World Health Organization

4.1

PREVENTING HIV THROUGH SAFE VOLUNTARY MEDICAL MALE CIRCUMCISION FOR ADOLESCENT BOYS AND MEN IN GENERALIZED HIV EPIDEMICS

WEB ANNEX 4.1

GRADE TABLES, SUMMARY OF STUDIES AND EVIDENCE-TO-DECISION TABLE ON SAFETY AND ACCEPTABILITY OF MALE CIRCUMCISION DEVICES: COLLAR CLAMP, ELASTIC COLLAR COMPRESSION AND SURGICAL ASSIST DEVICES

Preventing HIV through safe voluntary medical male circumcision for adolescent boys and men in generalized HIV epidemics: recommendations and key considerations. Web Annex 4.1. GRADE tables, summary of studies and evidence-to-decision table on safety and acceptability of male circumcision devices: collar clamp, elastic collar compression and surgical assist devices

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WEB ANNEX 4.1
GRADE TABLES, SUMMARY OF STUDIES AND EVIDENCE-TO-DECISION TABLE ON SAFETY AND ACCEPTABILITY OF MALE CIRCUMCISION DEVICES: COLLAR CLAMP, ELASTIC COLLAR COMPRESSION AND SURGICAL ASSIST DEVICES

Contents

Table A4.1.1. GRADE evidence profile: PICO question. Can the collar clamp device (conventional placement technique) be used as an alternative to surgery in men ages 15–49 years seeking circumcision for HIV prevention?

Author(s): Tim Farley

Date: 11-10-2018 (updated 20-08-2019)

Question: Can collar clamp device (conventional placement technique) be used as an alternative to surgery in men ages 15–49 years seeking circumcision for HIV prevention?

Settings: Low resource settings

Quality assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Collar clamp device	Surgery	Relative (95% CI)	Absolute (95% CI)	Quality	Importance
Efficacy (complement of failure, assessed with: proportion of clients requiring an additional intervention to complete circumcision)												
3 [1,2]	randomized trials (Africa)	some risk of bias [a]	no serious inconsistency	no serious indirectness	some imprecision [b]	none	1/264 (0.4%)	0/273 (0.0%)	RR 1.66 (0.21 to 13)	10 more per 1000 (from 10 fewer to 30 more)	●●●○ MODERATE	CRITICAL
2 [3,4]	concurrent cohorts (Africa)	some risk of bias [a]	no serious inconsistency	no serious indirectness	some imprecision [b]	none	7/841 (0.8%)	0/247 (0.0%)	RR 2.4 (0.30 to 19)	8 more per 1000 (from 2 to 14 more)	●●○○ LOW	CRITICAL
6 [5-9]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	no serious imprecision	none	3/2235 (0.1%)				●●○○ LOW	CRITICAL
1 [10]	randomized trial (China)	some risk of bias [a]		serious indirectness [c]	some imprecision [b]	none	0/314 (0.0%)	0/314 (0.0%)	not estimatable	not estimatable	●○○○ VERY LOW	CRITICAL
5 [11–15]	observational cohorts (China)		no serious inconsistency	serious indirectness [c]	no serious imprecision	none	2/2252 (0.1%)				●○○○ VERY LOW	CRITICAL
Safety (severe and moderate adverse events, assessed with: proportion of clients experiencing event)												
3 [1,2]	randomized trials (Africa)	some risk of bias [a]	some inconsistency [d]	no serious indirectness	some imprecision [b]		33/263 (12.5%)	20/273 (7.3%)	RR 1.8 (1.1 to 3.0)	15 more per 1000 (from 24 fewer to 54 more)	●●○○ LOW	CRITICAL
2 [3,4]	concurrent cohorts (Africa)	some risk of bias [a]	no serious inconsistency	no serious indirectness	some imprecision [b]		10/834 (1.2%)	1/247 (0.4%)	RR 1.9 (0.33 to 10)	11 more per 1000 (from 0 to 21 more)	●●○○ LOW	CRITICAL
6 [5–9]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	no serious imprecision	none	36/2232 (1.6%)				●●○○ LOW	CRITICAL
1 [10]	randomized trial (China)	some risk of bias [a]		serious indirectness [c]	no serious imprecision	none	87/314 (27.7%)	105/314 (33.4%)	RR 0.83(0.65 to 1.05)	57 fewer per 1000 (from 129 fewer to 15 more)	●○○○ VERY LOW	CRITICAL
5 [11–15]	observational cohorts (China)		no serious inconsistency	serious indirectness [c]	no serious imprecision	none	84/2252 (3.7%)				●○○○ VERY LOW	CRITICAL

Table A4.1.1. (continued)

Quality assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Collar clamp device	Surgery	Relative (95% CI)	Absolute (95% CI)	Quality	Importance
Procedure times (assessed with: duration of device placement or surgical procedure)												
2 [1]	randomized trials (Africa)	some risk of bias [a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	197 (mean 7.2, SD 2.0 minutes)	201 (mean 20.3, SD 4.7 minutes)		mean 12.8 minutes shorter (from 12.2 to 13.4 minutes shorter)	●●●○ MODERATE	IMPORTANT
2 [3,4]	concurrent cohorts (Africa)	some risk of bias [a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	838 (mean 5.7, SD 2.4 minutes)	247 (mean 14.9, SD 5.6 minutes)		mean 7.9 minutes shorter (from 7.3 to 8.5 minutes shorter)	●●●○ MODERATE	IMPORTANT
5 [5,7-9]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	no serious imprecision	none	2180 (mean 7.1, SD 3.0 minutes)				●●○○ LOW	IMPORTANT
1 [10]	randomized trial (China)	some risk of bias [a]		serious indirectness [c]	no serious imprecision	none	314 (mean 5.9, SD 2.3 minutes)	314 (mean 21.4, SD 5.8 minutes)		mean 15.5 minutes shorter (from 14.8 to 16.2 minutes shorter)	●●○○ LOW	IMPORTANT
3 [11,13,14]	observational cohorts (China)		no serious inconsistency	serious indirectness [c]	no serious imprecision	none	2192 (mean 3.7, SD 2.6 minutes)				●●○○ LOW	IMPORTANT
Procedure times (assessed with: duration of device removal procedure)												
10 [1,3-9]	randomized trials, concurrent cohorts and observational cohorts (Africa)		no serious inconsistency	no serious indirectness	no serious imprecision	none	3236 (mean 4.0, SD 2.0 minutes)				●●○○ LOW	IMPORTANT
1 [14]	observational cohort (China)			serious indirectness [c]	no serious imprecision	none	74 (mean 1.4, SD 0.4 minutes)				●○○○ VERY LOW	IMPORTANT
Pain during device placement (assessed with: client-reported pain on visual analogue scale (0 = no pain at all; 10 = worst pain imaginable))												
3 [1,2]	randomized trials (Africa)	some risk of bias [a]	no serious inconsistency	no serious indirectness	no serious imprecision	subjective pain scale	263 (mean 3.1, SD 2.2)	273 (mean 3.3, SD 1.9)		mean 0.1 higher (from 0.2 lower to 0.4 higher)	●●●○ MODERATE	IMPORTANT
2 [7]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	no serious imprecision	subjective pain scale	1147 (mean 1.5, SD –)				●●○○ LOW	IMPORTANT
1 [10]	randomized trial (China)	some risk of bias [a]		serious indirectness [c]	no serious imprecision	subjective pain scale	314 (mean 5.8, SD 2.1)	314 (mean 6.2, SD 2.2)		mean 0.4 lower (from 0.1 to 0.7 lower)	●●○○ LOW	IMPORTANT
2 [12,14]	observational cohorts (China)		no serious inconsistency	serious indirectness [c]	no serious imprecision	subjective pain scale	134 (mean 0.3, SD 0.6)				●●○○ LOW	IMPORTANT
Pain during device removal (assessed with: client-reported pain on visual analogue scale (0 = no pain at all, 10 = worst pain imaginable))												
3 [5,6,9]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	no serious imprecision	subjective pain scale	565 (mean 2.3, SD 1.6)				●●○○ LOW	IMPORTANT
3 [12–14]	observational cohorts (China)		some inconsistency [e]	serious indirectness [c]	no serious imprecision	subjective pain scale	1054 (mean 4.5, SD 1.4)				●○○○ VERY LOW	IMPORTANT

Table A4.1.1. (continued)

