Non-surgical Adult Male Circumcision Using the PrePex Device: Task-Shifting from Physicians to Nurses

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Abstract

The Republic of Rwanda is implementing a program of voluntary male circumcision (MC) to reduce HIV transmission but lacks the infrastructure for conventional surgical MC on a nationwide scale. Nonsurgical MC using the PrePex device was first assessed in 5 subjects on an inpatient basis. Subsequent procedures were on an outpatient basis. Physicians performed 100 outpatient procedures (Phase 1 of this study) and trained nurses in the technique; the nurses then independently performed 47 procedures (Phase 2). All subjects achieved complete circumcision and healing within 6 weeks. There were no cases of infection or bleeding. In Phase 1, one case of transient moderate diffuse edema occurred. In Phase 2, no adverse events were reported. Thus, outcomes of MC performed by nurses using the PrePex device were not inferior to outcomes achieved by physicians, suggesting that task-shifting MC by this method from physicians to nurses is feasible in Rwanda. (Afr J Reprod Health 2014; 18[1]: 61-70).

Keywords: Circumcision, device, nurses, Rwanda, safety, task-shifting

Résumé

La République du Rwanda met en œuvre un programme de circoncision masculine volontaire (CM) pour réduire la transmission du VIH, mais n'a pas l'infrastructure pour la CM chirurgicale classique à l'échelle nationale. CM non chirurgicale en utilisant le dispositif PrePex a été évaluée pour la première fois en cinq sujets en milieu hospitalier. Les procédures postérieures ont été basées sur une consultation externe. Les médecins ont effectué 100 interventions basées sur les consultations externes (phase 1 de cette étude) et ont formé les infirmières formés dans la technique. Les infirmières, à leur tour, ont effectuées indépendamment 47 procédures (phase 2). Tous les sujets atteints une circoncision complète et la guérison dans 6 semaines. Il n'y avait aucun cas d'infection ou de saignement. Dans la phase 1, un cas d'œdème modéré diffuse transitoire s'est produit. Dans la phase 2, aucun effet indésirable n'a été signalé. Ainsi, les résultats de CM effectuées par des infirmières à l'aide du dispositif PrePex n'étaient pas inférieurs aux résultats obtenus par les médecins, ce qui suggère que la délégation des tâches à la CM par cette méthode est possible au Rwanda. (Afr J Reprod Health 2014; 18[1]: 61-70).

Mots clés: circoncision, dispositif, infirmières, Rwanda, sécurité, délégation des tâches

Introduction

Randomized controlled studies have shown that male circumcision (MC) can reduce the risk of transmission of human immunodeficiency virus (HIV) by 53\%–60\%\textsuperscript{1,2} and meta-analyses of available data have confirmed the risk reduction with MC\textsuperscript{4,7}. The World Health Organization (WHO) and Joint United Nations Programme on HIV/AIDS recommend consideration of MC as a means of HIV prevention\textsuperscript{8}. Over 38 million adolescent and adult males in Africa would be candidates for MC for this purpose\textsuperscript{9,10}, and WHO estimates that at least 20 million procedures must be performed to achieve the desired impact\textsuperscript{11}.

In 2010, the government of Rwanda initiated a program of voluntary MC to reduce the incidence of HIV. However, conventional surgical MC
would not be cost-effective in Rwanda, because the HIV prevalence is relatively low compared to many other African nations and the nation has only about 300 physicians (2.4 per 100,000 people), among whom only 48 are surgeons; moreover, the population is largely rural and lacks easy access to surgical facilities. It was therefore decided that the most practical approach would be task-shifting MC from a surgical procedure performed by physicians at a hospital to a nonsurgical procedure that could be performed by nurses using a device that entails no need for anesthesia, suturing, or sterile surgical setting. (In contrast, a task-shifting program in Kenya involves training nurses to perform surgical MC.)

