

1.0 BACKGROUND

- PrePex™ is a nonsurgical circumcision device being promoted to speed up the scale-up of voluntary medical male circumcision (VMMC) in Africa.
- Concerns over odour and the risk of anaerobic infection such as tetanus when the foreskin is left for a week, undermines its acceptability.
- A modified PrePex™ procedure where the foreskin is removed on day 0 (Day 0 Foreskin Removal Procedure (Day0 FRP)) may address these concerns.
- We assessed the safety and acceptability of the Day0 foreskin removal procedure in adolescent and adult men aged 13-49 years seeking VMMC services Kisumu, Kenya.



2.0 METHODS

Study design: A phase IV, open-label, single-center, single-arm study.

PrePex Device Procedures

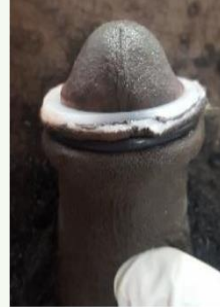
PrePex Device Application



Numbness Assessment



Foreskin Removal



Follow-up: Phone follow-up on days 3, 21, 28, 35 and 42 and in-person follow-up on Days 7, 14 and 49.

Analysis: Percentages were used to summarize selected attributes on safety and acceptability.

3.0 RESULTS

3.1 Socio-Demographics and Behavioural Characteristics

Enrolled: 515

Age Group: 45 (8.7%) 13-17 years; **470 (91.3%)** 18-49 years

Employment: 341 (81.1%), salaried or self-employed

Marital Status: 223 (52.1%), married

Having more than 1 Sexual Partner: 129 (11.8%)

Not using Condom Consistently: 186 (44.1%)

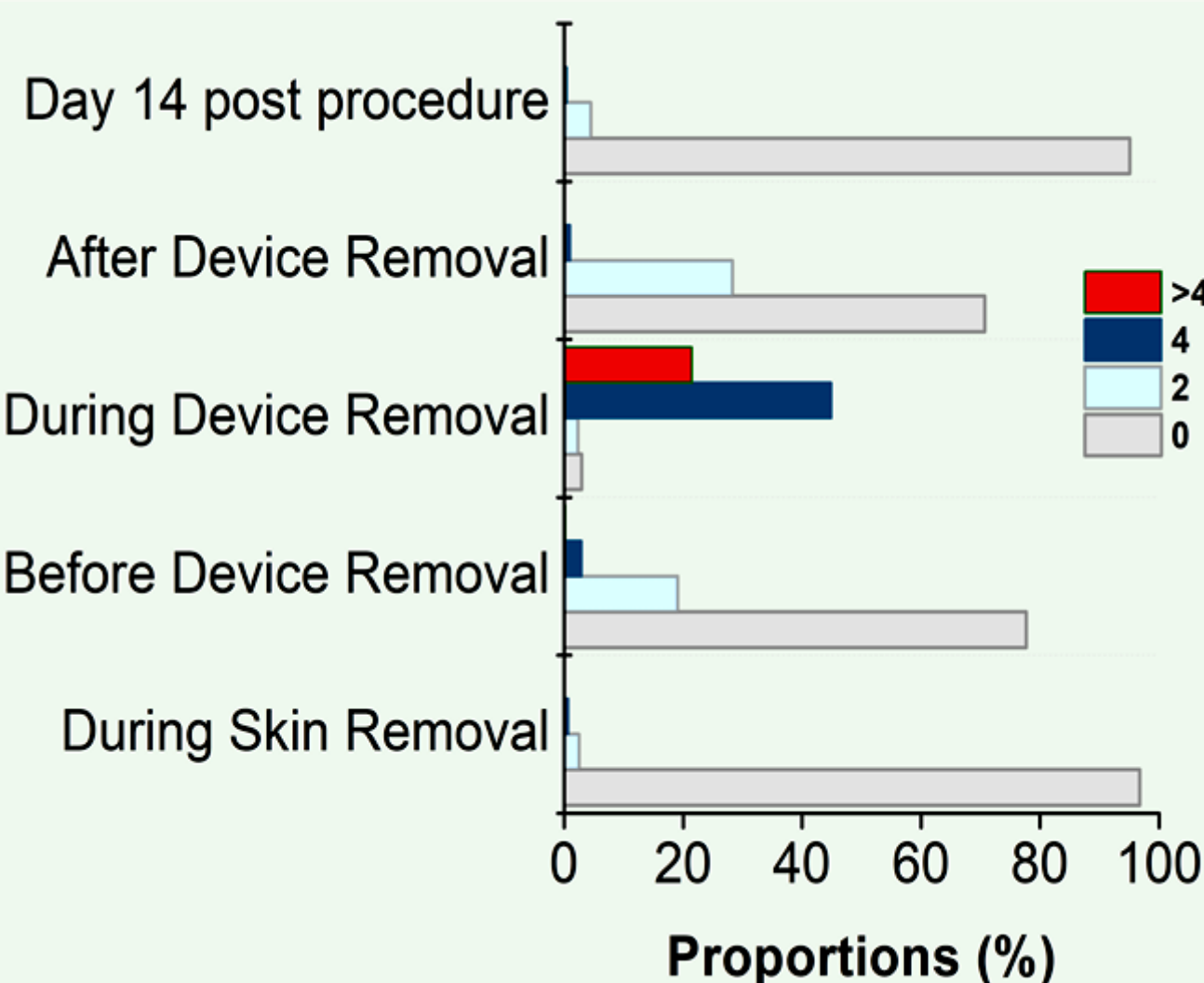
Fig. 1. Map of estimated HIV prevalence in Nyanza region, Kenya *



* Kisumu is one of counties in the Nyanza region with high HIV prevalence and home to the Luo community that constitute approximately 70% of Kenya's traditionally non-circumcising ethnic groups.

3.2 Pain levels

Fig. 2. VAS pain levels during the circumcision and follow ups*



* Visual analog score (VAS): 0 - No pain; 2 – hurts just a little; 4 – hurts just a little more; 6 – hurts even more; 8 – hurts a whole lot; 10 – hurts worse

- Pain was highest (2, IQR; 2-4) during device removal

3.3. Adverse Events (AEs)

- 3 Moderate AEs** (2 self-removals and 1 device displacement)
- 1 SAE** (suspected mild tetanus not related to MC procedure and Prepex device).



Table 1. Adverse events (AEs) observed during the study

Time points	Number of AE (n)	Rate of AE (%)	95% CI
Day 0 - 7	3	0.58	0.11 - 1.78
Day 7 - 14	0	0	
Day 14 - 21	1	0.19	0.01 - 1.21
Day 21 - 49	0	0	
Total	4	0.78*	0.23 - 2.06

* Overall AE rate was lower than the hypothesized rate of 0.95% for the study

3.4 Post device placement concerns

- Odour - 2.3%** reported unusual odour
- Wound healing – 3%** were not fully healed by day 49
- Voiding - 5% (25/496)** had difficulty in passing urine.
- Disturbance - 5% (23/511)** reported that wearing the device affected their usual daily activities.

4.0 CONCLUSION

- Day 0 FRP PrePex™ circumcision is acceptable and relatively safe
- The method should be offered for men concerned with surgical circumcision or odour following PrePex Day 7 FRP.