




CLINICAL ARTICLE

Management of Medial Collateral Ligament Insufficiency During Total Knee Arthroplasty with a Screw and Rectangular Spiked Washer: A Case Series of 14 Patients

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Objective: To describe the technique of primary repair of medial collateral ligament (MCL) insufficiency using a screw and rectangular spiked washer in a case series of 14 patients.

Methods: Fourteen patients undergoing MCL repair by a screw and rectangular spiked washer during TKA between March 2018 and March 2019 were retrospectively reviewed. Among them, half injuries were avulsion of the femoral origin, and the other half were MCL laxity. There were 12 women and two men included in the study, with an average age of 63.6 years (range, 49–79 years) at the time of surgery. This series were followed up with a focus on range of motion (ROM), coronal alignment, Hospital for Special Surgery (HSS) knee scores, their subjective sense of joint instability, and related complications. At the last follow-up, function of the MCL was assessed by manually applying a valgus stress to the knee at both 0° and 30° of knee flexion.

Results: The mean follow-up time for all patients was 15.6 months (range, 13–20 months). Repair of the MCL was successful in all patients. ROM improved from a mean of 70.7° ± 35.1° before surgery to 103.9° ± 6.8° at latest follow-up ($P = 0.001$). All patients were able to perform a half squat easily, but none were able to do full squatting. The mean preoperative HSS score was 43.6 ± 13.4 and increased to a mean of 85.6 ± 3.8 postoperatively ($P < 0.001$). The femorotibial angle improved from a mean of -3.22° ± 9.47° before surgery to a mean of 5.16° ± 3.14° at the final follow-up ($P = 0.006$). At the time of final follow-up, no patient required revision and manipulation under anesthesia following the index arthroplasty. No radiolucencies or migration were observed in association with the knee prostheses. No displacement of the screw and rectangular spiked washer was found. There were no clinical complications. No patient reported subjective instability of the knee. Upon physical examination, no patient was found to have laxity in the coronal plane in either 30° of flexion or full extension.

Conclusions: The screw and rectangular spiked washer is a simple and effective method for treating MCL insufficiency in TKA, and a study with a larger cohort and extended follow-up is requisite to claim its role in preventing coronal instability and component failure.

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Introduction

Medial collateral ligament, the primary restraint to valgus force on the knee, is critical for coronal plane stability and soft tissue balance after total knee arthroplasty^{1, 2}. Although a rare complication, MCL injury can lead to adverse outcomes such as instability, accelerated implant wear, and eventually failure³⁻⁵. Surgeon-related maneuvers leading to MCL injury mainly include the use of oscillating saw under inadequate protection, pie-crusting technique, excessive medial release, and hyperflexion of the knee^{5, 6}. Obesity, osteoporosis, inflammatory arthritis, and severe valgus deformity are recognized as patient-dependent risk factors for ligament damage and attenuation in the literature⁶⁻⁸. In case of MCL injury during surgery, many authors have previously recommended using a condylar constrained knee (CCK) implant, which can provide immediate stability^{9, 10}. However, the additional constraint inherent in the design increases stresses at the implant–cement and cement–bone interfaces, which may result in increased polyethylene wear and resultant aseptic loosening^{10, 11}. Thus, a direct conversion to a CCK implant is generally discouraged. A study by Koo *et al.*¹² analyzed 15 primary TKAs complicated with intraoperative complete detachment of the MCL from tibial insertion, which were all treated conservatively without any other additive procedures or hinge braces considering its excellent healing capacity, and found no significant difference compared with MCL-intact contralateral knees. By contrast, currently, most surgeons tend to perform MCL reconstruction or augmentation, which are safer for enhanced recovery^{13, 14}. In terms of midsubstance disruption of MCL, it can be repaired using suture, tendon autograft, and synthetic materials. MCL avulsion of the proximal tibia can be treated by suture anchors or bone staples, and avulsion of the ligament from the distal femur using a screw and washer^{14, 15}.