Quality assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Collar clamp device	Surgery	Relative (95% CI)	Absolute (95% CI)	Quality	Importance
Time to wound healing (assessed with: clinician-assessed days to complete healing)												
2 [1]	randomized trials (Africa)	some risk of bias [a]	some inconsistency [f]	no serious indirectness	no serious imprecision	one study excluded [g]	190 (mean 44.2, SD 11.6 days)	195 (mean 39.0, SD 9.4 days)		mean 5.5 days longer (from 3.5 to 7.6 days longer)	⨁⨁◯◯ LOW	IMPORTANT
1 [5]	observational cohort (Africa)		no serious inconsistency	no serious indirectness	some imprecision [b]	none	32 (mean 28.9, SD 7.0 days)				⨁⨁◯◯ LOW	IMPORTANT
1 [10]	randomized trial (China)	some risk of bias [a]		serious indirectness [c]	no serious imprecision	none	314 (mean 19.5, SD 6.3 days)	314 (mean 23.6, SD 9.3 days)		mean 4.1 days shorter (from 2.9 to 5.3 days shorter)	⨁⨁◯◯ LOW	IMPORTANT
2 [13,14]	observational cohorts (China)		some inconsistency [h]	serious indirectness [c]	no serious imprecision	none	992 (mean 13.3, SD 3.6 days)				⨁◯◯◯ VERY LOW	IMPORTANT
Time to wound healing (assessed with: clinician-assessed proportion healed by 6 weeks after device placement or surgery)												
2 [1]	randomized trials (Africa)	some risk of bias [a]	some inconsistency	no serious indirectness	no serious imprecision	one study excluded [g]	145/190 (76.3%)	167/195 (85.6%)	RR 0.89 (0.82 to 0.96)	99 fewer per 1000 (from 33 to 166 fewer per 1000)	⨁⨁◯◯ LOW	IMPORTANT
2 [3,4]	concurrent cohorts (Africa)	some risk of bias [a]	no serious inconsistency	no serious indirectness	no serious imprecision	assessed at 4 weeks	709/813 (87.0%)	239/240 (100%)	RR 0.89 (0.86 to 0.91)	117 fewer per 1000 (from 93 to 140 fewer per 1000)	⨁⨁◯◯ LOW	IMPORTANT
5 [6-9]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	no serious imprecision	none	1862/2173 (85.7%)				⨁⨁◯◯ LOW	IMPORTANT
Client satisfaction (assessed with: proportion of clients satisfied or very satisfied with appearance of penis)												
3 [1,2]	randomized trials (Africa)	some risk of bias [a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	231/253 (91.3%)	194/265 (73.2%)	RR 1.20 (1.12 to 1.29)	165 more per 1000 (from 108 to 223 more)	⨁⨁⨁◯ MODERATE	CRITICAL
2 [3,4]	concurrent cohorts (Africa)	some risk of bias [a]	no serious inconsistency	no serious indirectness	no serious imprecision	none	807/813 (99.3%)	240/240 (100%)	RR 0.99 (0.99 to 1.00)	7 fewer per 1000 (from 1 to 13 fewer)	⨁⨁⨁◯ MODERATE	CRITICAL
7 [5-9,16]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	no serious imprecision	none	2254/2328 (96.8%)				⨁⨁◯◯ LOW	CRITICAL
1 [10]	randomized trial (China)	some risk of bias [a]		serious indirectness [c]	no serious imprecision	none	231/314 (73.6%)	66/314 (21.0%)	RR 3.50 (2.80 to 4.38)	525 more per 1000 (from 459 to 592 more)	⨁⨁◯◯ LOW	CRITICAL
1 [11]	observational cohort (China)			serious indirectness [c]	no serious imprecision	none	1156/1200 (96.3%)				⨁◯◯◯ VERY LOW	CRITICAL

Table A4.1.1. (continued)

CI = confidence interval; RR = relative risk; SD = standard deviation

Notes

[a] Study personnel not blinded
[b] Small number of events
[c] Clients and providers from China only
[d] Approximately threefold higher proportion of clients with AEs in one RCT
[e] Lower pain scores with removal at two weeks instead of one week
[f] Large difference in healing times between study arms in one but not the other RCT
[g] One RCT [2] excluded from summary results as healing definitions not well standardized plus poor and differential follow-up between study arms
[h] Inconsistent definitions of healing between studies

Table A4.1.2. GRADE evidence profile: PICO question. Can the collar clamp device (no-flip placement technique) be used as an alternative to surgery in men ages 15–49 years seeking circumcision for HIV prevention?

Author(s): Tim Farley

Date: 11-10-2018 (updated 20-08-2019)

Question: Can the collar clamp device (no-flip placement technique) be used as an alternative to surgery in men ages 15–49 years seeking circumcision for HIV prevention?

Settings: Low resource settings

Quality assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Collar clamp device	Surgery	Relative (95% CI)	Absolute (95% CI)	Quality	Importance
Efficacy (complement of failure, assessed with: proportion of men requiring an additional intervention to complete circumcision)												
3 [17–19]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	some imprecision [a]	none	1/654 (0.2%)				●●○○ LOW	CRITICAL
1 [20]	concurrent cohort (China)			serious indirectness [b]	some imprecision	none	0/408 (0.0%)	0/94 (0.0%)	not estimatable	not estimatable	●○○○ VERY LOW	CRITICAL
2 [21,22]	observational cohorts (China)		no serious inconsistency	serious indirectness [b]	some imprecision [a]	none	0/166 (0.0%)				●○○○ VERY LOW	CRITICAL
Safety (severe and moderate adverse events, assessed with: proportion of clients experiencing event)												
3 [17–19]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	some imprecision [a]	none	17/654 (2.6%)				●●○○ LOW	CRITICAL
1 [20]	concurrent cohort (China)			serious indirectness [b]	no serious imprecision	none	11/408 (2.7%)	9/94 (9.6%)	RR 0.28 (0.12 to 0.66)	69 fewer per 1000 (from 7 to 130 fewer)	●○○○ VERY LOW	CRITICAL
2 [21,22]	observational cohorts (China)		no serious inconsistency	serious indirectness [b]	some imprecision [a]	none	4/166 (2.4%)				●○○○ VERY LOW	CRITICAL
Procedure duration (assessed with: duration of device placement)												
3 [17–19]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	some imprecision [a]	none	652 (mean 5.9, SD 2.4 minutes)				●●○○ LOW	IMPORTANT
1 [20]	concurrent cohort (China)			serious indirectness [b]	no serious imprecision	none	306 (mean 4.8, SD 0.9 minutes)	76 (mean 23.4, SD 4.3 minutes)		18.6 minutes shorter (from 17.6 to 19.6 minutes shorter)	●○○○ VERY LOW	IMPORTANT
2 [21,22]	observational cohorts (China)		no serious inconsistency	serious indirectness [b]	some imprecision [a]	none	166 (mean 6.4, SD 1.5 minutes)				●○○○ VERY LOW	IMPORTANT
Duration of device removal (assessed with: duration of removal procedure)												
2 [17,18]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	some imprecision [a]	none	223 (mean 3.0, SD 2.9 minutes)				●●○○ LOW	IMPORTANT
1 [22]	observational cohort (China)			serious indirectness [b]	some imprecision [a]	none	62 (mean 5.6, SD 1.4 minutes)				●○○○ VERY LOW	IMPORTANT

Table A4.1.2. (continued)

Quality assessment							No. of patients		Effect			
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Collar clamp device	Surgery	Relative (95% CI)	Absolute (95% CI)	Quality	Importance
Pain on device placement (assessed with: client-reported pain on visual analogue scale (0 = no pain at all; 10 = worst pain imaginable))												
1 [19]	observational cohort (Africa)			no serious indirectness	some imprecision [a]	subjective pain scale	344 (mean 0.2, SD 0.5 minutes)				●●○○ LOW	IMPORTANT
1 [20]	concurrent cohort (China)			serious indirectness [b]	no serious imprecision	subjective pain scale	306 (mean 1.8, SD 1.3 minutes)	76 (mean 3.1, SD 1.4 minutes)		score 1.3 lower (from 1.0 to 1.6 lower)	●●○○ LOW	IMPORTANT
2 [21,22]	observational cohorts (China)		no serious inconsistency	serious indirectness [b]	no serious imprecision	subjective pain scale	166 (mean 0.5, SD 1.0)				●○○○ VERY LOW	IMPORTANT
Pain on device removal (assessed with client-reported pain on visual analogue scale (0 = no pain at all; 10 = worst pain imaginable))												
2 [17,18]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	no serious imprecision	subjective pain scale	214 (mean 4.2, SD 2.6)				●●○○ LOW	IMPORTANT
1 [22]	observational cohort (China)			serious indirectness [b]	no serious imprecision	subjective pain scale	62 (mean 5.0, SD 2.1)				●○○○ VERY LOW	IMPORTANT
Time to wound healing (assessed with: clinician-assessed days to complete healing)												
2 [17,18]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	no serious imprecision	none	299 (mean 34, SD 10 days)				●●○○ LOW	IMPORTANT
1 [22]	observational cohort (China)			serious indirectness [b]	no serious imprecision	none	62 (mean 30, SD 5 days)				●○○○ VERY LOW	IMPORTANT
Time to wound healing (assessed with: clinician assessed proportion healed by 6 weeks after device placement)												
2 [18,19]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	no serious imprecision	none	486/552 (88.0%)				●●○○ LOW	IMPORTANT
Client satisfaction (assessed with: proportion of clients satisfied or very satisfied with appearance of penis)												
3 [17–19]	observational cohorts (Africa)		no serious inconsistency	no serious indirectness	no serious imprecision	none	592/615 (96.3%)				●●○○ LOW	CRITICAL
1 [20]	concurrent cohort (China)			serious indirectness [b]	no serious imprecision	none	295/306 (96.4%)	55/76 (72.4%)	RR 1.33 (1.16 to 1.53)	240 more per 1000 (from 138 to 343 more)	●●○○ LOW	CRITICAL
1 [21]	observational cohort (China)		no serious inconsistency	serious indirectness [b]	no serious imprecision	none	90/104 (86.5%)				●●○○ LOW	CRITICAL

