Effect of Bone Plugging at the Distal Femoral Drilled Hole in Total Knee Arthroplasty on Early Clinical Outcomes

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Purpose: *Bone plugging at the intramedullary (IM) femoral drilled hole in total knee arthroplasty (TKA) is performed with expectation to decrease blood loss. We hypothesized that the retained blood in IM canal may affect postoperative thigh & leg heaviness (TLH), quadriceps peak torque (QPT) and immediate clinical outcomes.*

Methods: *Eighty-one patients undergoing unilateral TKA using IM femoral bone cut were randomly divided into 2 groups; group I: drilled hole plugged with a bone graft, and group II: drilled hole was left open. Postoperatively, clinical parameters were sequentially evaluated until 12 weeks.*

Results: *There were 41 knees in group I and 40 knees in group II. Preoperative demographic data of both groups were not different. There was no difference in blood collected from drain and transfusion rate. The TLH similarly changed from severe grade at 2 weeks to none and mild grade at 12 weeks. The QPT was similarly decreased by 38% at 2 weeks, and improved to preoperative level at 12 weeks. There were no differences in visual analog scale (VAS), range of motion (ROM), Western Ontario and McMaster Universities Arthritis Index (WOMAC) and Knee Society System (KSS) scores between both groups.*

Conclusion: *Comparing between plugging or unplugging femoral IM hole in TKA, the present study found no difference in blood loss, and retained blood in IM canal did not have effect on TLH, QPT and other immediate clinical outcomes. Plugging of the femoral IM hole provided no harm or advantages which could be performed according to surgeon's preference.*

Keywords: *femoral drilled hole, plug, total knee arthroplasty, TKA, thigh, leg, heaviness, quadriceps peak torque*

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Introduction

Total knee arthroplasty (TKA) is an effective surgical procedure for definite treatment of end-stage knee osteoarthritis (OA). From one year after surgery, most patients reported satisfactory clinical outcomes, in terms of pain relief and functional improvement[(1)]. Although modification of surgical technique and pain management, such as minimal invasive surgery (MIS)[(2,3)] and multimodal pain control,[(4)] have been developed, at immediate postoperatively period, patients usually have functional limitations due to activity-related pain and quadriceps weakness[(5,6)]. Using intramedullary (IM) technique for distal femoral bone cut, earlier studies reported that bone plugging at the drilled hole decreased postoperative blood loss in primary TKA[(7-9)]. However, recent studies did not have similar results[(9,10)]. In fact, the effect of bone plugging on other early clinical outcomes, such as thigh & leg heaviness (TLH), quadriceps peak torque (QPT), pain, and knee range of motion (ROM), have not been investigated. We hypothesized that plugging of the femoral IM canal could collect and retain the blood which might cause thigh and leg heaviness and other delayed functional improvements at immediate postoperative period.

The purposes of the present study were to determine the effect of distal femoral bone plugging on immediate clinical outcomes, in terms of perception of TLH, QPT, pain, ROM and reducing postoperative blood loss after MIS-TKA.

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Material and Methods

A Prospective randomized double blinded controlled trial with approval of the Institutional Review Board (COA No. 015/2014 IRB No. 461/56) was performed. Inclusion criteria were patient's age from 45 to 85 years old, having written informed consent before enrollment, late-stage primary knee OA, scheduled for unilateral primary TKA. Patients with history of inflammatory arthritis, previous knee surgery, bleeding disorders or current usage of anticoagulant were excluded from the study. Eighty-one patients (81 knees) were enrolled. All patients underwent TKA using IM technique for femoral bone cut and were randomly divided into 2 groups using computer-generated number. In Group I, the drilled hole at distal femur was plugged with an autologous strut bone graft. In Group II, the drilled hole was left open.

