Adult Male Circumcision Tool for Use in Traditional Ceremonies

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Public health officials are currently supporting adult male circumcision to minimize the transmission of HIV during intercourse. Estimates indicate that more than 3 million lives could be saved in sub-Saharan Africa alone if the procedure were widely adopted. Complications including infection and accidental cutting/amputation of the glans during traditional circumcision ceremonies can lead to permanent injury or death. A low cost, adjustable (one-size-fits-most), culturally appropriate adult male circumcision tool was designed for use in traditional circumcision ceremonies to increase the likelihood of safe outcomes.
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1 Introduction

Acquired immunodeficiency syndrome (AIDS) is a devastating global epidemic responsible for more than 25 million deaths since 1981. In 2007, an estimated 33 million people were living with human immunodeficiency virus (HIV); 2.7 million additional people become infected each year [1]. Sub-Saharan Africa continues to be the region most heavily affected by HIV, accounting for 67% of HIV cases and 72% of AIDS deaths in 2007 [1].

Among a number of behavioral, medical, and sociopolitical interventions that have been attempted, "adult male circumcision is the first and thus far only proven efficacious biomedical intervention for the prevention of sexually transmitted HIV infection in adults" [2]. Circumcision reduces the risk of contracting and spreading HIV by as much as 60% [3–6]. Because the inner layer of the foreskin is thin and highly permeable to bodily fluids, it may harbor fluids for extended periods and thereby allow relatively easy entry for HIV into the bloodstream through the mucosa [7–9]. Removal of the foreskin greatly reduces the number of target cells available for the uptake of HIV [10,11]. In addition, circumcision has been shown to lower the incidence of other sexually transmitted infections [12] and promote women's health by decreasing the risk for human papillomavirus (HPV) infection and cervical cancer [13]. Traditional procedures in rural Africa have received substantial attention lately because of injuries and deaths resulting from complications such as infection and accidental cutting/amputation of the glans [7]. Furthermore, there is a significant relationship between HIV prevalence and circumcision rates [9]. In West Africa, where circumcision is common, HIV rates are less than 5%, while in southern Africa, where circumcision is much less common, HIV rates range from 10% to 40% of the population [14]. It is estimated that 3 million lives could potentially be saved in sub-Saharan Africa alone if safe mass circumcision becomes a common practice [3].

Boys of ages 16–26, depending on their respective cultural practices, are often expected to participate in a circumcision ceremony as a rite of passage to manhood [15]. According to the elders of the Xhosa people, for example, the physical punishment associated with traditional circumcisions is an essential part of the transition to manhood [16]. Therefore, boys must either partake in the traditional ceremony and risk medical complications or refrain and risk cultural embarrassment and subsequent increased likelihood of contracting an infection such as HIV.

Traditional circumcision cultural practices and ceremonies vary greatly from region to region in sub-Saharan Africa. However, the means of performing the circumcision cut is relatively consistent among communities. In each ceremony, the young man is positioned so that a traditional cutter can perform the procedure quickly. During the procedure, the traditional cutter first pulls the foreskin into tension distal from the head of the penis and then removes the foreskin beyond the tip of the penis using a traditional knife or razorblade [16]. Generally, few precautions are taken during the healing of the skin, resulting in high complication rates that are currently twice as high for traditional procedures as clinical procedures in sub-Saharan Africa [7]. These relatively high complication rates stem from inadequate sterilization procedures, old or inadequate instruments and supplies, and improper training of the traditional cutter. Adverse events include bleeding, infection, excessive pain, lacerations, torsion, gangrene, and erectile dysfunction [7].

