

An Evaluation of the Need for Blood Transfusion When Using Patient Specific Instrumentation for Total Knee Arthroplasty

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Abstract: The aim of this study was to compare the need for blood transfusion and other outcomes when using patient-specific instrumentation (PSI) versus traditional instrumentation. 45 patients underwent TKA with either PSI (12 unilateral/9 bilateral) or traditional instrumentation (19 unilateral/5 bilateral) using the same final implants. Use of PSI demonstrated shorter operative/ tourniquet times, and shorter length of stay compared to traditional TKA, but no difference in the need for blood transfusion. Post-hoc subgroup analysis demonstrated that bilateral PSI replacement had a significantly decreased need for blood transfusion, shorter length of stay, and shorter operative/tourniquet times than bilateral replacement with traditional instrumentation. Use of PSI resulted in shorter length of stay and shorter operative/tourniquet times, with bilateral PSI also having a decreased need for blood transfusion.

Keywords: Blood transfusion, total knee arthroplasty, patient-specific instrumentation.

INTRODUCTION

Total knee arthroplasty (TKA) is one of the most commonly performed orthopaedic procedures and remains the treatment standard for definitive management of advanced arthritis of the knee [1]. However, the procedure is potentially associated with significant intra-operative and post-operative blood loss that may require blood transfusion. Several methods have been studied with the aim of decreasing the need for allogenic blood transfusion or decreasing the blood loss associated with TKA. These include: preoperative autologous donation [2], intra-operative and post-operative blood re-transfusion [3], the use of tissue adhesives or sealants [4], the intra-articular or systemic application of tranexamic acid or other cocktails [5], the use of computer-assisted navigation [6], the use of a tourniquet [7], and the use of extramedullary alignment guides [8].

Patient-specific instrumentation (PSI) is a relatively new technology for TKA in which pre-operative imaging including CT, MRI, and/or radiographs are used to create custom, disposable cutting blocks for the femur and tibia. These blocks allow the surgeon to make bone cuts without the need for intramedullary or extramedullary guides. This technology allows the

determination of bony resections, implant rotation, implant position, and implant sizes before surgery with the use of an interactive, computer-based planning tool. This can eliminate a number of intra-operative steps, while also reducing the total amount of instrumentation necessary [9].

The purpose of this retrospective study was to compare the need for blood transfusion in patients receiving PSI knee replacement (Legion, Visionaire; Smith & Nephew, Inc, Memphis, Tenn) versus traditional TKA (Legion, Journey, Smith & Nephew, Inc, Memphis, Tenn) and also to compare the unilateral and bilateral subgroups. We compared the operating room (OR) time, tourniquet time, hemoglobin change, platelet change, perioperative complications, and length of stay. Our hypothesis was that patients receiving PSI knee replacements had a decreased need for allogenic blood transfusion compared to traditional TKA for both unilateral and bilateral procedures.

METHODS

Between June 2008 to February 2013, 22 patients received PSI knee replacement with the Legion implant using the Visionaire patient specific system (Smith & Nephew, Inc, Memphis, Tenn) and 24 patients received knee replacements using traditional instrumentation with either the Legion (20 patients) or Journey (4 patients) implants (Smith & Nephew, Inc, Memphis, Tenn) All procedures were performed by the same

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surgeon (senior author), a fellowship-trained adult reconstruction surgeon who performs a high volume of TKA. To enhance the validity of the study, we chose to limit the comparison between PSI and traditional TKA to those procedures performed with the Legion or Journey implants only. All patients who had TKA performed by the senior author during the time period were eligible. Patients elected to undergo knee replacement with PSI after being informed of potential but unproven benefits, with the added need of having to obtain a preoperative MRI. The patients who received traditional instrumentation were offered PSI but they declined. Exclusion criteria were similar to other studies regarding blood transfusion after TKA, and included: pre-operative hemoglobin <10mg/dL, use of an anti-platelet agent within 7 days prior to surgery, age less than 18 years of age, or a history of liver or renal failure. One patient was excluded from the PSI group due to a pre-operative hemoglobin <10mg/dL. Patients with rheumatoid arthritis were included in the study. Of the remaining 21 patients in the PSI group, 12 patients received unilateral replacement and 9 patients received bilateral replacement. Of the 24 patients in the traditional group, 19 patients received unilateral replacement and 5 patients received bilateral replacement.

