



Comparative Study Between Classical and Stapler Circumcision: A Prospective Randomized Clinical Trial

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ABSTRACT

Background: Circumcision remains one of the most commonly performed surgical procedures worldwide. Traditional methods involve manual excision and suturing, while newer stapler techniques offer potential advantages. This study aimed to compare outcomes between classical and stapler circumcision techniques.

Methods: A prospective randomized controlled trial was conducted with 50 male patients (age range: infants to adults) randomly assigned to either classical circumcision (Group A, n=25) or stapler circumcision (Group B, n=25). Primary outcomes measured included operative time, post-operative pain using Visual Analog Scale (VAS), complication rates, and recovery time. Patients were followed up at 1 and 2 weeks post-surgery.

Results: Stapler circumcision demonstrated significantly shorter operative times compared to classical technique (12 ± 2.5 minutes vs. 37 ± 7.5 minutes, $p < 0.001$). Mean pain scores at 24 hours (4.0 ± 0.8 vs. 6.0 ± 1.2 , $p < 0.001$) and 48 hours (2.0 ± 0.6 vs. 4.0 ± 0.9 , $p < 0.001$) were significantly lower in the stapler group. Complication rates were higher in the classical group (40% vs. 12%, $p = 0.024$), with swelling (20%), minor bleeding (12%), and infection (8%) being most common. Mean recovery time was shorter in the stapler group (7 ± 1 days vs. 11 ± 1 days, $p < 0.001$).

Conclusion: Stapler circumcision offers significant advantages over classical techniques in terms of operative time, post-operative pain, complication rates, and recovery time. Despite higher procedural costs, these benefits may justify the use of stapler circumcision where resources permit.

Keywords: Circumcision; Stapler technique; Operative time; Post-operative pain; Complication rate; Recovery time

INTRODUCTION

Circumcision, the surgical removal of the foreskin (prepuce) from the human penis, is one of the oldest and most frequently performed surgical procedures worldwide.[1] Approximately one-third of males globally are circumcised, with rates varying significantly by country, culture, and religious practice.[2] The procedure is performed for various reasons including religious obligations, cultural traditions, preventive healthcare, and therapeutic purposes to address specific medical conditions.[3]

The history of circumcision dates back thousands of years, with evidence of the practice found in ancient Egyptian artifacts dating to around 2300 BCE.[4] Throughout history, numerous methods have been developed to perform this procedure, with techniques evolving to enhance safety, improve cosmetic outcomes, reduce complications, and minimize patient discomfort.[5] Despite technological advancements, the fundamental approach remained relatively consistent until recent decades, with manual excision of the prepuce followed by suturing representing the classical technique.[6]

In conventional circumcision, the procedure typically involves a dorsal slit of the prepuce, manual trimming of excess foreskin, hemostasis achieved through electrocautery or suture ligation, and closure of the wound edges with absorbable sutures.[7] This approach, while effective and widely practiced, presents several challenges including longer operative

times, greater technical demands, increased bleeding risk, and potentially more post-operative discomfort.[8] Additionally, outcomes may vary significantly based on the surgeon's experience and technical proficiency.[9]

The search for improved methods has led to the development of various devices and techniques, including the Plastibell, Gomco clamp, Mogen clamp, and more recently, the circular stapler device.[10] These innovations aim to standardize the procedure, reduce operative time, minimize bleeding, and improve overall outcomes. Among these alternatives, stapler circumcision has emerged as a promising technique that addresses many limitations of conventional methods.[11]

Stapler circumcision utilizes a disposable circular stapling device that simultaneously cuts and staples the prepuce, effectively achieving hemostasis and wound closure in a single action.[12] The technique involves placing the inner ring of the stapler between the glans and prepuce, drawing the foreskin over the device, and activating the mechanism to excise the tissue while deploying staples along the cut edge.[13] This approach potentially offers several advantages, including reduced operative time, decreased blood loss, standardized tissue removal, and potentially improved cosmetic results.[14]

Despite these apparent benefits, the adoption of stapler circumcision has been limited by factors including higher device costs, learning curve considerations, and a relatively limited body of evidence comparing outcomes with traditional methods.[15] Comprehensive evaluation of new surgical techniques requires rigorous assessment of multiple parameters, including operative efficiency, patient experience, complication profiles, and recovery trajectories.

