

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

Godfrey Kigozi, MB, ChB, MPH,\* Richard Musoke, MHS,\* Stephen Watya, MB, ChB, MMed,\*† Nehemiah Kighoma, BA,\* Paschal Ssebowa, MB, ChB,\* David Serwadda, MB ChB, MMed, MPH,\*‡ Fred Nalugoda, MHS,\* Frederick Makumbi, MHS, PhD,\*‡ Philip Li, MD,§ Richard Lee, MD, MBA,§ Marc Goldstein, MD,§ Maria Wawer, MD, MSH,\*|| Nelson Sewankambo, MB, ChB, MMed, MSc,\*¶ and Ronald H. Gray, MD, MSc\*||

**Objectives:** Medical male circumcision (MMC) is recommended for HIV prevention in men. We assessed the acceptability and safety of the Shang Ring device compared with those of 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 related to surgery and to remove the Shang Ring. Wound healing was assessed at 4 weeks postoperatively.

**Results:** Six hundred twenty-one 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%) that required surgical hemostasis and wound closure. Five hundred men received the Shang Ring and postoperative surgery-related moderate adverse events were 1.0%, compared with 0.8% among dorsal slit recipients. Complete wound healing at 4 weeks was 84% with the Ring and 100% with the dorsal slit ( $P < 0001$ ). Resumption of intercourse before 4 weeks was 7.0% with the Ring and 15.0% with the 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. The mean time for Ring removal was 2.2 minutes.

**Conclusions:** 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.

**Key Words:** male circumcision, Shang ring, Rakai, Uganda

(*J Acquir Immune Defic Syndr* 2013;63:617–621)

## INTRODUCTION

Three randomized trials have demonstrated that medical male circumcision (MMC) reduces HIV acquisition in men by 50%–60%,<sup>1–3</sup> and UNAIDS/World Health Organization recommended MMC as an integral component of HIV prevention strategies in 2007.<sup>4</sup> 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.<sup>5</sup> Since 2007, most priority countries have adopted policies promoting MMC, but by the end of 2010, <600,000 MMCs, representing <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 1 day. There has been an interest in the use of MMC devices such as the Shang Ring<sup>6</sup> and PrePex device,<sup>7</sup> 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,<sup>6</sup> but there is limited experience with this device in sub-Saharan Africa. Two studies reported low rates of adverse events (AEs),<sup>8–10</sup> and a safety study showed that the optimum time for ring removal was 7 days.<sup>11</sup> A randomized trial of the Shang Ring compared with conventional surgery in Kenya and Zambia reported similar rates of AEs (3.0%), greater cosmetic satisfaction with the Shang Ring than with standard surgery, and all providers preferred the Shang Ring method.<sup>12</sup>

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.

Received for publication October 25, 2012; accepted February 18, 2013.

From the \*Rakai Health Sciences Program, Entebbe, Uganda; †Department of Urology, Mulago Hospital, Kampala, Uganda; ‡School of Public Health, Makerere University, Kampala, Uganda; §Department of Urology, Weill Cornell Medical College, Cornell University, New York, NY; ||Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD; and ¶College of Health Sciences, Makerere University, Kampala, Uganda.

Supported by grant UO1 AI075115-0451 from the Division of AIDS, National Institutes of Allergy and Infectious Diseases, National Institutes of Health.

The authors have no conflicts of interest to disclose.

Correspondence to: Ronald H. Gray, MD, MSc, Department of Epidemiology, Bloomberg School of Public Health, Johns Hopkins University, 627 N Washington Street, Baltimore, MD 21205 (e-mail: rgray@jhsph.edu).

Copyright © 2013 by Lippincott Williams & Wilkins

## 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/sexually transmitted infection prevention, and were offered voluntary HIV counseling and testing 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 bupivacaine 0.5%. The dorsal slit was performed as described in the WHO Manual for MMC,<sup>13</sup> and the Shang Ring was applied as described in the Training Manual for Adult Male Circumcision Using the Shang Ring.<sup>14</sup> In brief, the inner Ring was placed around the penis at the coronal sulcus, the foreskin was held with 4 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.<sup>14</sup> Patients were instructed to keep the wound clean and dry and to abstain from intercourse until full wound healing was certified.

