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## ORIGINAL ARTICLE

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# Disposable circumcision suture device: clinical effect and patient satisfaction

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In our experience patients undergoing circumcision are mostly concerned about pain and penile appearances. We conducted a prospective randomized trial to assess the benefits of a new disposable circumcision suture device (DCSD). A total of 942 patients were equally divided into three groups (conventional circumcision, Shang ring and disposable suture device group). Patients in the DCSD group were anesthetized with compound 5% lidocaine cream, the others with a 2% lidocaine penile block. Operation time, intra-operative blood loss, incision healing time, intra-operative and post-operative pain, the penile appearance and overall satisfaction degree were measured. Operation time and intra-operative blood loss were significantly lower in the Shang ring and suture device groups compared to the conventional group ( $P < 0.001$ ). Intra-operative pain was less in the suture device group compared with the other two groups ( $P < 0.001$ ); whereas post-operative pain was higher in the conventional group compared to the other two groups ( $P < 0.001$ ). Patients in the suture device (80.57%) and Shang ring (73.57%) groups were more satisfied with penile appearances compared with the conventional circumcision group (20.06%,  $P < 0.05$ ). Patients in suture device group also healed markedly faster than the conventional group ( $P < 0.01$ ). The overall satisfaction rate was better in the suture device group (78.66%) compared with the conventional (47.13%) and Shang ring (50.00%) groups ( $P < 0.05$ ). The combination of DCSD and lidocaine cream resulted in shorter operation and incision healing times, reduced intra-operative and post-operative pain and improved patient satisfaction with the cosmetic appearances.

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## INTRODUCTION

Phimosis and redundant prepuce are common male genital conditions, which can induce recurrent balanitis and posthitis, cause premature ejaculation<sup>1</sup> and increase the incidences of sexually transmitted diseases and penile cancer. Circumcision is an effective option to reduce the risk of acquiring sexually transmitted diseases and minimize the risk of penile cancer.<sup>2–6</sup> Conventional circumcision and use of Shang ring and Han ring are frequently used surgical methods for circumcision.<sup>7–11</sup> Operative and post-operative pain, surgical complications and lack of overall satisfaction with penis appearance are common patient reported outcomes that result from these approaches.<sup>8–11</sup>

Circumcision is regarded as a simple operation. General fears associated with circumcision are the operative procedure itself and the risk of complications. A patient's feelings and psychological state are almost never taken into account. Previous reports suggest that knowledge of different methods of circumcision and their outcomes vary from patient to patient and that healthcare providers should address the sensitivity of genital surgeries; a patient's pre-operative psychological state including any procedural fears they might have; intra-operative and post-operative pain; and genital integrity.<sup>12</sup>

Issues concerning genital health are inherently stressful for patients and often lead to a poor psychological state, affecting treatment efficiency and incision healing.<sup>13</sup> In this study, we report the results of a patient survey which was conducted to help understand the level of procedural knowledge patients have as well as their pre- and post-operative fears about circumcision. We also report the use of a disposable circumcision suture device (DCSD) that was modified for ease of use, faster post-operative incision healing and cleaner post-procedural penis appearance.

## PATIENTS AND METHODS

### Patients

This study is a prospective randomized trial. All patients requiring circumcision for phimosis redundant prepuce or phimosis at five different hospitals between October 2012 and May 2013 were randomly allocated into three groups (allocation by random number table): the conventional circumcision group, the Shang ring group and the DCSD group. Patients under 18 years, those with dense adhesions between glans and foreskin and obese patients with partly buried penis were excluded. The study was approved by the ethics committee (number: 2012-Research-52). All patients signed informed consent forms and were not undergoing any other clinical procedure.