All surgeries were performed by one of two senior surgeons using a uniform minimal invasive surgical approach under spinal anesthesia in a bloodless field with use of pneumatic tourniquet at a pressure of 320 mmHg. A midline skin incision and a mini-midvastus arthrotomy were used in all knees. Further soft tissue exposure, bone cuts, and soft tissue balancing were performed in the same sequence. Femoral IM and tibial extramedullary bone cuts were used in all cases. One of the three posterior-stabilized TKA systems was chosen based on surgeon's preference included NexGen LPS-Flex (Zimmer, Warsaw, IN, USA), Vanguard (Biomet, Warsaw, IN, USA) and PFC sigma (Depuy, Warsaw, IN, USA). Following a satisfied trial reduction of components, the femoral IM canal was irrigated with pulsatile lavage (Pulsavac, Zimmer, Warsaw, IN, USA). In Group I, a single-piece autologous bone graft from the resected femoral intercondyle was plugged into the entry hole of the femoral IM canal (Fig. 1). In Group II, the intramedullary canal was left open. Because PFC sigma has a close box design that may interfere with blood loss from IM canal, the plastic plug at intercondylar box was taken off to eliminated this problem. After cementing of actual total knee prosthesis, the wound was closed in layers with vacuum drainage. The tourniquet was released and the mechanical stocking extending from toes to the proximal thigh was applied.

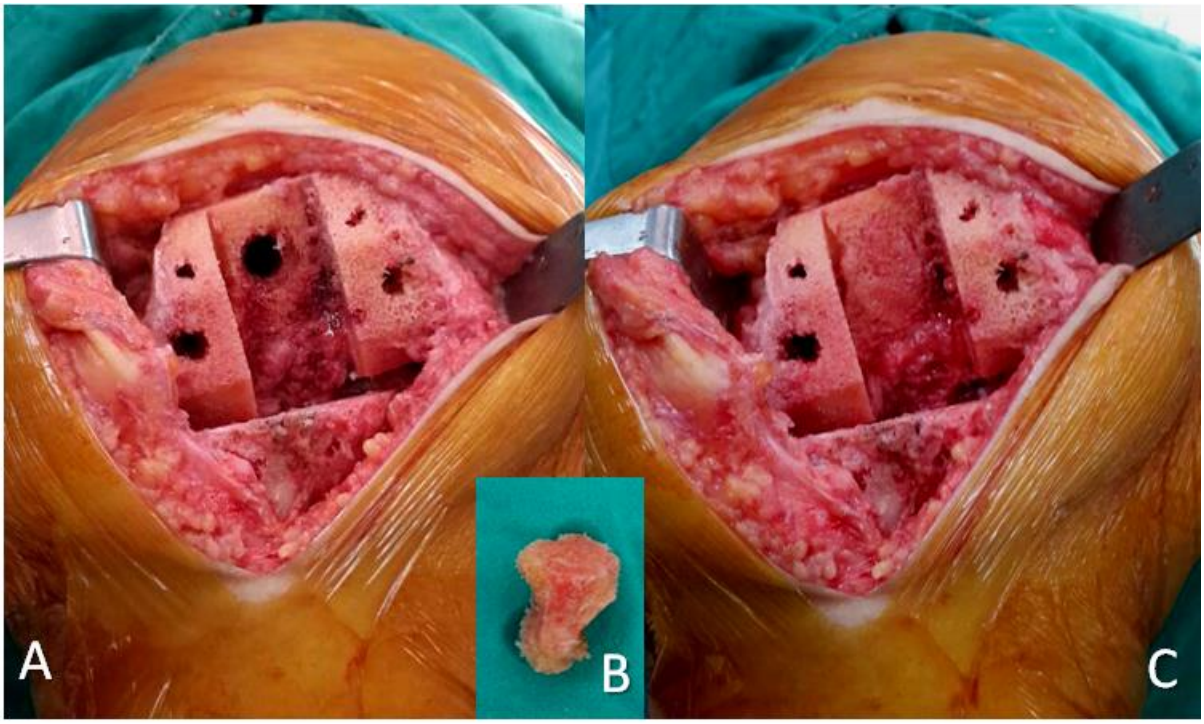

Fig. 1 A: Distal femoral drill hole for intramedullary femoral alignment is demonstrated.
B: Bone graft from resected femoral intercondyle is trimmed to fit the hole.
C: The bone graft is impacted into the femoral drill hole.

