



## Original Article

## Hand-Made Extra-Corporeal Knotting Versus Clip for Stump Closure in Laparoscopic Appendectomy

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## ABSTRACT

Acute appendicitis represents one of the most frequent surgical emergencies encountered in Pakistan. The delayed appendicitis and increased infection risks may impact postoperative outcomes and surgical decision-making. **Objectives:** To evaluate and compare hand-made extracorporeal knotting with polymeric clip closure in laparoscopic appendectomy, focusing on intraoperative performance measures and the incidence of early postoperative complications, including postoperative ileus, wound infection, and intra-abdominal infection within 15 days.

**Methods:** A randomized controlled trial (NCT ID: 07281612) was carried out in the Department of Surgery, Abbas Institute of Medical Sciences, Muzaffarabad, over a period of twelve months. Using simple lottery-based random allocation, 190 patients diagnosed with uncomplicated acute appendicitis were recruited and assigned to either the hand-made extracorporeal knotting group (n=95) or the polymeric clip closure group (n=95). Relevant demographic, clinical, and intraoperative parameters were systematically documented. **Results:** The two groups demonstrated broadly comparable baseline profiles. However, the mean duration of surgery was modestly but significantly greater in the knotting group than in the clip group ( $45.8 \pm 8.9$  vs  $42.8 \pm 8.2$  minutes;  $p=0.025$ ). Intra-abdominal infection was observed in 1.1% of patients undergoing knotting compared with 6.3% of those receiving polymeric clips ( $p=0.049$ ). On logistic regression, polymeric clip use was associated with increased odds of intra-abdominal infection (adjusted odds ratio 4.82; 95% confidence interval 1.01–22.73;  $p=0.048$ ). **Conclusions:** Hand-made extracorporeal knotting results in a significantly lower rate of intra-abdominal infection compared to polymeric clip closure. Despite a modest increase in operative time, the knotting technique may offer a safer and more effective option for stump closure.

## INTRODUCTION

Acute appendicitis is one of the most common causes of emergency abdominal surgery worldwide [1]. Laparoscopic appendectomy has become the preferred approach in many centers because it is associated with reduced postoperative pain, shorter hospital stays, and improved cosmetic outcomes compared with open appendectomy; however, secure closure of the appendiceal stump remains a critical step, and no single technique has been universally accepted as the standard of care [2]. Several techniques are used for appendiceal

stump closure during laparoscopic appendectomy. These include endoloops, endostaplers, metallic clips, polymeric clips, and hand-timed intracorporeal or extracorporeal knots [3]. Most studies show low complication rates with all common methods in uncomplicated appendicitis. Differences are mainly seen in operative time, technical difficulty, and device use rather than major clinical outcomes [4]. A systematic review found that approximately 20% of laparoscopic appendectomies use polymeric clips for stump closure, while 30% rely on

