ABSTRACT

Objective: To assess safety, preliminary efficacy, and acceptability of the Shang Ring, a novel disposable device for adult male circumcision in Kenya. Methods: Forty HIV-negative men were recruited in Homa Bay, Kenya. Circumcisions were performed by a trained physician or nurse working with 1 assistant. Follow-up was conducted at 2, 7, 9, 14, 21, 28, 35, and 42 days after circumcision. Rings were removed on day 7. Pain was assessed using a visual analog scale (VAS) (0 = no pain, 10 = worst possible). Men were interviewed at enrollment and on days 7 and 42. Results: All 40 procedures were completed successfully. Mean procedure and device removal times were 4.8 (SD \pm 2.0) and 3.9 (SD \pm 2.6) minutes, respectively. There were 6 mild adverse events, including 3 penile skin injuries, 2 cases of edema, and 1 infection; all resolved with conservative management. In addition, there were 3 partial ring detachments between days 2-7. None required treatment or early ring removal. Erections with the ring were well tolerated, with a mean pain score of 3.5 (SD ± 2.3). By day 2, 80% of men were back to work. At 42 days, all participants were very satisfied with their circumcision and would recommend the procedure to others. Conclusions: Our results demonstrate that the Shang Ring is safe for further study in Africa. Acceptability of the Shang Ring among participants was excellent. With short procedure times, less surgical skill required, and the ease with which it can be used by nonphysicians, the Shang Ring could facilitate rapid roll-out of male circumcision in sub-Saharan Africa.