Safety and Efficacy of the PrePex Device for Rapid Scale-Up of Male Circumcision for HIV Prevention in Resource-Limited Settings

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Objective: To assess the safety and efficacy of the PrePex device for nonsurgical circumcision in adult males as part of a comprehensive HIV prevention program in Rwanda.

Methods: Single-center 6-week noncontrolled study in which healthy men underwent circumcision using the PrePex device, which employs fitted rings to clamp the foreskin, leading to distal necrosis. In the first phase of the study, the feasibility of the procedure was tested on 5 subjects in a sterile environment; in the main phase, an additional 50 subjects were circumcised in a nonsterile setting by physicians or a nurse. Outcome measures included the rate of successful circumcision, time to complete healing, pain, and adverse events.

Results: In the feasibility phase, all 5 subjects achieved complete circumcision without adverse events. In the main phase, all 50 subjects achieved circumcision with 1 case of diffuse edema after device removal, which resolved with minimal intervention. Pain was minimal except briefly during device removal (day 7 after placement in most cases). The entire procedure was bloodless, requiring no anesthesia, no suturing, and no sterile settings. Subjects had no sick/absent days associated with the procedure. Median time for complete healing was 21 days after device removal. There were no instances of erroneous placement and no mechanical problems with the device.

Conclusion: The PrePex device was safe and effective for nonsurgical adult male circumcision without anesthesia or sterile settings and may be useful in mass circumcision programs to reduce the risk of HIV infection, particularly in resource-limited settings.

Key words: Africa, bloodless, device, HIV prevention, male circumcision, nonsurgical

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INTRODUCTION

Randomized controlled trials have shown that male circumcision reduces the lifetime risk of HIV infection by 53%–60%.[1–3] Recent meta-analyses confirm that male circumcision can curtail the heterosexual spread of HIV.[4–7] The World Health Organization and the Joint United Nations Program on HIV/AIDS recommend consideration of male circumcision along with other preventive measures in countries with predominantly heterosexual epidemics.[8] More than 38 million adolescent and adult males in Africa could benefit from circumcision for HIV prevention.[9,10]

In the Republic of Rwanda, only 15% of men are circumcised.[11] The government of Rwanda is implementing a nationwide program to circumcise 2 million men by the end of 2012. Given limited resources, such a goal is achievable only with a nonsurgical method that can be performed by nonphysician staff in a nonsterile setting. This report describes a government-sponsored study to test the PrePex device for adult male circumcision.

MATERIALS AND METHODS

The study was approved by the Republic of Rwanda National Ethics Committee in March 2010. This single-center study enrolled healthy uncircumcised men who provided signed informed consent after receiving an explanation of the study and seeing photographs of the procedure.

The Device

The PrePex device (certified CE Class IIa, meeting the safety and health standards of the European Union) consists of an inner ring, elastic ring, placement ring, and a verification thread; there is also a sizing accessory, a template with 5 holes of differing size to guide the selection of ring size (Fig. 1). The device works by compressing the foreskin so as to cut off circulation distally, after which the distal foreskin becomes necrotic, allowing easy and bloodless removal.

Although the components are created for single use and disposal, the placement ring and sizing accessory were reused in the study (disinfected with chlorhexidine between subjects). For this study, the PrePex devices were donated by the manufacturer, Circ MedTech Limited (Tortola, British Virgin Islands).