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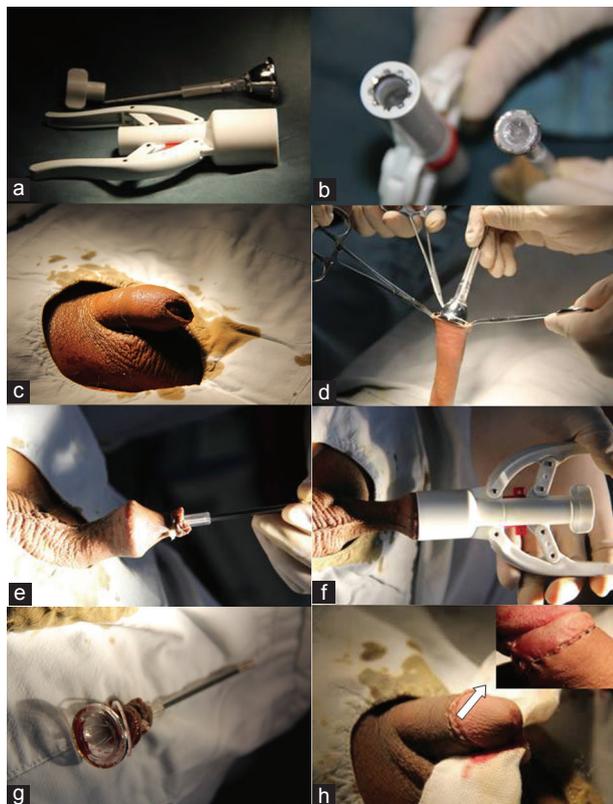
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### Surgical process

We used compound 5% lidocaine cream (Ziguang Pharmaceutical Co., Ltd. Beijing, China) alone for anesthesia. A volume of 2–5 ml of compound 5% lidocaine cream were evenly applied to the surface of the penis (including the glans and the penile body and root) at 30 and 10 min before the operation.

A DCSD (Jiangxi Yuansheng Lang He Medical Instrument Co., Ltd. Ji'an, China) was used for patients in the DCSD group. It mainly consists of bell-shaped glans pedestal, suture staple, ring-shaped blade, handle and shell (Figure 1a and 1b). Five different size devices are available for adults (F12, F18, F26, F30, F36). The glans was covered by the U-shaped glans rest with the edge of the U-shape at the level of the coronary sulcus (Figure 1c–1e). After the foreskin of the patient being wrapped around the rod, the rod was inserted into the center hole of the circumcision device (Figure 1f). The application knob was tightened, the safe buckle was removed and the rod was pushed down to trigger the circumcision device. After triggering the knob when the ring-shaped blade hidden in the shell was pushed out with the staples. The blade cut the foreskin instantly, while simultaneously staples are placed (Figure 1g and 1h), by tightening the knob at the bottom for 3–5 s and then releasing it. The operation time was recorded.

For patients in the conventional circumcision group, 2% lidocaine injection (10 ml) was injected for dorsal penile nerve block and a traditional electrosurgical knife and absorbable suture were used for the operation.



**Figure 1:** (a) Decomposition structure of the disposable circumcision suture device. (b) Ring-shapes blade and staple container. (c) Routine disinfection and draping of the skin. (d) The U-shaped glans was wrapped by the foreskin. (e) The foreskin wrapped around the rod. (f) The rod was pushed down to trigger the circumcision device. (g) The excess foreskin was incised using the circumcision device. (h) The penis after circumcision.

For patients in the Shang ring group, 2% lidocaine injection (10 ml) was injected for dorsal penile nerve block and a suitable sized device was used for the operation.<sup>10</sup>

### Surgeons

One experienced surgeons was chosen from each of the five hospitals. The assigned surgeons all had performed conventional and Shang ring circumcisions more than 300 times and were trained to use the devices before the study began. The training included the understanding of the questionnaire, healing standard, the surgery skills. An assessment was taken by a specialist after the training to see if the surgeon was qualified. In order to reduce the bias caused by surgeons subjective judgment, we defined assessment standards for incision healing: the incision is closed and covered by skin, no rupture under moderate exercise; with time, the healed incision can withstand certain stretching force and pressure, the pigmentation is relieved and is close to the color of normal skin; return to the intact normal skin function.

### Data collection

Incidences of post-operative complications including hematoma, edema, disruption of incision, incision infection and incision healing time were recorded at 1 week, 2 weeks and 1 month post-operation. The healing time was judged by the doctors based on the observation of the wound and inquiry of the patients at three time points. The intra-operative and post-operative pain were measured using a visual analog scale, as a generally validated tool (not specifically validated for circumcision) with pain levels recorded as 0–10 by pain degree (Supplementary Information). Intra-operative pain was graded immediately after the operation; the post-operation pain was graded at 1 week. We also recorded intra-operative blood loss, operation time and incision healing time. A self-designed non-validated questionnaire (Supplementary Information) was used to assess patients' satisfaction with penis appearance and overall patient satisfaction rates.

