

Spontaneous Detachment of the Shang Ring following Adult Male Circumcision

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Background

The Shang Ring is a novel device for adult male circumcision that could facilitate circumcision scale-up in Sub-Saharan Africa. According to the label instructions, the device is left on the penis for seven days, then removed by a health provider.

To explore safety issues if men did not return for removal and to help determine whether a separate removal visit is needed, we explored the possibility of spontaneous detachment when removal is delayed beyond seven days.



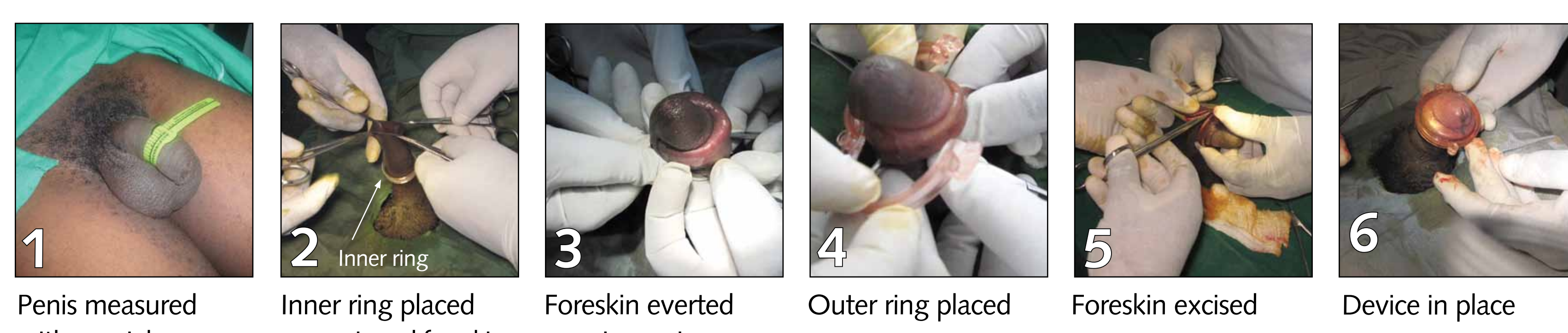
Study design

- Open-label, parallel group, randomized study
- Ethical approval: FHI and KEMRI
- Regulatory approval: Kenya Pharmacy & Poisons Board

50 men	Randomized	Follow-up
<ul style="list-style-type: none"> • 18–54 years of age • Uncircumcised • In good general health • HIV-negative • No symptomatic sexually transmitted infections (STIs) 	<ul style="list-style-type: none"> Day 7 ring removal (n=15) Day 14 ring removal (n=15) Day 21 ring removal (n=20) 	<ul style="list-style-type: none"> • 7 days • 14 days • 21 days • 28 days • 42 days • 2 days after ring removal

Data collection October 2010–January 2011

Shang Ring circumcision



Circumcision (n=50)	
Mean (± standard deviation) procedure time	6.5 ± 2.0 minutes
Cases where a small cut was needed in the foreskin because it was too tight to evert	9 (18.0%)
Cases with complications during surgery	0