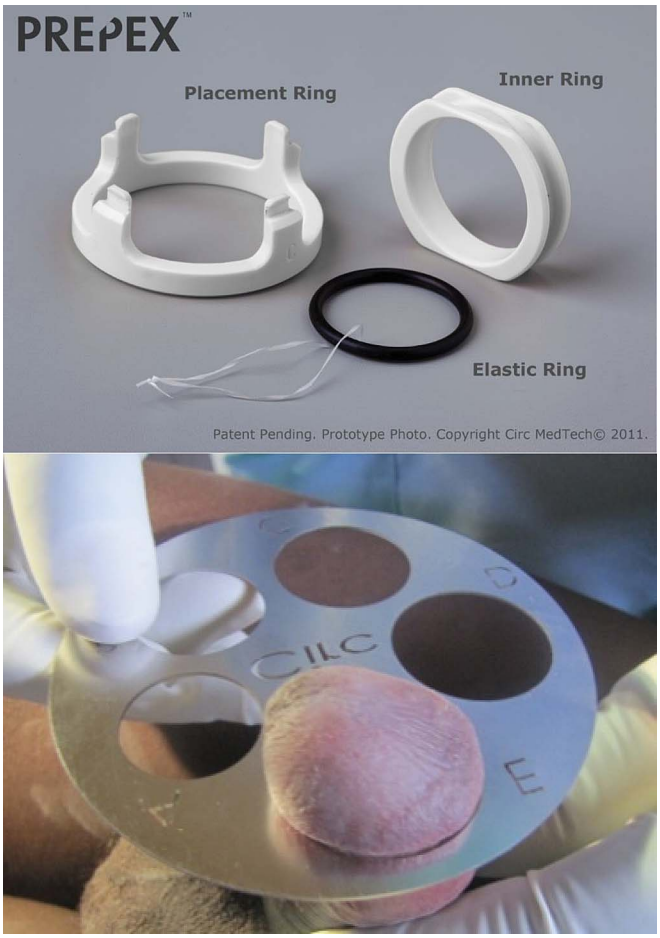

FIGURE 1. Components of the PrePex device (top); sizing accessory measures penis shaft under the coronal sulcus (bottom).

Study Design

Potential subjects were evaluated at the Kanombe District and Military Hospital, Kigali (which serves civilians and soldiers) for suitability based on inclusion/exclusion criteria (Table 1), HIV testing, and HIV counseling. Suitability included the investigator's assessment of factors that could affect study compliance, including subjects' proximity to the study site.

The 6-week study was conducted in 2 phases. The protocol did not call for anesthesia at any point in either phase. The initial phase assessed the feasibility of the procedure in a small number of subjects. Procedures were performed in a sterile setting, with surgical drapes and staff wearing sterile gloves; subjects were hospitalized for the first 3 weeks and then followed on an outpatient basis for the remaining 3 weeks. The second and main phase of the study utilized insights gained in the initial phase. Procedures were performed in a nonsterile setting (because the device comes in contact only with intact skin), with no surgical drapes and staff wearing clean examination gloves; subjects were seen entirely on an outpatient basis.

Table 2 shows the purpose of scheduled visits in the main phase. Routine attempts at follow-up were made when subjects failed to appear for scheduled visits. Participants were reimbursed for travel expenses associated with visits to the clinic.

The Procedure

Day 1 was device placement. For each subject, ring size was selected by placing the sizing accessory immediately under the coronal sulcus (Fig. 1). The penis was disinfected with Betadine and dried. The circumcision line was marked using a surgical marker. Vaseline was then applied to the foreskin, glans, and sulcus. The elastic ring was loaded onto the placement ring, which was positioned at the base of the penis (Fig. 2). The foreskin was held and stretched on each side using 2 fingers and gauze pads for a secure grip. The inner ring was inserted and pushed down as far as possible (Fig. 3). The placement ring facilitated precise placement of the elastic ring above the marked circumcision line (Fig. 4).

When properly deployed, the elastic ring clamps the foreskin against the inner ring (Fig. 5). The elastic ring has a verification thread, which is removed after visually verifying proper placement; in case of erroneous placement, the thread provides a grip to pull off the elastic ring without discomfort.

In the feasibility phase, we explored a strategy of allowing up to 2 weeks after device placement for the necrotic foreskin to self-detach, along with the device. However, this strategy proved impractical. In the physicians' judgment, the appearance of the foreskin in 2 of the 5 subjects suggested that self-detachment should have already occurred at 12 days and active removal was therefore performed. In the other 3 subjects, the foreskin had not self-detached after 14 days and was actively removed on day 15. Another problem with waiting for self-detachment was that removal of the device while the foreskin was still in place required the nonprotocol use of a local anesthetic because the area was sensitive and the investigators wanted to avoid causing discomfort to these first subjects undergoing the procedure. Therefore, in the main phase of the study, active removal of the foreskin and the device became a scheduled procedure.

After placement of the device, subjects were instructed not to touch it. Subjects in the main phase of the study were examined 3–6 hours postplacement and then discharged with instructions to return 3 days later.

Active removal in the main phase of the study was carried out by trimming the necrotic foreskin close to the elastic ring, leaving a remnant (2–4 mm) of foreskin still attached (Fig. 6). After foreskin removal, the elastic ring was removed using a scalpel (size 25), after which the inner ring was extracted by hand or using standard nontoothed dissecting forceps (Fig. 7).