### Statistical analysis

SPSS 16.0 software was used for the analysis. Mean, standard deviation and percentages are used for a description of data. Analysis of variance least significant difference method and Chi-square test were used to compare the overall satisfaction rates among different groups.  $P < 0.05$  was considered to be statistically significant.

## RESULTS

A total of 942 patients were recruited for the study, with 314 patients in each treatment arm. Mean age across the groups was  $31.5 \pm 5.4$  years (range, 18–58 years). No significant age differences were found between the three groups ( $P > 0.05$ ). 186 patients were treated for phimosis with retractile foreskin and 756 for irretractile foreskin. All patients were followed-up. Initial non-attenders (37 patients at week 1, 85 patients at week 2, 112 patients at 1 month) were visited by a staff member.

### Comparisons of the operation time and the intra-operative blood loss

The results for operative data, healing time and pain scores are summarized in Table 1. The operation time was shorter in the Shang ring and the DCSD groups compared to the conventional circumcision group ( $5.9 \pm 2.3$  and  $7.6 \pm 4.5$  vs  $21.4 \pm 5.8$  min,  $P < 0.001$ ). Intra-operative blood loss was less in the Shang ring and the DCSD groups compared to the conventional circumcision group ( $3.0 \pm 2.3$  and  $3.8 \pm 2.6$  vs  $16.5 \pm 4.7$  ml,  $P < 0.001$ ).

### Comparison of the incision healing time

The incision healing time was shorter in the DCSD group compared to the conventional circumcision and the Shang ring groups ( $15.5 \pm 4.3$

vs  $23.6 \pm 9.3$  and  $19.5 \pm 6.3$  days,  $P < 0.01$ ). There was no significant difference in the incision healing time between the Shang ring and the conventional circumcision group.

#### Comparison of the pain scores

The intra-operative pain score was lower in the DCSD group compared to the conventional circumcision and the Shang ring groups ( $1.9 \pm 1.3$  vs  $6.2 \pm 2.2$  and  $5.8 \pm 2.1$ ,  $P < 0.001$ ). There was no significant difference between the Shang ring group and the conventional circumcision group. The post-operative pain score at 1 week was lower in the DCSD and the conventional circumcision groups compared with the Shang ring group ( $2.7 \pm 0.9$  and  $3.3 \pm 0.8$  vs  $6.4 \pm 2.0$ ,  $P < 0.001$ ). There was no difference between the modified and conventional circumcision groups.

#### Comparison of the procedural complications

The data are summarized in **Table 2**. The incidences of incision infection were 2.6%, 4.1% and 0% in the conventional circumcision, Shang ring and DCSD groups, respectively. The incidences of disruption of incision were 4.5%, 5.1% and 3.2% in the conventional circumcision, Shang ring and DCSD groups, respectively. The incidences of edema were 21.3%, 18.5% and 1.9% in the conventional circumcision, Shang ring and DCSD groups, respectively. The incidences of hematoma were 5.1%, 0% and 3.2% in the conventional circumcision, Shang ring and DCSD groups, respectively.

#### Comparison of the penile appearance and overall satisfaction

Results are summarized in **Tables 3 and 4**. Patients in the DCSD group were more satisfied with penile appearances compared to patients in the Shang ring and the conventional circumcision groups (92 vs 78 and 33 out of 314 extremely satisfied,  $P < 0.05$ ). Similar differences were seen for overall satisfaction (97 vs 58 and 45 out of 314 extremely satisfied,  $P < 0.005$ ).

## DISCUSSION

The earliest historical record of circumcision comes from Egypt, in the form of an image of the circumcision of an adult carved into the tomb of Ankh-Mahor at Saqqara, dating to about 2400–2300 BCE. Since then, the number of surgical techniques has increased; however, the psychological implications for patients have largely been neglected. Clinicians rarely pay sufficient attention to the psychological states of patients receiving circumcision. Patients tend to be more anxious about genital surgeries than similar surgeries related to other organs. Preliminary studies showed that, currently the satisfaction rate of circumcision was rather low, only 60%.<sup>14,15</sup> Clinicians should be aware of the major factors that influence patients' satisfaction and improve surgical procedures accordingly.

