

Randomized Trial of the Shang Ring for Adult Male Circumcision With Removal at One to Three Weeks: Delayed Removal Leads to Detachment

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Objectives: To assess healing with Shang Ring removal at different prespecified times; whether spontaneous detachment occurs with delayed removal; problems, complaints, and acceptability of wearing the device; satisfaction among participants; and acceptability of the procedure among providers.

Methods: Fifty HIV-negative men underwent a Shang Ring circumcision in Kenya. Men were randomly assigned for device removal at 7 (15 men), 14 (15 men), or 21 days (20 men). Follow-up visits were at 7, 14, 21, 28, and 42 days after circumcision and 2 days after removal.

Results: Circumcision and device removal were conducted without significant problems. Mean times for circumcision and device removal were 6.5 (SD = 2.4) and 2.5 (SD = 0.8) minutes, respectively. Complete detachment of the device occurred in 22 (66.7%) men who wore it more than 7 days. Seven men (14.0%) with partial detachments requested removal 8–14 days postcircumcision due to pain/discomfort. Healing progressed normally in all participants; cumulative probabilities

of complete healing were similar across groups. No severe or serious adverse events occurred. Acceptability among participants was high. Providers reported that Shang Ring circumcision was “very easy” compared with the forceps-guided procedure.

Conclusion: The Shang Ring is safe and easy to use according to label instructions (7 day removal). Detachments occurred without significant problems, although some men requested removal of partially detached rings. Removal time had little effect on healing. These data help allay concerns about men not returning for ring removal and expand the evidence base suggesting the Shang Ring could facilitate rapid male circumcision rollout in sub-Saharan Africa.

Key Words: Shang Ring, circumcision devices, adult male circumcision, wound healing

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INTRODUCTION

Based on recommendations from the World Health Organization and the Joint United Nations Programme on HIV/AIDS,¹ over a dozen African countries are scaling-up male circumcision for HIV prevention.² The Shang Ring (Wuhu SNNDA Medical Treatment Appliance Technology Co, LTD, Wuhu City, China), is a novel disposable, single-use, minimally invasive device, used to circumcise over 200,000 Chinese men (personal communication NQ Lu and Jianzhong Shang). Numerous studies have shown the device is safe, effective, and well accepted. Circumcision and device removal were rapid and uneventful, and adverse event (AE) rates were comparable with or less than with conventional adult circumcision.^{3–9}

Results of a study in Kenya were also favorable.¹⁰ All procedures were successfully completed, with mean circumcision and device removal (7 days postcircumcision) times of 4.8 and 3.9 minutes, respectively. There were no severe or moderate AEs. Three cases of partial device detachment were seen when men returned for ring removal; all healed normally. Mean time from circumcision to complete healing was 28.9 days.

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Participants reported little disruption in their lives while wearing the device, and all said they would recommend it.

With short procedure times, a lower level of surgical skill required, and ease of use by nonphysicians, the Shang Ring could facilitate rapid rollout of circumcision in sub-Saharan Africa. It was important to determine if problems might arise should men not return for device removal.¹¹ Published studies from China report device removal 7–10 days postcircumcision and have not described partial detachment,^{3–6} however, Kenya data suggest the device might spontaneously detach, perhaps obviating the need for a removal visit.¹⁰

The primary objectives of this study were to assess wound healing time with Shang Ring removal at different prespecified times and determine whether the device would spontaneously detach if removal was delayed beyond the current label instructions of 7 days. Secondary objectives included assessing problems, complaints, and acceptability of wearing the device for these prespecified periods; satisfaction among participants; and acceptability of the device among providers in a sub-Saharan African context.

METHODS

Study Setting, Design, and Participants

This open-label parallel group randomized study was conducted at the Homa Bay District Hospital in Kenya. Healthy, uncircumcised, HIV-negative men 18–54 years seeking circumcision were informed of the study. Interested men underwent informed consent procedures, including HIV prevention and risk reduction counseling per national guidelines.

