

**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?	4
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?	8
Table A4.1.3. Studies of collar clamp device (conventional placement technique), by date order within region and design	10
Table A4.1.4. Studies of collar clamp device (no-flip placement technique), by date order within region and design	12
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?	16
Table A4.1.6. Studies of elastic collar compression device, by study type and date order	17
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?	20
Table A4.1.8. Studies of the surgical assist device, by date order	22
Table A4.1.9. Evidence-to-decision table on use of device-based methods of circumcision	24

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		Quality		Importance			
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 inconsistency	no serious indirectness	no serious imprecision	none	3/2235 (0.1%)		not estimatable		●●○○ LOW	CRITICAL
1 ¹⁰	randomized trial (China)	some risk of bias ^a	serious indirectness ^c	serious indirectness ^c	some imprecision ^b	none	0/314 (0.0%)	0/314 (0.0%)	not estimatable		●○○○ VERY LOW	CRITICAL
5 ¹¹⁻¹⁵	observational cohorts (China)	no serious inconsistency	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 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	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	no serious inconsistency	serious indirectness ^c	no serious imprecision	none	84/2252 (3.7%)				●○○○ VERY LOW	CRITICAL

Table A4.1.1. (continued)

Quality assessment										Effect		Quality		Importance
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 ^{3,6,9}	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		Quality		Importance		
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 RCT² 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		Quality		Importance		
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		Quality		Importance		
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	no serious inconsistency	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 inconsistency	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	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 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 inconsistency	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 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 inconsistency	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 inconsistency	no serious indirectness	no serious imprecision	none	486/532 (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 inconsistency	no serious indirectness	no serious imprecision	none	592/615 (96.3%)				●●○○ LOW	CRITICAL
1 ²⁰	concurrent cohort (China)	serious indirectness ^b	no serious inconsistency	serious indirectness ^b	no serious imprecision	none	295/306 (96.4%)	55/76 (72.4%)		RR 1.33 (1.16 to 1.53)	●●○○ LOW	CRITICAL
1 ²¹	observational cohort (China)	no serious inconsistency	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) electrothome (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 measuring 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

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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)	Quality	Importance
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 ^{1,3,6,10,12,14,15,18}	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 ^{1,3,6,12,14-18}	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 ⁹	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 studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	No. of patients		Effect		Quality	Importance
							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

- Blinding of participants and personnel not possible
- Difference between device and comparison groups inconsistent across studies
- Context of research environment does not necessarily reflect device use in clinical practice
- Small number of events
- Not applicable as only one study
- Pain assessment tools and scales not standardized across studies nor validated
- 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.
- Large difference between device and surgical arms between studies
- 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

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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										Effect	Quality	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Surgical assist device	Surgery	Relative (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

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

Factor	Explanation/evidence	Judgment
Quality of evidence	<ul style="list-style-type: none"> 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. 	<p>Moderate quality of evidence for device use among males ages 15 years and older</p> <p>Low quality of evidence for those 10 through 14 years</p>
Benefits and harms	<ul style="list-style-type: none"> 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. 	<p>Neutral – some device types may have some benefits over surgical VMMC, although not clearly advantageous at this time.</p> <p>More evidence needed.</p>
Acceptability	<ul style="list-style-type: none"> 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. 	<p>Mostly acceptable to recipients, but specific aspects of acceptability (for example, odour) vary by type of device.</p>
Values and preferences	<ul style="list-style-type: none"> 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. 	<p>No judgment, as evidence is limited</p>
Resource use and cost	<ul style="list-style-type: none"> 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. 	<p>Limited data</p>
Equity and ethics	<ul style="list-style-type: none"> Evidence lacking on the impact of device-based VMMC on health equity. 	<p>No evidence that use of devices increases equity</p>
Feasibility	<ul style="list-style-type: none"> 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. 	<p>Mixed</p>

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