CI = confidence interval; RR = relative risk; SD = standard deviation

Notes

[a] Small numbers

[b] Clients and providers in China only

Table A4.1.3. Studies of collar clamp device (conventional placement technique), by date order within region and design

Reference	Country	Design [a]	Period	Exposure [b]	Age range	Outcome(s)	Notes
Africa – randomized controlled trials							
Sokal 2014 [1]	Kenya	RCT (2 m, 95%)	Mar 2011 – Jun 2011	Shang Ring™ (97) surgical MC (103)	18–38 y (median 19 y)	pain, AEs, satisfaction, cosmetic result, healing, procedure times	
Sokal 2014 [1]	Zambia	RCT (2 m, 95%)	Mar 2011 – Jun 2011	Shang Ring™ (100) surgical MC (98)	18–41 y (median 22 y)	pain, AEs, satisfaction, cosmetic result, healing, procedure times	
Kanyago 2013 [2]	Uganda	RCT (3 w, NS)	Apr 2011 – May 2011 *	Shang Ring™ (66) forceps-guided MC (72)	median 22 y [IQR 21–23 y]; range not stated	procedure times, healing, AEs, pain, satisfaction	* From clinicaltrials.gov record NCT01757938
Africa – concurrent cohort studies							
Kigozi 2013 [3]	Uganda	self-selection concurrent cohort (4 w, 97%)	not stated; assumed May 2012 – Oct 2012	Shang Ring™ (508) dorsal slit MC (113)	>18 y (mean 25 y, estimated from frequency distribution)	AEs, healing, procedure times, post-circumcision sex	
Kigozi 2014 [4]	Uganda	self-selection concurrent cohort (4 w, 97%)	May 2013 – Nov 2013 †	Shang Ring™ (337) dorsal slit MC (80)	13–17 y (mean 15 y)	AEs, healing, procedure times, post-circumcision sex	† G Kigozi, personal communication
Africa – observational cohorts							
Barone 2011 [5]	Kenya	cohort (6 w, 80%)	Oct 2009 – Feb 2010	Shang Ring™ (40)	18–45 y (median 21 y)	procedure times, pain, healing, AEs, satisfaction	
Barone 2012 [6]	Kenya	RCT (6 w, 86%)	Sep 2010 – Jan 2011	Shang Ring™ with scheduled removal on Day 7 (15), Day 14 (15) or Day 21 (20)	18–38 y (median 21 y)	AEs, time to spontaneous detachment, healing	
Sokal 2014 [7]	Kenya	field study (6 w, 95%)	Feb 2012 – May 2012	Shang Ring™ (554)	18–54 y (mean 22 y)	AEs, healing, satisfaction	included 48 men with HIV infection. Long-term follow-up reported in Feldblum 2015.17
Sokal 2014 [7]	Zambia	field study (6 w, 95%)	Feb 2012 – May 2012	Shang Ring™ (595)	18–54 y (mean 26 y)	AEs, healing, satisfaction	included 36 men with HIV infection
Feldblum 2015 [16]	Kenya	cohort (32 m, 35%)	2012	Shang Ring™ (194)	>18 y (mean 25 y)	cosmetic result, acceptability, satisfaction	Extended follow-up of subset of 552 men in field study in Kenya (Sokal 2014 [7]). No data on short-term operative outcomes.
Feldblum 2016 [8]	Zambia	RCT (6 w, 98%)	Oct 2014 – Jul 2015	Shang Ring™ standard (255) or reduced (241) ring size inventory	18–49 y (median 24 y)	AEs, healing, satisfaction	
Feldblum 2016 [9]	Malawi	cohort (6 w, 99%)	May 2015 – Oct 2015	Shang Ring™ (498)	18–49 y (mean 21 y)	pain, AEs, acceptability, healing	
China – randomized trial							
Lv 2014 [10]	China	RCT	Oct 2012 – May 2013	Shang Ring™ (314) surgical MC (314)	18–58 y (mean 32 y)	procedure times, healing, pain, cosmetic result, satisfaction	Study included a third arm circumcised with the Langhe Disposable Circumcision Suture Device.

Table A4.1.3. (continued)

Reference	Country	Design [a]	Period	Exposure [b]	Age range	Outcome(s)	Notes
China – observational cohorts							
Peng 2008 [11]	China	cohort (NS)	Oct 2005 – Sep 2007	Shang Ring™ (1200)	5–95 y	AEs, pain, cosmetic result	
Peng 2010 [12]	China	cohort (1 w, 100%)	Jun 2009 – Sep 2009	Shang Ring™ (60)	7–50 y (mean 25 y)	AEs, intraoperative pain, need for supplemental injectable anaesthesia	local anaesthesia with jet injection technique
Wu 2013 [13]	China	cohort (1 m, 100%)	2010–2012	Shang Ring™ (918)	adults [18–65 y] (702) children [7–17 y] (216)	AEs, pain, healing time	
Cheng 2012 [14]	China	RCT (4 w, 100%)	Dec 2011 – Feb 2012	Shang Ring™ with next smaller (39) or next larger (35) ring size	not stated	AEs, procedure times, healing, pain	Clients with penis size falling between two ring sizes were randomized to next higher or next lower ring size.
Cheng 2014 [15]	China	cohort (median 19 m, range 9–28 m)	2009–2012	Shang Ring™ (103)	2–40 y (mean 28 y)	cosmetic result, healing, sexual performance 1–2 y after circumcision	no data on short-term operative outcomes
Chinese language, full text only							
Cheng 2009 [23]	China	cohort (NS)	not stated	Shang Ring™ (328)	18–58 y (mean 28 y)	AEs, pain, wound healing, procedure times, satisfaction	
Li 2010 [24]	China	RCT (NS)	not stated	Shang Ring™ (402) surgical MC (322)	not stated	procedure duration, blood loss, satisfaction	
Peng 2010 [25]	China	cohort (NS)	not stated	Shang Ring™ (351)	4–58 y (mean 31 y)	AEs	
Cheng 2011 [26]	China	concurrent cohort (NS)	not stated	Shang Ring™ (479) surgical MC (354)	not stated	AEs, pain, wound healing, procedure times, satisfaction, costs	
Wang 2013 [27]	China	concurrent cohort (NS)	not stated	conventional circumcision (279) sleeve circumcision (354) Shang Ring™ (258)	not stated	procedure times, pain, wound healing, satisfaction, complications	
Liu 2014 [28]	China	RCT (NS)	not stated	Shang Ring™ (65) surgical MC (65)	not stated	procedure times, blood loss, pain, satisfaction, AEs	
Xie 2014 [29]	China	concurrent cohort (NS)	not stated	Shang Ring™ (254) no-flip Shang Ring™ (273)	not stated	procedure times, pain, wound healing, satisfaction, complications	
Tang 2016 [30]	China	concurrent cohort (NS)	not stated	Shang Ring™ (422) electrotome (120)	not stated	procedure times, pain, wound healing, satisfaction	
Wang 2016 [31]	China	concurrent cohort (1 m, NS)	Jun 2013 – Mar 2015	Shang Ring™ (158) Disposable Circumcision Suture Device (162)	not stated	procedure times, pain, wound healing, satisfaction, complications	

AEs = adverse events; MC = male circumcision; RCT = randomized controlled trial; y = years

Notes

[a] Type of study (longest duration of follow-up [d = day, w = week, m = month, NS = duration not stated], percentage of clients followed to specified duration)

[b] Number of clients exposed to circumcision method

Table A4.1.4. Studies of collar clamp device (no-flip placement technique), by date order within region and design

