The Shang Ring Device for Adult Male Circumcision: A Proof of Concept Study in Kenya

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Objective: To assess safety, preliminary efficacy, and acceptability of the Shang Ring, a novel disposable device for adult male circumcision in Kenya.

Methods: Forty HIV-negative men were recruited in Homa Bay, Kenya. Circumcisions were performed by a trained physician or nurse working with 1 assistant. Follow-up was conducted at 2, 7, 9, 14, 21, 28, 35, and 42 days after circumcision. Rings were removed on day 7. Pain was assessed using a visual analog scale (VAS) (0 = no pain, 10 = worst possible). Men were interviewed at enrollment and on days 7 and 42.

Results: All 40 procedures were completed successfully. Mean procedure and device removal times were 4.8 (SD ± 2.0) and 3.9 (SD ± 2.6) minutes, respectively. There were 6 mild adverse events, including 3 penile skin injuries, 2 cases of edema, and 1 infection; all resolved with conservative management. In addition, there were 3 partial ring detachments between days 2–7. None required treatment or early ring removal. Erections with the ring were well tolerated, with a mean pain score of 3.5 (SD ± 2.3). By day 2, 80% of men were back to work. At 42 days, all participants were very satisfied with their circumcision and would recommend the procedure to others.

Conclusions: Our results demonstrate that the Shang Ring is safe for further study in Africa. Acceptability of the Shang Ring among participants was excellent. With short procedure times, less surgical skill required, and the ease with which it can be used by nonphysicians, the Shang Ring could facilitate rapid roll-out of male circumcision in sub-Saharan Africa.

Key Words: circumcision devices, HIV prevention, male circumcision, proof of concept study

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INTRODUCTION

Three randomized controlled trials in Kenya, Uganda, and South Africa demonstrated that male circumcision reduces the risk of men acquiring HIV by approximately 60%.[1–3] In fact, male circumcision is the only HIV prevention method shown to be consistently efficacious in reducing HIV risk.[4,5] The World Health Organization (WHO) and the Joint United Nations Program on HIV/AIDS (UNAIDS) recommend that countries with low male circumcision rates, high HIV prevalence, and predominantly heterosexual epidemics, consider scaling-up male circumcision as part of their HIV prevention interventions.[6]

A major obstacles to roll-out of adult male circumcision in sub-Saharan Africa has been the relative technical difficulty of the 3 WHO/UNAIDS-recommended surgical techniques;[7] roll-out could be greatly facilitated and accelerated with a simplified bloodless methods.[8] No devices for adult circumcision have gained widespread acceptance due to high complication rates, difficult surgical techniques, high cost, or the cumbersome nature of available devices.

The Shang Ring, manufactured by Wu Hu SNNDA Medical Treatment Appliance Technology Co, LTD, Wu Hu City, China, is a novel disposable circumcision device that consists of 2 concentric plastic rings (Fig. 1). Rings are commercially available in China in 32 sizes, ranging from 9–42 mm in diameter, for use with neonates to adults. Hemostasis provided by compression of the foreskin between the locking rings minimizes bleeding and obviates the need for sutures. The design eliminates the need to make scalpel cuts directly on the penis.

Results from three Chinese studies utilizing the Shang Ring have demonstrated excellent safety and use profiles, with high acceptance among study participants. Peng et al[9] reported complication rates of 0.58% bleeding, 0.67% local infection,

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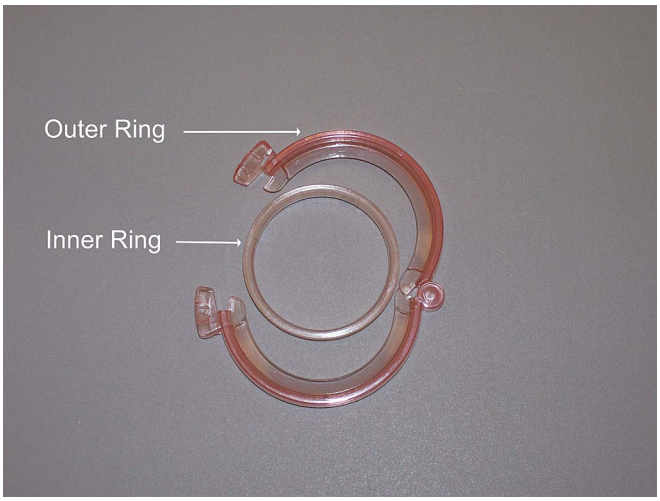