Participants were randomized immediately before circumcision using computer-generated sequentially numbered opaque-sealed envelopes. Randomization groups were device removal on day 7 (15 men), 14 (15 men), or 21 (20 men) postcircumcision. Randomization was unbalanced in an effort to have 10–15 men reach 21 days follow-up with the device on, accounting for possible detachments and removal requests. Randomization was stratified by provider; each performed similar numbers of procedures in each removal group. Sample size for this phase-1 type study was based on clinical rather than statistical considerations.

Ethical approval was obtained from FHI360 and the Kenya Medical Research Institute IRBs. Regulatory approval was obtained from the Kenya Pharmacy and Poisons Board. The trial was registered on ClinicalTrials.gov (Identifier: NCT01247844).

Procedures

Participants were interviewed to gather baseline demographic, sexual function, and behavioral information. A clinical exam was carried out to ensure eligibility. Men with active genital infection, prior circumcision, an anatomic abnormality, or another condition that contraindicated elective surgery under local anesthesia (eg, bleeding diathesis, lidocaine allergy) were ineligible.

Two physicians and 2 nurses, all experienced with forceps-guided circumcision and trained to conduct Shang Ring procedures in China, performed the circumcisions.

During each, the primary circumciser (a physician or nurse) was assisted by one of the others.

A special measuring strip was used to determine which device size to use. Devices were available in 11 sizes (31–42 mm in diameter). After administration of dorsal penile nerve and ring blocks with 1% lidocaine, circumcision was performed as previously described.^{4,10} The inner ring was held near the coronal sulcus. The foreskin was everted over the inner ring and the outer ring secured over the inner, sandwicheing the foreskin. The foreskin distal to the device was excised with blunt-tipped surgical scissors, and several nicks made on the incision line with a scalpel to prevent formation of a stiff circumferential scab. Men received 1 g paracetamol (acetaminophen) after circumcision.

For removal, skin around the device was sprayed with 1% lidocaine to moisten healing tissue and potentially provide some anesthesia. The ratchet closure of the device was opened using a scalpel handle-like tool and the outer ring removed. The inner ring was carefully pulled back from the wound edge and cut into 2 using blunt scissors. A bandage was applied to the wound.

Follow-up visits were at 7, 14, 21, 28, and 42 days postcircumcision and 2 days after device removal. Men were encouraged to return any time if they experienced a complication, excessive pain, or other problem. At each visit, a genital exam and interview were conducted. Clinical outcome measures included AEs, degree of detachment, and complete healing (defined as no scab and complete reepithelialization, that is, dry skin covering the surgical site with no exudate or moisture). Detachment was categorized as follows: none, <25%, 26%–50%, 51%–75%, 76%–99%, and complete. Photographs were taken to document healing and AEs.

Men were asked about problems with the device, either in place or after removal depending on the visit, and about their satisfaction with the circumcision at 42 days. Participants were asked to rate their pain at various points (eg, during and shortly after circumcision and removal, in the first 2 days postcircumcision, during erections) using a visual analog scale¹² displaying numbers, faces, and words describing levels of pain from 0 = no pain to 10 = worst pain possible. Men were also asked to report how pain associated with the device interfered with daily activities using the visual analog scale (0 = no interference and 10 = completely interferes).

Participants were given a small cash stipend of approximately US \$2.60 for transport to and from the site for each follow-up visit. Circumcision and follow-up care were provided at no cost.

After study completion, providers completed a questionnaire about their experience, including how easy they thought Shang Ring circumcision was compared with forceps guided and if they would recommend men wear the device until it detached by itself.

Statistical Analysis

We analyzed participants according to randomization group using intent-to-treat analysis. No missing data were imputed. Cumulative probabilities and 95% confidence intervals for complete healing and spontaneous detachment

were estimated using Kaplan–Meier methods with Greenwood standard error estimates. Healing times were compared between groups using Mantel–Cox tests, stratified by circumcision provider.¹³ Tests were conducted using a 2-sided 0.05 significance level without adjustment for multiple comparisons.