In our practice, MCL insufficiency during TKA mainly included MCL avulsions and MCL laxity. MCL avulsion of the femur is more likely to appear among patients with poor bone stock due to osteoporosis, inflammatory arthropathy, and multiple surgical histories. MCL laxity may occur when more extensive release is performed¹⁶. Reattachment of MCL to the femoral origin calls for stable fixation. What's more, the MCL laxity can also be addressed by overlapping and screw-and-washer fixation. However, the plain surface of the conventional washers do not provide sufficient grip to hold the avulsed bone stock and/or the ligament tendon. As a result, the bone stock or tendon slips under the washer. To solve this problem, we designed a novel rectangular washer with cone-shaped spikes. There have been biomechanical studies indicating that spiked washers can provide better initial fixation and less tissue necrosis for reattached ligaments¹⁷.

The purpose of the present study was: (i) to determine the outcome of repairing MCL insufficiency by using the screw and rectangular spiked washer; (ii) to evaluate the range of motion and clinical scores of the knee joint with repaired MCL insufficiency; and (iii) to evaluate the need of using implants of increased constraint after repairing MCL insufficiency.

Material and Methods

Inclusion and Exclusion Criteria

The inclusion criteria were: (i) adult patients with knee arthritis with severe and intolerable pain; (ii) MCL avulsion of the femur or MCL laxity was present and repaired by a screw and rectangular spiked washer during TKA; (iii) postoperative follow-up for a minimum of 1 year, with clinical and radiological evaluation performed; and (iv) retrospective study. The exclusion criteria included: (i) patients with midsubstance disruption of MCL; and (ii) MCL injury was managed by other methods.

Patients

We retrospectively reviewed a consecutive series of 14 patients who underwent MCL repair by a screw and rectangular spiked washer during TKA between March 2018 and March 2019. Among them, half of the injuries were avulsion of the femoral origin, and the other half were MCL laxity. Use of the screw and rectangular spiked washer was approved by the hospital's institutional review board, and informed consent was obtained. There were 12 women and two men included in the study, with an average age of 63.6 years (range, 49–79 years) at the time of surgery (Table 1).

Screw and Rectangular Spiked Washer

The screw and rectangular spiked washer is manufactured from titanium by three-dimensional printing technology. Unlike the conventional washers, it is similar to the soft tissue plate, with a rectangular shape in the cross-section. It has four cone-shaped spikes positioned at its corners and these are mounted on the top of posts. Posts are designed with circular groove to enhance biting. The device has one central hole for screw attachment and six pinholes at the periphery for sutures (Fig. 1).

Surgical Technique

All surgeries were performed by well-trained arthroplasty surgeons under general anesthesia in the supine position. A midline straight longitudinal skin incision and a standard medial parapatellar approach was employed for all knees. Following eversion of the patella, flexion of the knee, and

TABLE 1 Demographic data in 14 patients

Patients	Age (years)	Sex	Diagnosis	Type of injury	Height (m)	Weight (kg)	BMI (kg/m ²)	Follow-up (months)
1	79	M	Rheumatoid arthritis	AF	1.63	60	22.58	20
2	64	F	Osteoarthritis	Laxity	1.55	62	25.81	18
3	49	F	Rheumatoid arthritis	AF	1.55	49	20.40	18
4	63	M	Osteoarthritis	Laxity	1.80	90	27.78	17
5	61	F	Osteoarthritis	Laxity	1.50	65	28.89	16
6	69	F	Osteoarthritis	Laxity	1.55	78	32.47	16
7	64	F	Osteoarthritis	AF	1.59	82	32.44	16
8	63	F	Osteoarthritis	Laxity	1.62	63	24.01	15
9	77	F	Osteoarthritis	Laxity	1.45	59	28.06	14
10	61	F	Osteoarthritis	AF	1.55	72	29.97	14
11	63	F	Osteoarthritis	Laxity	1.53	80	34.17	14
12	63	F	Posttraumatic arthritis	AF	1.53	62	26.49	14
13	49	F	Rheumatoid arthritis	AF	1.56	49	20.13	13
14	65	F	Osteoarthritis	AF	1.62	72	27.43	13

AF, avulsion off femur origin; BMI, body mass index; F, female; M, male.