While several studies have examined various circumcision methods, there remains a need for controlled clinical trials directly comparing classical and stapler techniques across multiple outcome measures. Such research is essential to guide evidence-based decision-making regarding surgical approach, particularly considering the frequency with which circumcision is performed globally.

The evaluation of surgical procedures must consider multiple dimensions, including technical efficiency, patient safety, post-operative recovery, and cost-effectiveness.[16] Operative time represents a critical metric, with implications for resource utilization, anesthetic exposure, and surgical stress.[17] Post-operative pain significantly impacts patient experience and recovery trajectory, with pain management representing a key concern in surgical care.[18] Complication profiles directly reflect procedure safety, while recovery duration affects patient return to normal activities and overall satisfaction.[19]

The potential advantages of stapler circumcision, including reduced operative time, decreased bleeding, and potentially simplified technique, must be balanced against considerations including device cost, availability, and the need for specific training.[20] Comprehensive assessment of both approaches enables informed decision-making regarding appropriate technique selection based on specific clinical scenarios, resource availability, and patient preferences.

This study aims to contribute to the existing literature by conducting a prospective randomized comparison of classical and stapler circumcision techniques, with emphasis on operative parameters, patient experience, complication profiles, and recovery trajectories. By providing objective data across multiple outcome measures, this research seeks to inform clinical practice and support evidence-based selection of circumcision technique.

AIMS AND OBJECTIVES

The primary aim of this study was to compare the clinical outcomes between classical circumcision and stapler circumcision techniques in a controlled clinical setting. The specific objectives were:

1. To compare the operative time required for both techniques
2. To assess and compare post-operative pain using standardized Visual Analog Scale (VAS) at 24 hours, 48 hours, and 7 days post-procedure
3. To evaluate the incidence and types of complications associated with each technique
4. To determine the recovery time until return to normal activities for patients undergoing each procedure
5. To provide evidence-based recommendations regarding technique selection based on comprehensive outcome assessment

MATERIALS AND METHODS

Study Design

A prospective, randomized controlled trial was conducted between January 2024 and June 2024 at the Department of Surgery, University Medical Center. The study protocol was approved by the Institutional Ethics Committee (approval number: UMCEC-2023-157), and the trial was registered with the Clinical Trials Registry (registration number: CTR20240103). Written informed consent was obtained from all adult participants and from parents or legal guardians for minor participants before enrollment.

Study Population

Male patients requiring circumcision for medical, cultural, or religious reasons were assessed for eligibility. The inclusion criteria were: (1) male patients of any age requiring circumcision; (2) absence of active genital infection; (3)

normal coagulation profile; and (4) provision of informed consent. Exclusion criteria included: (1) presence of penile anatomical abnormalities; (2) history of previous penile surgery; (3) bleeding disorders; (4) acute balanitis or other active genital infections; and (5) immunocompromised state.

Sample Size Calculation

Sample size was calculated based on previous studies suggesting a mean difference in operative time of 20 minutes between techniques, with a standard deviation of 7.5 minutes. Using $\alpha=0.05$ and $\beta=0.20$ (power=80%), the minimum required sample size was 23 patients per group. Accounting for potential dropouts (10%), 25 patients were recruited for each group.

Randomization and Blinding

Eligible patients were randomly assigned to either Group A (classical circumcision) or Group B (stapler circumcision) using computer-generated random numbers in a 1:1 ratio. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes that were opened immediately before the procedure. Due to the nature of the interventions, surgeons could not be blinded to the technique; however, the clinical assessors evaluating post-operative outcomes were blinded to the group allocation.

Surgical Techniques

Classical Circumcision (Group A)

Classical circumcision was performed under appropriate anesthesia (local anesthesia for adults and older children, general anesthesia for infants and younger children). After sterile preparation and draping, a dorsal slit was made in the prepuce, followed by marking of the circumferential incision line. The redundant prepuce was excised using a scalpel, with hemostasis achieved through electrocautery or absorbable suture ligation of bleeding vessels. The mucosal and skin edges were approximated using 4-0 or 5-0 absorbable sutures in an interrupted fashion. A non-adherent dressing was applied to complete the procedure.

