

# Assessment of the Use of the PrePex Device in Kenya

**P**rePex is a small plastic device designed for use in performing male circumcision in adults. Compared to conventional surgical circumcision, the PrePex procedure takes a shorter time, requires no stitches, involves minimal bleeding and eliminates the need for injected anesthesia.

On 31 May 2013, PrePex became the first device for circumcision of adult men to be prequalified by the World Health Organization, based on studies in Rwanda, Uganda and Zimbabwe. Prequalification means that the device meets international standards, paving the way for ministries of health to consider its use.

But ministries of health first need local data to assess whether PrePex-assisted male circumcision could be a safe, acceptable and feasible complement to the conventional surgical procedure in their own countries. A study of PrePex by the Male Circumcision Consortium (MCC), under the leadership of Kenya's National AIDS/STI Control Programme (NASCO), was designed to provide that information in Kenya.

## Study Design

The study was conducted in the Nyanza region in 2013 by Paul Feldblum and colleagues from FHI 360 and the University of Illinois at Chicago, working closely with the Nyanza Reproductive Health Society. It involved 427 men ages 18 to 49 who sought VMMC services, consented to participate in the PrePex study and had the device placed.

The first 50 men were circumcised and provided with other HIV-prevention services at the UNIM Research and Training Centre in Kisumu. They received intensive follow-up care, returning to the center after seven days to have the PrePex device removed, and then weekly for the next five weeks to monitor wound healing.



PHOTO: SILAS ACHAR/FHI 360

- **PrePex was an effective and well-accepted method for adult male circumcision in routine service delivery in Kenya.**
- **Healing time is longer after PrePex-assisted male circumcision compared to conventional surgery.**
- **Clear counseling about wound care after placement of the device and the risks of tampering with it during wear will enhance safety and effectiveness.**

After an independent review of the results for the first 50 men, another 375 men were enrolled at the UNIM site and at two outreach VMMC sites. They received the standard follow-up care at seven days and 42 days post-procedure.

The study assessed the safety of the PrePex procedure by measuring rates of moderate or severe complications and side effects. Participants were interviewed during each study visit, and the healing of their circumcision wounds was monitored.



The Male Circumcision Consortium worked with the Government of Kenya and other partners — including the US President's Emergency Plan for AIDS Relief (PEPFAR), which supports service delivery — to prevent HIV and save lives by expanding access to safe and voluntary male circumcision services. FHI 360 received a grant from the Bill & Melinda Gates Foundation to collaborate on the consortium with EngenderHealth and the University of Illinois at Chicago, working with the Nyanza Reproductive Health Society.

## Results

**Placement and removal procedures averaged three to four minutes each.** No complications were observed during placements or removals.

**The rate of moderate or severe complications and side effects following the procedure was 5.9 percent.** All complications, such as more bleeding, swelling or pain than expected, were easily resolved with medical treatment.

**A higher rate of complications and side effects was reported among the first 50 participants (10 percent).** The likely reasons are easier access to treatment at the fixed site, greater opportunity to observe complications at more frequent follow-up visits and reductions in complications as providers gained more experience.

**The overall rate of complications was higher than those reported for surgical male circumcision in Kenya or PrePex studies in Rwanda,** perhaps because of the intensive follow-up of the first 50 participants and other measures to improve detection of adverse events.

**Device displacement occurs, so surgical backup is required.**

Circumcision was completed surgically for five men after their devices became displaced. At least three and possibly all the displacements resulted from men attempting to remove the devices themselves.

**Healing tends to take longer than the 42-day healing period for conventional surgery.** About half of all study participants were certified as healed by day 42, compared to 94 percent of men completely healed by 42 days after surgical circumcision. Among the first 50 men, there was a 90 percent likelihood of being completely healed by day 56.\*

**PrePex was well accepted by participants, though odor while wearing the device and pain at removal were issues for some.** Virtually all (99 percent) of the men were satisfied with the appearance of the circumcised penis and would recommend PrePex-assisted circumcision to others. Most said the procedure was less painful than they had expected.

**The direct cost per circumcision was slightly higher with use of PrePex compared to conventional surgery.** If demand for PrePex-assisted VMMC were significantly higher than it is for the surgical procedure, costs savings could be realized because the PrePex procedure requires less time.

### References

Feldblum PJ, Odoyo-June E, Obiero W, Bailey RC, Combes S, Hart C, Lai JJ, Fischer S, Cherutich P. Safety, effectiveness and acceptability of the PrePex device for adult male circumcision in Kenya. PLoS ONE 2014; 9(5): e95357. doi:10.1371/journal.pone.0095357.

Bratt J, Fischer S, Odoyo-June E, Bailey, RC. Evidence on Direct Costs of PrePex and Costs of Training PrePex Providers in the Context of Kenya. MCC report, 25 March 2014.

*\* Because investigators were deliberately conservative in determining wound healing, the study data are not necessarily comparable to published data from other sites.*



The PrePex device consists of an elastic mechanism that fits closely around an inner plastic ring, clamping the foreskin and cutting off its blood supply. The foreskin then dries up and is removed.

## RECOMMENDATIONS

- Programs must ensure that surgical backup is readily available to handle cases of device displacement.
- Clients should be counseled on the risks of tampering with the device or engaging in sexual activity while it is in place, and messages on wound management should be precise.
- Pain management could be enhanced through specific messages about when pain is most likely to occur (days 2 to 3 and again around day 5); odor prevention with a regimen of gentle penile rinsing should be addressed explicitly with each patient.
- The longer time to complete healing after PrePex-assisted male circumcision — and thus the need for a longer period of sexual abstinence after the procedure — should be clearly addressed in pre- and post-VMMC counseling.

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