

A Prospective Randomized Controlled Study of Stratafix versus Standard-of-Care for Deep Tissue Closure in Orthopedic Surgery

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Background: Orthopedic deep surgical incisions require the approximation of 1 or multiple tissue layers. This prospective randomized controlled study aimed to assess the usefulness and effectiveness of a barbed suture technique (Stratafix symmetric PDS plus) versus the conventional interrupted knotted suture technique for deep tissue closure in orthopedic surgery by comparing deep fascia suture time, relative cost, and wound-related complications.

Methods: A total of 254 patients with deep surgical incisions who underwent orthopedic surgery between October 1, 2020, and June 30, 2021, were recruited. Their general characteristics (age, sex, weight, height, body mass index, American Society of Anesthesiologists physical status score, total operation time, and length of deep incision) and factors related to deep incision wounds (suture type and number, wound closure time, and operation site outcomes) were collected.

Results: The general characteristics did not differ between the Stratafix and conventional groups. There were no between-group differences observed in total operation time or total anesthesia time. The wound suture times differed significantly. In the conventional group, the suture time per unit length was lower in the group with the length of deep incision under 20 cm but did not differ significantly for each wound size. In the Stratafix group, the suture time per unit length was lower in the group under 15 cm, with the shortest time observed for 10–14.9 cm, followed by 5.0–9.9 cm and the group under 5 cm. The conventional group developed 4 cases of superficial wound infection or surgical wound necrosis. One case of protruded suture tap occurred in the Stratafix group.

Conclusions: The average suture time per unit length increased for lengths under 5 cm as barbed sutures required more time from the start of the first suture to finish of the last suture. There was no significant benefit for very short suture length. One barbed suture material allows a suture of approximately 10–12 cm; sutures beyond that require more time because the surgeon has to start again. The Stratafix group used less suture material than the conventional group.

Keywords: Surgical wound, Suture technique, Orthopedic procedure, Wound infection

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Surgical site infection (SSI) accounts for approximately 15% of all medical-related infections, ranking third among these infections. In the United States, SSI occurs in approximately 2%–5% of patients who undergo surgery. Efforts to reduce SSI include minimizing tissue exposure time, aseptic handling of tissue, and minimizing damage and gripping of the exposed tissue.^{1–4)}

Careful suturing of the deep fascia is important in orthopedic surgery to prevent discharge, seroma, wound dehiscence, and infection. However, the conventional interrupted knotted suture technique damages the exposed

tissue when gripping it during suturing and due to different tensions in each knot, leading to wound discharge when loose and tissue ischemia when very tight.^{5,6)}

The barbed suture technique, mainly used in laparoscopic or robot-assisted surgeries, causes less tissue damage because fine barbs on the surface hold the sutured tissue better. Moreover, this suture can maintain continuous sutures stably, resulting in reduced exposed tissue time. Thus, barbed sutures can minimize damage and grip and reduce deep fascia suture time dramatically compared to the conventional interrupted knotted suture technique. However, although barbed suture is expected to be effective in reducing complications, including SSI, to the best of our knowledge, no systematic comparative study has been reported.

This prospective randomized controlled study has a twofold purpose. First, deep fascia suture time was compared between the conventional interrupted knotted and barbed suture techniques. The second purpose of this study was to compare relative cost and wound-related complications.

METHODS

This controlled randomized clinical trial was approved by the Ethics Committee of Chosun University Hospital (Res. No. CHOSUN-2020-09-003). All of the procedures were performed in accordance with the relevant policies in South Korea and adhered to the tenets of the Declaration of Helsinki. After assessing eligibility, patients were randomized to 1 of the 2 study arms by opening a sealed envelope containing the randomization code. Randomization was performed using a pre-set computer-generated allocation table. All patients underwent orthopedic surgery with deep fascial surgical dissection. All patients provided informed consent to participate in the study.