Ring removal after 7, 14, or 21 days



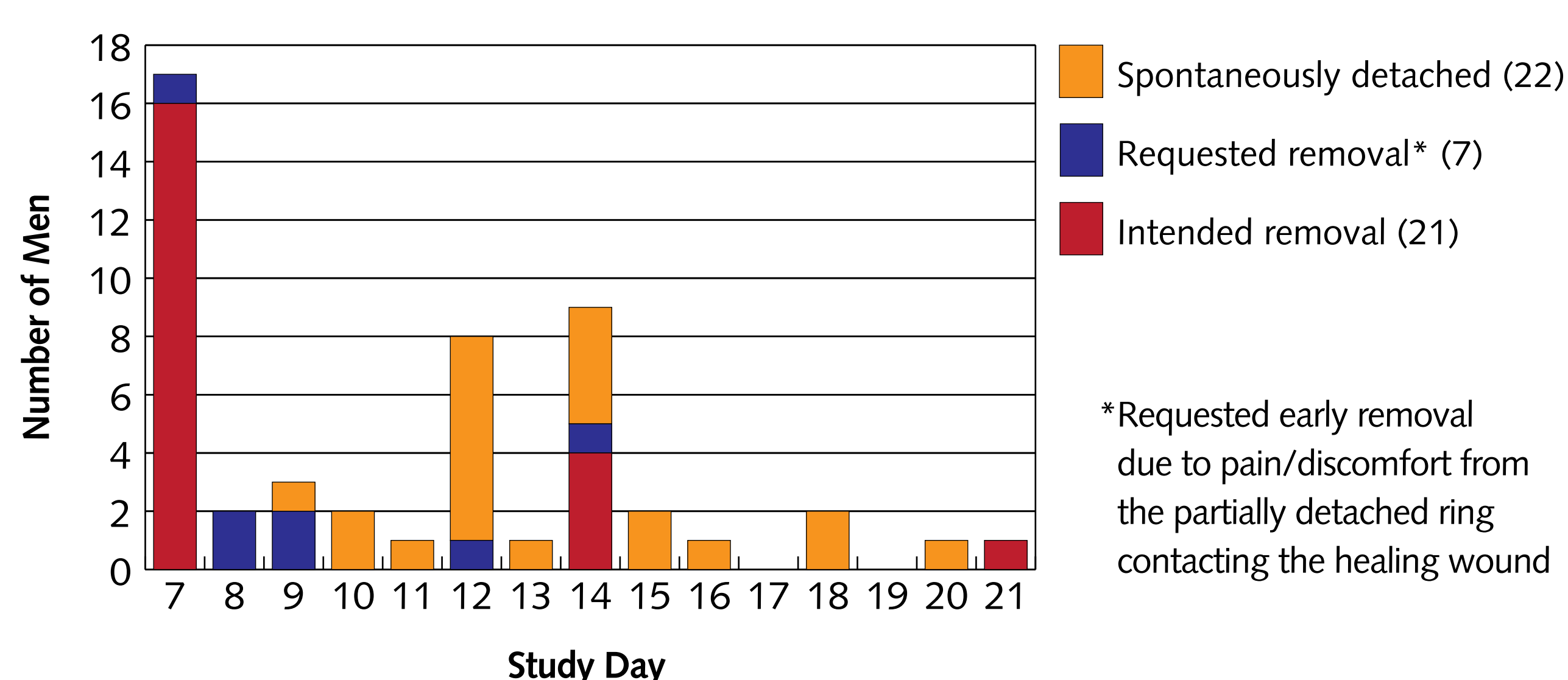
Removal (n=28)	
Mean time (± standard deviation) procedure time	2.5 ± 0.8 minutes
Difficulties with removal	0
Mean greatest pain during removal*	3.8 ± 2.3
Mean pain 10 minutes post removal*	1.0 ± 1.3

*Visual analog pain scale 0=no pain, 10=worst possible pain

Selected baseline finding

Median age in years (range)	21 (18–38)
Ethnic group—Luo	48 (96.0%)
Relationship with primary sex partner	
Not married, no live-in partner	26 (52.0%)
No primary sex partner	12 (24.0%)
Married	8 (16.0%)
Other	4 (8.0%)
Primary reason for circumcision	
Partial HIV protection	37 (74.0%)
Hygiene	7 (14.0%)
Other	6 (12.0%)
Had vaginal sex, in past year	38 (76.0%)

Timing of removals and detachments



*Requested early removal due to pain/discomfort from the partially detached ring contacting the healing wound

Spontaneous detachment

- Complete detachment occurred in 22 men—i.e., 67% of those wearing the ring more than seven days.
- Most (18/22) detachments occurred from 10 to 16 days after circumcision.
- Some participants returned with the ring completely off their penis (Fig. A). In others, the ring slid down the penile shaft and was removed by a provider (Fig. B); it might have been painful for the participant to slide the ring over the healing wound himself, or edema might have made it difficult.



15 days post-circumcision

Adverse events

Adverse event	Randomization group			Totals
	Day 7 Removal	Day 14 Removal	Day 21 Removal	
Severe	0	0	0	0
Moderate*				
Wound disruption	0	1	2	3
Pain	0	2	1**	3
Total adverse events	0	3	3	6

* All were managed conservatively (without oral antibiotics or additional surgery) and resolved in a timely fashion.

**Pain deemed a moderate adverse event occurred immediately postoperatively.

Participants' experiences & satisfaction

Greatest interference when wearing ring (n=50) Mean (SD) (Scale: 0=None, 10=Completely Interferes)	
Walking	1.0 (2.3)
Sleeping	2.0 (2.5)
Working	1.1 (2.5)
Maximum pain during erection while wearing ring (n=50) Mean (SD)	3.8 (2.0)
Satisfaction with appearance at 6 weeks (n=43)	
Very satisfied	38 (88.3%)
Somewhat satisfied	4 (9.3%)
Somewhat dissatisfied	1 (2.3%)
Would recommend circumcision to others (n=43)	43 (100%)
Things liked about Shang Ring (n=43)	
Procedure quick	39 (90.6%)
Happy with appearance	20 (46.5%)
Less pain than expected	16 (37.2%)
No stitches	13 (30.2%)
Things disliked about Shang Ring (n=43)	
Pain/discomfort during erection	11 (25.5%)

Conclusions

- These data confirm that the Shang Ring is safe, acceptable, and easy to use according to label instructions for removal at seven days.
- Spontaneous detachments occurred without significant problems when the ring was left in place beyond seven days.
- Our data suggest that allowing the Shang Ring to fall off on its own could be a suitable strategy in settings where a removal visit may be impractical; other adult devices require removal by a trained provider.
- The Shang Ring has the potential to facilitate the safe, effective and inexpensive delivery of adult male circumcision by trained non-physicians.



Cosmetic results six weeks after circumcision