Randomized Controlled Trial of the Shang Ring Versus Conventional Surgical Techniques for Adult Male Circumcision: Safety and Acceptability

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Objective: To compare clinical profiles of Shang Ring versus conventional circumcisions.

Design: Parallel group open-label randomized controlled trial with one-to-one allocations in 2 sites.

Methods: We enrolled HIV-negative men aged 18–54 years in Homa Bay, Kenya, and Lusaka, Zambia and followed them at 2, 7, 14, 21, 28, 42, and 60 days after Shang Ring versus conventional circumcision. We compared the duration of surgery, postoperative pain using a visual analog scale, adverse events rates, time to complete wound healing by clinical assessment, participant acceptability, and provider preferences between circumcision groups.

Results: We randomized 200 men to each group; 197 and 201 contributed to the Shang Ring and conventional surgery analyses, respectively. Adverse event rates were similar between groups. Pain scores at most time points were similar, however, the Shang Ring group reported higher scores for worst pain during erections (3.5 ± 1.9 vs. 2.3 ± 1.7; $P < 0.001$). Significantly more men were satisfied with the cosmetic appearance following Shang Ring male circumcision (MC), 95.7% versus 85.9% ($P = 0.02$) in Kenya, and 96.8% versus 71.3% ($P < 0.01$) in Zambia. Although median time to complete wound healing was 43 days in both groups, conventional circumcisions healed on average 5.2 days sooner ($P < 0.001$). Shang Ring procedures took one-third the time of conventional MC, 7 versus 20 minutes. All circumcision providers preferred the Shang Ring.

Conclusions: Safety profiles of the 2 techniques were similar, all MC providers preferred the Shang Ring technique, and study participants preferred the Shang Ring's cosmetic results. The Shang Ring should be considered for adult MC as programs scale-up.

Key Words: randomized controlled trial, male circumcision, Shang Ring, device

(*J Acquir Immune Defic Syndr* 2014;65:447–455)

Received for publication August 5, 2013; accepted November 2, 2013.

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Supported by a Grant from the Bill and Melinda Gates Foundation to FHI 360 (Grant OPPGH5166).

Presented at the International Conference on AIDS and Sexually Transmitted Infections in Africa (ICASA), December 4–8, 2011, Addis Ababa, Ethiopia; Annual meeting of the University of Nairobi Collaborative Centre for Research and Training in HIV/AIDS/STIs, January 23–27, 2012, Nairobi, Kenya; Annual meeting of the American Urological Association, May 19–23, 2012 (por), Atlanta, GA; and 2012 Meeting of the International AIDS Society, July 21–27, 2012, Washington, DC. Abstract no. TUAC0404.

The authors have no conflicts of interest to disclose.

D.C.S. had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. D.C.S. was a member of the Protocol Executive Committee and was overall team leader for the study. He provided scientific leadership, and participated in drafting the protocol, study implementation, analysis, and drafting the article. P.S.L. was a member of the Protocol Executive Committee and clinical leader for the study. He prepared surgical training material, helped interpret the results, and reviewed the article. R.Z. was the site clinician for the Zambia site and was involved in data collection and interpretation, and reviewed the article. Q.D.A. helped with training of study staff, study co-ordination, data collection (informed consent process, performing surgical procedures, and follow-up visits), verification and management, data analysis and interpretation, presented the results in various forums and reviewed the article. S.L.C. participated in the design and conduct of the study, including preparation of the protocol and other study documents, provided overall coordination for the study, and managed and performed training activities, data analysis and interpretation, and reviewed and finalized the article. R.O.S. was the senior clinician at the Kenya site, performed some MC procedures and helped evaluate and interpret adverse events and time to healing data and reviewed the article. R.L. helped with data analysis and interpretation and reviewed the article. C.H. assisted with study design, data collection, study specific training, clinical monitoring, and review of the acceptability data. P.P. contributed review of findings, article review, and provided administrative support. H.J.H. contributed to review of the study instruments, study implementation, administrative support in Lusaka, and reviewed the article. K.B. was the clinical leader for the Zambia site, and provided scientific leadership, guidance on ethical issues and reviewed the article. M.G. mentored the Weill Cornell Medical College study team and helped interpret the results and finalize the article. M.A.B. was a member of the Protocol Executive Committee. He participated in the design and conduct of all aspect of the study, including providing scientific leadership, writing the protocol, developing the study instruments, managing oversight for the Kenya study site, interpreting study data, and drafting the article.

Trial registration: NCT01300910 at ClinicalTrials.gov. Ethical committee approvals for the trial were obtained from FHI 360, the Kenya Medical Research Institute, and the University of Zambia. The Zambia Ministry of Health also granted permission to conduct the study.

