

User-Based Design Approach to Develop a Traditional Adult Male Circumcision Device

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1 Background

HIV/AIDS is a devastating global epidemic responsible for more than 25 million deaths since 1981 [1]. The World Health Organization (WHO) concludes that “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]. Thus, public health organizations, along with most of Africa’s ministries of health, have either launched or are preparing to launch mass male circumcision roll-out plans [3]. In sub-Saharan Africa, adult male circumcision occurs in both clinical settings and traditional ceremonies. Unlike male infant circumcision, adult circumcision requires suturing for homeostasis and wound closure that makes the procedure more difficult and longer, thus resulting in higher complication rates [4].

ShangRing and PrePex, both of which have attracted the attention of public health authorities in Africa, are new devices that claim to accommodate clinical adult male circumcision by enabling less-trained health workers to perform the task [5,6]. Traditional male circumcision (TMC) ceremonies are often considered a rite of passage into manhood for boys between ages 6–24; however, these ceremonies are associated with high adverse events, as high as 48%, including bleeding, infection, excessive pain, lacerations, erectile dysfunction, and even death [7]. A detailed description of TMC practice and its cultural importance in Uganda has been discussed in [8]. However, devices such as the ShangRing and PrePex are not suitable for use in traditional settings due to their cultural inappropriateness, complexity and high cost. Given the continuing practice of TMC in sub-Saharan Africa, there is a need for a biomedical intervention to ensure safe, healthy, and effective outcomes. Addressing health and safety concerns and adopting a pragmatic user-based approach throughout the design and revision process allowed us to develop a culturally acceptable, low-cost, single-use, and safe device for use in TMC. The co-creative design process, which involved the end-users, is explained here.

2 Methods

Based on published literature and input from Kenyan and American surgeons, we generated an initial compilation of the user requirements of uncircumcised males and traditional cutters. We assessed the weights and interdependencies of user requirements by using quality function deployment.

Qualitative and quantitative measures were used to assess the time required to apply and remove the device, the ease of application, the degree of glans protection, and the length of foreskin cut using fresh male cadavers. After designing the first-generation

prototype, we traveled to Uganda to meet with ethnic group leaders and traditional cutters in 12 focus group discussions (FGDs), and to interview local and national public health officials and clinical experts. During this visit, we established the urgency and appropriateness of the need for the device and developed a list of cultural and technical requirements by engaging with the potential end-users. Based on feedback from Ugandan communities practicing TMC and our cadaver testing results, we generated 20 additional concepts. We performed down-selection using go/no-go feasibility tests, Pugh Charts, and parameter analyses. We then fabricated prototypes of the top five concepts and performed more experimental tests on cadavers to evaluate each prototype against the list of revised user requirements. Additional feedback on the revised prototypes was gathered via follow up FGDs and interviews with stakeholders in Uganda.

3 Results

A. First-generation prototype: As mentioned, the design of the prototype (Fig. 1) was based on user requirements gathered through meetings with American clinicians, phone interviews with several African health care providers, and the literature review. Six compliant arms embrace the penile glans and protect the penis during the cut [9]. We performed engineering analyses to characterize the relationships between arm dimensions (length, width) and geometries (radius of curvature), and to find the optimum number of arms and various dimensions needed to control the removal of an adequate amount of foreskin.

B. Prototype iteration: We traveled to Uganda and interviewed public health experts, who affirmed the critical need for innovative methods to make TMC safer. We conducted FGDs with traditional cutters, their assistants, and clan leaders from the ethnic groups still practicing TMC in Uganda. The objectives were to understand the cultural significance and rituals, obtain feedback on the prototype, and assess the willingness of the ethnic groups to use a new device, or to modify their practices for reasons of health and safety. Participants in FGDs commented on the need for a device to enable a fast cut, provide full coverage of the glans, and anchor securely to the penis while the foreskin was being pulled in tension. They also wanted the low-cost device manufactured in three sizes. Table 1 shows the ranked-order user requirements used for the first-generation prototype, and the refined list of user requirements.

The second-generation prototype has two parts: a strong solid shell that provides complete protection of the glans against the cut, and a latex sleeve that covers the shell and anchors the device to the glans (Fig. 2). The non-deployed (rolled) latex sleeve, resembling a condom in its material, shape, and usability, rolls up so that it sits on top of a groove at the end of the shell. After the shell is placed over the glans, the foreskin is retracted and the latex sleeve is deployed by rolling it over the glans until it covers the coronal sulcus.



Fig. 1 First-generation device prototype

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Table 1 List of original and revised user requirements and engineering specifications

Original requirements	Original engineering specifications	Revised user requirements	Revised engineering specifications
1. Fast cut	120 sec	1. Fast cut	Cutting time < 10 sec
2. Number of procedural steps	10	2. Safe cut	Full (100%) glans protection
3. Number of parts	3	3. Strong grip	Should not fall off while cutting the foreskin
4. Adjustable diameter	15.2–40.6 mm	4. Low cost	Final cost < \$1.00
5. Glans coverage	50%	5. Three sizes	S, M, L

**Fig. 2 Revised design. Left: shell with non-deployed latex rolled at the groove. Right: shell with deployed latex.**

Latex was chosen as the sleeve material due to its ability to firmly grip and anchor the device to the penis while the foreskin is being pulled over the shell.

To increase functionality, a medical grade elastic band, which can be applied over the foreskin and against the device's groove, helps to hold the foreskin in place and provides a visual cue to guide the cutter. The applied compression to the foreskin minimizes blood loss. Three shell sizes were designed to accommodate the 5th–95th% adult glans diameter.

4 Validation

A. First-generation prototype: The don/doff testing of the original design revealed that the six arms were too cumbersome to simultaneously maneuver during application (the average time required to apply and remove the device was 3 min). Both the experimental and simulated results suggested that greater than 70% coverage of the glans surface area could not be achieved with this design. Due to the insufficient elastic nature of the prototype materials, some arms broke during application. In more than 80% of the trials, the prototype did not adequately grip the coronal sulcus. Possible displacement when the foreskin was pulled into tension could increase procedure time and decrease protection due to ineffective placement and an inability to control for a consistent cut.

B. Second-generation prototype: We changed the prototype based on feedback from stakeholders and engineering analyses. Careful testing on fresh cadavers showed that this revised design provided 100% glans coverage during a cut, could be applied and removed in approximately 5 sec, and provided excellent grip on the glans. Finally, we added an auto-disable feature to prevent reuse.

5 Discussion

Interviews with over 30 leaders in circumcision policies and practices and an additional 15 FGDs in Uganda during the

summer of 2011 gauged community interest in the revised device and its use by TMC cutters, and the extent of support by surgeons and the Ministry of Health. Participants in the FGDs were asked to compare the prototype and the revised design; a Likert scale found that 80% of cutters and their assistants ($n = 51$) and 97% of clan leaders ($n = 40$) chose the revised device for its simplicity, ease of use, and perceived increased protection. When asked if they would use and/or support the revised device if public health officials supported its usage and the TMC cutters were properly trained, 74% of cutters and assistant cutters and 88% of clan leaders “strongly agreed” that they would do so. The design experience described reinforced our belief that engaging stakeholders actively, especially to confirm the need and to elicit continuous feedback on early prototypes, is essential to a product's development and eventual successful adoption.

6 Conclusion

A respectful collaboration captured feedback and input at all stages of design development and testing. After appropriate clinical evaluation, this new device has the potential to help traditional communities in Uganda to both preserve the culture and assist with a proven public health approach for reducing HIV/AIDS in a safe manner.

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