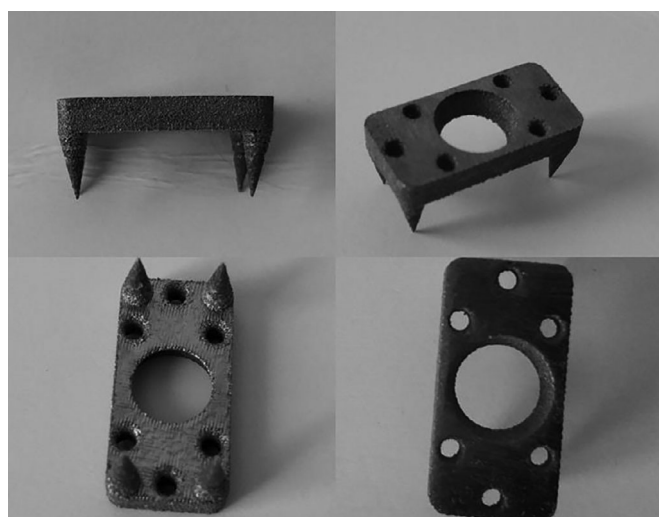


Fig. 1 The contour of our rectangular spike washer manufactured from titanium by three-dimensional printing technology.

transection of the anterior cruciate ligament, a subperiosteal release beneath the deep MCL started at the tibial joint line and proceeded distally under direct vision. As the dissection proceeded distally and posteriorly, the tibial insertion of MCL was well-preserved. During tibial and femoral bone resection, retractors were placed judiciously to protect the sleeve of the MCL from injury. Avulsion of femoral origin of MCL or MCL laxity was typically identified during exposure, MCL release, or assessment of ligament balance with the trial components. Authors could hear the popping sound of detachment, or notice a sudden unexpected medial laxity. The avulsed bone stock was confirmed by exposure and direct visualization. Commonly, the avulsed bone stock was thin and the cancellous bone underneath was demineralized and soft. After final femoral and tibial components were

cemented into place and a trial liner had been inserted, repair of the MCL was performed. As for MCL avulsion, the damaged end of MCL was reattached to its anatomical origin by transosseous sutures at first, and then the rectangular spiked washer was placed on top of the avulsed bone stock. As for MCL laxity, portions of MCL adjacent to femoral origin could be overlapped and pressed by the rectangular spiked washer in the same way. Following this the device was gently malletted into position until it was fully seated. A 3.2-mm hole was then drilled through the central hole into the bone surface, and a depth gauge was used to evaluate the passage length. A 6.5-mm AO cancellous screw was used for fixation (Fig. 2). Based on the medial gap opening, additional locking stitches might be passed through the MCL to strain the ligament. Finally, stability was confirmed by manually applying valgus stress in flexion and in extension to ensure an adequate repair. The use of CCK implant was left to the surgeon's discretion about the preoperative deformity, integrity of ligament, and the extent of instability. No hinged knee designs were used in this study.

Postoperatively, patients treated with the CCK implant were allowed early motion and immediate weightbearing. Other patients wore an unlocked hinged knee brace with a free range of motion for six weeks and were allowed to bear weight as tolerated. All patients were administered deep venous thrombosis prophylaxis for 2 weeks (Fig. 3).

ROM Measurement

The angle of maximum passive flexion and flexion contraction were measured by a goniometer before and after surgery. The ROM was calculated as the difference value of those two parameters. At the last follow-up, their squatting ability was evaluated. Half squat was defined as the position when the inguinal fold is in a straight horizontal line with the top of the knee, while full squat was carried out until the top of the thighs fall below the horizontal plane (Fig. 4).

