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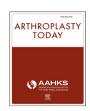
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# **Arthroplasty Today**

journal homepage: http://www.arthroplastytoday.org/



# Original research

# Comparing the Water-Tight Closure of Barbed and Conventional Suture Under Static and Dynamic Conditions in an Ex-Vivo Human Knee Arthrotomy Model

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#### ARTICLE INFO

Article history:
Received 23 January 2021
Received in revised form
26 July 2021
Accepted 3 August 2021
Available online 14 October 2021

Keywords:
Barbed suture
Total knee arthroplasty
Arthrotomy

#### ABSTRACT

*Background:* Barbed suture has become popular for closure of the arthrotomy and overlying tissues in total knee arthroplasty. STRATAFIX Symmetric PDS Knotless Tissue Control Device, a unique and novel barbed suture, with barbs formed integral to the suture core provides greater suture strength than the more common cut barbed suture designs. It is the only barbed suture commercially available with an indication in high tension areas, such as fascia. The purpose of this study was to evaluate the use of this novel barbed suture in the formation of a water-tight arthrotomy closure, using a continuous suture pattern, compared to conventional Coated VICRYL (polyglactin 910) Suture, using an interrupted suture pattern, in a cadaveric knee arthrotomy.

Methods: Twenty fresh-frozen cadaver knees underwent randomization to provide donor-paired matching of the knee arthrotomy closures using barbed suture in a continuous pattern or conventional suture in an interrupted pattern. Each specimen underwent 5 phases of testing that included 1) predynamic static leak testing; 2) dynamic motion leak testing; 3) postdynamic static leak testing; 4) suture release static leak testing; and 5) postsuture release dynamic motion leak testing, to assess the fluid leak rate.

Results: Under the initial static conditions, watertightness was similar for the 2 types of sutures. However, in all subsequent phases of testing, continuous barbed suture created a better watertight closure than interrupted conventional suture.

*Conclusions:* In this study, it was observed that closure of a knee arthrotomy using the novel barbed suture provided improved watertightness compared to conventional interrupted closure under dynamic conditions and suture release.

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# Introduction

Traditionally, the arthrotomy after a total knee arthroplasty (TKA) has been closed using interrupted sutures composed of a biodegradable material [1]. However, the use of barbed suture for fascia and arthrotomy closure has begun to displace traditional closure with interrupted sutures. Barbed sutures were introduced

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on the premise that they have numerous advantages compared to traditional interrupted sutures including the ability to achieve better watertight closures of the wound, [2,3] better distribution of tension along the wound, [3] shortened operative time, [4–10] and reduced cost [5–8,11]. Wound-related complications, and in particular, wound drainage, is an important factor that can increase the risk of surgical site infection and/or periprosthetic joint infection after total joint arthroplasty [12,13].

A watertight closure of the arthrotomy and sealed soft-tissue closure is essential to avoid wound complications after TKA [2]. Recent studies have shown that barbed sutures provide the most biomechanically secure and watertight arthrotomy closure in

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cadaveric models [1-3]. Vakil et al. performed biomechanical testing of continuous barbed and traditional interrupted closures in a cadaveric knee arthrotomy model, which demonstrated, under cyclical loading, a continuous barbed closure could experience more ruptures in the suture before failure of the arthrotomy closure [1]. However, the barbed suture used in the cadaveric models [1-3] was a bidirectional barbed suture with the barbs manufactured by cutting into the core of the suture. The barbed suture presented in this study is a technology with the barbs being formed integral to the core of the suture without cutting into the suture core, which is hypothesized to provide a substantial increase in tensile strength to the suture.

The purpose of the present study was to assess the watertightness of a knee arthrotomy closure with traditional interrupted suture and a novel barbed suture under static and dynamic conditions and after suture release. We hypothesize the novel barbed suture would provide a similar watertight arthrotomy to a traditional interrupted suture under static conditions but provide improved watertightness under dynamic conditions.