Study Design and Patient Management

We included 254 patients scheduled for orthopedic surgery with deep surgical incisions between October 1, 2020, and June 30, 2021. The inclusion criteria were as follows: (1) adults aged 18–80 years who agreed to participate in the study; (2) patients who understood and could voluntarily consent to participate in the research; (3) those able to visit a medical institution according to the study protocol; and (4) those who could speak and understand Korean fluently. The exclusion criteria were as follows: (1) patients with a body mass index (BMI) of 40 kg/m² or more; (2) those with a history of bleeding-related diseases; (3) patients diagnosed with infectious disease, collagen disease (Scleroderma) or other diseases related to wound

healing; (4) patients who received radiation therapy at the site of orthopedic surgery up to 6 months before surgery or who had received systemic chemotherapy; and (5) those with medical or family history of hypertrophic wounds.

Surgical Conditions and Perioperative and Postoperative Surveillance

Surgery was performed in the same surgical unit of the same institution. All surgical procedures were performed by 4 surgeons (GL, JL, SJ and HP) with more than 5 years of orthopedic surgical experience. Following the pre-planned orthopedic main procedures, the patients allocated to the conventional group (controls) with deep fascial surgical wounds were sutured using the conventional interrupted knotted suture technique, while those in the Stratafix (intervention) group were sutured using the barbed technique. Before suturing the deep fascia, the surgical wound was first measured using a ruler (unit, mm). Then, to determine the total suture time of both groups, each deep fascial surgical wound was measured and recorded in seconds from the start of the suture to the end of the last suture (Fig. 1). The 4 orthopedic surgeons who participated in this study were fully experienced with the barbed suture technique using Stratafix and had at least 4 hours of practice. Other medical staff working in the operating room were trained in advance to perform the barbed suture technique through video-assisted training. Re-education was provided anytime when desired. After the procedure, the patients were followed up for up to 3 months to record the development or absence of surgical complications.

Data Collection

General characteristics, including age, sex, weight, height, BMI, American Society of Anesthesiologists (ASA) physical status score, total operation time, and length of deep incision (mm) were collected. In addition, information on factors related to the deep incision wounds, including the name and number of used suture materials, time of wound closure (seconds), and outcome of deep incision sites (infection, hematoma, and wound dehiscence of the operation sites) were also collected. The patients were followed up postoperatively at 1 day, 7 days, 2 weeks, 1 month, and 3 months in the orthopedic ward and outpatient clinic.

Statistical Analysis

The patients' general characteristics and basic data were summarized using *t*-test and chi-square test. The differences in suture time and length between the 2 groups were analyzed using independent *t*-tests. The suture time

