

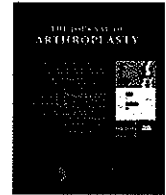


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Efficacy in Deep Vein Thrombosis Prevention With Extended Mechanical Compression Device Therapy and Prophylactic Aspirin Following Total Knee Arthroplasty: A Randomized Control Trial



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ABSTRACT

Background: Aspirin at 325 mg twice daily is now included as a nationally approved venous thromboembolism (VTE) prophylaxis protocol for low-risk total knee arthroplasty (TKA) patients. The purpose of this study is to examine whether there is a difference in deep vein thrombosis (DVT) occurrence after a limited tourniquet TKA using aspirin-based prophylaxis with or without extended use of mechanical compression device (MCD) therapy.

Methods: One hundred limited tourniquet TKA patients, whose DVT risk was managed with aspirin 325 mg twice daily for 3 weeks, were randomized to either using an MCD during hospitalization only or extended use at home up to 6 weeks postoperatively. Lower extremity duplex venous ultrasonography (LEDVU) was completed on the second postoperative day, 14 days postoperatively, and at 3 months postoperatively to confirm the absence of DVT after treatment.

Results: The DVT rate for the postdischarge MCD therapy group was 0% and 23.1% for the inpatient MCD group ($P < .001$). All DVTs resolved by 3 months postoperatively. Patient satisfaction was 9.56 (± 0.82) for postdischarge MCD patients vs 8.50 (± 1.46) for inpatient MCD patients ($P < .001$).

Conclusion: Limited tourniquet TKA patients who were mobilized early, managed with aspirin for 3 weeks postoperatively, and on MCD therapy for up to 6 weeks postoperatively experienced superior DVT prophylaxis than patients receiving MCD therapy only as an inpatient ($P < .05$). The 0% incidence of nonsymptomatic DVTs prevented by aspirin and extended-use MCD further validates this type of prophylaxis in low DVT risk TKA patients.

OUTSTANDING RESULTS!!

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Among total joint surgery complications, the risk of venous thromboembolism (VTE) is of the utmost concern warranting VTE prophylaxis in even low-risk patients. Patients undergoing total knee arthroplasty (TKA) are particularly at risk of VTE with an incidence rate of 17%–53% depending on the method of prevention

[1], therein warranting routine prevention in even low-risk patients [2–7]. Standard of care guidelines implemented by the American Academy of Orthopedic Surgeons (AAOS) have mandated a regimen of thromboprophylaxis for all total hip or knee arthroplasty patients and have outlined those regimens with updated research evidence, taking into account the patient's history and risk of thrombosis [2]. The 2014 guidelines on VTE management are the result of the Surgical Care Improvement Project, a national partnership of organizations including the Joint Commission and the Centers for Medicare and Medicaid Services, with the goal of reducing surgical complications and publishing a uniform set of national hospital quality measures. This goal is currently limited by the lack of conclusive evidence that would allow the endorsement of one regimen over another, and so the prevention method of choice remains controversial [2]. The conflicting evidence is well

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documented in the AAOS Guidelines citing such reasons as lack of standardized drug doses, unstandardized routes of administration, unstandardized durations of therapy, a dearth of placebo-controlled studies, as well as nonrepresentative research populations, or underpowered studies [2].

The AAOS guidelines have been revised to include aspirin in the list of acceptable thromboprophylactic regimens [2]. In a large level II evidence registry study, 3060 total joint arthroplasty patients receiving at least 10 days of MCD with or without aspirin were found to have similar incidence of VTE to patients receiving standard chemoprophylactics [3]. The AAOS recognizes that a surgeon may prefer to administer the safe and convenient aspirin over other common chemoprophylactic agents [7]. When using aspirin, the AAOS advises the addition of a mechanical compression device (MCD) to increase the efficacy of aspirin in VTE prevention [2].

MCDs have an assortment of modalities, such as pneumatic compression or sequential compression; although there is inconclusive evidence as to effectiveness between processes, MCDs are thought to influence Virchow's triad by reducing venous stasis, thereby reducing the incidence of DVT or PE [7,8]. When used in combination with the AAOS-indicated antiplatelet agent, aspirin, adequate thromboprophylaxis may be obtained, reducing the risk of debilitating side effects or severe bleeding associated with warfarin and other chemoprophylactics.