Four co-investigators (D.S., P.L., R.L., M.B.) reviewed AE forms and photographs. After this review, 5 AEs originally classified as moderate were reclassified as mild. This included 2 cases that did not meet criteria for moderate bleeding in the new “Adverse Event Action Guide for Male Circumcision”.¹⁴ Also, 3 cases of wound dehiscence/disruption were reclassified from moderate to mild based on our understanding of normal healing after Shang Ring circumcision. When the device is removed, a scab and pink granulation tissue are often seen, representing healing by secondary intention as previously described and illustrated,¹⁵ although it may seem abnormal to those familiar with suture-based circumcision. Severity of wound dehiscence after conventional circumcision is defined by the number of sutures disrupted and the circumferential length of disruption,¹⁴ which is not applicable to the Shang Ring because sutures are not used and healing is by secondary intention. We defined moderate wound dehiscence/disruption as a mucocutaneous gap greater than approximately 1 cm (longitudinal measurement, that is, along the shaft of the penis, between the edges of the wound) and involving deeper tissues. The definition of severe disruption was similar to that in the Action Guide¹⁴; wound disruption greater than 1cm longitudinally, that is, along the shaft of the penis between the edges of the wound and requiring surgical intervention.

RESULTS

Fifty men were enrolled and randomized (Fig. 1). Table 1 shows selected baseline characteristics. At entry, participants were uncircumcised, free of genital ulcerations or infections, and had no anatomic abnormalities or conditions that would preclude circumcision.

All circumcisions were completed without complications. Forty-four (88.0%) men completed 6 weeks follow-up, 1 (2.0%) was discontinued due to geographic relocation, and 5 (10.0%) were lost to follow-up, none before device removal or spontaneous detachment (Fig. 1).

In 9 (18.0%) men, the foreskin was too tight to evert over the inner ring and it was necessary to make a small slit (median 1.5cm) in the foreskin before circumcision. Ten device sizes were used; 80% were between 31-mm to 35-mm diameter (40 mm—1 man, 39 mm—2 men, 37 mm—2 men, 36 mm—2 men, 35 mm—6 men, 34 mm—6 men, 33 mm—8 men, 32 mm—12 men, 31 mm—8 men, and 30 mm—3 men). The mean circumcision time, after anesthesia onset, was 6.5 (SD = 2.4) minutes. The mean postoperative pain score (1 hour after start of the procedure) was 4.5 (SD = 2.0).

Seventeen men had the device removed on day 7, including the 15 participants randomized to the 7-day group, 1 participant from the 14-day group whose device was mistakenly removed, and 1 participant from the 21-day group who requested device removal (Fig. 2). Of the 28 (56.0%) participants overall, who had the device removed, 21 were on the intended removal day and 7 were removed early at the participant’s request due to pain/discomfort from the partially detached ring contacting the healing wound (4 in the 14-day group and 3 in the 21-day group) (Fig. 2).

Removals were uneventful; mean time was 2.5 (SD = 0.8) minutes. The mean score reported for highest degree of pain during removal was 3.8 (SD = 2.3), which decreased to 1.0 (SD = 1.3) approximately 10 minutes after removal. On the day of removal, partial detachment was seen in half (14 of 28) of the men. Among men still wearing the device, the cumulative probability of at least partial detachment on days 7, 14, and 21 was 26.0%, 94.1%, and 100.0%, respectively.

Complete detachment occurred in 22 (66.7%) men who wore the device more than 7 days; most (18 of 22) between days 10–16 postcircumcision (Fig. 2). Some participants returned to the clinic with the device completely off their penis (Fig. 3A). For others, the device slid down the penile shaft and was removed by a provider because it was not possible to easily slide it off due to edema or potential to

