

A Prospective, Randomized and Controlled Study on Tissue Adhesive for Skin Incision in Total Knee Arthroplasty

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Research article

Keywords: total knee arthroplasty, tissue adhesive, incision closure, dressing change

Posted Date: January 15th, 2020

DOI: <https://doi.org/10.21203/rs.2.20714/v1>

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Version of Record: A version of this preprint was published at Therapeutics and Clinical Risk Management on August 1st, 2020. See the published version at <https://doi.org/10.2147/TCRM.S260007>.

Abstract

Background

The study focusing on the tissue adhesive in total knee arthroplasty (TKA) was rare. This study aimed to evaluate the clinical outcomes and economic costs of tissue adhesive when acting as the adjunct to standard incision closure in TKA.

Methods

From September 2019 to November 2019, we prospectively enrolled the consecutive patients who underwent simultaneous bilateral TKA in our institute. The allocation whether using the tissue adhesive was done after the subcuticular suture in right knee first and another method was applied in the left knee automatically. The patients' demographics, length of stay (LOS), times of dressing changes and incision-related cost, range of motion (ROM), incision-related complications and incision evaluation scores were recorded.

Results

Thirty-two patients were enrolled in this study and followed at two months after surgery. In the knees of tissue adhesive, the times of dressing change and patient scar assessment scores (PSAS) were significantly less than those in the control group ($p=0.000$; $p=0.003$). Although there were no significant differences of the delayed discharge, incision-related cost, ROM, incision-related complications and Vancouver scar score (VSS) between two groups, 65.6% (21/32) patients preferred the tissue adhesive and only 15.6% (5/32) patients preferred the standard incision closure.

Conclusions

Tissue adhesive could effectively reduce postoperative wound drainage and improve patients' satisfaction rate with no difference in medical costs and ROM in TKA. The application of tissue adhesive and subcuticular sutures might be a relatively ideal method of skin closure in TKA.

Background

In order to improve postoperative rehabilitation and patient satisfaction, the concept of enhanced recovery after surgery (ERAS) has gained huge attentions in joint surgery. The ideal incision closure, as an important part of ERAS, should resist some tension, promote skin healing, inconspicuous scars and less complications [1, 2].

At present, the standard methods of incision closure in total knee arthroplasty (TKA) are staples and sutures [3, 4]. However, the above methods have several obvious flaws [1, 5]. Firstly, skin staples and sutures doesn't solve the underlying problem of wound drainage. Secondly, the postoperative regular wound care, including disinfection and dressing changes, increased surgeons' workload and economic

burden. Thirdly, the residual scar has poor appearance and lowered the patient's satisfaction. Thus, the standard methods of incision closure in TKA are far from perfect.

In recent years, tissue adhesive has been used in surgery and reported to have satisfying clinical results [6–11]. 2-Octylcyanoacrylate, the main ingredients of tissue adhesive, could form a firm bond in 30 seconds when contacting the water or blood. The firm bond could cut off the wound from the outside environment and eliminate wound drainage effectively [12, 13]. So the tissue adhesive may be an ideal alternative to incision closure.

Although several clinical studies have validate the safety and effectiveness of tissue adhesive, there was no clinical trial focusing on the effect of tissue adhesive when acting as the adjunct to standard incision closure in TKA. Therefore, this prospective and self-control study aims to compare the clinical outcomes and economic costs of tissue adhesive and subcuticular suture for incision closure versus just subcuticular suture in simultaneous bilateral TKA.

Patients And Methods

Study population and design

From September 2019 to November 2019, we prospectively enrolled the consecutive patients who underwent simultaneous bilateral TKA because of osteoarthritis (OA) in our institute. The study was approved by the local ethics committee (S2019-166-01) and registered at Chinese Clinical Trial Registry (the clinical trial registration number: ChiCTR1900025730). Inclusion criteria: 1. the same kind of prosthesis used in bilateral knee; 2. bilateral surgeries were performed through the anterior knee midline incision and median parapatellar approach; 3. the written informed consent was obtained prior to participating in this study. Exclusion criteria: 1. previous scar or suspected infection around the surgical skin; 2. keloid, psoriasis, eczema or other skin diseases; 3. allergy to the tissue adhesive; 4. underlying malignant tumors; 5. regular anticoagulation therapy; 6. peripheral vascular diseases such as venous thrombosis of lower limbs or arterial occlusion of lower limbs.