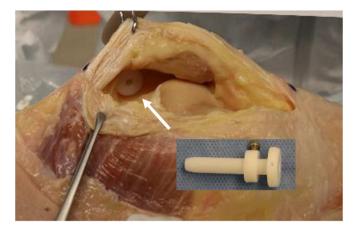
#### Materials and methods

Study design

A human cadaveric study was performed using 20 fresh-frozen specimens from 10 donors (10 right legs and 10 left legs). The cadaveric specimens were obtained from Science Care (Phoenix, AZ), and all specimens were fully intact lower extremities from donors with no history of inflammatory arthritis, septic arthritis. cancer, knee trauma, radiation therapy, or prior lower extremity surgery. Each cadaver specimen was stored at -20°C and allowed to thaw at room temperature for a minimum of 48 hours before the start of the study. All procedures and arthrotomy closures were performed by an adult reconstruction fellowship-trained orthopedic surgeon. Arthrotomy closure was performed with either the test suture of STRATAFIX Symmetric PDS Plus (Size 1, CT-1 needle; Ethicon Inc, Somerville, NJ) or the control suture of Coated VICRYL Suture (Size 1, CT-1 needle; Ethicon Inc, Somerville, NJ). Using an "out of the hat" randomization, one knee was selected to be closed using the test suture in a continuous pattern, and the contralateral knee from the same donor was closed using the control suture in an inverted figure-8 interrupted pattern.

# Cadaver knee preparation

For each cadaveric specimen, the leg was positioned on a surgical table with the knee in approximately 30° of flexion. The skin and subcutaneous tissue was dissected from the anterior knee taking care to maintain the underlying musculature, quadriceps tendon, and retinacular tissue. A standard mini-medial parapatellar arthrotomy was performed with the arthrotomy extending from 3 cm proximal to the superior pole of the patella to the proximal medial aspect of the tibial tubercle [14]. An infusion cannula and Millar pressure transducer were then inserted in the superolateral aspect of the knee under direct visualization to ensure intraarticular placement (Fig. 1). Markings were placed over the length of the arthrotomy using a template with holes 8 mm apart to approximate the desired intersuture spacing (Fig. 2) and depth of bite for both the control and test suture. Closure with the test suture was performed in a continuous suture pattern, per the manufacturer's Instruction For Use obtaining full-thickness passage of the needle 4-6 mm from the arthrotomy edge and intersuture spacing of 8 mm. Closure with the control suture was performed using an inverted figure-8 interrupted suture pattern obtaining full-thickness passage of the needle 4-6 mm from the arthrotomy

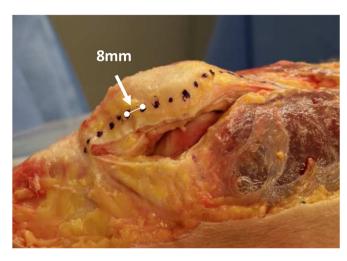


**Figure 1.** Cannula (white arrow) placement in the superolateral aspect of the knee. The cannula had a novel design of a broad base with multiple fenestrations to maintain the position of the cannula to ensure fluid was being delivered intraarticularly and a central opening for delivery of the Millar pressure transducer.

edge and intersuture spacing of 8 mm. Absorbent pads were secured to the edge of the skin to capture any extraneous fluid from the subcutaneous tissue to prevent it from contaminating fluid leakage collected from the arthrotomy (Fig. 3). After completion of the arthrotomy closure, the mid-point of the closure was marked for easy visualization to identify the suture to be cut during the suture release phase of testing. The knee was then secured into a Continuous Passive Motion (CPM) machine (OptiFlex-K1; DJO, Dallas, TX) on an inversion table, with the machine set to 30° of flexion (Fig. 4). The table and CPM containing the leg were then inverted to allow for gravity collection of fluid (Fig. 5) and to ensure no trapped air was present against the suture line. A constant pressure gravity feed infusion system and intraarticular Millar pressure transducer was used to monitor, maintain, and regulate the intraarticular pressure.

