SAFETY OF THE NO-FI P TECHNIQUE AND SPONTANEOUS CIRCUMCISION IN BOYS AND MEN: RESULTS FROM A RANDOMIZED CONTROLLED TRIAL

Awon O1, Lee R2, Ouma D1, Obura N1, Oundo M1, Mwamkita D1, Chirchir B3, Barasa M2, Kirui M3, Macharia P3,4

BACKGROUND

- Clinical data demonstrates the advantages of using clips for voluntary medical male circumcision (VMMC) in HIV prevention programs in Africa.
- A single-clip vs. two-clip incision device in simple to use, safe, and well accepted in males ages 15 and older. It has been World Health Organization (WHO) preferred for use in this age-group.
- A new clinical study from China suggests that the innovative ‘no-clip’ technique can simplify the ShangRing technique. With this technique, there also need to be inserted on the foreskin or to make small split on the edge of the foreskin, as is required with the original ShangRing technique. The ‘no-flip’ technique, the inner ring, is placed on the side of the foreskin and the outer ring is repositioned over the inner ring, sandwiching the foreskin between the rings.
- Another innovation that has the potential to simplify the ShangRing technique is the delivery of a ring, being able to fold on the ring (known as spontaneous detachment). This phenomenon may be significant for a removal visit. A pilot study in Kenya suggests that spontaneous detachment is safe and is acceptable to many men.

OBJECTIVES

- PRIMARY OBJECTIVES
  - Assess the safety of the no-flip ShangRing technique in males ages 15 and older
  - Evaluate satisfaction with the no-flip technique amongst study participants and providers.
  - Evaluate the acceptability of wearing the ShangRing beyond seven days following circumcision.

- SECONDARY OBJECTIVES
  - Assess the time to ring detachment and comfort from the partially detached ring 1–3 weeks after circumcision.
  - Determine the occurrence and safety of spontaneous detachment, stratified by age-group into two groups—for removal on Day 7 or for spontaneous detachment, based on age-group.

STUDY DESIGN

- Study population: Males aged 10 years and older
- Randomization: All participants were randomized to either the no-flip technique or the traditional ‘flip’ technique
- Follow-up: Participants were followed up at 7, 14, 21, 28, 35, and 42 days.
- Outcome measures: Degree of ring detachment, Incidence of adverse events, Duration of pain, Quality of wound healing

OUTCOMES: CIRCUMCISIONS AND REMOVALS

- All participants were successfully circumcised using the no-flip ShangRing technique.
- There were no significant differences in adverse events by randomization group.
- Six moderate adverse events were reported—four infections and two cases of edema.

ADVERSE EVENTS, * BY RANDOMIZATION GROUP

- Six moderate adverse events were reported—four infections and two cases of edema.
- No statistically significant differences in adverse events by randomization group.
- All cases of infection were reported by newly trained providers from one site and clustered during the earlier stages of the study.
- All adverse events resolved with conservative management and without sequela.

CONCLUSIONS

- The no-flip technique was safe, effective, and well accepted by participants, irrespective of age.
- The no-flip technique was performed by providers—mostly by those who had previous experience with the original ShangRing technique.
- More men were willing to wait longer for complete healing, and client preference between the seven-day removal and spontaneous detachment groups.
- There was also no significant difference in the time to ring detachment between younger and older participants.
- Three out of four participants in the spontaneous detachment group were able to remove the ring until it fell off on its own. This demonstrates a significant improvement in the safety of VMMC, as well as adherence.
- More important, there were increased risks of adverse events if users do not come back for removal.
- Participants who requested early removal were more likely to be older.

ACKNOWLEDGMENTS

This research was supported in part by a grant from the Bill & Melinda Gates Foundation to conduct research on the ShangRing, in collaboration with EngenderHealth, Well Cornell Medical College, and the Kenya Ministry of Health.

Questions or Comments? Please contact:
Open to all: April
In-person: EngenderHealth
Email: Qaveo@engenderhealth.org +254 722 913 614

EngenderHealth
Well Cornell Medical College, West Haven, CT
www.engenderhealth.org