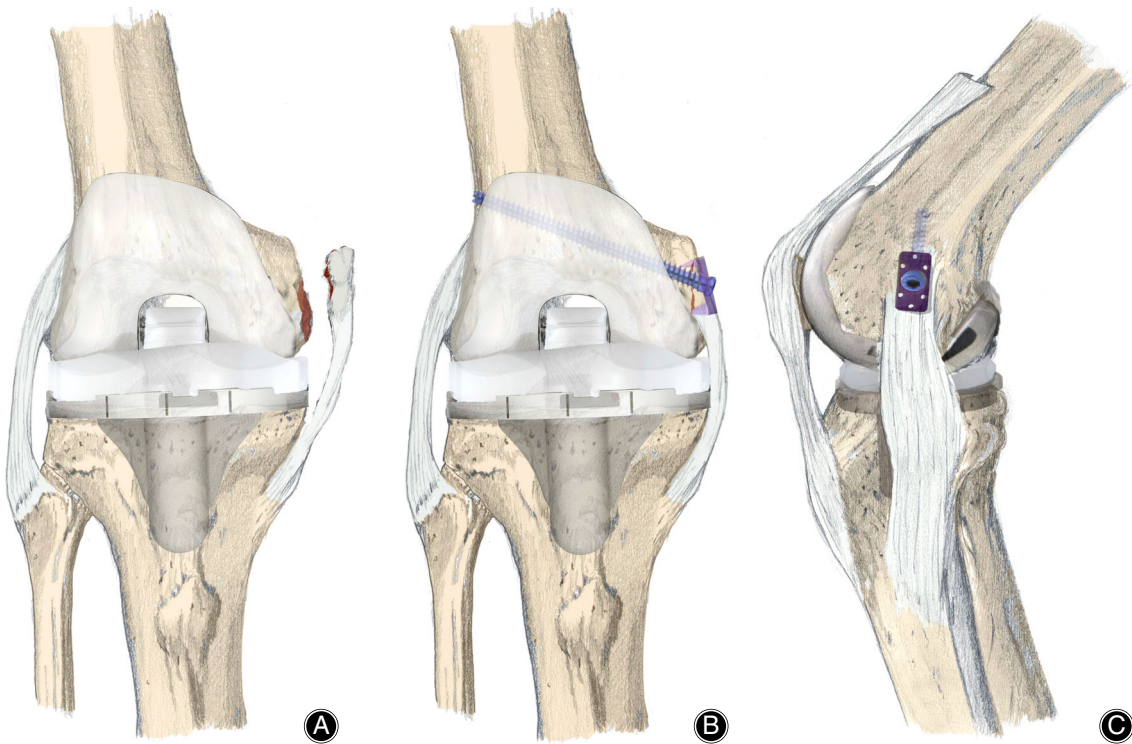


Fig. 2 (A) Avulsion off femoral origin of MCL was identified; (B) Rectangular spiked washer was placed on the proximal end of the MCL and a 6.5-mm AO cancellous screw was used to enhance the fixation; (C) Lateral view of the device position.



Fig. 3 F The patient was a 79-year-old man diagnosed with rheumatoid arthritis. (A) Preoperative X-ray; (B) X-ray taken 1 day after surgery; (C) X-ray taken 20 months after surgery; (D) Intraoperative photograph.

HSS Knee Score

The HSS knee score was used to evaluate knee function before surgery and at the latest follow-up. The HSS score system mainly includes the four aspects of pain, function, range of motion, and stability. The score ranged between 0 (worst outcome) to 100 (best outcome). The outcome categories were based on the following cut points: excellent (≥ 85), good (70–84), fair (55–69), and poor (<55) (Fig. 5).

Evaluation of the Coronal Alignment

Full-length hip-to-ankle radiographs were reviewed before surgery and at the latest follow-up. Coronal alignment was defined as the minor angle formed by the intersection of lines through the centers of the tibial and femoral medullary canals (femorotibial angle). The angle was recorded as positive values when the femoral axis lay laterally to the tibial axis, and conversely as negative values. Femorotibial angle

