Rapid, minimally invasive adult voluntary male circumcision with the Unicirc, a novel disposable device

To the Editor: I congratulate Millard *et al.*[1] on their publication. My co-workers and I have studied the PrePex male circumcision device in three clinical trials,[2-4] and I would like to share our opinions.

The Unicirc is intended to be used exclusively with glue. We therefore consider that any suturing that is necessary with the device should be defined as an adverse event and should have been documented as such, as in the authors' previous reported study.[5]

We have some concerns about the safety of using cyanoacrylate glue in adult circumcisions. According to recommendations, adhesives such as DermaBond (2-octyl cyanoacrylate)[6] are contraindicated for skin that may be regularly exposed to body fluids, as the foreskin is, and should also not be used in high skin tension areas (knuckles, elbows and knees) unless they are immobilised; erections cannot be immobilised, so the use of this type of glue on the penis poses risks.

Millard *et al.*'s[1] report of healing time lacks a definition of complete healing. Moreover, in their previous report[5] they stated that 'there was no independent, objective measure of wound healing outcomes'.

Their conclusion that 'The cost of expendable materials was similar using the two techniques' is puzzling, as in the same article[5] they report the following costs of expendables for the two arms: surgical = $15; Unicirc + glue = $4 + $5 + $20 = $29.

Regarding the reported procedure time, we could not work out whether the waiting time for the local anaesthetic to numb the foreskin was included.

Millard *et al.*[1] report that removal of the PrePex is unpleasant. What scientific research was performed to back up this statement? We have data on acceptability from questionnaires and have reported satisfaction rates as high as 92 - 100% with regard to men's experience during the removal procedure.[4]

In respect of the report of odour, we have recently determined that any odour is directly related to the patient's personal foreskin hygiene and not to the device or the necrotic foreskin (article under review).

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2. Bitega JP, Ngeruka ML, Hategekimana T, et al. Safety and efficacy of the PrePex device for rapid scale up of male circumcision for HIV prevention in resource-limited settings. J Acquir Immune Defic Syndr 2011;58(5):e127-e134. [http://dx.doi.org/10.1097/QAI.0b013e3182354e65]
3. Mutabazi V, Kaplan SA, Rwamasirabo E, et al. HIV prevention: Male circumcision comparison between a nonsurgical device and a surgical technique in resource-limited settings: A prospective, randomized, no masked trial. J Acquir Immune Defic Syndr 2012;61(1):49-55. [http://dx.doi.org/10.1097/QAI.0b013e3182631d69]
4. Mutabazi V, Kaplan SA, Rwamasirabo E, et al. One arm, open label, prospective, cohort field study to assess the safety and efficacy of the PrePex device for scale up of non-surgical circumcision when performed by nurses in resource limited settings for HIV prevention. J Acquir Immune Defic Syndr 2013;63(3):315-322. [http://dx.doi.org/10.1097/QAI.0b013e31828e6412]
5. Millard PS, Wilson HR, Veldkamp PJ, Sitoe N. Rapid, minimally invasive adult voluntary male circumcision: A randomised trial. S Afr Med J 2013;103(10):736-742. [http://dx.doi.org/10.7196/SAMJ.6856]
6. Dermabond. Topical skin adhesive. http://www.accessdata.fda.gov/cdrh_docs/pdf/P960052c.pdf (accessed 24 March 2014).

Dr Millard responds: We appreciate Dr Mutabazi's thoughtful comments and agree that the need for intra-operative suturing in 17% of the volunteers undergoing the Unicirc procedure was an adverse event. We subsequently added extensions to the thumb screws to increase the compressive force of the device, and our post-study case series of 50 volunteers (Table 6 of our paper) required no intra-operative suturing. There is a video of the revised instrument in operation (http://www.youtube.com/user/unicircglobal).

We cannot take credit for the game-changing use of cyanoacrylate tissue adhesive in circumcision. Numerous previous studies have shown that it is safe and effective in boys[1] and men.[2] Other researchers have not found adhesive failure to be a problem, and we had two partial wound separations (>2 cm in length, none requiring treatment) in 100 Unicirc procedures in our study,[3] and none in 50 procedures in our post-study case series. We did have a higher level of adhesive failure in our earlier Gomco adhesive study in Mozambique,[4] which we attributed to men finding it difficult to keep themselves dry during the rainy season; clearly further research is needed on this important issue in less developed settings.

Our two studies were modelled on the World Health Organization's *Framework for Clinical Evaluation of Devices for Adult Male Circumcision*.[5] Rather than repeat study definitions in the Unicirc paper, we referred to Table 1 of our previous paper, which defined a healed wound as 'completely epithelialised; no superficial ulcerations or granulation tissue present'. We defined the duration of the procedure as 'time from first clamp on foreskin until dressing placed'.[4]

With regard to cost of expendable materials, a disposable pack for surgical circumcision (including sutures) costs $15; the much simpler pack for the Unicirc costs $5, and adhesive costs $4 in South Africa.

Comparison of the total cost therefore depends on the market price of the Unicirc instrument, which has not yet been determined. Reduced personnel costs because of the speed of the procedure and the fact that no subsequent intervention is needed for device removal will result in large cost-savings with the Unicirc method.

We appreciate Dr Mutabazi's groundbreaking research on the PrePex device. Delayed healing by secondary intention is a critical drawback common to all necrotising plastic ring devices like the Prepex, and we have a profound obligation to the millions of men who are receiving this lifesaving intervention to quantify the pros and cons of each technique. We therefore invite Dr Mutabazi to join us in conducting a comparative study of Prepex v. Unicirc circumcision.

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5. World Health Organization. Framework for Clinical Evaluation of Devices for Adult Male Circumcision. Geneva: WHO, 2011.

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