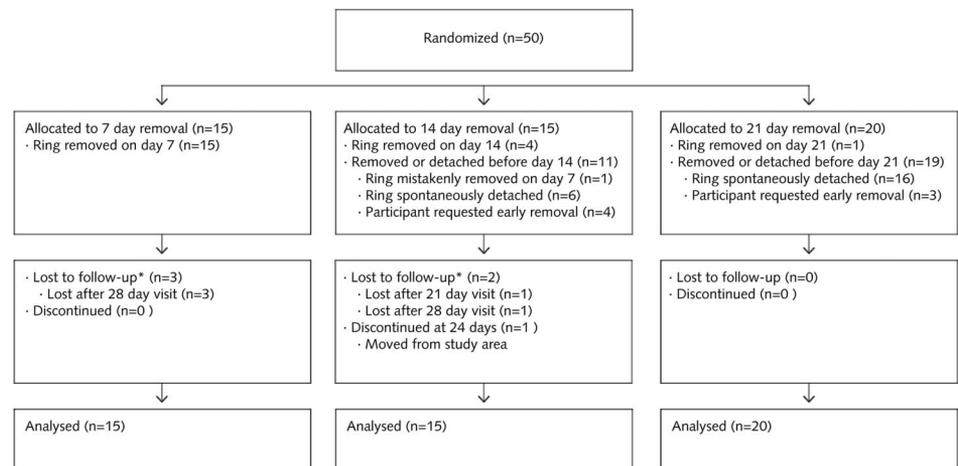


FIGURE 1. Flow of study participants. * No men were lost prior to ring removal or documentation of spontaneous detachment.

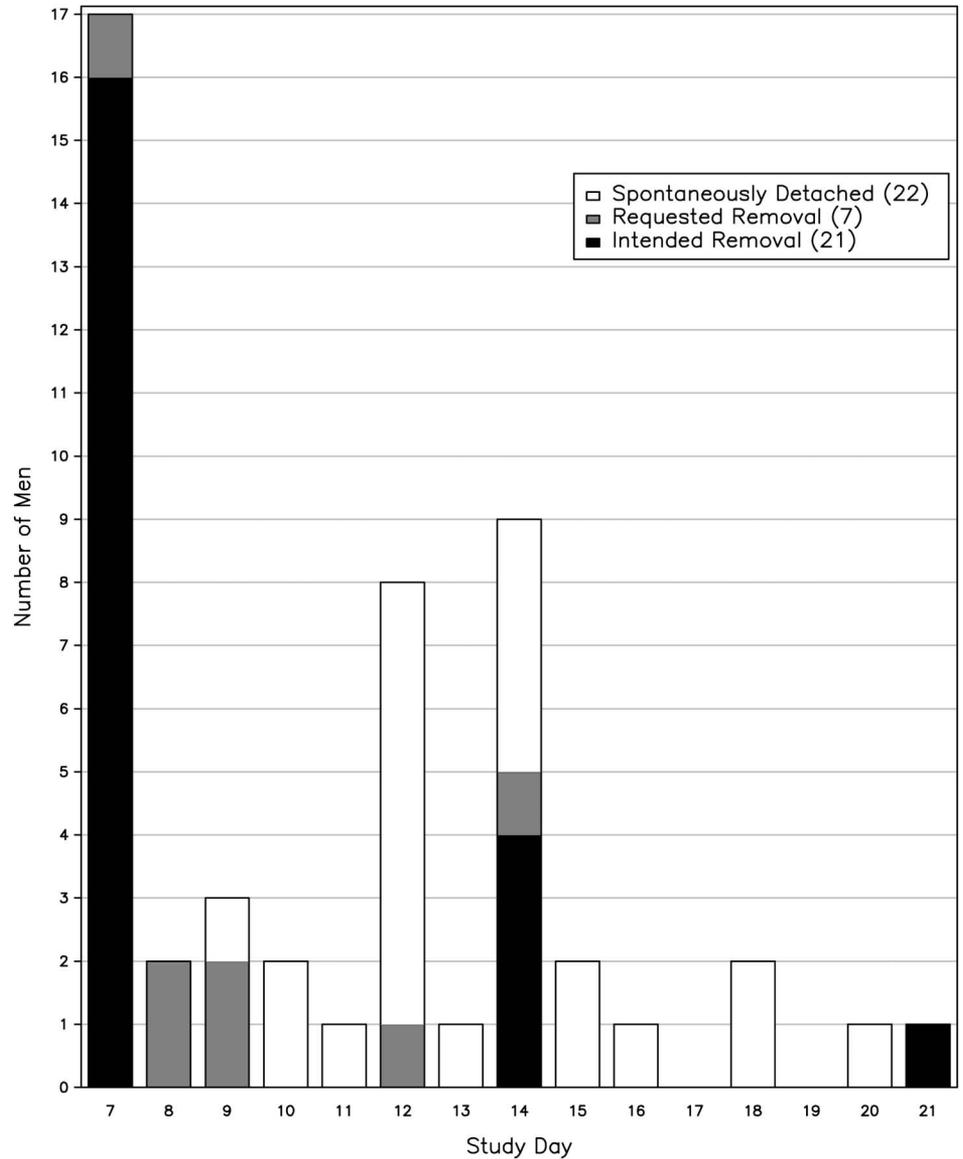


FIGURE 2. Timing of removals and spontaneous detachments among 50 men circumcised with the Shang Ring.

