

Psychosocial Results from a Phase I Trial of a Nonsurgical Circumcision Device for Adult Men in Zimbabwe

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Abstract

Male circumcision (MC), an effective HIV prevention tool, has been added to Zimbabwe's Ministry of Health and Child Care HIV/AIDS Prevention Program. A Phase I safety trial of a nonsurgical male circumcision device was conducted and extensive psychosocial variables were assessed. Fifty-three men (18 and older) were recruited for the device procedure; 13 follow-up clinical visits were completed. Interviews conducted three times (before the procedure, at 2 weeks and 90 days post-procedure) assessed: Satisfaction; expectations; actual experience; activities of daily living; sexual behavior; and HIV risk perception. Using the Integrated Behavioral Model, attitudes towards MC, sex, and condoms, and sources of social influence and support were also assessed. Men (mean age 32.5, range 18–50; mean years of education = 13.6; 55% employed) were satisfied with device circumcision results. Men understand that MC is only partially protective against HIV acquisition. Most (94.7%) agreed that they will continue to use condoms to protect themselves from HIV. Pain ratings were surprisingly negative for a procedure billed as painless. Men talked to many social networks members about their MC experience; post-procedure (mean of 14 individuals). Minimal impact on activities of daily living and absenteeism indicate possible cost savings of device circumcisions. Spontaneous erections occurred frequently post-procedure. The results had important implications for changes in the pre-procedure clinical counseling protocol. Clear-cut counseling to manage pain and erection expectations should result in improved psychosocial outcomes in future roll-out of device circumcisions. Men's expectations must be managed through evidence-based counseling, as they share their experiences broadly among their social networks.

Introduction

RANDOMIZED CONTROLLED TRIALS (RCT) showed that adult medical male circumcision (MC) reduces the lifetime risk of HIV acquisition among men up to 60%;^{1–3} now up to a 75% protective effect.⁴ Community-based cross-sectional surveys in Orange Farm, South Africa, showed a drop in HIV incidence of between 57–61%.⁵ Ongoing research also showed that male circumcision prevents acquisition of other sexually transmitted infections (STIs) among men, including herpes simplex virus type 2, human papillomavirus (HPV), and genital ulcer disease, and it reduces HPV, genital ulcer disease, bacterial vaginosis, and trichomoniasis among female partners.⁶

Based on the strong MC RCT findings, the World Health Organization (WHO) and UNAIDS proposed MC be included in HIV prevention programs in countries where HIV prevalence is high, and MC rates are low.⁷ MC programs have been implemented in 14 sub-Saharan African countries. To have the greatest impact on the AIDS epidemic, 80% of adult men aged 18–30 need to be circumcised as soon as possible.^{8–10} In Zimbabwe, HIV incidence could be reduced up to 42% if 80% of adult men were circumcised.¹¹ Zimbabwe's Ministry of Health and Child Care (MOHCC) prioritized adult MC as one of its HIV prevention strategies and rolled out the program with a priority targeting of adult HIV negative men in 2010.¹² The current goal is to circumcise 1.3 million men by 2017. About 192,000 men were

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circumcised by the end of 2013 (MOHCC, 2014); achieving only 15% of the goal.¹³

While significant investments have been made in service provision for surgical circumcision procedures in provincial and district hospitals in Zimbabwe, capacity could be further improved by facilitating broader dissemination of MC services to Primary Health Care Centers (PHCC). Research shows that one predictor of circumcision uptake among men is having services available in local clinics.¹⁴ The basic medical facilities available in PHCCs preclude a surgical program but a nonsurgical procedure for circumcision may be useful for increasing circumcision capacity in these resource limited settings.¹⁵ Nurses are an intrinsic part of the MOHCC circumcision program through their roles in PHCCs, where upon provider initiated HIV testing, they provide circumcision referrals to HIV negative patients.