Allocation and randomization

All patients underwent the right TKA firstly and left secondly. The fixed surgical team performed the surgeries and two residents performed the incision closure. Tranexamic acid (TXA, 1.0g) was given intravenously twice before exposure and incision closure. Incision closures were performed in four layers in approximately 45° flexion of knee (Table 1).

The allocations were done after the subcuticular suture in right knee. The surgeon and the assistants remained blinded before the allocations. The method of incision closure was randomized using the computer-generated method in the opaque envelopes. One represented the tissue adhesive group and two represented the control group. The left knee automatically entered another group (Figure 1).

The residents applied the tissue adhesive evenly on the skin surface and waited for 30 seconds before employing the sterile dressing. During the hospital stay, the patients would have dressing change if blood or exudate soaked the dressing. All patients received antibiotics within 24 hours and aspirin in postoperative 14 days. In our institute, the discharge guideline for simultaneous bilateral TKA is four days after surgery if there was no wound drainage.

Sample size calculation

According to the previous study and our preliminary results, we set $\alpha=0.05$, $\beta=0.10$, the mean difference of dressing change was 1.0. An estimated 24 patients would be needed to provide 90% power [14]. Finally, we decided to enroll 30 patients, which allowed for 20% loss to follow up.

Follow-up and incision evaluation

The preoperative, intraoperative and postoperative information of each patient, including age, gender, body mass index (BMI), postoperative length of stay (LOS), the times of dressing changes and the incision-related cost, were collected. Any delay in regular discharge (postoperative 4 days) due to incision was recorded.

Incision-related cost was the sum of cost of the suture, tissue adhesive, dressing, prolonging the use of antibiotics and other additional materials.

At two-month follow-up after surgery, the range of motion (ROM), incision-related complications and incision evaluation scores were recorded. ROM was measured by the electronic protractor through its two dividing rods running along the long axis of the femur and tibia. Incision-related complications were defined as redness, dehiscence, subcutaneous hematoma, delayed wound drainage (>4days). Incision evaluation scores included patient scar assessment score (PSAS) and Vancouver scar score (VSS). PSAS was evaluated by the patients themselves. ROM and VSS were evaluated by two independent orthopedic residents (KXP and YMZ), who were unknown to which side adopted the tissue adhesive. Both two residents received professional training and maintain satisfying consistency of incision evaluation prior to conducting the clinical trial. The mean two degrees and scores evaluated by the two resident were regarded as the final scores. In addition, all patients were asked which knee of incision closure they preferred.

1. Patient scar assessment score (PSAS): the scoring system mainly refers to the patient's own feeling and the evaluation of incision [15]. Six represents normal skin and sixty represents worst imaginable scar in the patient's scale (Table 2).
2. Vancouver scar score (VSS): the scoring system includes 4 items, which includes vascularity, pliability, height and pigmentation [16]. On this scale, lower scores represent a more normal appearance (Table 3).

Statistical analysis

All statistical analyses were performed by SPSS version 22 (Inc., Chicago, IL, USA). Data are showed as median, mode and inter quartile range (IQR) (skewed distributio) or mean±standard deviation (SD) (normal distribution). Measurement data were analyzed by student's tests or rank-sum test. Count data were analyzed by rank-sum test or Fisher exact test. A value of $\alpha=0.05$ suits all tests. The intraclass correlation coefficient (ICC) was used to assess the observers' agreement: 0.81 to 1.00, nearly perfect reliability; 0.61 to 0.80, strong reliability; 0.41 to 0.60, moderate reliability; 0.21 to 0.40, fair reliability; and 0 to 0.20, poor reliability. The inter-observer agreements of ROM and VSS were found to have nearly perfect reliability (ICC >0.81).

Results

Forty-one patients met the inclusion and exclusion criteria, and five patients declined to participate in the clinical trial. Three patients failed to complete the regular two-month follow-up and one patient underwent knee revision because of periprosthetic femoral fracture on the postoperative 10th day. Finally, the remaining thirty-two patients were enrolled in this study (Figure 2).

Among the remaining 32 patients, 62.5% (20/32) patients were female. The median age was 58 years and the mean postoperative LOS was 4 days (Table 4). In the knees of tissue adhesive, the times of dressing change and PSAS were significantly less than those in the control group ($p=0.000$; $p=0.003$). There were no significant differences of the incision-related costs, incision-related complications, VSS, delayed discharge and ROM between two groups (Table 5).