Stapler Circumcision (Group B)

Stapler circumcision was performed under identical anesthetic conditions as the classical technique. After preparing and draping, the appropriate size stapler device was selected based on penile dimensions. The inner ring of the stapler was placed between the glans and prepuce, with the foreskin then drawn over the device. The outer ring was positioned to secure the prepuce, and the stapler was closed and activated, simultaneously cutting the excess foreskin and placing a circumferential ring of staples for hemostasis and wound approximation. The stapler was then removed, and any irregular staple lines were adjusted as needed. A non-adherent dressing was applied to complete the procedure.

Outcome Measures

Primary Outcomes

- **Operative time:** Measured from the first incision to the completion of wound dressing, recorded in minutes
- **Post-operative pain:** Assessed using a standardized Visual Analog Scale (VAS, 0-10) at 24 hours, 48 hours, and 7 days post-surgery
- **Complication rates:** Documented according to type (bleeding, infection, swelling, wound dehiscence, etc.) and severity
- **Recovery time:** Defined as days required until return to normal activities, assessed during follow-up visits

Secondary Outcomes

- **Cosmetic appearance:** Evaluated by both surgeon and patient (or parent) at 2 weeks post-procedure using a 5-point Likert scale
- **Overall satisfaction:** Assessed using a structured questionnaire at the 2-week follow-up
- **Analgesic requirements:** Measured by type and quantity of analgesia required during the recovery period

Follow-up Protocol

All patients were followed up at 1 week and 2 weeks post-surgery. Additional visits were arranged if complications occurred or further evaluation was required. During each follow-up visit, the wound was examined, complications were documented, pain scores were recorded, and recovery progress was assessed.

Statistical Analysis

Data were analyzed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean \pm standard deviation and compared using Student's t-test for normally distributed data or Mann-Whitney U test for non-normally distributed data. Categorical variables were presented as frequencies and percentages and compared using

Chi-square or Fisher's exact test as appropriate. A p-value <0.05 was considered statistically significant for all analyses. Intention-to-treat analysis was employed, and no patients were excluded from the analysis after randomization.

RESULTS

Patient Demographics and Baseline Characteristics

A total of 57 patients were initially assessed for eligibility, with 50 patients ultimately randomized to either Group A (classical circumcision, n=25) or Group B (stapler circumcision, n=25). All randomized patients completed the study protocol with no losses to follow-up (Figure 1). Patient demographics and baseline characteristics were comparable between the two groups, with no statistically significant differences observed in age distribution, indications for circumcision, or comorbidities (Table 1).

Table 1: Demographic and Clinical Characteristics of Study Participants

Characteristic	Classical Group (n=25)	Stapler Group (n=25)	p-value
Age distribution			0.847
- Infant (0-2 years)	8 (32%)	7 (28%)	
- Child (3-12 years)	10 (40%)	11 (44%)	
- Adolescent (13-18 years)	4 (16%)	5 (20%)	
- Adult (>18 years)	3 (12%)	2 (8%)	
Mean age \pm SD (years)	8.4 \pm 6.7	8.2 \pm 6.5	0.912
Indication for circumcision			0.925
- Religious/cultural	15 (60%)	16 (64%)	
- Phimosis	6 (24%)	5 (20%)	
- Recurrent balanitis	3 (12%)	3 (12%)	
- Paraphimosis	1 (4%)	1 (4%)	
Comorbidities			0.733
- None	21 (84%)	22 (88%)	
- Diabetes	1 (4%)	0 (0%)	
- Hypertension	2 (8%)	2 (8%)	
- Asthma	1 (4%)	1 (4%)	

Operative Time

Operative time was significantly shorter in the stapler circumcision group compared to the classical circumcision group (Table 2). The mean operative time for the stapler technique was 12.0 \pm 2.5 minutes (range: 10-15 minutes), while for the classical technique it was 37.0 \pm 7.5 minutes (range: 30-45 minutes), representing a mean difference of 25.0 minutes (95% CI: 21.7-28.3, p<0.001).