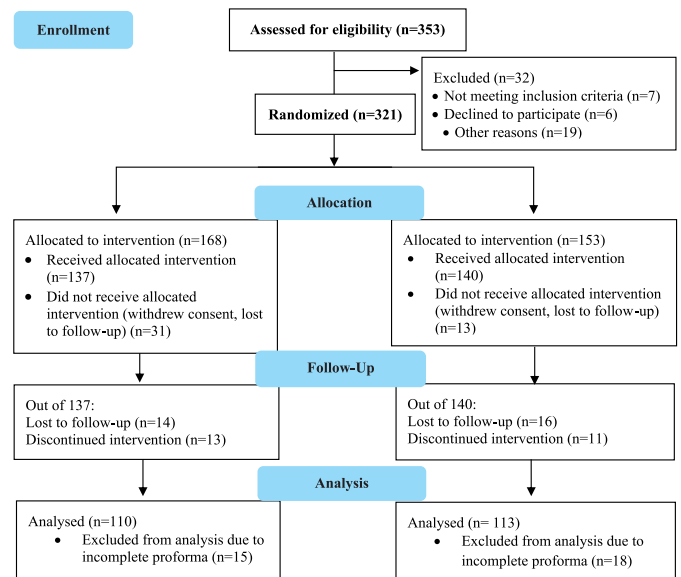
intracorporeal knotting, with significant variability in technique preference across different regions [5]. A study in India found that hand-made knotting resulted in lower postoperative infection rates (2%) compared to clips (5%) in laparoscopic appendectomy for uncomplicated appendicitis [6]. Polymeric clips have gained popularity due to their ease of application and potential to reduce operative time; however, concerns remain about their performance in cases with a wide or inflamed appendiceal base, where secure clip placement may be challenging. Hand-made extracorporeal knotting offers a low-cost and versatile alternative that can be adapted to varying stump diameters and tissue conditions, making it particularly attractive in resource-limited settings. Several randomized and observational studies comparing extracorporeal knotting and polymeric clip closure have reported broadly comparable safety outcomes, though results regarding operative time and postoperative infection have varied across populations [7]. Evidence from low- and middle-income countries remains limited, and findings from high-resource health systems may not be fully generalizable to surgical practice in Pakistan due to differences in case presentation, infection burden, and resource availability [8-10].

In Pakistan, the lack of locally generated randomized data means that the stump-closure technique is often determined by device availability and cost rather than comparative effectiveness or context-specific outcomes. Given these uncertainties, further randomized evaluation of stump-closure techniques is needed to clarify their relative safety and feasibility in settings with higher rates of delayed presentation and limited resources. Therefore, this randomized controlled trial was conducted to compare hand-made extracorporeal knotting and polymeric clip closure of the appendiceal stump in laparoscopic appendectomy for uncomplicated acute appendicitis, focusing on early postoperative outcomes relevant to clinical practice in Pakistan.

## METHODS

This randomized controlled trial took place in the Department of Surgery, Abbas Institute of Medical Sciences, Muzaffarabad as a one-year-long trial (Reference No. AIMS/SGR/1980/2024) following the College of Physicians and Surgeons, Pakistan (CPSP) approval of the study synopsis and the ethical permission granted by the Institutional Review Board of the Abbas Institute of Medical Sciences, Muzaffarabad. The study duration was from August 2024 to August 2025. The research was retrospectively enrolled on the clinicaltrials.org site with ID NCT07281612, which was registered. Patients were enrolled consecutively as they presented and met the predefined inclusion criteria, until the required sample size

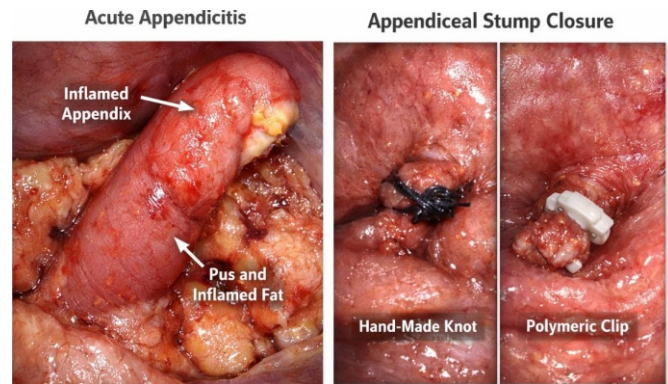
was achieved. Consecutive enrollment was used only for participant recruitment and did not determine group assignment. After enrollment and confirmation of eligibility, participants were randomly allocated to one of the two intervention groups using the predefined lottery-based randomization method. Thus, consecutive sampling ensured complete recruitment, while random allocation ensured unbiased group assignment. This was a single-centre, hospital-based study. The required sample size was calculated using the World Health Organization (WHO) sample size calculator for comparing two independent proportions. The calculation used a 95% confidence level ( $\alpha = 0.05$ ) and 80% power ( $\beta = 0.20$ ). Expected intra-abdominal infection rates were taken as  $p_1 = 0.0\%$  in the hand-made extracorporeal knotting group and  $p_2 = 6.3\%$  in the polymeric clip group, based on prior published data [11]. The sample size per group was computed using the standard formula for two proportions:  $n = [Z_{1-\alpha/2\sqrt{pq}}(2P(1-P)) + Z_{1-\beta\sqrt{p_1(1-p_1) + p_2(1-p_2)}}]2 \sqrt{(p_1-p_2)^2}$ . This yielded a minimum of 95 participants per group (total  $n = 190$ ). The study illustrates the CONSORT flow chart of patient selection and inclusion of patients in the RCT (Figure 1).



