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Use of a disposable circumcision suture device versus conventional circumcision: a systematic review and meta-analysis

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This systematic review assessed the safety and efficacy of the disposable circumcision suture device (DCSD) and conventional circumcision (CC) in the treatment of redundant prepuce and phimosis. Two independent reviewers conducted a literature search for randomized controlled trials (RCTs) using the DCSD and CC for the treatment of redundant prepuce or phimosis in China and abroad. Nine RCTs (1898 cases) were included. Compared with the CC group, the DCSD group had a shorter operative time (standardized mean difference [SMD] = -21.44; 95% confidence intervals [95% CIs] [-25.08, -17.79]; $P < 0.00001$), shorter wound healing time (SMD = -3.66; 95% CI [-5.46, -1.85]; $P < 0.0001$), less intraoperative blood loss (SMD = -9.64; 95% CI [-11.37, -7.90]; $P < 0.00001$), better cosmetic penile appearance (odds ratio [OR] = 8.77; 95% CI [5.90, 13.02]; $P < 0.00001$), lower intraoperative pain score, lower 24-h postoperative pain score, lower incidence of infection, less incision edema, and fewer adverse events. There were no differences between the CC and DCSD groups in the incidences of dehiscence, or hematoma. The results of this meta-analysis indicate that the DCSD appears to be safer and more effective than CC. However, additional high-quality RCTs with larger study populations are needed.

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Keywords: conventional circumcision; disposable circumcision suture device; meta-analysis; phimosis; redundant prepuce; systematic review

INTRODUCTION

Redundant prepuce and phimosis are the most common penile malformations. The main treatment method for these malformations is male circumcision. Male circumcision has been practiced on a large scale for more than 5000 years.¹ Male circumcision is used to remove the redundant foreskin to expose the glans; it is one of the most commonly performed surgical procedures in the world.²

Male circumcision can prevent several diseases in both men and women. It effectively decreases the rate of balanitis^{3,4} and the incidence of penile cancer,⁵ and also improves sexual satisfaction through decreased penile sensitivity.^{6,7} Several studies have shown an obvious decrease associated with male circumcision in the rates of viral transmission via sexual activity, including human immunodeficiency virus,^{8–11} human papillomavirus,^{12–14} and herpes simplex virus type 2.¹⁵ In addition, inflammation and cervical cancer are effectively prevented in the female partner of men who have undergone circumcision.^{5,11}

At present, multiple male circumcision methods are used, such as conventional circumcision (CC), sleeve circumcision, Shang Ring circumcision, Ali's clamp technique, and surgery with the disposable circumcision suture device (DCSD).^{16–20} Dorsal incision circumcision

is the traditional method of circumcision, but has the disadvantages of a longer operation time, stitch removal pain, and easy infection of the wound; furthermore, surgeons who are new to the technique can easily generate adverse events such as irregular or postoperative hematoma.^{21–27} In contrast, use of the DCSD requires suturing or hemostasis, has a shorter operation and wound healing times, yields less intraoperative blood loss, and results in better cosmetic penile appearance than other methods.^{20,28–36}

This study is a systematic review and meta-analysis of the safety and efficacy of the use of the DCSD and CC for the treatment of redundant prepuce or phimosis.

MATERIALS AND METHODS

Study search strategy

This systematic review was performed according to the preferred reporting items for systematic reviews and meta-analysis statements.³⁷ We searched the following databases for relevant literature from their inception to May 15, 2015: PubMed, EMBASE, Medline, Cochrane Central Register of Controlled Trials, Google Scholar, Chinese Science Citation Database, CBM disc, and China National Knowledge Internet. In addition, the reference lists of all relevant publications were

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examined. The English keywords used were as follows: “phimosis” AND “redundant prepuce” OR “excess foreskin” AND “disposable circumcision suture device” OR “circumcision stapler” AND “conventional circumcision” OR “traditional circumcision” AND “systematic review” OR “meta-analysis.”

