# The Safety Profile and Acceptability of a Disposable Male Circumcision Device in Kenyan Men Undergoing Voluntary Medical Male Circumcision

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**Purpose:** We established the safety and effectiveness as well as the acceptability of the Alisklamp® device for male circumcision among Kenyan men.

**Materials and Methods:** To qualify for this hospital based, prospective, interventional cohort study one needed to be an uncircumcised adult male who was HIV negative with no comorbid factors or genitourinary anomalies precluding circumcision. A total of 58 men were recruited from a population of 90. Outcome measures were the safety profile of Alisklamp and its efficiency and acceptability by participants.

**Results:** All 58 procedures were completed without device malfunction, hemorrhage or undesirable preputial excision. Mean ± SD procedure time was 2.43 ± 1.36 minutes and mean device removal time was 15.8 ± 7.4 seconds. There were 2 adverse events, including mild edema and superficial wound infection related to poor hygiene in 1 case each. All men resumed routine activity immediately after circumcision. Of the 58 participants 25.9% experienced mild nocturnal erectile pains that required no medication. During 6-week followup all men were satisfied with the procedure, tolerated the device well and would recommend it to a friend.

**Conclusions:** Alisklamp has an excellent safety profile and excellent acceptability among men who undergo circumcision using the device. This technique is easy to teach and it would prove to be a handy device to scale up the rate of male circumcision. Based on these findings the device merits a comparative clinical trial.

**Key Words:** penis; circumcision, male; instrumentation; HIV; Kenya

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AROUND 20% of men globally and 35% in developing countries are circumcised for religious, cultural, medical and other reasons, such as hygiene, esthetics and peer pressure.[1] Approximately 80% of Kenyan men are circumcised.

Three landmark trials of male circumcision done in the Rakai District of Uganda, Kisumu in Kenya and Orange Farm, South Africa, respectively, revealed a decreased risk of acquired HIV infection of between 51% and 60%.[2–4] Promoting male circumcision has become an additional important strategy to prevent heterosexually acquired HIV infection in men but the scale up should be safe and appropriate. It is hoped that surgical devices can further improve the cost-effectiveness of male circumcision.

Approximately 20 surgical devices are currently available worldwide. They may be broadly categorized by

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the method of hemostasis as crush, clamp or ligature devices. However, there are still insufficient independent data on their safety for male circumcision. We share the findings of a study done in Kenya to determine the safety profile and acceptability of Alisklamp.

## MATERIALS AND METHODS

This study was performed at the Uasin Gishu District Hospital in Eldoret Town, Rift Valley Province, Kenya, after receiving approval from the institutional research and ethics committee of Moi Teaching and Referral Hospital, Eldoret. A total of 58 men were recruited into the study from a group of 90 who presented during 5 days of screening. Prospective participants were counseled and tested for HIV. To qualify for the study one needed to be an uncircumcised adult male who was HIV negative with no comorbid factors or genitourinary anomalies precluding circumcision, and have a fixed abode and a functional mobile phone contact. Men who qualified provided informed consent to participate.

### Procedures

Five physicians, 7 clinical officers and 3 nursing officers involved in the study received a 3-day training session to learn circumcision using Alisklamp. Circumcision was done by an experienced provider from the Turkish Professional Circumcisers' Association, assisted by Kenyan counterparts.

Lidocaine 2% for local anesthesia was administered circumferentially at 1 to 5 mg/kg to a maximum of 10 ml as a block at the penile base after standard surgical preparation and draping of the site. The appropriate size of the device was determined using a measure that is a component of the circumcision kit.

The prepuce was retracted, the cylindrical appliance of the appropriate size was applied over the glans penis, the prepuce was replaced over the appliance and the clamp was then applied over the prepuce. The prepuce was excised proportionate to the device landmarks for safe circumcision. Monitoring was done intraoperatively and for at least 30 minutes after surgery, as recommended by WHO. The device was left in place a maximum of 7 days.

Participants had a contact person available at the hospital. If there were any adverse events, patients were to present to the health facility and expenses would be met by the study.

The clamp was initially scheduled to be removed on day 7. However, 6 participants presented on day 6 of followup. In these cases the clamp had been partially shed since the devitalized skin over the clamped portion of the prepuce had sloughed off. We then adjusted clamp removal time to 5 days and compared the effects between patients with the clamp removed before and at 7 days after circumcision.

Followup was done on day 2 after circumcision, on device removal day, 2 days after device removal and weekly to a complete followup of 6 weeks. We determined the presence, type pattern and degree of adverse events, and any need for intervention. Fares for these followups were reimbursed by the study at US$2.50 per visit in Kenyan shillings upon presentation to the review site. If participants failed to present on the appointed days, they were contacted by telephone to have a telephone review or reschedule the visit.