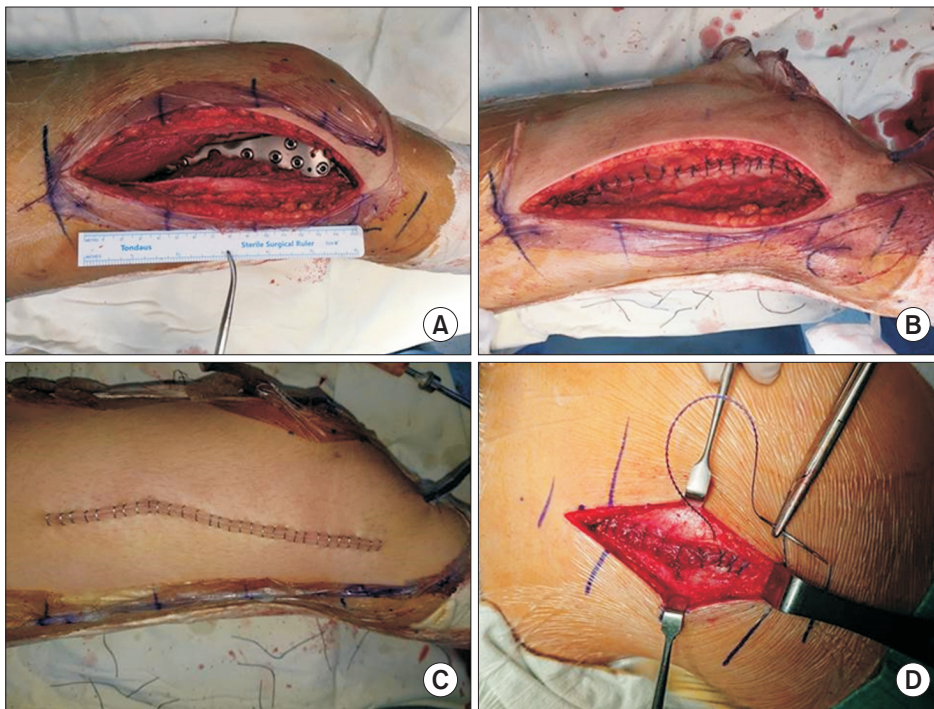


Fig. 1. Surgical procedure and perioperative surveillance. (A) Following the preplanned orthopedic main procedure, before suturing the deep fascia, the surgical wound is measured with a ruler (unit: mm). (B) Deep fascial surgical wounds in patients allocated to the conventional (control) group were sutured using the conventional interrupted knotted suture technique. (C) Skin suture by stapler. (D) Patients in the Stratafix (intervention) group were sutured using the barbed suture technique after the preplanned orthopedic main procedure.

per unit length was analyzed using analysis of variance (ANOVA). All statistical analyses were performed using IBM SPSS version 22.0 (IBM Corp.). The results were considered statistically significant at $p < 0.05$.

RESULTS

Demographic Data

Of the 254 patients, the conventional group included 61 men (48.0%) and 66 women (52.0%), while the Stratafix (barbed suture) group included 74 men (58.3%) and 53 women (41.7%). The mean ages were 56.57 years (range, 20–79 years) in the conventional group and 53.67 years (range, 19–79) in the Stratafix group. The mean weight differed significantly between the groups (64.78 ± 11.64 kg vs. 69.76 ± 17.00 kg; $t = -2.72$; $p = 0.007$). The mean heights in the conventional and Stratafix groups were 163.79 ± 9.35 cm and 165.56 ± 9.19 cm, respectively, and the mean BMI was 24.08 kg/m² and 25.32 kg/m², respectively. The mean ASA score was 1.85 ± 0.57 in the conventional group and 1.80 ± 0.60 in the Stratafix group. The mean total operation and anesthesia times were 103.79 ± 59.55 minutes and 116.76 ± 59.64 minutes, respectively, in the conventional group and 105.87 ± 55.43 minutes and 119.46 ± 55.42 minutes, respectively, in the Stratafix group. Drains were placed in 58 patients (45.7%) and 53 patients (41.7%) in the conventional and Stratafix groups, respectively. The general characteristics, excluding body

weight, were homogeneous, without significant difference between the 2 groups (Table 1).

Comparison of Suture Time per Unit Length between the Conventional and Stratafix Suture Groups

A total of 265 operation sites were obtained from 127 patients in the conventional group, and among them, less than 5 cm was the most common with 154, followed by 10–14.9 cm with 50, and more than 20 cm with 11. In the conventional group, the suture time per unit length was lower in those under 20 cm, but had no significant difference for each wound size. A total of 257 operation sites were obtained from the same number of Stratafix group patients, and among them, 131 operation sites less than 5 cm were the most common, followed by 5.0–9.9 cm and 10–14.9 cm with 49 each, and 20 cm or more was the least. In the Stratafix group, the suture time per unit length was lower in those under 15 cm, with the shortest time observed for 10–14.9 cm, followed by 5.0–9.9 cm and under 5 cm. ANOVA analysis with post-hoc analysis was conducted in the Stratafix group. Regarding suture time per unit length, the group under 5 cm was longer than the other groups, and the 5.0–9.9 cm group was longer than the 10–14.9 cm group (Table 2).