This publication describes detailed psychosocial results of a Phase I Safety Trial of a nonsurgical circumcision device conducted by the MOHCC in Zimbabwe. Device circumcisions in the trial used the PrePex™ device, a certified CE Class IIa apparatus consisting of an inner hard plastic ring, an elastic ring, a placement ring, and a verification thread. Foreskin circulation is cut off distally, allowing for bloodless removal of the necrotized foreskin 7 days following application.¹⁶ The device was found to be safe for use for adult male circumcisions.^{16,17}

Although clinical safety results were presented previously,¹⁶ the current safety study is the first one independent of the manufacturer, and the first to have such extensive psychosocial measures. These measures are important to collect, as knowledge of the psychosocial effects during and after a circumcision procedure can lead to better and more evidence-based counseling by nurses who are often the implementers in PHCCs. The psychosocial measures were used to: (1) determine the psychosocial effects of device circumcisions; (2) assess whether and what barriers exist; (3) design counseling to ameliorate possible negative effects or experiences; and (4) collect data for the design of evidence-based messaging to promote adoption of devices as an additional resource for voluntary medical male circumcisions.

Methods

Participants

This single-center safety study enrolled healthy, seronegative uncircumcised men, at least 18 years old, who were coming in for a medical circumcision at the MOHCC MC Centre. Men agreed to the nonsurgical device procedure after a group information session where the trial of the device was described to them. All potential participants were provided informed consent and were examined to determine if they fit the clinical criteria for inclusion or exclusion. The study was approved by the Medical Research Council of Zimbabwe (MRCZ) and the Battelle Institutional Review Board. The overall Trial was observed by international monitors from the Research Support Centre, College of Medicine of Malawi, for Good Clinical Practices and international standards (i.e., ISO 14155). A Data Safety Monitoring Board was established to provide required oversight in all three phases of the trial. The trial was registered at clinicaltrials.gov (NCT01956370). Data were collected between June and August 2012.

Study design

The design for the clinical safety study included at least weekly reviews by study nurses over a 9-week period: pre-procedure and up to 8 weeks post-procedure (13 clinical reviews). The clinical procedures used for the nonsurgical circumcisions are described elsewhere.¹⁷ Psychosocial interviews were conducted at three time points: immediately prior to the procedure, and at 2-week and 90-day follow-ups. Data were collected by trained psychosocial interviewers in private face-to-face interviews at the MC Center. A total of 53 men underwent nonsurgical device circumcisions in the Safety Phase of the trial. Due to MRCZ review delays of the psychosocial component, these data were collected from 38 men (72%) prior to their procedure. However, 46 men (87%) completed 2-week and 45 men (85%) completed 90-day follow-up interviews post circumcision. A total of 32 men completed all three interviews.

Measures and procedures

The psychosocial interview was adapted from an instrument used and validated in a study exploring factors predicting male circumcision uptake, conducted in Zimbabwe.¹⁴ The instrument was based on extensive formative research capturing men's issues with circumcision, and was informed by the Integrated Behavioral Model (IBM).^{18,19} The interview measured demographics, MC information sources, acceptability, expectations, satisfaction, participants' physical and psychosocial experience with the circumcision procedure, conversations with social network members about MC, perceptions of their partner's attitudes towards the circumcision, sexual behavior, and attitude and social influence (IBM constructs).

Attitude has two components: (1) experiential attitude, one's emotional or affective response to the idea of performing a behavior;^{18,20} and (2) instrumental attitude, cognitively based beliefs regarding positive or negative consequences or attributes of performing a behavior. These components capture the 'thinking fast (emotional) and thinking slow (cognitive)'²¹ aspects of attitudes. Each component was measured as a multiple item scale.

Social influence has two normative components: (1) beliefs about other's expectations (injunctive norm) regarding behavioral performance; and (2) beliefs about what others are doing in regards to the behavior (descriptive norm). Attitude and social influence regarding circumcisions were assessed at all three time points using multi-item scales. Because circumcision decisions had already been made by men in the study, the personal agency component of the IBM was not included as a measure.

The two attitude components were measured with 5-point semantic differential and 5-point Likert agree-disagree scales, and measured 11 experiential (emotional) attitude items and 21 behavioral beliefs (cognitive), respectively. Social norm was captured by asking men about their perceptions of: (1) normative support for their circumcision (injunctive norm), and (2) about who in their social networks may get a circumcision (descriptive norm). Both aspects of social influence are important drivers of behavior.^{18,20} Diffusion of innovations postulates that individuals are more likely to adopt innovations or behaviors if they perceive that these are adopted by their friends and peers.²² For injunctive norm ratings, men were asked to rate on 5-point scales ranging from 'strongly against'

to 'strongly for' how they perceived 11 different social referents may or may not support their circumcision. Descriptive norm questions asked on 5-point scales ranging from 'strongly disagree' to 'strongly agree' about their perception of which of three key social referents would get circumcised. Men were also asked how many individuals in their social networks they spoke to before and after their circumcisions.

