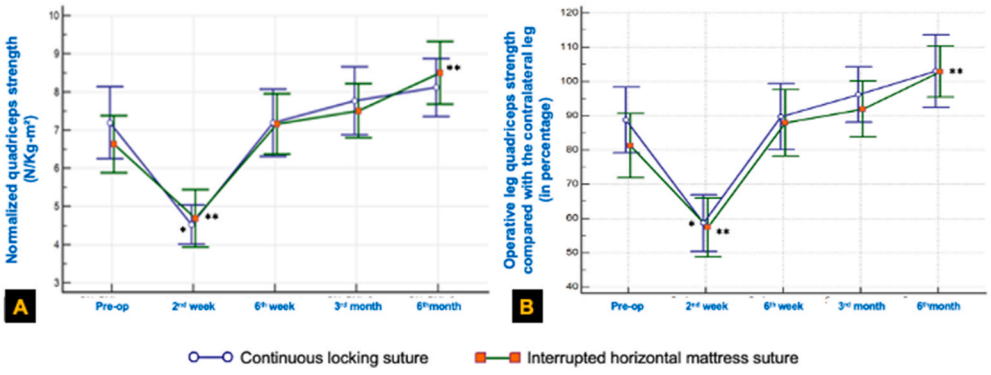

Fig. 3. The line graphs demonstrate the changes in the (A) isometric quadriceps strength as normalized quadriceps strength (N-QS) and (B) operative leg quadriceps strength compared to the contralateral quadriceps strength (OL-QS) during the study period. The N-QS and OL-QS in both CLS and IHM groups significantly decreased at 2nd week postoperatively, then returned to the preoperative level within 6 weeks. However, no significant difference of the N-QS and OL-QS was found between both groups, calculated by the repeated measure ANOVA ($p = 0.55$). * and ** indicate the significant changes from the pre-operative values, with p-values less than 0.05, of the CLS and IHM groups, respectively.

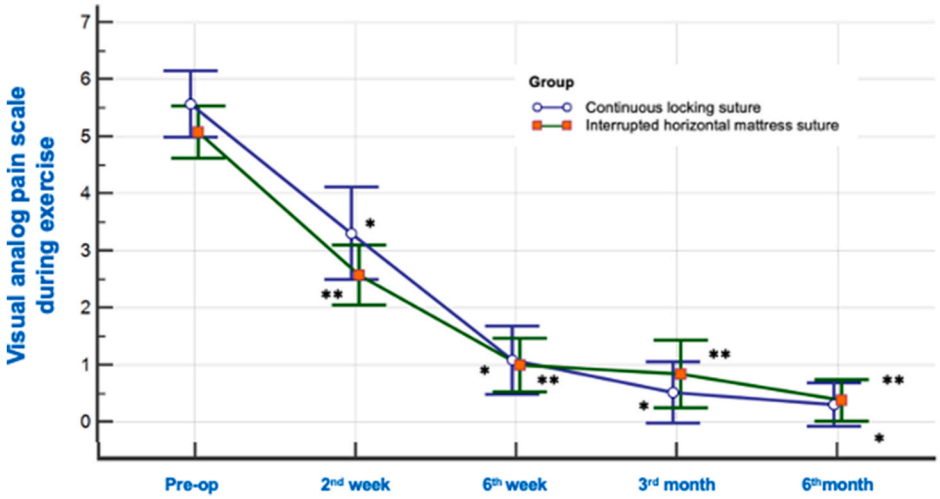

Fig. 4. The line graph shows that the mean visual analog pain scale (VAS) during exercise in both groups significantly decreased, compared to the preoperative values, from 2 weeks to 6 months postoperatively. However, there was no significant difference of the mean VAS between both groups, calculated by the repeated measure ANOVA ($p = 0.47$). * and ** indicate the significant changes from the pre-operative values, with p-values less than 0.05, of the CLS and IHM groups, respectively.

demonstrated a significantly faster duration in the modified TUGT compared to the preoperative values after 6 weeks postoperatively, whereas the IHM group had experienced a significant improvement after 3 months. However, the CLS group did not show any significant difference in the modified TUGT compared to the IHM group during the 6-month study period ($p = 0.20$) (Fig. 5).