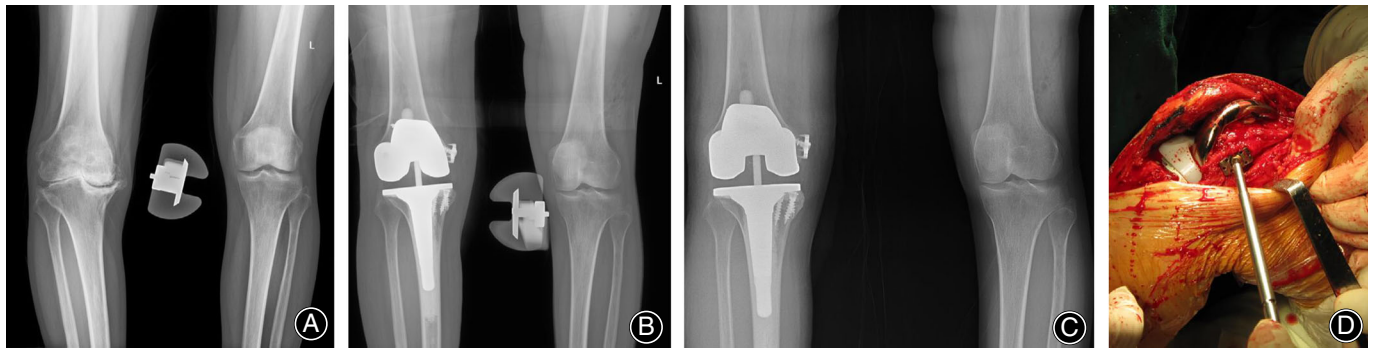


Fig. 4 The patient was a 49-year-old woman diagnosed with rheumatoid arthritis. (A) Preoperative X-ray; (B) X-ray taken 1 day after surgery; (C) X-ray taken 13 months after surgery; (D) Intraoperative photograph.

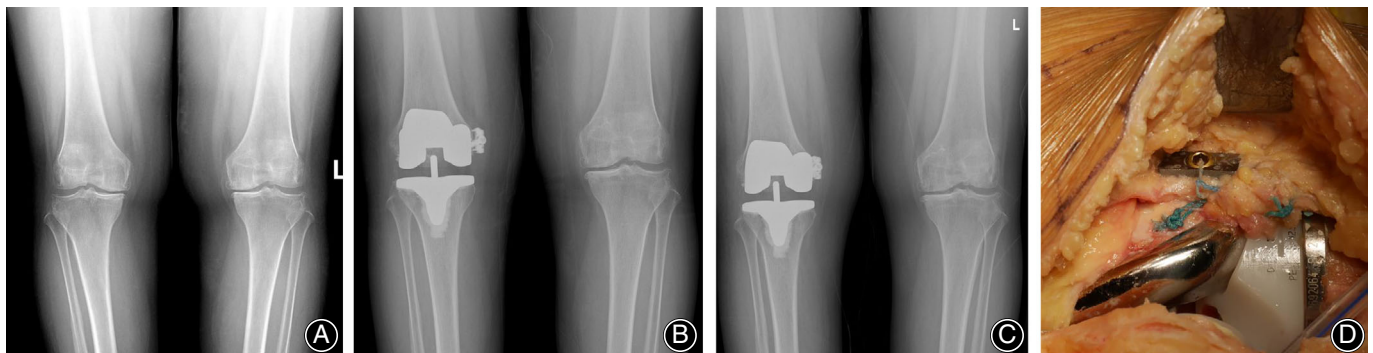


Fig. 5 The patient was a 64-year-old woman diagnosed with osteoarthritis. (A) Preoperative X-ray; (B) X-ray taken 1 day after surgery; (C) X-ray taken 16 months after surgery; (D) Intraoperative photograph.

was categorized as varus/neutral (varus or $\leq 7^\circ$ of valgus) or valgus ($>7^\circ$ of valgus).

Radiographic Assessment of the Implant Stability

The radiographic assessment included the presence of radiolucent lines, osteolysis, and component loosening. Radiolucent lines were evaluated in terms of location, width (in millimeters), and progression as recommended by the Knee Society¹⁸. In cases with present radiolucent lines, serial radiographs were compared for progression of lucent lines or shift in component position. Osteolysis in the radiographs was defined as a nonlinear region of periprosthetic cancellous bone loss with delineable margins. Component loosening was defined as a change in position of the component on plain radiographs.

Assessment of Joint Stability

Patients were asked about their subjective sense of joint stability and about any need to use a knee brace for walking. On physical examination, stability of the medial collateral ligament was assessed by manually applying a valgus stress to the knee at both 0° and 30° of knee flexion. The failure

criteria were defined as the absence of a fixed endpoint resistance to valgus stress in either position.

ROM measurement, clinical score evaluation, radiographic review, and physical examination for each patient were performed by different surgeons than the operating surgeons.

