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Simple Circumcision Device: Proof-of-Concept for a Single-visit, Adjustable Device to Facilitate Safe Adult Male Circumcision

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Abstract

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

Patients—5 adult males

Interventions—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, post-operative pain, cosmetic outcomes and participant satisfaction at 3, 8, 30 and 90 days post-operatively.

Results—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 post-operative 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.

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Conflicts of Interest: None

Meetings: Aspects of this manuscript were presented at the American Urologic Association 2012 and 2013 National Meeting. It has not been submitted to any other journal for consideration.

Conclusions—This proof-of-study suggests that the Simple Circumcision Device (SCD) may facilitate delivery of safe adult male circumcision services.

Keywords

HIV; AIDS; Circumcision; surgical device

INTRODUCTION

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 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 non-physician 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 performed by non-physician medical providers, however, both require subjects to wear the plastic devices for one week to allow necrosis of the prepuce, 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 & METHODS

Study population

The study protocol was approved by the internal review board at the VA Puget Sound Veterans’ Administration Hospital, Seattle, WA IRB#00434. The trial was also registered on clinicaltrials.gov under ID VAPSHCS-00434 in accordance with ICJME 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. Following 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 supervision of a single surgeon (JK). 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, 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 (Figure 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 (Figure 1B). 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, accurate skin re-approximation, then DermaBond™ surgical glue (Johnson & Johnson, New Brunswick, NJ, USA) was applied. The incision was covered with Vaseline gauze (Covidien, Mansfield, MA, USA), then an Elastoplast™ compression dressing (Beiersdorf, North Ryde, Australia).

Statistical analyses

Demographic, clinical and procedural data were collected and averages, standard deviation and percentages were calculated using STATA v11 (College Station TX, USA).

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 (Table 1). The medical indications for circumcision were phimosis in two men, recurrent balanitis in two men and for 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 cc (range 2 – 7 cc, Table 2). The average ease of the procedure recorded by both the surgeon (JK) and the assistants (LC, MM) was rated 7.6 on the 10-point Leikert scale.

At the postoperative day 3 visit, all subjects stated that they would recommend the procedure to another patient. Patients reported that their average postoperative pain score was 4.4 (range 2 – 6) with all subjects indicating they felt less postoperative discomfort than expected. The average surgeon rated score for cosmetic outcome was 8.2 (range 7 – 10). At the day 30 visit one subject reported wound separation on the ventral surface of the glans and a blister on the glans after intercourse (Table 3). This resolved without intervention. There were no wound infections or other adverse events. All subjects were able to engage in masturbation or intercourse within 2 weeks after the procedure without pain.

DISCUSSION

Our study demonstrates that the SCD developed in the applied physics laboratory at the University of Washington is promising as a simple, safe, effective device to provide cosmetically acceptable adult male circumcision with acceptable postoperative pain in a sexually potent population in our hospital setting. All subjects stated that they would recommend this method of circumcision to others.

Development of this device is timely and important as three large trials in South Africa (N=3,274), Uganda (N=4,996) and Kenya (N=2,784) between 2002 and 2006 demonstrated that adult male circumcision was associated with a resultant incident risk ratio for contracting HIV of 0.50 (95% confidence interval: 0.34–0.72) at 12 months; and 0.46 at 21 or 24 months (95% confidence interval: 0.34 to 0.62)(1–3). This is thought to primarily reflect decreased numbers of Langerhans cells (primary HIV receptors) that are harbored in the inner surface of the foreskin, a decreased rate of penile injuries, and decreased sexually transmitted infection rates among circumcised men. HIV-1 has shown an in-vitro tropism for Langerhans cells (9). Circumcision also reduces rates of balanitis and penile cancer (10). These benefits led the World Health Organization to recommend that circumcision should be offered to adult males at risk for HIV infection and to large scale efforts to circumcise high-risk male populations in sub-Saharan Africa (11).

In resource-limited settings, multiple factors limit widespread implementation of adult male circumcision to reduce rates of HIV, sexually transmitted diseases and penile cancer. These factors include limited numbers of providers able to provide male circumcision services, supply chain problems and already stressed health care delivery systems. (13) (14). Circumcision devices offer one approach to increasing availability of male circumcision services.

