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A study comparing two circumcision techniques in adult men with phimosis: effects on surgery time, penis length, sexual function, and sensitivity

Submission date
03/04/2026

Recruitment status
No longer recruiting

Registration date
08/04/2026

Overall study status
Completed

Last Edited
08/04/2026

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Phimosis is a condition where the foreskin is too tight to be pulled back over the head of the penis. It can cause pain, infections, problems with urination, and difficulties during sexual activity. Circumcision, which is the surgical removal of the foreskin, is the standard treatment for this condition. Circumcision can be performed using different techniques. The traditional method is done by the surgeon using standard surgical tools. A newer method uses a special disposable device that allows the procedure to be performed more quickly and in a more uniform way. Previous studies suggest that device-assisted circumcision may take less time and cause less bleeding during surgery. However, it is still unclear whether it affects recovery, sexual function, or sensitivity differently compared to the traditional method. The aim of this study is to compare these two circumcision techniques in adult men with phimosis. We will look at how long the procedure takes and how it affects penis length, sexual function, sensitivity, and overall patient experience.

Who can participate?
Adult men over the age of 18 who were diagnosed with phimosis and required circumcision as part of their treatment

What does the study involve?
Participants will be randomly assigned to one of two types of circumcision. This means that each person has an equal chance of receiving either the traditional surgical method or the device-assisted method. All procedures will be carried out under local anaesthesia (numbing medication), so patients will be awake but should not feel pain during the surgery. The procedure is performed as a day case, which means patients can go home the same day. After the surgery, they will receive clear instructions on how to care for the wound, including hygiene, dressing changes, and when it is safe to return to normal activities. Before the procedure, participants will be asked to complete simple questionnaires about their symptoms, sexual function, and how they feel about the appearance of their genitals. Doctors will also take

measurements of penis length and assess sensitivity using a standard medical device. The total time of the procedure will be recorded, as this is one of the main outcomes of the study. Pain during and after the procedure will also be assessed using a simple rating scale. After the surgery, participants will return for follow-up visits. The first visit will take place at around 4 weeks, when doctors will check wound healing, remove any remaining stitches or staples if needed, and assess recovery. A final follow-up will take place at around 3 months after the procedure. At that time, participants will again complete questionnaires, and repeat measurements of penis length and sensitivity will be performed. Throughout the study, doctors will monitor for any complications or side effects to ensure patient safety.

What are the possible benefits and risks of participating?
There were no direct benefits associated with participating in the study. However, the benefits of participating in the study included the results of the circumcision procedure. It appears that the results of this study may influence patients' future decisions regarding their choice of circumcision method. The risks associated with participation in the study included typical post-circumcision complications, such as bleeding, surgical site infection, and wound dehiscence.

Where is the study run from?
Medical University of Gdańsk (Poland)

When is the study starting and how long is it expected to run for?
March 2024 to December 2024

Who is funding the study?
Medical University of Gdańsk (Poland)

Who is the main contact?
Jakub Gondek, kba@gumed.edu.pl

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
A comparison between forceps-guided and stapler-assisted circumcision in adult phimosis: procedure time and 3-month changes in penile length, sexual function and vibratory sensitivity - a randomised trial

Study objectives
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.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/03/2024, Bioethics Committee for Scientific Research, Medical University of Gdańsk (Dębinki 7, Gdańsk, 80-211, Poland; +48 (0)58 349 10 11; komisja.bioetyczna@gumed.edu.pl), ref: KB/87/2024

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Device feasibility, Treatment

Study type(s)

Health condition(s) or problem(s) studied
Phimosis

Interventions
Patients were recruited consecutively and randomized in a 1:1 ratio using the National Cancer Institute Clinical Trial Randomization Tool - MTI method: maximal (National Cancer Institute. Clinical Trial Randomization Tool. https://ctrandomization.cancer.gov [accessed 18 March 2024]). The allocation sequence was generated in advance and stored in a secure, password-protected

format accessible only to a study team member not involved in the eligibility assessment or surgery. Treatment assignment was obtained sequentially only after eligibility confirmation and the completion of baseline assessments.

Circumcisions were performed under local anaesthesia using 10 ml of lidocaine 2% and 10 ml of bupivacaine 0.5%, administered circumferentially at the base of the penis.

CircC technique: The device size was selected individually based on the penile circumference measured with the manufacturer-provided tape to ensure an appropriate fit of the glans-protective bell and stapling ring. Following frenuloplasty, a glans-protective bell was inserted beneath the foreskin. In instances where the preputial opening was constricted, a dorsal incision was made to facilitate insertion. Once the bell was positioned, the CircCurer™ device was applied and activated, simultaneously cutting and inserting the metal staples. Haemostasis was verified, and a pressure dressing was applied to manage the bleeding.

FGC technique: Following frenuloplasty, the foreskin was grasped with two forceps to standardise traction, and a third transverse forceps was used as the cutting guide. The prepuce was excised distal to the clamp using a scalpel, haemostasis was obtained with bipolar cautery, and the skin edges were approximated with interrupted rapidly absorbable sutures, consistent with standard forceps-guided descriptions.

Postoperatively, all patients were observed for several hours and discharged on the same day with instructions on penile elevation, twice-daily dressing changes, wound disinfection with antiseptic agents, and topical fusidic acid application for 14 days.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Total procedure time measured using a stopwatch and presented in minutes and seconds at the end of the procedure

Key secondary outcome(s)
1. Intraoperative pain measured using visual analogue scale (VAS) reported by the patient at the end of the procedure

2. Postoperative complications measured using Clavien-Dindo (CD) classification at the end of the procedure, 1 month and 3 months

3. Stretched penile length measured using a specialized measuring tape and presented in centimeters at baseline and 3 months

4. Sexual function measured using the International Index of Erectile Function (IIEF-15) at baseline and 3 months

5. Visual effect measured using the Male Genital Self-Image Scale (MGSIS-7) at baseline and 3 months

6. Itching, burning, pain at rest, pain during intercourse, and sensations of heat, cold, and vibration, measured using visual analogue scale (VAS) at baseline and 3 months

7. Feeling of vibrations measured using biothesiometry and calculated to penile sensitivity ratio glans/finger (PSRG/F) at baseline and 3 months

Completion date
30/12/2024

Eligibility

Key inclusion criteria
1. Male sex
2. Age ≥18 years
3. Clinical diagnosis of pathological phimosis requiring circumcision
4. Ability to provide written informed consent
5. Willingness to complete the planned follow-up visits

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Male

Total final enrolment
81

Key exclusion criteria
1. Active genital infection or balanoposthitis at the time of surgery
2. Suspected penile malignancy requiring broader oncological management
3. Known allergy to local anaesthetic
4. Contraindication to local anaesthetic

Date of first enrolment
01/03/2024

Date of final enrolment
02/09/2024

Locations

Countries of recruitment
Poland

Study participating centre
Department of Urology, University Clinical Centre, Medical University of Gdańsk
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Sponsor information

Organisation
Gdańsk Medical University

ROR
https://ror.org/019sbgd69

Organisation
University Clinical Centre, Gdańsk

Funder(s)

Funder type

Funder Name
Gdański Uniwersytet Medyczny

Alternative Name(s)
Medical University of Gdańsk, MUG

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Poland

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			07/04/2026	No	No
Protocol file			07/04/2026	No	No