FIGURE 1. The Shang Ring consists of an inner and outer plastic ring. The inner ring has a silicone band around its outer surface.

and 2.42% wound dehiscence after ring removal among 1200 Shang Ring circumcisions. Similarly, low complication rates (0.6% bleeding, 0.6% wound infections, 0.6% wound dehiscence, and 4.5% wound edema) were seen in a series of 328 men circumcised with the Shang Ring in Ningbo, China.[10] In addition, Li et al[11] reported in 2010 that compared with the dorsal slit technique, Shang Ring circumcisions demonstrated significantly fewer complications, lower pain levels during and after the procedure, and higher participant satisfaction. Average procedure times, after onset of local anesthesia, were reported to be between 3 and 5 minutes, with achievement of excellent cosmetic results.[9–11]

We report here the results of a proof of concept study to assess safety, preliminary efficacy in terms of facilitating circumcision, and acceptability of the Shang Ring for adult male circumcision in a Kenyan population to determine if the device is appropriate for further study in Africa. Acceptability included measures of participant satisfaction such as pain, disruption of work/social activities, and problems encountered while the device was in place. To our knowledge, this is the first use of the device outside of China.

METHODS

Study Setting, Design, and Participants

Forty men seeking male circumcision were recruited for this noncomparative proof of concept study, which was conducted at the Homa Bay District Hospital in Nyanza Province, Kenya. In accordance with Kenyan national guidelines, men were offered HIV counseling and testing. Uncircumcised healthy men 18–54 years old who tested HIV negative were asked if they were interested in participating in the study, and informed consent was obtained from those who were. Men received HIV prevention and risk reduction counseling and were screened for sexually transmitted infections according to Kenyan national guidelines. Men who tested HIV positive or had active genital infections, anatomic abnormalities of the penis, or other medical conditions contraindicating circumcision or surgery were excluded from participation.

Procedures

Shang Ring circumcisions and removals were performed as previously described[9–12] by 2 physicians and a nurse who were trained on the technique and postsurgical management in China. Each circumcision was conducted by 2 people: one of the physicians or the nurse, with the assistance of one of the others. Penile circumference was measured using the Shang Ring measuring tape to determine the ring size needed.

After a standard surgical scrub, 6–20 cc of 1% lidocaine without epinephrine were injected circumferentially around the penis to achieve a penile block. The inner ring was placed on the penis at the level of the coronal sulcus. Using clamps at the 3, 6, 9, and 12 o'clock positions, the foreskin was everted over the inner ring. The outer ring was then secured over the inner ring with the ratchet closure, sandwiching the foreskin in-between the 2 rings. Excess foreskin distal to the ring edge was excised using surgical scissors and 3–4 nicks made on the incision line using a scalpel blade to prevent formation of a constricting circumferential scab and to allow for adequate expansion of the scab during erections. Rings were removed 7 days after circumcision. Removal involved breaking the ratchet closure of the outer ring using the Shang Ring opener, carefully pulling the inner ring back from the edge of the wound and cutting the inner ring at the 3 o'clock and 9 o'clock positions using blunt-end scissors. The wound was covered with a bandage. Men were instructed to remove the bandage after 24 hours and to keep the wound clean and dry.

To ensure safety of participants, follow-up was frequent and clinically comprehensive. The day of the Shang Ring circumcision was considered day 0. Men were asked to return for a clinical exam on days 2, 7, 9, 14, 21, 28, 35, and 42. The exam on day 2 was to ensure that the Shang Ring was still properly placed and that there were no indications of complication or complaints from the participant that might require device removal or other attention. Rings were removed at the day 7 visit, the wound was checked and initial outcomes assessed. The exam on day 9 was to ensure that wound healing was progressing without problems 2 days after device removal. The clinical exam at the remaining visits was to assess progress of wound healing and outcome assessment. Men were told to return at any time if they experienced a problem, potential complication, or had another concern. As an additional safety precaution, in case there were any unexpected problems with the device, only 5 men were initially recruited, had their circumcision performed, and were then observed closely for 2 weeks before additional participants were recruited. All men were interviewed before the procedure and at the 1 and 6 week follow-up visits to gather information on demographics, experience with the Shang Ring, and satisfaction with the circumcision.