In the knees of tissue adhesive, one patient with delayed wound drainage received pressurized dressing and prolonged use of antibiotics. In the knees of standard incision closure, four patients occurred delayed wound drainage. Three of them received pressurized dressing and prolonged use of antibiotics. One of them received re-suture and prolonged use of antibiotics. All these five patients' incision healed well before discharge. There was no periprosthetic joint infection or other incision-related complications in this cohort.

Finally, 65.6% (21/32) patients preferred the tissue adhesive and only 15.6% (5/32) patients preferred the standard incision closure (Figure 3).

The appearances of incisions in simultaneous bilateral TKA at postoperative two month showed in Figure 4.

Discussion

Tissue adhesive is a sterile glue that exists in liquid form. Its chemical composition (2-octylcyanoacrylate) could rapidly polymerize in contact with hydroxyl ions of the blood and water. The resultant polymer is biodegradable within about ten days and bacteriostatic to gram-positive bacteria [9].

Incision closure can be a key factor in early rehabilitation of TKA. Skin sutures and staples have proven to have satisfying safety in clinical practise [4, 8]. However, the advent of ERAS promotes more earlier rehabilitation and less hospital stays following TKA, which draws two additional demand for incision closure. One is more cosmetic appearance, another one is less incision care, including regular disinfectant and removal of sutures or staples.

To cater to fast rehabilitation and cosmetic need, some surgeons introduced the tissue adhesive in orthopedic surgeries [17–19]. But the clinical study on the comparison with subcuticular suture in joint surgery was rare [10, 20–22].

Roumeliotis and Graham reported that tissue adhesive with subcuticular suture application was a viable option for skin closure after lower limb arthroplasty and can reduce the incidence of prolonged wound discharge [23]. However, their study had several obvious limitations. Firstly, the study was retrospective and two groups of patients came from different time periods. Secondly, the incidence and duration of prolonged wound exudate were extracted from the medical records, but the bias in the subjectivity and reliability of medical record can't be controlled properly. Thirdly, the study enrolled the patients undergoing total hip or knee arthroplasty and TKA accounted for only a third.

In another similar randomized and self-controlled study, Gromov et al enrolled 29 patients undergoing simultaneous bilateral TKA [14]. They found that tissue adhesive plus skin staples could reduce the number of dressing changes after surgery, but not change the appearance or healing of the wound at postoperative 3 weeks. Their study only analyzed the wound drainage during the first postoperative 72 hours and didn't compared the medical costs and satisfaction rate between two groups.

Although some surgeons have successfully applied the tissue adhesive in TKA, it is still too reckless to completely replace skin sutures or staples by tissue adhesive for skin closure. One prospective randomized and controlled clinical trial compared 2-octylcyanoacrylate, subcuticular suture and skin staples for skin closure following hip and knee replacement. They found that tissue adhesive in knee replacement was more directly associated with prolonged wound discharge [7]. So we adopted the tissue adhesive as the supplement to, not substitute for subcuticular closure in this study.

This was the first study on comparing the clinical outcome, medical cost and patient preference of tissue adhesive plus subcuticular sutures with just subcuticular sutures in simultaneous bilateral TKA. The prospective and self-controlled clinical trial has eliminated the patients' personalized characteristics, such as BMI, individual healing abilities and systemic disease.

In this study, we found that tissue adhesive combining with subcuticular sutures could effectively reduce postoperative wound drainage with the similar medical cost and ROM in TKA. The application of tissue adhesive and subcuticular sutures might be a relatively ideal method of skin closure for fast-recovery TKA.

Although the mere subcuticular sutures could provide the patients with superior cosmetic appearance and enough resistance to skin tension during knee flexion, it still left the problem of incision drainage unresolved [24–26]. In this study, just the application of subcuticular sutures in TKA was more likely to be

the dragging reason of delayed discharge, especially in obese patients. Prolonged fat liquefaction or aseptic exudation could form a flow channel, where microorganisms can cause superficial or even deep infections. The tissue adhesive could isolate the internal incision and prevent the outside microorganisms from invading through the unhealed incision. Several studies also approved this view. As El-Gazzar and Gromov et al reported, when the tissue adhesive worked as an adjunct to skin staples after TKA, it could decrease post-operative wound drainage [11, 14]. Easier care of incision and fewer need of physicians could facilitate the patients' early daily life greatly. The patients can go straight home from the hospital without having to go to the rehabilitation institute or clinic just for incision observation. With the similar medical costs during the hospital stay, patients preferred the combination of tissue adhesive and subcuticular suture than the control group. If the incision-related costs after discharge were took into consideration, perhaps the additional material cost of the tissue adhesive would be offset or even exceed. The use of tissue adhesive could increase the patients' satisfaction and confidence in surgery, which was also found in other studies [10, 27].