Men were also asked about their expectations regarding the circumcision procedure prior to it, and about their actual experiences with the procedure at both post-procedure interviews. The pre-procedure interview was designed to: (1) capture men's attitudes and norms about circumcision to gauge the factors that influenced their circumcision decisions; and also (2) evaluate how men feel before a procedure so that clinician's counseling can better address issues men may report. Assessing changes in expectations and experience after the procedure provides a basis for documenting men's actual experiences, and also indicates what men may relay to friends and family members with whom they are talking. Men were asked to rate on 5-point scales ('strongly disagree' to 'strongly agree') whether they thought that a variety of factors (such as complications) would occur, or how anxious they were about the procedure.

Satisfaction with the circumcision procedure was also rated on a 5-point Likert 'agree-disagree' scale. In the two post-procedure interviews (2-week and 90-day), men were asked to rate their satisfaction regarding their circumcision on 5-point scales ranging from 'not at all satisfied' to 'extremely satisfied'.

Specific questions on Activities of Daily Living (ADLs) and days missed from work captured those effects of the device circumcision. For ADLs, men were asked to rate on 5-point scales ('strongly disagree' to 'strongly agree') whether they thought that a variety of home, work, and social activities ($n = 17$) would be impacted by the procedure. ADLs were assessed at all three time points to capture expectations prior to the procedure and actual post-procedure experience.

In addition, sexual history, current activity (intercourse, masturbation, spontaneous erections), sexual satisfaction, and condom use with different types of partners were also assessed at each time point. Follow-up interviews asked about onset of post-circumcision sexual intercourse, and assessed reactions to device removal and the healing process. Sexual practices and sexual satisfaction for men, and perceived satisfaction with sexual activity for female partners after circumcision, and how they may have altered, were also measured. Finally, perceived risk of HIV acquisition over an individual's lifetime was assessed at all three interviews.

The psychosocial data, collected over three time points, allowed changes in attitudes towards, feelings about, and satisfaction with men's circumcisions to be discerned. Data also allowed changes in circumcision procedure experience and expectations to be captured. Changes in how men communicated with their social networks were also captured over time. Effects on ADLs were also measured longitudinally to capture changes.

Data analysis

Data entry screens were designed using the Statistical Package for the Social Sciences (SPSS) with logic checks, skip patterns, and range checks. Data management, record

maintenance, data checking, data cleaning, and double entry verification for quantitative trial data, as well as psychosocial data, were handled by the Zimbabwe Community Health Intervention Research (Zichire) office team. When ready, data was encrypted and sent to Seattle for analyses. Analyses were conducted using IBM SPSS V.19. Descriptive analyses were conducted followed by Generalized Linear Models for repeated measures to examine longitudinal data and trends over time. When significant differences over time were found, post-hoc binary comparisons were performed using repeated measures *t*-tests. The longitudinal study design allowed changes in outcomes across time to be tested.

Results

Participant characteristics

The majority of men in the sample identified as Shona (95%), Christian (95%), and were married (63%). Men's mean age was 32.5, range 18–50. These men were well educated (mean = 13.6 years of education) and employed predominately as professional, technical, managerial, or government workers (55% inclusive). Pre-procedure interviews showed 81% of participants were employed, with an average monthly income of US\$1016.

These men were not representative of the general population of Zimbabwe, though they tend to be representative of men who choose to get circumcised in Zimbabwe.²³ Most men who had heard or seen circumcision information identified radio (84%), newspapers (66%), or billboards (58%) as primary sources of information. Only a third of participants (37%) indicated they had received information about circumcision from a physician or nurse at a clinic, prior to their MC appointment.

Experiential and instrumental attitudes

Scales for both experiential and instrumental attitudes were constructed with high reliability, Cronbach's $\alpha = 0.71$ and 0.70 , respectively. We found a significant change over time among men undergoing nonsurgical MC on both scales. Table 1 shows the mean rating at each time point along with the *F*-value. As can be seen in the table, even after using a conservative Bonferroni correction for multiple comparisons, the change over time was significant. At the 2-week post-procedure interview, experiential attitudes toward MC remained effectively unchanged while instrumental attitudes became more positive, and the increase over the 2 weeks was statistically significant in the post-hoc pairwise comparison of instrumental attitude between baseline and 2 weeks post-procedure. For both attitude measures post-hoc comparisons found significant changes from baseline to 90 days post procedure.