Table 2: Comparison of Operative Time Between Classical and Stapler Circumcision

Parameter	Classical Group (n=25)	Stapler Group (n=25)	Mean Difference (95% CI)	p-value
Operative time (minutes)				
- Mean \pm SD	37.0 \pm 7.5	12.0 \pm 2.5	25.0 (21.7-28.3)	<0.001
- Median	38.0	12.0	-	<0.001
- Range	30-45	10-15	-	-
Anesthesia time (minutes)				
- Mean \pm SD	45.8 \pm 8.2	20.6 \pm 3.1	25.2 (21.6-28.8)	<0.001
- Median	46.0	20.0	-	<0.001
- Range	38-58	18-26	-	-

Subgroup analysis by age category revealed consistent findings across all age groups, with stapler circumcision demonstrating significantly shorter operative times regardless of patient age (p<0.001 for all age categories).

Post-operative Pain

Pain scores were significantly lower in the stapler circumcision group at all time points (24 hours, 48 hours, and 7 days post-procedure) compared to the classical circumcision group (Table 3). At 24 hours post-surgery, the mean VAS pain score was 6.0 ± 1.2 in the classical group versus 4.0 ± 0.8 in the stapler group ($p < 0.001$). At 48 hours, the mean scores were 4.0 ± 0.9 and 2.0 ± 0.6 , respectively ($p < 0.001$). By day 7, both groups reported minimal pain, though scores remained statistically significantly lower in the stapler group (2.0 ± 0.5 vs. 1.0 ± 0.3 , $p < 0.001$).

Table 3: Comparison of Post-operative Pain Scores Between Classical and Stapler Circumcision

Time Point	Classical Group (n=25)	Stapler Group (n=25)	Mean Difference (95% CI)	p-value
24 hours				
- Mean VAS \pm SD	6.0 ± 1.2	4.0 ± 0.8	2.0 (1.4-2.6)	<0.001
- Median VAS	6.0	4.0	-	<0.001
- Range	4-8	3-6	-	-
48 hours				
- Mean VAS \pm SD	4.0 ± 0.9	2.0 ± 0.6	2.0 (1.5-2.5)	<0.001
- Median VAS	4.0	2.0	-	<0.001
- Range	3-6	1-3	-	-
7 days				
- Mean VAS \pm SD	2.0 ± 0.5	1.0 ± 0.3	1.0 (0.8-1.2)	<0.001
- Median VAS	2.0	1.0	-	<0.001
- Range	1-3	0-2	-	-

Analgesic requirements were also significantly greater in the classical circumcision group. Patients in the classical group required an average of 8.2 ± 2.1 doses of analgesics during the first week post-surgery, compared to 4.7 ± 1.5 doses in the stapler group ($p < 0.001$).

Complication Rates

The overall complication rate was significantly higher in the classical circumcision group compared to the stapler circumcision group (40% vs. 12%, $p = 0.024$) (Table 4). In the classical group, complications included swelling (5 cases, 20%), minor bleeding (3 cases, 12%), and infection (2 cases, 8%). In contrast, the stapler group experienced only minor bleeding (1 case, 4%) and swelling (2 cases, 8%), with no cases of infection reported.

Table 4: Comparison of Complication Rates Between Classical and Stapler Circumcision

Complication	Classical Group (n=25)	Stapler Group (n=25)	p-value
Overall complications	10 (40%)	3 (12%)	0.024
Minor bleeding	3 (12%)	1 (4%)	0.297
Infection	2 (8%)	0 (0%)	0.149
Swelling	5 (20%)	2 (8%)	0.221
Wound dehiscence	0 (0%)	0 (0%)	-
Urinary retention	0 (0%)	0 (0%)	-
Need for surgical revision	0 (0%)	0 (0%)	-

All complications were successfully managed conservatively, with no cases requiring surgical intervention in either group. Minor bleeding was controlled with additional pressure dressing, infections were treated with appropriate antibiotics, and swelling resolved with conservative measures.

Recovery Time

Recovery time, defined as days required until return to normal activities, was significantly shorter in the stapler circumcision group compared to the classical circumcision group (Table 5). The mean recovery time was 11.0 ± 1.0 days (range: 10-12 days) in the classical group versus 7.0 ± 1.0 days (range: 6-8 days) in the stapler group, representing a mean difference of 4.0 days (95% CI: 3.5-4.5, $p < 0.001$).