1.1. Surgical Technique

The surgical protocol and technique were the same for both groups except for the choice of instrumentation during the procedure. All patients were given 650mg of acetaminophen, 200mg of celebrex, and 10mg of oxycodone extended release in the preoperative area prior to surgery. All patients received femoral nerve catheters on the operative side and spinal anesthesia unless contra-indicated. Bilateral femoral nerve catheters and spinal anesthesia were administered in patients receiving bilateral replacements. All operations were performed by the same surgeon (senior author) at a single institution (Long Island Jewish Medical Center). A tourniquet was used in all cases and all patients received 24 hours of peri-operative antibiotics. The tourniquet was inflated just prior to incision and deflated once the final components were cemented. A hemovac drain was placed only if a lateral release was performed. When performing a bilateral procedure, the first knee was completely closed and a sterile dressing was placed. The first knee was then covered with a sterile drape and the second knee uncovered. The second knee procedure was then started and performed as described. The operative time and tourniquet time for each knee was recorded, and there

was no overlap between finishing the first knee and starting the second knee. One unilateral PSI, 1 bilateral PSI, and 2 unilateral traditional patients did not receive spinal anesthesia due to a history of spinal surgery. Placement of a femoral nerve catheter was attempted but unsuccessful in 1 unilateral traditional patient

1.2. Post-Operative Protocol

All patients were placed in a knee immobilizer immediately post-op. Continuous passive motion (CPM) was started in the recovery room with the knee immobilizer removed. The knee immobilizer was worn at all times, except during CPM, while the femoral nerve catheter was in place. Patients were seen by physical therapy daily starting on post-operative day 1 and encouraged to begin ambulation. All patients received subcutaneous enoxaparin bridging to therapeutic warfarin except for one patient who was given fondaparinux due to a medical contra-indication. If placed, the hemovac drain was discontinued on post-operative day 2. The femoral nerve catheter was managed by the anesthesia pain service and discontinued on post-operative day 2 or 3 at their discretion. Patients were discharged to home or a rehabilitation facility once they had met physical therapy goals, their pain was controlled, and they were medically stable.

1.3. Transfusion Criteria

Patients were given a transfusion of allogenic packed red blood cells (pRBCs) for a hemoglobin <8mg/dL, or for a hemoglobin <10mg/dL with associated symptoms such as: tachycardia, orthostatic hypotension/ tachycardia, palpitations, or lightheadedness. Intra-operative transfusion was left up to the discretion of the anesthesiologist.

1.4. Statistical Analysis

Statistical analyses were conducted using SPSS ver. 12.0 (SPSS Inc., Chicago, IL, USA). The continuous variables were analyzed using a two-tailed Student's t -test. The continuous variables analyzed included: age, body mass index (BMI), operative time, tourniquet time, hemoglobin (Hgb) change (POD#1 or #3; Hgb subtracted from the pre-operative Hgb), platelet change (POD#3; platelet count subtracted from the pre-operative platelet count), and length of stay. The incidence of transfusion, a categorical variable, was analyzed using Fisher's exact test, as was the number of male and female patients, the number of complications, and the number of unilateral

Table 1: Demographic Data for Study Participants

Patient variables	Unilateral TKA			Bilateral TKA		
	PSI n=12	Traditional n=19	p value	PSI n=9	Traditional n=5	p value
Sex No. Male	7(58.3%)	6(31.6%)	0.26	5(55.6%)	5(100%)	0.22
Age in years	58.5±7.8	54.9 ± 8.3	0.24	54.9 ± 7.1	57.4 ±7.8	0.55
BMI (kg)/(m ²)	30.9 ±4.3	33.1 ±7.0	0.34	37.6 ± 6.6	30.9 ± 4.4	0.07
Arthritis Type	Ra: 1 (8.3%) OA: 11 (91.7%)	1 (5.3%) 18 (94.7%)	1.00	0 (0.0%) 9 (100%)	1 (20.0%) 4 (80.0%)	0.36