Selection criteria

The following inclusion criteria were used: (1) English or Chinese language, (2) full text available, (3) the study involved a randomized controlled trial (RCT); non-RCTs and low-quality studies were excluded, (4) subjects randomly assigned to treatment groups and blinded to their group assignment, (5) the study included male patients requiring circumcision for phimosis or redundant prepuce, and (6) sufficient data were provided for the meta-analysis, including the total number of subjects and, at least, one predefined outcome measurement. Studies involving patients with abnormalities of the genitalia, urinary tract infection, blood coagulation dysfunction, or diabetes were excluded.

Quality assessment of included studies

Quality assessment of the retrieved RCTs, including assessment of sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting of outcomes and other possible sources of bias, was conducted using the Jadad scale.³⁸ The methodological quality of each study was assessed based on the method of treatment allocation, concealment of the allocation procedures, blinding, and data loss due to attrition. The studies were then classified qualitatively according to the guidelines of the Cochrane handbook for systematic reviews of interventions version 5.1.0.17.³⁷ Based on the quality assessment criteria, review scores ranging from 0 to 5 points were assigned to each study. Studies with a score of 0–2 were defined as low quality, whereas studies with a score of 3–5 were considered as high quality. The evaluation was performed by two independent assessors to improve the validity of the results.

Evaluation for bias

Two independent assessors assessed the risk of bias for each included RCT using the Cochrane Collaboration's tool that assesses the selection, performance, attrition, detection, and reporting bias.

Data extraction

The following data were extracted from each study: name of first author, year of publication, study design, criteria for patient inclusion, basic objectives of the study, outcome measurements, and number of patients included. The outcomes included: (1) operative time, (2) wound healing time, (3) intraoperative blood loss, (4) cosmetic penile appearance, (5) 24-h postoperative pain score, (6) intraoperative pain score, (7) incision dehiscence, (8) incision edema, (9) infection, (10) hematoma, and (11) adverse event rate. Data extraction was performed independently by two reviewers (ZC Huo and F Liu). Any discrepancies were resolved through discussion with a third reviewer.

Statistical analysis and meta-analysis

All statistical analyses were performed using Review Manager version 5.1.0 (Cochrane Collaboration, Oxford, UK).³⁷ The results of statistical analysis of dichotomous variables (cosmetic penile appearance, incision dehiscence, incision edema, infection, hematoma, and adverse event rate) were expressed as odds ratios (ORs) and 95% confidence intervals (95% CIs); the results of continuous variables (operative time, wound healing time, intraoperative blood loss, 24-h postoperative pain score, and intraoperative pain score) were expressed as standardized mean differences (SMDs) and 95% CI.

$P < 0.05$ was considered statistically significant. The Mantel–Haenszel Chi-square test for heterogeneity was conducted. Heterogeneity was assessed using the I statistic. Values $\leq 50\%$ were defined as acceptable, whereas $I > 50\%$ indicated high levels of heterogeneity. Where there was an acceptable level of heterogeneity, a fixed-effect model was applied; where heterogeneity was $> 50\%$, a random-effect model was applied.

RESULTS

A total of 203 studies were identified through the database search. According to the selection criteria, 143 studies were excluded after reading their titles and abstracts. From the remaining 60 potentially relevant studies, 18 studies were judged to be relevant based on the full text. One of these 18 studies was excluded because it was retrospective, five studies were excluded because they lacked useful data, and three studies were excluded because of inadequate study design and a lack of relevant outcome measurement. A final total of nine studies were included in the analysis (Figure 1). The characteristics of the studies are shown in Table 1.

Operation time

Operation time (min) was reported in all nine included studies (1898 patients), with a total of 1039 patients in the DCSD group and 859 patients in the CC group. The meta-analysis detected heterogeneity among the included studies ($P < 0.00001$; $I^2 = 99\%$). In the meta-analysis of the eight studies using the random-effect model, the pooled estimates showed that the DCSD group had a shorter operation time compared with the CC group (SMD = -21.44 ; 95% CI [$-25.08, -17.79$]; $P < 0.00001$; Figure 2).