Statistical Analysis

SPSS version 26.0 (IBM Inc., Armonk, New York) was used for the statistical analyses. The descriptive statistics were used to determine ranges, means, and standard deviations. Paired t-test was used to evaluate differences between pre- and post-operative quantitative data including ROM, HSS knee score, and femorotibial angle. Student t-test or non-parametric test was used to evaluate the difference based on the type of injury. A P -value <0.05 was considered significant.

Results

The mean follow-up time for all patients was 15.6 months (range, 13–20 months). All patients were followed up by inpatient visit. At the time of final follow-up, no patients required revision following the index arthroplasty, and no patients required manipulation under anesthesia due to

TABLE 2 Results of HSS scores, ROM and coronal alignment

Patients	Prosthesis (thickness of insert, mm)	HSS score (point)		ROM(°)				Femorotibial angle(°; varus (-)/valgus(+))	
		Preop	Postop	Preop flexion	Postop flexion	Preop FC	Postop FC	Preop	Postop
1	PS/CI (10)	13	87	25	90	25	0	-1.15	6.08
2	PS (15)	62	90	100	110	10	0	-10.92	13.01
3	CCK (10)	54	90	45	100	40	0	-12.59	3.22
4	PS/CI (15)	50	86	100	100	10	0	-13.32	3.08
5	PS (15)	41	92	110	110	5	0	-6.74	5.89
6	CR (14)	45	87	100	110	0	0	-8.56	0.26
7	PS (12.5)	60	85	110	110	5	0	-1.08	3.52
8	PS/CI (15)	53	89	90	110	0	0	-7.06	6.07
9	PS (14)	38	83	70	110	10	0	-3.41	4.11
10	CR (12)	29	80	90	95	0	0	-4.62	4.53
11	PS (10)	49	85	95	110	0	0	-10.12	4.47
12	PS (12.5)	48	80	70	100	0	0	6.65	1.85
13	CCK (10)	28	83	90	100	45	0	21.65	7.76
14	PS (12.5)	40	82	75	100	30	0	6.14	8.34
Mean (SD)		43.6 (13.4)	85.6 (3.8)	83.6 (24.5)	103.9 (6.8)	12.9 (15.7)	0	-3.22 (9.47)	5.16 (3.14)

CI, constrained insert; FC, flexion contracture; HSS, Hospital for Special Surgery; Preop, preoperatively; Postop, postoperatively; ROM, range of motion; SD, standard deviation.

stiffness. There were no clinical complications. The ROM, HSS knee scores, and femorotibial angle before and after surgery were summarized in Table 2.

Intraoperative Results

Among our series, seven injuries were due to avulsion of the femoral origin and seven were due to MCL laxity. Five cases of avulsion of femoral origin of MCL occurred with hyperflexion during exposure of the knee, and two occurred during forced extension after component trial reduction. All seven MCL laxity injuries resulted from excessive release with pie-crusting technique. Among these MCL laxity cases, a sudden unexpected medial laxity was observed.

After fixation with the device, it's important to evaluate the medial gap opening. Additional stitches to strain the ligament were required in 10 out of 14 cases. During that process, we tested the medial gap repeatedly to achieve appropriate balancing.

In two patients who were diagnosed as having rheumatoid arthritis, implants of increased constraint (TCIII; DePuy) were used. In the remaining cases, cruciate retaining (CR) prosthesis was used in two cases, and posterior stabilized (PS) prosthesis was used in 10 cases. Three of these 10 patients were implanted with a more constrained tibial insert. Thickness of tibial insert was 10 mm in four cases, 12 mm in one case, 12.5 mm in three cases, 14 mm in two cases, and 15 mm in four cases.

Improvement of ROM

No flexion contracture was observed at the last follow-up. ROM improved from a mean of $70.7^\circ \pm 35.1^\circ$ before surgery

to $103.9^\circ \pm 6.8^\circ$ at latest follow-up ($t = -4.019$, $P = 0.001$). All patients were able to perform a half squat easily, but none were able to do full squatting.