The risk of allergy to tissue adhesive can't be ignored, while we didn't find any allergic contact dermatitis in this cohort. Several studies reported that the rate of allergy to tissue adhesive ranged from 0.5–1.7% [28, 29]. Another limiting factor for tissue adhesive was the additional costs. Notice, however, that the overall costs remain unchanged or even reduced when using tissue adhesive [20, 21].

The present study also had several important limitations. Firstly, the sample size and follow-up were small and short. Larger sample size and longer follow up are needed to analyze the incidence of infection and readmission. In fact, given that the prospective controlled clinical trial and incision healing period, it has already applied enough information and data. Secondly, the incision evaluation scales had subjective bias. Fortunately, the evaluation scores between the two observers had NEARLY PERFECT RELIABILITY. Thirdly, because the price of tissue adhesive varied in different regions and the incision-related costs after discharge were not included, the overall medical cost in this study might not applicable to other institutes. Fourthly, the patients undergoing simultaneous bilateral TKA generally have fewer medical disease when compared with the patients undergoing unilateral TKA, which might interfere with the incision healing.

Conclusions

Tissue adhesive could effectively reduce postoperative wound drainage and improve patients' satisfaction rate with no difference in medical costs and ROM in TKA. The application of tissue adhesive and subcuticular sutures might be a relatively ideal method of skin closure in TKA.

Abbreviations

ERAS: enhanced recovery after surgery; TKA: total knee arthroplasty; OA: osteoarthritis; TXA: tranexamic acid; BMI: body mass index; LOS: length of stay; ROM: range of motion; PSAS: patient scar assessment score; VSS: Vancouver scar score; IQR: inter quartile range; SD: standard deviation; ICC: intraclass correlation coefficient.

Declarations

Ethics approval and consent to participate: The study was approved by the medical ethics committee of Chinese PLA General Hospital (S2019-166-01) and registered at Chinese Clinical Trial Registry (clinical trial registration number: ChiCTR1900025730; Registered 6 September 2019; <http://www.chictr.org.cn/edit.aspx?pid=43067&htm=4>). All procedures were conducted in compliance with the guidelines of the Declaration of Helsinki. The patients were informed consent prior to their participation in the study.

Consent for publication: We have obtained consent for publication.

Availability of data and material: All data generated or analyzed during this study are included in this published article.

Competing interests: The authors declare that they have no competing interests.

Funding: Beijing Municipal Natural Science Foundation (L182063).

Author Contributions: All authors have made substantial contributions to: (1) the conception and design of the study, acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; (3) final approval of the version to be submitted. WC and YW: primarily responsible for oversight of the research project, including all data acquisition and analysis, manuscript preparation and approval. WC and YW were the co-corresponding authors. XK and MY: primarily responsible for all computational analyses in the article and the drafting of the manuscript. XK and MY were the co-first authors. RG and JC: revised the manuscript and helped perform the analysis with constructive discussions. All authors have read and approved the final submitted manuscript.

Acknowledgement: Not applicable.

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Tables

Table 1. Suture material for incision closure in different layers.

Layer	Tissue adhesive group	Control group
Joint capsule	2-0 absorbable knotless barbed suture (Quill, Surgical Specialties Corporation, IL, USA); 2-0 Ethibond non-absorbable suture W4843 (Ethicon, Somerville, NJ, USA)	No difference
Subcutaneous tissue	4-0 coated Vicryl Plus antibacterial suture (Ethicon, Somerville, NJ, USA)	No difference
Subcuticular tissue	4-0 absorbable knotless barbed suture (Ethicon, Somerville, NJ, USA)	No difference
Skin	HISTOACRYL® tissue adhesive (B.Braun, Melsungen, German)	None

Table 2. Patient scar assessment score (PSAS).

*	1	2	3	4	5	6	7	8	9	10
Is the scar painful?										
Is the scar itching?										
#	1	2	3	4	5	6	7	8	9	10
Is the color of the scar different?										
Is the scar more stiff?										
Is the thickness of the scar different?										
Is the scar irregular?										
Total score Patient Scar Score										
* 0 means “no, no complains”,10 means “yes, more imaginable”										
# 0 means “no, as normal skin”,10 means “yes, very different”										

Table 3. Vancouver scar score (VSS).