Values are given as the frequency, mean, or percentage, and standard deviation. †denotes significance.

or bilateral replacements within the PSI or traditional instrumentation group as a whole. A complication was defined as: hemarthrosis, infection, painful leg swelling, acute chest pain, dyspnea, lower limb thrombosis, pulmonary embolism, myocardial infarction, stroke, arthrofibrosis, or a return to the operating room within 3 months after the index procedure. The PSI and traditional instrumentation groups were compared as a whole, and post-hoc subgroup analysis comparing unilateral PSI to unilateral traditional TKA and comparing bilateral PSI to bilateral traditional TKA was performed. A p-value <0.05 was considered to be significant.

RESULTS

The PSI study group included 21 patients, of which 12 patients received unilateral replacement and 9 patients received bilateral replacement (Table 1). Seven males and 5 females received unilateral PSI, and 5 males and 4 females received bilateral PSI. Of the 24 patients in the traditional TKA group, 19 received unilateral replacement and 5 received bilateral replacement. Six male and 13 female patients received unilateral traditional TKA, and 5 male patients received bilateral traditional TKA. There was no significant difference in age, sex, BMI, primary diagnosis of osteoarthritis (OA) or rheumatoid arthritis (RA) between the PSI and traditional knees, or between the unilateral or bilateral subgroups. The type of surgery, unilateral or bilateral, was not significantly different between the PSI and traditional groups (p=0.19).

No intra-operative blood transfusions were performed on any of the patients. There were zero post-operative blood transfusions in the PSI patients (including the 9 patients who received bilateral replacement). Five of the 24 (20.8%) traditional TKA

patients received allogenic blood transfusion. Two of the 19 (10.5%) unilateral traditional TKA patients required transfusion (1 for Hgb<8.0 mg/dL and 1 for tachycardia with Hgb<10.0 mg/dL) and 3 of the 5 (60.0%) bilateral traditional TKA patients required transfusion (2 for Hgb<8.0 mg/dL and 1 for lightheadedness/syncope with Hgb<10.0 mg/dL). The need for blood transfusion was not significantly different when comparing the PSI group as a whole to the traditional group (p=0.05). In post-hoc subgroup analysis, there was no significant difference in the need for transfusion when comparing unilateral PSI to unilateral traditional TKA (p=0.51), though there was significantly less need for blood transfusion when comparing bilateral PSI to bilateral traditional TKA (p=0.03) (Figure 1, Table 2).

Need for transfusion after TKA: comparison between PSI and traditional technique subgroups

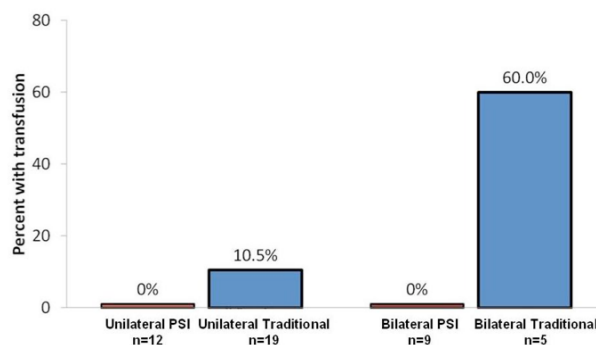


Figure 1: The percentage of patients who required blood transfusion, divided into unilateral and bilateral subgroups.

The operative time and tourniquet time were significantly less with the PSI group as a whole (p<0.01 for both operative and tourniquet times) and when comparing the unilateral and bilateral subgroups (p<0.01 for both operative and tourniquet times). The mean PSI operative time was 99.7 ± 18.0 minutes, the