Improvement of HSS Knee Score

The mean preoperative HSS score was 43.6 ± 13.4 and increased to a mean of 85.6 ± 3.8 postoperatively ($t = -12.406$, $P < 0.001$). All patients were capable of community ambulation without an assistive device. Nine knees had an excellent result and five had a good result.

Improvement of Coronal Alignment

The femorotibial angle improved from a mean of $-3.22^\circ \pm 9.47^\circ$ before surgery to a mean of $5.16^\circ \pm 3.14^\circ$ at the final follow-up ($t = -3.311$, $P = 0.006$). The postoperative femorotibial angle ranged from 0.26° to 13.01° , with 11 out of 14 cases defined as normal and three out of 14 cases defined as valgus.

Radiographic Assessment of the Implant Stability

No radiolucencies, osteolysis, or migration were observed in association with the knee prostheses. No displacement of the screw and rectangular spiked washer was found. All implants were defined as stable.

Assessment of the Joint Stability

No patient required bracing beyond 6 weeks postoperatively, and no patient reported subjective instability of the knee. Upon physical examination, no patient was found to have laxity in the coronal plane in either 30° of flexion or full extension.

Subgroup Analysis According to the Type of Injury

To further this analysis, we compared the knees of avulsion injury with those of MCL laxity. The avulsion cohort had similar postoperative HSS score to laxity cohort, 83.86 ± 3.72 vs 87.43 ± 3.10 ($t = -1.952$, $P = 0.075$), but lower postoperative knee flexion, 99.29° vs 108.57° ($u = 0.312$, $P = 0.001$). BMI was higher in the laxity cohort, 28.74 ± 3.55 vs 25.63 ± 4.76 , but without statistical significance ($t = -1.383$, $P = 0.192$). Besides, all three cases of rheumatoid arthritis and one case of post-traumatic arthritis were within the avulsion cohort. Five of six knees with stiffness ($ROM < 90^\circ$) preoperatively occurred due to avulsion injury. Although there was no difference, preoperative knee score in avulsion cohort was approximately 10 points lower than that in laxity cohort ($t = -1.357$, $P = 0.200$). All these factors may indirectly indicate more complexity among avulsion cases.

Subgroup Analysis According to the Follow-Up Time

The median follow-up time was 15.5 months. Therefore we classified our cohort into two groups based on the follow-up time: Shorter Group (≤ 15 months) and Longer Group (> 15 months). There was no statistical significance in age, BMI, and the proportion of preoperative diagnosis and type of injury between the two groups. The Longer Group had similar postoperative knee flexion to the Shorter Group, 104.29° vs 103.57° ($u = -0.350$, $P = 0.726$). However, in HSS score, the Longer Group had 5 points more than the Shorter Group ($t = 3.278$, $P = 0.007$).

Discussion

Intraoperative MCL insufficiency is a rare but serious complication of TKA, with recent studies demonstrating the rate ranged from 0.43%–2.7%^{3, 14, 19, 20}. In the present study, we introduced our experience of a screw and rectangular spiked washer for repairing MCL avulsion of the femoral origin and MCL laxity. We found that our technique might be a feasible alternative for conventional screw-and-washer approach, with no instability of the knee at the last follow-up.

Effects on Repairing MCL Insufficiency by Using the Screw and Rectangular Spiked Washer

The screw and washer is the most commonly used device for MCL reattachment. However, conventional washers may not provide adequate grip to hold the avulsed bone stock, with the concerns of tendon slip and nonunion remaining. To our knowledge, there is no device like ours reported in the treatment of MCL insufficiency yet. Our device acts as both spiked washer and staple. A four-prong bone staple (Smith and Nephew) was reported to deal with MCL avulsion²¹. Although no complication was reported, the prong on the staple, with a length of 22 mm, might further damage the osteoporotic bone. The design of spikes on the washer has been applied in treatment of various kinds of soft tissue injury, such as posterior cruciate ligament bony avulsions,

conoid ligament disruptions^{22, 23}. Biomechanical studies demonstrated spiked metal washer provided secure fixations and allowed normal microcirculation of tissues beneath the washer for the reattachment of avulsed ligaments¹⁷. Our screw and rectangular spiked washer is adequate to cover the avulsed bone stock or the overlapped portions of ligament. As the cancellous screw is gradually advanced, the rectangular spiked washer above the avulsed fragment or ligament tendon will firmly lodge into the bone. Radiological assessment of healing of avulsion site might be inaccurate without computed tomography (CT) scanning. Since MCL has an excellent capacity to heal following injury, no migration of the device and no joint instability can be used as a surrogate for healing. A universal drawback of all washers is their potential to cause irritation of the surrounding tissue and implant-associated complaints. In our cohort, no patients complained of local discomfort around medial femoral epicondyle.

