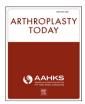
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Original research

A Single-Center Randomized Prospective Study Investigating the Efficacy of Various Wound Closure Devices in Reducing Postoperative Wound Complications

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ABSTRACT

Background: Sutures and staples are the mainstay wound closure techniques in total joint arthroplasty. Newer techniques such as zipper devices and novel skin adhesives have emerged because of their potential to decrease operative time and possibly minimize complications. The aim of this study is to compare these newer techniques against conventional sutures with respect to wound complications, closure time, and costs.

Methods: A single-center randomized control trial was conducted on 160 patients (52 zipper, 55 suture, 53 mesh) who underwent primary total hip or knee arthroplasty between February 2017 and May 2018. Patients were divided into 3 closure groups: zipper device, monofilament suture plus adhesive, and monofilament plus polyester mesh with adhesive. The primary endpoint was closure time (superficial skin layer). Secondarily we collected perioperative complication rates, including infection, persistent (14-day) wound drainage, 90-day readmission, and emergency room visit rates as well as compared material costs.

Results: There were no differences in baseline characteristics between groups for age, body mass index, and American Society of Anesthesiologists classification. There was a trend toward decreased time to closure for the suture group. There were no significant differences between groups for our secondary endpoint, complications.

Conclusions: Our study shows that the suture group trended toward shorter closure time but suggests that each of the closure methods after total joint arthroplasty has equivalent complication rates. With small differences in closure time and no significant differences in complications, the decision to use one wound closure device or technique over another should be driven by institutional costs and provider familiarity.

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Introduction

In a health-care climate of escalating costs, there is a continued need for increased efficiency in care, with the goal of maintaining high-quality standards while simultaneously minimizing the financial burdens on the patient, hospital, and payer. This is especially relevant to total joint arthroplasty (TJA) as payment models are trending toward bundled payment models, pay-forperformance, and episodes of care and away from the model of payments for each individual service provided [1-3]. Given that the demand for TJA is projected to increase substantially over the next few decades, it is essential to identify factors that may improve clinical outcomes of TJA and reduce costs per episodes of care [4,5]. One area that has garnered increased attention for its potential to improve clinical outcomes while diminishing costs is the investigation of the optimal wound closure technique after TJA. The 3 most common options for wound closure after TJA include sutures, staples, and skin adhesives [6,7].

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The skin adhesive most commonly used today is 2-octyl cyanoacrylate (OCA), a high-viscosity, flexible glue [7–11]. Its use has been associated with decreased wound closure times. highly satisfactory cosmetic results, and surgical outcomes comparable to conventional sutures [10,11]. However, while affective, OCA use has been shown to lead to allergic contact dermatitis [12]. Zipper wound closure technology is a newer wound closure device that is an alternative to the commonly used conventional staples or sutures [13,14]. The device acts similar to a scaffold to stabilize the adjacent sides of the wound to minimize forces that can disrupt normal healing of the skin. Finally, the polyester mesh plus skin adhesive closure technique combines the OCA topical skin adhesive with a flexible, self-adhesive polyester mesh that has proven to reduce wound closure times and have a significantly greater skin holding strength than skin staples or subcuticular sutures in one study [15].

Wound closure techniques have been well-studied in a variety of other disciplines, however only recently has the wound closure after TJA been more thoroughly investigated [10-14]. A recent meta-analysis specifically compared staples and sutures for total knee arthroplasty (TKA) wound closure [14]. The difference in complication rates did not reach significance but favored staples. Staples were also faster and therefore saved operative time. This led to the present study, which was designed to compare newer closure techniques and once again look at complications, closure time, and costs. This randomized control trial compares operative wound closure times as well as perioperative outcomes, complications, and costs associated with zipper technology, synthetic absorbable monofilament suture plus skin adhesive, and monofilament with polyester mesh plus skin adhesive after TKA and total hip arthroplasty (THA). We hypothesize that the zipper and mesh closures will have similar outcomes and rates of complication to the more traditional suture and adhesive closure. In addition, we expect these closures to take approximately the same amount of time as the suture and adhesive closure when performed by a range of providers at an academic center.