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INTRODUCTION

Since the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS, recommended male circumcision (MC) as a valuable tool for HIV prevention in 2007,[1] evidence has accumulated on the benefit of adult MC. Gray et al[2] showed that MC protection persisted for 5 years in Uganda and data from long-term follow-up in Kenya suggested that protection against HIV persisted for at least 6 years.[3] In South Africa, roll-out of MC services in Orange Farm has significantly reduced HIV prevalence among circumcised men.[4] MC has in addition been shown to reduce not only the risk of HIV infection but human papillomavirus and herpes simplex virus as well.[5]

The Shang Ring (Wuhu SNNDA Medical Treatment Appliance Technology Co., LTD., Wuhu City, China), is a novel disposable, single-use, minimally invasive device that has been used to circumcise over 300,000 Chinese men. Chinese studies have shown the device is safe, quicker than conventional surgery and well accepted with high client satisfaction rates (>98%). Adverse event (AE) rates have been comparable with or less than with conventional adult circumcision.[6–9]

Results of a pilot study of Shang Ring MC in Kenya were favorable.[10] There were no severe or moderate AEs. More recently, a safety study in Kenya explored outcomes when men did not return as scheduled for device removal at 7 days.[11] Researchers randomized 50 men to removal 1, 2, or 3 weeks after circumcision. Complete detachment of the device occurred spontaneously in 22 men (66.7%) who wore it more than 7 days, most (18/22) between days 10–16 postcircumcision. Healing progressed normally in all participants, and times to complete healing were similar across groups. No severe or serious AEs occurred, and acceptability was high. All providers reported that Shang Ring circumcision was "very easy" compared with the widely used surgical forceps-guided technique.

The primary objective of this study was to compare the clinical profile of the Shang Ring circumcision with conventional surgical techniques in terms of: (1) safety, including time to complete wound healing; (2) pain and acceptability; and (3) ease of procedures and provider preferences between the Shang Ring MC and conventional MC. This study was designed to detect differences between groups to evaluate the superiority of the Shang Ring circumcision over the conventional method.

METHODS

Study Design, Participants, and Settings

This was an open-label parallel randomized controlled trial with 2 groups: Shang Ring MC and conventional surgery. At the Homa Bay District Hospital in Homa Bay, Kenya, the conventional surgical procedure was the forceps-guided MC technique. At the New Start YWCA Male Circumcision Centre, in Lusaka, Zambia, it was the dorsal slit MC technique.

Healthy, uncircumcised, HIV-negative men ages 18–54 years seeking circumcision were informed of the study. Men with active genital infection, previous circumcision, or an anatomic abnormality or another condition that contraindicated elective surgery under local anesthesia (eg, bleeding diathesis, lidocaine allergy) were ineligible. Interested men underwent informed consent procedures, including HIV prevention and risk reduction counseling per national guidelines.

Procedures

After obtaining informed consent, we interviewed participants to gather baseline data and conducted a clinical exam to ensure eligibility. Two physicians and 4 nurses, experienced with surgical circumcision and trained on Shang Ring procedures in China, performed the circumcisions in both groups.

The Shang Ring and conventional surgical techniques have been described.[7,10,12,13] Men in both groups received 1 g paracetamol just before the circumcision and were given additional paracetamol to take home for postoperative pain relief as needed. Dorsal penile nerve and ring blocks were administered to both groups with 1% lidocaine. Shortly before completion of the study, the Zambia site began using a mixture of lidocaine and bupivacaine; this mixture was applied to all subsequent Zambian patients.

Follow-up visits were at 2, 7, 14, 21, 28, 42, and 60 days postcircumcision. Men in the Shang Ring group had the device removed at the 7-day visit. Men were encouraged to return at any time if they experienced a complication, excessive pain, or other problem. At each visit, genital exams and interviews were conducted. We took photographs to document complete healing and AEs. We gathered acceptability data at the 60-day visit.

Outcome Measures

Outcome measures were:

1. Safety: We evaluated all circumcision-related AEs, gathered data on device-related incidents such as early ring removal and compared time to complete wound healing.

We also classified AEs as serious or nonserious per the usual criteria.[14] We used the Public Services International/WHO Adverse Event Action Guide[15] to classify AEs as mild, moderate or severe, and focused on the moderate and severe events. The definition of moderate wound dehiscence was problematic because it is defined by the number of disrupted sutures—but sutures are not used with the Shang Ring. In addition, after Shang Ring removal, a scab and healthy pink granulation tissue are part of the normal healing process,[16] although to those familiar with suture-based circumcision it may appear abnormal.[12] Therefore, we modified the Action Guide definition for moderate wound dehiscence for Shang Ring cases to be a mucocutaneous gap greater than approximately 1 cm between the edges of the wound. The definition of severe dehiscence was similar to that in the Action Guide, ie, requiring surgical intervention.

In our previous Shang Ring studies in Kenya,[10,11] we identified cases of cutaneous pinches on the shaft of the penis,

which were considered surgical errors, albeit minor in terms of severity. In training the providers for this study, we advised them to carefully inspect the skin and gently pull on the skin of the penile shaft before completely closing the outer ring to minimize the occurrence of these events.