Among the MC devices considered by the Rwandan Ministry of Health, the PrePex™ device seemed most suitable, and a formal assessment program under the guidelines of WHO was instituted. The initial investigation demonstrated that the device fulfills the goal of achieving MC safely and effectively, with no need for injected local anesthesia, suturing, or sterile settings. An initial evaluation in the inpatient setting assessed feasibility and safety in 5 volunteers, all of whom were successfully circumcised with no adverse events. Thereafter, the main part of the study commenced, in which the procedures were performed on an outpatient basis. From the initial group of volunteers, 50 men underwent the procedure performed by physicians, and all achieved complete circumcision with only 1 reported adverse event, which quickly resolved with conservative management, as previously reported.

In view of these favorable results, the WHO Technical Advisory Group on Innovations in Male Circumcision evaluated and approved the use of the device in Rwanda, recommending phased implementation with active surveillance of the first 1000 clients. Accordingly, it was decided to enrol a second group of volunteers, to include 100 subjects, with outpatient MC to be performed in the first 50 men by physicians and in the remainder by nurses.

**Methods**

The study (clinicaltrials.gov identifier NCT 01150370) was approved by the Republic of Rwanda National Ethics Committee in March 2010; the amendment to perform additional procedures with the PrePex device, including procedures to be performed by nurses, was approved in April 2011.

The study protocol invited healthy, HIV-seronegative, uncircumcised men, ages 18 to 54 years, to have MC performed with the PrePex device. The procedures would be performed at Kanombe Military Hospital (which also serves civilians) in Kigali. Volunteers were screened according to inclusion/exclusion criteria (Table 1). Individuals who did not meet the criteria for participation were offered alternative treatment (surgical MC for men with narrow foreskin or paraphimosis; or medical treatment for men with penile lesions, fever, or other disease, with the option of surgical MC following resolution of the condition).

Table 1: Criteria for participation

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncircumcised male, age 18–54 years</td>
<td>Already circumcised; outside age range</td>
</tr>
<tr>
<td>HIV seronegative</td>
<td>HIV seropositive</td>
</tr>
<tr>
<td>Generally healthy</td>
<td>Active genital infection; phimosis or paraphimosis; warts under the prepuce; torn or tight frenulum; narrow opening of the prepuce; hypospadias; any other penile condition that would preclude circumcision; diabetes mellitus</td>
</tr>
</tbody>
</table>

Able to understand and comply with study procedures and requirements such as providing written signed consent, abstaining from sexual intercourse and masturbation for up to 6 weeks post-procedure, and returning to the facility for follow-up visits as instructed for up to 6 weeks post-
After the initial assessment of feasibility in 5 inpatients, the study of outpatient MC using the PrePex device was conducted in two phases, and in two groups of subjects; the second group spanned both phases (see Figure 1). In Phase 1, voluntary MC using the PrePex device was performed by physicians, who then taught the procedure to nurses; in Phase 2, nurses performed the procedure. The sequential nature of the study (Phase 1 procedures performed by physicians, followed by Phase 2 procedures performed by nurses) was dictated by safety concerns: the physicians had to practice the procedure and optimize their techniques before they could teach it to the nurses. Consequently, outcomes from Phase 1 and Phase 2 could not be assessed in the manner of a randomized parallel-group study. In summary, Phase 1 of the study, in which subjects were seen by physicians, comprised the first 100 outpatient procedures performed (on 50 subjects from the first group of volunteers and 50 from the second group); Phase 2, in which subjects were seen by nurses, comprised the next 47 outpatient procedures performed (all on subjects from the second group).

Candidates received a detailed verbal and photographic depiction of the procedure, including the fact (for subjects in Phase 2) that nurses would perform the procedure. Subjects received HIV counseling and were instructed to abstain from sexual activity for 8 weeks following device removal. It was emphasized that MC reduces but does not eliminate the risk of HIV infection, and that condoms are still recommended. Enrolled subjects provided signed informed consent; counseling and the consent form were in the local language (Kinyarwanda).