Looking more closely at the individual items that make up attitudes, we find that men held very favorable experiential/emotional attitudes toward the circumcision prior to their procedure. All men believed that the upcoming circumcision was either "quite" or "extremely" good, hygienic, and smart. Additionally, all men ($N = 38$) suggested that the circumcision was either "quite" or "extremely" healthy and the decision to get circumcised was up to them. This is not unexpected considering these men had already made the decision to get a circumcision prior to participating in the device safety study.

TABLE 1. BEHAVIORAL BELIEFS REGARDING CIRCUMCISION

	<i>Pre-procedure</i>	<i>Two weeks post-procedure</i>	<i>90 days post-procedure</i>	<i>F-value</i>	<i>p Value</i>	<i>Post-hoc binary comparisons (p < 0.05)</i>
Experiential Attitude Scale	4.5	4.4	4.8	14.2	<0.000 ^b	Baseline <90 day 2 week <90 day
Instrumental Attitude Scale	4.0	4.1	4.5	32.7	<0.000 ^b	Baseline <2 week Baseline <90 day 2 week <90 day
Injunctive Norms Scale	4.7	4.6	4.7	0.54	0.586	NA
Descriptive Norms Scale	4.6	4.7	4.4	1.53	0.224	NA
Activities of Daily Living Scale	1.4	1.5	1.3	1.08	0.346	NA
Satisfaction	NA	3.8	4.5	3.6	0.001 ^b	NA

^a<0.05 level of significance; ^b<0.008 the adjusted threshold for significance based on the Bonferroni correction for six tests (0.05/6).

Three-quarters of the men (75.9%) felt that the procedure would be “quite” or “extremely” easy and 94.8% thought that MC was either “quite” or “extremely” beneficial.

All experiential attitude items remained positive through the 90-day interviews. Almost all men agreed that the circumcision had been “quite” or “extremely”: good, safe, hygienic, worthwhile, smart, beneficial, desirable, healthy, and up to them. Comparing pre- to post-procedure experiential attitudes, men held even greater positive attitudes after the experience and healing had been completed. Of particular note, among experiential attitude measures, perceptions of safety had the greatest magnitude of change. Prior to the procedure, less than 40% of men strongly believed that device circumcision was safe. At 2 weeks, 61% of men rated the procedure “extremely” safe and by 90 days, fully 89% did so, showing a statistically significant increase in ratings of safety ($p < 0.001$) in the post-hoc analysis.

The instrumental attitude scale results showed that men improved their overall instrumental attitude ratings, with a mean belief score moving from 4.0 (Baseline) to 4.5 at 90-days ($p < 0.000$) (see Table 1). Changes among specific behavioral beliefs comprising the instrumental attitude construct are important to document because they indicate how men’s experience may have affected them. Table 2 shows mean ratings for each behavioral belief at each time point, with the last column indicating which post-hoc comparisons were significant. Men’s ratings of beliefs about the procedure and possible complications (first 7 items in Table 2), improved significantly over time for all belief items, but for some the temporal trajectory of the change was curvilinear.

Though all instrumental attitude behavioral belief items became more positive, the greatest positive effects were for the items measuring procedures and healing. Men went into the procedure believing that it would be somewhat painful, take time to heal, and that there was risk of bleeding, infection, and disfigurement. At 2 weeks, men could see they had not been disfigured and bleeding had not been severe. Thus, their beliefs about these aspects of the procedure changed quickly and improved with time.

Conversely, after just 2 weeks, beliefs about pain from the procedure and healing had not changed and beliefs about the

MC taking too long to heal had become less positive. It was not until 90 days after the procedure that men indicated pain and healing were not an issue.

Several of the beliefs about how the device MC would impact men’s sexual activity also changed over time, but the change tended to be short rather than long term. At 2 weeks, on average men were less likely to agree that the procedure would improve either their or their partner’s sexual pleasure, but after 90 days their ratings were almost identical to pre-procedure beliefs and strongly positive. In fact, at 90 days post procedure over half of men “strongly agreed/believed” that the procedure enhanced their and their partner’s sexual pleasure. In contrast, less than 4% disagreed sexual pleasure was enhanced.