We did not predefine likely AEs; rather we report on all moderate and severe AEs. We defined complete wound healing as the absence of a scab with a completely epithelialized and dry skin surface based on clinical assessment. Although such an assessment is subjective, it is a standard definition of wound healing in circumcision studies.[17] Wound healing was assessed at each site independently by the clinician examining the patient.

2. Pain and acceptability: Participants were asked to rate their pain at various time points (eg, during and shortly after circumcision and removal, in the first 2 days post-circumcision and during erections) using a visual analog scale (VAS).[18] We rated the pain 1 hour after the start of the procedure to obtain a more objective comparison. Two days after circumcision, men were asked to report how postoperative pain had interfered with daily activities (eg, walking, sleep, work) using a VAS (0 = no interference and 10 = completely interferes). To evaluate acceptability, we asked men whether they would recommend circumcision to their friends, and how satisfied they were with their cosmetic results.
3. Ease of use and provider preferences: We measured the duration of surgery in minutes (excluding the time for injection and induction of anesthesia); we documented all surgical difficulties; and providers completed a standardized questionnaire.

Randomization and Masking

Participants were randomly assigned to MC procedures in a 1:1 ratio, stratified by site. Random sequences were generated using permuted blocks with randomly chosen block size. Assignments were provided to site staff through sequentially numbered, opaque, sealed, tamper-evident envelopes prepared by a nonstudy statistician at FHI 360. Envelopes were to remain sealed until being opened immediately before circumcision. Because of the nature of the interventions, it was not possible to conceal the study group from participants, clinicians, or other staff.

Statistical Analysis

We chose the sample size and number of sites based on the WHO Framework for Clinical Evaluation of Devices for Adult MC,[19] ie, 2 different countries, and 100 Shang Ring cases per country. From a statistical perspective, this sample size would provide at least 80% power (2-sided test at the 0.05 significance level) to detect between-group differences in proportions of at least 20 percentage points, and for pain scores, a mean between-group difference of 1 point on the 11-point scale. An interim analysis was planned after 100 men had been circumcised at each site; the 3-person Data Safety and Monitoring Board was asked to recommend halting the study if they saw notably more severe AEs among the Shang Ring cases. The Data Safety and Monitoring Board recommended that the study continue.

We analyzed participants according to the actual method received because safety and acceptability outcomes depend on the method received. No missing data were imputed. Cumulative probabilities and 95% confidence intervals for complete healing were estimated using Kaplan–Meier methods with Greenwood standard error estimates, censoring noncompleters at date of last contact. The proportions of men completely healed at nominal study visits (defined as intervals around nominal visit dates) were compared between groups using Mantel–Cox tests, stratified by site.[20] All tests were conducted at the 2-sided 0.05 significance level without adjustment for multiple comparisons.

RESULTS

We enrolled and randomized 400 men, 200 at each site (Fig. 1) from March to June 2011. Nonphysicians performed 82% of the procedures, a physician and a nonphysician 17%, and 2 physicians performed the remainder.

Three men randomized to the Shang Ring in Kenya had conventional procedures: 1 man had an unusually thick foreskin and the outer ring could not be closed; the other 2 men needed Shang Ring sizes that were out of stock. Two men in the conventional surgery group were excluded from analysis at the request of the Zambia ethics committee due to inadequate documentation of informed consent; these consents specifically were incomplete or could not be verified on review. Table 1 shows selected baseline characteristics of study participants. Most men were young, with median ages 19 in Kenya and 22.5 years in Zambia, and unmarried, 55% and 74%, respectively. Most participants reported sexual intercourse in the past year, but fewer reported intercourse in the past week.

There were a total of 25 moderate or severe AEs that were deemed to be at least possibly related to the circumcision procedure. We measured no clinically meaningful difference between the number of AEs in the Shang Ring and conventional surgery group (15 vs. 10 events, respectively; Table 2). One severe AE was reported, an occurrence of procedural pain that occurred in the Shang Ring group. The other AEs were moderate in severity and included: 6 cases of wound dehiscence in the Shang Ring group versus 4 in the conventional group; 1 case of bleeding leading to a moderate hematoma in the conventional group before the 2-day visit; 6 versus 3 cases of postprocedure pain in the Shang Ring and conventional groups, respectively; and 1 report each of swelling and anesthetic complication in the Shang Ring group. Antibiotics were prescribed to 2 men in the conventional group due to wound infection versus none in the Shang Ring group. No MC-related AEs were considered serious. All AEs resolved without sequelae.