Antibiotic cream (chloramphenicol 3%) and a sterile dressing were applied. Subjects were instructed not to touch the dressing or allow it to get wet and to return in 2 days for removal of the dressing, assessment of the site, and documentation of adverse events or pain. Subjects then returned for weekly follow-up until complete healing was achieved (complete epithelialization with no drainage from the circumcision site) as determined by visual inspection by the physician (Fig. 8).

TABLE 1. Criteria for participation

Inclusion Criteria	Exclusion Criteria
Uncircumcised male, age 18–54 years	Already circumcised; outside age range
Generally healthy	Any of these conditions:
	Active genital infection
	Phimosis or paraphimosis
	Warts under the prepuce
	Torn or tight frenulum
	Narrow opening of the prepuce
	Hypospadias
	Any other penile disease, anatomic abnormality, or other condition that, in the investigator's opinion, would preclude circumcision
	Diabetes mellitus
HIV seronegative	HIV seropositive
Able to understand study procedures and requirements:	Unable to understand study procedures and requirements
Agrees to undergo measurement of width of penis in flaccid state	
Provides written signed consent to undergo circumcision	
Agrees to abstain from sexual intercourse and directly rubbing circumcised area (eg, masturbation), until the end of the follow-up (up to 6 weeks postprocedure)	
Agrees to return to the health care facility for follow-up visits (or as instructed) for up to 6 weeks postprocedure	
Considered by the investigator to have potential for good compliance throughout the study	Considered by the investigator to be an unsuitable candidate for the study

In the main phase, procedure time for device placement was defined as the period from the start of rings placement on the penis to the patient standing up postplacement; procedure time for device removal was defined as the period from picking up the forceps to the beginning of wound dressing postremoval.

Photographs were taken of each subject's penis postplacement, preremoval, postremoval, and at every weekly follow-up visit. Using a standard clinical report form, information was gathered on the rate of success in achieving circumcision (glans fully exposed); time to complete healing; the incidence and severity of adverse events; and levels of pain (documented using a Visual Analog Scale [VAS] on which scores ranging from 0 to 10 represent no pain to the most severe pain) at several defined times (Table 3). Additional information was collected on nonphysicians' self-reporting of their sense of ease or difficulty in performing the procedure and time lost by subjects from work.

TABLE 2. Schedule for the main phase of the study

Visit #	1	2	3	4	5	6	7	8	9	10
Purpose of visit	Screening	Device placement	Genital examination	Device removal	Follow-up	Follow-up	Follow-up	Follow-up	Follow-up	Follow-up
Day	–7 to 0	0	3	4*, 7†	7*, 9†	14	21	28	35	42
Activities										
Informed consent, verify inclusion/exclusion criteria, obtain medical history and demographic profile	X	—	—	—	—	—	—	—	—	—
Review current medication including pain killers; genital examination; and photography	X	X	X	X	X	X	X	X	X	X
Application of device	—	X	—	—	—	—	—	—	—	—
Removal of device and foreskin	—	—	—	X	—	—	—	—	—	—
Assessment of discomfort, other side effects and adverse events	—	X	X	X	X	X	X	X	X	X
Safety and statistical analysis of data	—	—	—	—	—	—	—	—	—	X

*First 5 subjects in the main phase.
†Subsequent 45 subjects in the main phase.

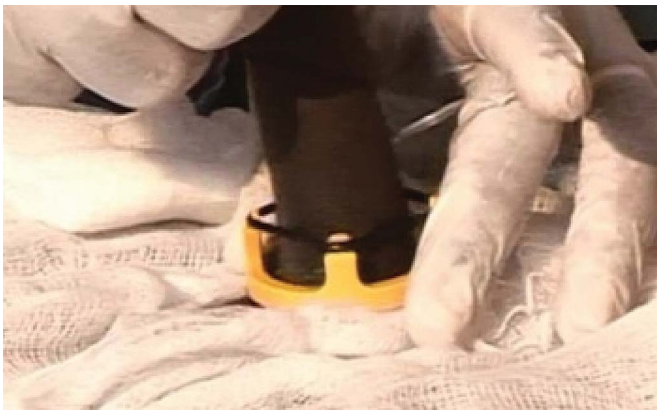

FIGURE 2. The PrePex delivery ring and elastic ring at the base of the penis.

