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# The Acceptability and Safety of the Shang Ring for Adult Male Circumcision in Rakai, Uganda

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## Abstract

**Objectives—**Medical male circumcision (MMC) is recommended for HIV prevention in men. We assessed the acceptability and safety of the Shang Ring device compared to the dorsal slit method.

**Methods—**HIV-negative, uncircumcised men aged 18 years or older who requested free MMC services in rural Rakai, Uganda were informed about the Shang Ring and dorsal slit procedures and offered a free choice of procedure. Men were followed at 7 days postoperatively to assess adverse events (AEs) related to surgery and to remove the Shang Ring. Wound healing was assessed at 4 weeks postoperatively.

**Results—**621 men were enrolled, of whom 508 (81.8%) chose the Shang Ring and 113 the dorsal slit. The Shang Ring was provided to 504 men, among whom there were 4 failures of Ring placement (0.8%) which required surgical hemostasis and wound closure. 500 men received the Shang Ring and postoperative surgery-related moderate AEs were 1.0%, compared to 0.8% among dorsal slit recipients. Complete wound healing at 4 weeks was 84% with the Ring and 100% with dorsal slit ($p<0001$). Resumption of intercourse before 4 weeks was 7.0% with the Ring and 15.0% with dorsal slit ($p=0.01$.) The mean time for surgery was 6.1 minutes with the Ring and 17.7 minutes with the dorsal slit. Mean time for Ring removal was 2.2 minutes.

**Conclusion—**The Shang Ring is highly acceptable and safe in this setting, and could improve the efficiency of MMC services. However, back up surgical services are needed in cases of Ring placement failures.

### Keywords

Male circumcision; Shang Ring; Rakai; Uganda

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## Introduction

Three randomized trials have demonstrated that medical male circumcision (MMC) reduces HIV acquisition in men by 50–60%,[1–3] and UNAIDS/WHO recommended MMC as an integral component of HIV prevention strategies in 2007.[4] The agency set a goal of providing MMC to 20.3 million men by 2015 in 14 priority southern and eastern African countries where the prevalence of MMC is low and HIV prevalence is substantial.[5] Since 2007, most priority countries have adopted policies promoting MMC, but by the end of 2010, fewer than 600,000 MMCs, representing less than 3% of the UNAIDS goal, had been achieved in the region.

A constraint on service delivery is the time required for conventional surgery which limits the number of procedures per provider that can be performed in one day. There has been an interest in use of MMC devices such as the Shang Ring[6] and PrePex device,[7] which do not require suturing or hemostasis, and can reduce the procedure time to approximately 5 minutes, potentially increasing program efficiency. Both devices require removal 7 days after placement.

The Shang Ring has been evaluated in a number of Chinese studies,[6] but there is limited experience with this device in sub-Saharan Africa. Two studies reported low rates of adverse events,[8–10] and a safety study showed that the optimum time for ring removal was 7 days.[11] A randomized trial of the Shang Ring compared with conventional surgery in Kenya and Zambia reported similar rates of adverse events (3.0%), greater cosmetic satisfaction with the Shang Ring than with standard surgery, and all providers preferred the Shang Ring method.[12]

We assessed the acceptability and safety of the Shang Ring relative to conventional surgery using the dorsal slit method in a service program in Rakai, Uganda.

## Methods

In a male circumcision program in Rakai, Uganda, men requesting free MMC service were provided with preoperative health education on circumcision and on HIV/STI prevention, and were offered voluntary HIV counseling and testing (VCT) using a three rapid test algorithm. Uncircumcised, HIV-negative men aged 18 and older were then provided with basic information on the Shang Ring and dorsal slit MMC procedures and asked to provide written informed consent for participation in a study of acceptability and safety.

Consenting men were provided with detailed information on the Shang Ring and dorsal slit methods of MMC, and offered a free choice of procedure. They were then provided with the procedure of their choice unless there were contraindications or complications. MMC was performed by clinical officers in sterile conditions in outpatient operating rooms under dorsal penile nerve block local anesthesia using a mixture of lignocaine 1% and bupivicaine 0.5%. The dorsal slit was performed as described in the WHO Manual for Medical Male Circumcision,[13] and the Shang Ring was applied as described in the Training Manual for Adult Male Circumcision Using the Shang Ring.[14] In brief, the inner Ring was placed around the penis at the coronal sulcus, the foreskin was held with four clamps and drawn over the inner Ring. The outer Ring was then positioned and clamped shut, and the foreskin removed with curved tissue scissors. The wound was cleaned with iodine and dressed with dry gauze. [14] Patients were instructed to keep the wound clean and dry, and to abstain from intercourse until full wound healing was certified.