Wound healing time

Wound healing time (days) was reported in seven included studies (1594 patients), with a total of 887 patients in the DCSD group and 707 patients in the CC group. Heterogeneity was present among these studies ($P < 0.00001$; $I^2 = 98\%$), which may be associated with patient competent factors. The pooled estimates generated using the random-effect model revealed that the DCSD group experienced a significantly shorter wound healing time compared with the CC group (SMD = -3.66 ; 95% CI [$-5.46, -1.85$]; $P < 0.0001$; Figure 3).

Intraoperative blood loss

Intraoperative blood loss (ml) was reported in all nine studies (1898 patients), with a total of 1039 patients in the DCSD group and 859 patients in the CC group. The meta-analysis showed that heterogeneity was present among the included studies ($P < 0.00001$; $I^2 = 98\%$). Data from the nine trials were pooled for the meta-analysis

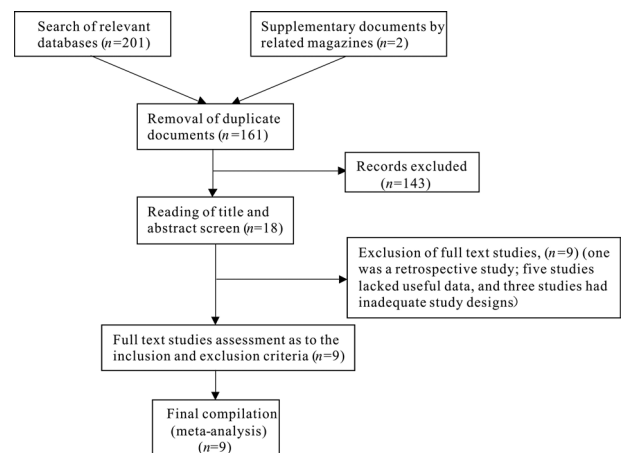


Figure 1: Study retrieval flow chart.

Table 1: Characteristics of the included studies

Study	Design	Intervention	Number of patients	Age (year)	Age range (year)	Quality levels	Follow-up (day)	Outcome indicators
Huo <i>et al.</i> 2015 ³²	RCT	DCSD/CC	120/60	30.4±9.1/31.7±11.7	-	High	30	(1) (2) (3) (4) (5) (7) (8) (9) (10)
Jing <i>et al.</i> 2014 ³³	RCT	DCSD/CC	111/40	26.9±3.1/25.8±3.4	8–63/8–63	High	30	(1) (2) (3) (4) (5) (7) (8) (9) (10) (11)
Pang <i>et al.</i> 2015 ³¹	RCT	DCSD/CC	28/28	21.3±2.5	12–61/12–61	High	ND	(1) (2) (3) (4) (9) (11)
Li <i>et al.</i> 2014 ³⁰	RCT	DCSD/CC	129/120	27.19±7.57/26.68±4.43	-	High	30	(1) (2) (3) (4) (5) (6) (7) (8) (9) (10) (11)
Lv <i>et al.</i> 2014 ²⁰	RCT	DCSD/CC	314/314	31.5±5.4	18–58/18–58	High	30	(1) (2) (3) (4) (5) (6) (7) (8) (9) (10)
Cao <i>et al.</i> 2013 ³⁴	RCT	DCSD/CC	49/61	27.0±15.2/31.1±14.8	6–58/6–58	High	30	(1) (2) (3) (7) (10)
Ren <i>et al.</i> 2014 ²⁹	RCT	DCSD/CC	136/84	-	7–56/7–56	High	30	(1) (2) (3) (7) (11)
Wang <i>et al.</i> 2014 ³⁵	RCT	DCSD/CC	60/60	26.2±7.6/26.9±10.8	18–48/17–67	High	30	(1) (2) (3) (5)
Miao <i>et al.</i> 2015 ³⁶	RCT	DCSD/CC	92/92	24.0±7.3/23.0±4.3	12–56/12–56	High	90	(1) (2) (3) (5) (6) (8) (9) (10) (11)