Pain was measured using a VAS[13] at the time of the circumcision, ring removal, and follow-up visits. The VAS included numbers, words, and faces to describe different levels of pain, from 0 = no pain to 10 = worst possible pain.

Approvals were obtained from the Weill Cornell Medical College Institutional Review Board and from the Kenyatta National Hospital Ethics and Research Committee. The trial was registered on ClinicalTrials.gov before the start of the study (Identifier: NCT00993811). Men were provided approximately US $2.50 in Kenya Shillings for each follow-up visit to cover cost of transport and their time.

Statistical Analysis

The primary outcome measure was adverse events (AEs) recorded during the procedure and 6-week follow-up period. AEs were graded on a 3-point scale of severity (mild, moderate, or severe) according to predefined objective criteria. Male circumcision providers determined whether AEs were considered serious (eg, life threatening, permanent disability). AEs were also categorized as to their relatedness to the circumcision (not related, possibly related, probably related, definitely related) according to predefined definitions and based on consensus opinion of the investigators. In addition, device hazards (ie, when the device did not behave as we had expected based on the Chinese experience) were also recorded. Device hazards were not considered AEs if they had no clinical consequences.

Secondary clinical outcomes included measures regarding technical acceptability and ease of use of the device among the 2 physicians and 1 nurse who served as the primary circumcision surgeons. Specifically, we assessed ability to complete the Shang Ring procedure, problems with use of the device (during circumcision and removal), and procedure times (circumcision and removal). Progression of wound healing was documented and average wound healing time calculated. The wound was considered healed when there was no scab and the skin was dry. Participant satisfaction was measured through documentation of reported pain at various times, problems while wearing the device, disruption of work/daily activities caused by the device, whether they would recommend the device to others, if they were happy with the appearance of their circumcision, and overall satisfaction with their male circumcision. Given the small sample size and proof of concept nature of the study, tests of statistical significance were not conducted.

RESULTS

Forty adult men were enrolled in the study. Selected baseline characteristics are shown in Table 1. All of the 40 Shang Ring procedures were completed without problems—surgeons did not have any difficulty using the device and there were no intraoperative complications. Because of moderate to severe phimosis, 4 (10%) participants required a small (mean 8 mm) slit in the foreskin to facilitate eversion of the foreskin over the inner ring. The mean time for the Shang Ring circumcision procedure (excluding local anesthesia) was 4.8 minutes (SD ± 2.0, range = 2–11). Eight different sized rings were used as follows: 38-mm diameter for 1 man, 37 mm for 6 men, 36 mm for 2 men, 35 mm for 4 men, 34 mm for 8 men, 33 mm for 7 men, 32 mm for 5 men, and 31 mm for 7 men.

TABLE 1. Baseline Characteristics of Study Participants

Age (yrs)	Median 20.5; range 18–45
Ethnic group	
Luo	39 (97.5%)
Other	1 (2.5%)
Education	
Some primary (< 8 years)	2 (5.0%)
Completed primary (8 years)	10 (25.0%)
Some secondary (9–11 years)	5 (12.5%)
Completed secondary (12 years)	5 (12.5%)
Post secondary (>12 years)	18 (45.0%)
Current employment	
Student	17 (42.5%)
Professional/managerial	5 (12.5%)
Laborer	4 (10.0%)
Hawker/small scale business	4 (10.0%)
Unemployed	4 (10.0%)
Other	6 (15.0%)
Marital status	
Single	31 (77.5%)
Married, living with partner	6 (15.0%)
Married, not living with partner	2 (5.0%)
Divorced/separated	1 (2.5%)
Sexually active in past 3 months	31 (77.5%)
Number of sex partners past 3 months	Mean 1.0 ± 0.91; range 0–4
Current STI genital complaints	0 (0%)
Foreskin or preputial complaints	
Occasional itching	2 (5.0%)
Abnormal genital findings on physical exam	0 (0%)
Current circumcision status on physical exam	
Foreskin covers one-half or more of the glans	40 (100%)

STI, sexually transmitted infection.

