

## Modified Circumcision Using the Disposable Circumcision Suture Device in Children: A Randomized Controlled Trial



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| <b>OBJECTIVE</b>   | To evaluate and compare the surgical outcomes and complications of the modified circumcision using disposable circumcision suture device (device group) and the conventional dorsal slit circumcision (conventional group) in children.   |
| <b>METHODS</b>     | A total of 284 patients were randomized to either device group or conventional group. All patients were preoperatively assessed and evaluated at 4 weeks after surgery. The perioperative data and postoperative outcomes were compared between the 2 groups.   |
| <b>RESULTS</b>     | No statistical differences were observed in the average age and indications between the 2 groups preoperatively ( $P > .05$ ). Compared with the conventional group, patients in the device group were shorter mean operative time, less blood loss, lower intraoperative and postoperative pain score, faster incision healing time and a higher satisfaction rate of penile cosmetic appearance ( $P < .01$ ). Similarly, the incidences of complication were significantly lower in the device group than in the conventional group (4.3% vs 12.3%, $P < .05$ ). |
| <b>CONCLUSIONS</b> | The modified circumcision using disposable circumcision suture device is a simple, safe, faster, and effective procedure and may become the attractive alternative to the conventional technique for the children, with a relatively lower complication rate and better cosmetic results. With the improvement of disposable circumcision suture device, the modified circumcision using disposable circumcision suture device has the potential to be widely used in the world. UROLOGY 143: 206–211, 2020. © 2020 Elsevier Inc.                                   |

Male circumcision (MC) is one of the most common surgical procedures performed in the world.<sup>1</sup> This procedure can reduce penile cancer rates, improve penile topical hygiene, decrease the risk for HIV infection,<sup>2-5</sup> and helps reduce cervical cancer rates in female partners.<sup>6,7</sup> Besides, it can improve sexual pleasure and function for most men with foreskin problems and possibly decrease coital injuries.<sup>8</sup>

The conventional circumcision recommended by World Health Organization, including forceps guided, dorsal slit (DS), and sleeve resection method, is generally considered the gold-standard surgery in most MC programs, of which DS is used most widely worldwide.<sup>1,9,10</sup> However, these procedures are time-consuming and have

some drawbacks, including bleeding, wound infection, pain, and unsatisfactory cosmetic results.<sup>10,11</sup> In order to overcome these problems, many newer devices have been developed for MC.

Recently a new disposable circumcision suture device (DCSD) (Jiangxi Yuansheng Langhe Medical Instrument Co. Ltd, China) has been introduced. It is proved to be effective and safe in adults, with shorter operation time, reduced complications, rapid recovery, and improved penile cosmesis.<sup>9,12-21</sup> However, a disadvantage of DCSD is that the condition of inner foreskin layer could not be observed by operators when removal of foreskin is performed, resulting in either too much or too little skin removed, especially for beginners.<sup>20,21</sup> To our knowledge, DCSD is used in the pediatric circumcision and its outcomes and complications compared with conventional procedures have not yet been published. To reduce surgical complication and improve the penile cosmetic results, we modified the DCSD circumcision for children and presented the initial outcomes compared to conventional DS method in a randomized controlled study.

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## PATIENTS AND METHODS

### Patients

The study was performed in patients aged 7-16 ( $9.7 \pm 2.7$ ) years undergoing circumcision between July 2017 and July 2018. All of the participating parents/legal guardians were told about details of operations, complications and postoperative care before randomization. Two hundred eighty-four patients were randomized to device group or conventional group according to the literature methods<sup>22</sup> after ethical committee approval, and the written informed consent of parents/legal guardians were obtained. Patients were preoperatively evaluated by medical history and physical examination. Laboratory studies included routine blood and blood coagulation tests. Inclusion criteria were phimosis, recurrent balanoposthitis and redundant prepuce. A patient > 4 years was defined as having phimosis when his prepuce could not be fully retracted behind glans penis.<sup>23</sup> Exclusion criteria were active genital infections, severe adhesion between glans and prepuce, anatomic abnormalities of penis or prepuce, patients with bleeding diathesis or requiring general or spinal anesthesia, and emergent circumcision due to paraphimosis or trauma, history of prepuce or penile surgery, penile cancer, and penis size or shape (nonerection) incompatible with the surgical device available in 5 sizes (D12, D15, D18, D26, and D30).