ROM and Clinical Scores of the Knee Joint After Repairing MCL Insufficiency

All patients showed fair improvement in the ROM and HSS knee scores, and were capable of community ambulation without an assistive device. Although operation seems more complicated in avulsion cohort, similar knee score has been observed in the laxity cohort, which indicates the versatility and efficacy of our device. Apart from two patients who use CCK implants, 12 patients wore a brace for 6 weeks postoperatively. No patient reported knee stiffness. Bohl *et al.* observed stiffness in $> 10\%$ of the patients (four manipulations and one revision)²⁰. The use of hinged knee brace and obesity was believed to be risk factors. Although all our patients have made great progress after surgery, they still cannot achieve excellent function. The maximum of knee flexion after surgery was no more than 110° , which made it difficult for patients to do full squatting. It was similar to the results described by White *et al.*²⁴. They observed that outcome scores in the patients who underwent staple reapproximation for superficial MCL avulsion from the tibia were a bit lower than uncomplicated ones, but much higher than patients who underwent revision TKA for instability. MCL insufficiency is more likely to be encountered by patients with poor bone stock, delicate ligament, and comorbidities. This meant that their level of mobility before surgery and capability of attending rehabilitation exercise may more or less hinder their improvement.

Need of Increasing Constraint of Implants

The option for using an unconstrained implant and primarily repairing the MCL instead of using a CCK implant has been the focus of many recent studies. However, the data from the literature are confusing^{3, 12, 25, 26}. In recent years, most arthroplasty surgeons do not recommend direct conversion to CCK implants in patients with intraoperative

MCL injury, because the CCK implants do have some disadvantages. CCK implants transmit increased stresses to the bone–cement and implant–cement interfaces^{10, 11}, which are more prone to decreased implant longevity and wear⁸. Additionally, they also require removal of considerably more femoral intercondylar bone, decreasing the remaining bone stock available for revision in the future. By contrast, conservative treatment for iatrogenic intraoperative MCL disruption with the use of an unconstrained implant with primary ligament repair has been successfully reported^{20, 24}. Thus we can see that constrained constructs are less than optimal for use in primary TKA when a more conservative option is available. CCK implants were used in two patients who were diagnosed with rheumatoid arthritis and poor quality of ligaments and bone stock. Three patients with PS prosthesis were implanted using a more constrained tibial insert. Namely, when primary repair of the MCL cannot provide adequate stability or there is preexisting weakness and attenuation of the MCL, constrained implants are likely to be used. In the early stage, constrained implants can provide a stable environment for MCL to heal and thrive. In the future, an intact MCL will decrease the stress caused by constrained implants.

Limitations of the Study

There are three limitations in our study. Firstly, it is limited by its small sample size. However, MCL sufficiency during

TKA is a rare complication. Secondly, the follow-up was of short term with a mean of 15.6 months. Extended follow-up studies will be required due to the uncertainty about the longevity of components. Thirdly, this study lacks a control group which uses alternative fixing devices to compare findings. However, to our knowledge, no devices like ours have been reported in treating MCL insufficiency.

Conclusion

Although no gold standard technique exists for the treatment of MCL insufficiency during TKA, the results of this study demonstrate that repair with our screw and rectangular spiked washer is a simple and effective technique. No patient required revision for instability, and no subjective instability occurred. However, due to the rarity of MCL insufficiency during TKA and the resulting lack of sufficient cases, as well as the short term follow-up period, a study with a large cohort and extended follow-up is requisite to claim that this technique provides a definite means of preventing coronal instability and component failure.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee in accordance with the standards of the National Research Council. Written informed consent was obtained from all participants.

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