**Figure 1:** CONSORT 2010 Flow Diagram of the Included Participants

Only patients with uncomplicated acute appendicitis were included in the study. Patients with perforated appendix, appendicular abscess, appendicular mass, generalized or localized peritonitis, or friable appendiceal base were excluded. The subjects who chose to undergo an open appendectomy, or were found to have complicated appendicitis, before or during operative diagnosis, were left out. People with generalized or localized peritonitis, friable appendix base, or inflammatory disease of the pelvis were also not included. After taking informed written consent, demographic and clinical information were

recorded in a structured proforma. Pre-operative laboratory investigations included hemoglobin, random blood sugar, and total leukocyte count. Diagnosis of acute appendicitis was made clinically and radiologically. Ultrasound findings considered diagnostic included a non-compressible, blind-ended tubular structure in the right lower quadrant with an outer diameter greater than 6 mm, associated peri-appendiceal inflammatory changes, or the presence of an appendicolith. All patients underwent laparoscopic appendectomy under general anesthesia performed by the same surgical team. Randomization into two groups was done by the lottery method. Participants were randomly assigned in a 1:1 ratio to hand-made extracorporeal knotting or polymeric clip closure. The allocation sequence was generated before the start of recruitment using a simple lottery method. Equal numbers of identical slips (95 for Group A and 95 for Group B) were prepared, folded to the same size, and placed in an opaque container. For each eligible patient, one slip was drawn by an operating-room staff member who was not involved in enrollment, surgery, or outcome assessment. The drawn slip determined the stump-closure technique. The slip was revealed only after diagnostic laparoscopy confirmed uncomplicated appendicitis and eligibility, to avoid allocating patients who were later excluded for complicated disease. The allocation record was stored separately and was not available to the postoperative assessor. The laparoscopic appendectomy was performed using a standardized three-port technique. A 10-mm camera port was placed at the umbilicus, and two 5-mm working ports were placed in the left lower abdomen and suprapubic region. The mesoappendix was divided using monopolar electrocautery, and the appendicular artery was secured with double ligation using non-absorbable suture material (polypropylene 3-0). No advanced energy devices were used, and conventional ligation was performed for securing vessels. Appendiceal stump closure was done using either hand-made extracorporeal knotting (modified Tayside technique) or a non-absorbable polymeric double clip (Hem-o-Lok), depending on the randomized group assignment. In Group A, appendiceal stump closure was achieved using hand-made extracorporeal knotting by the modified Tayside method with two knots using non-absorbable suture material. In Group B, the stump was secured using a non-absorbable polymeric double clip. Each procedure was performed according to standard surgical guidelines, and the choice of technique was determined by random allocation rather than operator preference. The study shows an inflamed appendix and stump closure using a handmade knot and a polymeric clip (Figure 2).