Postoperative pain scores were similar between the 2 study groups at most time points. In Kenya, the mean end-of-procedure pain score was significantly lower in the Shang Ring group, 0.2 versus 1.2 ($P < 0.001$), but scores were similar 1 hour after surgery (combined mean = 3.8, SD = 1.8). Conversely, in Zambia, the end-of-procedure pain score

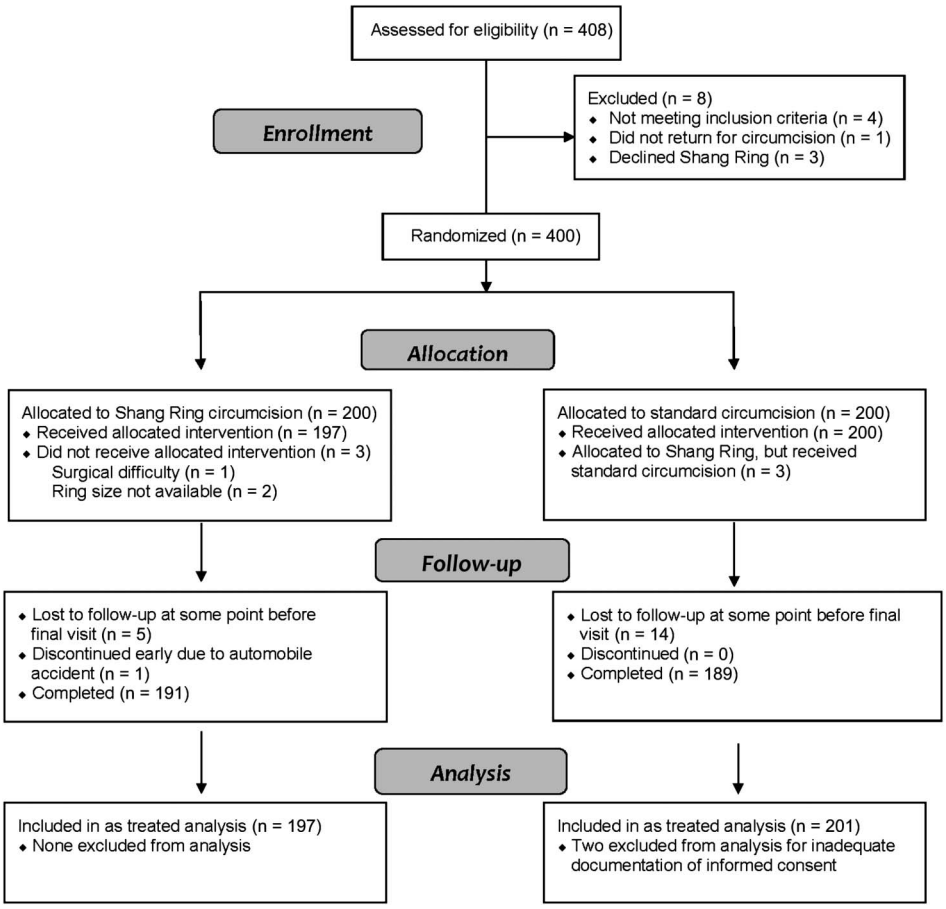

FIGURE 1. Flow of study participants: combined Kenya and Zambia data.

was slightly higher in the Shang Ring group, 0.6 versus 0.2 ($P = 0.046$); pain scores were similar 1 hour after surgery (combined mean = 3.4, SD = 1.9).

The median number of paracetamol 500 mg tablets taken by participants in each group during the first 2 days after circumcision was identical, 6 tablets on the first day and 2 on the second. At the 2-day visit, pain scores were similar in both groups, with median scores of 1.0.

At the 2 day visit, interference with walking, sleep, work or other general activities were generally low and similar, with median VAS scores of 0–2. At the 7-day visit, men in the Shang Ring group reported higher scores for the worst pain during erections, with a mean of 3.5 ± 1.9 versus 2.3 ± 1.7 for conventional surgery ($P < 0.001$).

Two men requested early removal of the Shang Ring due to pain. One participant requested removal on day 3 postcircumcision. He had a small cutaneous pinch and he was judged to have mild wound dehiscence on his 21-day visit. The other participant requested his ring be removed on day 5; he had no apparent abnormalities. Both men subsequently healed without problems. Including the early removal case described above, 6 men in the Shang Ring group were noted to have cutaneous pinches; all cases were considered to be mild and healed without problems.

Although each site used the same definition for time to complete healing, Zambian clinicians interpreted the criteria more conservatively and in general estimated longer healing times than Kenya clinicians, especially for the conventional surgery cases (Table 3). Because of this difference we did a post hoc analysis of time to healing for each site separately. In Kenya, the surgical group healed significantly faster (median 29.0 vs. 42.0 days; $P < 0.001$), whereas in Zambia, there was no statistically significant difference in healing time between the 2 groups (median 43.0 days for the Shang Ring and for the conventional group; $P = 0.82$) (Table 3). Figure 2 illustrates the difference in healing evaluation by site.

The overall median time to healing was the same in the Shang Ring and conventional surgery groups (43 days; Table 3).

At the 60-day visit, significantly more men in the Shang Ring group compared with the conventional circumcision group were "very satisfied" with cosmetic appearance, 95.7% versus 85.9% ($P = 0.02$) in Kenya, and 96.8% versus 71.3% ($P < 0.01$) in Zambia. All except one of the study participants said they would recommend circumcision to a friend or family member.