Differences among MCD products, or what modality of compression they employ, do not appear to have an impact on efficacy of thromboprophylaxis. The most marked indication of thromboprophylaxis is patient compliance, and the location of the compression [8]. Thus, ease of operation, reliability, and the ability to gauge compliance may be the most relevant features of an effective MCD.

The Cothra VPULSE Compression and Cold Therapy System (Cothra, LLC, Plano, TX) was FDA approved in 2013 and is designed for home use allowing extended postoperative therapy. The VPULSE device has the ability to provide intermittent sequential pneumatic compression for the prevention of venous thrombosis related to hospitalization [9], therein fulfilling the AAOS requirements following TKA [2]. The device is designed to be user-friendly and records usage data which will be instrumental for monitoring patient compliance for the purposes of this study [9].

As a multifactorial disease, VTE onset may occur during the knee surgery through periods of high flexion and tourniquet use; thus, VTE prophylaxis safety and efficacy may be maximized by the implementation of a multimodal thromboprophylactic regimen [7,10,11]. Multimodal enhancements strengthen protocols for VTE prevention in TKA patients. The use of a tourniquet during the TKA procedure results in venous stasis, trauma to the endothelium of deep veins in the leg, hypoxia of the leg, and increased clotting factors upon release of the tourniquet [7,11]. When compared with standard tourniquet utilization during TKA, a minimized tourniquet technique is associated with a lower rate of VTE [12]. Recent evidence suggests that postoperative recovery and early range of motion of the knee may be superior in a minimized tourniquet procedure [13]. Lack of mobilization may facilitate venous stasis and as such is a contributing factor for DVT, which makes early mobilization of the patient crucial in a multimodal regimen [14]. This study attempts to provide a randomized control trial providing clarification on a multimodal VTE approach that includes rapid postoperative mobilization of the patient, limiting the use of a tourniquet to no more than 5 minutes during cementation, prophylactic aspirin, and MCD therapy.

Materials and Methods

This study was an institutional review board–approved, prospective, randomized, control trial conducted in Cincinnati Ohio.

Primary total knee arthroplasty patients 18 years or older were included if they were determined to be at low risk of VTE. Patients were excluded if they had a high-risk body mass index of greater than 40 kg/m², had an American Society of Anesthesiologist score greater than III, and experience nonsteroidal anti-inflammatory drug intolerance, or any orthopedic or medical comorbidity that would prevent postoperative rapid mobilization and compliance with MCD use. All subjects consented into the study were randomized by the research coordinator in a 1:1 ratio to either group A or group B by a permuted mixed block size randomization table. Group A served as the control group, only receiving MCD therapy while an inpatient following total knee arthroplasty. Group B, the experimental group, continued the MCD therapy for up to 6 weeks following discharge from the hospital. All patients underwent a multimodal VTE prophylactic regimen consisting of administration of 1 g of preoperative tranexamic acid, and limiting tourniquet application to a maximum of 5 minutes only during exsanguination to improve cementation and to minimize blood loss. Early rapid mobilization was facilitated, and all subjects received prophylactic aspirin at 325 mg twice daily for 3 weeks immediately postoperatively. To standardize the therapy among groups, the MCD used was the Cothra VPULSE for all study patients. Use of the MCD was initiated immediately postoperatively and continued for at least 3 weeks, and up to 6 weeks depending on when the patients had their second postoperative visit scheduled.

Postoperatively, bilateral lower extremity duplex venous ultrasonography (LEDVU) was conducted on all patients 2 days postoperatively and at 2 weeks (14–19 days) postoperatively to detect the incidence of DVT. Patients were seen 10 days (± 7 days) postoperatively in the surgeon's office for routine follow-up knee examination. Patients were also seen at 3–6 weeks postoperatively for routine follow-up and to complete an overall satisfaction assessment. The VPULSE data chip was collected for recording the total number of hours of MCD usage. Length of hospital stay (LOS) and 30-day adverse events were recorded, and overall patient satisfaction was evaluated with a 10-point Likert scale [15].