RESULTS

From a large number of volunteers, 81 men were deemed suitable for formal screening. Of these candidates, 58 were selected by the Principal Investigator; among those not selected, 2 were rejected because of phimosis (candidates with a relatively flexible foreskin were preferred, to facilitate placement of the device). All of the selected subjects showed up for the procedure, but 1 subject was later excluded when it was discovered that he was HIV positive.

The remaining 57 men ranged in age from 18 to 35 years (although the protocol allowed age up to 54, no one over age 35 enrolled); average age was 22.5 (SD: 4.3) years. Two subjects were subsequently excluded due to narrow prepuce opening, which had not been previously detected. Thus, the final study population comprised 55 men (5 soldiers, 50 civilians).

There were no cases of erroneous placement of the device in either phase of the study, and no device-related incidents (such as the device slipping out of position).

Initial Phase

The first 5 subjects, comprising the population in the feasibility phase of the study, ranged in age from 21 to 31 years. Notwithstanding the previously described problems relating to waiting for self-detachment, all 5 subjects were successfully circumcised, with no adverse events reported over the 6-week study. Complete healing was documented by day 28 in all subjects.

Main Phase

The remaining 50 subjects comprised the population in the main phase; average age was 23.6 (SD: 4.3) years; median, 22.5; range, 18–35. All subjects were successfully circumcised. The majority of procedures were performed by physicians; 3 placement procedures and 1 removal procedure were performed by a certified nurse.

Active removal of the foreskin and the device was performed on day 4 in the first 5 subjects; however, to allow for more complete necrosis, removal was rescheduled to day 7 in the remaining 45 subjects. There were no differences in outcomes related to date of removal.

After the initial 20 subjects, we administered 1 g of paracetamol 30 minutes before device deployment and 30 minutes before device removal because some patients were experiencing discomfort postdeployment and/or during removal. Otherwise, mean VAS pain scores were predominantly low (Table 3). The preplacement use of paracetamol reduced postdeployment pain but preremoval use had no appreciable effect on the brief pain that subjects experienced during extraction of the inner ring.

After device removal, the only reported adverse event was diffuse edema in a patient with chronic urethritis from a belatedly reported sexually transmitted disease; the edema, presumably related to circumcision itself, resolved in 2 days with the oral anti-inflammatory ibuprofen. There were no cases of infection, bleeding, hematoma, delayed necrosis, or wound dehiscence.

Two subjects had light oozing after foreskin removal, which resolved with 10 seconds of applied pressure. There were 9 cases of painless, mild, localized edema of the frenulum, all of which resolved spontaneously (8 cases resolving in 3 days, 1 case in 2 weeks). The remnant of necrotic foreskin retained after device and foreskin removal dropped off spontaneously within 1–2 weeks (ie, between day 14 and day 21; median, day 14). In some cases, the physicians could detect an odor from the necrotic tissue, but no subjects made any complaint about smell.

Mean time for complete healing was 25.3 (SD: 5.7) days after device removal; median, 21 days. Complete healing was documented in 48 subjects (2 subjects missed their last follow-up visit before complete healing was documented). Complete healing was achieved by day 21 (2 weeks after device removal) in 26 subjects; at day 28 in another 16 subjects; at day 35 in another 4 subjects; and at day 42 in 2 subjects. Most subjects did not return after being told that complete healing had been achieved. Thus, among the 50 subjects in the main phase, 49

FIGURE 3. Inserting the inner ring.