damage the healing wound (Fig. 3B). Cumulative probabilities of complete spontaneous detachment at 7, 14, and 21 days were 0.0%, 56.1%, and 93.7%, respectively.

Complete healing was observed in 46 of 50 (92.0%) men. Two men were lost to follow-up before complete healing: 1 had removal on day 7 as scheduled and was followed through 28 days; the other experienced complete detachment on day 10 and was followed through 21 days. Two men were not completely healed by 42 days but did not return for additional follow-up as follows: 1 had removal on day 14 as scheduled and experienced a moderate wound disruption AE (below); the other, randomized to 21-day removal, requested removal on day 8, and experienced no subsequent events.

The earliest time point at which participants were observed to have healed completely was 21 days. Cumulative probabilities of complete healing were similar across randomization groups ($P = 0.86$; Table 2). Although not significant,

there was a tendency towards faster healing among men whose device was removed or detached at approximately 14 days ($P = 0.13$; Table 2). Complete healing also tended to be sooner in men whose device was removed or spontaneously detached after 7 days compared with those whose ring was removed on day 7, although differences were not significant ($P = 0.18$). For example, cumulative probabilities at 21 and 28 days were 18.2% and 74.8% versus 11.8% and 52.9% in those men whose device was left on beyond 7 days compared with those whose device was removed at 7 days, respectively.

There were no severe and 6 moderate AEs (4 of the 6 were among men who requested early ring removal). One man experienced excessive pain immediately post-op. He was treated with an oral analgesic, additional local anesthetic, and eventually an intramuscular injection of a nonsteroidal anti-inflammatory before discharge from the clinic. Two other pain-related AEs were reported, both by men in the 14-day

TABLE 1. Selected Baseline Characteristics of Study Participants Undergoing Adult Male Circumcision With the Shang Ring in Kenya

	Randomization Group			Total n (%)
	Day 7 Removal n (%)	Day 14 Removal n (%)	Day 21 Removal n (%)	
No. participants	15	15	20	50
Median age in years (Range)	21 (18–36)	20 (18–38)	22 (18–33)	21 (18–38)
Relationship with primary sex partner				
Married	2 (13.4)	1 (6.7)	4 (20.0)	8 (16.0)
Not married without live-in partner	9 (60.0)	7 (46.7)	10 (50.0)	26 (52.0)
No primary sex partner	2 (13.3)	5 (33.3)	5 (25.0)	12 (24.0)
Other	2 (13.3)	1 (6.7)	1 (5.0)	4 (8.0)
Ethnic group				
Luo	15 (100)	15 (100)	18 (90.0)	48 (96.0)
Other	0 (0.0)	0 (0.0)	2 (10.0)	2 (4.0)
Highest level of education				
Some primary	1 (6.7)	1 (6.7)	2 (10.0)	4 (8.0)
Completed primary	4 (26.7)	3 (20.0)	7 (35.0)	14 (28.0)
Some secondary	4 (26.7)	2 (13.3)	1 (5.0)	7 (14.0)
Completed secondary	3 (20.0)	4 (26.7)	2 (10.0)	9 (18.0)
Postsecondary	2 (13.3)	4 (26.7)	7 (35.0)	13 (26.0)
Other	1 (6.7)	1 (6.7)	1 (5.0)	3 (6.0)
Current employment status				
Employed and receiving a salary	6 (40.0)	5 (33.3)	7 (35.0)	18 (36.0)
Self-employed	1 (6.7)	0 (0.0)	0 (0.0)	1 (2.0)
Unemployed	3 (20.0)	1 (6.7)	2 (10.0)	6 (12.0)
Student	5 (33.3)	9 (60.0)	11 (55.0)	25 (50.0)
Primary reason for circumcision				
Partial HIV protection	11 (73.3)	10 (66.7)	16 (80.0)	37 (74.0)
Hygiene	3 (20.0)	3 (20.0)	1 (5.0)	7 (14.0)
Sexual pleasure	0 (0.0)	1 (6.7)	2 (10.0)	3 (6.0)
Other	1 (6.7)	1 (6.7)	1 (5.0)	3 (6.0)
Vaginal sex, past year	13 (86.7)	10 (66.7)	15 (75.0)	38 (76.0)
Vaginal sex, past 7 days	5 (33.3)	3 (20.0)	4 (20.0)	12 (24.0)