Reference	Country	Design [a]	Period	Exposure [b]	Age range	Outcome(s)	Notes
Africa – observational cohorts							
Awori 2017 [17]	Kenya	bridging study (6 w, 95%)	Jul 2013 – Nov 2013	no-flip Shang Ring™ (80)	3 m-17 y (mean 7 y)	procedure times, AEs, healing, satisfaction	
Barone 2019 [18]	Kenya	RCT (6 w, 98%)	May 2015 – Sep 2015	no-flip Shang Ring™ with scheduled Day 7 removal (114) or spontaneous detachment (116)	10–54 y (mean 18.2 y)	time to ring detachment or removal, AEs, healing	
Awori 2019 [19]	Kenya	RCT (6 w, 95%)	Nov 2015 – Jul 2016	no-flip Shang Ring™ with topical (226) or injectable (118) anaesthesia	>10 y (mean 17 y)	pain, procedure times, AEs, healing, satisfaction	
China – concurrent cohort							
Lei 2016 [20]	China	self-selection concurrent cohort (4 w, 76%)	Oct 2012 – Apr 2014	no-flip Shang Ring™ (408) dorsal slit MC (94)	18–76 y (mean 25 y)	AEs, pain, procedure times, satisfaction	devices not actively removed at 7 days
China – observational cohorts							
Fang 2018 [21]	China	RCT (3 m, 100%)	Jan 2013 – Sep 2013	no-flip Shang Ring™ sized from measur-ing tape (32), diameter of penis (37) or diameter of glans (35)	6–14 y (mean 10 y)	duration of surgery, need for dorsal slit, pain scores, complications, satisfaction	
Han 2017 [22]	China	RCT (1 m, 100%)	Feb 2014 – Oct 2014	no-flip Shang Ring™ (62) Henry Medical penile circumcision suturing device (PCSD) (62)	18–65 y (mean 27 y)	blood loss, pain, scar, healing, cosmetic result, AEs	Reported data on clients allocated to Henry Medical PCSD arm are not included in summary of no-flip Shang Ring™ technique, as comparability of PCSD with conventional surgical circumcision is not well established.
Chinese language, full text only							
Xie 2014 [29]	China	concurrent cohort (NS)	2009–2012	Shang Ring™ (254) no-flip Shang Ring (273)	18–54 y (mean 35 y)	procedure times, pain, wound healing, satisfaction, complications	
Yang 2014 [32]	China	cohort (NS)	Jan 2011 – Sep 2013	no-flip Shang Ring™ (528)	18–58 y (mean 35 y)	procedure times, blood loss, pain, wound healing, satisfaction, complications, time to spontaneous detachment in subset	
Lei 2014 [33]	China	cohort (4 w, NS)	Mar 2012 – Sep 2012	no-flip Shang Ring™ (167)	18–72 y (mean 28 y)	AEs, pain, procedure times	

AEs = adverse events; MC = male circumcision; PCSD = penile circumcision suturing device; RCT = randomized controlled trial; y = years

Notes

[a] Type of study (longest duration of follow-up [d = day, w = week, m = month, NS = duration not stated], percentage of clients followed to specified duration)

[b] Number of clients exposed to circumcision method

References for Tables A4.1.1–A4.1.4

1. Sokal DC, Li PS, Zulu R, Awori QD, Combes SL, Simba RO, et al. Randomized controlled trial of the Shang Ring versus conventional surgical techniques for adult male circumcision: safety and acceptability. J Acquir Immune Defic Syndr. 2014; 65(4): 447–55.
2. Kanyago S, Riding DM, Mutakooha E, Lopez de la OA, Siedner MJ. Shang Ring versus forceps-guided adult male circumcision: a randomized, controlled effectiveness study in southwestern Uganda. J Acquir Immune Defic Syndr. 2013; 64(2): 130–3.
3. Kigozi G, Musoke R, Watya S, Kighoma N, Ssebbowa P, Serwadda D, et al. The acceptability and safety of the Shang Ring for adult male circumcision in Rakai, Uganda. J Acquir Immune Defic Syndr. 2013; 63(5): 617–21.
4. Kigozi G, Musoke R, Kighoma N, Nkale J, Serwada D, Sewankambo N, et al. The acceptability and safety of the Shang Ring for adolescent male circumcision in Rakai, Uganda (TUPE148). 20th International AIDS Conference; July 20–25, 2014; Melbourne, Australia (http://www.abstract – archive.org/Abstract/Share/18795).
5. Barone MA, Ndede F, Li PS, Masson P, Awori Q, Okech J, et al. The Shang Ring device for adult male circumcision: a proof of concept study in Kenya. J Acquir Immune Defic Syndr. 2011; 57(1): e7–12.
6. Barone MA, Awori QD, Li PS, Simba RO, Weaver MA, Okech JO, et al. Randomized trial of the Shang Ring for adult male circumcision with removal at one to three weeks: delayed removal leads to detachment. J Acquir Immune Defic Syndr. 2012; 60(3): e82–9.
7. Sokal DC, Li PS, Zulu R, Awori QD, Agot K, Simba RO, et al. Field study of adult male circumcision using the ShangRing in routine clinical settings in Kenya and Zambia. J Acquir Immune Defic Syndr. 2014; 67(4): 430–7.
8. Feldblum PJ, Zulu R, Linyama D, Long S, Nonde TJ, Lai JJ, et al. Randomized controlled trial of the ShangRing for adult medical male circumcision: safety, effectiveness, and acceptability of using 7 versus 14 device sizes. J Acquir Immune Defic Syndr. 2016; 72 (Suppl 1): S30–5.
9. Feldblum PJ, Mwambula C, Selemani M, Long S, Telela DJ, Mwenyekonde E, et al. Prospective observational study of the ShangRing device for adult medical male circumcision in a routine clinical setting in Malawi. Afr J Reprod Health. 2016; 20(4): 60–6.
10. Lv BD, Zhang SG, Zhu XW, Zhang J, Chen G, Chen MF, et al. Disposable circumcision suture device: clinical effect and patient satisfaction. Asian J Androl. 2014;16(3): 453–6.
11. Peng YF, Cheng Y, Wang GY, Wang SQ, Jia C, Yang BH, et al. Clinical application of a new device for minimally invasive circumcision. Asian J Androl. 2008;10(3): 447–54.
12. Peng Y, Masson P, Li PS, Chang Y, Tian L, Lee R, et al. No-needle local anesthesia for adult male circumcision. J Urol. 2010; 184(3): 978–83.
13. Wu X, Wang Y, Zheng J, Shen W, Yan JA, Ji H, et al. A report of 918 cases of circumcision with the Shang Ring: comparison between children and adults. Urology. 2013; 81(5): 1058–63.
14. Cheng Y, Wu K, Yan Z, Guo C, Ma J, Su X, et al. How to choose appropriate ring size for Shang Ring male circumcision. J Acquir Immune Defic Syndr. 2012;61(5): 606–9.
15. Cheng Y, Wu K, Yan Z, Yang S, Li F, Su X. Long-term follow-up for Shang Ring male circumcision. Chin Med J (Engl). 2014; 127(10): 1879–83.
16. Feldblum PJ, Okech J, Ochieng R, Hart C, Kiyuka G, Lai JJ, et al. Longer-term follow-up of Kenyan men circumcised using the ShangRing device. PLoS One. 2015;10(9): e0137510.
17. Awori QD, Lee RK, Li PS, Moguche JN, Ouma D, Sambai B, et al. Use of the ShangRing circumcision device in boys below 18 years old in Kenya: results from a pilot study. J Int AIDS Soc. 2017; 20(1): 21588.
18. Barone MA, Li PS, Lee RK, Ouma D, Oundo M, Barasa M, et al. Simplifying the ShangRing technique for circumcision in boys and men: Use of the noflip technique with randomization to removal at 7 days vs. spontaneous detachment. Asian J Androl. 2019; 21(4): 324–31.
19. Awori QD, Li PS, Lee RK, Ouma D, Oundo M, Barasa M, et al. Use of topical versus injectable anaesthesia for Shang Ring circumcisions in men and boys in Kenya: Results from a randomized controlled trial. PLoS ONE 2019; 14(8): e0218066.
20. Lei JH, Liu LR, Wei Q, Xue WB, Song TR, Yan SB, et al. Circumcision with "no –flip Shang Ring" and "dorsal slit" methods for adult males: a single-centered, prospective, clinical study. Asian J Androl. 2016; 18(5): 798–802.
21. Fang L, Zhu W, Xie Z, Wu K, Wang G, Yan Z, et al. Choosing the appropriate ShangRing size for paediatric circumcision using the no-flip technique. J Paediatr Child Health. 2018; 54(1): 42–8.
22. Han H, Xie DW, Zhou XG, Zhang XD. Novel penile circumcision suturing devices versus the ShangRing for adult male circumcision: a prospective study. Int BrazJ Urol. 2017; 43(4): 736–45.
23. Cheng Y, Peng YF, Liu YD, Tian L, Lu NQ, Su XJ, et al. [A recommendable standard protocol of adult male circumcision with the Chinese Shang Ring: outcomes of 328 cases in China]. [CH] Zhonghua Nan Ke Xue [Natl J Androl]. 2009; 15(7): 584–92.
24. Li HN, Xu J, Qu LM. [Shang Ring circumcision versus conventional surgical procedures: comparison of clinical effectiveness]. [CH] Zhonghua Nan Ke Xue [Natl J Androl]. 2010; 16(4): 325–7.
25. Peng YF, Yang BH, Jia C, Jiang J. [Standardized male circumcision with Shang Ring reduces postoperative complications: a report of 351 cases]. [CH] Zhonghua Nan Ke Xue [Natl J Androl]. 2010; 16(11): 963–6.
26. Cheng Y, Yan Z, Su X, Fang H, Hu J, Wu K, et al. [A clinical comparative study of Chinese Shang Ring circumcision versus conventional circumcision]. [CH] Chinese J Urol. 2011; 32(5): 333–5.
27. Wang R, Chen WJ, Shi WH, Xue YF. [Shang Ring, sleeve and conventional circumcisions for redundant prepuce and phimosis: A comparative study of 918 cases]. [CH] Zhonghua Nan Ke Xue [Natl J Androl]. 2013; 19(4): 332–6.
28. Liu C, Liu XJ, Mu JG, Liu D, Ren YS, Zhang CL. [Shang Ring circumcision by transverse incision in the distal penis foreskin and pull –up of the interior board for short frenulum praeputii]. [CH] Zhonghua Nan Ke Xue [Natl J Androl]. 2014; 20(4): 329–33.
29. Xie ST, Chen GY, Wei QH, Liu XT, Jiao L, Tang Y. [Outward versus inward placement in Shang Ring circumcision for phimosis and redundant prepuce in adult men: analysis of 527 cases]. [CH] Zhonghua Nan Ke Xue [Natl J Androl]. 2014; 20(4): 325–8.
30. Tang XH, Zhang P, Ding H, Zhao JH, Tang LL, Fang Q. [Shang Ring scissor circumcision versus electrotome circumcision for redundant prepuce]. [CH] Zhonghua Nan Ke Xue [Natl J Androl]. 2016; 22(10): 877–81.
31. Wang SX, Zhang ZB, Yang SF, Yang EM, Pan DS, Xie XQ, et al. [Shang Ring versus disposable circumcision suture device in the treatment of phimosis or redundant prepuce]. [CH] Zhonghua Nan Ke Xue [Natl J Androl]. 2016; 22(6): 534–7.
32. Yang BH, Jia C, Liu T, Peng YF. [Novel no-flip Shang Ring circumcision for adult males: a clinical application study of 528 cases]. [CH] Zhonghua Nan Ke Xue [Natl J Androl]. 2014; 20(8): 709–14.
33. Lei JH, Liu LR, Lu X, Cheng SH, Cai YC, Chen YJ, et al. [Circumcision with no-flip Shang Ring technique for adult males: analysis of 168 cases]. [CH] Zhonghua Nan Ke Xue [Natl J Androl]. 2014; 20(4): 320–4.