Material and methods

This study is a single-center, multisurgeon, randomized control trial at a tertiary, urban, academic orthopedic institution. Patients included in our study were recruited from those who had elected to undergo primary TKA or THA between February 2017 and May 2018. A total of 160 TJA patients were recruited for this study with no patients being lost to follow-up. Patients were eligible to participate if their age was greater than or equal to 18 years at the time of their surgery and were undergoing an elective primary TKA or THA. Key clinical exclusion criteria included traumatic injury that required urgent TJA, bilateral TJA, revision TJA, history of previous open surgery to the knee/hip, septic arthritis, and active infections in the operative leg or joint. The study was approved by our institutional review board.

All participants' surgical wounds were closed with one of the 3 newer treatment devices, either zipper (Zip Surgical Skin Closure; ZipLine Medical Inc, Campbell, CA), synthetic absorbable subcuticular monofilament suture (Monocryl; Ethicon, Somerville, NJ) plus skin adhesive (Dermabond Advanced; Ethicon, Somerville, NJ), or the same subcuticular monofilament suture with a polyester mesh skin adhesive system (Dermabond Prineo; Ethicon, Somerville, NJ). Different types of zipper devices are available. The Zip Surgical Skin Closure used in this study consists of an adhesive strip placed on either side of the wound connected by a series of interlocking closure devices, giving the appearance of a zipper. For the polyester mesh closure, the mesh is laid over the wound, and an OCA preparation specific to this system is painted over the wound and mesh. Although the manufacturer recommends that this system may be applied without running a subcuticular suture, our practice is to use the mesh over a wound closed with running monofilament suture.

No modifications to the normal standard of practice other than the randomization of closure was implemented. At the time of preoperative planning, informed consent was obtained for participation in the study. Enrolled patients were computer-randomized to one of the closure groups. Given the nature of the application of the wound closure device, which would be visible to the surgeon at the time of application and to the patient postoperatively, the study was not blinded to either the surgeon or the patient. Because the clinical setting for this study was a large urban academic hospital, wound closure was performed by a variety of providers including physician assistants and house staff with between one and 6 years of postgraduate orthopedic surgical training.

Patient demographics were collected from our electronic medical record (Epic Hyperspace; Epic Systems, Verona, WI). The demographic characteristics that we evaluated were age, sex, race, body mass index, obesity status, and smoking status (never, former, or current). Inpatient and surgical records that were reviewed included date of surgery, date of discharge, length of stay, and surgical time. Complication data collected in the present study were limited to infections, both deep and superficial, and postoperative drainage due to study design. Emergency room visits within 90 days of the operation and readmissions within 90 days were also recorded from our electronic medical record.

Finally, during surgical wound closure, the surgical team would briefly pause to record the start time of the final layer of epidermis. The closure end time was routinely recorded by OR staff. After completion of wound closure, the incision length was measured. Wounds were evaluated by the operating physician immediately postoperatively for healing and any abnormalities.

Statistical analysis

Dichotomous data outcomes were analyzed using chi squared tests while continuous data were analyzed individually for each technique using student t-tests and analysis of variance testing. Descriptive data are represented as means \pm standard deviation while categorical is represent as counts. Significance was set a priori at 0.05. A power analysis was performed before the start of the study to determine how many patients were required to show a difference in wound closure time outcomes for the combined TJA cohort. Our final TJA cohort was fully powered (power = 95.89%, [alpha = 0.05], two-sided) to show this difference in wound closure time.

Results

One hundred sixty TJA patients were included in this study, with 52, 55, and 53 patients in the zipper, suture, and mesh groups, respectively. In this TJA cohort, 61 were THA patients while 99 were TKA patients. Patient demographics, including age, body mass index, smoking status, and American Society of Anesthesiologists class, were not different between wound closure technique groups for either the TJA, THA, or TKA cohorts (Table 1).

For the TJA, TKA, and THA cohorts, there were no cases of 90-day emergency room visits or 90-day inpatient readmissions between wound closure devices. No statistically significant difference was demonstrated between wound closure groups in regard to infection rates, wound drainage, or length of stay (Table 2).