There is a need to develop a low cost, adjustable (one-size-fits-most), and culturally acceptable tool to reduce the risk of hemorrhage, damage to the glans, and infection during traditional circumcision procedures. Existing circumcision devices such as the Mogen clamp, Gomco clamp, and various plastic bell devices (Table 1) do not readily integrate into a traditional ceremony because of their associated complexity (in terms of operation time and number of procedural steps) and relatively high cost. The Mogen clamp is a reusable (sterilized using an autoclave) stainless steel device that assists clinicians by compressing the foreskin to reduce bleeding and by providing a guide to facilitate the cut. The greatest shortcoming of the Mogen clamp is the uncertain protection of the glans since the top of the penis is not visible during placement of the device. The Gomco clamp, one of the oldest and most refined circumcision devices, applies compression to the foreskin, effectively minimizing blood loss during the procedure. However, it does not readily accommodate penises of various sizes; at least three different bells are used. The plastic bell device (e.g., Plastibell or TaraKLamp) is a one-time use, disposable device originally designed for infant/pediatric circumcisions. It is worn for up to 7–10 days, falling off once the foreskin necrotizes at the compression line. The use of a plastic bell device for adults is limited because of the possibility of erections, forcing the device off of the penis prior to healing. To the best of the authors' knowledge, while more than a dozen different devices have been used to facilitate clinical circumcision, there has been no development focused on a culturally appropriate technology to interface with traditional rites of passage.

2 Methods

A formal design process that included the establishment of end-user requirements, translation of these requirements into corre-

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Table 1 Comparison of current devices

Category	Mogen clamp	Gomco clamp	Plastic bell
Time for foreskin removal	~12 min	5–15 min	7–10 days
Procedural steps	12	14	10
% of glans covered	0%	~60%	~75%
Material	Steel	Steel	Plastic
Market price (US $)	$40–$550	~$250	~$25

sponding engineering specifications, concept generation/selection, and subsequent engineering analysis, was used to develop the prototype presented in this paper.

2.1 End-User Requirements. Interviews with clinicians were conducted in combination with an in-depth literature review in order to generate user requirements of traditional cutters and uncircumcised adult males. The information obtained from these interviews was in agreement with the published collaborative work of the Gates Foundation, WHO, and UNAIDS [3]. These requirements include: ceremonial acceptance; ease of use; short procedure time; glans protection; reduction/elimination of infection; ability to fit different sized glans; handheld form factor; promotion of straight, consistent, complete cutting; incorporation of an auto-disable feature promoting one-time use; reduction/elimination of bleeding; and low cost. The two identified end-user groups did not necessarily share the same requirements. Requirements important to the cutter are based on the traditions of his people and his ability to perform the procedure; they include ceremonial acceptance, ease of use, and a short procedure time. The circumcisee is more concerned with his personal well being; therefore, protecting the glans and reducing/eliminating bleeding and infection are most important to him.

2.2 Engineering Specifications. Based on the end-user requirements, a list of engineering specifications was developed by first creating a quality function deployment (QFD) diagram. Some of these specifications (Table 2) affected more requirements than others and therefore were given a higher relative weight. Procedure time ranked as the most important engineering specification for several reasons: 1) it is directly related to duration of pain, and 2) it limits the number of circumcisions that can be performed at a given ceremony. Minimizing this specification, as well as the number of procedural steps (the second most important specification), will promote ease of use and reduce incidence of error. To obtain target values for the specifications, current devices on the market were evaluated and preliminary calculations were performed. The procedure time target was set at 120 s based on the current traditional procedure that lasts between 30 s and 120 s. The target for the number of procedural steps was set based on the minimum number of steps for devices currently on the market. Fewer steps equate to a shorter procedure, easier use, less risk of misuse, and less training required, all of which benefit both the cutter and circumcisee. The target dimensions were set as $50.8 \times 50.8 \times 152.4\ \text{mm}^3$ to ensure that the tool could be held and manipulated easily by an adult male hand. Reducing the number of tool parts is also crucial to making the tool simple and easy to use. Our target of three or fewer parts is better than the TaraKLamp by one part if one considers the multiple components of the TaraKLamp individually. These numbers provided rough benchmarking estimates for use in designing a tool that improves upon those currently available.