Table A4.1.5. GRADE evidence profile: PICO question. Can the elastic collar compression device be used as an alternative to surgery in men ages 15–49 years seeking circumcision for HIV prevention?

Author(s): Tim Farley

Date: 11-10-2018 (updated 20-07-2019)

Question: Can the elastic collar compression device be used as an alternative to surgery in men ages 15–49 years seeking circumcision for HIV prevention?

Settings: Low resource settings

Quality assessment							No. of patients		Effect		Quality	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Elastic collar comp device	Surgery	Relative (95% CI)	Absolute (95% CI)		
Eligibility (complement of non-eligibility, assessed with: proportion of clients with contraindications to device placement)												
17 [1-17]	observational studies in adults		no serious inconsistency	no serious indirectness	no serious imprecision	none	508/8944 (5.7%)				●●○○ LOW	CRITICAL
2 [18,19]	observational studies in adolescents		no serious inconsistency	no serious indirectness	no serious imprecision	none	360/1391 (25.9%)				●●○○ LOW	CRITICAL
Safety (severe and moderate adverse events excluding moderate pain, assessed with: proportion of clients experiencing event)												
3 [2,4,20]	comparative research studies	some risk of bias [a]	some inconsistency [b]	some indirectness [c]	some imprecision [d]	none	9/652 (1.4%)	3/233 (1.3%)	RR 0.69 (0.15 to 3.2)	10 more per 1000 (from 1 to 19 more)	●●○○ LOW	CRITICAL
5 [1,3,5,6,18]	observational research studies		no serious inconsistency	some indirectness [c]	some imprecision [d]	none	8/1054 (0.8%)				●●○○ LOW	CRITICAL
12 [7-17,19]	observational pilot implementation or active surveillance		no serious inconsistency	no serious indirectness	no serious imprecision	none	170/7694 (2.2%)				●○○○ VERY LOW	CRITICAL
1 [21]	comparative VMMC programme	some risk of bias [a]	N/A [e]	no serious indirectness	no serious imprecision	none	37/3452 (1.1%)	116/41 416 (0.3%)	RR 3.8 (2.6 to 5.5)	8 more per 1000 (from 4 to 11 more)	●●○○ LOW	CRITICAL
Procedure duration (assessed with: duration of device placement or surgical procedure)												
3 [2,4,20]	comparative research studies	some risk of bias [a]	no serious inconsistency	some indirectness	no serious imprecision	none	651 (mean 3.8, SD 2.1 minutes)	232 (mean 12.2, SD 3.9 minutes)		mean 6.9 minutes shorter (from 6.5 to 7.3 minutes shorter)	●●○○ LOW	IMPORTANT
7 [1,7,9,10,12,13,15]	observational research, pilot implementation or active surveillance		no serious inconsistency	no serious indirectness	no serious imprecision	none	2419 (mean 3.5, SD 2.4 minutes)				●●○○ LOW	IMPORTANT
Procedure duration (assessed with: duration of device removal)												
7 [1,4,9,10,12,13,15]	comparative and observational research, pilot implementation or active surveillance		no serious inconsistency	no serious indirectness	no serious imprecision	none	2624 (mean 3.4, SD 1.7 minutes)				●●○○ LOW	IMPORTANT

Table A4.1.5. (continued)

Quality assessment							No. of patients		Effect		Quality	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Elastic collar comp device	Surgery	Relative (95% CI)	Absolute (95% CI)		
Pain on device placement (assessed with: client-reported pain on visual analogue scale (0 = no pain at all; 10 = worst pain imaginable))												
2 [2,20]	comparative research studies	some risk of bias [a]	some inconsistency [f]	some indirectness	no serious imprecision	none	304 (mean 0.4, SD 0.8)	153 (mean 3.5, SD 1.1)		mean 3.2 lower (from 3.0 to 3.3 lower)	⨁⨁◯◯ LOW	IMPORTANT
9 [1,3,8-10,12,14, 15,18]	observational research and pilot implementation studies		some inconsistency [f]	no serious indirectness	no serious imprecision	none	3700 (mean 0.8, SD 1.2)				⨁⨁◯◯ LOW	IMPORTANT
Pain during erection while wearing device (assessed with: client-reported pain on visual analogue scale (0 = no pain at all; 10 = worst pain imaginable))												
2 [2,20]	comparative research studies	some risk of bias [a]	some inconsistency [f]	some indirectness [c]	no serious imprecision	none	301 (mean 1.8, SD 1.5)	153 (mean 3.4, SD 1.8)		mean 1.3 lower (from 1.0 to 1.6 lower)	⨁⨁◯◯ LOW	IMPORTANT
3 [7-9]	observational pilot implementation studies		N/A [e]	no serious indirectness	no serious imprecision	none	1168 (mean 2.9, SD 1.7)				⨁◯◯◯ VERY LOW	IMPORTANT
Pain on device removal (assessed with: client-reported pain on visual analogue scale (0 = no pain at all; 10 = worst pain imaginable))												
13 [1-3,8-12,14-18]	comparative and observational research, pilot implementation and active surveillance		some inconsistency [f]	no serious indirectness	no serious imprecision	none	6098 (mean 4.2, SD 2.2)				⨁⨁◯◯ LOW	IMPORTANT
Healing (assessed with: time to complete healing)												
1 [2]	comparative research study	some risk of bias [a]	N/A [e]	no serious indirectness	no serious imprecision	none	144 (mean 37, SD 12 days)	73 (mean 23, SD 8)		mean 14 days longer (from 11 to 17 days longer)	⨁⨁◯◯ LOW	IMPORTANT
5 [1,3,6,7,9]	observational research and pilot implementation studies		no serious inconsistency	no serious indirectness	no serious imprecision	none	1279 (mean 42.8, SD 8.5 days)				⨁⨁◯◯ LOW	IMPORTANT
Healing (assessed with: proportion healed by 4 or 6 weeks)												
2 [4,20]	comparative research studies	serious risk of bias [g]	serious inconsistency [h]	some indirectness [c]	no serious imprecision	none	322/483 (67%)	135/155 (81%)	RR 0.73 (0.67 to 0.79)	293 fewer per 1000 (from 241 to 345 fewer)	⨁◯◯◯ VERY LOW	IMPORTANT
7 [8-10,12,13,15,18]	observational research and pilot implementation studies		some inconsistency [i]	no serious indirectness	no serious imprecision	none	1908/2755 (69%)				⨁◯◯◯ VERY LOW	IMPORTANT
Satisfaction (assessed with: proportion reporting to be "satisfied" or "very satisfied" with appearance (or at least 60 on a 1–100 satisfaction scale [one study])												
1 [20]	comparative research studies	some risk of bias [a]		no serious indirectness	no serious imprecision	none	97/110 (88%)	48/51 (94%)	RR 0.94 (0.85 to 1.03)	59 fewer per 1000 (from 148 fewer to 29 more)	⨁⨁◯◯ LOW	IMPORTANT
8 [8-11,15,16,18,19]	observational research or pilot implementation studies		no serious inconsistency	no serious indirectness	no serious imprecision	none	3265/3545 (92%)				⨁⨁◯◯ LOW	IMPORTANT

Table A4.1.5. (continued)

Quality assessment							No. of patients		Effect		Quality	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Elastic collar comp device	Surgery	Relative (95% CI)	Absolute (95% CI)		
Odour (assessed with: proportion reporting unpleasant smell or odour while wearing device)												
7 [4,5,8,9,11,14,16]	observational research or pilot implementation studies		no serious inconsistency	no serious indirectness	no serious imprecision	none	1844/3173 (58%)				●●○○ LOW	IMPORTANT