The linear length of surgical wounds was not different between closure groups in the TJA, THA, or TKA cohorts. Analysis of the time to complete wound closure demonstrated a strong trend favoring

 Table 1

 Demographics and baseline characteristics.

Demographic	data			
THA + TKA				
	Mesh $(n = 53)$	Suture (n = 55)) Zipper (n = 54)	ANOVA P value
Age BMI Gender	61.49 ± 8.75 31.17 ± 5.59	63.6 ± 12.71 29.07 ± 5.75	65.48 ± 13.85 30.68 ± 6.09	.551 .161 .759
Male	19	21	17	
Female ASA Smoking	34 2.43 ± 0.67	34 2.45 ± 0.603	37 2.40 ± 0.60	.886 .59
status Never	17	16	21	
Former	15	10	11	
Current	21	28	22	
THA	_	_	_	_
	Mesh $(n = 19)$	Suture (n = 24)) Zipper (n = 18)	ANOVA P value
Age	58.74 ± 8.70	59.54 ± 12.51	56.67 ± 15.49	.756
BMI	27.84 ± 4.81	26.94 ± 6.43	29.20 ± 5.51	.468
Gender				.645
Male	9	8	7	
Female	10	16	11	
ASA	2.10 ± 0.57	2.37 ± 0.58	2.33 ± 0.68	.324
Smoking status				.267
Never	14	11	9	
Former	5	9	6	
Current	0	4	3	
TKA				
	Mesh $(n = 34)$	Suture (n = 31)) Zipper $(n = 36)$	ANOVA P value
Age	63.03 ± 8.53	66.74 ± 8.61	64.31 ± 10.4	.268
BMI	32.94 ± 5.20	30.76 ± 4.58	31.46 ± 6.33	.27
Gender				.414
Male	10	13	10	
Female	24	18	26	
ASA	2.73 ± 1.75	2.42 ± 1.23	2.44 ± 1.40	.442
Smoking status				.728
Never	17	16	21	
Former	15	11	11	
Current	2	4	4	

ANOVA, analysis of variance; ASA, American Society of Anesthesiologists; BMI, body mass index; THA, total hip arthroplasty; TKA, total knee arthroplasty.

suture with adhesive, but this did not reach significance for the TJA cohort (P = .056). When looking only at THA, the suture with adhesive closure was significantly faster (P = .032).

For all cases together (THA plus TKA), sutures with adhesive were the fastest, with an average time of 6:43 (6.71 minutes). Zipper device closure averaged nearly 1 minute slower, with a mean time of 7:40 (7.67 minutes), followed by the (monofilament suture with) polyester mesh plus skin adhesive with an average of 7:45 (7.75 minutes) (Table 2) (P = .056). The suture was consistently the fastest method for both the THA and TKA cohorts (Table 2).

Discussion

There is a continued interest in evaluating new means for efficiencies in health care, and all stakeholders seek to reduce costs without diminishing quality of care. In light of the projected demands for TJA in the near future, it is essential to identify ways to achieve these goals. As newer TJA wound closure technologies emerge, it is worthwhile to evaluate their efficacy, complications, and efficiency.

The 3 common options for wound closure after TJA include sutures, staples, and skin adhesives. Conventional sutures and skin

Table	2
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Perioperative and postoperative characteristics.

Perioperative and postoperative characteristics						
	Mesh	Suture	Zipper	ANOVA P value		
THA + TKA						
Mean incision length (cm)	15.35 ± 8.19	15.03 ± 4.41	14.51 ± 2.40	.751		
Mean direct closure time (min)	7.75 ± 2.65	6.71 ± 2.08	7.67 ± 2.61	.056		
Infections (percent)	1 (1.89)	0(0)	0(0)	.387		
Drainage (percent) THA	3 (5.67)	5 (9.09)	5 (9.26)	.647		
Mean incision length (cm)	13.25 ± 1.96	13.63 ± 3.48	13.56 ± 2.47	.905		
Mean direct closure time (min)	6.88 ± 1.81	5.46 ± 1.39	6.70 ± 2.47	.032		
Infections (percent)	0(0)	0(0)	0(0)	-		
Drainage (percent)	1 (5.26)	2 (8.33)	1 (5.55)	.959		
TKA						
Mean incision length (cm)	16.58 ± 10.04	16.11 ± 4.79	15.10 ± 2.20	.677		
Mean direct closure time (min)	8.29 ± 2.95	7.71 ± 2.01	8.21 ± 2.56	.631		
Infections (percent)	1 (2.94)	0 (0)	0(0)	.405		
Drainage (percent)	2 (5.88)	3 (9.68)	4 (1.11)	.666		