Injunctive and descriptive social norms

Prior to their procedures, men perceived that their social network generally supported their circumcisions (Injunctive norm mean = 4.7) and men continued to believe so post-MC (2-week post-procedure mean = 4.6; 90 days post-procedure mean = 4.7; NS). Men who came in for a circumcision, generally believed that men in their social network (descriptive norms) will get circumcised and this did not vary significantly over time (mean = 4.6 at pre-procedure, 4.7 at 2-week post-procedure, 4.3 at 90-day post-procedure interviews). Thus, we found no significant change in injunctive nor descriptive norms over time.

Conversations

Significant change occurred across time with regard to conversations men had about their circumcision. In the pre-procedure interview, 37% of men said that they had known someone who had recently (within the past month) gotten a circumcision. The vast majority of men (92%) spoke to someone (friends, wives, and other family members) about their decision (mean = 5.6 people spoken to in the last month, 1.4 per week). At the 2-week follow-up, 59% of participants reported knowing someone who had a recent circumcision, and 96% of men spoke to someone (friends, workmates, family members) about their own experience.

TABLE 2. BEHAVIORAL BELIEFS REGARDING CIRCUMCISION

	<i>Pre-procedure</i>	<i>Two weeks post-procedure</i>	<i>90 days post-procedure</i>	<i>Post-hoc binary comparisons</i>
<i>Behavioral beliefs about the procedure</i>				
The procedure will be painful ^a	2.5	2.5	1.8	90 < B, 90 < 2
The healing will be painful ^a	2.6	2.5	1.7	90 < B, 90 < 2
It may take too long to heal ^a	2.4	2.8	1.3	90 < B, 90 < 2
It might not heal properly and cause disfigurement ^a	2.3	1.6	1.0	2 < B, 90 < B, 90 < 2
The doctor might make a mistake and cause you to be disfigured ^a	2.5	1.3	1.0	2 < B, 90 < B, 90 < 2
You may have too much bleeding ^a	2.1	1.1	1.0	B > 2, B > 90
It may get infected and swollen ^a	2.5	1.8	1.1	2 < B, 90 < B, 90 < 2
<i>Behavioral beliefs about sexual activity and practices</i>				
It means having to wait too long to have sex ^a	4.1	3.5	3.2	B < 3
It will enhance sexual pleasure/enjoyment for you ^a	4.4	4.0	4.3	B > 2
It will enhance sexual pleasure/enjoyment for your partner ^a	4.4	4.0	4.4	B > 2
Would lead you to be tempted to have more sex partners	1.3	1.2	1.1	
Your wife/girlfriend may think that you intend to seek pleasure from others (that you will have other partners)	1.8	1.6	1.6	
It may compromise your sexual performance	1.5	1.5	1.3	
You may not be able to have children	1.0	1.2	1.1	
<i>Behavioral beliefs about ridicule</i>				
It will cause girls/women to shun you and say your penis is different from what is considered normal in the community	1.6	1.5	1.1	
Your friends may laugh at you and you will be embarrassed (reversed)	1.2	1.3	1.1	
Your wife/girlfriend will like how you look	4.4	4.1	4.5	
<i>Behavioral beliefs about HIV, STI protection and hygiene</i>				
You would be protected from HIV even if a condom breaks	1.8	1.6	2.3	
Your penis will be clean, and protect you from bacterial infections	4.7	4.7	4.4	
You would not need to use condoms because you would be protected from HIV	1.7	1.4	1.2	
Your wife/girlfriend will think you are cleaner	4.7	4.3	4.6	

^aChange significant, $p < 0.05$.

The men spoke to an average 13.7 people (6.9 per week); 46% reported speaking to 10 or more individuals. At 90 days post-procedure, 38% of men reported knowing someone who had a recent circumcision, and men continued to talk about their MCs with a range of friends and family members (mean = 11.6 or 0.97 per week). There was a significant difference in the mean numbers of individuals spoken to ($p = 0.036$) across both post-procedure interviews, with the highest concentration of conversations occurring in the two weeks following the circumcision.