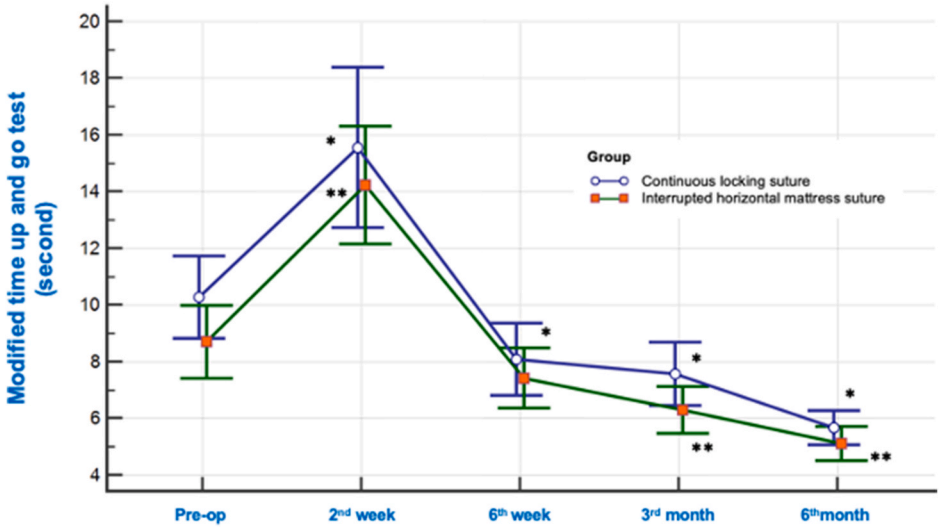

Fig. 5. The line graph demonstrates the changes in the modified timed up and go test (TUGT) in both groups. CLS and IHM group showed a significant improvement in the modified TUGT after 6 weeks and 3 months, respectively ($p < 0.05$ all). Nonetheless, there was no significant difference in the modified TUGT between both groups during the study period, calculated by the repeated measure ANOVA ($p = 0.2$). * and ** indicate the significant changes from the pre-operative values, with p-values less than 0.05, of the CLS and IHM groups, respectively.

Regarding the functional scores for the WOMAC knee score and the KSS, the CLS group demonstrated a non-significant difference in the preoperative values compared with the IHM group ($p = 0.16$ and 0.84, respectively). Both groups experienced a significant improvement in the WOMAC knee score and the KSS over the follow-up period ($p < 0.05$ all). However, there was no significant difference in these scores between the CLS and IHM groups during the 6-month study period ($p = 0.24$ and 0.98, respectively (Fig. 6A and B).

There was no incidence of reoperation from any causes during the study period. Both groups showed normal wound healing response without postoperative wound complications or surgical site infections.

4. Discussion

The arthrotomy repair is one of the most important steps in wound closure after TKR due to the relationship between the extensor mechanism recovery and postoperative wound complications. Although the traditional interrupted suture is considered the standard technique for arthrotomy repair, continuous or running techniques with barbed suture had recently been popular due to the faster closure time, better watertightness, and potential cost reduction.[7,10] However, to the best of our knowledge, no previous studies had established the data related to the efficacy of CLS on the arthrotomy repair and its related outcomes. This study therefore aimed to evaluate the effectiveness of CLS for the arthrotomy repair in TKR compared to the standard IHM, in terms of quadriceps strength and related functional outcomes.

Our results showed that the arthrotomy repair with the CLS technique significantly decreases the capsular closure time (with the mean difference at 155 sec, Table 2) without any significant difference in the postoperative QS, functional outcome, operative time, and wound-related complications, compared to the IHM technique, during the 6-month follow-up period (Tables 2 and 3). In terms of the postoperative QS recovery, both groups experienced a significant drop in NQS and OL-QS at 2 weeks, but then recovered 6 weeks after TKR. These findings were different than the previous studies that demonstrated the significant postoperative QS deficit as 59%–62% at the first month and the recovery to the preoperative level at 6 months after TKR.[5,21,22] This difference could be explained by the following areas with differences in methodology between the previous studies and the present study: the QS assessment method (electromechanical dynamometer vs. handheld dynamometer), the knee position during the measurement (60^0-75° knee flexion vs. 30° knee flexion), the inhibitory effect of preoperative pain and postoperative pain recovery on QS measurement, and the possible effect of blood loss reduction on functional recovery by tranexamic acid injection.[23] However, our findings supported that the postoperative QS deficit in the early postoperative period after TKR could be improved with a meticulous surgical technique with appropriate multimodal perioperative pain management and strict postoperative rehabilitation protocol.

Regarding the postoperative functional outcome after TKR, the CLS groups also showed a non-significant difference in the modified TUGT, WOMAC knee score, and KSS compared to the IHM group during the study period ($p > 0.05$ all). These findings are comparable to those from previous studies using continuous barbed suture in TKR,[5,7,9,10] which can be explained by the successful arthrotomy repair and the uneventful healing of the knee extensor mechanism in both groups during the strict postoperative protocol.