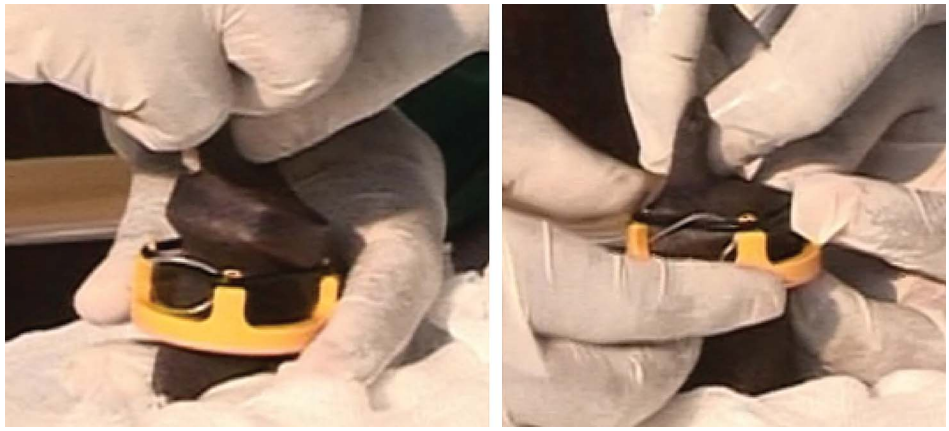

FIGURE 4. Aligning the elastic ring and delivery ring over the foreskin and inner ring (left) and making final adjustments to match the elastic ring and circumcision line (right). Verification thread is now removed.

appeared for follow-up at week 3; 48 at week 4; 36 at week 5, and 17 at week 6. None of the subjects missed any days of military service or work relating to the circumcision.

Procedure times ranged from 3.0 to 5.1 (mean 4.3) minutes for device placement and from 1.9 to 5.8 (mean 3.8) minutes for removal. Personnel reported increasing ease in performing the procedures as they gained experience.

DISCUSSION

Prior studies with other products for adult male circumcision have reported advantages over conventional surgical circumcision, such as elimination of sutures and reduction in procedure time.[12–16] However, we believe that all of these other methods require injection of local anesthesia for device placement and/or removal and that our study is the first report of adult male circumcision as a public health initiative performed without anesthesia.

Another adult male circumcision device is the Shang Ring (Wuhu SNNDA Medical Treatment Appliance Technology Co Ltd, Wuhu, China). A 2011 report describes a 6-week study of this device in Kenya. Similar to the present study, device placement was on day 1 and removal was on day 7.[17] Of 40 procedures performed, all resulted in successful circumcision.

FIGURE 5. The PrePex device is deployed, firmly clamping the skin.

Both the Shang Ring and the PrePex device are single-use devices supplied in multiple sizes. The Shang Ring immediately crushes the foreskin and thus requires anesthesia (6–20 cc of 1% lidocaine without epinephrine, injected circumferentially around the penis) before placement; the PrePex device applies controlled radial elastic pressure and hence requires no anesthesia (though we found it helpful to provide 1 g of paracetamol to reduce discomfort postplacement). Use of the Shang Ring is a surgical procedure that requires a sterile setting because the live distal foreskin is removed immediately after placement of the device (in addition, 4 small incisions are made around the cut edge of the foreskin to minimize wound contraction and to limit pain from nocturnal erection[15]); use of the PrePex device is a nonsurgical procedure that can be performed in a standard consultation room because the distal foreskin is necrotic when removed, bloodlessly. Time for placement and removal of the Shang Ring averaged 4.8 and 3.9 minutes, respectively (total: 8.7 minutes), not counting time for anesthesia to be administered and to take effect; time for placement and removal of the PrePex device averaged 4.3 and 3.8 minutes (total: 8.1 minutes), and there was no need for anesthesia. There were 3 instances of partial detachment of the Shang Ring before removal; there were no mechanical incidents with the PrePex device. The Shang Ring was associated with 6 mild adverse events (3 cases of penile skin trauma, 2 of edema, and 1 of infection) in 40 subjects; the PrePex device was associated with 1 mild adverse event (diffuse edema in a man with chronic urethritis) in the 55 subjects in both phases of the study. In the Shang Ring study, 80% of the men returned to work within 2 days after device placement; in this study of the PrePex device, 100% of the men returned to work the day after device placement. Time to complete healing averaged 28.9 days with the Shang Ring and 25.3 days after removal of the PrePex device (ie, 32 days after placement). In a separate report on 328 Chinese men circumcised with the Shang Ring, major complications included infection (0.6%), bleeding (0.6%), wound dehiscence (0.6%), and edema (4.9%).[15]

The success of any public program encouraging adult circumcision depends on acceptability by candidates for the procedure. The large number of unsolicited volunteers who approached us before and during the study suggests adequate acceptability within the target population. Several subjects