The participants were followed up at 7 days post-operatively to remove the Shang Ring and to assess predefined AEs used in the randomized trial with additional items for the Shang Ring (eg, 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 after surgery or Ring removal was assessed by a visual analog scale of 0–10.

The participants were followed up at 4 weeks post-operatively 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  $\chi^2$  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 AEs 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  $\chi^2$  tests. Predefined AEs were categorized as mild requiring no intervention, moderate requiring conservative

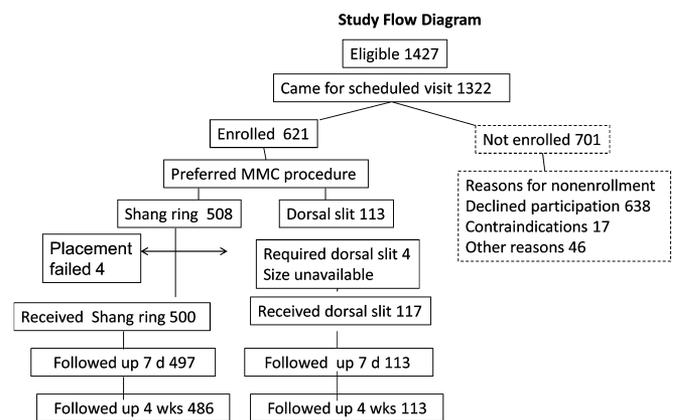
treatment, or severe requiring surgical intervention or hospitalization. If the foreskin was damaged during Ring placement and sutures were required to repair such damage, the event was considered as a failure of ring placement. The proportion of men with complete wound healing was assessed at the 4-week-scheduled 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 that comprised 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 cleared the Shang Ring for marketing in the United States (August 2012).

## RESULTS

Figure 1 shows the study flow diagram. One thousand four hundred twenty-seven 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 before 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 nonenrolled 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%).



**FIGURE 1.** Study flow diagram.

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 to 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

**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
	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 the past year					
None	124	24.6	35	29.9	0.433
1	201	39.9	46	39.3	—
≥2	179	35.5	36	30.8	—
Nonmarital sex partners					
None	225	44.6	61	52.1	0.316
1	156	31	33	28.2	—
≥2	123	24.4	23	19.7	—
Condom use in the 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					
No	290	57.5	70	59.8	0.651
Yes	214	42.5	47	40.2	—

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 with 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 1 severe AE unrelated to surgery involving hospitalization for dislocation of the ankle due to trauma. The frequencies of intraoperative Ring failures and postoperative AEs are given in Table 2, and the specific postoperative AEs summarized in Table 3. The rates of moderate/severe AEs, 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 AEs was 1.0% with the Shang Ring (5/500) and 0.8% (1/117) with the dorsal slit. Nine men in the Shang Ring arm had mild AEs (Table 3).

Three men removed the Shang Ring themselves (0.6%). One man who experienced postoperative pain removed the Ring himself on the fifth postoperative day, but when seen, the wound was in good condition. Two men were absent for the scheduled seventh postoperative day visit and both removed the Rings themselves on the eighth postoperative day. Both reported pain at the time of removal and 1 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-week 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 before the fourth 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 before self-perceived wound healing (0.6%). The proportions of men reporting that they were satisfied or very satisfied with their chosen procedure were 99.1% with the Shang Ring and 100% with the dorsal slit. The Shang Ring recipients (99.8%) and dorsal slit recipients (100%) reported that they were satisfied or very satisfied with the cosmetic appearance.

**TABLE 2.** Failure of Ring Placement and AEs 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 AEs

	Number	Severity
Shang ring		
Swelling/hematoma	1	Mild
Postoperative 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

## 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 after training, but this finding emphasizes the need for back up surgical facilities. The postoperative rates of AE with the Shang Ring were low and comparable with those with the dorsal slit method in this study. Also, the AEs were similar to rates observed with the dorsal slit or sleeve methods of MMC in a general programmatic setting in Rakai.<sup>15</sup> Substantially less time was required for Shang Ring placement than for 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 the 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 because early resumption of sex is associated with increased risks of AEs,<sup>16</sup> and in HIV-infected men, it is also associated with increased risk of transmission of HIV to female partners.<sup>16</sup>

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 because 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 nonenrollment. There were minor differences in the characteristics of enrolled men who selected the Shang Ring vs those choosing the dorsal slit method, but none of these differences affected the comparisons between surgical methods in terms of AEs or rates of complete wound healing. At follow-up, the only difference between the 2 procedures was that fewer Shang Ring recipients had complete wound healing and had resumed intercourse by the fourth postoperative week than the dorsal slit recipients did. 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 seems 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 the case of failures of Ring placement.