The Procedure

A detailed description of the procedure, with photographs at each step, has previously been published. Briefly, the bloodless nonsurgical procedure began with device placement (day 0). Sizing was determined by placing the Sizing Plate under the coronal sulcus. The penis was washed with dilute chlorhexidine solution and dried. The circumcision site, a line corresponding to the coronal sulcus, was marked on the foreskin.

In Phase 1, petroleum jelly was used as a lubricant to facilitate insertion of the Inner Ring. However, because some subjects experienced mild pain in the first few hours after placement of the device, dermal anesthetic cream (5% lidocaine), which also serves as a lubricant, was used in Phase 2. (This decision was made based on interim assessment of the experience with all 100 procedures performed in Phase 1.)

The Elastic Ring was loaded onto the Placement Ring, which was then placed around the base of the penis. With the foreskin held stretched out, the Inner Ring was inserted and slid down on the glans. The Placement Ring then deployed the Elastic Ring directly above the marked circumcision line, clamping the foreskin against the Inner Ring. Subjects received 1 gram of oral paracetamol (acetaminophen) immediately after placement of the device and were examined 1–4 hours post-placement; they were then discharged with instructions not to move or touch the device.

On day 7 (1 week after device placement), the dry, necrotic foreskin was removed using scissors and forceps; there was no bleeding and no need for suturing. The Elastic Ring was then removed using a #10 scalpel, after which the Inner Ring was extracted.

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The sterile gauze dressing was applied around the circumcision site. In Phase 1, an antibiotic cream was applied after device removal; however,
because the site was not open or bleeding at any time during healing after device removal, this step was skipped in Phase 2. Subjects were instructed not to touch the dressing or allow it to get wet, and to return in 2 days and then weekly until the end of the study (days 14, 21, 28, 35, 42, 49, 56, and 63).

Thus, the key differences between the procedures performed by physicians in Phase 1 and by nurses in Phase 2 were the type of topical agent applied to the foreskin prior to insertion of the Inner Ring (petroleum jelly in Phase 1, dermal anesthetic cream in Phase 2) and the use of antibiotic cream after device removal in Phase 1 versus non-use in Phase 2. In addition, a more vigorous definition of complete healing was adopted after the first 50 subjects in Phase 1, and this new criterion applied to the remaining subjects in Phase 1 and all subjects in Phase 2.

Assessments

At each visit, subjects’ perspectives were elicited by interview, photographs for documentation photographs were obtained, and specific information on safety, pain, and findings on genital examination was recorded on a clinical report form.

Efficacy assessments included achievement of complete circumcision (glans fully exposed) and time to complete healing (complete epithelialization with no scab, crust, or drainage). Device-related and procedure-related adverse events were recorded at each visit. Pain was reported using a standard visual analog scale (VAS) on which scores of 0 to 10 represent no pain to the most severe pain; ratings were obtained during device placement, 1–4 hours post-placement, prior to device removal, during foreskin removal, during device removal, 1 minute post-removal, and at every weekly follow-up visit.

Rigorous statistical analysis for hypothesis testing (whether outcomes with nurses performing the procedure would be inferior to outcomes achieved by physicians) was not feasible given the design of the study. Phases 1 and 2 were conducted sequentially rather than in parallel (for reasons of safety, as previously mentioned); consequently, there could be no randomization (because patients were seen consecutively; the first 100 were seen by physicians, the next 47 by nurses); and there could be no blinding (because subjects as well as staff personnel were aware of who was performing the procedure in each participant). However, to assess the key question—could the task of performing MC using the PrePex device be shifted from physicians to nurses?—post hoc t tests were utilized to compare the results from Phases 1 and 2. Post hoc testing was considered warranted in this study, given that the same MC procedure was followed in both phases. (Because the feasibility assessment was done on an inpatient basis for purposes of safety, data from those 5 subjects could not be combined with data from the outpatient procedures done in Phase 1; however, as previously reported, all 5 inpatient procedures resulted in successful circumcision with no adverse events.) Although the results of post hoc testing should be interpreted cautiously, these data can provide at least some indication of whether outcomes with nurses are comparable to or inferior to the outcomes achieved by physicians.