group and due to pain caused by rubbing of the partially detached ring against the healing wound. Devices were removed at the participant's request; 1 on day 7 and 1 on day 8.

The other 3 were wound disruptions that met the revised definition of moderate dehiscence/disruption (Methods). Moderate wound disruption was noted in 1 participant after his scheduled device removal on day 14. The other 2 men were in the 21-day group; 1 with moderate disruption on day 8 and the other on day 14. Both requested device removal



FIGURE 3. Photos taken on the day of spontaneous device detachment in 2 participants circumcised with the Shang Ring. A, The Shang Ring came off the penis after spontaneously detaching on day 9 postcircumcision. B, The device slipped down the shaft of the penis on day 15 postcircumcision.

because of pain caused by rubbing of the partially detached ring against the healing wound. All 3 were managed conservatively, that is, without antibiotics or surgical intervention.

After independently reviewing participant's photographs, 2 PIs (D.S., M.B.) identified 9 cases of small penile shaft cutaneous injuries. Site investigators had classified 4 as mild AEs and 5 as within normal limits. Of the 9, 3 were very similar to cases seen previously in Kenya.¹⁰

Irrespective of AEs, removal day, spontaneous detachment, or request for early removal, men with documented complete healing healed without problems and with excellent cosmesis. At the 6-week follow-up the majority (38 of 43) were "very satisfied" with the appearance of their circumcised penis. The remainder were "somewhat satisfied" (4 of 43) or "somewhat dissatisfied" (1 of 43). Although the numbers are small, men who were not "very satisfied" were in the 14 day (3 men) and 21 day (2 men) groups.

TABLE 2. Kaplan–Meier Estimates of Cumulative Probability of Complete Healing (95% Confidence Interval) After Shang Ring Circumcision in Kenyan Men

Visit day	Randomization group			Total
	Day 7 Removal (n = 15)	Day 14 Removal (n = 15)	Day 21 Removal (n = 20)	
7	0.0% (0.0% to 0.0%)	0.0% (0.0% to 0.0%)	0.0% (0.0% to 0.0%)	0.0% (0.0% to 0.0%)
14	0.0% (0.0% to 0.0%)	0.0% (0.0% to 0.0%)	0.0% (0.0% to 0.0%)	0.0% (0.0% to 0.0%)
21	13.3% (3.5% to 43.6%)	13.3% (3.5% to 43.6%)	20.0% (8.0% to 44.9%)	16.0% (8.3% to 29.5%)
28	60.0% (37.2% to 83.5%)	71.1% (47.2% to 91.0%)	70.0% (49.9% to 87.7%)	67.2% (54.1% to 79.8%)
42	100.0% (100.0% to 100.0%)	90.4% (66.2% to 99.4%)	94.0% (76.4% to 99.6%)	94.5% (84.1% to 99.0%)

Visit day	Approximate day ring was actually removed or completely detached			Total
	Day 7 Removal (n = 24)	Day 14 Removal (n = 22)	Day 21 Removal (n = 4)	
7	0.0% (0.0% to 0.0%)	0.0% (0.0% to 0.0%)	0.0% (0.0% to 0.0%)	0.0% (0.0% to 0.0%)
14	0.0% (0.0% to 0.0%)	0.0% (0.0% to 0.0%)	0.0% (0.0% to 0.0%)	0.0% (0.0% to 0.0%)
21	16.7% (6.6% to 38.5%)	18.2% (7.2% to 41.5%)	0.0% (0.0% to 0.0%)	16.0% (8.3% to 29.5%)
28	51.80% (33.5% to 72.8%)	81.8% (63.7% to 94.3%)	75.0% (35.5% to 99.1%)	67.2% (54.1% to 79.8%)
42	94.0% (76.2% to 99.6%)	93.9% (76.8% to 99.5%)	100.0% (100.0% to 100.0%)	94.5% (84.1% to 99.0%)