Rings were removed at 7 days without major problems. The mean removal time was 3.9 minutes (SD ± 2.6, range = 1–12). In one case removal was prolonged due to pain the participant was experiencing. The mean pain score during the ring removal was 4.9 (SD ± 2.5, range 0–10), which decreased to 2.2 (SD ± 1.8, range 0–6) immediately after removal was complete.

The only AEs that were observed were 6 mild ones, all classified as definitely related to the Shang Ring circumcision. These included 3 cutaneous injuries (Fig. 2), 2 cases of edema outside the expected range and 1 infection. There were no cases of bleeding. The infection was treated with a short course of oral antibiotics, and the others were observed and resolved on their own. The cutaneous injuries occurred with the ring in place in the following circumstances: a motorcycle taxi driver who returned to work the day of his circumcision, a man who was in a car accident, and a man who jumped over a fence.

There were 3 device hazards; all related to partial detachment of the ring between days 2 and 7. No treatment was required. Detachment was less than a quarter of the circumference in one man, approximately half in another and about three-quarters in the third.

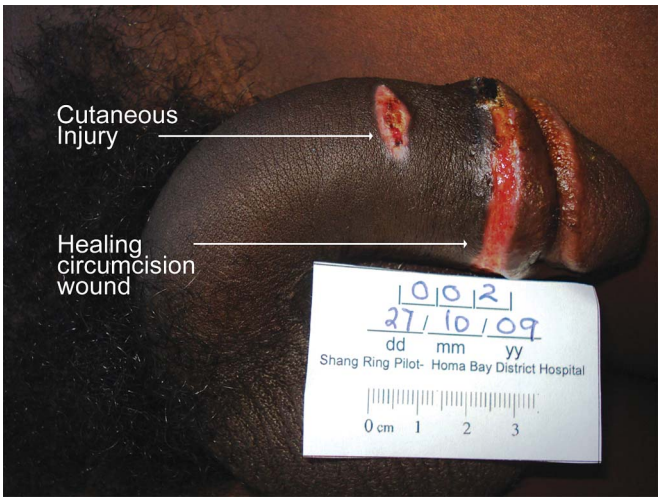

FIGURE 2. Minor cutaneous injury of the skin of the penis caused by the Shang Ring. Photo taken on day 14.

No participant reported problems with the ring in place at day 2, whereas 4 (10%) men did at the day 7 visit. No participant requested early removal of the ring. The 4 men with problems reported at the day 7 visit included one of the men with a cutaneous injury, 2 who experienced partial detachment, and 1 who reported painful erections. At day 7, all men reported having had erections with the ring in place with no problems during erections other than some pain. Mean maximal pain score during erections was 3.5 (SD ± 2.3).

Mean time to complete wound healing was 28.9 days (range 14–43). Thirty-two (80%) men completed 6 weeks of follow-up. Of the participants who were lost to follow-up, 1 was last seen on day 9, 1 on day 21, 2 on day 28, and 4 on day 35. Only the participant whose last visit was day 9 had an incompletely healed wound when he was last seen.

In general, men reported minimal disruption to their activity with the Shang Ring in place (Table 2). Most (32 of 40, 80.0%) men were back to their normal work schedule within 2 days of their circumcision, having returned to work after 1.1 days on average (SD ± 0.9). Reasons for not returning to work included too much pain or discomfort, the presence of the ring making work difficult, and concern about the possibility of causing a problem or damage to the penis. Twenty-eight (70.0%) men had resumed routine leisure activities by day 7 (mean 1.7 days, SD ± 1.6), with reasons for not having done so the same as those given by men not returning to work by day 7. Twenty-eight (70%) said that they would have felt comfortable being circumcised by a female provider.