This study represents merely a proof of concept trial for our device. We believe that our results and several features of the SCD recommend it above devices that have been developed and tested in other countries and are currently further along in the validation process. Regarding our methods, performing this trial in a VA cohort with the approval of a standard institutional review board in the United States provided two advantages. First, the VA patient population includes men of all ages, many with significant medical comorbidities including smoking and diabetes. All study participants had medical indications for circumcision such as phimosis and recurrent balanitis. In these respects our population was more heterogeneous than populations evaluated in trials of other circumcision devices. For

example, the study populations used in the published trials of the Shang ring and Prepex, were healthy, young African men. Second, the SCD was built to FDA standards in the United States and was tested in a VA hospital where the attending surgeon was assisted by urology trainees who were unfamiliar with the device, similar to the medical officers and other service providers who currently perform the majority of adult male circumcisions in many African settings.(2)

While other adult circumcision devices are not available in the US for direct comparison trials, we feel that the SCD design offers several advantages over devices currently being trialed in other countries. The SCD, a single-use adjustable device may address important limitations of other male circumcision devices. First, the SCD requires only one procedure whereas the devices furthest along in development, PrePex, Shang ring and TaraKlamp all require at least two visits. These devices also require a number of sizes (either at 1 or 2 mm increments) and work by compression of tissue with the need for two procedures, one for device application and another for device removal. In contrast, the SCD employs primary wound healing unlike the PrePex, Shang ring and TaraKlamp, which employ secondary wound healing after tissue necrosis taking at least one week longer than surgical wound healing. Studies demonstrate that multiple visits to a physician and the requirement of wearing a device on the penis for a week both limit scale up efforts for an adult circumcision device.(15, 16)

Second, the SCD design incorporates a number of attractive safety features. These safety features include the protective guide that limits risk that the penile shaft may be cut during excision of the prepuce and a protective cap that shields the glans penis from injury. The cutting guide assures that there is a high probability that excision of the prepuce will follow the planned and marked incision line and that excision will be perpendicular to the skin surface, facilitating healing. Suture guides assure accurate placement of the initial four “quadrant” sutures that can be used to guide placement of any other sutures that may prove necessary or desirable. Multiple features assure a high probability of effective hemostasis including the initial compression provided by the device, guided placement of sutures and an external compression bandage. We anticipate that most problems with bleeding will be immediately apparent, allowing placement of additional sutures, ties, cautery or other hemostatic methods. The skin edges are in close apposition as assured by the device compression process, suture placement as well as the surgical glue. Finally, significant problems with the circumcision should be immediately apparent in the surgical setting (although we found none in our small trial). Admittedly, the ideal circumcision procedure would be bloodless with no open wounds. Yet, our SCD procedures were associated with small blood loss, averaging 4.2 cc, and other devices, such as Shang, Tara, and Prepex, involve open wounds that heal by granulation. Thus, there is clearly a need to further improve devices to facilitate adult male circumcision.

Further, work has demonstrated that it takes over 100 procedures for medical personnel in Africa to reduce operative times from 40 minutes to 25 minutes, whereas our device required an average of 16.4 minutes for novices to complete on men who would not have even met inclusion criteria for many other surgical trials.(12) Beginning residents found the procedure easy to learn. The SCD may also offer advantages over standard surgical procedures for

adult male circumcision. These advantages include a substantially lower provider skill level and easier provider training requirements. The single sized device allows for very few instruments and no need for cautery to achieve hemostasis. We found a need for simple sutures only, with most placed using the built in suture guides, in contrast to the need to place more complicated horizontal and vertical mattress sutures commonly used for surgical circumcision.(17)

With regard to the cost of this simple, single-size, single use device, initial estimates from manufacturing sources indicate that device could be made for approximately US\$5.00 per unit. Per unit cost data for the other adult circumcision devices that are being trialed outside the US is not available to us. However, it is likely that the projected low per unit cost of our device added to the advantage of not having to stock multiple sizes of the device would likely make this a financially viable option in a resource limited setting.

Other technical approaches might be implemented to improve the SCD procedures. Although we employed standard local anesthetic methods, it is possible that premedication with analgesics and use of topical agents may reduce patient's discomfort during the procedure. We chose to employ sutures and surgical glue for wound closure. It is possible that use of disposable surgical staples might make wound closure easier.

This is a preliminary study of the device to ensure that it is safe, effective and cosmetically acceptable under supervision of an experienced urologist. Our findings provide proof-of-concept and support the need for additional studies in other populations and with other cadres of providers to further assess the utility of the SCD under field conditions.

CONCLUSIONS

This pilot study of the SCD at our institution involving a small population of American men demonstrates that the device is safe and effective, with an acceptable ease of use for the service providers. It is the first prospective pilot trial of a circumcision device performed in the US with intended use in the US as well as in developing nations. Future trials in Africa are planned to evaluate SCD use by other classes of providers and to assess the SCD as a tool to facilitate scale-up of circumcision efforts.

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Figure 1. Schematic of Circumcision Device

Glans is protected by darker grey glans cap depicted in picture above. Foreskin is placed between outer compression ring and glans cap to provide excellent hemostasis and hold tissue to facilitate suturing through the grooves in the suture guide.

Figure 2. Pictorial description of circumcision device

A. Adjustable circumcision device.

B. Placement of inner preputial ring under foreskin (banana peel) and adjustable outer ring around foreskin.

C. Ratchet on outer adjustable ring maintains both rings in place around foreskin.

D. Circumferential incision to remove foreskin, glans is fully protected by device.

E. Suture guides allow even distribution of reapproximating and hemostatic sutures.

F. Completed circumcision with device removed.