RCT: randomized controlled trial; DCSD: disposable circumcision suture device; CC: conventional circumcision; ND: not described; (1): operative time; (2): wound healing time; (3): intraoperative blood loss; (4): cosmetic penile appearance; (5): 24-h postoperative pain score; (6): intraoperative pain score; (7): incision dehiscence; (8): incision edema; (9): infection; (10): hematoma; (11): adverse event rate

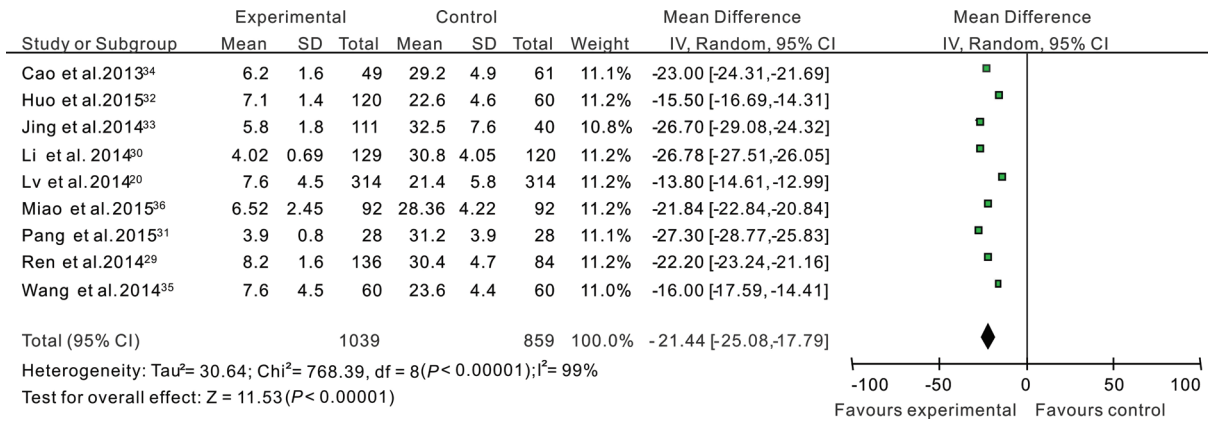


Figure 2: Forest plot of the operative time of the disposable suture circumcision device (DCSD) group and the conventional circumcision (CC) group.

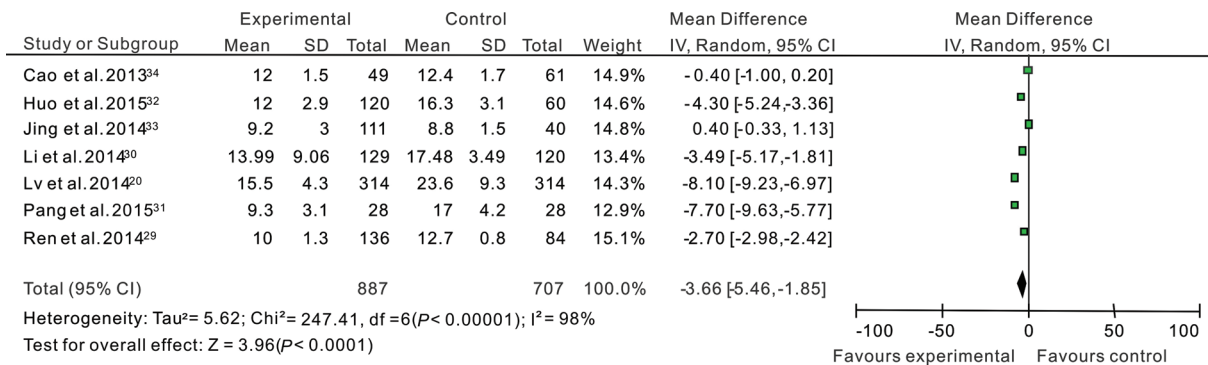


Figure 3: Forest plot of the wound healing time in the disposable suture circumcision device (DCSD) group and the conventional circumcision (CC) group.

using the random-effect model. The DCSD group experienced significantly less intraoperative blood loss compared with the CC group (SMD = -9.64; 95% CI [-11.37, -7.90]; P < 0.00001; **Figure 4**).