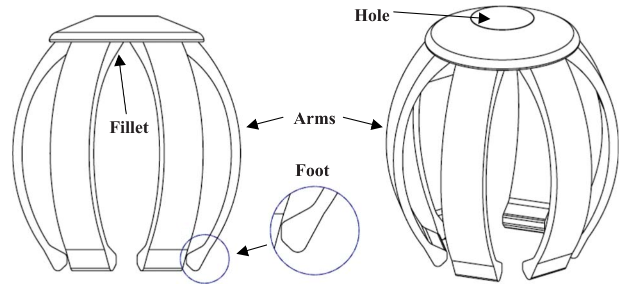

Fig. 1 Circumcision tool design

2.3 Concept Generation/Selection. Following the determination of the end-user requirements and engineering specifications, the critical functions of the tool were evaluated. Five functions were identified, including: adjustability, coverage of the glans, securing of the foreskin, cutting action, and closing of the wound. For each of these functions, an in-depth brainstorming session was carried out to establish different forms in which each of these functions could be realized. These forms were then evaluated and selected based on feasibility and technology-readiness criteria. The best form for each function was determined using Pugh charts. To produce complete tool concepts, the highest ranking and most compatible forms were chosen for each of the five functions and integrated. From these complete concepts, a system Pugh chart was used to select the best design.

3 Results

3.1 Design. The key features of the circumcision tool design (shown in Fig. 1) include: a hole on the top of the tool, arms, arm fillets, and a foot at the end of each arm. The arms essentially create a cage around the penis, protecting it from being cut or damaged if the cutter makes a mistake.

The hole at the top of the tool is present for occasions when the uncircumcised male needs to urinate while he is wearing the tool. At the base of the hole, a small fillet was added to aid in fluid flow

Table 2 Engineering specifications and targets

Rank	Relative weight (%)	Specification	Target
1	14	Time for foreskin removal	120 s
2	13	Number of surgical procedural steps	10
3	12	Physical dimensions	$50.8 \times 50.8 \times 152.4\ \text{mm}^3$
4	10	Number of parts	3
5	7	Diameter of tool (adjustable)	15.2–40.6 mm
6	7	Percentage of glans covered	50%
7	7	Number of hands required	2
8	7	Material hardness (Vickers hardness, HV)	3.4 HV
9	6	Force to remove (N)	25 N
10	6	Force to apply (N)	25 N
11	5	Manufacturing price	$1/unit
12	3	Mass	113 g

Fig. 2 Prototype

out of the tool without hindering the structure's strength ($<1\%$ change).

Compliant arms were selected to accommodate different glans sizes and to protect the penis during the procedure. To acquire this flexibility and still provide adequate coverage of the penis, the number of arms, arm shape, and material were considered. The arms essentially act as snap-fit cantilever beams that fit over the head of the penis to provide protection. The important dimensions when designing the shape of the arms include the width, thickness, length, and radius of curvature. The width provides the proper percentage of glans coverage. The thickness of each arm determines its flexibility. The length also determines flexibility and affects how much foreskin is removed based on how far the cutting edge rests from the tip of the penis. The radius of curvature provides ergonomic comfort and a means for securing the tool to the penis. Based on the selected dimensions, six arms were included in the design to provide 65% coverage of the glans.

Fillets were added where the top of each arm meets the tool body. Through finite element analysis (FEA), it was determined that this connection was the location of maximum stress. This fillet was used to redistribute the stress down the arm and over a larger area, lowering the applied force needed and increasing the maximum possible deflection.

The foot at the end of each arm helps guide the arm outward while applying the tool and secures the tool to the circumcisee's penis throughout the procedure. Without this feature, the arms would have a tendency to buckle inward as opposed to expanding outward, preventing the tool from adjusting to larger glans sizes. While on the penis, the feet secure themselves below the corona (base of the glans).

Rapid prototyping was used to fabricate physical models. Figure 2 shows the form fabricated for initial validation/assessment using stereolithography (3D printing).