ANOVA, analysis of variance; THA, total hip arthroplasty; TKA, total knee arthroplasty.

staples with or without adhesive are the most commonly used closure techniques in TJA. However, there are newer options that warrant investigation. Skin adhesives have been associated with decreased wound closure times, highly satisfactory cosmetic results, and surgical outcomes comparable to those of conventional sutures. Newer devices such as zipper technology and variations of skin adhesives have also been sources of experimentation. The zipper wound closure device acts similar to a scaffold to stabilize the adjacent sides of the wound to minimize forces that can disrupt normal healing of the skin. Finally, the polyester mesh plus skin adhesive closure device combines a preparation of the OCA topical skin adhesive with a flexible, self-adhesive polyester mesh that has reduced wound closure times and a significantly greater skinholding strength than skin staples or subcuticular sutures in one study [15,16].

In this study, we investigated the efficacy of the Zip Surgical Skin Closure, Monocryl suture plus Dermabond Advanced, and Monocryl suture plus Dermabond Prineo wound closure techniques in regard to 2 outcome measures. The primary endpoint measured the time needed for closure of the superficial layer of the epidermis, and the secondary endpoint examined the complication rates and direct material cost. Complication rates were equivalent between the 3 groups. Although it failed to meet our threshold for significance, sutures demonstrated a strong trend toward faster closure time than the other closure techniques.

Wound drainage after TJA has been associated with increased rates of infection and may require secondary surgical intervention [17]. A recent study in Denmark compared the use of skin adhesive against no adhesive in patients undergoing simultaneous bilateral total knee replacements [18]. Each patient's first knee was randomized to adhesive or no adhesive, and the contralateral knee became an internal control for the first knee with the opposite treatment. Although these authors used skin adhesive with a different composition (N-butyl-2-cyanoacrylate rather than OCA), they found that sealing the wound with adhesive significantly decreased the number of dressing changes needed. Their goal was to investigate the efficacy of skin adhesive used in conjunction with modern joint replacement protocols, with rapid mobilization, and without using a tourniquet or drain.

The results of our study do not align with previous studies in the literature with respect to closure time. In the present study, we found that sutures trended toward faster closure times but that the 3 techniques had average closure times that were roughly within a minute of each other which has limited clinical significance. Several studies evaluating the duration associated with various types of closure techniques have shown that zipper technology and skin adhesives have a faster closure time than traditional sutures at no increased rate of complications [13,16,19,20]. Roolker et al. demonstrated the zipper technology resulted in a seven-fold reduction of closure time compared with intracutaneous sutures (P = .01) [20]. Limitations of Roolker's study include the recruitment of patients with more varied orthopedic surgical wounds, including knee, hip, and spine wounds. Another limitation is the use of a different zipper device, which uses a zipper similar to those used in the garment industry. Limitations of the other studies that demonstrated reduced closure times were that these studies were performed by a single surgeon at a nonacademic orthopedic hospital setting, compared with the academic institution where we performed our study [13,20]. We feel that it is important to distinguish the surgical setting, as there is an inherent learning curve associated with individuals of different training levels who typically perform closure at academic settings.