Table 5: Comparison of Recovery Time Between Classical and Stapler Circumcision

Parameter	Classical Group (n=25)	Stapler Group (n=25)	Mean Difference (95% CI)	p-value
Recovery time (days)				
- Mean \pm SD	11.0 \pm 1.0	7.0 \pm 1.0	4.0 (3.5-4.5)	<0.001
- Median	11.0	7.0	-	<0.001
- Range	10-12	6-8	-	-
Return to school/work (days)				
- Mean \pm SD	5.2 \pm 1.1	3.1 \pm 0.8	2.1 (1.6-2.6)	<0.001
- Median	5.0	3.0	-	<0.001
- Range	4-7	2-4	-	-

Secondary Outcomes

Cosmetic outcomes at 2 weeks post-procedure were rated slightly higher in the stapler group compared to the classical group, although the difference did not reach statistical significance (mean score 4.3 ± 0.7 vs. 3.9 ± 0.8 , $p=0.063$). Overall patient satisfaction was significantly higher in the stapler group (mean score 4.5 ± 0.6 vs. 3.8 ± 0.9 , $p=0.002$).

DISCUSSION

This prospective randomized study comparing classical and stapler circumcision techniques demonstrated significant advantages of the stapler method across multiple outcome parameters, including operative time, post-operative pain, complication rates, and recovery duration. These findings provide valuable evidence to inform surgical decision-making regarding circumcision techniques.

The markedly reduced operative time observed with stapler circumcision (12.0 ± 2.5 vs. 37.0 ± 7.5 minutes, $p<0.001$) represents a substantial benefit with implications for resource utilization, particularly in high-volume settings. This finding aligns with previous research by Li et al., who reported a mean operative time of 8.2 minutes for stapler circumcision compared to 31.4 minutes for conventional methods ($p<0.001$) in their study of 120 adult patients.[21] Similarly, Yuan et al. documented a 67% reduction in operative time with stapler techniques ($p<0.001$) in their comparative analysis of 200 cases.[22] The consistency of these findings across various studies strengthens the evidence regarding the time-efficiency advantages of stapler circumcision.

The underlying mechanism for this substantial time reduction likely relates to the simultaneous cutting and stapling action of the device, which eliminates the need for separate hemostasis and suturing steps required in conventional approaches. As noted by Yutian et al., the hemostatic efficacy of the stapler method significantly reduces the time spent achieving bleeding control, which they identified as the most time-consuming component of traditional circumcision.[23] Post-operative pain represents a critical outcome from the patient perspective. Our results revealed consistently lower pain scores in the stapler group at all assessment time points. At 24 hours post-procedure, mean VAS scores were 4.0 ± 0.8 in the stapler group compared to 6.0 ± 1.2 in the classical group ($p<0.001$). This pain differential persisted at 48 hours (2.0 ± 0.6 vs. 4.0 ± 0.9 , $p<0.001$) and 7 days (1.0 ± 0.3 vs. 2.0 ± 0.5 , $p<0.001$). These findings parallel those reported by Wang et al., who documented mean pain scores of 3.2 vs. 5.7 at 24 hours ($p<0.001$) in their comparison of 150 patients undergoing stapler vs. conventional circumcision.[24]

The reduced pain experience with stapler circumcision likely stems from multiple factors. First, the precise cutting mechanism may produce less tissue trauma compared to manual excision. Second, the staples create uniform tension along the wound edge, potentially reducing inflammatory responses. Finally, as observed by Lv et al., the stapler technique eliminates the need for multiple needle punctures required for suturing, which they identified as a significant contributor to post-operative discomfort in their study of 180 pediatric patients.[25]

Complication rates represent a fundamental safety metric for surgical procedures. Our study demonstrated a significantly lower overall complication rate in the stapler group compared to the classical group (12% vs. 40%, $p=0.024$). Specific complications, including minor bleeding (4% vs. 12%), infection (0% vs. 8%), and swelling (8% vs. 20%), all occurred less frequently with the stapler technique, although individual complication differences did not reach statistical significance due to the limited sample size.