Participants were followed up at 7 days postoperatively to remove the Shang Ring and to assess predefined adverse events (AEs) used in the randomized trial with additional items

for the Shang Ring (e.g., Ring detachment). The Shang Ring was removed under 10% lidocaine spray for pain control. The outer Ring was unlocked and removed, then the inner Ring was cut using the Inner Ring Cutter and removed. The wound was cleaned and dressed with a dry bandage. Men were provided with acetaminophen tablets qid, for postoperative pain control as needed. Pain following surgery or Ring removal was assessed by a visual analog scale of 0–10.

Participants were followed up at 4 weeks postoperatively to ascertain late onset AEs and to assess wound healing. Men with incomplete wound healing at the 4 week visit were followed up at weekly intervals until full wound healing was certified. Men who encountered difficulties were also free to return for unscheduled visits at any time.

The acceptability of the Shang Ring was assessed by the proportion of enrolled men opting for this method of MMC, and the reason for their preference was ascertained. The characteristics of men opting for the Shang Ring or dorsal slit were tabulated and compared using Chi-square tests. If the surgeon found difficulty placing the Shang Ring and determined that the participant required dorsal slit, the event was classified as a failure of Ring placement. The frequency of adverse events related to surgery was tabulated as the proportion of men with surgery-related AEs and differences in AE rates by MMC method was assessed using Chi-square tests. Pre-defined adverse events were categorized as mild requiring no intervention, moderate requiring conservative treatment or severe requiring surgical intervention or hospitalization. If the foreskin was damaged during Ring placement and sutures were required to repair such damage, the event was considered as a failure of ring placement. The proportion of men with complete wound healing was assessed at the 4 week scheduled visit. Complete wound healing was defined as an intact scar visualized with a magnifying glass, with no scab formation or stich sinus present. Photographs were used to document wounds deemed to have incomplete healing. This study was approved by Institutional Review Boards in Uganda and at Johns Hopkins University, and was overseen by a Safety Monitoring Committee comprised of a Urologist, statistician, ethicist and program scientist. The Uganda National Drug Authority reviewed the study protocol and approved the use of this new device for research purposes. The US Food and Drug Administration (FDA) cleared the Shang Ring for marketing in the US (August, 2012).

## Results

Figure 1 shows the study flow diagram. 1427 men were eligible for the study of whom 1322 (92.6%) came for a prescheduled surgical visit and 621 (47.0%) of these latter men consented to study enrollment. Of the 701 eligible men not enrolled, the majority (638 or 91.0%) declined enrollment prior to receiving full information on the Shang Ring because they did not want to adhere to the study follow up schedule or were not interested in the study. There were 17 non-enrolled men (2.4%) who had medical contraindications including phimosis, tight foreskins, abnormalities of the genitalia or anemia.

Among the 621 enrolled men, 508 (81.8%) chose the Shang Ring and 113 preferred to have the dorsal slit procedure. Men were asked the reasons for their preferences and could give multiple responses. The reasons men cited for preferring the Shang Ring were the shorter time required for surgery (51.9%), a belief that it is safer (52.7%), would cause less pain (41.4%) and that wound healing would be faster (25.3%). The predominant reasons for opting for the dorsal slit procedure were that this is the standard method (42.0%), that it would be safer (48.2%), did not require removal (29.5%) and that healing would be faster (33.9%).

