CLINICAL STUDY PROTOCOL

Version: 1.0

Document Date: October 11, 2023

NCT06232018

Title:

A Comparison of 2-Octyl Cyanoacrylate Skin Adhesive and Polyester Mesh for Wound Closure in Total Knee Arthroplasty: A Randomized Controlled Study

Sponsor:

Hatyai Hospital, Songkhla, Thailand

Principal Investigator:

Pooriwat Lertsurawat, MD

Email: Pooriwat999@gmail.com

Phone: +66-876329824

IRB Approval:

HYH EC 059-66-01

1. Background and Rationale

Nowadays, there are many methods of wound closure in Total Knee arthroplasty, such as nylon, skin staple, and sterile strip, which differ in advantages and disadvantages of each technique. However, these methods have the same disadvantages: wound discharge, which may lead to infection, wound separation, and the need for wound dressing. It is also a burden for patients and caregivers. In travelling to change the wound in a hospital, There are many costs in terms of wound dressing equipment, travel costs and time off from work for caregivers to take patients to get wound dressing.

Skin adhesive is an innovation for wound closure in total knee arthroplasty. It reduces the problem of wound separation, with no need for wound dressing.

Skin adhesive mesh has been studied in many studies, showing that it can be used well. Strong It is no different from traditional wound closure; the scar is more beautiful. Patients are more satisfied. But the disadvantage is the high price.

Skin adhesive without polyester mesh has the advantage of being cheaper three times than polyester mesh but less intense than with mesh. This makes it unpopular.

No studies have been found comparing wound dressings with mesh and no mesh After knee replacement surgery.

Therefore, this study is to compare skin adhesive and skin adhesive plus polyester mesh in closure wound total knee arthroplasty.

Are there differences in patient satisfaction Are wound complications such as wound oozing, wound separation, superficial wound skin infection, and contact dermatitis different?

2. Objectives

Primary Objective:

To compare POSAS scores between skin adhesive alone and skin adhesive with polyester mesh at 6 weeks.

Secondary Objectives:

To compare Vancouver Scar Scale scores, wound leakage area (mm2), wound complications, and allergic contact dermatitis.

3. Study Design

Prospective, single-center, randomized controlled parallel-group study with 80 participants randomized 1:1.

4. Eligibility Criteria

Inclusion:

- Age 50–80 years

- Undergoing primary unilateral TKA

Exclusion:

- Prior knee surgery

- Keloid scar history

- Psoriasis at operative site

- Contact dermatitis to adhesive

- Cognitive impairment

5. Randomization and Blinding

Block randomization using block sizes 4 and 6. Allocation concealed with opaque envelopes. Outcome assessor blinded.

6. Interventions

:Every patient received TKA using the same surgical methods and instruments.

Group 1: 2-octyl cyanoacrylate skin adhesive

Group 2: 2-octyl cyanoacrylate skin adhesive + polyester mesh

7. Outcome Measures

Primary:

POSAS total score at 6 weeks.

Secondary:

POSAS score at 3 months

Vancouver Scar Scale (VSS) at 6 weeks.

Wound leakage area measured using 1 mm2 grid.

Wound complications: dehiscence, superficial infection, allergic contact dermatitis.

8. Study Procedures and Follow-Up

- Every patient received TKA using the same surgical methods and instruments and received standard postoperative protocol.

- Following subcuticular suturing, patients were randomized into two treatment arms

- All wounds in both groups were then covered with a 20 × 10 cm Waterproof Wound Dressing

- Follow up at 2 weeks post-operative to evaluate wound drainage by placing the waterproof dressing on the table grid, then use a millimeter grid to count the number of grid squares stained with blood. (Wound leakage measurement).

- Scar evaluation at 6 weeks (POSAS, VSS).

9. Statistical Analysis Plan

Continuous variables assessed for normality.

- Mann–Whitney U test for nonparametric outcomes.

- Independent t-test for parametric variables.

Categorical outcomes: chi-square or Fisher's exact test.

Significance level: $p < 0.05$.

10. Ethics

This protocol was approved by the institutional ethics committee (Protocol no. HYH EC 059-66-01) and was conducted in accordance with the Declaration of Helsinki

11. Data Handling and Confidentiality

Participant data will be de-identified and securely stored. Only the research team will have access, and confidentiality will be strictly maintained.

12. Funding

Supported by Hatyai Hospital Research Fund. No commercial funding.

End of Protocol.