Regarding comparison within each suture material, there was no significant difference in suture time by wound length in the conventional side, but a significant difference in the Stratafix side. As a result of the student

Table 1. General Characteristics (N = 254)

Category	Conventional (n = 127)	Stratafix (n = 127)	p-value
Sex			0.313
Male	61 (48.0)	74 (58.3)	
Female	66 (52.0)	53 (41.7)	
Age (yr)	56.57 ± 16.01	53.67 ± 16.85	0.161
Weight (kg)	64.78 ± 11.64	69.76 ± 17.00	0.007
Height (cm)	163.79 ± 9.35	165.56 ± 9.19	0.131
BMI (m/kg ²)	24.08 ± 3.44	25.32 ± 5.06	0.023
Type of anesthesia			0.366
General	178 (70.1)	93 (73.2)	
Spinal	76 (29.9)	34 (26.8)	
ASA physical status score	1.85 ± 0.57	1.80 ± 0.60	0.606
Total operation time (min)	103.79 ± 59.55	105.87 ± 55.43	0.774
Total anesthesia time (min)	116.76 ± 59.64	119.46 ± 55.42	0.709
Number of operation sites	2.06 ± 1.34	2.04 ± 1.29	0.780
Drain			0.527
Yes	58 (45.7)	53 (41.7)	
No	69 (54.3)	74 (58.3)	
Surgical type			0.776
Open reduction and internal fixation	41 (32.3)	39 (30.7)	
Arthroplasty	26 (20.5)	20 (15.7)	
Arthroscopic surgery	17 (13.4)	16 (12.6)	
Spine surgery	9 (7.1)	9 (7.1)	
Implant removal	27 (21.3)	37 (29.1)	
Others (excision, biopsy)	7 (5.5)	6 (4.7)	
Surgery site			0.310
Upper extremity	15 (11.8)	26 (20.5)	
Lower extremity	86 (67.7)	77 (60.6)	
Trunk	21 (16.5)	20 (15.7)	
Others (foot, hand)	5 (3.9)	4 (3.1)	

Values are presented as number (%) or mean ± standard deviation.
 BMI: body mass index, ASA: American Society of Anesthesiologists.

t-test for suture time per unit length between the conventional group and the Stratafix group, no statistical significance was found in the group less than 5 cm ($p = 0.056$), but statistical significance was found in all other groups.

Relative Cost

The number of suture materials used per wound size for the relative cost analysis was fewer for the Stratafix group than the conventional suture group (1.53 ± 0.58 vs. 2.42

Table 2. Comparison of Suture Time Per Unit Length Between the Conventional and Stratafix Suture Groups

Operation site incision length	Conventional			Stratafix		
	No. (%)	Suture time per unit length (sec/cm, mean \pm SD)	<i>p</i> -value	No. (%)	Suture time per unit length (sec/cm, mean \pm SD)	<i>p</i> -value
< 5 cm	154 (58.1)	5.33 \pm 5.63	0.717	131 (51.0)	3.34 \pm 0.81	0.001
5–9.9 cm	34 (12.8)	4.63 \pm 0.25		49 (19.1)	1.91 \pm 0.56	
10–14.9 cm	50 (18.9)	4.53 \pm 0.30		49 (19.1)	1.45 \pm 0.50	
15–19.9 cm	16 (6.0)	4.46 \pm 0.06		18 (7.0)	1.45 \pm 0.50	
\geq 20 cm	11 (4.2)	4.56 \pm 0.27		10 (3.8)	1.47 \pm 0.59	
Total	265 (100.0)	5.00 \pm 4.31		257 (100.0)	2.50 \pm 1.11	

SD: standard deviation.



Fig. 2. Surgical wound complication in the conventional (control) suture group. (A) Superficial surgical wound necrosis in the distal end of a total knee arthroplasty site, in which delayed wound closure was performed after daily dressing. (B) Superficial wound infection in the proximal wound and insertion site of an intramedullary nail cephalomedullary screw, in which delayed wound closure was performed after daily dressing. (C) Superficial surgical wound necrosis in half of the posterior decompression of a lumbar spinal stenosis site, in which delayed spontaneous healing occurred after daily dressing.

