Published in final edited form as:

J Acquir Immune Defic Syndr. 2013 October 1; 64(2): . doi:10.1097/QAI.0b013e3182a333ad.

Proper surgical training and grading of complications for Shang Ring Circumcision are necessary

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To the Editor

We read with some concern the recent article by Kanyago, et al., entitled “Shang Ring versus forceps-guided adult male circumcision: a randomized controlled effectiveness study in southwestern Uganda”.¹

Our Shang Ring study groups strongly believe in the need for high quality surgical training to decrease the number of postoperative complications, particularly with a new surgical device.² It appears that although the surgeon in the study had performed over 100 forceps-guided circumcisions, the paper does not report any hands-on surgical training with the Shang Ring. Moreover, it is unclear why all ring sizes were not available for the study.

The authors neither reference nor compare their experience with prior trials in Africa that demonstrated the safety of the Shang Ring. None of these trials observed the relatively high complication rates reported in this study.³⁻⁶ Also, the small study was underpowered to show differences in the primary endpoint.

We note that there was a 25% loss to follow-up in the group of patients undergoing forceps-guided circumcision, vs. 0% for the Shang Ring group, which raises the possibility of significant selection bias. The authors assumed that the 25% of patients lost to follow-up in the conventional circumcision group were “healed on the day of their next scheduled follow-up appointment,” e.g. a patient presenting for a day 3 visit but not for subsequent appointments was considered healed on study day 7, an unlikely scenario for conventional circumcision. The authors in addition assumed that no complications occurred in this group of patients, which is surprising given that their complication rate in the forceps-guided group was a relatively high 18% in the intention-to-treat analysis. This for example is in contrast to the 0.8% moderate/severe complication rate for dorsal slit circumcision vs. 1.8% for Shang Ring circumcision ($p=0.697$) as reported by Kigozi, et al.⁶

The 32% infection rate reported with Shang Ring circumcision in this study far exceeds the rates in all other Shang Ring studies and suggests 1) inappropriate surgical technique, 2) inaccurate diagnosis, or 3) lack of experience with Shang Ring wound healing.^{3,4,6} We are also puzzled by the 12.3% of men classified as “healed” at the 7 day visit for Shang ring

removal, and 34.3% healed by day 14. This is inconsistent with the detailed study by Barone, et al. which reported the earliest complete wound healing was 21 days.³ We also question the definition of “persistent wound” as a complication of the procedure. Indeed, it is unclear how 30% patients undergoing Shang Ring circumcision could be listed as having a persistent wound vs. 8% in the forceps-guided group, when the time to complete healing was similar in both groups ($p=0.08$).

Despite these concerns, it is gratifying to see that Shang Ring circumcision was nevertheless faster to perform and allowed patients to resume normal activity more quickly compared to the forceps-guided group while maintaining at least an equivalent major complication rate and greater patient satisfaction. This article highlights the need for proper surgical training and an understanding of the wound healing process so as to avoid misclassification of complications for a device that could potentially increase the efficiency of surgery essential to the scale up of adult circumcision services in Africa.

References

1. Kanyago S, Riding DM, Mutakooa E, Lopez de la OA, Siedner MJ. Shang Ring versus forceps-guided adult male circumcision: a randomized controlled effectiveness study in southwestern Uganda. *J Acquir Immune Defic Syndr*. Apr 17.2013
2. Bailey RC, Egesah O, Rosenberg S. Male circumcision for HIV prevention: a prospective study of complications in clinical and traditional settings in Bungoma, Kenya. *Bulletin of the World Health Organization*. Sep; 2008 86(9):669–677. [PubMed: 18797642]
3. Barone MA, Awori QD, Li PS, et al. Randomized trial of the Shang Ring for adult male circumcision with removal at one to three weeks: delayed removal leads to detachment. *J Acquir Immune Defic Syndr*. Jul 1; 2012 60(3):e82–89. [PubMed: 22343180]
4. Barone MA, Ndede F, Li PS, et al. The Shang Ring device for adult male circumcision: a proof of concept study in Kenya. *J Acquir Immune Defic Syndr*. May 1; 2011 57(1):e7–12. [PubMed: 21346586]
5. Bratt JH, Zyambo Z. Comparing direct costs of facility-based Shang Ring provision versus a standard surgical technique for voluntary medical male circumcision in Zambia. *J Acquir Immune Defic Syndr*. Mar 11.2013
6. Kigozi G, Musoke R, Watya S, et al. The Acceptability and Safety of the Shang Ring for Adult Male Circumcision in Rakai, Uganda. *J Acquir Immune Defic Syndr*. Apr 22.2013