Mean Shang Ring procedure times were 7.0 (SD = 1.9) and 7.3 (SD = 2.1) minutes compared with 20.7 (SD = 6.0) and 19.8 (SD = 2.9) minutes for conventional surgery in Kenya and Zambia, respectively. The mean time from first anesthetic injection to beginning the circumcision procedure (for both arms combined) was 4.1 (SD = 3.3) and 5.5 (SD = 2.3) minutes, respectively, in Kenya and Zambia. It was

TABLE 1. Selected Baseline Characteristics of Men Undergoing Shang Ring or Conventional Surgical Circumcision Procedures in Kenya and Zambia

	Kenya		Zambia	
	Shang Ring (N = 97), n (%)	**Conventional Surgery (N = 103), n (%)**	**Shang Ring (N = 100), n (%)**	**Conventional Surgery (N = 98), n (%)**
Age (in yrs)				
18–24	80 (82.4)	94 (91.2)	67 (67.0)	57 (58.2)
25+	17 (17.5)	9 (8.8)	33 (33.0)	41 (41.8)
Median (range)	19.0 (18–36)	19.0 (18–38)	22.0 (18–39)	23.0 (18–41)
Total	97	103	100	98
Relationship with primary sex partner				
Married or live-in partner	17 (17.5)	11 (10.7)	22 (22.0)	17 (17.3)
Not married and without live-in partner	50 (51.5)	59 (57.3)	72 (72.0)	74 (75.5)
No primary sex partner	28 (28.9)	32 (31.1)	6 (6.0)	5 (5.1)
Other	2 (2.1)	1 (1.0)	0 (0.0)	2 (2.0)
Total	97	103	100	98
Ethnic group				
Luo (Kenya)	96 (99.0)	103 (100)		
Bemba (Zambia)			40 (40.0)	27 (27.6)
Nyanja (Zambia)			23 (23.0)	26 (26.5)
Tonga (Zambia)			4 (4.0)	17 (17.3)
Lozi (Zambia)			8 (8.0)	5 (5.1)
Other (Kenya/Zambia)	1 (1.0)	0 (0.0)	25 (25.0)	23 (23.5)
Total	97	103	100	98
Highest level of education				
Some primary	12 (12.4)	12 (11.7)	0 (0.0)	1 (1.0)
Completed primary	13 (13.4)	20 (19.4)	1 (1.0)	2 (2.0)
Some secondary	37 (38.1)	37 (35.9)	20 (20.0)	21 (21.4)
Completed secondary	15 (15.5)	18 (17.5)	44 (44.0)	39 (39.8)
Postsecondary	20 (20.6)	16 (15.5)	35 (35.0)	35 (35.7)
Total	97	103	100	98
Vocational or technical training				
None	62 (63.9)	75 (72.8)	57 (57.0)	45 (45.9)
Some	12 (12.4)	16 (15.5)	16 (16.0)	21 (21.4)
Completed	23 (23.7)	12 (11.7)	27 (27.0)	32 (32.7)
Total	97	103	100	98
Current employment status				
Employed and receiving a salary	15 (15.5)	15 (14.6)	24 (24.0)	31 (31.6)
Self-employed	16 (16.5)	9 (8.7)	13 (13.0)	18 (18.4)
Unemployed	11 (11.3)	23 (22.3)	34 (34.0)	19 (19.4)
Student	55 (56.7)	56 (54.4)	29 (29.0)	30 (30.6)
Total	97	103	100	98
Primary reason for circumcision				
Partial HIV protection	75 (78.1)	91 (89.2)	89 (89.0)	87 (88.8)
Hygiene	14 (14.6)	8 (7.8)	10 (9.0)	9 (9.2)
Other	7 (7.3)	3 (3.0)	1 (1.0)	2 (2.0)
Total	96	102	100	98
Had sexual intercourse in past year?				
No	25 (25.8)	20 (19.4)	35 (35.0)	29 (29.6)
Yes	72 (74.2)	83 (80.6)	65 (65.0)	69 (70.4)
Total	97	103	100	98
Had sexual intercourse in the last 7 days?*				
No	50 (69.4)	64 (77.1)	41 (63.1)	47 (69.1)
Yes	22 (30.6)	19 (22.8)	24 (36.9)	21 (30.9)
Total	72	83	65	68

*Excluding men without intercourse in the past year.

TABLE 2. Frequency of At least Possibly Related Adverse Events by Severity: Both Sites Combined*

AE	Circumcision Group					
	Shang Ring (N = 197)		Standard Surgery (N = 201)		Total (N = 398)	
Severity: Description	No. Men	% of Men	No. Men	% of Men	No. Men	% of Men
Moderate						
Wound dehiscence	6	3.0	4	2.0	10	2.5
Postprocedural pain	6	3.0	3	1.5	9	2.3
Wound infection	0	0.0	2	1.0	2	0.5
Anesthetic complication	1	0.5	0	0.0	1	0.3
Postprocedural hemorrhage	0	0.0	1	0.5	1	0.3
Postprocedural edema	1	0.5	0	0.0	1	0.3
Severe						
Postprocedural pain	1	0.5	0	0.0	1	0.3
Total	15	7.6	10	5.0	25	6.3

*Any event is only counted once for each man using the highest severity.

necessary to make a small cut in the foreskin in 18% of study participants in Kenya and 23% in Zambia to facilitate use of the Shang Ring device.