Experimental phases to assess water tightness (phases 1-5)

Each specimen underwent 5 sequential phases of testing to examine critical questions related to the clinical scenario. The 5 phases included 1) predynamic static leak test, 2) dynamic motion leak test, 3) postdynamic static leak test, 4) suture release static

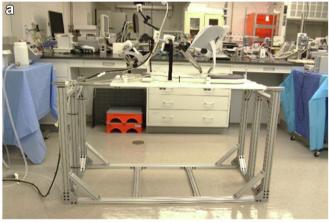


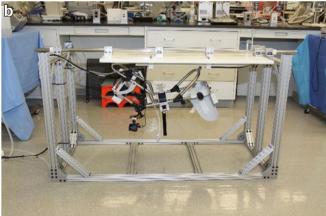
**Figure 2.** Arthrotomy edge that had been marked with a custom flexible template to mark locations 8 mm apart to help minimize variation with intersuture spacing.



**Figure 3.** Absorbent pads were secured around the skin and subcutaneous edges to eliminate extraneous fluid weeping from the surrounding tissues and avoid contamination of fluid collected from the arthrotomy suture line.

leak test, and 5) postsuture release dynamic motion leak test. The suture line fluid leakage was collected and measured at specific timepoints in each phase of testing. In the event a leak was too high for the gravity feed infusion system to maintain the desired constant pressure, it was defined as a critical leak. The details of each phase are outlined in the following paragraphs.





**Figure 4.** Inversion table is a custom-made table designed to support the CPM machine with the leg and allow for the tabletop to rotate. Right photo: table in upright position. Left photo: table in inverted position.

#### Phase 1: Predynamic static leak test

The knee was secured into the CPM machine stationary at  $30^{\circ}$  and inverted with a collection bin below the arthrotomy to capture any leaked fluid. The intraarticular pressure was raised to 30 mmHg, and for a period of 3 minutes, any leaked fluid was collected and measured, which was repeated for intraarticular pressures of 40, 50, 60, 70, and 80 mmHg each for a collection period of 3 minutes.

#### Phase 2: Dynamic motion leak test

Immediately after phase 1 testing, the intraarticular pressure was maintained at 80 mmHg in  $30^\circ$  of flexion. The knee was then moved to  $0^\circ$  of extension in the CPM machine after which it was taken through 20 cycles of motion from  $0^\circ$  to  $120^\circ$  and then back to  $0^\circ$  at a rate of 100 seconds per cycle. The fluid leaked from the arthrotomy was collected and measured during the entire range of motion cycle at the  $5^{th}$ ,  $10^{th}$ ,  $15^{th}$ , and  $20^{th}$  cycles.

## Phase 3: Postdynamic static leak test

Immediately after phase 2, the knee was moved to  $30^\circ$  of flexion in the CPM machine. The intraarticular pressure was adjusted to 30 mmHg, and for a period of 3 minutes, any leaked fluid was collected and measured, which was repeated for intraarticular pressures of 40, 50, 60, 70, and 80 mmHg each for a collection period of 3 minutes.

#### Phase 4: Suture release static leak test

Immediately after phase 3, the intraarticular pressure was maintained at 80 mmHg in 30° of flexion. The midpoint suture loop, representing the location of highest tension of the arthrotomy closure, was cut to simulate breaking of a suture in the arthrotomy. The leaked fluid from the arthrotomy was collected and measured for a 3-minute period during which the intraarticular pressure was maintained at 80 mmHg. In the event that the leak rate was so high that the gravity feed infusion system was not able to supply enough fluid volume to maintain a constant pressure of 80 mmHg, the arthrotomy leakage was defined as a critical leak.

# Phase 5: Postsuture release dynamic motion leak test

Immediately after phase 4, the intraarticular pressure was maintained at 80 mmHg in 30° of flexion, and then the knee was taken through 5 full range of motion cycles during which the fluid leaked from the arthrotomy was collected and measured during each range of motion cycle.

#### Statistical analysis

Descriptive statistics were calculated for the treatment and control suture groups. The mean leak rates were compared between groups using the two-sided paired t-test.