For study purposes adverse events were grouped as 1) not related—clearly explained by a cause other than Alisklamp circumcision, eg assault or road traffic accident; 2) possibly related—might be explained by circumcision but could equally be explained by other causes, such as poor hygiene or cultural practices; and 3) definitely related—a clear complication due to circumcision.

Adverse events were also categorized as severe—causing inability to perform usual activity, moderate—interfering with usual activity and mild—causing awareness but not interfering with usual activity. A threshold for stopping the study was set at a 5% incidence of serious events definitely related to Alisklamp use on preliminary analysis.

Pain was assessed by verbal feedback. Participants were asked to gauge pain severity on a range of 1 to 10 with 10 as the worst possible pain. Pain was then graded as mild—less than 5, moderate—5 to 8 and severe—9 or 10.

### Analysis

The primary outcome measure was the Alisklamp safety profile with reference to the number and severity of adverse events related to Alisklamp use for male circumcision and to possible device malfunctioning.

Secondary outcome measures were based on the acceptability of the device by study participants. This was done by assessing pain control during circumcision and device removal, the duration of the respective procedures, tolerance of the device before removal, disruption of participant routine activity with the clamp in place, disordered erection, completion of followup and whether the participant would recommend this circumcision method to a friend.

## RESULTS

A total of 58 HIV negative men with a mean ± SD age of 23.2 ± 5.6 years (range 18 to 45) were recruited into the study. Of the men 22 (38.0%) had a secondary education, 30 (51.7%) had completed primary education and 6 (10.3%) had no formal education or had not completed primary education. No patient had a university education.

The mean amount of 2% lidocaine used was 4.6 ± 0.6 ml (range 3 to 6). There was an adequate anesthetic effect during circumcision with only 8 patients (13.8%) reporting a pain score of 1 to 4 on a scale of 0 to 10. The average pain score during the procedure was 0.3. Clamp size was 20 in 1 man (1.7%), 26 in 18 (31.0%), 30 in 26 (44.8%) and 34 in 13 (22.5%). About a third of the men required a size below 30.

Average circumcision time was 2.43 ± 1.36 minutes (range 1 to 4.15). None of the men required dilation or a dorsal slit of the prepuce. There was no device malfunction during the procedures and no undesirable preputial removal. All men were com-

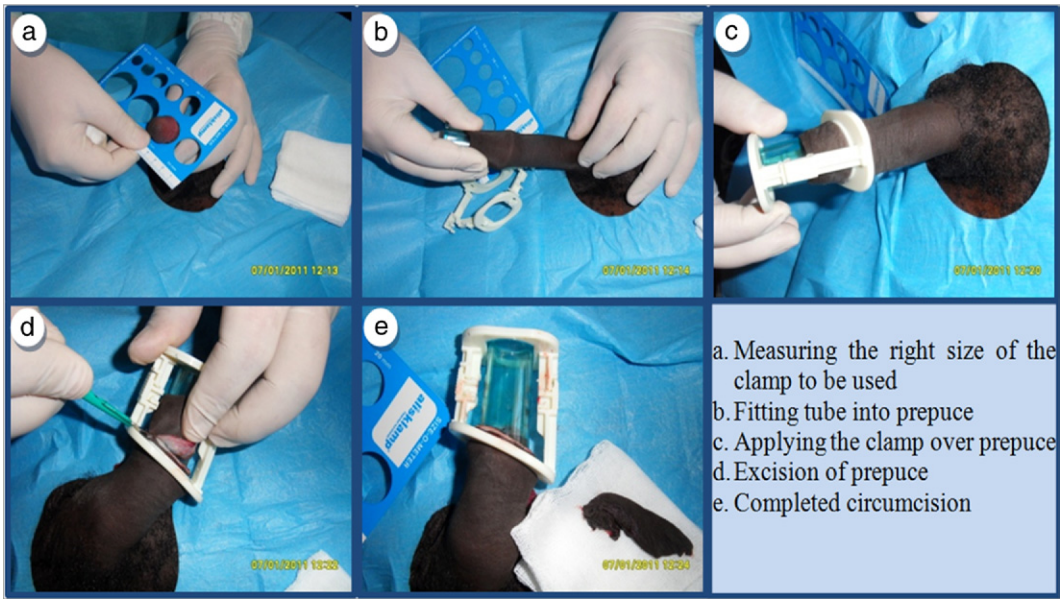


**Figure 1.** Circumcision process using Alisklamp

fortable wearing normal clothes and they resumed routine activity after circumcision (figs. 1 and 2, *A*).