No self-removals or accidental displacements of the Shang Ring were noted. Mean Shang Ring removal time was 2.5 (SD = 1.2) minutes in Kenya and 3.7 (SD = 2.2) minutes in Zambia. All 6 clinicians preferred the Shang Ring technique and considered it "much easier" to perform than conventional surgery.

DISCUSSION

Our study is the first multicenter randomized controlled trial to compare an adult MC device with conventional

TABLE 3. Time to Complete Wound Healing* by Country and Circumcision Method, As Treated Population (Cumulative Kaplan-Meier Probabilities)

	Kenya			
	Shang Ring		Conventional Surgery	
Visit†	n‡	Probability % (95% CI)	n	Probability % (95% CI)
Day 14	94	0.0 (0.0)	98	2.0 (0.5 to 7.8)
Day 21	88	6.4 (2.9 to 13.7)	73	26.1 (18.6 to 35.9)
Day 28	56	40.4 (31.3 to 51.0)	21	77.1 (68.4 to 84.8)
Day 42	13	86.2 (78.4 to 92.2)	3	96.7 (91.6 to 99.1)
Day 60§	0	100.0	0	100.0
	Median 42.0 days		Median 29.0 days	
	$P < 0.001$			

	Zambia				Overall			
	Shang Ring		Conventional Surgery		Shang Ring		Conventional Surgery	
Visit†	n	Probability % (95% CI)	n	Probability % (95% CI)	n	Probability % (95% CI)	n	Probability % (95% CI)
Day 14	99	0.0 (0.0)	95	0.0 (0.0)	193	0.0 (0.0)	193	1.0 (0.3 to 4.0)
Day 21	99	0.0 (0.0)	95	0.0 (0.0)	187	3.1 (1.4 to 6.8)	168	13.4 (9.3 to 19.0)
Day 28	95	4.0 (1.5 to 10.4)	89	6.3 (2.9 to 13.5)	151	21.8 (16.6 to 28.3)	110	42.3 (35.7 to 49.6)
Day 42	32	66.8 (57.5 to 75.9)	25	73.7 (64.6 to 82.1)	45	76.8 (70.0 to 82.0)	28	85.3 (79.9 to 89.9)
Day 60§	0	100.0	0	100.0	0	100.0	0	100.0
	Median 43.0 days		Median 43.0 days		Median 43.0 days		Median 43.0 days	
	$P = 0.82$				Mean (SD): 44.1 days (12.6)		Mean (SD): 38.9 days (12.6)	
					Mean difference (95% CI) = 5.2 days (2.7 to 7.8); $P < 0.001$			

CI, confidence interval.
*Time to complete wound healing is from circumcision date to the date of the visit on the form where complete healing is first noted by the health care provider.
†Interval around nominal visit day, eg, the day 28 interval defined as visits between day 26 and day 35, inclusive. The day 60 interval includes all subjects still in analysis at day 51.
‡The number of participants still in the analysis on the day on which the cumulative estimate is calculated. Probabilities are per 100 men.
§Hundred percent probability at day 60 visit interval reflects censoring at study exit and healing.