Our results also showed uneventful wound healing response without the incidence of wound complications, such as surgical site infections and reoperation, in both groups during the 6-month follow-up period. These findings were comparable to the previous studies,[12,13] which implied that either the CLS or IHM techniques with traditional braided suture materials are safe. Moreover, the previous studies demonstrated that using barbed suture for superficial wound closure in TKR might be associated with higher risk for wound complications.[11,24,25]

Our study had some limitations. First, the QS measurement protocol used in this study was slightly different from the previous studies. Due to the evaluation of the QS recovery after arthrotomy repair and the prevention of suture breakage, our study was designed to use HHD and assess QS in 30° knee flexion with the earliest follow-up visit as 2 weeks, whereas the previous studies on QS recovery after TKR were performed using various measurement tools (such as isokinetic dynamometer, electromechanical dynamometer, or chair-fixed dynamometer) and testing in knee positions varying from 30° to 75° knee flexion with the earliest follow-up visit at 1 month.[5,22,23,26] Moreover, the reliability of the QS assessment in some patients might be affected by the knee pain as the mean VAS at 2 weeks postoperatively was 2.9 ± 18 in the CLS group and 2.2 ± 1.4 in the IHM group (Fig. 4). Therefore, although HHD had been known for its reliability for patients undergoing TKR,[19,27,28] our results could not be directly compared with the previous studies. Second, although this study was a double-blinded RCT, our sample size was relatively small and might not detect some postoperative complications related to the CLS technique, such as suture breakage or wound infection. Third, our study did not explore the other factors that might affect the QS recovery, such as surgeon experience,[29] prosthesis design,[21] and the use of barbed suture.[30] Therefore, future prospective and multicenter RCTs with a large sample size are required to assess the effect of CLS in the general population.

5. Conclusion

The results from the present study confirmed that the arthrotomy repair in conventional TKR could be successfully achieved by combining a meticulous surgical technique, such as either CLS or IHM, and using only the traditional braided suture without any clinically significant postoperative complications.

Authors' contribution

SW and PS: Conceptualization, Methodology, Software. **SW and KC**:

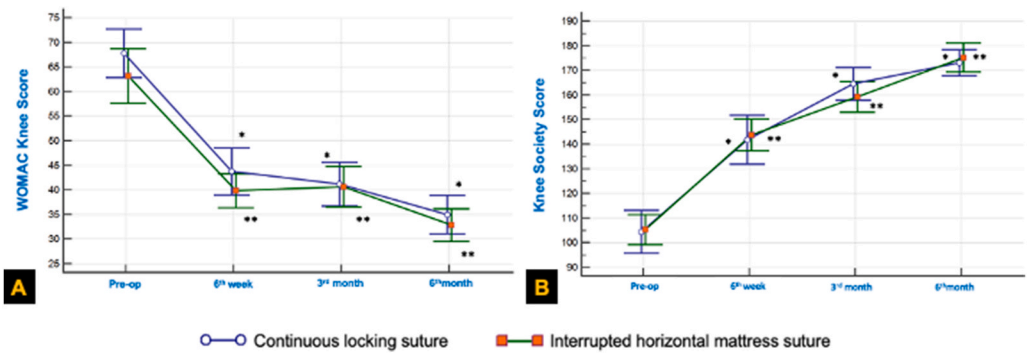

Fig. 6. The line graphs show the changes in the knee functional score, as (A) WOMAC knee score (A) and (B) Knee Society Score (KSS) during this study. Both groups demonstrated significant improvement in both knee functional scores after 6 weeks postoperatively ($p < 0.05$ all). However, there was no significant difference in the WOMAC knee score and KSS between both groups at all follow-up sessions ($p = 0.24$ and 0.98, respectively). * and ** indicate the significant changes from the pre-operative values, with p-values less than 0.05, of the CLS and IHM groups, respectively.

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Ethics approval and consent to participate

This study was approved from ethical clearance committee of Human Right Related to Research Involving Human Subjects of the Faculty of Medicine Ramathibodi Hospital, Mahidol University (Protocol ID: 12-57-10). All participants were informed and consent prior study enrollment.

This study was registered in Thai Clinical Trials Registry on December 2015 (https://www.clinicaltrials.in.th). The registration number was TCTR20151208003.

Consent for publication

All authors have read the final version and give consent for the article to be published.

Availability of data and materials

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

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