To gain primary insight into the fears of patients undergoing circumcision surgery, we retrospectively performed a health and satisfaction survey on 508 patients who had recently undergone circumcision. We found that safety and pain were the issues that mainly concerned patients before the operation, while pain and penile appearance were the most concerning issues after the operations were performed. According to our survey, patients' fears about the surgery were justified. It was consistent that pain is the most concern before surgery and the most bothering after surgery, what is different is that patients worried most about the safety before surgery, this worry was relieved after surgery, but was replaced by the worry about the appearance of the penis. We think it is because that the success of the operation eliminated patients' the concerns about the safety, but the incision increased the worries upon the cosmetic appearances. Besides, pain may be associated with lidocaine injection for dorsal penile nerve block, which is generally used as anesthesia during currently used circumcision techniques. Lidocaine injection often results in severe

**Table 1: Comparison of results among the three groups (mean±s.d.)**

Circumcision technique	Conventional circumcision (n=314)	Shang ring (n=314)	DCSD (n=314)
Operation time (min)	21.4±5.8	5.9±2.3***	7.6±4.5***
Intra-operative blood loss (ml)	16.5±4.7	3.0±2.3***	3.8±2.6***
Incision healing time (day)	23.6±9.3	19.5±6.3	15.5±4.3**
Intra-operative pain score	6.2±2.2	5.8±2.1	1.9±1.3*****
Post-operative pain score	3.3±0.8	6.4±2.0***	2.7±0.9***

DCSD: disposable circumcision suture device; SD: standard deviation. \* $P < 0.05$ ; \*\* $P < 0.01$ ; \*\*\* $P < 0.001$  comparing with conventional circumcision group. \* $P < 0.05$ ; \*\* $P < 0.01$ ; \*\*\* $P < 0.001$  comparing with Shang ring group

**Table 2: Comparison of post-operative complications (n=314)**

Post-operative complications (%)	Conventional circumcision (%)	Shang ring (%)	DCSD (%)
Incision infection	2.6 (8/314)	4.1 (13/314)	0 (0/314)
Disruption of the incision	4.5 (14/314)	5.1 (16/314)	3.2 (10/314)
Edema	21.3 (67/314)	18.5 (58/314)	1.9 (6/314)
Hematoma	5.1 (16/314)	0 (0/314)	3.2 (10/314)

DCSD: disposable circumcision suture device

**Table 3: Comparison of penile appearance satisfaction rates (n=314)**

Circumcision technique	Extremely dissatisfied	Dissatisfied	Neutral	Satisfied	Extremely satisfied
Conventional circumcision (n, %)	44 (14.0)	78 (24.8)	129 (41.1)	30 (9.6)	33 (10.5)
Shang ring (n, %)	21 (6.7)	13 (4.1)	49 (15.6)	153 (48.7)	78 (24.8)
DCSD (n, %)	11 (3.5)	6 (1.9)	44 (14.0)	161 (51.3)	92 (29.3)

DCSD: disposable circumcision suture device

**Table 4: Comparison of overall satisfaction (n=314)**

Circumcision technique	Extremely dissatisfied	Dissatisfied	Neutral	Satisfied	Extremely satisfied
Conventional circumcision (n, %)	34 (10.8)	22 (7.0)	110 (35.0)	103 (32.8)	45 (14.3)
Shang ring (n, %)	26 (8.3)	36 (11.5)	95 (30.3)	99 (31.5)	58 (18.5)
DCSD (%)	9 (2.9)	7 (2.2)	51 (16.2)	150 (47.8)	97 (30.9)

DCSD: disposable circumcision suture device

intraoperative pain because of incomplete block and can introduce several complications including allergic and toxic reactions and penile hematoma.<sup>16,17</sup> Post-operative penile appearance can be affected as conventional circumcision procedures may result in uneven and asymmetric incisions and polyps of the frenulum.