\pm 1.27). When the length or number of surgical wounds is not considered, the conventional interrupted knotted suture technique group tends to use 1.6 times suture materials per unit. The price of Stratafix should not exceed 1.6 times that of conventional suture materials for the barbed suture technique to be cheaper than the conventional interrupted knotted suture technique for a surgical wound suture of the same length.⁷⁾

Wound-Related Complications

Four surgical wound complications occurred in 3 patients in the conventional group, including superficial wound infections and surgical wound necrosis (Fig. 2). In the Stratafix group, only 1 case of surgical wound complication (protruded initial suture tap) was observed (Fig. 3).

DISCUSSION

Barbed sutures are monofilament sutures with protruding barbs.⁸⁾ With improvements to this suture technology, they have been widely applied in various surgical fields⁹⁻¹²⁾ that are proven effective in cosmetic skin and deep tissue closures.¹³⁻¹⁵⁾ They also provide wound strength comparable to or superior to closure with conventional sutures, and decrease long-term scarring, displacement, wound infection, adverse skin tissue reactions, and surgical times.¹⁶⁻²¹⁾ Studies have compared barbed sutures to conventional closure techniques in muscle belly repair, total knee arthroplasty, total hip arthroplasty, and gastrointestinal surgery.¹⁹⁻²²⁾

Although the Stratafix group had 2–3 times faster suture time than the conventional group, the average suture time per unit length increased for those under 5 cm. More time is required from the first start and finish of the last suture for the barbed suture technique; thus, there was no significant benefit for very short suture lengths. A single length of barbed suture material allows a suture of approximately 10–12 cm; above this length, more time is required because the surgeon has to start again. Stratafix is judged to be the most effective in a 10–12-cm sized surgical wound or its multiples.

Overall, the barbed suture technique group used 1.53 pieces, whereas the conventional interrupted knotted suture technique group used 2.42 pieces. When the length