The maximum scores, over all visits before removal or detachment, for interference with various activities from pain associated with wearing the device were (mean, SD): walking 1.0 (2.3), sleeping 2.0 (2.5), working 1.1 (2.5), and enjoying life 0.9 (2.0). All but 1 man returned to normal work wearing the device. Among men returning to work while wearing the device, all were back to work within 2 days of circumcision (median = 1 day).

When asked at 6 weeks what they liked about the circumcision, participants most commonly mentioned that the procedure was quick (39 of 43), they were happy with the appearance of their penis (20 of 43), they experienced less pain than expected (16 of 43), and stitches were unnecessary (13 of 43). The only commonly (11 of 43) mentioned complaint about the circumcision was pain/discomfort during erections. All men reported experiencing erections while wearing the device. The mean of the maximum pain scores reported by each participant during an erection while wearing the device and after removal/spontaneous detachment were 3.8 (SD = 2.0) and 0.9 (SD = 1.4), respectively. All men who completed the study said they would recommend circumcision to a friend or family member.

All 4 providers reported that Shang Ring circumcision was “very easy” compared with the forceps-guided procedure. However, all said they would not recommend letting men wear the ring until it detached because they perceived it was sometimes too painful.

DISCUSSION

These results confirm that the Shang Ring is safe and easy to use per label instructions of removal at 7 days. As in previous studies,^{3–6,10} all circumcisions were completed as planned with no significant problems or intraoperative complications. Mean circumcision time was 6.5 minutes, less than reported for conventional suture circumcision, which ranges from 20 to 40 minutes.^{6,16,17}

We demonstrated that if removal is delayed beyond 7 days, the device will eventually detach without significant

problems. There seem to be no serious consequences if removal is delayed or men do not return for removal. Indeed, most men randomized to the 14-day and 21-day groups had spontaneous detachments. Although 7 men in the delayed removal groups requested early removal due to pain/discomfort from the partially detached device rubbing against the healing wound (not pain during erections), there were also 22 men who had complete detachment without seeking early removal. In some men, the device detached from the circumcision site and slipped back onto the penile shaft but was not easily removed due to edema or concern about disrupting the healing wound. In these cases, providers removed the device using standard removal procedures, and thus we could not follow men to document if any problems might occur after the ring slipped onto the penile shaft or if waiting until the device could be slipped off the penis would present any concerns.

Unlike some pediatric circumcision devices that are left to fall off, all adult devices currently described in the literature require removal.^{17–19} Waiting for the Shang Ring to fall off might be a suitable service delivery strategy in settings where a removal visit may be inconvenient; implementation research would be needed to evaluate larger scale use of this approach, including assessment of outcomes in men whose ring slips back toward the base of the penis rather than falling off. Men could, for example, be told that the device will fall off on its own, most likely within 14–16 days, and that they should return to the clinic if they experience problems or have concerns.

Healing progressed normally in all men, whether the device was removed or detached spontaneously. Device removal at different times postcircumcision had no significant effect on time to complete healing, although there was a suggestion of a trend toward faster healing among men who wore the device more than 7 days. It is possible that the small number of participants did not allow us to detect differences that may have existed.

The need for a small slit in the foreskin in 18.0% of patients to facilitate use of the device was not unexpected,

having been reported with the Shang Ring^{3–6,10} and other adult devices.^{17–19} Making the slit was not problematic and was painless because the penis was anesthetized.

There were 6 moderate and no severe AEs. Three men from the 14-day and 21-day groups developed moderate wound disruption 8–14 days postcircumcision; healing progressed without intervention. Moderate wound disruption was not seen in men whose device was removed at 7 days in this study or the previous Kenya study,¹⁰ suggesting that it may have been caused by wearing the device beyond 7 days.