TABLE 2. Reported Degree of Disruption in Sleep, Daily Activities, and Work Caused by Having the Shang Ring in Place for One Week

	Not at all n (%)	Very Little n (%)	Somewhat n (%)	A Lot n (%)
Sleep	21 (52.5)	8 (20.0)	9 (22.5)	2 (5.0)
Daily activities	34 (85.0)	4 (10.0)	2 (5.0)	0 (0.0)
Work	33 (82.5)	3 (7.5)	3 (7.5)	1 (2.5)

At the 42-day follow-up visit, all of the 32 men interviewed said they would recommend circumcision generally and specifically with the Shang Ring. The main reasons for recommending circumcision were improved hygiene and protection from HIV and other sexually transmitted infections. The primary reason for recommending the Shang Ring was because the procedure was quick; the lack of stitches was also seen as favorable. Men reported that their erections were normal and that they had no problems due to tight skin or deviation of the penis. All participants were "very satisfied" with their circumcision and happy with the appearance of their penis (Fig. 3).

No participant reported having had sexual intercourse before ring removal, and 8 of 32 (25.0%) reported sexual activity by the 42-day visit. One reported having some pain during intercourse, with the others reporting no problems.

DISCUSSION

Our results from this proof of concept study, the first use of the Shang Ring for adult male circumcision outside of

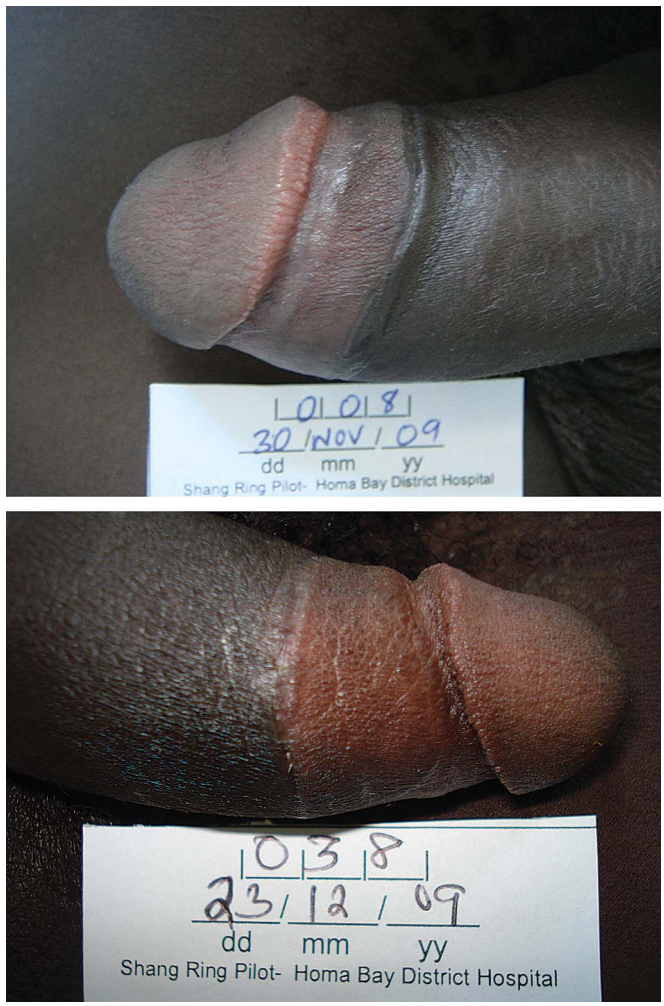

FIGURE 3. Appearance of the healed circumcision wound at 42 days in 2 study participants.

China, demonstrate that the device is safe for further study in Africa. There were no problems during any of the circumcision procedures, and theoretical concerns about potential difficulties with use of the Shang Ring in Africa (eg, thick foreskins, devices too small and problems with erections when the ring was in place) were not realized. Hemostasis provided by the locking rings controlled bleeding and we saw no bleeding-related AEs. In contrast, after conventional circumcision, bleeding and hematomas are among the most common complications[1–3,14,15]; both are rare after Shang Ring circumcision.[9–12] In addition, the design of the device eliminates the need for sutures, which take time to place, can break or disrupt during healing, and may leave stitch marks that take time to resolve.

All AEs were mild and resolved in a timely manner with little or no intervention. The 3 cutaneous injuries were unexpected (not reported in China[9–11]), however, all may have been due to physical activity soon after Shang Ring placement (eg, jumping over a fence or driving a motorcycle taxi on rough roads). Upon close examination, we found that a few edges of the rings, for example, the hinge of the outer ring (Fig. 1) could be smoother and may have caused the injuries. The manufacturer has smoothed the edges to address this, and we will monitor for similar injuries in our next study.