In 4 (0.8%) of the 508 men who opted for the Shang Ring the Ring placement failed either because the Ring slipped off after removal of the prepuce (n=3) or there was damage to the prepuce after placement (n=1), and the surgeon secured hemostasis and skin closure using sutures. These cases of Ring placement failure are likely to be due to provider inexperience rather than the presence of preputial abnormalities. . These cases were considered failures of Ring placement. Another 4 men who chose the Shang Ring could not receive this method of MMC due to stock outs of the appropriate Ring size and were offered and accepted dorsal slit surgery. Thus, 500 men received the Shang Ring, 117 men received the dorsal slit and 4 men had failed Ring placement and received MMC after repair. Retention at the 7 day visit was 99.4% (497/500) for the Shang Ring recipients, 96.6% (113/117) for the dorsal slit and 75% (3/4) for the 4 Ring placement failures. Follow up at the scheduled 4 week visit was 97.2% (486/500) for the Shang Ring recipients, 96.6% (113/117) for the dorsal slit and 100% for the 4 Ring failures.

As shown in Table 1, the characteristics and behaviors of men who received the Shang Ring or dorsal slit procedures were generally comparable, except that a higher proportion of dorsal slit recipients (30.8%) than Shang Ring recipients (20.2%) were not sexually active and this was of borderline statistical significance (p=0.07). The mean duration of surgery for the Shang Ring was 6.1 minutes (SD ±2.7), compared to 17.7 minutes (SD ±7.3) with the dorsal slit method. The time required for removal of the Shang Ring was 2.2 minutes (SD ±1.3).

There was one severe adverse event unrelated to surgery involving hospitalization for dislocation of the ankle due to trauma. The frequency of intra-operative Ring failures and postoperative adverse events are given in Table 2, and the specific postoperative adverse events summarized in Table 3. The rates of moderate/severe adverse events, including Ring placement failures, were 1.8% with the Shang Ring (9/504) and 0.8% with the dorsal slit (1/117). This difference was not statistically significant (Fisher exact p=0.697). Excluding the 4 Ring failures, the frequency of surgery-related postoperative moderate/severe adverse events was 1.0% with the Shang Ring (5/500) and 0.8% (1/117) with the dorsal slit. Nine (9) men in the Shang Ring arm had mild adverse events (Table 3.)

Three men removed the Shang Ring themselves (0.6%). One man who experienced postoperative pain removed the Ring himself on the $5^{th}$ postoperative day, but when seen, the wound was in good condition. Two men were absent for the scheduled $7^{th}$ postoperative day visit and both removed the Rings themselves on the $8^{th}$ postoperative day. Both reported pain at time of removal and one reported mild bleeding from the wound, but when seen at the 4 weeks scheduled visit, both men had satisfactory wound healing.

The proportions of men with certified wound healing at the 4 weeks follow up were 84.0% (408/486) for Shang Ring recipients and 100% (113/113) among dorsal slit recipients (Fisher exact p<0.001). Resumption of intercourse prior to the $4^{th}$ week visit was reported by 7.0% of Shang ring recipients and 15.0% of dorsal slit recipients (p = 0.01). Three Shang ring recipients reported that they resumed intercourse prior to self-perceived wound healing (0.6%). The proportions of men reporting that they were satisfied or very satisfied with their chosen procedure was 99.1% with the Shang Ring and 100% with the dorsal slit. 99.8% of Shang Ring recipients and 100% of dorsal slit recipients reported that they were satisfied or very satisfied with the cosmetic appearance.

## Discussion

The Shang Ring was highly acceptable in this rural adult Ugandan population where after receiving full information on both methods of circumcision, 82% of men chose the Ring in

preference to the dorsal slit method of MMC. However, 4 men (0.8%) who opted for the Shang Ring had failures of Ring placement requiring surgical repair of the wound. These failures were attributed to inexperience of the surgeons and occurred early in the study following training, but this finding emphasizes the need for back up surgical facilities. The postoperative rates of adverse event with the Shang Ring were low and comparable to those with the dorsal slit method in this study. Also, the adverse events were similar to rates observed with the dorsal slit or sleeve methods of MMC in a general programmatic setting in Rakai.[15] Substantially less time was required for Shang Ring placement than the dorsal slit MMCs. Therefore, we conclude that the Shang Ring is highly acceptable and safe in rural Uganda, and potentially could increase efficiency/throughput of circumcision surgeries in this setting. However, the need to return for removal of the Shang Ring adds to the programmatic burden of this method of MMC. The finding that Shang Ring recipients were less likely than dorsal slit recipients to resume intercourse (7% vs 15%, respectively) may be an advantage since early resumption of sex is associated with increased risks of adverse events,[16] and in HIV-infected men, it is also associated with increased risk of transmission of HIV to female partners.[17]