CI = confidence interval; N/A = not applicable; RR = relative risk

Notes

[a] Blinding of participants and personnel not possible
[b] Difference between device and comparison groups inconsistent across studies
[c] Context of research environment does not necessarily reflect device use in clinical practice
[d] Small number of events
[e] Not applicable as only one study
[f] Pain assessment tools and scales not standardized across studies nor validated
[g] In one study participants allocated to device arm were followed weekly until healed; those allocated to control arm were followed at 3 days, 1 and 6 weeks.
[h] Large difference between device and surgical arms between studies
[i] More stringent definition of healing adopted in one study

Table A4.1.6. Studies of elastic collar compression device, by study type and date order

Reference	Country	Design [a]	Period	Exposure [b]	Age range	Outcome(s)	Study quality (risk of bias) and notes
Research studies							
Bitega 2011 [1]	Rwanda	case series (6 w, 96%)	Jun 2010 – Sep 2010	PrePex™ (55)	18–35 y (mean 23 y)	eligibility, AEs, procedure times, pain, healing time	
Mutabazi 2012 [2]	Rwanda	RCT (9 w, 97%)	Feb 2011 – Apr 2011	PrePex™ (144) surgical MC (73)	21–54 y (mean 25 y)	eligibility, AEs, procedure times, pain, healing time	
Mutabazi 2014 [3]	Rwanda	cohort (6 w, 91%)	Phase 2: May 2011 – Jul 2011	PrePex™ (97)	18–40 y (mean 25 y)	AEs, pain, healing time	comparison of outcomes when procedures performed by physicians (50) or by nurse providers (47); first 55 clients in Phase 1 reported in Bitega 2011 [1]
Tshimanga 2016 [20]	Zimbabwe	RCT (3 m, 99%)	Nov 2011 – Jan 2012	PrePex™ (160) surgical MC (80)	>18 y (mean 29 y)	AEs, procedure times, pain, healing time, satisfaction with cosmetic result	
Kigozi 2014 [4]	Uganda	concurrent cohort (4 w, 93%)	Nov 2012 – May 2013	PrePex™ (350) surgical MC (79)	18–49 y (mean 25 y)	eligibility, AEs, procedure times, healing time, odour	
Tshimanga 2016 [18]	Zimbabwe	bridging study – adolescents (9 w, 98%)	Aug 2013 – Jan 2014	PrePex™ (402)	13–17 y (15 y)	eligibility, AEs, pain, healing time, satisfaction with cosmetic result	
Mutabazi 2015 [5]	Rwanda	RCT (1 w, 100%)	Nov 2013 – Dec 2013	PrePex™ (101)	21–49 y (mean or median not reported)	eligibility, AEs, odour	two foreskin hygiene methods to reduce odour while wearing device (rinse under foreskin with soapy water or chlorhexidine solution daily) compared with standard care (standard washing). Study period from clinicaltrials.gov NCT02153658.
Tshimanga 2017 [6]	Zimbabwe	bridging study – men with HIV (3 m, 97%)	Oct 2015 – Feb 2016	PrePex™ (400)	mean 40.3, IQR 33.5–46.0, range 28–70	eligibility, AEs, healing time	men with HIV
Pilot implementation							
Mutabazi 2013 [7]	Rwanda	cohort (6 w, 64%)	Jul 2011 – Oct 2011	PrePex™ (590)	21–54 y (mean 25 y)	eligibility, AEs, procedure times, pain, healing time	nurse and physician providers
Galukande 2014 [8]	Uganda	cohort (8 w, NR)	Aug 2012 – Oct 2012	PrePex™ (625)	18–49 y (mean 24 y)	eligibility, AEs, pain, healing time, satisfaction, cosmetic result, odour	further information on long-term follow-up of subset of men (304/625, 49%) in Galukande 2017 [22]
Feldblum 2014 [9]	Kenya	cohort (6 w, 98%)	Nov 2012 – Sep 2013	PrePex™ (427)	18–49 y (median 20 y)	eligibility, AEs, procedure times, pain, healing time, satisfaction with cosmetic result, odour	supplemented with information on study dates from www.clinicaltrials.gov NCT01711411 and AEs from Odoyo 2016 [23]
Cummings 2016 [10]	Mozambique	cohort (6 w, 95%)	May 2013 – Jul 2013	PrePex™ (504)	18–49 y (median 24 y)	eligibility, AEs, procedure times, pain, healing time, satisfaction with cosmetic result	data on eligibility, AEs, procedure times and healing from Feldblum 2016 [13]
Musiige 2016 [11]	Botswana	cohort (6 w, 92%)	May 2013 – Sep 2013	PrePex™ (806)	18–48 y (mean 28 y)	eligibility, AEs, pain, satisfaction with cosmetic result, odour	
Lebina 2015 [12]	South Africa (3 sites)	cohort (8 w, 91%)	Aug 2013 – Apr 2014	PrePex™ (adolescents: 83; adults: 315)	adolescents 14–17 y (mean 16 y) adults 18–45 y (mean 26 y)	eligibility, AEs, procedure times, pain, healing time	data on mean removal time from Feldblum 2016 [13]
Feldblum 2016 [13]	Zambia	cohort (6 w, 95%)	Oct 2013 – Apr 2014	PrePex™ (499)	18–49 y (median 25 y)	eligibility, AEs, procedure times, healing time	

Table A4.1.6. (continued)

Reference	Country	Design [a]	Period	Exposure [b]	Age range	Outcome(s)	Study quality (risk of bias) and notes
Kohler 2016 [14]	Malawi (3 sites)	cohort (6 w, 99%)	Apr 2014 – Sep 2014	PrePex™ (791)	18–49 y (mean 24 y)	eligibility, AEs, pain, odour	
Ansari 2017 [15]	Indonesia	cohort (6 w, 58%)	Jun 2015 – Dec 2015	PrePex™ (411)	18–49 y (mean 27 y)	eligibility, AEs, procedure times, pain, healing time, uptake, satisfaction with cosmetic result	
Active surveillance							
Mavhu 2016 [16]	Zimbabwe	VMMC programme (1 w, 98%, 2 w, 6 w)	Apr 2014 – May 2014	PrePex™ (1000)	>18 y	eligibility, AEs, pain, odour, satisfaction	subset of 500 clients interviewed on Day 14
Lebina 2018 [17]	South Africa (6 VMMC sites)	active surveillance cohort (1 w, 2 w, 6 w; NR)	Jul 2014 – Mar 2015	PrePex™ (1004)	18–45 y (median 25 y)	eligibility, AEs, pain	analysis of pain on device removal according to range of pain control regimens available in each site
Mavhu 2019 [19]	Zimbabwe	VMMC programme (1 w, 2 w, 6 w; NR)	Oct 2015 – Oct 2016	PrePex™ (618)	13–17 yr	eligibility, AEs, pain, satisfaction	active surveillance of first cohort of adolescents circumcised with device in VMMC programme
VMMC programme							
Bochner 2017 [21]	Zimbabwe (36 sites)	VMMC programme (2 w, 96%)	Oct 2014 – Sep 2015	PrePex™ (3452) surgical MC (41 416)	PrePex™: >18 y (mean 24 y) surgical: >10 y (mean 16 y)	AEs	

AEs = adverse events; IQR = interquartile range; RCT = randomized controlled trial; y = years

Notes

[a] Type of study (longest duration of follow-up [d = day, w = week, m = month, NS = duration not stated], percentage of clients followed to specified duration [NR = not reported])