The other 3 moderate AEs were pain related. One participant experienced significant pain immediately post-op. The other 2 complained of pain during follow-up that met the moderate AE definition (ie, pain requiring bed rest for more than one-half day); neither had infection, significant wound disruption, or other problems. These pain-related AEs might be considered mild under the draft AE definitions recently prepared by PSI and the World Health Organization; moderate pain is defined as “disrupting normal daily activities for 4–7 days.”¹⁴

In the previous Kenya study, small cutaneous injuries, thought to be related to a slightly sharp edge on the device, were seen on the penile shaft in 3 participants.¹⁰ We saw similar lesions, even though the manufacturer modified the devices we used. Based on the location of these lesions and observations of the providers, we believe they may be caused when a small fold of skin from the penile shaft is pinched between the rings as the outer ring is applied. These lesions were considered mild or within normal limits.

Clearly pain experience or tolerance is individual. Although all 4 providers would not recommend removal beyond 7 days or waiting for the device to detach because of pain they perceived men might experience, most participants reported minimal interference with daily activities due to pain associated with the device, and all but 1 returned to work within 2 days postcircumcision. One-quarter did mention pain or discomfort during erections as a reason they disliked the device. However, the mean of the maximum pain scores men reported experiencing during erections while wearing the device was 3.8, and no participant asked to have the device removed due to pain during erections. Overall, satisfaction with the device and final appearance was excellent, with men reporting they liked the short procedure time and lack of sutures.

Efforts to scale-up adult male circumcision are ongoing in sub-Saharan Africa,² male circumcision as part of a comprehensive HIV prevention package has been shown to be cost saving,^{20,21} and recent computer modeling suggests that the benefits to women might be greater than previously thought.²² Interest in devices for adult male circumcision continues to be high in an effort to find techniques that are sutureless, bloodless, and simpler than conventional circumcision. Such a device would address drawbacks of the current techniques that limit the potential for rapid scale-up in resource-limited settings.^{20,23}

Unfortunately, progress has been slow. The TaraKlamp, successfully used in boys,^{24,25} has been disappointing in men with a high number of AEs, the need to revert to conventional circumcision in some cases, and high refusal rates anecdotally related to size of the device and perceived potential discomfort while wearing it.¹⁸ Results were recently published from

a randomized study of a template device versus the sleeve method for adult circumcision. Although procedure time was significantly reduced with the device, the procedure was still lengthy (mean 27.5 minutes), and the design of the device does not eliminate the need for suturing.¹⁷ More promising is the Alisklamp, a disposable device, which like the Shang Ring is bloodless, sutureless, and a quick procedure. Few complications and good healing were seen in adult men circumcised using the device.¹⁹

Although there is now one promising published report on the recently developed PrePex device, suggesting that it can be used without anesthesia, additional data are needed to confirm these results and its safety and acceptability in other populations.²⁶ Further, data are needed to determine what happens if a man does not return for device removal and to quantify the percentage of men for whom the device is not suitable due to a tight foreskin that would prevent insertion of the inner ring.

The Shang Ring, PrePex, and the Alisklamp are best described as “minimally invasive”, and we expect that all could be used by trained nonphysician providers in similar settings. By minimally invasive, we mean no exposure of subcutaneous tissues, and no need for hemostasis or sutures. With all 3 devices, the procedure times are dramatically reduced relative to conventional techniques.

The main limitation of this study was the small sample size, which may have affected our ability to detect differences in healing times or AEs between groups.

CONCLUSIONS

Our results contribute to the growing body of evidence that the Shang Ring could facilitate rapid rollout of male circumcision in sub-Saharan Africa given short procedure times, favorable reviews from study participants and providers, and the ease with which it can be used by trained nonphysicians. We found no evidence of serious consequences if men do not return on time for removal, although approximately 20% of men who wore the ring beyond 7 days requested their ring be removed due to some degree of pain/discomfort. Most devices left on longer than 7 days spontaneously detached, falling off the penis in some men, and sliding back toward the base of the penis in others. In the latter group, the device was removed by a provider, and thus we were unable to follow these men to document if waiting until the device could be slipped off the penis would be problematic. Ring removal or detachment at different times seemed to have little effect on healing.

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