Study Protocol

Randomised Trial of Forceps-Guided Versus Stapler-Assisted Circumcision in Adult Phimosis

Jakub Gondek[1], Mateusz Czajkowski[1], Agata Błaczkowska[2], Michalina Grudzińska[3], Maciej Dolny[1], Marcin Matuszewski[1]

1 Department of Urology, Medical University of Gdańsk, Gdańsk, Poland

2 Division of Radiology Informatics and Statistics, Medical University of Gdańsk, Gdańsk, Poland

3 Student Scientific Circle at the Department of Urology, Faculty of Medicine, Medical University of Gdańsk, Gdańsk, Poland

Corresponding author: Jakub Gondek, Department of Urology, Medical University of Gdańsk, Smoluchowskiego 17, 80-214 Gdańsk, Poland. E-mail: kba@gumed.edu.pl. Tel. +48 58 349 31 60.

Key protocol information

Trial design	Prospective, single-centre, parallel-group, randomised controlled trial with 1:1 allocation.
Setting	Department of Urology, Medical University of Gdańsk, Gdańsk, Poland.
Population	Adult men with pathological phimosis requiring circumcision.
Interventions	Stapler-assisted circumcision with the disposable CircC device versus standard forceps-guided circumcision.
Primary endpoint	Total procedure time, defined prospectively as the sum of anaesthesia time, circumcision time, and dressing time.
Key secondary endpoints	Intraoperative pain; postoperative complications; stretched penile length; IIEF-15; MGSIS-7; symptom-specific VAS domains; $PSR_{G/F}$ at 3 months.
Follow-up schedule	Baseline, day of surgery, 4 weeks, and 3 months.
Planned sample	Approximately 80–100 participants enrolled pragmatically during the recruitment period.

1. Introduction and hypotheses

Phimosis is a pathological narrowing of the preputial orifice that prevents full retraction of the foreskin beyond the glans and may lead to pain, recurrent inflammation, voiding difficulty, and impaired sexual activity.[1,2] Important associated conditions include short frenulum, chronic inflammatory disorders, and balanitis xerotica obliterans as a manifestation of lichen sclerosus.[3,4] Chronic foreskin pathology is also linked to an increased risk of penile malignancy, and circumcision remains the definitive treatment for pathological phimosis while also conferring substantial protection against invasive penile cancer.[5–8]

Although circumcision is one of the oldest and most frequently performed operations worldwide[9,10], the standard adult operation remains the open surgical technique using forceps or clamps, excision of the foreskin, and haemostasis with sutured skin approximation.[11] Device-assisted approaches, including circular stapler systems, were introduced to shorten operative time and simplify tissue apposition. Meta-analytic data suggest that these devices substantially reduce operative time and intraoperative blood loss, but they may increase total cost and some studies have reported mixed findings for postoperative pain or wound events.[12–14] Comparative randomised evidence in adult pathological phimosis remains limited, particularly when outcomes beyond procedural efficiency are considered.

The CircC device is a disposable circular stapling and cutting system that enables rapid sleeve-type circumcision with simultaneous tissue excision and staple-line closure. Forceps-guided circumcision (FGC) is a conventional, widely taught open technique that remains routinely used in many centres. The present trial was designed to compare these two operative approaches in adult men with pathological phimosis under standardised single-surgeon conditions.

The protocol is organised in a standard clinical trial format covering the scientific rationale, design, interventions, assessments, safety procedures, and planned statistical analyses.

2. Design

2.1 Trial design and setting

This study was designed as a prospective, single-centre, parallel-group randomised controlled trial comparing CircC with FGC in adult men requiring circumcision for pathological phimosis. The trial was conducted at the Department of Urology, Medical University of Gdańsk, Gdańsk, Poland. Recruitment was planned to begin in March 2024 and continue until November 2024, with the final 3-month follow-up visit planned for February 2025.

All procedures were planned to be performed by the same experienced urologist under local anaesthesia using standardised perioperative care pathways. Because the interventions are surgically distinct, blinding of the operating surgeon and participants was not feasible.

2.2 Eligibility criteria

Inclusion criteria: male sex, age ≥18 years, a clinical diagnosis of pathological phimosis requiring circumcision, ability to provide written informed consent, and willingness to complete the planned follow-up visits.