Table 2: Comparison of Out Come Variables

Patient Variables	Unilateral TKA			Bilateral TKA		
	PSI n=12	Traditional n=19	p value	PSI n=9	Traditional n=5	p value
NO. patients transfused	0 (0.0%)	2(10.5%)	0.51	0(0.0%)	3(60.0%)	0.03 [†]
Hemoglobin change POD#1 (mg/dL)	-2.6± -0.5	-2.7 ± -0.9	0.34	-2.4 ± -0.9	-4.0 ± -0.8	0.01 [†]
Hemoglobin change POD#3 (mg/dL)	-3.2 ± -1.3	-3.1 ±-1.0	0.81	-3.3 ± -1.3	-4.9 ± -2.2	0.12
Operative time per knee (minutes)	89.6 ±14.7	116.1 ±23.1	<0.01 [†]	106.4 ± 14.1	146.1±14.1	<0.01 [†]
Tourniquet time per knee (minutes)	57.6 ±13.0	91.8 ±19.0	<0.01 [†]	73.5 ±13.9	115.4 ± 14.1	<0.01 [†]
Platelet change POD#3 (k/uL)	-52.6 ±21.1	-639 ±-363	0.34	-442 ±-25.8	-352 ±-375	0.60
Length of stay (days)	3.1±0.3	3.5 ±0.8	0.07	3.1 ±0.3	3.8 ±0.4	0.01 [†]
No. of complications	1(8.3%)	3 (15.8%)	0.94	0 (0.0%)	0(0.0%)	1.00

Values are given as the frequency, mean, or percentage, and standard deviation. [†]denotes significance.

unilateral PSI mean operative time was 89.6 ± 14.7 minutes, and the bilateral PSI mean operative time per knee was 106.4 ± 17.2 minutes. The mean traditional operative time was 126.4 ± 27.7 minutes, the unilateral traditional mean operative time was 116.1 ± 23.1 minutes, and the bilateral traditional mean operative time per each knee was 146.1 ± 14.1 minutes (Figure 2). The mean PSI tourniquet time was 67.1 ± 15.5 minutes, the unilateral PSI mean tourniquet time was 57.6 ± 13.0 minutes, and the bilateral PSI mean tourniquet time per each knee was 73.5 ± 13.9 minutes. The mean traditional tourniquet time was 95.6 ± 23.0 minutes, the unilateral traditional mean tourniquet time was 91.8 ± 19.0 minutes, and the bilateral traditional mean tourniquet time per each knee was 115.4 ± 14.1 minutes (Figure 3).

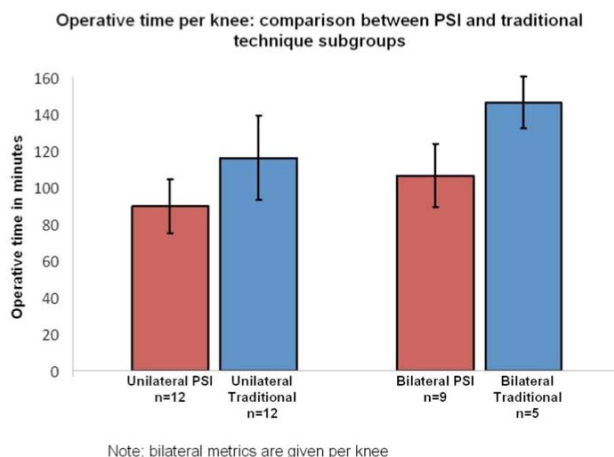


Figure 2: The operative times for the unilateral and bilateral subgroups.

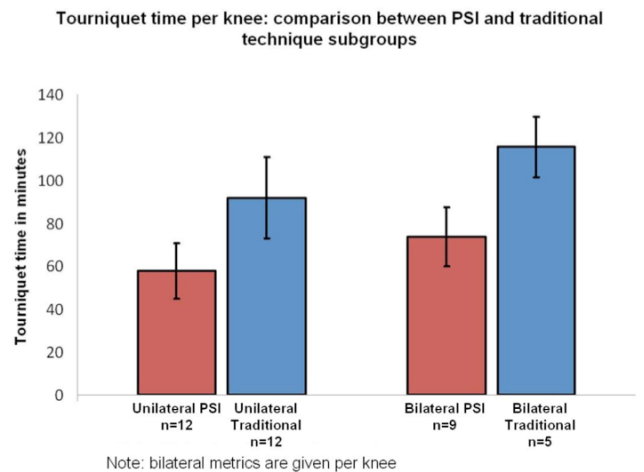


Figure 3: The tourniquet times for the unilateral and bilateral subgroups.