[b] Number of clients exposed to circumcision method

References for Tables A4.1.5–A4.1.6

1. Bitega JP, Ngeruka ML, Hategekimana T, Asiimwe A, Binagwaho A. Safety and efficacy of the PrePex device for rapid scale-up of male circumcision for HIV prevention in resource-limited settings. J Acquir Immune Defic Syndr. 2011; 58(5): e127–34.
2. Mutabazi V, Kaplan SA, Rwamasirabo E, Bitega JP, Ngeruka ML, Savio D, et al. HIV prevention: male circumcision comparison between a nonsurgical device to a surgical technique in resource-limited settings: a prospective, randomized, nonmasked trial. J Acquir Immune Defic Syndr. 2012; 61(1): 49–55.
3. Mutabazi V, Bitega JP, Ngeruka LM, Hategekimana T, Kaplan SA, Karema C, et al. Non-surgical adult male circumcision using the PrePex device: task-shifting from physicians to nurses. Afr J Reprod Health. 2014; 18(1): 61–70.
4. Kigozi G, Musoke R, Watya S, Kighoma N, Nkale J, Nakafeero M, et al. The safety and acceptance of the PrePex device for non-surgical adult male circumcision in Rakai, Uganda. A non-randomized observational study. PLoS One. 2014; 9(8): e100008.
5. Mutabazi V, Bitega JP, Ngeruka LM, Karema C, Binagwaho A. Assessing odor level when using PrePex for HIV prevention: a prospective, randomized, open label, blinded assessor trial to improve uptake of male circumcision. PLoS One. 2015; 10(5): e0126664.
6. Tshimanga M, Makunike-Chikwinya B, Mangwiro T, Tapiwa Gundidza P, Chatikobo P, Murenje V, et al. Safety and efficacy of the PrePex device in HIV- positive men: a single-arm study in Zimbabwe. PLoS One. 2017; 12(12): e0189146.
7. Mutabazi V, Kaplan SA, Rwamasirabo E, Bitega JP, Ngeruka ML, Savio D, et al. One-arm, open-label, prospective, cohort field study to assess the safety and efficacy of the PrePex device for scale-up of nonsurgical circumcision when performed by nurses in resource-limited settings for HIV prevention. J Acquir Immune Defic Syndr. 2013; 63(3): 315–22.
8. Galukande M, Duffy K, Bitega JP, Rackara S, Bbaale DS, Nakaggwa F, et al. Adverse events profile of PrePex a non-surgical device for adult male circumcision in a Ugandan urban setting. PLoS One. 2014; 9(1): e86631.
9. Feldblum PJ, Odoyo-June E, Obiero W, Bailey RC, Combes S, Hart C, et al. Safety, effectiveness and acceptability of the PrePex device for adult male circumcision in Kenya. PLoS One. 2014; 9(5): e95357.
10. Cummings B, Necochea E, Ferreira T, Soares B, Mahomed M, Muquingue H, et al. Acceptability and satisfaction associated with the introduction of the PrePex circumcision device in Maputo, Mozambique. J Acquir Immune Defic Syndr. 2016; 72 (Suppl 1): S56–2.
11. Musiige AM, Ashengo TA, Stolarsky G, Dialwa RT, Manda R, Ntsuape CO, et al. Participant experiences and views of odor and PrePex device removal pain in a VMMC pilot study in Botswana. J Acquir Immune Defic Syndr. 2016; 72 (Suppl 1): S73-7.
12. Lebina L, Taruberekera N, Milovanovic M, Hatzold K, Mhazo M, Nhlapo C, et al. Piloting PrePex for adult and adolescent male circumcision in South Africa-- Pain is an issue. PLoS One. 2015; 10(9): e0138755.
13. Feldblum P, Martinson N, Bvulani B, Taruberekera N, Mahomed M, Chintu N, et al. Safety and efficacy of the PrePex male circumcision device: results from pilot implementation studies in Mozambique, South Africa, and Zambia. J Acquir Immune Defic Syndr. 2016; 72 (Suppl 1): S43–8.
14. Kohler PK, Tippett Barr BA, Kang'ombe A, Hofstee C, Kilembe F, Galagan S, et al. Safety, feasibility, and acceptability of the PrePex device for adult male circumcision in Malawi. J Acquir Immune Defic Syndr. 2016; 72 (Suppl 1): S49–55.
15. Ansari MR, Lazuardi E, Wignall FS, Karma C, Sumule SA, Tarmizi SN, et al. Voluntary Medical Male Circumcision to prevent HIV in Tanah Papua, Indonesia: Field trial to assess acceptability and feasibility. Curr HIV Res. 2017; 15(5): 361–71.
16. Mavhu W, Hatzold K, Ncube G, Xaba S, Madidi N, Keatinge J, et al. Safety and acceptability of the PrePex device when used in routine male circumcision service delivery during active surveillance in Zimbabwe. J Acquir Immune Defic Syndr. 2016; 72(Suppl 1): S63–8.
17. Lebina L, Milovanovic M, Otwombe K, Abraham P, Manentsa M, Nzenze S, et al. PrePex circumcision surveillance: Adverse events and analgesia for device removal. PLoS One. 2018; 13(3): e0194271.
18. Tshimanga M, Hatzold K, Mugurungi O, Mangwiro T, Ncube G, Xaba S, et al. Safety profile of PrePex male circumcision device and client satisfaction with adolescent males aged 13-17 years in Zimbabwe. J Acquir Immune Defic Syndr. 2016; 72 (Suppl 1): S36–42.
19. Mavhu W, Hatzold K, Madidi N, Maponga B, Dhlamini R, Munjoma M, et al. Is the PrePex device an alternative for surgical male circumcision in adolescents ages 13-17 years? Findings from routine service delivery during active surveillance in Zimbabwe. PLoS One. 2019; 14(3): e0213399.
20. Tshimanga M, Mangwiro T, Mugurungi O, Xaba S, Murwira M, Kasprzyk D, et al. A Phase II randomized controlled trial comparing safety, procedure time, and cost of the PrePex device to forceps guided surgical circumcision in Zimbabwe. PLoS One. 2016; 11(5): e0156220.
21. Bochner AF, Feldacker C, Makunike B, Holec M, Murenje V, Stepaniak A, et al. Adverse event profile of a mature voluntary medical male circumcision programme performing PrePex and surgical procedures in Zimbabwe. J Int AIDS Soc. 2017; 19(1): 21394.
22. Galukande M, Nakaggwa F, Busisa E, Sekavuga Bbaale D, Nagaddya T, Coutinho A. Long-term post PrePex male circumcision outcomes in an urban population in Uganda: a cohort study. BMC Res Notes. 2017; 10(1): 522.
23. Odoyo-June E, Feldblum PJ, Fischer S, Bailey RC, Obiero W, Hart C, et al. Unexpected complications following adult medical male circumcision using the PrePex device. Urol Int. 2016; 96(2): 188–93.

Table A4.1.7. GRADE evidence profile: PICO question. Can the surgical assist device be used as an alternative to surgery in men ages 15–49 years seeking circumcision for HIV prevention?

Author(s): Tim Farley

Date: 11-10-2018 (updated 23-08-2019)

Question: Can the surgical assist device be used as an alternative to surgery in men ages 15–49 years seeking circumcision for HIV prevention?

Settings: Low resource settings

Quality assessment							No. of patients		Effect		Quality	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Surgical assist device	Surgery	Relative (95% CI)	Absolute (95% CI)		
Eligibility (complement of non-eligibility, assessed with: proportion of clients with contraindications to device placement)												
5 [1–4]	observational studies		no serious inconsistency	no serious indirectness	no serious imprecision	none	0/364 (0.0%)				●●○○ LOW	CRITICAL
Safety (severe and moderate adverse events, excluding moderate pain; assessed with: proportion of clients experiencing event)												
2 [1,3]	comparative research studies	some risk of bias [a]	no serious inconsistency	some indirectness [b]	some imprecision [c]	none	48/150 (32.0%)	11/75 (14.7%)	RR 2.1 (1.2 to 3.9)	136 more per 1000 (from 33 to 240 more)	●●○○ LOW	CRITICAL
3 [1,2,4]	observational research studies		no serious inconsistency	no serious indirectness	some imprecision [c]	none	11/214 (5%)				●●○○ LOW	CRITICAL
Procedure duration (assessed with: duration of circumcision procedure)												
2 [1,3]	comparative research studies	some risk of bias [a]	no serious inconsistency	some indirectness [b]	no serious imprecision	none	146 (mean 12.7, SD 3.7 minutes)	69 (mean 23.5, SD 7.8 minutes)		mean 10.2 minutes shorter (from 8.5 to 12.0 minutes shorter)	●●○○ LOW	IMPORTANT
3 [1,2,4]	observational research studies		no serious inconsistency	no serious indirectness	no serious imprecision	none	214 (mean 9.1, SD 0.8 minutes)				●●○○ LOW	IMPORTANT
Pain during circumcision procedure (intra-operative pain; assessed with: client-reported pain on visual analogue scale (0 = no pain at all; 10 = worst pain imaginable))												
1 [3]	comparative research studies	some risk of bias [a]	no inconsistency	some indirectness [b]	serious imprecision [d]	none	50 (mean 1.0, SD 1.1)	25 (mean 1.0, SD 1.4)		mean 0.0 lower (from 0.6 lower to 0.6 higher)	●○○○ VERY LOW	IMPORTANT
1 [4]	observational research studies		no inconsistency	no serious indirectness	serious imprecision [d]	none	54 (mean 1.0, SD 0.7)				●○○○ VERY LOW	
Pain after circumcision procedure (post-operative pain; assessed with: client-reported pain on visual analogue scale (0 = no pain at all; 10 = worst pain imaginable))												
1 [3]	comparative research studies	some risk of bias [a]	no inconsistency	some indirectness [b]	serious imprecision [d]	none	50 (mean 1.0, SD 1.1)	25 (mean 1.0, SD 3.6)		mean 0.0 lower (from 1.4 lower to 1.4 higher)	●○○○ VERY LOW	IMPORTANT
Pain after circumcision procedure (post-operative pain in first 24 hours after circumcision; assessed with: client-reported pain on visual analogue scale (0 = no pain at all; 10 = worst pain imaginable))												
1 [1]	comparative research studies	some risk of bias [a]	no inconsistency	some indirectness [b]	some imprecision [e]	none	100 (mean 4.2, SD 2.7)	50 (mean 3.1, SD 2.4)		mean 1.1 higher (from 0.2 to 2.0 higher)	●●○○ LOW	IMPORTANT

Table A4.1.7. (continued)