# Results

#### Cadaveric specimens

The mean donor age was 56 years (range, 38 to 69 years), mean body mass index was 26.5 kg/m $^2$  (range, 20.8 to 30.7 kg/m $^2$ ), and 7 donors were male.

# Phase 1: Predynamic static leak test

The mean ( $\pm$ SD) leak rate at 30, 40, 50, 60, 70, and 80 mmHg for the STRATAFIX Symmetric PDS Plus Device was 0.06 ( $\pm$ 0.14), 0.16 ( $\pm$ 0.34), 0.23 ( $\pm$ 0.45), 0.22 ( $\pm$ 0.43), 0.29 ( $\pm$ 0.56), and 0.43 ( $\pm$ 0.71) mL/min (table 1), respectively. The mean ( $\pm$ SD) leak rate at 30, 40,



Figure 5. After the leg was secured to the CPM machine, the device was inverted to allow for accurate measurement of fluid leaking from the arthrotomy suture line.

50, 60, 70, and 80 mmHg for the coated vicryl suture was 0.13 ( $\pm$ 0.22), 0.21 ( $\pm$ 0.29), 0.26 ( $\pm$ 0.27), 0.33 ( $\pm$ 0.31), 0.36 ( $\pm$ 0.33), and 0.47 ( $\pm$ 0.40) ml/min (Table 1), respectively. The mean fluid leak rates at all pressures for the test and control suture were similar (P=.67, P=.86, P=.98, P=.61, P=.75,and P=.89,for 30, 40, 50, 60, 70, and 80 mmHg, respectively). When paired donor specimens were compared, 3 of the paired donors demonstrated lower leak rates during each intraarticular pressure for the STRATAFIX Symmetric PDS Plus Device, 2 of the paired donors demonstrated lower leak rates for the Coated VICRYL Suture, and 5 of the paired donors had neither suture with a lower leak rate at all measured intraarticular pressures.

#### Phase 2: dynamic motion leak test

The mean (±SD) fluid volume leaked for the 5th, 10th, 15th, and 20th range of motion cycles for the STRATAFIX Symmetric PDS Plus Device was 9.21 ( $\pm$ 7.57), 12.62 ( $\pm$ 14.08), 11.88 ( $\pm$ 9.04), and 14.36  $(\pm 14.26)$  mL (Table 2), respectively. The mean  $(\pm SD)$  fluid volume leaked for the 5th, 10th, 15th, and 20th range of motion cycles for the Coated VICRYL Suture was 13.66 ( $\pm$ 12.52), 24.26 ( $\pm$ 19.73), 26.84  $(\pm 21.13)$ , and  $28.05 (\pm 20.76)$  mL (Table 2), respectively. The mean fluid volume leaked was significantly higher for the Coated VICRYL Suture than that for STRATAFIX Symmetric PDS Plus Device for all range of motion cycles except for the 5th cycle (P = .11, P = .03, P = .01, and P = .01.01, for the 5th, 10th, 15th, and 20th cycles, respectively). When paired donor specimens were compared, 8 of the paired donors had a lower leak volume during each measured cycle for the STRATAFIX Symmetric PDS Plus Device while only one of the paired donors demonstrated a lower leak volume during each measured cycle for the Coated VICRYL Suture, and one of the paired donors had neither suture with a lower fluid leak from each knee at all measured cycles.

#### Phase 3: Postdynamic static leak test

As a method to gauge the effect of the 20 range of motion cycles on approximation of the arthrotomy by the suture, the delta

**Table 1**Predynamic static leak test (phase 1) results.

Pressure (mmHg)	STRATAFIX VICRYL (n = 10, mL/min, ±SD) (n = 10, mL/min, ±		P value
30	0.06 (±0.14)	0.13 (±0.22)	.67
40	0.16 (±0.34)	0.21 (±0.29)	.86
50	0.23 (±0.45)	0.26 (±0.27)	.98
60	0.22 (±0.43)	0.33 (±0.31)	.61
70	0.29 (±0.56)	0.36 (±0.33)	.75
80	0.43 (±0.71)	0.47 (±0.40)	.89