3.2 Material Selection. Compliant mechanisms, such as the tool being proposed, require a flexible and strong material due to the absence of hinges or joints. Low-density polyethylene (LDPE) was chosen primarily because of its low Young's modulus and relatively high yield stress. A low modulus (0.2–0.4 GPa) means that the material is more elastic than rigid, a key characteristic of compliant mechanisms. A high yield stress (10–14 MPa) means that the material can withstand a large force without permanently deforming. Since it is a thermoplastic, LDPE can also be injection molded for mass production, an ideal method for potential manufacture of the tool.

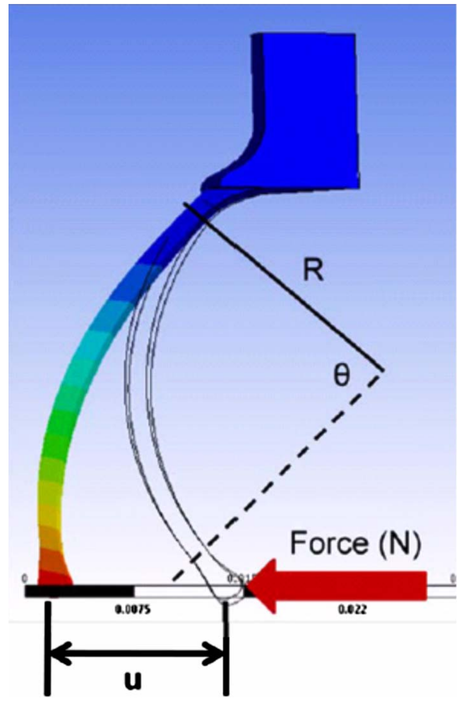

Fig. 3 FEA beam deflection path

3.3 Engineering Analysis. To estimate analytically the amount of deflection for each arm and to optimize the arm dimensions, a refined beam deflection equation was derived:

$$u = \frac{FR^3}{EI} \times \left(\frac{3}{2}\theta - 2\sin(\theta) + \frac{1}{2}\cos(\theta)\sin(\theta)\right) \quad (1)$$

where F (N) is the force applied to the end of the arm, R (m) is the radius of curvature, E (GPa) is the Young's modulus of the material, I is the moment of inertia that takes into account the thickness and width of the arm, and θ (rad) is the angle that defines the arc of the arm. This equation allows an estimation of maximum arm deflection as a function of these parameters, enabling optimization of arm dimensions.

Since the beam equation given above offers a conservative estimate of the tool's possible deflection, FEA (ANSYS WORKBENCH) was employed to obtain more realistic values. The initial analysis consisted of modeling a single arm, using typical values of the Young's modulus (200 MPa) and yield stress (12 MPa) of LDPE. The results demonstrated that the target adjustable range of the tool diameter was achievable by deflection given the arm dimensions and material choice. High stresses, however, were observed at the intersection between the arm and the top of the tool. Therefore, a fillet with the maximum radius possible (while maintaining an adequate urination hole), was added between each arm and the top of the tool to redistribute the maximum stress. FEA was performed to compare the magnitude of maximum equivalent von Mises stresses between the filleted and nonfilleted models in response to a displacement at the end of the arm of approximately 0.5 in. (1.27 cm) (Fig. 3). The maximum von Mises stress for the nonfilleted model was 5.85 MPa versus 5.33 MPa for the filleted model. The fillet improved the factor of safety to yield by 10%.