There are limitations to this study. In this implementation science study, men self-selected their preferred method of circumcision because we wished to ascertain the acceptability of the Shang Ring device since if acceptability was low, introduction of this method may not be culturally appropriate. Therefore, the study lacked the benefits of randomization. It is possible that 638 men who declined study enrollment may have done so because they only wanted to receive standard surgery using the dorsal slit method. These men had been informed of the availability of the Shang Ring, and if these 638 men who declined enrollment plus the 113 men who elected for dorsal slit (total 1446) are considered to have rejected the Shang Ring, then the minimum acceptability of the Ring in this population was 35.1%. However, the men who declined study enrollment did not cite rejection of the Ring as their reason for non-enrollment. There were minor differences in the characteristics of enrolled men who selected the Shang Ring versus those choosing the dorsal slit method, but none of these differences affected the comparisons between surgical methods in terms of adverse events or rates of complete wound healing. At follow up, the only difference between the two procedures was that fewer Shang Ring recipients had complete wound healing and had resumed intercourse by the 4$^{th}$ postoperative week than the dorsal slit recipients. An additional limitation is that only men aged 18 and older were enrolled because they had reached the age of majority and could consent to the procedures, thus we cannot generalize the findings to adolescents and we will shortly conduct a further study of the Shang Ring in adolescent boys aged 13–17 years.

In summary, the Shang Ring appears to be an acceptable and safe method of MMC in rural Africa and its introduction into MMC programs could markedly reduce the time required for surgery and increase the efficiency of MMC services. However, back up surgical facilities are needed in case of failures of Ring placement.

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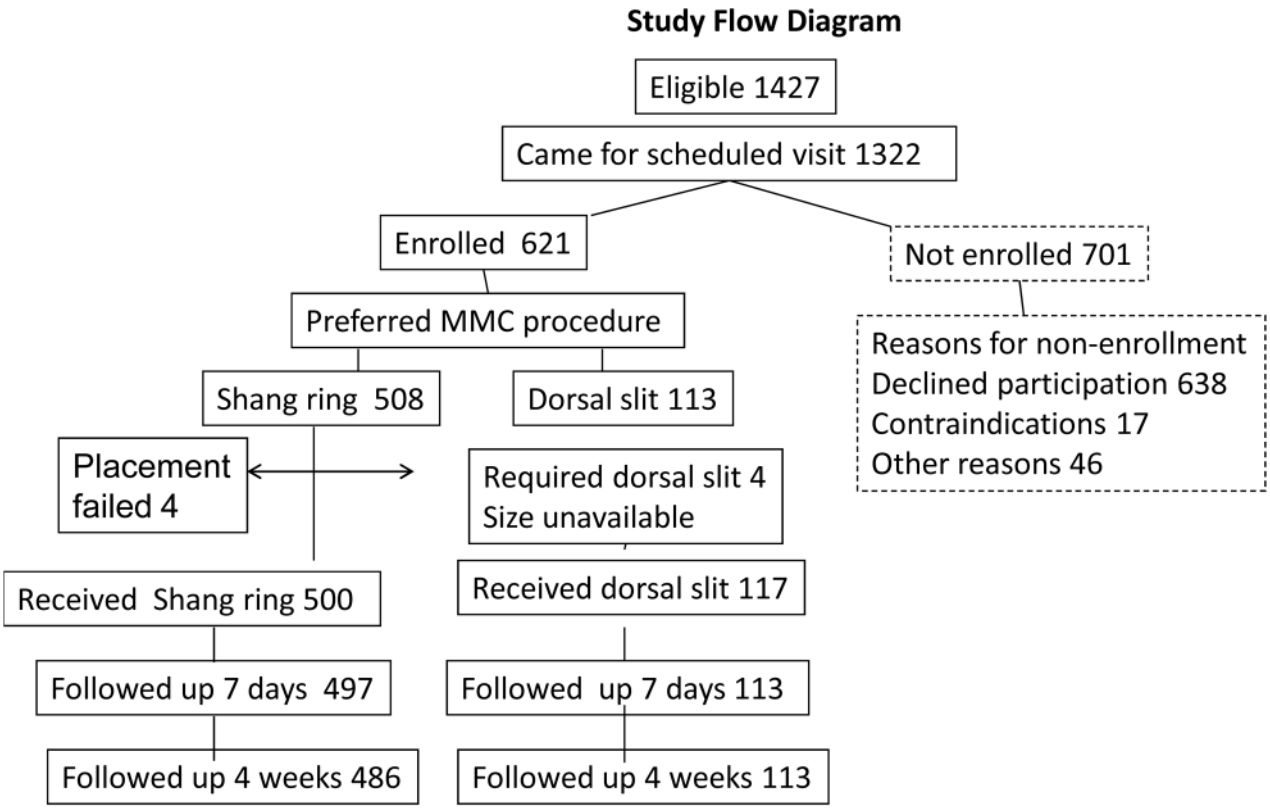