between phase 3 and phase 1 leak rates was compared. The mean (±SD) delta at 30, 40, 50, 60, 70, and 80 mmHg for the STRATAFIX Symmetric PDS Plus Device was 1.02 ( $\pm 1.17$ ), 0.78 ( $\pm 0.90$ ), 0.80  $(\pm 0.90)$ , 0.90  $(\pm 0.84)$ , 0.85  $(\pm 0.75)$ , and 0.97  $(\pm 1.13)$  mL/min (Table 3), respectively. The mean  $(\pm SD)$  delta at 30, 40, 50, 60, 70, and 80 mmHg for the Coated VICRYL Suture was 2.15 ( $\pm 2.95$ ), 2.12  $(\pm 2.70)$ , 2.11  $(\pm 3.24)$ , 2.64  $(\pm 4.51)$ , 3.64  $(\pm 6.58)$ , and 4.57  $(\pm 8.88)$  mL/ min (Table 3), respectively. The mean delta was higher for the Coated VICRYL Suture compared to STRATAFIX Symmetric PDS Plus Device for all pressures; however, the differences between test and control articles did not reach statistical significance (P = .12, P = .10, P = .19, P = .22, P = .20, and P = .22, for 30, 40, 50, 60, 70, and 80 mmHg, respectively). When paired donor specimens were compared, 6 of the paired donors demonstrated a lower delta between phase 3 and phase 1 at each intraarticular pressure for the STRATAFIX Symmetric PDS Plus Device while only 2 of the paired donors demonstrated a lower delta between phases for the Coated VICRYL Suture, and 2 of the paired donors had neither suture with a lower delta between phases at all measured intraarticular pressures.

#### Phase 4: Suture release static leak test

Two specimens with the Coated VICRYL Suture experienced a critical leak after the suture release while none of the specimens in the STRATAFIX Symmetric PDS Plus Device group experienced a critical leak. The mean ( $\pm$ SD) leak rate of all specimens for the STRATAFIX Symmetric PDS Plus Device was significantly lower than that for Coated VICRYL Suture (98.8 [ $\pm$ 286.2] and 711.8 [ $\pm$ 804.6] mL/min, respectively; P=.04). After exclusion of the 2 Coated VICRYL Suture specimens with a critical leak and the paired donor STRATAFIX Symmetric PDS Plus Device specimen, the mean ( $\pm$ SD) leak rate for the STRATAFIX Symmetric PDS Plus Device and Coated VICRYL Suture was 123.3 ( $\pm$ 319.1) and 378.9 ( $\pm$ 445.6) mL/min, respectively (P=.08).

Phase 5: Postsuture release dynamic motion leak test

Two specimens with the Coated VICRYL Suture experienced a critical leak during postsuture release dynamic motion while none

**Table 2**Dynamic motion leak test (phase 2) results.

ROM cycle	$STRATAFIX \ (n=10,mL, \pm SD)$	$\text{VICRYL}(n=10,\text{mL,}\pm\text{SD})$	P value
5th	9.21 (±7.57)	13.66 (±12.52)	.11
10th	12.62 (±14.08)	24.26 (±19.73)	.03
15th	11.88 (±9.04)	26.84 (±21.13)	.01
20th	14.36 (±14.26)	28.05 (±20.76)	.01

**Table 3**Postdynamic static leak test (phase 3) results.

Pressure (mmHg)	STRATAFIX	VICRYL	P value
	$(n = 10, mL/min, \pm SD)$	$(n = 10, mL/min, \pm SD)$	
30	1.02 (±1.17)	2.15 (±2.95)	.12
40	0.78 (±0.90)	2.12 (±2.70)	.10
50	0.80 (±0.90)	2.11 (±3.24)	.19
60	0.90 (±0.84)	2.64 (±4.51)	.22
70	0.85 (±0.75)	3.64 (±6.58)	.20
80	0.97 (±1.13)	4.57 (±8.88)	.22