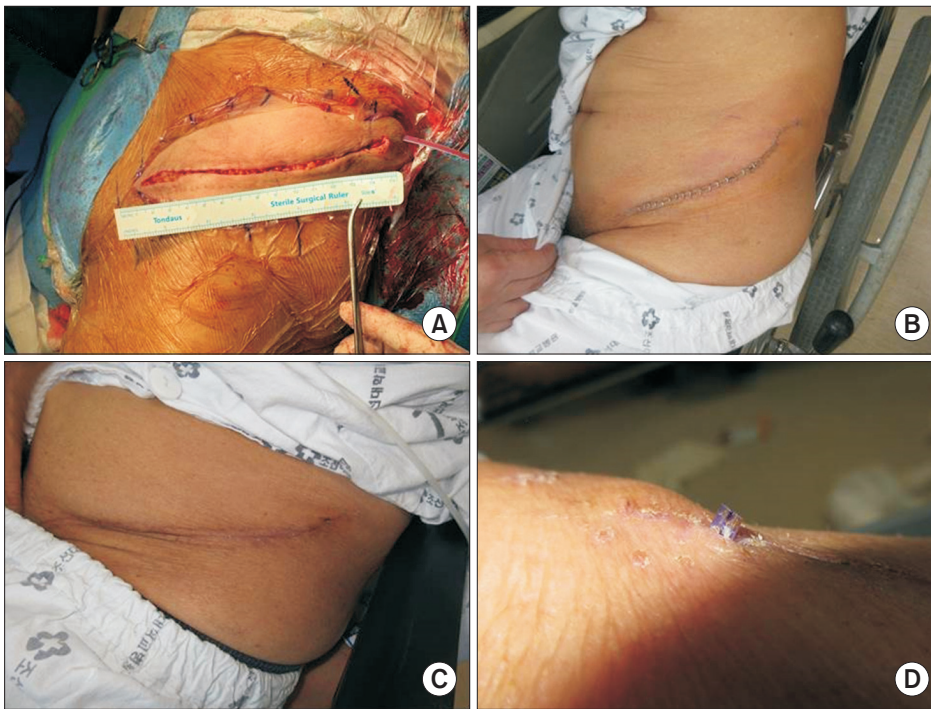


Fig. 3. Surgical wound complication in the Stratafix (intervention) group. (A) The wide marginal excision was performed through a skin incision applied along the iliac crest. (B) On the seventh day after surgery, no specific abnormalities were observed around the Stapler skin suture and the suction drain was removed. (C) On the tenth day after surgery, total stitch out was performed, with no abnormal findings around the surgical wound. (D) On the third week after the operation, the patient complained of discomfort in the proximal surgical wound, with the superficially located initial tap exposed through the skin. The tap was removed from the base using a blade, with complete wound healing after a few days without additional procedures.

or number of surgical wounds is not considered, the conventional interrupted knotted suture technique group tend to use 1.6 times suture materials per unit. The price of Stratafix should not exceed 1.6 times that of conventional suture materials for the barbed suture technique to be cheaper than the conventional interrupted knotted suture technique for a surgical wound suture of the same length.⁷⁾

Conventional sutures require multiple knots, which may aggravate foreign body reactions and act as a nidus of infection, increasing the chance of stitch abscess formation and wound infection. However, the complication of the barbed suture technique group in this study, in which the initial tap protruded through the surgical wound, occurred due to a lack of surgical skill and relatively thin subcutaneous tissue near the anterior superior iliac spine of the pelvis. The authors attempted to verify the effectiveness of this technique in the field of orthopedic surgery, especially in various areas of the extremities. In this study, the authors intended to report the results of using the barbed suture technique in a rather complex and diverse situation in all areas of orthopedic surgery, and the number of cases was determined based on realistic limitations and experiences from previous studies. The limitation of this study is that it covers orthopedic surgery under very diverse conditions through 254 patients in a relatively short period of time.

The barbed suture technique requires prior training and is expected to have a learning curve, which was not evaluated in this study. Barbed suture training using

the suture model was performed, and the training emphasized how to handle the initial tap and the final backward suture. During the training using the suture model, once excessive tension was applied, it was impossible to reduce the tension by pulling it back again. In the barbed suture technique, it was easy to solve when loose tension was applied to the tissue; however, once excessive tension is performed, it cannot be loosened while maintaining the corresponding suture knot, while in conventional sutures, this problem is solved by cutting the knot wherein excessive tension is applied and then re-suturing.

The average suture time per unit length increased for lengths under 5 cm as barbed sutures required more time from the first start and finish of the last suture. There was no significant benefit for very short suture length. One barbed suture material allows a suture of approximately 10–12 cm; sutures beyond that require more time because the surgeon has to start again. The Stratafix group used less suture material than the conventional group.

CONFLICT OF INTEREST

No potential conflict of interest relevant to this article was reported.