The 10-point Likert scale was determined to be the best way to keep track of patient satisfaction because of its consistency and reliability in conveying patient responses. Ten points were chosen to try and maximize reliability, validity, and discriminating power without comprising consistency or test-retest reliability [16]. On the last study visit of each patient, the study coordinator asked each participant, "Overall on a scale of 1 to 10, where 1 is very dissatisfied, 5 is neutral, and 10 is very satisfied, where would you rate your satisfaction with the total knee arthroplasty you have received from the start of the study to today?". Although the study coordinator was not able to be blinded to the randomization groups, the question was asked in exactly the same way with each patient. There was no leading of the patient, and no further inquiry into the patient's satisfaction to avoid leading the study subject into a higher satisfaction score. These patient-reported satisfaction scores were collected to ascertain whether the patient associated the MCD usage as a burden for his or her overall patient experience.

The sample size was determined to be 100 patients based on a meta-analysis comparing DVT incidence among 4 commonly ascribed treatment regimens [1], understanding that no prior studies had combined the same regimen of 325 mg aspirin twice daily for 3 weeks postoperatively in conjunction with MCD therapy. The assumption was made that this sample size would suffice for a medium effect size at 80% power and alpha <.05. DVT incidence rate was determined to be the primary outcome, as analyzed by a univariate chi-square analysis.

All statistical analyses were performed using IBM SPSS Statistics for Windows version 21 (IBM Corporation, Armonk, NY). Demographic variables included patient age, gender, race, anesthesia

Table 1
Subject Demographics.

Demographics and Clinical Data	Total (N = 100), Mean (SD); n (%)	Postdischarge VPULSE (n = 48), Mean (SD); n (%)	Inpatient VPULSE (n = 52), Mean (SD); n (%)	P Value
Age (y)	62.76 (9.24)	59.85 (8.20)	65.44 (9.40)	.002
Gender				.369
Male	40 (40.0)	17 (35.4)	23 (44.2)	
Female	60 (60.0)	31 (64.6)	29 (55.8)	
Race				.367
Caucasian	98 (98.0)	47 (97.9)	51 (98.1)	
African American	1 (1.0)	1 (2.1)	0 (0.0)	
Other	1 (1.0)	0 (0.0)	1 (1.9)	
BMI	30.09 (4.22)	30.85 (4.17)	29.38 (4.18)	.081
Comorbidity				
Hypertension (yes)	39 (39.0)	17 (35.4)	22 (42.3)	.480
CAD (yes)	4 (4.0)	3 (6.3)	1 (1.9)	.279
Diabetes (yes)	8 (8.0)	2 (4.2)	6 (11.5)	.162
Anesthesia type				.645
General	11 (11.0)	6 (12.5)	5 (9.6)	
Spinal	89 (89.0)	42 (87.5)	47 (90.4)	
Other	1 (1.0)	0 (0.0)	1 (1.9)	
ASA score				.711
1	7 (7.0)	4 (8.3)	3 (5.8)	
2	62 (62.0)	29 (60.4)	33 (63.5)	
3	30 (30.0)	14 (29.2)	16 (30.8)	
4	1 (1.0)	1 (2.1)	0 (0.0)	
Surgery				.961
Left TKA	56 (56.0)	27 (56.3)	29 (55.8)	
Right TKA	44 (44.0)	21 (43.8)	23 (44.2)	

SD, standard deviation; BMI, body mass index; CAD, coronary artery disease; ASA, American Society of Anesthesiologist; TKA, total knee arthroplasty.

type, American Society of Anesthesiologist score, body mass index, surgery side, and associated comorbidities (Table 1). Secondary clinical outcome variables included LOS, tourniquet time, estimated blood loss, hemoglobin, hematocrit, days per week of physical therapy, hours of continuous passive motion, MCD usage type and hours, adverse events, and overall satisfaction (Table 2). A univariate chi-square analysis or Fisher exact test was employed to compare the postdischarge VPULSE group with the inpatient VPULSE group on DVT occurrence at postoperative day 2 and at 2 weeks postoperatively. An independent-samples *t*-test was performed on all normally distributed data and a nonparametric Mann-Whitney *U* test was used for non-normally distributed data. All *P* values were 1-tailed, and *P* value <.05 was considered statistically significant.

