Simple circumcision device: proof of concept for a single-visit, adjustable device to facilitate safe adult male circumcision

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Objective: To conduct a proof-of-concept study to determine the potential utility of a novel, adjustable single-visit, disposable device to facilitate rapid adult circumcision.
Design: Prospective pilot trial of a novel surgical device.
Setting: Tertiary care Veterans Administration medical center.
Patient(s): Five adult males.
Intervention(s): Circumcisions performed by junior trainees using an adjustable, single-size surgical-assist device constructed by the University of Washington Applied Physics Laboratory.
Main Outcome Measure(s): The attending surgeon and trainees completed standardized forms after each procedure to assess technical problems and ease of use. Follow-up visits were scheduled to evaluate adverse events, postoperative pain, cosmetic outcomes, and participant satisfaction at 3, 8, 30, and 90 days postoperatively.
Result(s): The average operative time was 16.4 minutes. All cases were performed with local anesthesia, and no case required electrocautery or conversion to standard surgery. At the postoperative day 3 visit, all subjects were happy with their results and would recommend the procedure to another patient. One participant had a minor wound separation noted at the 30-day visit that resolved during follow-up. There were no wound infections, hematomas, or other adverse events.
Conclusion(s): This proof-of-study suggests that the Simple Circumcision Device may facilitate delivery of safe adult male circumcision services. (Fertil Steril® 2014;101:1266–70. ©2014 by American Society for Reproductive Medicine.)
Key Words: HIV, AIDS, circumcision, surgical device

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Promoting adult male circumcision has become an important strategy to limit HIV infection risk among heterosexual in men in sub-Saharan Africa (1–5). However, in resource-limited settings, both medical providers and surgical materials are not adequate to perform the vast numbers of circumcision procedures that are needed to achieve this important public health goal.

As an alternative to traditional surgical procedures that require substantial training and experience, several circumcision devices have been evaluated to help achieve the goals of providing safe, cosmetic circumcision that can be performed by nonphysician medical providers. Currently, the most studied adult male circumcision devices are the Shang ring and the Prepex (6, 7). These devices have been shown to have generally acceptable results and can be

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performed by nonphysician medical providers, however, both require subjects to wear the plastic devices for 1 week to allow necrosis of the prepuce and then require additional time for the wounds to heal from the skin edges after sloughing of the preputial tissue (7, 8). Further, these "slow compression devices" require a second visit for device removal. The slow compression devices also require a substantial inventory of device sizes.

To address inherent limitations of available devices for male circumcision, we developed a simple, adjustable, single-use male circumcision device, the Simple Circumcision Device (SCD), to facilitate circumcision procedures under local anesthesia. The aim of this study was to conduct a small proof-of-concept study to evaluate the SCD under clinical conditions. We found that the SCD required minimal provider training, had high client acceptability, and provided good cosmetic outcomes without requiring patients to wear the device home.

MATERIALS AND METHODS

Study Population

The study protocol was approved by the Internal Review Board at the Puget Sound Veterans' Administration Hospital, Seattle, Washington, IRB#00434. The trial was also registered on clinicaltrials.gov under ID VAPSHCS-00434 in accordance with International Committee of Medical Journal Editors requirements. Five healthy, sexually potent volunteers with medical indications for circumcision were recruited.

Study Timeline

Subjects had an initial clinic visit for evaluation, including a medical history, physical examination, and written informed consent. After the surgical procedures, routine follow-up visits were scheduled at 3, 8, 30, and 90 days after the procedure with patients instructed to return sooner if they experienced bleeding, infection, or excessive pain. These times were chosen to correspond to the published experience during the Kisumu randomized clinical trial of adult male circumcision to prevent HIV infections (2). At each visit, the wound was checked, and standard questions from previous work were assessed, including the return to activities of daily living, potential adverse events (AEs), and the participants' and partners' satisfaction with the circumcision.

Surgical Method

All procedures were performed by junior residents who had minimal operative experience and likely had no previous training in the procedure, under the supervision of a single surgeon (J.K.). The genitalia were prepared with povidone-iodine solution, and procedures were performed using 10 mL of 2% xylocaine for dorsal nerve and ring penile blocks. The incision was outlined parallel to the coronal sulcus on the epithelial surface of the prepuce with a marking pen. The outer SCD ring was placed around the penile shaft and positioned at the base of the phallus. The prepuce was grasped at the 3 and 9 o'clock positions using two mosquito clamps and then pulled over the glans. A straight clamp was then used to crush the prepuce parallel to the shaft at the 12 o'clock position, and a dorsal slit was made along the crushed line. Using the mosquito clamps, the prepuce was pulled over the glans, and the inner protective, interlocking cap was placed over the glans. Then the SCD device was locked below the planned incision (Fig. 1A). The prepuce was excised with a scalpel by cutting on the cutting guide. Four 3/0 chromic traction sutures were placed at the 3, 6, 9, and 12 o'clock positions using the SCD suture guide (Fig. 1). The SCD was removed. Figure 2 illustrates the aforementioned steps. Additional sutures were placed as needed, using the traction sutures to assure hemostasis and/or accurate skin reapproximation; then DermaBond surgical glue (Johnson & Johnson) was applied. The incision was covered with Vaseline gauze (Covidien) and then an Elastoplast^{M} compression dressing (Beiersdorf).

Statistical Analyses

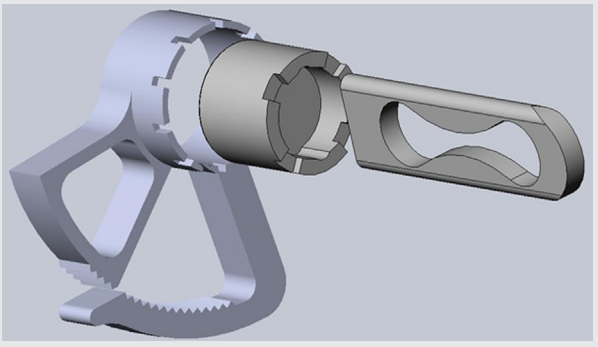
Demographic, clinical, and procedural data were collected, and averages, SD, and percentages were calculated using STATA, version 11.

RESULTS

The five subjects were between 25 and 87 years of age (mean, 46 years). Of the five, four were sexually active, and all were former or current smokers. The medical indications for circumcision were phimosis in two men, recurrent balanitis in two men, and cosmetic reasons in one man.

The average operative time was 16.4 minutes (range, 10–30 minutes). No case required electrocautery or conversion to standard surgical procedures. The average total number of sutures placed was 6.8 (range, 4–9). The average estimated blood loss was 4.2 mL (range, 2–7 mL). The average ease of the procedure recorded by both the surgeon (J.K.) and the assistants (L.C., M.M.) was rated 7.6 on the 10-point Leikert scale.

FIGURE 1



Schematic of circumcision device. The glans is protected by the darker gray glans cap depicted in the picture above. The foreskin is placed between the outer compression ring and glans cap to provide excellent hemostasis and hold tissue to facilitate suturing through the grooves in the suture guide.

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