Cosmetic penile appearance

Cosmetic penile appearance rate was reported in seven included studies (1594 participants), with a total of 887 patients in the DCSD group and 707 patients in the CC group. Heterogeneity was identified among the included studies (P = 0.61; I² = 0%). This heterogeneity may be associated with patient competent factors. The random-effect model was used for the pooled analysis. Patients in the DCSD group reported significantly higher levels of satisfaction with their cosmetic penile appearance compared with patients in the CC group (OR = 8.77; 95% CI [5.90, 13.02]; P < 0.00001; **Figure 5**).

Evaluation of other indices reflecting safety and clinical efficacy

The DCSD group had significantly lower intraoperative pain scores (SMD = -1.36; 95% CI [-1.96, -0.76]; P < 0.00001; **Table 2**) and 24-h postoperative pain scores (SMD = -2.36; 95% CI [-2.50, -2.22]; P < 0.00001; **Table 2**) compared with the CC group. Each of the five included RCTs that reported on incision edema found that the DCSD group had significantly less incision edema than the CC group (OR = 0.30; 95% CI [0.20, 0.44]; P < 0.00001; **Table 2**). The DCSD group had a significantly lower incidence of infection compared with the CC group (OR = 0.26; 95% CI [0.12, 0.59]; P = 0.001; **Table 2**). No significant differences were found between the two groups in the incidence of hematoma (OR = 0.82; 95% CI [0.47, 1.43]; P = 0.48; **Table 2**) or dehiscence (OR = 0.92; 95% CI [0.44,



1.93]; $P = 0.82$; **Table 2**). The DCSD group had a significantly lower adverse event rate than the CC group (OR = 0.60; 95% CI [0.41, 0.87]; $P = 0.008$; **Table 2**).

DISCUSSION

Circumcision is one of the oldest and most commonly performed surgical procedures in practice today.^{39,40} Circumcision is the main treatment for phimosis and redundant prepuce. Although dorsal incision circumcision is the traditional method of circumcision, it has the disadvantages of long operation time, stitch removal pain, and easy infection of the wound; furthermore, surgeons who are new to the technique can easily generate adverse events such as an irregular

incision and postoperative hematoma.^{21–26} Surgery with the DCSD is the newest method of circumcision. Compared with CC, which requires scalpels and operating scissors, circumcision with the DCSD is easy, convenient, and reduces operative complications.^{20,28–36}

All nine studies included in this meta-analysis described the operation time, and verified that the operation time of the DCSD group was much shorter than that of the CC group; this is due to the operation of the DCSD stitching instrument.^{41–43} By forming a tubular gastrointestinal cutting anastomosis, the DCSD serves as a mechanical operation method. The DCSD is used to cut the foreskin tissue and then stitch the wound with “circular knives” using the principle of “similar stapler sewing machine.” Circular knives cut into the long foreskin