Exclusion criteria: active genital infection or balanoposthitis at the time of surgery, suspected penile malignancy requiring broader oncological management, known allergy or contraindication to local anaesthetic

agents, inability to complete patient-reported outcome measures, and any other condition that, in the investigator's judgment, made trial participation inappropriate or unsafe.

2.3 Recruitment, consent, randomisation, and allocation concealment

Potentially eligible patients attending the urology clinic were to be screened consecutively. After explanation of the study, written informed consent was to be obtained before any study-specific assessments.

Participants were to be randomised in a 1:1 ratio using the National Cancer Institute Clinical Trial Randomization Tool.[15] The allocation sequence was to be generated in advance and stored in a secure, password-protected file accessible only to a study team member not involved in eligibility assessment or surgery. Treatment assignment was to be revealed sequentially only after eligibility confirmation and completion of baseline assessments.

2.4 Ethics and oversight

The protocol was approved by the Institutional Bioethics Committee of the Medical University of Gdańsk (decision no. NKBBN/87/2024; 29 February 2024). The trial was designed to be conducted in accordance with the Declaration of Helsinki and local regulatory requirements. All participants were required to provide written informed consent prior to enrolment.

Given the short duration, single-centre setting, and low-risk nature of the interventions, a separate data safety monitoring board was not planned. Safety oversight was to be provided by the treating investigator and supervising surgical team, with serious adverse events documented and reported to the Bioethics Committee in accordance with institutional requirements.

3. Protocol overview

3.1 Interventions

3.1.1 CircC arm

Participants allocated to CircC were planned to undergo circumcision with the disposable circular circumcision suture device (CircC). After local anaesthesia, the appropriate bell size was to be selected according to glans diameter and inserted to protect the glans. The foreskin was then to be positioned over the device, the external component applied, and the device fired to achieve simultaneous circumferential excision of redundant preputial tissue and staple-line closure.

Device-specific instructions, including device sizing, alignment, haemostasis, and post-procedure inspection, were to be followed in accordance with the manufacturer's instructions for use and local operating practice.

3.1.2 Forceps-guided circumcision arm

Participants allocated to FGC were planned to undergo standard open circumcision. After local anaesthesia, the foreskin was to be mobilised, the amount of tissue to be excised determined under traction with forceps, and the prepuce excised with haemostasis secured in the conventional manner. Skin edges were then to be reapproximated with interrupted absorbable sutures.

3.2 Perioperative care

All participants were to receive the same local anaesthetic protocol and standard written postoperative instructions. Wound care advice, analgesia recommendations, and guidance on abstaining from sexual

intercourse until satisfactory healing were standardised between groups. Histopathological examination of excised foreskin tissue was planned as part of routine care and trial documentation.

3.3 Schedule of enrolment, intervention, and assessments

Study activity	Baseline / pre-op	Day of surgery	4 weeks	3 months
Eligibility check and informed consent	X			
Demographics, comorbidities, medication, smoking	X			
Randomisation	X			
Assigned intervention		X		
Total procedure time (anaesthesia + circumcision + dressing)		X		
Intraoperative pain VAS		X		
Histopathology of excised foreskin		X		
Wound healing and postoperative complications			X	
Readiness to resume sexual intercourse			X	
IIEF-15 and MGSIS-7	X			X
Symptom-specific VAS domains	X			X
Stretched penile length	X			X
Biothesiometry and $PSR_{G/F}$	X			X
Adverse event review		Continuous capture from randomisation to 3-month visit		

3.4 Outcome measures

Primary endpoint: total procedure time, defined prospectively as the sum of anaesthesia time, circumcision time, and dressing time, each measured with a stopwatch on the day of surgery.

Secondary endpoints: intraoperative pain assessed immediately after the procedure on a visual analogue scale (VAS); postoperative complications graded according to the Clavien–Dindo classification;[18] stretched penile length; IIEF-15 score; MGSIS-7 score; change in each symptom-specific VAS domain; and the penile sensitivity ratio glans/finger ($PSR_{G/F}$) at 3 months.[17]

Exploratory endpoint: histopathology of the excised foreskin, grouped descriptively as lichen sclerosus, nonspecific chronic inflammation, normal histology, or other pathology.