The 3-day postoperative rehabilitation program[4] was identical in both groups. On postoperative day (POD) 0, multimodal pain control, proper fluid balance and quadriceps setting exercise were addressed. On POD 1, the drain was removed in the morning and patients were allowed to start to walk with full weight-bearing for a minimum of 15 min/day. A 10-second isometric

quadriceps exercise in sitting position was instructed to patients for 50 cycles in a day. On POD 2, patients were encouraged to walk for a minimum of 30 min/day. From POD 3, patients were encouraged to walk for a minimum of 60 min/day, and were discharged unless their medical conditions were inadequately controlled. All patients were received modified DVT prophylaxis using rivaroxaban for 5 mg once daily from POD 1 to POD 10, if no contraindication.

The volume of postoperative drainage was measured and recorded at 18-20 hours after surgery. Hematocrit levels were recorded preoperatively and on the morning of POD 1. Patients received blood transfusion, if the postoperative hematocrit level was <30% or patients had a symptom of anemia such as tachycardia, hypotension, and orthostatic hypotension. The TLH was classified into 4 grades (grade 0: no, grade 1: mild, grade 2: moderate and grade 3: severe) according to patient's perception comparing to the non-operated side. The QPT was evaluated using a digital dynamometer (MicroFET2TM, Hoggan Health Industries, Salt Lake City, UT, USA) following the method described by Reinking and coinvestigators[11]. The Patient was test at 60 degrees of knee flexion and the force transducer was place at the lower leg (2 cm above the lateral malleolus) then patient was asked to perform a maximal voluntary knee extension. Testing was repeated for 3 times and the average amount of quadriceps peak torque was record at every patient's visit. The ROM was determined using a long-arm goniometer (30 cm of arm length) placing each arm at axis of femur and tibia at full extension and flexion.

The patient's demographic data, TLH, QPT, ROM, visual analog scale (VAS), Western Ontario and McMaster Universities Arthritis Index (WOMAC)[12] and Knee Society System (KSS) score[13] were recorded preoperatively, and then 2 weeks, 6 weeks, and 12 weeks, postoperatively by 2 independent evaluators who were blinded to the study.

Statistical analysis was performed using Graph Pad Prism version 6.00 for Windows, Graph Pad Software, La Jolla California USA, www.graphpad.com. Categorical variables were reported as frequencies and percentages, and continuous variables were reported as means and standard deviations. Unpaired t-test was use for quantitative data and chi-square and Fisher's exact test was use for qualitative data. The *P*-value of <0.05 was considered significance.

From review paper number of patient sufficient to demonstrate difference in term of functional outcome post Total Knee Arthroplasty, in this paper we use quadriceps function as a primary goal in determine sample size, would be at least 30 per group[2,5,6] with significant value of $P<0.05$.

Results

Forty-one patients were randomized into group I and 40 patients were randomized into group II. There were no differences in demographic data, preoperative and perioperative investigated parameters and between both groups, except body mass index (BMI), as shown in Table 1.

Table 1 Mean and SD of demographic data, preoperative and perioperative investigated parameters

Parameters	**Total** N=81	**Group I** N=41	**Group II** N=40	***P*-value**
Female Male	61 20	29 12	32 8	0.23
Mean age (y)	70.6 (6.6)	71.1 (6.8)	70 (6.4)	0.84
Mean BMI (kg/m^2)	27.8 (3.6)	27.5 (4.0)	28.1 (3.2)	0.03*
Preop VAS (point)	8.0 (1.2)	8.2 (1.1)	7.7 (1.3)	0.18
Preop KSS (point)	36.2 (10.0)	37.0 (10.7)	35.4 (9.3)	0.52
Preop WOMAC (point)	71.3 (9.9)	71.1 (9.9)	71.5 (9.9)	0.99
Preop ROM (deg)	115.3 (17.5)	115.0 (18.7)	115.5 (16.3)	0.67
Preop QPT (N/m)	118 (26.8)	122.8 (26.2)	113.1 (26.7)	0.94
Operative time (min)	102.9 (15.2)	107.7 (14.6)	98 (14.4)	0.25
Prosthesis Design Nexgen Vanguard PFC sigma	 40 23 18	 19 12 9	 21 11 9	