The health and satisfaction survey shows that patients undergoing surgery with the DCSD experienced reduced intra-operative and post-operative pain. This is likely due to our novel anesthesia method, which allows patients undergoing short surgery such as a circumcision to avoid pain associated with injection, a common anesthetic approach. The penis has typical anatomical features. The skin that wraps the penis is the thinnest and softest skin in the human body, without any subcutaneous adipose tissue. We believe that this makes the topical anesthesia route more efficient and suitable for patients receiving circumcision. In addition, previous studies have demonstrated that compound lidocaine cream can be absorbed easily and is very stable in tissue, anesthetizing the patients for a longer time, especially when applied to superficial skin.<sup>18</sup> In addition, using the DCSD did not involve the pain caused by the electric scalpel or compression.

Our results demonstrate that circumcision performed using the DCSD and Shang ring circumcision involved markedly less intra-

operative blood loss and a shorter operation time when compared to the conventional circumcision technique. We believe that the differences are, at least partly, because the DCSD and Shang ring circumcision aid in removal of the redundant foreskin and anastomose the incision using staples, nearly simultaneously. During the Shang ring technique, the foreskin is sandwiched between the inner and outer Rings before the redundant foreskin is removed by a cryoscalpel. This could substantially reduce intraoperative blood loss.

The use of the DCSD markedly decreased incision healing time. This could be because the use of an electric scalpel during conventional circumcision involves thermal injuries, larger incisions and longer exposure time and Shang ring requires the rings to sandwich the foreskin until the redundant foreskin becomes necrotized.

Other similar circumcision devices such as the gomco device, the accucirc device and others have been studied in recent years. None of them were considered as perfect because of various associated complications.<sup>19–21</sup> The present study demonstrated fewer post-operative complications when the DCSD was used. We believe that this is because the modified device avoids the use of an electric scalpel and manual suture as in the conventional approach and reduces the tissue compression that is associated with the use of Shang rings. In addition, the method of anesthesia is fundamentally different with the DCSD. Lidocaine injection for dorsal penile nerve block in the conventional and Shang ring approaches could induce subcutaneous hematoma and reflux blockage. The reduced edema and better blood supply in the DCSD group decreases the incidences of infection and incision disruption. Firstly, the device we used is a DCSD, the staple of the ring-shaped blade on this device can inosculate with the prepuce during the circumcision, thus the sharp incision of the foreskin can be achieved, thus reducing the risk of the influence of blood supply and getting recovered faster; secondly, one good thing about the staple is that it is double-row straight staple, thus reducing the risk of rupture and because of no irritation of the suture, the risk of local inflammation is low; thirdly, we used self-adhesive plaster for pressure bandaging and gave patients anti-erection medicine (the patients in each group were given 3 mg for consecutive 3 days post-operatively) orally for prevention. In the DCSD group of this study, 10 out of 314 had rupture of the incision site, we gave absorbable thread for local suture and no serious complication occurred.

Improved satisfaction with penile appearance was also achieved using the DCSD. We believe that it is because the device maintains an appropriate length of foreskin, achieves a symmetrical and uniform cutting edge and reduces local induration, dewlap of the preputial frenulum and scars associated with the incision.

In summary, our modification of the traditional anesthetic and surgical methods of circumcision based on our findings of the health satisfaction survey markedly reduced the number of incidences of post-operative complications, intra-operative and post-operative pain and improved penile appearance and patient satisfaction. Several cases of disruption of incision, delayed disappearance of the staples and hematoma were found in a few patients undergoing circumcision with our modified device, warranting further research on measures that must be taken to improve the clinical efficiency and acceptability of our novel surgical approach.

#### AUTHOR CONTRIBUTIONS

SGZ and BDL conceived of the study, and participated in its design and coordination and helped to draft the manuscript. XWZ and ZDC guided the study. JZ drafted the manuscript and performed the statistical analysis. GC participated in the statistical analysis and data reduction. SGZ, XWZ, MFC, HLS and ZJP participated in survey, operation and data collection. All authors read and approved the final manuscript.

#### COMPETING INTERESTS

All authors declare no competing interests.

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Supplementary Information is linked to the online version of the paper on the *Asian Journal of Andrology* website.

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