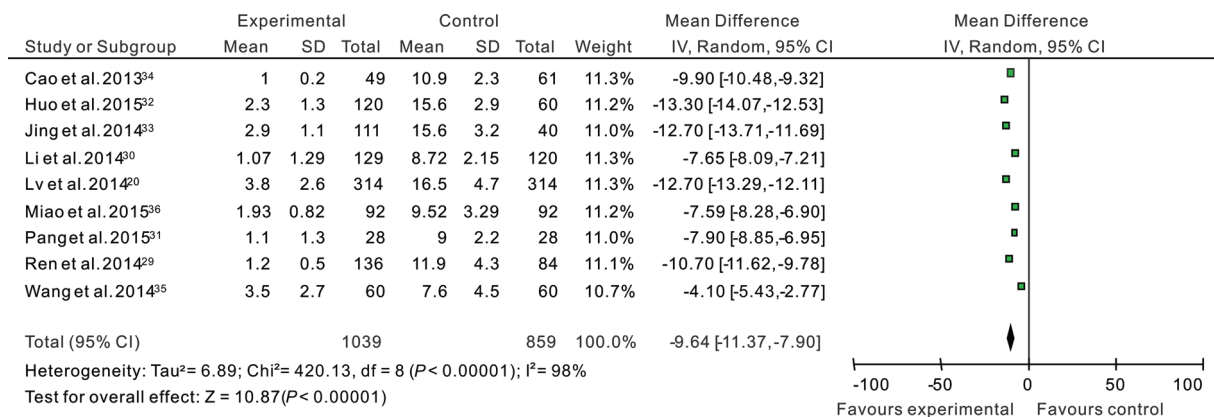


Figure 4: Forest plot of the intraoperative blood loss in the disposable suture circumcision device (DCSD) group and the conventional circumcision (CC) group.

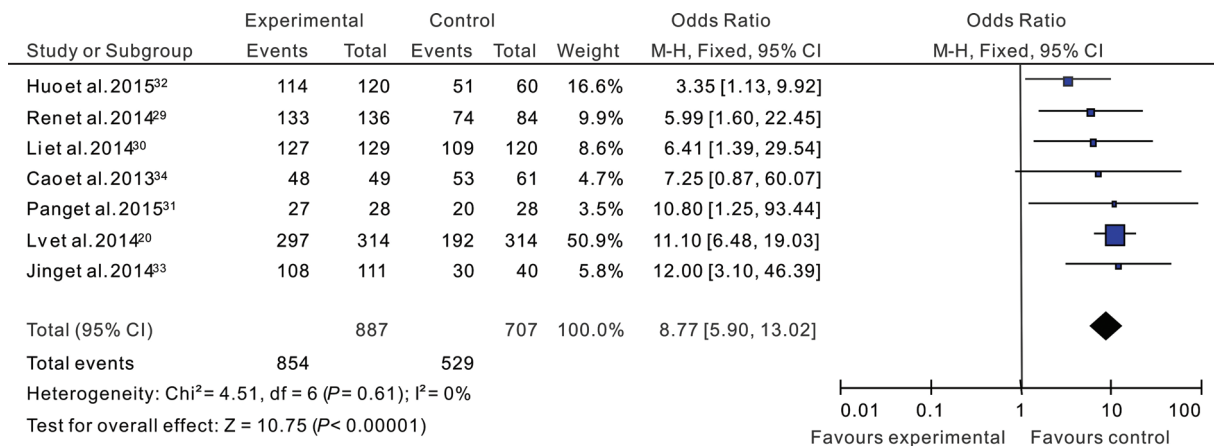


Figure 5: Forest plot of the cosmetic penile appearance in the disposable suture circumcision device (DCSD) group and the conventional circumcision (CC) group.

Table 2: Other indices for evaluating safety and clinical efficacy

Outcomes	DCSD/CC							
	Number of studies	Number of patients	P	SMD or OR (95% CI)	Heterogeneity			
					χ ²	df	P	I ² (%)
Intra-operative pain score	3	535/526	<0.00001	-1.36 (-1.96—-0.76)	50.34	2	<0.00001	96
Postoperative pain score	5	704/647	<0.00001	-2.36 (-2.50—-2.22)	1281.47	4	<0.00001	100
Incision edema rate	6	794/654	<0.00001	0.30 (0.20—0.44)	29.83	5	<0.0001	83
Incision infection rate	6	793/554	0.001	0.26 (0.12—0.59)	2.96	5	0.71	0
Incision hematoma rate	5	766/626	0.48	0.82 (0.47—1.43)	6.24	4	0.18	36
Incision dehiscence rate	2	443/434	0.82	0.92 (0.44—1.93)	1.99	1	0.16	50
Adverse event rate	6	545/425	0.008	0.60 (0.41—0.87)	11.14	5	0.05	55

SMD: standardized mean difference; OR: odds ratio; CI: confidence interval; df: degree of freedom; DCSD: disposable circumcision suture device; CC: conventional circumcision

tissue, and then a single seam suture is performed along the cut edge to complete the suturing of the tissue.^{41–48} A retrospective study by Ji *et al.*²⁸ showed that the mean operation time for the DCSD group was 5.0 ± 2.4 min compared with 25.0 ± 5.3 min for the CC group.