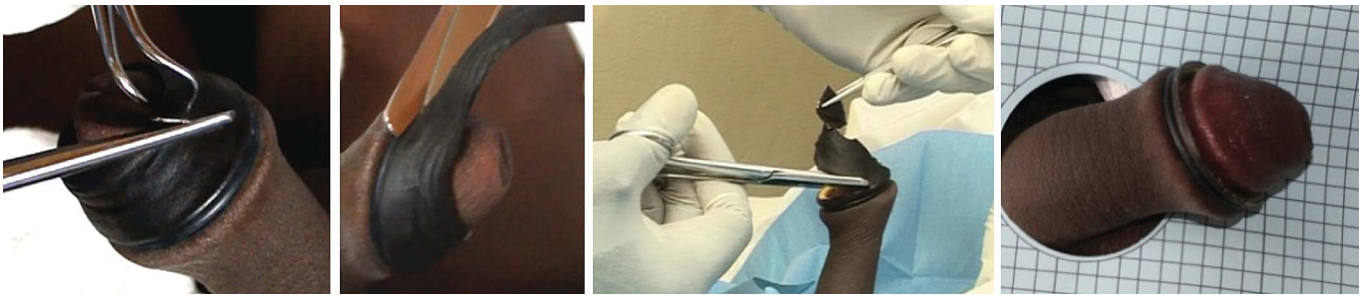

FIGURE 6. Removing the dry necrotic foreskin.

spontaneously expressed satisfaction with the procedure during the course of the study, and some said that they would recommend it to others.

Concerning the exclusion of men with phimosis, the present study was designed to assess a nonsurgical procedure for rapid scale-up programs in Sub-Saharan Africa; men with phimosis might be circumcised with the PrePex device after a small slit in the foreskin, as has been done with other devices, although that added step would transform the procedure from nonsurgical to surgical; future studies may explore this option. The true prevalence of phimosis is uncertain. In a study of 351 boys and men circumcised with the Shang Ring, 46 (13%) had phimosis,[18] whereas among 81 screened candidates in the present study, 4 (5%) were excluded (2 during screening, 2 after admission) because of phimosis. According to a report from the British Association of Paediatric Urologists, 5% of boys ages 16–17 still have nonretractible foreskin.[19]

Healing and Adverse Events

The average time for complete healing after surgical circumcision in adult males is 4–6 weeks.[10] In our study with the PrePex device, mean time to complete healing was 25.3 days after foreskin removal or 32 days after device placement, which is within the same range, and is similar to healing time with the Shang Ring.

Reported problems associated with surgical circumcision include postoperative bleeding, wound infection, anesthesia-related complications, and edema.[20] With the PrePex device, localized edema is an expected occurrence during healing. Edema incidence rates of 50%[12] and 14%[13] have been reported with other ring devices. In our study, all cases of localized edema (9 of 50 subjects) occurred after device removal and resolved spontaneously. There were no adverse events while the device was in place. The only reported adverse event after removal was the case of diffuse edema in a subject with chronic urethritis.

Foreskin Removal

During the initial phase of the study, self-detachment of the foreskin was explored but ruled out as unpredictable and impractical (although the experience suggested that there would be no acute danger if a man missed his scheduled visit for active removal). Accordingly, in the main phase, active removal of the foreskin and the device was a scheduled procedure, which took place on day 4 in the first 5 subjects and on day 7 in the remaining 45 subjects, to allow time for the foreskin to become more completely necrotic for bloodless removal with scissors. We noted no differences in outcomes related to removal on day 4 versus day 7.

Infection and Bleeding

There were no cases of infection or outright bleeding with the PrePex device, but 2 subjects had light, transient oozing after foreskin and device removal (stopped by local compression with gauze for 10 seconds). From various reports on the Shang Ring, the incidence of infection was 0.6%–2.5%, and the incidence of bleeding was 0.0%–0.6%.[12,15,17,18] From a systematic review of published reports of nontherapeutic surgical circumcision in men, the 2 most common adverse events were infection (incidence 1.47%) and postoperative bleeding (1.32%).[20]