Satisfaction

The level of satisfaction with their circumcision increased significantly from the 2-week to the 90-day follow-up, and the result held even after adjusting for multiple comparisons (Table 1). Satisfaction with the circumcision measured at 2 weeks was just 3.8 on average, but by 90 days post-procedure it had increased to a mean of 4.5 ($p < 0.001$). In the 2-week post-procedure interview, over 65% of men were ‘very’ or ‘extremely’ satisfied, but almost a third were less so (not tabled). By contrast at the 90-day post procedure inter-

view, all men indicated they were satisfied with the circumcision; over 95% rating they were ‘very’ or ‘extremely’ satisfied ($p < 0.001$). We also found that men reported that their partners were satisfied with their circumcision; over 30% reported that partners were ‘very’ or ‘extremely’ satisfied at the 2-week interview. By the 90-day follow-up, perceived partner satisfaction increased dramatically; over 70% reported that their partner was ‘very’ or ‘extremely’ satisfied ($p = 0.014$).

Procedure expectations and experience

Men reported anxiety in pre-procedure interviews (Table 3). Mean agreement with the statement “you are anxious about the procedure” was 3.7, with over 50% men reporting they “strongly agreed.” But men also indicated confidence that the procedure would proceed without complications, would confer benefits in the form of reduced HIV risk, and that benefits would outweigh any costs associated with pain. Men’s beliefs that they “were fully informed about the procedure” fell following the procedure from 92% “strongly agreeing” (pre-procedure) to 78% in post-procedure interviews; but the

TABLE 3. EXPECTATIONS AND EXPERIENCE WITH CIRCUMCISION PROCEDURE

	<i>Pre-procedure</i>	<i>Two weeks post-procedure</i>	<i>90 days post-procedure</i>
You are [were] anxious about the procedure ^a	3.7	3.4	3.3
You expect [expected] that you will not have any complications after the procedure	4.6	4.3	4.9
You feel [felt] fully informed about what is going to happen to you during the procedure	4.8	4.7	4.9
The pain was controllable with the analgesics you were given	NA	4.9	NA
You are [were] expecting to be completely satisfied with the procedure	4.9	4.9	5.0
The pain of the procedure seems like it will be [was] worth it for the protection offered	4.8	4.7	4.8
You understand that circumcision will protect you against HIV infection ^a	4.7	4.8	5.0
You will use condoms after the procedure because circumcision does not confer complete protection	4.9	4.9	4.9

^aChange significant, $p < 0.05$.

mean change was only 0.1, because 95% still “somewhat” or “strongly” agreed.

There was some increased concern that there could be complications at 2 weeks post procedure. Post-device removal, there were in fact only two mild infections reported among the 53 men, easily treated with antibiotics.¹⁷ Men reported more pain at the *two-week* interview after device removal, than their expectations in pre-procedure pain ratings (Table 3).

Activities of Daily Living (ADL)

Men were asked how they believed the circumcision would affect their ADLs prior to the procedure and then to rate how the circumcision *actually* impacted their daily activities at each of the follow-up interviews. The activities of daily living were combined into an activity scale (Cronbach’s Alpha = 0.649). In pre-procedure interviews, men expected that the MC would have a slight effect on a few of their ADLs, in particular: sexual activity, walking, and sleeping. In the 2-week and 90-day follow-ups, men generally confirmed pre-procedure expectations, showing that the circumcision had a minimal effect on their ADLs (pre-procedure ADL Scale mean = 1.4; 2-week post-procedure ADL Scale mean = 1.5; 90-day ADL Scale mean = 1.3; NS), thus there was no significant change in ADLs (Table 1). Activities most impacted were in line with pre-procedure expectations (i.e., sex was limited, as expected) as at 2 weeks post-procedure sex is proscribed.

Absenteeism from work for employed respondents was also assessed. In pre-procedure interviews, employed men expected to take an average of 4.2 days off after the procedure (range: 0–14 days). At 2-weeks post-procedure, men reported the actual number of days they took off work was only an average of about one (0.9) day; maximum = 7. This was significantly fewer days off than expected ($p < 0.01$). In fact, of the 46 men interviewed at the *two-week* follow-up, only five reported taking any time off after the procedure.