The wound healing time of the DCSD group was shorter than that of the CC group. Seven of the included studies described wound healing time. Although Jing *et al.*³³ reported that the wound healing time of the DCSD group was slightly longer than that of the CC group, the other six studies found that the wound healing time of the DCSD group was shorter than that of the CC group. The following aspects of circumcision with the DCSD explain its short wound healing time:^{40–47} (1) the suturing nail has arranged, and equal spacing and the suture is consistent; this avoids the problems of uneven stitching density and difference in ligation tightness, and, therefore, benefits wound healing; (2) suturing nails are metal to reduce foreign body reactions. The blood vessels and lymphatic vessels that come in contact with the suturing nail are small; this helps the reconstruction of the suturing site and its blood and lymphatic systems, which are on the far side of the suturing site. This, in turn, shortens wound healing time and promotes healing. The wound healing time reported by Jing *et al.*³³ is inconsistent with other reports, which may be due to the nonstandard method used in their study to evaluate wound healing time.

Regarding safety, the DCSD group showed much less intraoperative blood loss and less prepuce swelling than the CC group. This may be because the blood vessels and lymphatic vessels that come in contact with the suturing nail are small, reducing intraoperative bleeding and postoperative edema.^{41–48} No obvious differences in the incidence of wound infection, hematoma, or incision dehiscence were observed between the two groups.

In regards to clinical outcome, subjects in the DCSD group were more satisfied with their postoperative appearance and had lower degrees of an intraoperative and postoperative pain than the CC group. These results may be because mechanical cutting and suturing occur simultaneously with circumcision using the DCSD, yielding the following benefits:^{41–48} (1) the operation is simple and quick; (2) suturing can effectively reduce the influence of physician experience and other human factors by making the operation more standardized; (3) because the suturing nail has arranged and equal spacing, the suture is consistent, which can effectively avoid the problems of uneven stitching density and differences in ligation tightness.

Limitations of this study

The limitations of this study include the following: (1) the small number of patient included in the literature. In addition, the heterogeneity among the included studies may have been increased by insufficient or unclear allocation concealment, and study differences in factors including the evaluation of incision edema, intraoperative blood loss, and wound healing time. (2) The differences in patient characteristics were large. (3) The included studies were all from China, which may have increased the heterogeneity among the included studies. (4) The standards of measurement used in the included studies were different, which increased the heterogeneity.

To test the reliability of our meta-analysis results, we applied a sensitivity analysis on the indicators individually, deleted the studies one by one, and repeated the analysis. We found that our meta-analysis conclusion is stable, which increases our confidence in our meta-analysis results and conclusions.

CONCLUSION

This meta-analysis found that circumcision using the DCSD has the advantages of shorter operation time, easier manipulation, better

cosmetic penile appearance, fewer complications, no stitch removal pain, only mild postoperative pain, and improved wound healing compared with CC. However, these results were influenced by the sample size of the literature. The results of this meta-analysis require verification by multicenter, randomized, double-blinded studies with larger sample sizes.

AUTHORS' CONTRIBUTIONS

HZC and LG conceived the study, participated in its design, coordinated and drafted the manuscript. HZC, LG and LF performed the bias evaluation. HZC, GRH, FWJ, LPF and MDY collected the data. HZC, LXY, LF and HYZ performed the statistical analyses. HZC, LG, LF and GRH performed critical revision of the manuscript. All authors read and approved the final manuscript.

COMPETING INTERESTS

The authors declare no competing interests.

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