Results

A total of 190 volunteers were prescreened. Of 81 volunteers in the first group, 23 were excluded at prescreening, including 2 volunteers who had phimosis, which would make insertion of the Inner Ring difficult; other reasons included HIV-positive status and inability to come for follow-up visits due to geographic distance from the study site. Of the remaining 58 volunteers in the first group, 3 were subsequently excluded based on late discovery of phimosis or HIV-positive status, leaving 55 men in the first group (67.9% of 81). Of 109 volunteers in the second group, 12 were excluded at prescreening, leaving 97 in this group (89.0% of 109).

Phase 1 (MC performed by physicians, March–December 2010) included the 55 men from the first group and the first 50 men from the second group. Phase 2 (MC performed by nurses, May–July 2011) included the remaining 47 men in the second group. Figure 1 shows patient disposition for both groups through both phases of the study.

The enrolled population comprised healthy, uncircumcised male volunteers, all civilians, ages 18 to 40 years; mean age was 24.3 years (standard deviation [SD] 4.1) among the 100 subjects seen
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by physicians in Phase 1 and 23.8 years (SD 3.9) among the 47 subjects seen by nurses in Phase 2 (post hoc t-test, $P=0.0721$).

In all 147 outpatient-subjects, the PrePex device was successfully placed, and all subjects achieved complete circumcision and complete healing. Thus, the rate of success was 100% with both physicians and nurses.

CAPTION:
Disposition of patients in both groups, in both study phases. MC=male circumcision.

**Figure 1:** Patient disposition

No adverse events or device-related incidents (e.g., dislocation) were reported while the device was in place. Among the initial 50 subjects in Phase 1, the only adverse event reported after device removal was a case of diffuse edema, which resolved in 2 days with minimal intervention. No adverse events were reported in Phase 2. There were no instances of bleeding or infection in any patient at any time in either phase of the study. In an unusual incident in Phase 2, a subject removed the device himself, 3 days after placement; when he returned on day 7, the necrotic foreskin, still attached, was removed by the nurse, after which circumcision and healing ensued without complication.

Among expected mild events, light oozing after removal of the foreskin occurred in 7/100 subjects (7.0%) in Phase 1 and in 5/47 subjects (10.6%) in Phase 2, all cases resolving with 10 seconds of applied pressure; and mild and painless localized edema of the frenulum occurred in 16/100 subjects (16.0%) in Phase 1 and in 11/47 subjects (23.4%) in Phase 2, all cases resolving spontaneously within a few days. There was no significant difference in the incidence rates for these events in Phase 1 versus Phase 2 (post hoc Fisher’s exact test, $P=0.5222$ for light oozing; $P=0.3609$ for localized edema). Thus, overall safety seemed similar with nurses or physicians performing the procedure.

Patients’ VAS ratings of pain were recorded for each step of the procedure and later converted to the nearest whole-number rating (Table 2). During both phases of the study, mean pain scores were <1 (minimal pain) at all assessments except 1–4 hours after placement of the device and during removal of the device. At all assessments, mean pain scores were higher in Phase 1 (when petroleum jelly was applied before placement) than in Phase 2 (when dermal anesthetic cream was used).
was used); the difference between Phase 1 and Phase 2 was significant at placement (post hoc t-test, \( P=0.0013 \)), post-placement (\( P<0.0001 \)), and Inner Ring extraction (\( P<0.0001 \)). Inner Ring extraction was the only procedural step associated with notable pain; the incidence of VAS score 8 (the highest score recorded during the study) was 23.5% in Phase 1 versus 2.3% in Phase 2 (post hoc Fisher’s exact test, \( P=0.0012 \)). Pain at this procedural step was transient (5–10 seconds), ending when extraction was completed.