Both groups had no significant difference in amount of blood loss, decreasing of Hct level and transfusion rate (Table 2). Grade of TLH was also no significant difference in both group at 2-wk FU and gradually improved. At 12- week follow-up (FU), only grade 1 of TLH was found in 23% of the studied group with no difference between groups (Table 3). Regarding the QPT, both groups was decreased at 2 weeks with no significant difference then returned to preoperative level at 12 weeks. Although at 12-weekFU, all patients had significantly improved KSS scores, WOMAC scores, and VAS, there were no significant differences in these parameters between both groups at all intervals of FU (Table 4).

Table 2 Postoperative blood loss and Transfusion

	Total N=81	**Plugged group** N=41	**Unplugged group** N=40	***P*-value** (95%CI)
Blood in drainage (ml)	399.4 (180.3)	393.9 (173.3)	405 (189.2)	0.62 (-91.3-69.1)
Change of Hct. (%)	5.0 (3.5)	5.4 (3.3)	4.5 (3.7)	0.94 (-0.65-2.4)
Number of transfusion	30	12	18	0.17

Table 3 Patient's report on thigh & leg heaviness (TLH)

	Total				**Group I**				**Group II**				***P*-value**
	Gr0	**Gr1**	**Gr2**	**Gr3**	**Gr0**	**Gr1**	**Gr2**	**Gr3**	**Gr0**	**Gr1**	**Gr2**	**Gr3**	
2 weeks	0	54	20	7	0	29	10	2	0	25	10	5	0.47
6 weeks	49	28	4	0	23	16	2	0	26	12	2	0	0.80
12 weeks	66	15	0	0	32	9	0	0	34	6	0	0	0.57

Table 4 Mean and SD of investigated parameters at follow up

Parameters	**Total** N=81	**Group I** N=41	**Group II** N=40	***P*-value** (95%CI)
KSS 2 weeks (point)	71.5 (9.7)	72.6 (9.9)	70.4 (9.6)	0.35 (-2.2-6.5)
KSS 6 weeks (point)	85.4 (7.2)	85.6 (6.7)	85.2 (7.8)	0.44 (-2.9-3.6)
KSS 12 weeks (point)	86.4 (6.2)	86.8 (5.8)	86.1 (6.7)	0.26 (-2-3.5)
WOMAC 2 weeks (point)	48.7 (10.1)	49.2 (10.0)	48.2 (10.3)	0.88 (-3.5-5.5)
WOMAC 6 weeks (point)	34.4 (9.0)	34.3 (9.3)	34.4 (8.8)	0.77 (-4.2-3.9)
WOMAC 12 weeks (point)	20.4 (6.4)	20.8 (6.9)	19.9 (9.9)	0.13 (-2-3.7)
VAS 2 weeks	3.5 (1.5)	3.5 (1.4)	3.5 (1.7)	0.10 (-0.67-0.69)
VAS 6 weeks	1.1 (1.3)	1.1 (1.4)	1.1 (1.3)	0.79 (-0.57-0.62)
VAS 12 weeks	0.8 (0.8)	0.9 (0.8)	0.7 (0.8)	0.14 (-0.18-0.54)
ROM 2 weeks	99.6 (11.3)	100.3 (11.6)	98.9 (11.0)	0.57 (-3.5-6.5)
ROM 6 weeks	116.5 (11.1)	116.7 (11.3)	116.4 (11.0)	0.88 (-4.6-5.2)
ROM 12 weeks	116.8 (10.6)	117.2 (10.3)	116.3 (11.0)	0.58 (-3-4)
QPT 2 weeks (N/m)	74.7 (23.1)	76.8 (24.3)	72.7 (22.0)	0.38 (-6.1-14.4)
QPT 6 weeks (N/m)	120.7 (22.9)	121.2 (23.2)	120.2 (22.9)	0.85 (-9.1-11.3)
QPT12 weeks (N/m)	125.9 (19.7)	125.7 (19.5)	126.1 (20.2)	0.64 (-9.2-8.3)