Therefore, in academic settings, where individuals of all different skill levels and familiarity with closure devices perform wound closure, it may be more advantageous to use the device that is the least costly. The cost analysis performed by Roolker et al. described the costs as follows: zipper technology (Medizip; ATRAX Medical Group, Bermuda) \$13, OCA skin adhesive \$15, and intracutaneous sutures \$8 [20]. Their study used a different zipper device, which consisted of an actual zipper attached to adhesive pads and cost significantly less than the device used in our study. The ZipLine device uses a series of individually tensioned closure units aligned to resemble a zipper. Analysis results of our own institutional costs are as follows: Zipper closure \$110 (ZipLine), suture plus OCA skin adhesive \$24 (\$7 + \$17, respectively), and suture plus OCA with polyester mesh \$82 (\$7 + \$75, respectively). For reference, a surgical stapler costs \$34 at our institution. Our study suggests it may be most beneficial to use conventional sutures (with or without skin adhesive) in academic settings because of their reduced cost and equivalent closure times at no increased complication rate.

Wound closure techniques have been well-studied in a variety of other disciplines; however, there are few reports in the literature that look at the efficacy of various wound closure techniques after TJA at an academic center [13,20]. In a climate of escalating health-care costs, the cost of wound closure device should be weighed against reduced surgical time and complications.

Limitations

It is important to note the clinical setting of our study, as this may have affected the rate at which wound closure was performed. In an academic setting, closure may be performed by one or more different individuals at various levels of training. This can include the attending physician or a physician's assistant, or more commonly, surgical house staff of various training levels. There is also a learning curve associated with application and use of newer medical devices such as zipper devices and skin adhesive with mesh that will inherently reduce the speed at which these devices are used. Therefore, the combination of varied skill level and learning curve seen at academic institutions may have played a role in the results demonstrated by our study. In addition, all THAs in this study were performed via a posterior approach, and these results may therefore not be generalizable to direct anterior approach THA, which has been shown to have a higher rate of wound complication and prosthetic joint infection in some studies [21–23].

Conclusions

While the suture group trended toward shorter closure times in this study, there were no significant differences in our secondary outcome complication rates. We therefore looked to an additional secondary outcome, cost. The cost differential between these techniques is therefore the major distinguishing characteristic we found. The costs must be considered by each institution individually because the exact cost is different for each hospital or system, and the cost savings may or may not be considered a reason enough to deviate from a preferred closure. The senior author of this study has decided to continue the use of a running monofilament suture with an added adhesive as his preferred closure method as a result of the findings. Our findings suggest that the most cost-efficient method is suture with skin adhesive, which is associated with a strong trend toward a shortened closure time with a low complication rate in an academic setting.

Conflicts of interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: J. Vigdorchik received royalties from Corin U.S.A., is a paid consultant for Corin U.S.A., Intellijoint Surgical, Medacta, and Zimmer; has stock or stock options in Intellijoint Surgical and Motion Insights; received research support from Corin U.S.A.; is in the medical/orthopaedic publications editorial/governing board of Journal of Bone and Joint Surgery-British. W. J. Long received royalties from J&J, Ortho Development, Micro Port, and TJO; is in speakers bureau/gave paid presentations for Think Surgical; is a paid consultant for J&J, Micro Port, TJO, Think Surgical, Aerobiotics, Pacira, and Centrexion; received research support from Think Surgical, KCI, and Recro Pharma; received royalties, financial, or material support from Elsevier; is in the medical/orthopaedic publications editorial/ governing board of Journal of Arthroplasty; is a board member/made committee appointments for AAOS ICL Committee. R. Schwarzkopf received royalties from Smith & Nephew; is a paid consultant for Intelijoint and Smith & Nephew; has stock or stock options in Gauss surgical and Intelijoint; received research support from Smith & Nephew; is in the medical/orthopaedic publications editorial/governing board of Arthroplasty Today and Journal of Arthroplasty; is a board member/made committee appointments for AAOS and American Association of Hip and Knee Surgeons.

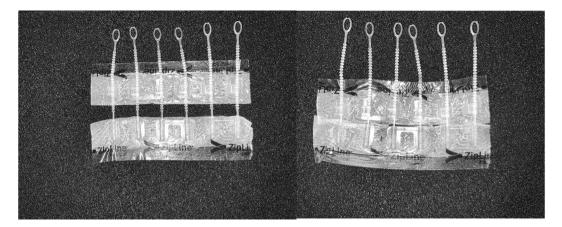
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Supplemental Figure 1. Zip surgical skin close device. Left: Slightly shortened device. Right: Fully closed Device.