Score	Vascularity	Pliability	Height	Pigmentation
0	Normal	Normal	Flat	Normal
1	Pink	Supple	< 2mm	Hypopigmentation
2	Red	Yielding	2-4mm	Mixed
3	Purple	Firm	> 4mm	Hyperpigmentation
4	-	Banding	-	-

Table 4. The demographic data in the thirty-two patients.

Demographics	Data
Age (median, mode, IQR) (years)	58, 55, 7
Male:Female	12: 20
BMI (mean $\pm$ SD) (kg/m ²)	26.34 $\pm$ 3.11
Postoperative LOS (mean, mode, IQR) (days)	4.5, 4, 2

IQR: inter quartile range. BMI: body mess index. SD: standard deviation. LOS: length of stay.

Table 5. Comparisons of closure time, dressing change, pain, incision evaluation scores and complications between two groups.

Evaluation index	Tissue adhesive group	Control group	P
Dressing change (median, mode, IQR)	1, 1, 0	2.5, 3, 2	0.000
Incision-related costs (mean±SD) (US dollar)	242.39±10.12	221.83±13.55	0.423
Incision-related complications	1/31	4/28	0.355
PSAS (mean±SD)	22.83±9.48	30.57±9.54	0.003
VSS (mean±SD)	5.13±1.16	5.77±1.16	0.737
Delayed discharge	1/31	4/28	0.355
ROM (°, mean±SD)	99.19±8.12	100.48±7.93	0.183

IQR: inter quartile range. SD: standard deviation. PSAS: patient scar assessment score. VSS: Vancouver scar score. ROM: range of motion.

Figures



Figure 1

The appearances of bilateral incisions in the operating room (right: tissue adhesive group; left: control group).

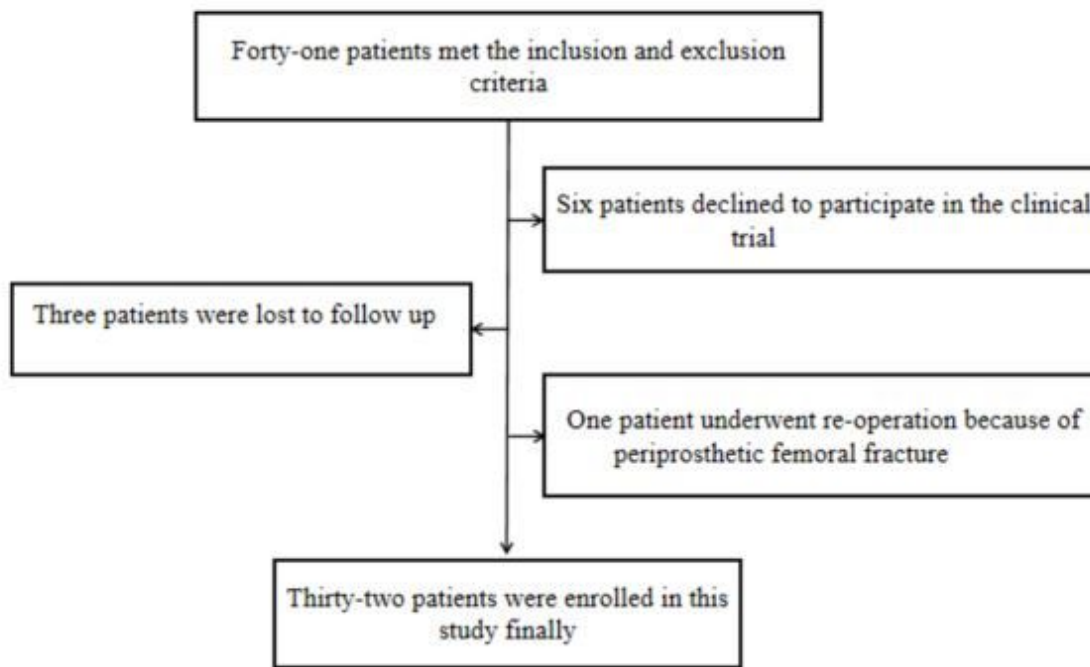


Figure 2

Flow chart of patient enrollment in this prospective study.



Figure 3

The preference distribution for incision closure in the thirty-two patients.



Figure 4

The appearances of bilateral incisions at postoperative two month (right: tissue adhesive group; left: control group).