The mean length of hospital stay was 3.1 ± 0.3 days for the PSI whole group, and for the unilateral and bilateral PSI groups. The mean length of stay was 3.6 ± 0.7 days for the traditional whole TKA group, 3.5 ± 0.8 days for unilateral traditional, and 3.8 ± 0.4 days for bilateral traditional TKA patients. The PSI patients as a whole had a significantly shorter length of stay (p=0.01) than the traditional TKA patients, as did the bilateral PSI patients when compared to the bilateral traditional patients (p=0.01). However, there was no significant difference in length of stay between the unilateral PSI and unilateral traditional patients (p=0.07) (Figure 4).

There was no significant difference in hemoglobin change from pre-operative values to post-operative day

(POD) #1 values between the PSI and traditional groups as a whole ($p=0.09$) or within the unilateral subgroup ($p=0.34$). The POD#1 hemoglobin change was significantly greater in the bilateral traditional patients than the bilateral PSI patients ($p=0.01$). There was no significant difference in the hemoglobin change at POD#3 between PSI and traditional groups ($p=0.60$), or between the unilateral ($p=0.81$) or bilateral ($p=0.12$) subgroups. There was also no significant difference in the platelet change at day #3 between PSI and traditional groups ($p=0.43$), or between the unilateral ($p=0.34$) or bilateral ($p=0.60$) subgroups.

Length of stay in days: comparison between PSI and traditional technique subgroups

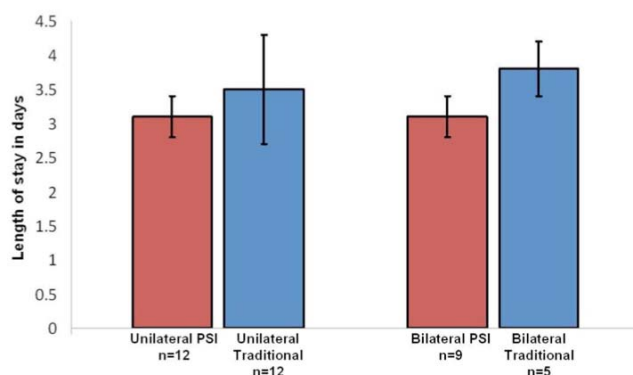


Figure 4: The length of stay for the unilateral and bilateral subgroups.

The complication rate for PSI patients was 1/21 (4.8%), unilateral PSI 1/12 (8.3%), and 0/9 bilateral PSI (0.0%). One PSI patient who had a unilateral replacement returned to the OR for manipulation under anesthesia due to arthrofibrosis. Three of the traditional TKA patients had complications. The complication rate for traditional TKA patients was 3/24 (12.5%), unilateral traditional 3/19 (15.8%), and 0/5 bilateral traditional (0.0%). One unilateral traditional patient returned to the OR for manipulation under anesthesia due to arthrofibrosis, another for an iliotibial band release, and a third was re-admitted due to gastritis. There were no complications in any of the bilateral PSI or bilateral traditional patients. The complication rates were similar in both groups ($p=0.61$), and in the unilateral ($p=0.94$) and bilateral ($p=1.0$) subgroups. There were no wound complications, bleeding problems, or thromboembolic events.

DISCUSSION

TKA is a common orthopaedic procedure that can be associated with significant blood loss requiring

transfusion. Allogenic blood transfusion carries a risk of febrile transfusion reactions, abnormal immunological responses, allergic reactions, and possible transmission of disease [10,11]. Blood loss following TKA can result in an increased risk of complications and disruption of recovery [12]. A variety of studies have examined different methods to reduce the need for blood transfusion and to reduce blood loss during TKA. These include: preoperative autologous donation [2], intra-operative and post-operative blood re-transfusion [3], the use of tissue adhesives or sealants [4], the intra-articular or systemic application of tranexamic acid or other cocktails [5], the use of computer-assisted navigation [6], the use of a tourniquet [7], and the use of extramedullary alignment guides [8].