of the specimens in the STRATAFIX Symmetric PDS Plus Device group experienced a critical leak. The mean (±SD) fluid volume leaked for the 1st, 2nd, 3rd, 4th, and 5th range of motion cycles for the STRATAFIX Symmetric PDS Plus Device was 348.3 (±999.9), 364.5 ( $\pm 1000.8$ ), 425.0 ( $\pm 1073.6$ ), 432.1 ( $\pm 1015.1$ ), and 468.7 (±1019.4) mL/min (Table 4), respectively. The mean (±SD) fluid volume leaked for the 1st, 2nd, 3rd, 4th, and 5th range of motion cycles for the Coated VICRYL Suture was 1078.7 (+1174.2), 1128.4 (+1123.4), 1124.2 (+1143.8), 1124.0 (+1136.8), and 1131.8 (+1128.7) mL/min (Table 4), respectively. The mean fluid volume leaked was higher for the Coated VICRYL Suture than that for STRATAFIX Symmetric PDS Plus Device for all range of motion cycles; however, the differences between the test and the control articles did not reach statistical significance (P = .12, P = .09, P = .14, P = .14, and P = .14.17, for the 1st, 2nd, 3rd, 4th, and 5th cycles, respectively). Similarly, after exclusion of the 2 Coated VICRYL Suture specimens with a critical leak and the paired donor STRATAFIX Symmetric PDS Plus Device specimen, the mean leak rate for each range of motion cycle was lower in the STRATAFIX Symmetric PDS Plus Device than that in the Coated VICRYL Suture, although the differences between groups did not reach statistical significance (P = .51, P = .36, P = .55, P = .57, and P = .65, for the 1st, 2nd, 3rd, 4th, and 5th cycles, respectively) (Table 5). When paired donor specimens were compared, 8 of the paired donors demonstrated lower fluid leaked during each measured cycle for the STRATAFIX Symmetric PDS Plus Device while only 2 of the paired donors demonstrated lower fluid leaked for the Coated VICRYL Suture.

# Discussion

Arthrotomy closure using a bidirectional barbed suture in TKA has been proven to have fewer wound complications and offers a cost-effective alternative to a traditional interrupted closure [15]. The present study was designed to evaluate the STRATAFIX Symmetric PDS Plus Device, a novel barbed suture, and compare that to Coated VICRYL Suture through an evaluation of a watertight closure of a knee arthrotomy. The STRATAFIX Symmetric PDS Plus Device was designed using a technology where the barbs are formed integral to the suture core, as opposed to forming the barbs by cutting into the core and thereby reducing the core structure and resultant tensile strength. In addition, this type of design provides a greater

**Table 4**Postsuture release dynamic motion leak test (phase 5) results, all specimens.

ROM cycle		$\begin{array}{l} \text{STRATAFIX (} n=10\text{,} \\ \text{mL/min)} \end{array}$		= 10, mL/	P value
	Mean	SD	Mean	SD	
1st	348.3	999.9	1078.7	1174.2	.12
2nd	364.5	1000.8	1128.4	1123.4	.09
3rd	425.0	1073.6	1124.2	1143.8	.14
4th	432.1	1015.1	1124.0	1136.8	.14
5th	468.7	1019.4	1131.8	1128.7	.17

**Table 5**Postsuture release dynamic motion leak test (phase 5) results, excluding matched pairs with a critical leak.

ROM cycle	STRATAF mL/min)	STRATAFIX (n = 8, mL/min)			
	Mean	SD	Mean	SD	
1st	433.3	1115.4	624.8	711.4	.51
2nd	450.4	1116.0	738.1	825.5	.36
3rd	522.1	1194.8	726.6	836.7	.55
4th	523.0	1129.8	722.0	813.5	.57
5th	557.3	1134.8	727.4	796.9	.65

holding strength because the barbs do not collapse in the same manner as cut barbs. However, the barbs in the novel suture are unidirectional and may be more rigid and larger in size, potentially leading to a "sawing effect" of tissue that may compromise the watertightness of the closure. The performance of the closure was examined through 5 specific phases designed to simulate multiple postoperative conditions that a patient undergoing TKA may experience. To accomplish this objective, a unique and clinically relevant ex-vivo model was designed to provide a highly controllable, consistent, repeatable, and discriminating test platform.

