

## ISSUES IN MEDICINE

### Circumcision – what's wrong with plastic rings?

Peter S Millard

A key issue facing countries that are scaling up circumcision services is the technical difficulty, resources used, complications, and time to healing using open surgical techniques, the only methods approved by the major external funding agency, PEPFAR. The WHO has developed a framework for evaluating new circumcision devices, and two promising disposable plastic devices that have been partially evaluated are the Shang Ring and the Prepex system. However, given South Africa's disastrous experience with the Tara KLamp, healthy scepticism about plastic ring devices is justified.

The Gomco clamp has been used in children and adults since 1935 in the USA, but there are no published studies demonstrating

its use in adults. Cyanoacrylate tissue adhesive, widely used in all areas of medicine, has been shown to be superior to sutures in circumcision in terms of safety, ease of use, operative time, and cosmetic results. Our experience in Mozambique suggests that Gomco clamp circumcision plus tissue adhesive closure meets all the WHO criteria for the ideal circumcision technique, and we strongly recommend that African researchers conduct clinical trials to compare it with open surgical circumcision.

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#### The problem

Many observational studies and three large randomised controlled trials conducted in Kenya, Uganda and Orange Farm, South Africa, show that male circumcision reduces HIV transmission from female to male by 60%.<sup>1</sup> Many sub-Saharan countries are scaling up male circumcision programmes. The World Health Organization (WHO) goal is to circumcise 20 million men in 14 sub-Saharan countries by 2015. So far, about 600 000 men have been circumcised; in South

Africa, where the goal is to circumcise 4.3 million 15 - 49-year-old males, about 145 000 circumcisions have been performed.<sup>2</sup>

A key issue facing countries that are scaling up circumcision services is the technical difficulty, resources used, complications, and time to healing using open surgical techniques. The WHO's *Manual for Male Circumcision under Local Anaesthesia*<sup>3</sup> describes three open surgical techniques (forceps-assisted, dorsal slit and sleeve techniques), which all involve exposure of subcutaneous tissues and suturing for haemostasis and skin closure. Open surgical techniques require surgical expertise and at least 20 minutes of operative time, and have a high rate of minor complications (principally haematoma, bleeding, infection and delayed healing),<sup>4</sup> which are reduced with surgical experience.<sup>5</sup> In spite of little research comparing techniques, open surgical techniques for circumcision are the only techniques the US Government's PEPFAR programme, a major funder of the effort, currently allows.

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Given the drawbacks of open surgical techniques, the WHO developed the *Framework for Clinical Evaluation of Devices for Adult Male Circumcision*.<sup>6</sup> This states: 'WHO and other health authorities wish to identify one or more devices that (a) would make the adult male circumcision procedure safer, easier, and quicker; (b) would have more rapid healing than current methods and/or might entail less risk of HIV transmission in the immediate post-operative period; (c) could be performed safely by health-care providers with a minimal level of training (mid-level providers); and (d) would be cost-effective compared with standard surgical methods for male circumcision scale up'.<sup>6</sup>

### Plastic ring devices: the solution?

There is much enthusiasm for plastic circumcision rings that are simple to apply and are removed at the health centre after 1 week. Using the same principle as the Plastibell used in circumcising neonates, the devices sandwich the mucosal and skin layers of the foreskin between concentric inner and outer rings, allowing for sutureless circumcision. After these devices have been applied, the distal foreskin can be excised or allowed to necrose.

Entrepreneurs and engineers have developed many ring devices, some which feature on YouTube (search for 'circumcision device'). The current best candidates are the Shang Ring and Prepex device.<sup>2</sup> The latter has been tested in only 55 subjects, but it can be applied and removed without local anaesthesia and has potential for use in non-sterile, resource-limited settings.<sup>7</sup>

### Caution needed

Depending on the clinical setting, different circumcision techniques may play important roles in scaling up circumcision. However, pitfalls are illustrated by the Orange Farm trial,<sup>8</sup> which compared the Tara KLamp and the forceps-guided method. Small prior studies suggested that the Tara KLamp was safe, but the complication rate of 37% led to premature discontinuation of the study. The Plastibell device can also occasionally cause severe complications.<sup>9</sup> There is no biological rationale for thinking that other plastic rings will be problem-free.

The Shang Ring,<sup>10-13</sup> the most studied device, is easy and quick to apply under local anaesthesia, but the penile circumference must be precisely measured and correct sizing is important. Multiple sizes of disposable clamps present supply chain issues, and it may be tempting to perform the procedure even if the correct-sized clamp is not available. Application is simple but there is a learning curve, and releasing incisions must be made on the underside of the foreskin, distal to the clamp. The device must be removed 1 week later using dedicated removal tools. The wound heals by secondary intention, which means a prolonged period of granulation healing after removal of the ring, during which the man may be more likely to contract and transmit sexually transmitted infections, including HIV.