This study was a retrospective study with low numbers of patients and included post-hoc subgroup analysis. Additionally, patients self-selected whether they would have PSI or traditional instrumentation, which may introduce a level of bias. The majority of patients who chose not to receive PSI did so because of the increased time necessary to proceed with surgery due to MRI authorizations, obtaining the necessary imaging, and awaiting for manufacture of the PSI cutting guides. A handful of patients received PSI TKAs due to post-traumatic arthritis with associated extra-articular deformities and retained hardware that would have prevented intra-medullary femoral instrumentation. Prior studies on PSI knee replacement have demonstrated shorter surgical times [13,14], shorter length of stay [15], and improved mechanical alignment [16]. However, Vundelinckx, *et al.*, [17] found no difference in blood loss, length of hospital stay, patient satisfaction, or radiographic outcomes when 31 PSI patients were compared to 31 traditional TKA patients at 200 days of follow-up. Another study with 80 patients demonstrated shorter surgical times but no difference in blood loss or need for blood transfusion [13].

In this study, patients who underwent knee replacement with PSI had significantly shorter length of stay and shorter operative/tourniquet times, but no difference in the need for blood transfusion. Bilateral PSI knee replacements had significantly less need for blood transfusion, shorter length of hospital stay, and shorter operative and tourniquet times than those patients who underwent bilateral TKA with traditional instrumentation. Patients receiving unilateral PSI did not have a shorter length of stay or a decreased need for blood transfusion than traditional unilateral TKA, but did have shorter operative and tourniquet times.

To the authors' knowledge, our study is the first to suggest a decreased need for blood transfusion when performing PSI knee arthroplasty, in this case within the bilateral PSI subgroup. However, the PSI group as a whole, and the unilateral subgroup did not demonstrate a decreased need for transfusion. Despite the small number of patients in the bilateral subgroup (PSI bilateral n=9, traditional bilateral n=5), statistically significant differences in the need for blood transfusion, length of stay, and operative and tourniquet times were observed with the use of PSI. This apparent decreased need for transfusion with the bilateral PSI knees could possibly be due to a combination of a reduction in intramedullary violation and a decrease in operative time, but the exact mechanism is unclear. Jeon *et al.* [8] demonstrated a decreased need for blood transfusion with the use of an extramedullary femoral cutting guide when compared to an intramedullary guide in 49 patients. For the PSI whole group and unilateral subgroup, it's possible that no difference in blood transfusion was found due to the low number of patients, although two prior studies have shown no difference in the need for blood transfusion with unilateral PSI replacement [13,17]. The unilateral PSI subgroup did not have significantly shorter length of stay than the unilateral traditional group ($p=0.07$), and this may also be due to the low number of patients in the study.

The rate of blood transfusion in both the unilateral PSI (0/9 = 0.0%) and unilateral traditional TKA groups (2/19 = 10.5%) were on the lower end of the spectrum when compared to other TKA studies. Blood transfusion rates after TKA vary greatly in the literature, ranging from 15-25% to 70-90% [18,19]. We believe the need for blood transfusion in this study was lower due to careful attention to control of bleeding during the surgery, and identifying and controlling bleeding by letting the tourniquet down after cementation of the final components was completed. The operative times for our TKAs (PSI = 99.7 ± 18.0 minutes per knee, Traditional = 126.4 ± 27.7 minutes per knee) appear to be on the longer end of the spectrum when compared to other studies (63-96 minutes) [13,18]. We believe our operative times are somewhat longer due to the extra time spent on achieving hemostasis, with a subsequently lower blood transfusion rate.

CONCLUSION

In our investigation, the use of PSI resulted in shorter length of stay and shorter operative/tourniquet times, but no difference in the need for blood

transfusion. Upon subgroup analysis, bilateral PSI knee replacement demonstrated a decreased need for blood transfusion, shorter length of stay, and shorter operative and tourniquet times when compared to bilateral TKA using traditional instrumentation. However, the use of PSI in unilateral knee replacement was associated only with shorter operative and tourniquet times, but no difference in blood transfusion or length of stay. We recommend further studies examining the need for blood transfusion and length of stay with the use of PSI with a larger number of patients, performed prospectively, as well as the evaluation of subjective outcomes and radiographic alignment. Although additional research is required to clarify these findings, this study suggests that using PSI when performing knee replacement may be beneficial, and that using PSI for bilateral knee replacement may decrease the need for blood transfusion. After this study was performed, the author uses only PSI technology for patients who wish to proceed with bilateral TKA.

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