Theoretical force-displacement values were compared with experimentally derived values for a rapid prototype model created using Accura 25 (Fig. 4). Experimental values were determined using a customized testing apparatus comprising a fixture, set of precision weights, pulley to guide the arm deflection, and wire to connect the weights to an arm. Based on anthropometric data describing 5th to 95th percentile adult male penis dimensions, the maximum outward displacement required from each arm on the

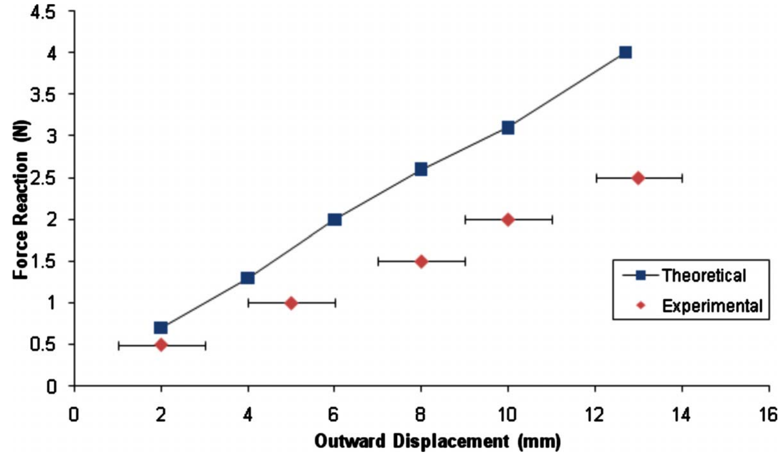

Fig. 4 Accura 25 prototype force-displacement curves

tool is approximately 13 mm. Incremental arm displacements were measured following 0.5 N weight increments until the desired deflection was achieved. FEA predicted force reaction values 40–60% greater than the experimentally determined values. One potential reason for this discrepancy is that the rapid prototyping process uses a material layering process that weakens the structure, resulting in greater compliance than that assumed for the computational results.

3.4 Circumcision Procedure. The procedure is meant to be quick and simple for the traditional cutter as well as safe for the circumcisee. Pictures of the procedure matching the step-by-step text described below are shown in Fig. 5.

1. Retract foreskin on to the shaft of the penis so that the glans is completely exposed.
2. Gently push the tool onto the glans until the six arms of the tool extend over the glans and the end of the arms rest on the penis shaft below the coronal sulcus.
3. Roll the foreskin over the tool so that it completely covers the tool.
4. Pull foreskin into tension (more tension results in more foreskin being removed). Keep the foreskin in tension.
5. Make a cut with the traditional knife or razorblade above the tool to remove excess foreskin.
6. Once the cut is made, carefully retract foreskin back onto the shaft and remove the tool.

4 Discussion

The objective of this work was to design a low cost, adjustable (one-size-fits-most), and culturally appropriate adult male circumcision tool for use during traditional circumcision ceremonies in sub-Saharan Africa.

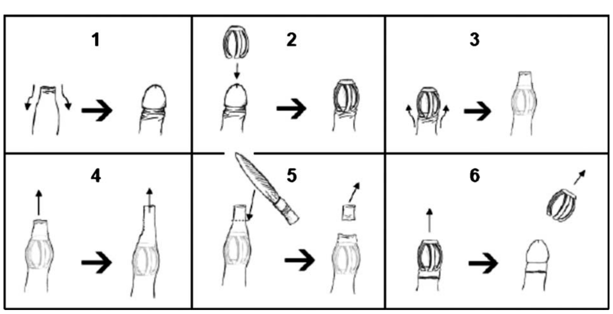

Fig. 5 Pictorial representation of procedural steps

The primary advantage of the design reported is its ability to fit the 5th to 95th percentile adult male using a single tool while still affording substantial protection of the glans. Due to its use of a compliant mechanism versus moving parts, an additional advantage is that it is relatively simple to manufacture by injection molding. Depending on the quantity, manufacturing costs would likely range between $0.50 and $3.00 per unit. For comparison, the wholesale cost of the TaraKLamp ranges between $23 and $26.

Potential implementation within a traditional circumcision ceremony was considered throughout the design process. Therefore, a simple and unobtrusive tool was desired and obtained. Design simplicity and design for intuitive use were also emphasized in order to minimize the potential for misuse, given that user manuals are frequently separated from equipment in the field. Straightforward pictorial instructions were developed to facilitate proper use of the tool given that the majority of traditional cutters either do not have medical training or are poorly trained [8].

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