Phase 1 (predynamic static leak test) simulated the status of the knee arthrotomy with intraarticular bleeding immediately after a TKA. A maximal intraarticular pressure of 80 mmHg was chosen because tissue perfusion and continued intraarticular bleeding would be expected to cease in the arthrotomy when the intraarticular pressure is nearing the minimum diastolic pressure [16]. Therefore, under the assumption of a normotensive diastolic pressure, 80 mmHg was chosen as the upper test limit for static leak testing. We demonstrate the running barbed suture and interrupted suture closures were effective methods to maintain a watertight closure with similar leak rates at all intraarticular pressures in the static mode. Importantly, the similar results for the 2 methods of closure demonstrate the lack of technical error or surgeon bias, which provides further validation to the subsequent phases of testing.

In phase 2 (dynamic motion leak test), the knee was cycled through a 0° to 120° range of motion with the CPM machine, replicating the physical therapy that the patient may undergo after TKA. Before initiating phase 2, the intraarticular pressure was held at 80 mmHg with the knee at 30° of flexion, but throughout the range of motion cycle, the peak intraarticular pressures reached 400-500 mmHg. In phase 3 (postdynamic static leak test), the static leak test of phase 1 was repeated to evaluate the status of the knee arthrotomy immediately after early physical therapy range of motion, which allowed for a direct comparison between the watertightness before and after a range of motion. The results of phases 2 and 3 demonstrate that the STRATAFIX Symmetric PDS Plus Device, with a continuous suture pattern, had a lower leak rate than a Coated VICRYL Suture using an interrupted suture closure pattern, indicating the dynamic motion of the knee did not create a "sawing effect" of the barbs on the tissue. Interrupted suture closure, however, experienced a dramatically higher leak rate after undergoing dynamic motion. The observed difference could represent residual slack of the multiple closed suture loops and knots after being subjected to dynamic motion, which is not present with a continuous knotless suture closure.

During phase 4 (suture release static leak test), the suture was cut at the midpoint of the arthrotomy closure to model the event of a suture breakage at the point with highest tension. As a result, phase 4 would simulate a patient who had completed physical therapy and experienced breakage of the suture at the highest tension location. Overall, STRATAFIX Symmetric PDS Plus Device resulted in a lower leak rate than interrupted Coated VICRYL Suture indicting better watertightness with no critical leaks. In phase 5

(postsuture release dynamic motion leak rest), the knee underwent range of motion cycles to simulate the patient undergoing physical therapy after experiencing suture breakage. Because the continuous barbed suture closure is a single loop, a theoretical concern would be the breakage puts the entire arthrotomy at risk of unwinding with dynamic motion. Our results would suggest the continuous barbed suture does not continue to unwind, and the barbed suture allows for better maintenance of the arthrotomy closure than an interrupted suture.

The study was designed to simulate a TKA arthrotomy as much as possible. Despite ensuring that every aspect of postoperative care of a TKA patient could be simulated, the study may have suffered some limitations. First, the use of cadavers and the logistic issues surrounding the use of cadavers prevented us in performing the experiments in a much larger cohort that would allow for powering a study to detect differences between groups using inferential statistics. The statistical tests were performed for posthoc comparisons and were not prospectively indicated and powered to detect significant differences between groups. The conclusion based on these results would have to be substantiated by further appropriately powered studies. Second, the arthrotomy procedure was performed on the cadaveric knee without the presence of an implant in the knee. However, we ensured that the same soft-tissue dissection and exposure was performed as for a TKA procedure. We do not believe that the absence of an implant impacted the findings of the study. Finally, our cadaveric model is only capable of assessing closure of the arthrotomy in the early postoperative period before a patient's tissue would begin to remodel and seal the arthrotomy. However, the most critical time point is during the early postoperative period when the integrity of the arthrotomy closure is solely dependent on the suture.