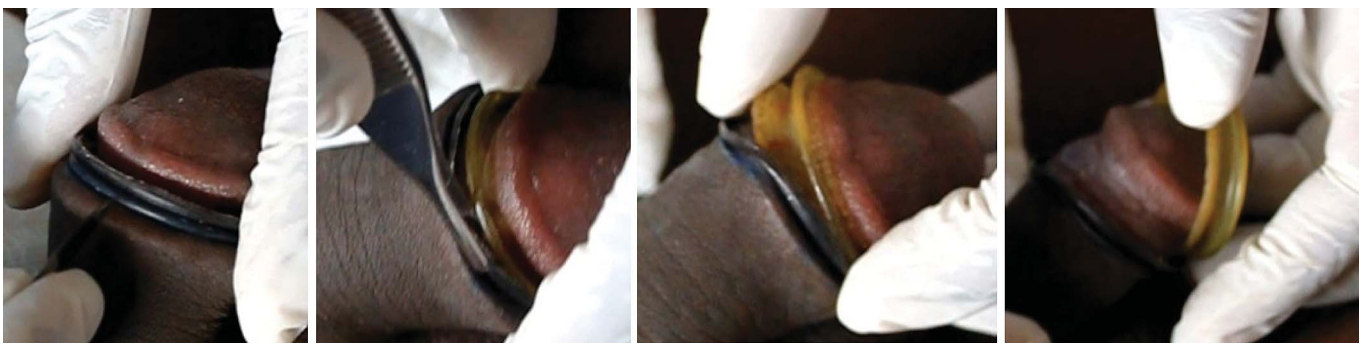

FIGURE 7. Removing elastic ring with scalpel and then extracting inner ring with forceps and/or fingers.

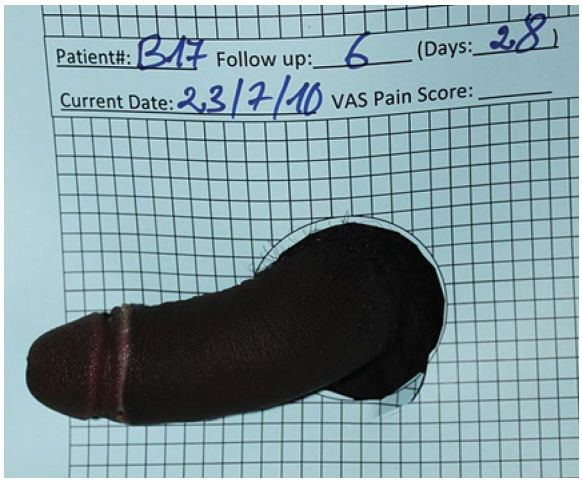

FIGURE 8. Complete circumcision with complete healing.

Pain

Because we noted that several of the first 20 subjects in the main phase experienced pain after placement and/or during removal of the device, we thereafter provided a 1-g dose of oral paracetamol 30 minutes before placement and before removal; no additional painkiller was required in any subject at any time. Subjects reported minimal pain at all other times. Paracetamol reduced postplacement discomfort but not the brief pain subjects experienced during removal of the inner ring. Circumcision using the Shang Ring requires injection of local anesthetic around the penis.[15,17]

We recommend that in future studies, VAS pain score should be checked earlier after device placement (in the present study, we checked 3–6 hours after placement). We now believe that ibuprofen administered immediately after placement may be a better means of managing discomfort at this step.

Among the 50 subjects in the main phase of our study, 10 reported minor discomfort with nocturnal erection while the PrePex device was in place, but this experience was not objectively measured. The need for a standardized means of assessing pain from nocturnal erection is suggested by contrasting the 20% incidence of pain on erection reported in the present study and the 86% incidence reported in one study of the Shang Ring.[12]

TABLE 3. VAS Mean Scores for Pain in the Main Phase of the Study

Procedure Step	Average (SD) VAS Score (0–10; No Pain to Most Severe Pain)
During device placement	0.53 (0.89)
3–6 hours postplacement*	
Without paracetamol	4.2 (2.8)
With paracetamol	0.16 (0.56)
3 days postplacement	0.4 (0.8)
Before device and foreskin removal	0.26 (1.2)
During foreskin removal	0.7 (1.6)
During device removal (with or without paracetamol)	5.4 (2.1)
1 minute postdevice removal	0.9 (1.9)
1 day postremoval and each weekly follow-up visit	<0.5

*The first 20 patients did not receive paracetamol before device placement and device removal.