**Figure 2:** Appendiceal Stump Closure Techniques

The operative time was measured from initial skin incision to completion of skin closure. The failure of technique was defined as any insecure knotting or clip dislodgement identified intra-operatively requiring conversion or revision. Patients were followed for 15 days post-surgery and evaluated for postoperative ileus, wound infection, and intra-abdominal infection confirmed by clinical features and imaging. In this study, complications were defined as follows: postoperative ileus was characterized by delayed return of normal bowel function, including abdominal distension, nausea, vomiting, and an inability to tolerate oral intake, with no passage of flatus or stool beyond 48 hours. Wound infection was diagnosed based on clinical signs of redness, warmth, swelling, or purulent discharge at the incision site. Intra-abdominal infection was identified by clinical symptoms such as fever, abdominal pain, or distension, accompanied by imaging findings confirming infection, occurring within 15 days post-surgery. These complications were monitored during the 15-day follow-up period. Postoperative pain at the operative site was assessed using a visual analogue scale (VAS) at 24 hours after surgery. All patients received standardized analgesia according to hospital protocol, including intravenous paracetamol and non-steroidal anti-inflammatory drugs, with additional analgesics administered as needed. The analgesic regimen was uniform for both groups to avoid bias in pain assessment. Postoperatively, patients were kept nil by mouth (NPO) for 6-12 hours until they tolerated oral intake, starting with liquids and progressing to a soft diet. Pain management was provided with standard analgesics. Patients were monitored for 48 hours for any complications, including wound infection and ileus. All patients were discharged after 2 days if stable and without complications. A 15-day follow-up was conducted to assess early postoperative outcomes, including wound infection, intra-abdominal infection, and postoperative ileus. To reduce bias, all the operations were performed by one team, and all the postoperative evaluation has been made by one resident who was not supposed to know the participant assignment. Data were collected using a

standardized proforma designed specifically for this study to ensure uniform and consistent documentation across both groups. The proforma was reviewed by senior faculty members for content validity before study initiation and was pilot-tested on a small number of cases to ensure clarity and completeness before final implementation. Possible confounding variables, such as comorbidities and duration of symptoms, were managed through stratified analysis when interpreting the data. All laboratory tests were in line with hospital requirements. The research procedures were conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants, or from guardians when participants were minors. All study data were de-identified and handled with strict confidentiality. Baseline demographic and clinical characteristics, including age, sex, body mass index, and duration of symptoms, were comparable between the two groups.

The data were analyzed by SPSS version 25.0. Continuous variables were first assessed for normality using the Shapiro-Wilk test. Normally distributed variables were summarized as mean  $\pm$  standard deviation and compared between groups using the independent samples t-test. Non-normally distributed continuous variables were expressed as median with interquartile range and compared using the Mann-Whitney U test. Categorical variables were presented as frequencies and percentages and compared using the chi-square test. Fisher's exact test was applied when expected cell counts were small. Binary logistic regression was performed as an exploratory analysis to evaluate factors associated with intra-abdominal infection, with results reported as odds ratios and 95% confidence intervals. A p-value of less than 0.05 was considered statistically significant. Intraoperative appearance, including the presence of gangrenous changes without perforation, was recorded as a clinical variable and analyzed as a potential confounder in exploratory analyses.

## RESULTS

A total of 190 patients with uncomplicated acute

appendicitis were included in the study, with 95 patients allocated to the hand-made extracorporeal knotting group and 95 to the polymeric clip group. All patients completed a 15-day follow-up, and no data were missing for primary or secondary outcomes. Baseline demographic and clinical characteristics, including age, sex, body mass index, and duration of symptoms, were comparable between the two groups, confirming successful randomization. Operative outcomes showed that the mean operative time was significantly longer in the knotting group compared with the clip group. Early postoperative outcomes were evaluated according to predefined criteria. Postoperative ileus and wound infection rates were low and comparable between the two groups. Intra-abdominal infection within 15 days was observed more frequently in the polymeric clip group than in the knotting group, and this difference reached statistical significance. The mean operative time was longer in the hand-made knotting group compared with the polymeric clip group ( $45.8 \pm 8.9$  vs  $42.8 \pm 8.2$  minutes). The mean difference was 3.0 minutes (95% confidence interval: 0.4 to 5.6 minutes), indicating a small but statistically significant increase in operative time with the knotting technique. The observed difference in intra-abdominal infection is clinically relevant, particularly in settings where patients often present late, and the inflammatory burden is higher. Although the adjusted odds ratio suggests higher odds of intra-abdominal infection with polymeric clips, the wide confidence interval (1.01–22.73) shows that the true effect size may be much smaller or much larger. The study shows the descriptive statistics of continuous variables, including age, operative time, and other time-related variables, in both study groups: hand-made extracorporeal knotting (n=95) and polymeric clip (n=95). Normality was assessed using the Shapiro-Wilk test. Variables following a normal distribution were expressed as mean  $\pm$  SD, while non-normal data were presented as median (IQR). This table demonstrates that most variables, such as age, were normally distributed. Operative time was significantly longer in the hand-made knotting group (p=0.025). Other continuous variables showed no statistically significant differences between groups (Table 1).