Several questions remain about plastic rings. Although published studies do not indicate an increased risk of infection, it is likely that, as with the Plastibell, the foreign body reaction increases the risk of swelling and wound infection.<sup>14</sup> Like the forceps-guided technique, the Shang Ring leaves a significant remnant of the mucosal layer of the foreskin, which may make it less effective in HIV prevention.<sup>15</sup>

For these reasons, the Shang and other plastic rings will probably never meet the WHO's criteria for an ideal device.

### Could the solution be right under our nose?

The Gomco clamp has been used widely for circumcising newborns in the USA since 1935. The 2011 WHO *Manual for Early Infant Male*

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Fig. 1. An advertisement of the Gomco clamp from the *Journal of the Canadian Medical Association* in 1970.

*Circumcision Under Local Anaesthesia*<sup>16</sup> highlights it as a method of choice: 'When used as directed with matching non-defective parts the Gomco clamp has an impeccable safety record, as the stainless steel bell protects the glans from the risk of amputation. In the USA, where it is estimated that well over 1 million neonates are circumcised each year, the Gomco clamp is the leading instrument used to perform non-ritual male circumcision'.<sup>16</sup>

Although it has been marketed and used in all age groups for many years (Fig. 1), it is unknown to what extent the Gomco clamp is used outside the newborn period. A search for research studies prior to 1970 found none. Like many surgical instruments, the Gomco clamp was apparently not subjected to rigorous study before it was marketed. However, a Google search for 'adult Gomco' reveals many companies that sell the Gomco in all sizes from 1.1 to 3.5 cm and we have purchased adult-sized Gomco clamps from Allied Medical in the USA and from several manufacturers in Pakistan.

The lack of information on use of the Gomco clamp beyond the neonatal period is puzzling. e.g. the *Manual of Male Circumcision under Local Anaesthesia*<sup>3</sup> in one line alludes to the availability of Gomco clamps in sizes for children and adults, but otherwise does not mention the technique. The Gomco clamp is FDA-approved for all age groups in the USA, but because the PEPFAR programme bases its recommendations on the *Manual*, it is not a method approved for adult circumcision by the PEPFAR programme in Africa.

Preputial anatomy does not change with age, and our experience in Mozambique shows that the Gomco clamp works as well in older age groups as it does in the neonatal period.<sup>17</sup> Why are there so few data on its use beyond the neonatal period? We speculate that most circumcisions beyond the neonatal period are done by surgeons who never needed a simplified method of circumcision. They trained with

open surgical techniques, and surgical training programmes continue to teach them because they are training surgeons, and not general doctors who are looking for a simpler technique.<sup>18</sup>

Until recently, a principal drawback of circumcisions using the Gomco clamp beyond the neonatal period was that the apposed wound edges needed to be sutured, because (unlike in the newborn period) the edges separate and bleed after the patient begins to move around and stress the wound. Tissue adhesives have changed this entirely.

Tissue adhesives (cyanoacrylates) are extensively used in medicine, but it was only after 2002 that studies showed their superiority to suture closure in circumcisions.<sup>18-21</sup> A systematic review of randomised controlled circumcision trials showed that, compared with sutures, tissue adhesive reduces operative time, improves cosmetic result, and increases patient satisfaction.<sup>19</sup> Adverse effects reported from tissue adhesive are minor and include wound separation, wound inflammation, and inadvertent incorporation of surrounding structures such as scrotal skin and hair into the wound.<sup>19</sup> The incision rarely bleeds, there is little postoperative swelling, and the adhesive is strong enough so the excision line does not separate during erections.<sup>18,20</sup> In most studies, the surgeons excised the foreskin using laser or diathermy, but several small studies used the combination of Gomco clamp and tissue adhesive in children and adults.<sup>18,21,22</sup>

The simple combination of Gomco clamp circumcision coupled with tissue adhesive results in a procedure that is bloodless and sutureless, simple to learn, rapid and applicable to all age groups, and heals quickly with excellent cosmetic results. It therefore meets all the WHO criteria for the ideal circumcision device.

Ironically, a device that has been extensively used in newborns for over 75 years is little known in older age groups. We urgently need randomised controlled trials in Africa that compare open surgical circumcisions with plastic rings, and with Gomco circumcisions using tissue adhesive.

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