Results

A total of 163 patients were screened and after meeting the study eligibility, 100 patients enrolled in the study and were randomized either to the inpatient VPULSE group (n = 52) or to the postdischarge VPULSE group (n = 48). Recruitment and follow-up started in April 2014 until January 2015, and follow-up continued until all patients had completed the study in February 2015. All patients' mean age was 62.76 ± 9.24 years with the postdischarge VPULSE group's mean age 59.85 ± 8.20 years, and the inpatient VPULSE group's mean age 65.44 ± 9.40 years (*P* = .002, statistically significant). The study population was 40% male and 60% female with 35.4% (n = 17) male in the postdischarge VPULSE group and 44.2% (n = 23) male in the inpatient VPULSE group, and 64.6%

Table 2
Patient Outcomes and Clinical Data.

Patient Outcomes	Total (N = 100), n (%)	Postdischarge VPULSE (n = 48), n (%)	Inpatient VPULSE (n = 52), n (%)	Overall P Value
Total DVTs ^a	12 (12.0)	0 (0.0)	12 (23.1)	<.001
DVT postop day 2 ^a	6 (6.0)	0 (0.0)	6 (11.5)	.017
DVT postop day 14 ^a	6 (6.0)	0 (0.0)	6 (11.5)	.017
Length of stay (d)	2.12 (0.33)	2.06 (0.25)	2.17 (0.38)	.086
Tourniquet time (min)	5.18 (0.95)	5.27 (0.95)	5.08 (0.94)	.329
Estimated blood loss (mL)	89.00 (27.60)	89.06 (32.58)	88.94 (22.37)	.684
Hemoglobin (g/dL)	11.33 (1.35)	11.25 (1.05)	11.41 (1.58)	.543
Hematocrit (%)	32.76 (3.22)	32.85 (3.07)	32.67 (3.38)	.78
Physical therapy (days per week)	2.62 (0.49)	2.63 (0.49)	2.62 (0.49)	.922
CPM ^b (hours per day)	5.07 (0.99)	5.19 (1.09)	4.96 (0.90)	.269
MCD usage				
VPulse SC (h) ^b	91.40 (72.58)	147.71 (68.87)	39.43 (10.77)	<.001
VPulse cooling (h) ^b	91.90 (74.69)	149.79 (71.16)	38.47 (9.85)	<.001
VPulse DC (h) ^b	76.90 (63.57)	120.32 (67.87)	36.04 (8.89)	<.001
Adverse events ^c	2 (2.0)	1 (1)	1 (1.0)	.536
Overall patient satisfaction ^d (NRS)	9.01 (1.31)	9.56 (0.82)	8.50 (1.46)	<.001

DVT, deep vein thrombosis; CPM, continuous passive motion; MCD, mechanical compression device; SC, sequential compression; DC, dynamic compression; NRS, numeric rating scale.

^a Chi-square analysis.

^b Mann-Whitney *U* test.

^c DVTs were not included as adverse events because the incidence of DVT was analyzed separately.

^d Independent-samples *t*-test.

($n = 31$) female in the postdischarge VPULSE group and 55.8% ($n = 29$) female in the inpatient VPULSE group. A significantly decreased risk of DVT was observed at both postoperative day 2 and week 2 in the postdischarge VPULSE group compared to the inpatient VPULSE group (0% vs 11.5%, $n = 6$, $P = .017$). The total incidence of DVT was 23.1% in the inpatient VPULSE group ($n = 12$) and 0% in the postdischarge VPULSE group ($P < .001$). VPULSE usage time was tested using nonparametric analysis, specifically the independent-samples Mann-Whitney U test, and a statistically significant difference was found in the postdischarge VPULSE group vs the inpatient VPULSE group, that is, patients used the machine significantly longer in the postdischarge VPULSE group. Finally, an independent-samples t -test demonstrated a significant increase in patient satisfaction in the postdischarge VPULSE group (9.56 ± 0.82) vs the inpatient VPULSE group (8.50 ± 1.46). This difference was significant at the $P < .001$ level (Table 2).

The absolute risk reduction (ARR), also termed the risk difference, was calculated by subtracting the proportion of patients with DVT in the postdischarge VPULSE group from that in the inpatient VPULSE group. Because 11.5% ($n = 6$) of the patients developed DVT in the inpatient VPULSE group, with no patients developing DVT in the postdischarge VPULSE group after day 2 and week 2 of observation, the ARR was 11.5% at each time point. Additionally, the relative risk reduction, calculated as the proportion of the ARR and the event rate in the control group, was 100%, with the overall ARR at 23.1%.

