

# A RANDOMISED FIELD TRIAL OF UNICIRC, A SINGLE-USE SURGICAL ASSIST MALE CIRCUMCISION INSTRUMENT



## BACKGROUND

The World Health Organization has recommended Voluntary Medical Male Circumcision (VMMC) as an essential component of HIV prevention in countries with a high burden. Current VMMC methods are relatively expensive and have limitations when it comes to scaling up at national level. This has led to a number of promising new VMMC methods.

The Unicirc offers one such method. Circumcision with the Unicirc is a closed procedure which uses a disposable surgical instrument, which can be used with a topical anaesthetic and cyanoacrylate tissue adhesive.

## METHOD

The study was a non-blinded randomised controlled field trial with 2:1 allocation ratio comparing open surgical circumcision under local anaesthetic and wound sealing with cyanoacrylate tissue adhesive. Seventy-five (75) men seeking VMMC were recruited by poster and through word of mouth from three clinics associated with Andrew Saffy Memorial Hospital serving the Lonmin group of platinum mines in Rustenberg in the North West Province of South Africa between 15 July and 7 August 2015.

The primary outcome was intraoperative time, while the secondary outcomes were intraoperative pain, post-operative pain, rate of adverse events, wound proportion that healed at four weeks, patient satisfaction and cosmetic result.

## RESULTS

	Unicirc	Open surgical
Intraoperative suturing, n (0%)	2 (4)	All by protocol
Operative time (min), median (IQR)	12 (11, 17)	25 (21, 35)
Estimated blood loss (ml) median (IQR)	1.5 (1.2)	40 (40, 50)
Intraoperative pain (10-point scale) (mean, SD)	1.7 (1.3)	1.9 (2.4)
Post-operative pain (10-point scale) (mean, SD)	1.0 (0.9)	1.4 (1.60)

The intraoperative time and blood loss was less with the Unicirc method, with a median duration of 12 vs 25 minutes ( $p < 0.001$ ) and a median blood loss of 1.5 vs 40 ml ( $p < 0.001$ ). The Unicirc method had a greater proportion of participants with a healed wound at four weeks when compared to the open surgical method (90.7% vs 69.6%) and cosmetic results were superior in the Unicirc group, while the rate of adverse events were similar in both groups.

## CONCLUSION

VMMC with the Unicirc, with topical anaesthetic and wound sealing with cyanoacrylate tissue adhesive, is rapid, with less blood loss, faster healing and superior cosmetic results. It is potentially also safer than open surgical VMMC.

## LITERATURE CITED

[www.unicircglobal.com](http://www.unicircglobal.com)  
<http://journals.plos.org/plosone/article?id=10.1371%2Fjournal.pone.0157065>  
<http://www.timeslive.co.za/thetimes/2016/06/22/Cutting-edge-circumcision-in-SA>



## SAFE, NEEDLE-LESS, BLOODLESS AND SUTURELESS PROCEDURE

The circumcision method with the Unicirc device, using topical anaesthesia and tissue adhesive, is a simple two-step application and removal procedure. The entire application - from start to finish - is done in approximately 12 minutes.

This means a complete surgical circumcision is performed at a single visit. No needles and no sutures are involved in the procedure.

### Preparation

- Apply topical anaesthesia



### Step 1: Application

- Apply transparent tube



### Step 2: Removal

- Remove foreskin and then remove device
- Complete the procedure by applying tissue adhesive and tape
- Glans protected at all times



## RAPID HEALING AND EXCELLENT COSMETIC RESULTS

Circumcision is completed at a single visit. Rapid healing happens by primary intention. Minimal post-operative pain.

Circumcision with the Unicirc ensures excellent cosmetic results.

At 28 days, 90.7% of wound healing is completed.