Discussion

The IM technique for femoral alignment in TKA was reported to cause appreciable bleed loss into the intramedullary canal from damage to cancellous bone and IM vasculature[14]. Keeping the femoral drilled hole open connects its IM canal to the knee joint. It allows blood draining from the IM canal into the joint space, which is potentially increasing blood loss, and risk of blood transfusion. Studies investigated whether plugging the femoral IM hole during TKA could decreased blood loss and blood transfusion were inconclusive[7-10]. Although 2 earlier studies concluded that plugging the IM canal provide benefits,[7,8] one of them found that it had no effect of rate of blood transfusion[8]. On the other hand, 2 later studies reported similar amount of blood loss with different conclusion on the rate of blood transfusion[9,10]. Although our finding showed that the unplugged group lost slightly more blood and more patients require blood transfusion than the plugged group, there were no statistical differences in both

parameters. Regarding the quadriceps peak torque, of which both groups similarly decreased at 2 weeks, and gradually return to preoperative strength at 12 weeks. This finding related directly to the muscular trauma at surgery which was in agreement with previous studies[6,15].

As the femoral IM canal, by shape, can collect at least 50 ml of fluid,[16] retained blood after IM canal plugging in TKA might cause thigh and leg heaviness and other delayed functional improvements at immediate postoperative period. However, the present randomized study could not demonstrate any significant differences between both groups, in terms of perception of heaviness along thigh and leg, quadriceps strength, ROM, VAS, WOMAC and KSS scores in every FU until 12 weeks.

The strength of present study was a randomized control trial with no bias in assessment of both groups for investigated parameters. There are two limitations of our study. Firstly, we included three implant systems which might interfere on clinical results; however, all knee systems were open femoral box, and the same diameter of femoral IM reamer was used. Secondly, the FU time was very short as the retained blood in IM canal would be absorbed, subsequently, and the pilot study of the present research did not found any differences after 12 weeks. The short FU could provide all patients available for complete evaluation and FU.

Conclusion

Retained blood in femoral intramedullary canal did not have effect on postoperative thigh and leg heaviness, quadriceps strength and immediate clinical outcomes. As plugging or unplugging of the femoral drilled hole in TKA provided any harm or advantages, it should be performed according to surgeon's preference.

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การศึกษาเปรียบเทียบผลทางคลินิกระหว่างการอุด และไม่อุดโพรงกระดูกต้นขาส่วนล่างในการผ่าตัดเปลี่ยนข้อเข่าเทียม

นที ธนทรัพย์สิน, พบ, อารี ตนาวลี, พบ, วิทวัส บุญญานุวัตร, พบ, สีหธัช งามอุโฆษ, พบ

ภูมิหลัง: *การเจาะรูที่โพรงกระดูกต้นขาส่วนล่าง เพื่อวัดแนวแกนกระดูกต้นขา (Distal femoral intramedullary guide) เป็นเทคนิคที่ได้รับการยอมรับ และเป็นที่นิยมในการผ่าตัดเปลี่ยนข้อเข่าเทียมชนิดเต็มข้อ (Total knee arthroplasty) การอุดโพรงกระดูกมักนิยมปฏิบัติภายหลังเสร็จสิ้นกระบวนการตัดกระดูกผิวข้อเพื่อปรับแนวแกนกระดูกต้นขาส่วนล่างแล้ว เพื่อลดปริมาณการสูญเสียเลือดภายหลังการผ่าตัด อย่างไรก็ตาม ไม่มีงานวิจัยใดศึกษาเกี่ยวกับผลกระทบของการอุดโพรงกระดูกต้นขาส่วนล่างที่อาจมีต่ออาการทางคลินิก*

วัตถุประสงค์: *เพื่อศึกษาผลกระทบจากการอุด และไม่อุดโพรงกระดูกต้นขาส่วนล่าง ทั้งทางด้านอาการทางคลินิก และการสูญเสียเลือดภายหลังการผ่าตัด*