Discussion

The results of this study demonstrate the utility of implementing an extended-use MCD in the prevention of DVT incidence and provide further evidence that a prophylactic regimen of aspirin and MCD therapy might be at least as effective as other comparable methods of thromboprophylaxis. The multimodal approach of limiting the use of a tourniquet to no more than 5 minutes, rapid postoperative patient mobilization, and 325 mg aspirin twice daily for 3 weeks postoperatively in combination with MCD therapy demonstrated a low nonsymptomatic incidence rate (12%), and an even lower symptomatic DVT incidence rate (1%), while minimizing bleeding complications (1%). Aspirin is a generally safe, inexpensive, and readily available thrombolytic agent and when used in combination with at least 3 weeks of MCD therapy demonstrates superiority to the standard treatment of MCD therapy only during the inpatient stay following TKA (0% DVT incidence compared to 12.0% DVT incidence). Low-risk VTE patients may benefit from the findings in this study, as the side effects of concurrent aspirin and extended MCD use minimized bleeding complications (0% in the postdischarge VPULSE patients). This awareness of a safe alternative to disproportionate use of high-risk chemoprophylactics contributes to the future development of effective VTE prevention in total joint arthroplasty guidelines.

Reitman et al examined the effects of a multimodal approach using intraoperative heparin before tourniquet inflation, hypotensive epidural anesthesia, inpatient use of pneumatic compression boots, and 6 weeks of aspirin (325 mg twice daily) and reported an overall DVT rate of 4.0% ($n = 954$ TKA patients). However, ultrasonography was only performed in this study population at the time of discharge, and they reported a longer average LOS (4.47 days vs 2.12 ± 0.33), which makes the DVT incidence rate difficult to compare. It also suggests evidence that the longer hospital stay and consequently the longer use of the MCD therapy might have decreased the DVT incidence rate in this study [7]. Furthermore, only performing ultrasonography at the time of discharge would have missed the 6% incidence of DVT in the inpatient VPULSE patients that developed DVT 2 weeks postoperatively, thus making

the discordant DVT incidence rates less significant (4% vs 6% inpatient VPULSE group, and 0% postdischarge VPULSE group).

Although preoperative baseline scans were not performed, the postoperative day 2 scan served as a baseline, because all patients were receiving equivalent treatments until this point. Following discharge, the postdischarge VPULSE group experienced no DVTs ($n = 0$), whereas the inpatient VPULSE group experienced the 6% incidence of DVT ($n = 6$). That DVT occurred before the experimental treatment in half of the patients found to develop a DVT may be attributed to an inherent increased risk of developing DVT in these patients. Although every effort was made to include only patients at low risk of developing DVT by identifying contributing factors preoperatively, these patients may have had an unknown slightly increased risk of DVT. Patients may not have known or reported certain risk factors such as an unknown family history of DVT, or an unknown vein condition.

Overall, only 1 patient (1%) was symptomatic for DVT developing mild pain in the calf of the operative leg at his postoperative day 2 scan, and this DVT persisted to his 2-week postoperative LEDVU scan (inpatient VPULSE group). The efficacy of this multimodal thromboprophylactic regimen becomes evident when compared to a 0.92% incidence rate of 3060 TKA and THA patients symptomatic for VTE (and confirmed by imaging) [3], as well as the superiority of the postdischarge VPULSE group's outcome. The low overall incidence of VTE (23.1% in the inpatient VPULSE group; and 0% in the postdischarge VPULSE group) in this study is significantly lower than the estimated nonsymptomatic DVT incidence rate of 17%–53% in TKA patients without optimal prophylaxis [1].

The mean LOS was 2 days, and the complication rate was 2% ($n = 2$). One such complication was a gastrointestinal bleed occurring after the patient had been placed on enoxaparin to alleviate a DVT found 2 weeks postoperatively (inpatient VPULSE group), and the other adverse event was an emergency room visit due to an acute case of gastritis (postdischarge VPULSE group), which was not definitively related to the procedure or aspirin administration, because all patients were treated with 10 mg of famotidine for up to 6 weeks.