Although male circumcision is an important HIV prevention method, currently available techniques and devices have limited its widespread deployment in the developing world due to human and material resource constraints. Although devices are common for neonatal circumcision, few studies of adult circumcision devices exist. A high rate of AEs seen in a randomized study of the Tara Klamp versus the forceps-guided method in adults led to early trial closure,[16] despite the fact that good results had been seen with the device in boys.[17,18] In contrast, our results suggest that the Shang Ring is safe for adult circumcision with low rates of AEs.

Results of a randomized study of the sleeve method versus a template-guided device found no significant differences in AEs or participant satisfaction, although mean procedure time (after onset of anesthesia) with the device was 27.5 minutes compared with 36.0 minutes for the sleeve resection.[19] Mean procedure time for Shang Ring circumcisions on the other hand was approximately 5 minutes after onset of anesthesia, with removal taking, on average, a minute less. Shang Ring circumcision is much faster than reported times for the WHO-recommended methods that average 20–40 minutes.[11,15,19] Use of the Shang Ring offers the possibility of sutureless circumcision, thus minimizing procedure time. This could mean significant savings in time and thus resources, especially in high-volume settings in Africa where large numbers are performed. This would allow for more circumcisions to be completed in a given time with the same staff. As with standard surgical approaches,[15] we would anticipate a decrease in procedure time and AEs as a provider's experience with the device increases.

Scarcity of trained providers hinders access to male circumcision services in resource-poor areas. Shang Ring circumcision is particularly appealing as an easy technique to teach and learn desirable in settings such as sub-Saharan Africa where doctors are in short supply and nonphysician providers (eg, nurses, clinical officers) are expected to play a major role in provision of adult male circumcision through task shifting and specialization.[8,20–22] We found Shang Ring circumcisions and removals could be uneventfully performed by a trained nurse. A highly skilled provider, whether a doctor or a nurse, could do Shang Ring circumcisions on his/her own, further reducing the impact of staff shortages on male circumcision rollout.

Shang Ring postoperative healing differs from conventional circumcision, with pressure from the ring allowing for formation of a scab along the wound surface. When the ring is removed, this scab along with healthy pink granulation tissue is visible (Fig. 2). This tissue, which may seem to be abnormal to those not familiar with Shang Ring healing, is standard healing for the device. There was no active bleeding or spotting in any of the participants, and the granulation tissue was not friable or fragile. There was no evidence of increased risk of wound infections. Good cosmesis of healed wounds was observed (Fig. 3). The absorbable sutures used in conventional adult male circumcision may leave stitch marks that take some time to resolve.

A potential disadvantage of the Shang Ring is the need to have multiple sizes. We used 8 different size rings, all within the range of sizes currently available from China. Hopefully, additional studies can provide direction regarding the more common sizes needed in Africa. Another potential disadvantage is the need to wear the Shang Ring for 1 week; however, neither participants in the Chinese studies[9–11] nor our study reported significant problems with this. Participant's experiences with the device in place were positive, satisfaction was high, and disruption of daily lives was minimal. No significant pain or problems were reported by men when they experienced erections with the ring in place, and no one asked to have the ring removed before the planned removal time. Men reported they would recommend the device to others. All indications suggest that the Shang Ring was well accepted by study participants. Although some may consider the need for a follow-up visit to be a disadvantage, WHO/UNAIDS guidelines recommend a follow-up visit within 7 days of surgery,[7] and male circumcision programs in sub-Saharan Africa are routinely asking men to return for 1 or more follow-up visits.[23–25]

In conclusion, the results of this proof of concept study suggest that the Shang Ring could be an efficient and suitable device for adult male circumcision in African men and that it is safe for more detailed study in Africa. The device was well tolerated and accepted by the study participants, who would recommend it to others. The simplicity of design and the elimination of the need for suturing set the Shang Ring apart from other adult male circumcision techniques. It has the potential to greatly facilitate the safe, effective, and inexpensive scale-up of male circumcision services, especially by trained nonphysicians, in settings with high HIV prevalence and low male circumcision use.

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