วัสดุ และวิธีการ: *ผู้ป่วยโรคข้อเข่าเสื่อมชนิดปฐมภูมิ (Primary OA knee) ที่ได้เข้ารับการรักษาโดยการผ่าตัดข้อเข่าเทียมชนิดเต็มข้อที่รพ.จุฬาลงกรณ์จำนวน 81 ราย (81 เข่า) ได้รับการสุ่มแบ่งเป็น 2 กลุ่ม โดยทั้ง 2 กลุ่มนี้จะได้รับการดูแลก่อน และหลังการผ่าตัดด้วยมาตรฐานเดียวกัน รวมถึงขั้นตอนในการผ่าตัดต่างๆ ในแบบเดียวกัน ยกเว้น ในกลุ่มที่ 1 ผู้ป่วยจะได้รับการอุดโพรงกระดูกด้วยชิ้นกระดูกจากตัวผู้ป่วยเอง (Autologous strut bone graft) และในกลุ่มที่ 2 จะไม่ได้รับการอุดโพรงกระดูกภายหลังจากการผ่าตัด*

ข้อมูลปริมาณเลือดที่ออกในขวดระบายเลือด, การลดลงของระดับความเข้มข้นเลือด (Hematocrit) และการได้รับการเติมเลือด จะได้รับการบันทึกไว้ รวมถึงข้อมูลในทางคลินิก ได้แก่ Thigh and leg heaviness (TLH), Quadriceps peak torque (QPT), ROM, visual analog scale (VAS), Western Ontario and McMaster Universities Arthritis Index (WOMAC) และ Knee Society score (KS) จะได้รับการประเมิน และบันทึกในระหว่างการตรวจติดตามอาการที่ 2 สัปดาห์, 6 สัปดาห์ และ 12 สัปดาห์

ผลการศึกษา: *มีผู้เข้าร่วมการวิจัยในกลุ่มที่หนึ่ง 41 คน และ กลุ่มที่สอง 40 คน ข้อมูลก่อนการผ่าตัดไม่มีความแตกต่างกันอย่างมีนัยสำคัญทั้งทางด้าน อายุ, QPT, ROM, VAS และ KS score ในผู้ป่วยทั้ง 2 กลุ่ม จากการติดตามอาการภายหลังการผ่าตัด พบว่า QPT ลดลง 38% ในช่วง 2 สัปดาห์แรก และจะค่อยๆกลับเข้าสู่สภาวะก่อนการผ่าตัดภายใน 12 สัปดาห์ อย่างไรก็ตามไม่พบความแตกต่างอย่างมีนัยสำคัญในแง่อาการทางคลินิกในผู้เข้ารับการวิจัยทั้ง 2 กลุ่ม ทั้งจาก TLH, ROM, VAS, WOMAC และ KS score*

ทางด้านการสูญเสียเลือดภายหลังการผ่าตัด พบว่าปริมาณเลือดที่ออกในขวดระบายเลือดไม่ได้แตกต่างกันอย่างมีนัยสำคัญ (P=0.61) ในกลุ่มที่ 1 ระดับความเข้มข้นของเลือดลดลง 5.4%±3.3% และในกลุ่มที่ 2 ลดลง 4.5%±3.6% (P=0.94) มีการเติมเลือดในกลุ่มที่ 1 จำนวน 12 ราย และในกลุ่มที่ 2 จำนวน 18 ราย (P=0.14)

สรุป: *แม้ว่าในบางงานวิจัยจะพบว่าการอุดโพรงกระดูกต้นขาส่วนล่างจะสามารถลดปริมาณการสูญเสียเลือดภายหลังจากการผ่าตัดได้ ทางผู้วิจัยไม่พบความแตกต่างทั้งในแง่ของการสูญเสียเลือด, การลดลงของระดับความเข้มข้นเลือด และการได้รับเลือด ในทั้ง 2 กลุ่ม รวมถึงไม่พบความแตกต่างกันของอาการทางคลินิกในช่วง 12 สัปดาห์แรกหลังการผ่าตัด ทั้งทางด้าน TLH, QPT, ROM, VAS, WOMAC และ KS score ดังนั้นการจะอุด หรือไม่อุดโพรงกระดูกต้นขาส่วนล่างนั้นก็สามารถกระทำได้ตามความเห็นชอบของศัลยแพทย์ผู้ทำการผ่าตัด*