Sexual activity

At the 2-week post-procedure interviews, no men reported having masturbated or having had sex. Men were also asked

about spontaneous erections at these interviews. This was to establish the frequency of these events to better counsel men who may seek the device procedure in the future. Men reported a range of zero (4 men) to 70 (2 men) spontaneous erections in the 2-week post-procedure period, mean 14.9. At baseline, 97% of participants strongly agreed that they could abstain for 6 weeks, but by the 90-day follow-up, only 87% strongly agreed and the decline in certainty was significant ($F = 4.2$; $p = 0.05$). In fact, by 90 days, 35 of the 45 men who completed the follow-up survey had resumed sex and 5 reported having had intercourse prior to the recommended 6-week recovery period.

Discussion

Men’s attitudes towards their device circumcision experience were favorable overall, indicating men came in with high expectations, and those improved over time. Conversely, some of these relationships were shown to be curvilinear, with a dip at the 2-week post-procedure interviews, which is precisely when the majority of conversations about the procedure are occurring. This indicates that men’s expectations may not have been met at the 2-week period. Clearly counseling by nurses before device deployment, and at the 1-week removal appointment, could be improved to better explain to men what they might expect and see during the removal and healing process. Management of men’s expectations may moderate negative commentary men may engage in if their expectations are not met.

Social normative measures toward men’s circumcisions were captured by two aspects: perceptions of normative support and perceptions regarding who in their social network may get circumcised. At all data points, men expressed the belief that their social networks conveyed support for their MC decision, and that their closest male social references were likely to get circumcised. The slight decline in men saying that their friends would get circumcised at the 90-day period is likely due to the actual conversations men had with their social referents. This allowed them to discover that counter to their original assumptions, their friends did not get circumcised at as high rates as they had expected.

The findings regarding men's conversations about their circumcision procedures suggest that men's decisions about circumcision and experiences following circumcision are not considered private events. Men undergoing the procedure rated both brothers and friends as significant sources of social influence supporting their MC decision. Almost all men (97%) talked to someone about their circumcision in the 2-week period following their procedure, and men spoke to almost 14 people on average. When men spoke, they spoke to a broad variety of men in their employment and social networks.

Thus, they are likely to affect the decision-making process of men in their social networks contemplating a circumcision. Research shows the valence of conversations individuals have regarding health behaviors predicts attitudes, self-efficacy, and subjective and descriptive norms regarding those behaviors.²⁴ If experiences are positive, these men may serve as effective advocates for adoption of MC within their social networks. Alternatively, if men experience negative outcomes, their communication with others may hinder the MOHCC goal of expanding voluntary circumcision among adult men as an HIV prevention strategy. It is therefore vital to provide consistent, positive, expectation-adjusted counseling for men undergoing the procedure to ensure men are promoters not opponents of circumcision.

This is particularly important as there is a large spike in the number of people respondents reported talking to in the 2 weeks following the circumcision; approximately seven per week in the 14 days following the procedure as opposed to one per week prior to their procedures. This means that there is a relatively short window during which a recently circumcised man will influence the highest concentration of others in his social network. This diffusion of information could be leveraged as a method of facilitating device circumcision uptake among men, complementing efforts made by the MOHCC information and education MC campaigns.

After their device circumcision, men were very satisfied and perceived that their female partners were pleased as well. Initial attitudes were positive and became more positive based on the actual experience. Satisfaction with the circumcision increased over time, with over 95% of men indicating they were "very" or "extremely" satisfied. This difference in satisfaction indicates that there needs to be a greater emphasis on managing early expectations, easily done at the pre-procedure and device removal appointments, so that satisfaction is higher in the short term. Procedure behavioral belief (instrumental attitude) ratings showed men came in to the procedure with some trepidation or anxiety, but expectations were high that things would go well. The finding that their actual experience and their satisfaction increased across time is a positive outcome of the device circumcisions.

The shorter term negative ratings for some of their behavioral beliefs, indicates that expectations need to be managed early on in the process. Failure to do so may result in negative word of mouth in the weeks immediately following the procedure and possibly an overall negative impact on demand for circumcision among men's social networks. This reaffirms the importance of men having a positive experience and feeling supported, because of their high likelihood of talking to friends about their procedure. If their experience is positive, their conversations with their male friends and family members, could lead to greater circumcision uptake.