On day 2 after circumcision 15 men (25.9%) reported mild nocturnal erectile pain that required no medication. One man had mild edema during this review.

The clamp was removed on days 5 to 7 in 26 (44.8%), 6 (10.4%) and 26 men (44.8%), respectively. Clamp removal was not delayed in any patient. The 8 episodes of mild to moderate pain (range 1 to 4) before clamp removal occurred in men with the clamp in place more than 5 days ($p < 0.001$). During clamp removal 37 men (63.8%) reported a mean pain score of 1.4 (range 1 to 5). Average clamp removal time was 15.8 seconds (range 7 to 50).

On day 2 after clamp removal there were no complaints of erection or any adverse events attributable to clamp use. During followup week 2 mild wound infection developed in 1 participant with poor hygiene, which resolved with topical antibiotic cream (silver sulfadiazine) wound care. It was well healed by followup week 4. One patient was lost to followup in week 2. This 24-year-old man had had no problems at the preceding reviews.

Subsequent followup after the 3-week healing period only revealed greater cosmesis and maturation of scar tissue. All except the 1 man lost to followup had healed well and were happy with the appearance (fig. 2, *B*). All would recommend the use of the device to a friend.

## DISCUSSION

With incontrovertible studies showing that male circumcision can prevent heterosexual transmission of


**Figure 2.** Appearance after circumcision. *A*, penis after clamp removal on day 5. *B*, healed penis on day 23.

HIV in men[2–4] male circumcision has acquired a stature akin to a life saver. However, scaling up male circumcision must be hand in hand with enhanced safety and acceptability of the procedure, culminating in an increased number of male circumcisions.[5]

The safety of male circumcision depends on the setting, equipment and expertise of the provider.[6] Alisklamp seems to fit the need for a blood-free, suture-free instrument with no device malfunction and no significant device related adverse events. Only 1 patient (1.7%) had mild edema after clamp application and another had possibly related superficial wound infection, which could also be explained by poor patient hygiene. There were no episodes of injury, hematoma or improper preputial removal. This compares favorably with some devices on the market with a high rate of adverse events.[7]

The ease of fitting and use makes Alisklamp a device that can easily be applied by individuals who would require little more than an introduction to and demonstration of the use of the device for male circumcision. In settings in which up to 70% of newly circumcised men experience a sense of likely stigma for choosing medical over traditional circumcision due to hostility between medically and traditionally circumcised men,[8] Alisklamp would solve many complications associated with traditional male circumcision. However, it should be used by those with the capacity to treat any complications that may arise.

All men in the study resumed routine activity with the clamp in place after an impressively short circumcision time. An average time of 2.43 minutes for circumcision is particularly helpful to decrease the burden of surgery at overwhelmed health care facilities. The amount of local anesthesia used with satisfactory outcomes makes Alisklamp a better option than WHO recommended methods that require an average of 20 to 40 minutes.[9–11]

Almost 26% of the men reported mild pain during nocturnal erection 2 days after circumcision. Pain after circumcision is a recognized event even for conventional circumcision and it is among the factors that act as barriers to male circumcision uptake in traditionally noncircumcising communities.[12] No patient complained of erectile problems during followup after clamp removal. However, we did not use standard charts and questionnaires, which may have deprived the study of more objective assessment of erectile dysfunction and quality of life. Optimal time for clamp removal is 5 days, given patient convenience and good circumcision outcome.

A total of 37 men (63.8%) reported mild pain during clamp removal. There was a significant correlation between reported pain and the number of days before removal. Men who complained of pain due to a clamp period of greater than 5 days were twice as likely to report pain during clamp removal.

Compliance with scheduled followup was excellent. One man (1.7%) was lost to followup and efforts to trace him proved futile. He had no problems at the preceding followup reviews and this probably remained as such. Overall this could reflect satisfaction with this method of male circumcision despite our limited sample size and lack of comparison with other methods, which are our main study limitations. By week 3 all cases had healed well with good cosmesis.

Alisklamp can have a major role in scaling up voluntary medical male circumcision to avert the 2 to 8 million HIV infections projected in 20 years.[3] With impressive findings in a comparative study of 7,500 pediatric patients in Turkey in whom the rate of adverse events was 2%, this device could be safe for male circumcision across all ages.[13]

## CONCLUSIONS

Alisklamp has an excellent safety profile and excellent acceptability among men who undergo circumcision using the device. This technique is easy to teach and it would prove a handy device for scaling up male circumcision. Based on the findings of this study the device merits a comparative clinical trial.

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