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.

**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 (61.1%), 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%)

3.2 Pain levels

![VAS pain levels during the circumcision and follow ups](image)

3.3. Adverse Events (AEs)

<table>
<thead>
<tr>
<th>Time point</th>
<th>Number of AE (n)</th>
<th>Rate of AE (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 0-7</td>
<td>3</td>
<td>0.58 (0.11 - 1.78)</td>
</tr>
<tr>
<td>Day 7 - 14</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Day 14 - 21</td>
<td>1</td>
<td>0.19 (0.01 - 1.21)</td>
</tr>
<tr>
<td>Day 21 - 49</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>4</td>
<td>0.78* (0.23 - 2.06)</td>
</tr>
</tbody>
</table>

*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% (23/451) 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.

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