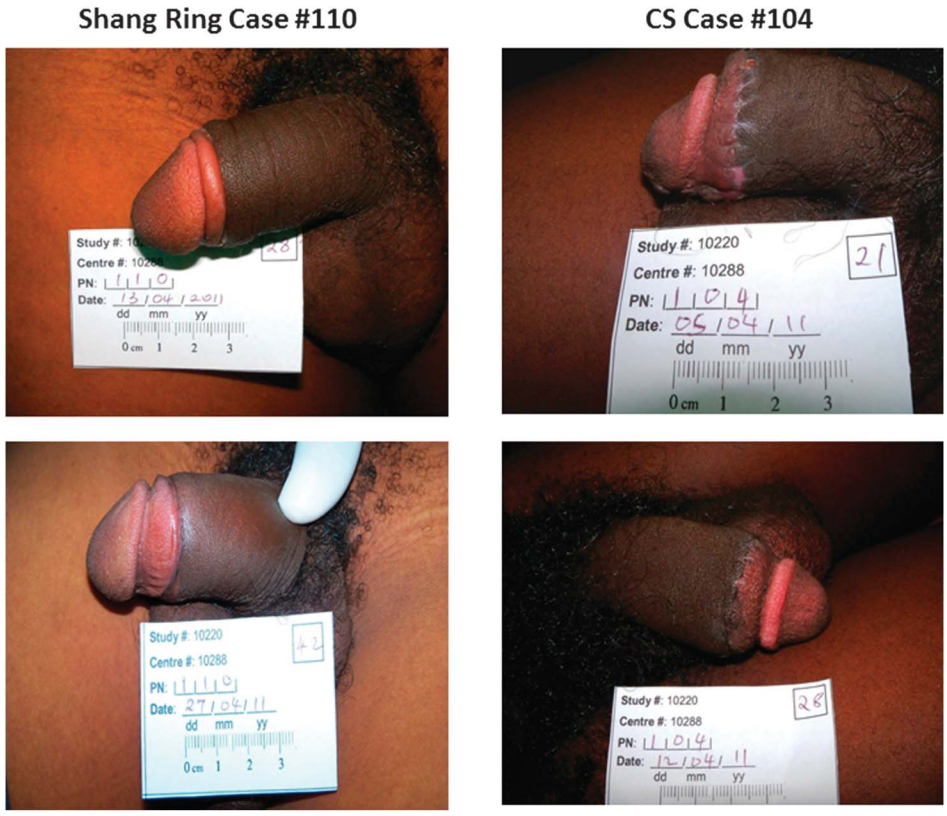

FIGURE 2. Photos showing different judgments of complete healing and typical differences in cosmetic results. The 2 left photos are a Shang Ring case, and the 2 right photos are a conventional surgery case. The Kenyan clinicians judged healing to be complete for the Shang Ring cases on day 28 versus day 42 for the Zambian clinicians (left photos). The Kenyan clinicians judged healing to be complete for the conventional circumcision cases on day 21 versus day 28 for the Zambian clinicians.

surgery in Africa. Our results show that the Shang Ring has the potential to contribute to rapid scale-up of MC programs in Africa. Shang Ring procedures took one-third the time of conventional MC and all circumcision providers preferred the Shang Ring over the conventional technique. The acceptability of the Shang Ring was extremely high. Only 3 men who met eligibility criteria for the study declined to participate. Additionally, significantly more men were satisfied with the cosmetic appearance of their penis after Shang Ring MC. AE rates were similar between groups, suggesting that the Shang Ring is as safe as currently used surgical techniques. No self-removals or accidental displacements of the Shang Ring were noted.

Pain scores at most time points after circumcision were similar. Although the Shang Ring group reported significantly higher scores for "worst pain during erections" during the first week after circumcision (ie, when the device was still in place), the mean pain scores in both arms were relatively low on the VAS and only 2 men out of nearly 200 requested early removal of the device due to pain. Complete wound healing was confirmed on average 5 days later than in the conventional surgery group.

A Chinese trial comparing 402 men with Shang Ring circumcision to 322 with a dorsal slit circumcision[9] had similar results to what we report here. The wound dehiscence rates were 1.7% versus 1.6% in the Shang Ring and conventional surgery groups, respectively, with significantly lower rates of wound infection (1% vs. 12%) and bleeding (1% vs. 12%) in the Shang Ring group, but that study did not ascertain AEs using the same scheme as our study. They also reported shorter ring placement times for the Shang Ring procedure compared with operating time for conventional circumcision, 5 versus 26 minutes, and greater satisfaction with cosmetic outcomes of the Shang Ring (99.5% vs. 69.6%), but longer healing time with the Shang Ring taking approximately 3 days longer to heal compared with conventional surgery. Significantly less pain was reported with the Shang Ring procedure during surgery and 24 hours after surgery.

In a Ugandan study, men were allowed to choose whether they wanted to be circumcised with the Shang Ring or the dorsal slit method.[21] Of the 621 men enrolled, 508 (81%) chose the Shang Ring, with the remaining 113 opting for the dorsal slit. The results of the Ugandan study are also similar to what we report here. 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. Five hundred men received the Shang Ring, and postoperative surgery–related moderate AEs were 1.0% compared with 0.8% among dorsal slit recipients.

In this study, the need to make a small cut in the foreskin in approximately 20% of participants to facilitate use of the Shang Ring in cases of phimosis was not surprising and is a routine practice, previously reported with the Shang Ring[10,11] and other adult devices.[22–24] Making the cut is not problematic and is painless because the penis is already anesthetized at this time.

Although median time to complete wound healing was the same in the 2 arms, the mean number of days to complete

wound healing was significantly longer in the Shang Ring group by approximately 5 days. This difference might be explained in part by the presence of a foreign body, ie, the ring, during wound healing. Or there may be a different mechanism of healing in this group. A longer complete wound-healing time compared with conventional methods also reinforces the importance of abstinence or barrier methods of contraception during recovery after Shang Ring circumcision.[1]

Comparing the risks and benefits of the Shang Ring versus conventional MC surgery, the occasional surgeon's technical error causing cutaneous pinches and the longer wound-healing time are main potential disadvantages of the Shang Ring. We were not able to find a description of cutaneous pinches in the Chinese literature on the Shang Ring. Our case in whom a cutaneous pinch may have contributed to wound dehiscence indicates the importance of good hands-on surgical training. It is not clear if prolonged healing time for Shang procedures is of clinical significance given that all men in the study were healed by the 60-day visit. It is relevant to the risk of infection, however. The recommended time for abstinence after MC is 6 weeks[13] although we know that in some cases men become sexually active before this time. Here, 18 and 55 men in the Shang Ring group and 19 and 51 men in the standard surgical group engaged in sexual activity by days 42 and 60 (data not shown).