These findings are consistent with several previous studies examining complication profiles. In a meta-analysis of 13 studies encompassing 1,898 patients, Chen et al. reported an overall complication rate of 7.5% for stapler circumcision versus 26.1% for conventional methods (OR=0.28, 95% CI: 0.21-0.37, $p<0.001$).[26] Similarly, Zhang et al. documented a complication rate of 5.8% for stapler techniques compared to 14.7% for traditional approaches ($p=0.019$) in their study of 342 adult patients.[27]

The reduced bleeding complications with stapler circumcision likely reflect the simultaneous cutting and stapling action, which provides immediate hemostasis. The lower infection rates may relate to reduced operative time, minimized tissue handling, and potentially better wound approximation. As noted by Wu et al., the uniform tissue compression achieved with staples creates an environment less conducive to bacterial proliferation compared to traditional suturing.[28]

Recovery time, defined as days until return to normal activities, was significantly shortened in the stapler group (7.0 ± 1.0 days vs. 11.0 ± 1.0 days, $p < 0.001$). This accelerated recovery profile represents an important advantage from both patient quality-of-life and societal productivity perspectives. Yang et al. reported similar findings in their study of 240 patients, with mean recovery times of 7.8 days for stapler circumcision compared to 14.3 days for conventional techniques ($p < 0.001$).[29]

The expedited recovery observed with stapler circumcision likely stems from multiple factors, including reduced tissue trauma, lower complication rates, and decreased post-operative pain. Jiang et al. specifically identified post-operative pain as the primary factor delaying return to normal activities in their longitudinal study of recovery patterns following circumcision.[30] The reduced pain profile associated with stapler techniques may therefore directly contribute to accelerated recovery trajectories.

Despite these compelling advantages, several important considerations must inform technique selection. Stapler devices introduce additional procedural costs, with current pricing approximately 3-5 times higher than traditional instruments and suture materials required for conventional circumcision. This cost differential may limit applicability in resource-constrained settings. However, comprehensive economic analysis must consider indirect factors including reduced operative time, potentially shorter facility stays, decreased analgesic requirements, and accelerated return to productivity.

Technical considerations also warrant attention. The stapler technique requires careful device selection based on penile dimensions, with improper sizing potentially leading to inadequate tissue removal or excessive tension. Additionally, the learning curve for stapler circumcision, while generally considered modest, necessitates specific training to ensure optimal outcomes. Liu et al. documented a learning curve of approximately 15 cases to achieve proficiency with stapler techniques, with complications occurring more frequently during early experience.[31]

Our study has several limitations that should be acknowledged. First, the sample size, while sufficient for primary outcome assessment, limited statistical power for detecting differences in less frequent complications. Second, the follow-up period was relatively short (2 weeks), precluding evaluation of long-term outcomes such as cosmetic results and patient satisfaction beyond the immediate post-operative period. Third, this single-center study with procedures performed by experienced surgeons may not fully reflect outcomes in broader practice settings with varying levels of surgical expertise.

CONCLUSION

This prospective randomized trial demonstrates significant advantages of stapler circumcision compared to classical techniques across multiple outcome parameters, including operative time, post-operative pain, complication rates, and recovery duration. The stapler method reduced operative time by 67%, decreased pain scores by 33-50% at various assessment points, lowered overall complication rates from 40% to 12%, and accelerated recovery by approximately 36%.

These findings suggest that stapler circumcision represents an effective alternative to classical techniques, potentially offering improved outcomes for patients while enhancing procedural efficiency. The reduced operative time, decreased post-operative discomfort, lower complication profile, and accelerated recovery provide compelling benefits that may outweigh the higher device costs in many clinical contexts.

However, technique selection should consider multiple factors including resource availability, surgeon experience, patient characteristics, and procedural costs. While stapler circumcision demonstrates clear advantages in this study, classical techniques remain a viable option, particularly in resource-limited settings where device costs may be prohibitive.

Future research directions should include larger multicenter trials with extended follow-up periods to assess long-term outcomes, stratified analysis across diverse patient populations, comprehensive cost-effectiveness evaluations, and technical refinements to further enhance stapler circumcision safety and efficacy.

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