Procedure Time

As the team gained experience, procedure time decreased. We anticipate that total procedure time would be less than 5 minutes when performed by experienced personnel. Total procedure time is marginally lower with the PrePex device than with the Shang Ring (8.1 versus 8.7 minutes), but anesthesia adds to the overall time required with the Shang Ring. In various reports, the time required for conventional surgical circumcision is 25–36 minutes.[16,21,22]

Topical Agents and Dressings

We used vaseline as a lubricant on the penis to ease insertion of the PrePex inner ring. In retrospect, we would recommend a water-based lubricant applied only on the Inner Ring itself.

After removal of the foreskin and the device, we covered the remnant of necrotic tissue with antibiotic cream and gauze dressing to reduce the risk of wound infection. In fact, there were no infections, and we suspect that there is no need for antibiotic cream; this question will be explored in future studies. An alternative would be a vaseline gauze dressing (as currently used in surgical circumcision) or a standard gauze dressing.

Staff and Facility Requirements

Circumcision using the PrePex device requires 2 trained staff members for device placement; both can be nurses, and at least 1 should have ample dexterity. Device removal requires 1 person with ample dexterity. Although most of the procedures were handled by physicians, we noted no differences in procedure time, pain, adverse events, or healing time related to whether procedures were performed by a nurse or a physician. Further study is warranted to document the feasibility of entrusting the procedure to nurses, but these preliminary results are encouraging and potentially important for large-scale male circumcision programs in Sub-Saharan Africa.

The main phase of our study was conducted in a standard consultation room. Aside from savings in costs and resource use from foregoing the sterile setting, men may feel less intimidated in a consultation room.

Costs

Binagwaho et al[23] have demonstrated that adult male circumcision is cost-effective even in regions with a relatively low HIV prevalence, such as Rwanda. Although there was no formal assessment of costs in this study, the use of the PrePex device may reduce costs, as the procedures can be performed by nonphysician staff, without anesthesia or suturing, in an ordinary consultation room. In the main phase of our study, none of the subjects missed any days of work after placement or removal of the device, which is relevant in a national scale-up program.

Study Limitations

Although we tried to select subjects with a more flexible foreskin, there was no validated method for assessing candidates on this basis. Also, we performed no methodical assessment of discomfort from erection while the PrePex device was in place; we recommend that future studies should obtain VAS pain scores during erection if subjects are cooperative. We did not formally analyze costs with the PrePex device versus other methods of circumcision, nor did we formally assess subjects' overall level of satisfaction with the procedure.

CONCLUSIONS

The PrePex device was safe and effective as a means of performing bloodless adult male circumcision that can be carried out by nonphysician staff without need for anesthesia, suturing, or sterile settings. Pending further research, such as a study in which the procedure is performed entirely by nonphysician personnel, these promising results could prove to be a significant advance in HIV prevention programs in sub-Saharan Africa.

ACKNOWLEDGMENTS

This study was particularly meaningful to us as physicians and public policy makers. Although many countries are seeking drastic solutions to reduce HIV incidence, we now feel close to having a viable solution. The results of this study are promising, as male circumcision programs are an effective means of HIV prevention when combined with safe sex education and counseling, and the PrePex device has the potential to enable large-scale circumcision programs in resource-limited areas. We thank our International Male Circumcision Advisory Committee members Dr Natan Bar-Chama, Mt Sinai Medical Center; Dr Steven Kaplan, Weill-Cornell Medical Center, Dr Emmanuel Kayibanda, President of the Surgical Society Rwanda; Dr Renee Ridzon, the Bill and Melinda Gates Foundation; Dr Thomas Serena, Serena Group of Advanced Wound Healing; and Dr Ira Sharlip, University of California San Francisco, for their invaluable contributions to this study and focusing our attention on the vital aspects of assessing a new medical device. We thank Dr Tim Farley, World Health Organization, for his technical assistance with the study; and Dr Kim Dickson, World Health Organization, and Dr Renee Ridzon, who visited Rwanda to witness procedures and follow-ups. Their dedication to finding solutions to stop the spread of HIV by male circumcision and other means is exceptional. We thank Tzameret Fuerst, CEO of Circ MedTech Limited, and the company, for donating devices and for their commitment to improve the device for the wellbeing of patients and convenience of health care providers. We thank Steven Tiger, PA, and his employer, Complete Healthcare Communications, Inc (Chadds Ford, PA), for contributing their time and editorial support gratis during the preparation of this article. Finally, we thank the Rwandan men who trusted us. They are the true heroes of this study, which could have an important impact on global public health.

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