There was little effect of the device circumcisions on activities of daily living. Men expected to take time off work, but in fact ended up taking little time off. This finding can be incorporated into counseling provided by nurses, telling men that they can return to normal activities, and do not need to interrupt their daily lives. This may be especially important for those men who do not get paid sick leave, an economic burden, if they lose pay if they have to miss work. This may be one significant contribution device procedures can make to the cost-savings of circumcisions, given that it is not clear that device circumcision is more cost-effective than surgical circumcision.²⁵ However, if a loss in productivity can be avoided given that men may not need time off work, this would be an overall cost savings.

Men's reports of greater pain than anticipated were likely due to their hearing from clinic nurses that device circumcision is virtually painless. This message was conveyed to clinicians during their trainings in Rwanda and reinforced by training in Zimbabwe. These results indicate where pre- or post-procedure counseling can be improved. It is vital that men's expectations around pain are addressed early in the process and are better managed. After the MOHCC was briefed on the psychosocial results, the nurses' pre-procedure counseling was changed to better reflect men's actual experience with pain for the next two phases of the trial.

The data show that spontaneous erections are a frequent enough occurrence that this information should be shared with men seeking device circumcisions. Men need to be told precisely about what to expect in their device circumcision procedure and follow-up, so they are clear about what to expect. This is especially important in light of the number of conversations men have after their procedures. Even though men had concerns about the length of time of sexual abstinence in pre-procedure interviews, most men managed to control sexual onset, post device removal. However, over 10% of men engaged in sex prior to the recommended period; a potential source of HIV transmission risk. These rates should be confirmed with larger studies, and effort should be made to emphasize the importance of abstinence by nurse counselors during post-procedure clinical appointments.

Though high acceptability for adult male circumcision was found early on,²⁶ uptake has generally been slower than anticipated.²⁷ Only 16% of the overall target of adult men has been reached across the priority countries by the end of 2013.²⁸ Device circumcisions could fill some of this gap, because they could be more widely disseminated into primary care settings than surgical circumcisions. Psychosocial indicators are important to consider because they affect the decisions men make about circumcision. This study points to issues that must be covered in counseling and messaging campaigns to better handle men's expectations.

In addition to showing that men's expectations must be managed, results from this trial also identify salient attitudes and beliefs that men hold regarding device circumcisions. These may help drive evidence-based counseling by nurses to improve men's outcomes and expectations. The findings can also provide specific information for where evidence-based messaging around device circumcisions should focus to increase men's uptake of this circumcision procedure. Theory-based communication strategies have a higher likelihood of changing behavior.^{14,29} Using these results in communications

campaigns may increase the effectiveness of future promotions and boost device circumcisions.

Recent publications³⁰ highlight how a nonsurgical MC procedure can be incorporated into MC programs and increase the efficiency of programs by increasing the number of circumcisions that can be performed. Our psychosocial research results from this and a previous study¹⁴ suggest that focusing on the efficiency of programs alone is not sufficient to increase the number of men who will come in to MC Centers to get circumcised. Many MC programs are already operating with sufficient capacity, with empty waiting rooms. Focusing on increasing capacity ignores the important psychosocial issues that drive men's circumcision decisions.

Research such as this documents those issues and anticipates them so evidence-based communications campaigns and improved counseling can ameliorate the effects of negative experiences and attitudes. Increasing circumcision among men is an extremely important reproductive health goal. A successful MC program will not only reduce the burden of HIV, but other STIs as well, and improve reproductive health by decreasing the sequelae of STIs among both men and their female partners. Thus, increasing circumcision with a more strategic and theory-driven approach to increase uptake among men is an important public health goal in countries burdened by HIV and STI epidemics.

Study limitations

The psychosocial results of this safety trial were generally positive. Such detailed psychosocial findings are unique in device circumcision research, but at least three limitations exist. First, men who were part of the trial were generally well-educated and half were employed, so they may not be representative of men in Zimbabwe. However, research shows that men in Zimbabwe who choose circumcision are better educated than men who do not.²³ Second, men coming in for a circumcision were already predisposed to have positive attitudes towards circumcision regardless of the method of circumcision.

Despite this, our results do show that positive attitudes and satisfaction with the procedure increased over time. Some of this increase could be attributed to cognitive dissonance. Third, this study is also limited in that there is no comparison group of men who received surgical circumcisions. It may be that any men getting circumcised, regardless of the procedure used for the circumcision, might well find the experience positive and gratifying. A comparison trial randomizing men to surgical versus device circumcisions would help in determining how or whether the psychosocial characteristics of each of these types of circumcisions may differ.

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