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REFERENCES

- Gentry LO, Feliciano DV, Lea AS, Short HD, Mattox KL, Jordan GL Jr. Perioperative antibiotic therapy for penetrating injuries of the abdomen. *Ann Surg.* 1984;200(5):561-6.
- Heller S, Rezapoor M, Parvizi J. Minimising the risk of infection: a peri-operative checklist. *Bone Joint J.* 2016;98(1 Suppl A):18-22.
- Daines BK, Dennis DA, Amann S. Infection prevention in total knee arthroplasty. *J Am Acad Orthop Surg.* 2015;23(6):356-64.
- Patel VP, Walsh M, Sehgal B, Preston C, DeWal H, Di Cesare PE. Factors associated with prolonged wound drainage after primary total hip and knee arthroplasty. *J Bone Joint Surg Am.* 2007;89(1):33-8.
- Jaberi FM, Parvizi J, Haytmanek CT, Joshi A, Purtill J. Procrastination of wound drainage and malnutrition affect the outcome of joint arthroplasty. *Clin Orthop Relat Res.* 2008;466(6):1368-71.
- Rattanaprichavej P, Laorueangthana A, Galassi M, Weerakul S, Rasamimongkol S. Contamination rate of burnt necrotic tissue after electrocoagulation in total knee arthroplasty. *Clin Orthop Surg.* 2020;12(1):43-8.
- Chan VW, 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):1474-7.
- Faour M, Khlopas A, Elmallah RK, et al. The role of barbed sutures in wound closure following knee and hip arthroplasty: a review. *J Knee Surg.* 2018;31(9):858-65.
- Shah A, Rowlands M, Au A. Barbed sutures and tendon repair: a review. *Hand (N Y).* 2015;10(1):6-15.
- Mikhail E, Wyman A, Hahn L, Hart S. Barbed sutures in minimally invasive gynecologic surgery. *Surg Technol Int.* 2016;28:185-91.
- Uccella S, Zorzato PC, Kho RM. Incidence and prevention of vaginal cuff dehiscence after laparoscopic and robotic hysterectomy: a systematic review and meta-analysis. *J Minim Invasive Gynecol.* 2021;28(3):710-20.
- Wiggins T, Majid MS, Markar SR, Loy J, Agrawal S, Koak Y. Benefits of barbed suture utilisation in gastrointestinal anastomosis: a systematic review and meta-analysis. *Ann R Coll Surg Engl.* 2020;102(2):153-9.
- Sull A, Inceoglu S, August A, Gregorius S, Wongworawat MD. Comparison of barbed sutures in porcine flexor tenorrhaphy. *Hand (N Y).* 2016;11(4):475-8.
- Regier PJ, Smeak DD, McGilvray KC. Security and biomechanical strength of three end-pass configurations for the terminal end of intradermal closures performed with unidirectional barbed suture material in dogs. *Am J Vet Res.* 2016;77(12):1392-400.
- Law AY, Butler JR, Patnaik SS, Cooley JA, Elder SH. Biomechanical testing and histologic examination of intradermal skin closure in dogs using barbed suture device and non-barbed monofilament suture. *Vet Surg.* 2017;46(1):59-66.
- Hurwitz DJ, Reuben B. Quill barbed sutures in body contouring surgery: a 6-year comparison with running absorbable braided sutures. *Aesthet Surg J.* 2013;33(3 Suppl):44S-56S.
- Koide S, Smoll NR, Liew J, et al. A randomized 'N-of-1' single blinded clinical trial of barbed dermal sutures vs. smooth sutures in elective plastic surgery shows differences in scar appearance two-years post-operatively. *J Plast Reconstr Aesthet Surg.* 2015;68(7):1003-9.
- Krishnamoorthy B, Shepherd N, Critchley WR, et al. A randomized study comparing traditional monofilament knotted sutures with barbed knotless sutures for donor leg wound closure in coronary artery bypass surgery. *Interact Cardiovasc Thorac Surg.* 2016;22(2):161-7.
- Elmallah RK, Khlopas A, Faour M, et al. Economic evaluation of different suture closure methods: barbed versus traditional interrupted sutures. *Ann Transl Med.* 2017;5(Suppl 3):S26.
- Li R, Ni M, Zhao J, et al. A modified strategy using barbed sutures for wound closure in total joint arthroplasty: a prospective, randomized, double-blind, self-controlled clinical trial. *Med Sci Monit.* 2018;24:8401-7.
- Goyal KS, Speeckaert AL, Goitz RJ, Tavana ML. A comparison of barbed suture versus traditional techniques for muscle belly repair. *Hand (N Y).* 2019;14(1):91-4.
- Manigrasso M, Velotti N, Calculli F, et al. Barbed suture and gastrointestinal surgery: a retrospective analysis. *Open Med (Wars).* 2019;14:503-8.