Quality assessment							No. of patients		Effect		Quality	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Surgical assist device	Surgery	Relative (95% CI)	Absolute (95% CI)		
Pain after circumcision procedure (post operative pain in first 48 h after circumcision; assessed with: client-reported pain on visual analogue scale (0 = no pain at all; 10 = worst pain imaginable))												
1 [1]	comparative research studies	some risk of bias [a]	no inconsistency	some indirectness [b]	some imprecision [e]	none	100 (mean 0.7, SD 1.6)	50 (mean 1.2, SD 2.0)		mean 0.5 lower (from 1.1 lower to 0.1 higher)	●●○○ LOW	IMPORTANT
Healing (assessed with: proportion healed by 4 weeks)												
2 [1,3]	comparative research studies	some risk of bias [a]	no inconsistency	some indirectness [b]	no serious imprecision	none	128/143 (90%)	65/73 (89%)	RR 0.93 (0.86 to 1.0)	57 fewer per 1000 (from 126 fewer to 11 more)	●●○○ LOW	IMPORTANT
3 [1,2,4]	observational research studies		no inconsistency	no serious indirectness	no serious imprecision	none	196/207 (95%)				●●○○ LOW	IMPORTANT
Cosmetic result (assessed with: proportion with "regular" cosmetic result at 4 weeks)												
2 [1,3]	comparative research studies	some risk of bias [a]	no inconsistency	some indirectness [b]	no serious imprecision	none	119/141 (84%)	22/71 (31%)	RR 2.2 (1.6 to 3.2)	635 more per 1000 (from 527 to 742 more)	●●○○ LOW	IMPORTANT
2 [1,2]	observational research studies		no inconsistency	no serious indirectness	no serious imprecision	none	151/154 (98%)				●●○○ LOW	IMPORTANT
Satisfaction (assessed with: proportion reporting to be "satisfied" or "very satisfied" with circumcision procedure)												
2 [1,3]	comparative research studies	some risk of bias [a]	no inconsistency	some indirectness [b]	no serious imprecision	none	121/142 (85%)	62/73 (85%)	RR 1.02 (0.93 to 1.11)	13 more per 1000 (from 65 fewer to 90 more)	●●○○ LOW	IMPORTANT
1 [2]	observational cohort		no inconsistency	no serious indirectness	no serious imprecision	none	103/104 (99%)				●●○○ LOW	IMPORTANT

CI = confidence interval; RR = relative risk; SD = standard deviation

Notes

[a] Blinding of participants and personnel not possible
[b] Research context does not necessarily reflect device use in clinical practice
[c] Small number of events
[d] Very few clients
[e] Small number of clients

Table A4.1.8. Studies of the surgical assist device, by date order

Reference [a]	Country	Design [b]	Period	Exposure [c]	Age range	Outcome(s)	Notes
Research studies							
Millard 2014 [1]	South Africa	RCT (4 w)	Jun 2013 – Aug 2013	Unicirc™ v1 (100) surgical MC (50)	>18 y	AEs, procedure time, pain, intra-operative blood loss, wound healing, satisfaction, cosmetic result	Injectable local anaesthesia (2% lidocaine with Marcaine subcutaneous ring block) Supplementary details at ClinicalTrials.gov NCT01877408
Millard 2014 [1]	South Africa	Cohort (NS)	Oct 2013 – Nov 2013	Unicirc™ v2 (50)	>18 y	AEs, procedure time, pain, intra-operative blood loss, wound healing, cosmetic result	Post-study modified device v2 tested in 50 clients. Exact dates uncertain, but study conducted between Aug 2013 and Jan 2014 (end date of prior study and start date of subsequent study). Supplementary details at ClinicalTrials.gov NCT01998360
Millard 2015 [2]	South Africa	Cohort (4 w)	Jan 2014 – Jul 2014	Unicirc™ v2 (110)	>18 y	eligibility, AEs, procedure time, wound healing, intra-operative blood loss, satisfaction, cosmetic result	Topical anaesthesia with mixture of lidocaine/prilocaine (EMLA cream) applied 30 minutes prior to circumcision. Supplementary details at ClinicalTrials.gov NCT02091726
Shenje 2016 [3]	South Africa	RCT (4 w)	Jul 2015 – Aug 2015	Unicirc™ v2 (110) surgical MC (25)	>18 y	AEs, procedure time, pain, wound healing, intra-operative blood loss, satisfaction, cosmetic result	Supplementary details at ClinicalTrials.gov NCT02443792
Millard 2019 [4]	South Africa	Case series (4 w)	Apr 2016 – Nov 2016	Unicirc™ v2 (54)	12–15 y	AEs, procedure time, pain, wound healing	No formal publication; outcomes from ClinicalTrials.gov NCT02593630

AEs = adverse events; MC = male circumcision; y = years

Notes

[a] First author and year
[b] Type of study (RCT = randomized controlled trial) and duration of follow-up (w = week, NS = not stated)
[c] Number of clients exposed to circumcision method

References for Tables A4.1.7–A4.1.8

1. Millard PS, Wilson HR, Goldstuck ND, Anaso C. Rapid, minimally invasive adult voluntary male circumcision: a randomized trial of Unicirc, a novel disposable device. S Afr Med J. 2014; 104(1): 52–7.
2. Millard PS, Goldstuck ND. No-needle, single-visit adult male circumcision with Unicirc: a multi-centre field trial. PLoS One. 2015; 10(3): e0121686.
3. Shenje J, Millard PS. Sutureless adult voluntary male circumcision with topical anesthetic: a randomized field trial of Unicirc, a single-use surgical instrument. PLoS One. 2016; 11(6): e0157065.
4. Millard PS. Unicirc adolescent 12–15 year old boys [NCT02593630] 2019. February 4, 2019 (https://clinicaltrials.gov).

Table A4.1.9. Evidence-to-decision table on use of device-based methods of circumcision

Factor	Explanation/evidence	Judgment
Quality of evidence	• Combining the evidence from the randomized trials and observational studies (for both in situ device types), the overall judgement was made that further research would be very unlikely to change the estimate of effect for the outcomes of eligibility, successful circumcision, procedure time or acceptability. More evidence needed on surgical assist type devices including on their use by mid-level non-physician health care workers. • The available data for males ages 10 through 14 years were limited to the collar clamp type device, and those data were few.	Moderate quality of evidence for device use among males ages 15 years and older Low quality of evidence for those 10 through 14 years
Benefits and harms	• A smaller proportion of men is eligible for circumcision with a device than by surgery. • Efficacy in achieving successful male circumcision was similarly high with the devices and with conventional surgery. • The frequency of mild, moderate and severe adverse events with devices was no higher than with conventional surgery when both types of procedures are performed by appropriately trained health care workers. However, one device type was associated with significantly higher rates of tetanus, which, although rare, had high case-fatality. Tetanus is preventable, but mitigation by vaccination several weeks before circumcision resulted in low VMMC uptake. • Healing times after devices procedures were one to two weeks longer than after surgical circumcision since healing is by secondary intention.	Neutral – some device types may have some benefits over surgical VMMC, although not clearly advantageous at this time. More evidence needed.
Acceptability	• Generally high rates of satisfaction with the cosmetic result reported among adult men and adolescent boys. • Studies consistently found that circumcision using devices interfered minimally with clients' work or daily activities; however, evidence was limited. • Existing evidence suggests that device-based VMMC is acceptable among adolescent and adult males. • Acceptability may vary by type of device and procedure.	Mostly acceptable to recipients, but specific aspects of acceptability (for example, odour) vary by type of device.
Values and preferences	• Evidence lacking on relative values and preferences; however, some understanding from commonly stated barriers of pain and odour. • Time to healing from the time of device placement takes about one to two weeks longer (variation in time across studies and methods) than with surgical methods. Men who undergo male circumcision with a device, therefore, need to be counselled to abstain from sex for a longer time than after a surgical MC method, or for a total of at least seven weeks. During the first week, while wearing the device, abstinence is essential. • The procedure times with the devices were less than the times required for conventional surgery. This includes times at both the visit to place and the visit to remove the device. • Providers say that ease of procedure is a key facilitator to acceptability. • Views of female sexual partners, the wider communities, policy-makers and funders are not currently unknown. • Programme managers expressed the importance of prequalification status to guide use of devices.	No judgment, as evidence is limited
Resource use and cost	• Costs for device-based VMMC varied according to the type of device used. • Consumables and staffing costs are substantial contributors to total cost. • The device-based approach involves shorter duration of the procedure than with surgical methods and, thus, is associated with lower cost of clinician time. However, the costs of the device itself and associated medical supplies as well as costs with subsequent device removal should be noted. • Existing evidence focussed on the use of elastic compression and collar clamp in situ devices. The costs of other VMMC devices remain unclear.	Limited data
Equity and ethics	• Evidence lacking on the impact of device-based VMMC on health equity.	No evidence that use of devices increases equity
Feasibility	• Evidence lacking on the constraints or barriers to implementing device-based VMMC recommendations. • To date, limited numbers of VMMCs have been performed using devices, but, where they have been used, this has been feasible, including permitting less surgically skilled providers to perform the procedure. The huge scale-up of VMMC has been achieved largely with surgical VMMC.	Mixed

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