The higher pain experienced during erections with the Shang Ring in place may also be a disadvantage, although men can always return for early removal. In the 2 cases of early removal in our study, we observed no problems and healing occurred normally; more data are needed to ensure that early removal is not problematic.

Conventional surgical MC techniques are more invasive, take about 3 times as long to perform, and provide less acceptable cosmetic results. Additionally, all of the circumcision providers preferred the Shang Ring over the conventional technique. Results from this study and from the comparative study in China[9] suggest that bleeding and wound infections may be less common after Shang Ring procedures. The Shang Ring did require a return visit for ring removal, with resultant increased time and transport costs. This requirement could be mitigated by a recent study, which suggested that the ring spontaneously detaches safely in the absence of removal.[11] In addition, a recent cost comparison found that the cost of a Shang Ring circumcision ($18.21) was similar to that of conventional MC ($17.67) as the lower costs of clinician time with the Shang Ring were offset by the higher costs of disposable supplies.[25]

The Shang Ring is but one device being studied for adult MC. A randomized trial of the Tara Klamp versus conventional surgery was conducted in South Africa, but was halted because of the occurrence of more AEs and poor acceptability in the Tara Klamp arm.[22] A randomized trial in Rwanda comparing the PrePex device and conventional surgery reported promising results.[26]

One limitation of our study was the difficulty in achieving uniform interpretation of clinical outcomes at 2 sites, especially evident in the different judgments of time to complete healing. At a poststudy meeting of investigators, we asked clinicians from each country to independently review serial wound photos, and the results suggested that the differences in wound healing were due to clinical judgment between the 2 sites, rather than a real difference in time to healing between the sites (data not shown).

Difficulties in standardizing AE definitions may limit the ability to compare our results with other studies. In the Ugandan study mentioned above, the reported rates of moderate AEs in both the Shang Ring and the dorsal slit group were lower (approximately 1%) than we reported here.[21] Our classification of AEs may have been unnecessarily or overly conservative. For example, the significance of moderate wound dehiscence among Shang Ring cases is unknown, seems to be unrelated to infection (unlike wound dehiscence in conventional MC), and resolves without treatment. Despite the potentially conservative nature of our AE classification, the randomized design protects the internal validity of our finding that the difference in the AE rates between the 2 study arms was not clinically meaningful.

In conclusion, because (1) the safety profiles of the 2 techniques are roughly comparable; (2) all of the MC providers preferred the Shang Ring over the conventional surgical techniques; and (3) the study participants preferred the cosmetic results from the Shang Ring, we believe that the Shang Ring is a very promising device for scaling up adult MC in sub-Saharan Africa.

The US Food and Drug Administration approved marketing of the Shang Ring in the United States on August 3, 2012. Data from this trial and from a larger subsequent field study were submitted to the WHO as part of their device prequalification process.[19] Future work will include extension of Shang Ring studies into the pediatric and adolescent population to examine safety and efficacy of the device in a younger population where MC would be potentially more cost effective. In addition, future studies will aim to simplify the Shang Ring technique with use of variants such as a no-flip technique that does not require eversion of the foreskin[16] and the replacement of injectable with topical anesthetics.

ACKNOWLEDGMENTS

The authors would like to thank their colleagues in Kenya and Zambia who assisted with the study and the participants who volunteered to take part in the study. In Kenya, the authors would like to thank Nicholas Muraguri, MBChB, National AIDS/STD Control Programme, Nairobi, Kenya; John Masasabi Wekesa, MBChB and Ojwang' Lusi, MBChB, Ministry of Medical Services, Kenya; Jackson Kioko, MBChB, Ministry of Public Health and Sanitation, Nairobi, Kenya; and Dr Ojwang Ayoma, Superintendent, Homa Bay District Hospital, for their support of the study. The authors also thank Jairus O. Okech, KRCHN and Alex O. Aduda, KRCHN, of Homa Bay District Hospital for providing clinical circumcision services. The authors also thank Daniel Ouma and Jared Nyanchoka, MBChB, for their assistance with study management in Homa Bay, and Lilian Were, FHI 360, for her assistance as study monitor at both sites. In Zambia, the authors would like to thank Christopher

Mubuyaeta, DIP CLN MED SC and Daniel Mashewani, DIP CLN MED SC, of the Society for Family Health for providing clinical circumcision services. The authors also thank Zude Zyambo and Dr Prisca Kasonde, FHI 360, for their assistance and support in Lusaka. The authors also offer their gratitude to Mr Jianzhong Shang, inventor of the Shang Ring, for his generous donation of the Shang Rings and associated supplies used in the study.

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