**Figure 1.**
Study flow diagram

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**Table 1**

Characteristics and behaviors of men who received the Shang Ring and dorsal slit circumcision.

| Characteristics of men | Shang Ring (N=504) | | Dorsal slit (N=117) | | P value |
|---|---|---|---|---|---|
| | Number | % | Number | % | |
| Age | | | | | |
| ≤24 | 315 | 62.5 | 79 | 67.5 | 0.179 |
| 25–29 | 78 | 15.5 | 16 | 13.7 | |
| 30–34 | 36 | 7.1 | 12 | 10.3 | |
| 35–39 | 42 | 8.3 | 8 | 6.8 | |
| ≥40 | 33 | 6.5 | 2 | 1.7 | |
| Marital status | | | | | |
| Currently married | 166 | 32.9 | 38 | 32.5 | 0.924 |
| Not married | 338 | 67.1 | 79 | 67.5 | |
| Education | | | | | |
| None | 16 | 3.2 | 2 | 1.7 | 0.453 |
| Primary | 258 | 51.2 | 67 | 57.3 | |
| Secondary or above | 230 | 45.6 | 48 | 41 | |
| Number of sex partners in past year | | | | | |
| None | 124 | 24.6 | 35 | 29.9 | 0.433 |
| 1 | 201 | 39.9 | 46 | 39.3 | |
| 2 or more | 179 | 35.5 | 36 | 30.8 | |
| Non-Marital sex partners | | | | | |
| None | 225 | 44.6 | 61 | 52.1 | 0.316 |
| 1 | 156 | 31 | 33 | 28.2 | |
| 2 or more | 123 | 24.4 | 23 | 19.7 | |
| Condom use in past year | | | | | |
| Not sexually active | 102 | 20.2 | 36 | 30.8 | 0.069 |
| None | 297 | 58.9 | 60 | 51.3 | |
| Inconsistent | 42 | 8.3 | 11 | 9.4 | |
| Consistent | 63 | 12.5 | 10 | 8.5 | |
| Alcohol use with sex | | | | | |

| Characteristics of men | Shang Ring (N=504) | | Dorsal slit (N=117) | | P value |
|---|---|---|---|---|---|
| | Number | % | Number | % | |
| No | 290 | 57.5 | 70 | 59.8 | 0.651 |
| Yes | 214 | 42.5 | 47 | 40.2 | |

## Table 2

Failure of Ring placement and adverse events related to surgery

| | Shang Ring (N=504) | | Dorsal slit (N=117) | |
|---|---|---|---|---|
| | **Number** | **%** | **Number** | **%** |
| Failure of Ring placement | 4 | 0.8 | 0 | |
| **Postoperative AEs** | (N=500) | | | |
| Mild | 9 | 1.8 | 0 | |
| Moderate | 5 | 1.0 | 1 | 0.8 |
| All failures of Ring placement and moderate surgery-related AEs | 9 | 1.8 | | |

## Table 3

Details of postoperative surgery-related adverse events

| | Number | Severity |
|---|---|---|
| **Shang Ring** | | |
| Swelling/Hematoma | 1 | Mild |
| Post operative pain | 6 | Mild |
| Insufficient skin removal | 1 | Mild |
| Other | 1 | Mild |
| Postoperative pain | 2 | Moderate |
| Insufficient skin removal | 1 | Moderate |
| Bleeding | 1 | Moderate |
| Wound dehiscence | 1 | Moderate |
| **Dorsal slit** | | |
| Pain, infection and wound dehiscence | 1 | Moderate |