The laterality of the DVTs that were found was primarily located in the operative limb, although 2 patients had DVTs in the nonoperative limb, and not in the operative limb. One patient had a right knee TKA and developed a right soleal vein DVT, whereas the other patient had a right knee TKA and was found to have a left soleal vein DVT. These 2 patients were in the inpatient VPULSE group and the DVTs were only identified during the 2-week postoperative LED scan. Of those DVTs that were located in the operative limb, 3 were found in the popliteal vein, 7 in the soleal vein, 2 in an unspecified location of the lower extremity, and 1 patient had a total occluding saphenous vein DVT. All DVTs, except for those found in 1 patient, found at the postoperative day 2 scan persisted to the postoperative week 2 scan. Once identified, all DVTs were treated with either warfarin or rivaroxaban until resolved. No transfusions were performed, no patients were readmitted, and all DVTs were resolved by the 3-month follow-up knee examination, as verified by LEDVU.

The multimodal regimen used in this study was chosen for its low risk and seemingly high efficacy; however, Parvizi et al presented the efficacy of a similar study using only 81 mg of aspirin twice daily concurrently with inpatient MCD therapy. This prospective study found no difference in VTE incidence between the high-dose and low-dose aspirin group (0% vs 0.2%), and a decrease in gastrointestinal bleeding among the low-dose aspirin patients [17]. Because low-dose aspirin is found to have sufficient antiplatelet properties, this would encourage a follow-up study with low-dose aspirin, MCD use, and LEDVU imaging to establish an equivalent or superior nonsymptomatic DVT rate.

Overall satisfaction was statistically higher ($P < .001$) among the postdischarge VPULSE group (9.56 ± 0.82) than the inpatient VPULSE group (8.50 ± 1.46). Although patient satisfaction was hypothesized to be statistically insignificant between the groups, the higher satisfaction may be an indication of improved satisfaction due to patient activation. Evidence suggests higher satisfaction scores when patients are involved in their own health improvement [18], such as compliant MCD usage. If the study were able to be blinded, then this hypothesis may be able to be supported or refuted, which cannot be done at this time. This study was only able to provide evidence that overall satisfaction scores with the patient experience were not compromised by instructing the patient to use the MCD consistently and reliably throughout the 3-week post-operative period.

The younger patient population in the postdischarge VPULSE group may also be attributed, at least in part, to the superior overall satisfaction in this group; however, this finding has not been supported by the literature. Although not well understood, younger patients are considered a high-risk patient population for reporting lower satisfaction scores following total knee arthroplasty [19,20], which was not reflected in this study. The mechanism behind the improved patient satisfaction requires further investigation, perhaps through the use of a blinded postoperative assessor rather than the study coordinator to prevent bias, or even through a more comprehensive satisfaction questionnaire.

Some weaknesses of this study include the data usage chip of the MCD. The postdischarge VPULSE group did use the sequential compression setting of the MCD more hours total than the inpatient VPULSE group (147.71 ± 68.87 vs 91.40 ± 72.58 , $P < .001$); however, the data chip of the MCD did not allow the researchers to examine how this usage was spread over the 3 weeks. This means that patient compliance in the postdischarge VPULSE group may have dropped off significantly following the first several days postdischarge.

Although this study could be improved by further describing patient compliance, this observation may be offset by the role of rapid mobilization that all patients underwent. In this way, the MCD therapy may act as a bridge between the inpatient hospital stay and the length of time before resumption of a patient's activities of daily living where venous stasis is mitigated, and the elements of Virchow's triad are interrupted [21]. The multimodal approach used in this study complemented the design of the clinical trial to minimize any conflicting factors, such as the varying hours of MCD therapy completed each day.

Although the implementation of postdischarge VPULSE MCD therapy was able to entirely reduce the risk of DVT for the patients in the postdischarge VPULSE group (relative risk reduction = 100%) eliminating the incidence in DVT among the 48 patients randomized to extended use of the device, this study did not establish the best VTE prevention protocol. However, additional examinations of the use of aspirin in conjunction with MCD therapy may reinforce the findings of this study and lead to the creation and subsequent implementation of optimized regimens that offer low incidence of VTE, and fewer bleeding and surgical wound complications in postoperative TKA patients.

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