### Table 2: Patients’ VAS ratings of pain at key steps in the procedure

<table>
<thead>
<tr>
<th>Day</th>
<th>Procedural Step</th>
<th>Phase 1 (MC by physicians)</th>
<th>Phase 2 (MC by nurses)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Range</td>
<td>Mean (SD)</td>
<td>Median*</td>
</tr>
<tr>
<td>0</td>
<td>Placement of device</td>
<td>0-6</td>
<td>1.1 (1.38)</td>
</tr>
<tr>
<td>1–4 h after placement</td>
<td>0-8</td>
<td>2.4 (2.55)</td>
<td>2 (0, 4)</td>
</tr>
<tr>
<td>7</td>
<td>Removal of foreskin</td>
<td>0-8</td>
<td>1.4 (2.02)</td>
</tr>
<tr>
<td></td>
<td>Extraction of Inner Ring***</td>
<td>2-8</td>
<td>5.1 (2.12)</td>
</tr>
<tr>
<td></td>
<td>Immediately after removal</td>
<td>0-8</td>
<td>0.8 (1.56)</td>
</tr>
</tbody>
</table>

*Median with interquartile range (25th, 75th percentiles)

**Pain during device removal was associated almost entirely with 1 step: extraction of the Inner Ring (time for this step, 5–10 seconds).

MC=male circumcision; SD=standard deviation; VAS=visual analog scale (0=absence of pain, 10=most severe pain; each individual rating was recorded as the nearest whole number).

In determining time to complete healing, 12 of the 100 subjects in Phase 1 missed at least 1 follow-up visit and then returned after complete healing had occurred; time to complete healing in those cases was taken as the date of return to the clinic. Nine of the 47 subjects in Phase 2 failed to return after healing was almost complete and were excluded from computation of time to complete healing. Mean time to complete healing was 29.3 days after device removal (SD 7.2) among 100 subjects in Phase 1 and 31.2 days (SD 5.6) among 38 subjects in Phase 2. Median times were 21 days in Phase 1 versus 28 days in Phase 2 (Kaplan-Meier analysis log-rank test, \( P<0.0001 \)). The incidence of complete healing week by week is shown in Table 3.

### Table 3: Week-by-week incidence of complete healing (non-cumulative)

<table>
<thead>
<tr>
<th>Time after device placement (day 0)</th>
<th>Phase 1 (n=100*): MC by physicians</th>
<th>Phase 2 (n=58**): MC by nurses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number %</td>
<td>Number %</td>
<td>Number %</td>
</tr>
<tr>
<td>Week 1 (day 7)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Week 2 (day 14)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Week 3 (day 21)</td>
<td>52 (52.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Week 4 (day 28)</td>
<td>36 (36.0)</td>
<td>17 (44.7)</td>
</tr>
<tr>
<td>Week 5 (day 35)</td>
<td>6 (6.0)</td>
<td>14 (36.8)</td>
</tr>
<tr>
<td>Week 6 (day 42)</td>
<td>6 (6.0)</td>
<td>7 (18.4)</td>
</tr>
<tr>
<td>Week 7 (day 49)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Week 8 (day 56)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Week 9 (day 63)</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Total</td>
<td>100 (100.0)</td>
<td>38 (100.0)</td>
</tr>
</tbody>
</table>

*Includes 12 subjects who missed ≥1 follow-up and returned when healing was complete; time of healing was taken as day of return to clinic.

**Excludes 9 subjects (of 47 enrolled) who did not return after a visit in which healing was noted to be almost complete.

MC=male circumcision.

### Discussion

For resource-poor areas, WHO considers innovative methods of MC suitable if they are simpler, less resource-intensive, usable by non-physician providers, acceptable to clients and providers, and as safe as surgical MC. Thus, the WHO Technical Advisory Group on Innovations...
in Male Circumcision approved the PrePex device for use in Rwanda\textsuperscript{15}. In addition to the PrePex device used in the present study, several other MC devices are available. Devices may be classified as those that crush the foreskin immediately upon placement (and therefore require anesthesia) and those that induce necrosis over several days (the PrePex device is in this category). The Shang Ring crushes the foreskin between concentric rings; in a study of MC using the Shang Ring in Kenya, 40 men were successfully circumcised, with 6 adverse events reported (3 penile skin injuries, 2 cases of edema, 1 infection)\textsuperscript{16}. Other crush devices include the Gomco clamp, the AlisKlamp, and the SmartKlamp. In contrast, the Plastibell (like the PrePex device) induces gradual necrosis; however, whereas the PrePex device employs an Elastic Ring, the Plastibell employs a string tied tightly around the foreskin to press in against a bell-shaped component that fits over the glans.