Safety endpoint: all intraoperative and postoperative adverse events from randomisation until completion of the 3-month visit.

3.5 Safety monitoring and adverse event reporting

Expected adverse events included pain at the surgical site, oedema, minor bleeding or oozing, local infection, delayed wound healing, partial wound dehiscence, and transient sensory changes. Serious adverse events included, but were not limited to, haemorrhage requiring surgical revision, severe infection requiring systemic antibiotic therapy or hospitalisation, extensive wound dehiscence requiring reoperation, urinary retention requiring intervention, or any life-threatening event.

Participants were to be instructed to contact the study team without delay in the event of excessive bleeding, progressive swelling, fever, purulent discharge, difficult urination, or pain not controlled by prescribed analgesia. Serious adverse events were to be documented in detail and reported to the Bioethics Committee according to institutional requirements.

3.6 Data capture, confidentiality, and dissemination

Each participant was to be assigned a study-specific identification code. Source data, allocation records, and analysis files were to be stored in secured institutional systems with access restricted to authorised study personnel. Any paper records were to be kept in locked cabinets within the Department of Urology.

Only data necessary to answer the study objectives were to be collected. After publication of the primary trial report, de-identified individual participant data underlying the main analyses, together with the analytic code, may be made available upon reasonable request to the corresponding author, subject to institutional approval and a signed data use agreement.

4. Statistical analysis

The intention-to-treat population was prespecified to include all randomised participants analysed according to their allocated intervention group, regardless of protocol deviations. The safety population was prespecified to include all randomised participants who underwent the allocated surgical procedure. The primary endpoint and intraoperative outcomes were planned to be analysed under the intention-to-treat principle. Three-month outcomes were to be analysed as complete cases, with the number and reasons for missing observations reported transparently.

Continuous variables were prespecified to be summarised as mean and standard deviation when approximately normally distributed or as median and interquartile range when distributional assumptions were not met. Categorical variables were to be presented as counts and percentages. All hypothesis tests were planned to be two-sided with a significance threshold of $p<0.05$. Secondary endpoints were prespecified as exploratory and no formal multiplicity correction was planned.

4.1 Sample size rationale

Sample size planning was based on the primary endpoint, total procedure time. Prior comparative studies of stapler-assisted versus conventional adult circumcision reported large reductions in operative time with device use.[13,14,19] Under conservative assumptions for the anticipated between-group difference and variability, the formal sample size requirement for the primary endpoint was very small. The trial therefore prespecified pragmatic enrolment of approximately 80–100 participants so that procedural outcomes, wound

complications, histopathological findings, sensory outcomes, and patient-reported measures could be described with greater stability than would be possible in a minimally powered time-efficiency study.

4.2 Planned analyses

Total procedure time and intraoperative pain VAS were prespecified to be compared between groups using the Mann–Whitney U test. Anaesthesia time, circumcision time, and dressing time were to be recorded separately and described to aid interpretation of the primary endpoint.

For continuous secondary endpoints assessed at baseline and 3 months (IIEF-15, MGSIS-7, stretched penile length, $PSR_{G/F}$, and each symptom-specific VAS domain), change scores were prespecified for each participant as postoperative minus preoperative values. Between-group differences in change scores were to be analysed using the Mann–Whitney U test, with 95% confidence intervals for differences in medians estimated using nonparametric bootstrap with 10,000 resamples. Within-group pre–post changes were planned to be analysed using the Wilcoxon signed-rank test.

Categorical outcomes, including complication rates and histopathological categories, were to be compared using the chi-square test or Fisher exact test as appropriate to cell counts. Missing 3-month outcomes were not to be imputed in the primary report; instead, missingness was to be described explicitly. No formal interim efficacy analysis was planned. Analyses were prespecified to be conducted in Python 3.11 or equivalent validated statistical software.

5. Summary

This trial was designed to provide a pragmatic randomised comparison of a disposable stapler-assisted circumcision device and a conventional forceps-guided technique in adult pathological phimosis. The principal objective was to determine whether CircC improves procedural efficiency without compromising perioperative safety or short-term sexual, sensory, and patient-reported outcomes. The present supporting file is intended to document the study protocol clearly for editorial review and to accompany the main trial manuscript.

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