**Table 1:** Descriptive Statistics of Continuous Variables (Mean  $\pm$  SD / Median (IQR)) in Both Groups

Variables	Shapiro-Wilk (p)	Hand-Made Extracorporeal Knotting (n=95)	Polymeric Clip (n=95)	Test Statistic	p-value
Age (years)*	0.094	27.9 $\pm$ 10.8	29.3 $\pm$ 12.0	t = 0.82	0.414
Duration of Symptoms (hours)†	<0.001	24 (18–36)	24 (18–40)	U = 4408.5	0.521
Operative Time (minutes)*	0.107	45.8 $\pm$ 8.9	42.8 $\pm$ 8.2	t = 2.26	0.025
Pain Score at 24 hrs*	0.069	3.8 $\pm$ 1.1	4.0 $\pm$ 1.2	t = 1.13	0.261
Length of Stay (days)†	<0.001	2 (2–3)	2 (2–3)	U = 4489.5	0.611

Data represented as Mean  $\pm$  SD (Independent t-test used for normally distributed data). †Data represented as Median (IQR) (Mann-Whitney U test used for non-normal data). Significance level = p < 0.050

The results show categorical variables, including gender, and postoperative complications in both study groups. Data are expressed as frequency (n) and percentage (%). Chi-square and Fisher's exact tests were applied according to expected

frequencies. This study demonstrates that both groups were similar in gender and comorbidity distribution ( $p > 0.050$ ). Intra-abdominal infection was significantly higher in the polymeric clip group (6.3%) compared with the knotting group (1.1%) ( $p = 0.049$ ). All other postoperative complications showed non-significant differences between groups (Table 2).

**Table 2:** Comparison of Categorical Variables Between Both Study Groups (n=190)

Variables	Hand-Made Knotting (n=95)	Polymeric Clip (n=95)	$\chi^2$ / Fisher's	p-value
Gender (Male)	57 (60.0%)	57 (60.0%)	0.00	1.000
Post-op Ileus	7 (7.4%)	9 (9.5%)	0.28	0.598
Wound Infection	6 (6.3%)	9 (9.5%)	0.69	0.407
Intra-Abdominal Infection	1 (1.1%)	6 (6.3%)	—	0.049

Data are presented as n (%). Statistical significance determined using Chi-square or Fisher's Exact test as appropriate. Significance =  $p < 0.050$

The study shows the binary logistic regression analysis for predictors of intra-abdominal infection following laparoscopic appendectomy. Independent variables included closure method and symptom duration > 48 hours. Odds ratios (OR) with 95% confidence intervals (CI) and p-values were calculated. This table demonstrates that polymeric clip closure independently predicted intra-abdominal infection with a statistically significant OR = 4.82 (95% CI 1.01-22.73,  $p = 0.048$ ). The confidence interval for this estimate was wide (95% CI 1.01-22.73), indicating imprecision and uncertainty in the magnitude of the effect, likely due to the small number of infection events. Other variables showed non-significant associations after adjustment for confounders (Table 3).

