Cover Page

WOUND CLOSURE AFTER TOTAL KNEE ARTHROPLASTY: COMPARISON OF POLYPROPYLENE AND POLYGLACTIN 910 SUTURE-A RANDOMISED CONTROLLED TRIAL

NCT no not yet assigned

Date: 04/02/2022

MATERIALS AND METHODS:

The present parallel randomized controlled trial was conducted to compare the outcomes of wound closure using polypropylene versus subcuticular polyglactin 910 sutures in patients undergoing total knee arthroplasty (TKA).

Ethical approval:

Approval for the Indus Hospital and Health Network institutional review board was obtained beforehand. (IRB# 2021_10_004)

Patient selection:

All patients aged 50-80 years, belonging to either sex, diagnosed with end-stage osteoarthritis or post-traumatic arthritis, and scheduled for bilateral primary total knee arthroplasty at the Department of Orthopedics, Indus Hospital and Health Network, Karachi were enrolled in the study. Exclusion criteria included patients having existing skin, neuromuscular, or connective tissue disorders, rheumatoid arthritis, immunosuppression, morbid obesity, and pregnancy. All patients provided voluntary informed written consent before enrolment in the study.

Intervention:

In all patients undergoing primary TKA, one knee was closed using polypropylene, whereas the other was closed with Polyglactin 910 sutures. All surgeries were performed by the same surgical team using a standard medial parapatellar approach. The number of sutures and wound closure techniques were standardized across both groups.

Outcomes:

Wound healing was then assessed in the postoperative period at regular intervals (days +3, +7, +15, and +30). Wound-related complications such as surgical site infection (SSI), dehiscence, delayed healing, and Hollander score were recorded. Patient-related outcomes such as pain levels and satisfaction with wound healing were also assessed.

Randomization:

The patients were randomized assigned into two groups. The samples were allocated into two groups by a simple randomization technique using computer generated random numbers. The

choice of procedure was determined based on whether the number fell into either group A or B. Group A had wound closure via polypropylene suture while Group B with polyglactin 910.

Statistical analysis:

Data analysis was performed using SPSS version 24.0. After assessing the normality of the data, all continuous variables were represented as medians (IQR). Discrete variables are shown as frequencies and percentages. The Hollander score prediction model was used to evaluate the correlation between the Hollander score and all independent variables. Statistical significance was set at $P < 0.05$.

Results:

A total of forty patients were enrolled in this study. There was a female predominance in the present study, with a M:F ratio of 1:2.07 (Table 1). The median (IQR) age of the study participants was 58 years (50.5 - 69.0 years). Hypertension was the most frequent comorbidity [33(82.5 %)], followed by diabetes mellitus [15 (37.5%)].

At baseline, ASA of Anesthesiologists grade II was the most frequently observed class in the study cohort (85%). The complications and the Hollander score of the patients as observed in the two suture groups are displayed in Table 2. Presentation of erythema was observed in more patients in the polypropylene group versus polyglactin 910 group for postoperative days 3, and 7 i.e. 21 versus 16, and 14 versus 12 respectively but then became vice versa for days 15, and 30 during which the polyglactin 910 group had more patients i.e. 5 versus 3 and 2 versus 0 respectively. The polyglactin 910 group had a higher number of patients in comparison to the polypropylene group for parameters such as wound dehiscence (3 versus 0), wound discharge (24 versus 16), blisters (3 versus 2), stitch abscess (3 versus 1), >1 cm of cellulitis (16 versus 12), step-off border (17 versus 15), >2mm width scar (10 versus 9), and suture removal due to infection (3 versus 1). The polyglactin 910 group also had a higher of patients with systemic symptoms compared to the polypropylene group (7 versus 4). Poor overall cosmesis was observed in an equal number of patients in both suture groups i.e. 8 (20%). The median Hollander score in both suture groups was reported to be 6. In terms of the correlation coefficient, age [-0.076 (0.042)], weight [-0.121 (0.047)], and presence of diabetes mellitus [-

1.335 (0.741)] had a positive while height [0.095 (0.045)] had a negative correlation on the prediction of Hollander score

IRB Number: IHHN_IRB_2021_10_004
PI Name: Nek Mohammad
PI version: v1, Oct 2021

CONSENT FORM

Study Title: Wound closure after Total knee Arthroplasty: comparison between polypropylene and polyglactin 910 sutures

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What you should know about the study:

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- You are a volunteer. You have the right to choose whether to participate or not participate in this study. If you decide to participate and later change your mind, you may do so without any penalty or consequences to your treatment here.

Purpose of research project:

To compare the wound healing in patient undergone Total Knee Arthroplasty, comparison between non-absorbable polypropylene and absorbable polyglactin 910. Currently in our setup we are using polypropylene for the wound closure and facing wound complication and prolong hospital stay of the patient. So with this study if we found polyglactin is superior then the polypropylene then we can switched to polyglactin for wound closure. We will be enrolled 60 participants in this study 30 in each group.

What you will be asked to do in this study

If you are agreed for this research, then you will be placed in one of the two groups.

Group A: wound closed with Non-absorbable polypropylene which is routine at The Indus hospital

Group B: wound closed with absorbable polyglactin 910.

Privacy: We assure you that your research information will be kept secret. We will use ID numbers instead of your name. Your name will not be given to anyone without your consent. Your doctor, researchers from Indus Hospital will be able to look at your medical records. It is possible that research papers may be published for scientific purposes; however, your name nor that of any other participant will not be used.

Risks and Discomfort:

No risk involved as it is a post-operative wound status comparison study of two different sutures.

Benefits:

If by doing this study if we found Non-absorbable polyglactin 910 has good result, then it will be beneficial for future patients undergone total knee arthroplasty.

Alternatives:

You have the choice of not being part of the study.

What happen if you choose not to be part of the study?

	APPROVED by IHHN Institutional Review Board **4 Feb 2022** Approved on **3 Feb 2023** Expires on **DO NOT USE THIS FORM AFTER APPROVAL EXPIRY**	IRB Number: IHHN_IRB_2021_10_004 PI Name: Nek Mohammad PI version: v1, Oct 2021

If you decide not to participate in this research, your operation at the hospital will continue as usual. Even after signing this consent form, you may stop participating at any time.

Cost of taking part in research: You do not have to pay for taking part in this study.

Payment for taking part in research: You will not get money to be part of this study.

Who do I call if have questions or problem?

If you have questions about this research, you can contact Dr. Nek Mohammad He can be contacted at The Indus Hospital, (Mobile 03153454744)

If you have questions about your rights in a research study as a volunteer, call or contact the Interactive Research & Development-IRB office between office hours on Monday to Friday 9am – 5pm at the Indus Hospital (Mobile 0300 827 2693)

SIGNATURES

If you agree to participate in this study, please sign this form. You will receive a copy of this form.

Sign of study volunteer/participant: _____ Date:_____

Sign of person taking consent: _____ Date: _____