## ACKNOWLEDGMENTS

*The authors wish to express their gratitude to study participants and the Safety Monitoring Committee (Drs Stephen Watya, Frederick Makumbi, Ben Kikaire, and Mr. Robert Ssekubugu).*

## REFERENCES

1. Auvert B, Taljaard D, Lagarde E, et al. Randomized, controlled intervention trial of male circumcision for reduction of HIV infection risk: the ANRS 1265 Trial. *PLoS Med.* 2005;2:e298.
2. Bailey RC, Moses S, Parker CB, et al. Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial. *Lancet.* 2007;369:643–656.
3. Gray RH, Kigozi G, Serwadda D, et al. Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial. *Lancet.* 2007;369:657–666.
4. UNAIDS. New data on male circumcision and HIV prevention: policy and programme implications. Available at: [http://data.unaids.org/pub/Report/2007/mc\\_recommendations\\_en.pdf](http://data.unaids.org/pub/Report/2007/mc_recommendations_en.pdf). Accessed May 27, 2013.
5. Hankins C, Forsythe S, Njehumeli E. Voluntary medical male circumcision: an introduction to the cost, impact, and challenges of accelerated scaling up. *PLoS Med.* 2011;8:e1001127.
6. Masson P, Li PS, Barone MA, et al. The Shang ring device for simplified adult circumcision. *Nat Rev Urol.* 2010;7:638–642.
7. Bitega JP, Ngeruka ML, Hategekimana T, et al. Safety and efficacy of the PrePex device for rapid scale-up of male circumcision for HIV prevention in resource-limited settings. *J Acquir Immune Defic Syndr.* 1999;58:e127–e134.
8. Barone MA, Ndede F, Li PS, et al. The Shang ring device for adult male circumcision: a proof of concept study in Kenya. *J Acquir Immune Defic Syndr.* 1999;57:e7–e12.
9. Cheng Y, Peng YF, Liu YD, et al. A recommendable standard protocol of adult male circumcision with the Chinese Shang ring: outcomes of 328 cases in China [In Chinese]. *Zhonghua Nan Ke Xue.* 2009;15:584–592.
10. Barone MA, Awori QD, Li PS, et al. Randomized trial of the shang ring for adult male circumcision with removal at one to three weeks: delayed removal leads to detachment. *J Acquir Immune Defic Syndr.* 2012;60:e82–e89.
11. Sokal DCAQ, Barone M, Simba R, et al. Randomized controlled trial of Shang ring versus conventional surgical techniques for adult male

- circumcision in Kenay and Zambia. In: *XIX International AIDS Conference*. Washington, DC; 2012.
12. WHO, JHPIEGO. *Manual for Male Circumcision Under Local Anesthesia*. Geneva, Switzerland: World Health Organization; 2009.
  13. Cheng Y, Li PS: *Male Circumcision Using the Shang Ring*. Beijing, China: People's Medical Publishing House; 2012.
  14. Buwembo DR, Musoke R, Kigozi G, et al. Evaluation of the safety and efficiency of the dorsal slit and sleeve methods of male circumcision provided by physicians and clinical officers in Rakai, Uganda. *BJU Int*. 2012;109:104–108.
  15. Kigozi G, Gray RH, Wawer MJ, et al. The safety of adult male circumcision in HIV-infected and uninfected men in Rakai, Uganda. *PLoS Med*. 2008;5:e116.
  16. Wawer MJ, Makumbi F, Kigozi G, et al. Circumcision in HIV-infected men and its effect on HIV transmission to female partners in Rakai, Uganda: a randomised controlled trial. *Lancet*. 2009;374:229–237.