**Table 3:** Binary Logistic Regression Analysis for Predictors of Intra-Abdominal Infection

Predictor Variables	$\beta$ Coefficient	Adjusted OR (95% CI)	Wald $\chi^2$	p-value
Polymeric Clip Closure	1.57	4.82 (1.01-22.73)	3.89	0.048
Symptom Duration > 48 hours	0.66	1.94 (0.61-6.18)	1.25	0.258

Significance =  $p < 0.050$  is considered statistically significant

## DISCUSSION

A large multicenter observational study from Europe reported generally low abscess rates following laparoscopic appendectomy but highlighted that stump closure technique and local infection control practices may influence outcomes [12]. Similarly, data from Germany involving over 600 patients showed comparable safety between polymeric clips and staplers, but emphasized careful patient selection and stump assessment, especially in inflamed bases [13]. In comparison to previous studies, our findings are consistent with much of the existing literature, which shows that both hand-made extracorporeal knotting and polymeric clip closure are safe and effective techniques for appendiceal stump closure.

Similar to an Asian study, which observed comparable complication rates between both methods, our study also demonstrated low complication rates, except for a statistically significant difference in intra-abdominal infection rates, favoring the knotting technique (1.1% vs. 6.3%,  $p = 0.049$ ) [14]. Overall, our results support the idea that, while polymeric clips may reduce operative time, the versatility and potentially lower infection rates of hand-made knotting make it a valuable alternative, particularly in resource-constrained environments where infection rates may be higher. Systematic reviews and meta-analyses from the United Kingdom and East Asia have generally concluded that both clips and ligatures are safe for uncomplicated appendicitis, with differences mainly related to operative time rather than complications [15]. In contrast, some randomized trials from Central Europe and the Middle East reported a trend toward higher infectious complications when clips were used in patients with thicker or more inflamed appendiceal bases, although statistical significance was not always reached [16]. These findings support the present results, suggesting that hand-made knotting may provide more secure closure in variable tissue conditions. Studies conducted in South Korea and China have shown that polymeric clips are easy to apply and reduce operative time, which is consistent with the shorter operative duration observed in the clip group in our study [17]. However, these studies were performed in settings with early presentation and lower rates of advanced inflammation, which may explain the lower reported infection rates compared with those seen in our population. International guidelines and large prospective studies from Europe and global cohorts emphasize that local disease patterns, surgeon experience, and resource availability should guide the choice of stump closure technique rather than a single universally preferred method [18-20]. In low- and middle-income countries such as Pakistan, where cost constraints and delayed presentation are common, hand-made extracorporeal knotting may offer an effective and economical alternative without compromising safety. Overall, the findings of this study align with contemporary evidence from diverse geographic regions while highlighting the importance of context-specific decision-making. The lower infection rate observed with extracorporeal knotting suggests that this technique may be particularly suitable for resource-limited settings, even if it requires slightly longer operative time. Large multicenter randomized trials with longer follow-up are still needed to confirm these findings and assess long-term outcomes.

This trial was registered retrospectively, which introduces a potential risk of reporting bias. Although the study protocol and outcomes were predefined before enrollment, retrospective registration may reduce transparency compared with prospective trial registration.

Several secondary outcomes were tested without adjustment for multiple comparisons, which may increase the risk of type I error.

## CONCLUSIONS

While both techniques resulted in similar postoperative outcomes, hand-made extracorporeal knotting was associated with a significantly lower rate of intra-abdominal infection compared to polymeric clip closure, despite a modest increase in operative time. The results suggest that, in settings with higher infection risks and resource limitations, hand-made knotting may provide a more secure and cost-effective option for stump closure. Further large-scale studies are needed to confirm these findings and evaluate long-term outcomes.

## Authors' Contribution

Conceptualization: HUH

Methodology: MSR, FM

Formal analysis: SZHS

Writing and Drafting: HUH, ZAK, Z, FM

Review and Editing: HUH, ZAK, MSR, SZHS, Z, FM

All authors approved the final manuscript and take responsibility for the integrity of the work

## Conflicts of Interest

All the authors declare no conflict of interest.

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