WHO recommendations for use of MC devices reflect the problems associated with conventional surgery in resource-poor areas: inadequate availability of qualified personnel and surgical facilities\textsuperscript{13}. Surgical MC also incurs a variable risk of adverse events. In 2 studies from Kenya, adverse event rates of 1.5\%\textsuperscript{2} and 17.7\%\textsuperscript{17} were reported, and a systematic review of 8 randomized controlled trials of nontherapeutic MC reported an overall adverse event rate of 4.8\%\textsuperscript{18}.

In resource-limited areas where HIV is prevalent, task-shifting of HIV/AIDS services is warranted when shown to be feasible\textsuperscript{19}. Our study provides preliminary evidence that task-shifting MC using the PrePex device from physicians to nurses can be accomplished without compromising outcome. The minor procedural differences in Phase 1 and Phase 2 do not alter the assessment of safety, which was our main focus.

Certain details of the present study merit further comment.

Pain

The experience gained by the physicians in Phase 1 of the study led to improved management of pain by the nurses in Phase 2. In Phase 1, the mean VAS pain score was <1 at all assessments except 1–4 hours after device placement and at extraction of the Inner Ring during device removal. Based on subjects’ reports of the mild nature of pain 1–4 hours post-placement, we replaced the petroleum jelly used in Phase 1 with a dermal anaesthetic cream in Phase 2. Consequently, mean VAS pain score at 1–4 hours post-placement fell from 2.4 in Phase 1 to 0.3 in Phase 2.

Pain during the extraction of the Inner Ring (mean VAS score 5.1 in Phase 1 and 3.0 in Phase 2) was brief, ending when extraction was accomplished. Initially, we administered paracetamol prior to device removal; however, the oral analgesic did not prevent pain at this step\textsuperscript{14} and we therefore no longer recommend its use. It is reasonable to ask whether dermal anaesthetic cream might be helpful in this step; our view is that topical anaesthetic cream is not a sterile product and should not be applied to a wound site. The best way to minimize pain during Inner Ring extraction is to reduce the brief time required for this step, and we have noted that extraction time was reduced as personnel gained experience.

Risk of Infection

In Phase 2, we discontinued use of antibiotic cream immediately after removal of the necrotic foreskin and the PrePex device. The fact that there were no cases of infection in either phase of the study and that the healing process was identical in both phases supports our view that the use of antibiotic cream is unnecessary because it does not alter clinical outcomes of MC using the PrePex device.

Procedure time

Because the primary aim of this study was to assess the safety of MC using the PrePex device, procedure time was not a pre-specified endpoint. However, we can report anecdotally that total procedure time (device placement time and removal time combined, but not including preparation time) became shorter for both the physicians in Phase 1 and the nurses in Phase 2 as they gained experience over the course of the study. There was no significant difference in mean procedure time in Phase 2 versus Phase 1. Procedure time with the PrePex device is

substantially shorter than the 25–36 minutes mean procedure time reported with conventional surgical
MC\textsuperscript{20–22}; this difference was verified in a
randomized controlled trial directly comparing
PrePex MC and conventional surgical MC, for
which the procedure times were 3.1 and 15.4
minutes, respectively (\(P<0.0001\))\textsuperscript{23}.