#### **Conclusions**

In this study, STRATAFIX Symmetric PDS Plus Device, in a continuous suture pattern, provided a better watertight closure of a knee arthrotomy than interrupted Coated VICRYL Suture under the various conditions tested including dynamic motion and suture release.

### **Conflicts of interest**

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Y.A.F. and J.P. both serve as paid consultants for Ethicon Inc.

#### Acknowledgments

The authors would like to thank Bogdan Ilie for assistance with the statistical analysis and review of the manuscript. The study was funded by Ethicon Inc.

#### References

- [1] Vakil JJ, O'Reilly MP, Sutter EG, Mears SC, Belkoff SM, Khanuja HS. Knee arthrotomy repair with a continuous barbed suture: a biomechanical study. J Arthroplasty 2011;26(5):710.
- [2] Nett M, Avelar R, Sheehan M, Cushner F. Water-tight knee arthrotomy closure: comparison of a novel single bidirectional barbed self-retaining running suture versus conventional interrupted sutures. J Knee Surg 2011;24(1):55.
- [3] Kobayashi S, Niki Y, Harato K, Udagawa K, Matsumoto M, Nakamura M. The effects of barbed suture on watertightness after knee arthrotomy closure: a cadaveric study. J Orthop Surg Res 2018;13(1):323.
- [4] Eickmann T, Quane E. Total knee arthroplasty closure with barbed sutures. J Knee Surg 2010;23(3):163.
- [5] Gililland JM, Anderson LA, Barney JK, Ross HL, Pelt CE, Peters CL. Barbed versus standard sutures for closure in total knee arthroplasty: a multicenter prospective randomized trial. J Arthroplasty 2014;29(9 Suppl):135.
- [6] Meena S, Gangary S, Sharma P, Chowdhury B. Barbed versus standard sutures in total knee arthroplasty: a meta-analysis. Eur J Orthop Surg Traumatol 2015;25(6):1105.
- [7] Sah AP. Is there an advantage to knotless barbed suture in TKA wound closure? A randomized trial in simultaneous bilateral TKAs. Clin Orthop Relat Res 2015;473(6):2019.
- [8] Smith EL, DiSegna ST, Shukla PY, Matzkin EG. Barbed versus traditional sutures: closure time, cost, and wound related outcomes in total joint arthroplasty. J Arthroplasty 2014;29(2):283.
- [9] Stephens S, Politi J, Taylor BC. Evaluation of primary total knee arthroplasty incision closure with the use of continuous bidirectional barbed suture. Surg Technol Int 2011;21:199.
- [10] Ting NT, Moric MM, Della Valle CJ, Levine BR. Use of knotless suture for closure of total hip and knee arthroplasties: a prospective, randomized clinical trial. J Arthroplasty 2012;27(10):1783.
- [11] Maheshwari AV, Naziri Q, Wong A, Burko I, Mont MA, Rasquinha VJ. Barbed sutures in total knee arthroplasty: are these safe, efficacious, and cost-effective? J Knee Surg 2015;28(2):151.
- [12] Chotanaphuti T, Courtney PM, Fram B, et al. Hip and knee section, treatment, algorithm: proceedings of international consensus on orthopedic infections. | Arthroplasty 2019;34(2S):S393.
- [13] Jaberi FM, Parvizi J, Haytmanek CT, Joshi A, Purtill J. Procrastination of wound drainage and malnutrition affect the outcome of joint arthroplasty. Clin Orthon Relat Res 2008:466(6):1368.
- [14] Heekin RD, Fokin AA. Mini-midvastus versus mini-medial parapatellar approach for minimally invasive total knee arthroplasty: outcomes pendulum is at equilibrium. J Arthroplasty 2014;29(2):339.
- [15] Chan VWK, Chan PK, Chiu KY, Yan CH, Ng FY. Does barbed suture lower cost and improve outcome in total knee arthroplasty? A randomized controlled trial. J Arthroplasty 2017;32(5):1474.
- [16] Whitesides TE, Haney TC, Morimoto K, Harada H. Tissue pressure measurements as a determinant for the need of fasciotomy. Clin Orthop Relat Res 1975;(113):43.