**Healing time**

In the initial report on the first 50 subjects in Phase
1 of the study\textsuperscript{14}, mean time to complete healing
was 25.3 days after device removal, whereas mean
times reported here for Phase 1 and Phase 2 were
29.3 and 31.2 days, respectively. However, this
difference should be considered in light of the fact
that a more rigorous definition of complete healing
was adopted after the first 50 subjects in Phase 1.
All subjects in both phases of study achieved
complete healing by day 42 (35 days after device
removal). Mean time to complete healing in this
study was consistent with the mean time of 31
days following device removal reported in the
comparative trial of MC with the PrePex device
versus conventional surgery\textsuperscript{23}. All subjects in our
study reported compliance with the instruction
relating to abstinence of sexual activity until
complete healing was achieved.

**Study limitations**

This study was not prospectively designed for
formal statistical verification of our main finding,
that outcomes achieved when the procedure is
performed by nurses are not inferior to outcomes
achieved when the procedure is performed by
physicians. Also, our study provides no long-term
verification of outcomes (1 year after complete
healing) and no insight into the medical and social
consequences of performing MC in subjects under
age 18 years.

Future research should also address other gaps
in the evidence relevant to task-shifting of adult
MC from physicians in the hospital setting to
nurses in the rural clinic setting. However,
although this study was conducted at Kanombe
Military Hospital in the city of Kigali, the
procedures were performed in a plain non-sterile
consultation room with a bed and a table for the

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device and the required implements, similar to the
settings available at rural clinics.

It remains to be demonstrated whether nurses at
rural clinics would be as adept at learning and
performing MC with the PrePex device as the
nurses at our district hospital have been. A formal
training program for nurses is currently under
development. As more data are accumulated, it
will also be possible to compare costs of
procedures performed at rural clinics with costs at
the district hospital.

Finally, the optimal strategy for men with
phimosis, in whom insertion of the Inner Ring
would be difficult, remains to be determined. The
prevalence of phimosis is uncertain; a 13% rate
was reported among 351 males ages 4–58 in a
study of MC using the Shang Ring device\textsuperscript{24},
whereas the rate we encountered in Phase 1 of our
study was 5% (4 of 81 screened volunteers), which
is consistent with a report from the British
Association of Paediatric Urologists showing a 5%
prevalence of non-retractable foreskin among boys
age 16–17 years\textsuperscript{25}. Such subjects might be
managed by introducing a slit in the foreskin prior
to device placement (which would transform the
PrePex procedure from nonsurgical to surgical) or
by resorting to conventional MC surgery.

**Conclusions**

Our study suggests that both physicians and nurses
can safely perform adult MC using the PrePex
device. The simplicity of this bloodless
nonsurgical procedure (no need for injected
anaesthesia, suturing, or sterile setting) obviates
many of the problems associated with
implementing a surgical MC scale-up program in
resource-limited settings. Pending the outcome of
larger studies with more formal assessments, the
positive results we report here support the
hypothesis that task-shifting adult MC using the
PrePex device from physicians in the hospital
setting to nurses in the clinic setting is feasible in
Rwanda.

**Competing Interests**

None of the authors has any potential conflict of
interest to declare.
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Contribution of Authors

Vincent Mutabazi participated in the conception and design of the study, acquisition of data, coordination of work by other authors, and critical revision of the manuscript. Jean Paul Bitega, Leon Muyenzi Ngeruka, and Corine Karema participated in the conception and design of the study, acquisition of data, and critical revision of the manuscript. Theobald Hategakimana and Steven A. Kaplan participated in the conception and design of the study and critical revision of the manuscript. Agnes Binagwaho participated in the conception and design of the study, coordination of work by other authors, and critical revision of the manuscript. All authors have read and approved the final manuscript before submission.

Acknowledgments

This study was sponsored by the Government of Rwanda. PrePex devices were donated by the manufacturer, Circ MedTech Ltd. Circ MedTech Ltd was not involved in the design of this study, data collection and analysis, or the preparation of this manuscript. Editorial assistance in the preparation of this manuscript was provided on a pro bono basis by Steven Tiger, with the cooperation of his employer, Complete Healthcare Communications, Chadds Ford, Pennsylvania, United States of America.

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