### Surgical Procedures

The patients were placed in the supine position. All procedures were performed under the regional dorsal penile block using 1 mg/kg of 1% lidocaine with the maximum dose of 10 mL at the penile base. Both procedures were performed by 2 highly experienced surgeons (Jian-Ming Rao and He Huang).

DCSD is mainly composed of strapping tape, wing nut, safety lock, bell-shaped glans pedestal and handler (Fig. 1A). DCSD was chosen properly based on the penis circumference in the flaccid state (Fig. 1B). The incision was marked at 0.5-1.0 cm proximal to the coronal sulcus using a suture at 6 o'clock and 12 o'clock positions (Fig. 1 C, D). The bell-shaped glans pedestal was adjusted to an appropriate position where its edges did not exceed the position of the marked incision after the foreskin was fixed onto it with strapping tape (Fig. 1E-G). Then suture was removed before operators tightened the wing nut counterclockwise. After removing the safety lock on the handler, operators squeezed and held the handles for 20 seconds, resulting in the prepuce removed and incision simultaneously anastomosed with staples (Fig. 1H). Wing nut was loosened to remove the bell-shaped glans pedestal and handler from the penis. The penile cosmetic appearance was showed after DCSD circumcision (Fig. 1I-K). In the conventional group, DS circumcision was performed as previously described.<sup>1,14</sup> The hemostasis was performed by bipolar electrocautery and ligatures. The skin edges were reapproximated in an interrupted manner with 5/0 absorbable sutures.

At the end of both procedures, the self-adhesive elastic bandages was used to cover the incision (Fig. 1L) and removed 7 days postoperatively. If bandage or wound was wet by urination, they were asked to return to our clinic for a bandage change in time. All patients were closely observed for 2 hours postoperatively and discharged to their homes if no complications were found. They were given oral antibiotic for 3 days to prevent infection while no antipyretic or analgesic drugs were administered. After removing the bandage, they were allowed to bathe. They were requested to return at any time if they had complications, serious discomfort or other problems. The staples usually started to fall off

spontaneously about 10 days postoperatively. If sutures or staples didn't spontaneously fall off, it is our institution's policy that sutures or staples were removed within 4 weeks.

Perioperative measured parameters included operation time, blood loss and pain. Both procedure times began when local anesthesia was performed. Both procedure times ended after incision was covered with self-adhesive elastic bandage. During the surgery, intraoperative blood loss was estimated with reference to Decastro et al.<sup>24</sup> We evaluated pain during operation and 24 hours postoperatively. Pain was recorded using a pain score defined using an internationally accepted visual analogue scale, which ranged from 0 to 10. All patients were followed up at 1 day, 3 days, 1 week, 2 weeks, and 4 weeks postoperatively, and by phone calls at other times. Patients with severe edema or bleeding or infection were followed up to 3 months. Postoperative edema, bleeding, infection and wound dehiscence rates were documented during the follow-up. If the perimeter of the inner foreskin layer, including edema, was >30% of the perimeter of the penile shaft, edema was classified as severe.<sup>25</sup> We judged the incision infection when the patient's wound turned red around surgical incision and pus under the skin. Incision healing time was recorded from the date of operation to the date when the surgical wound was completely healed, confirmed by an experienced urologist who was unaware of the method used. Upon wound complete healing, the cosmetic result was evaluated by an experienced senior urologist who was unaware of the method used. The results were categorized as satisfactory or poor.

### Statistical Analysis

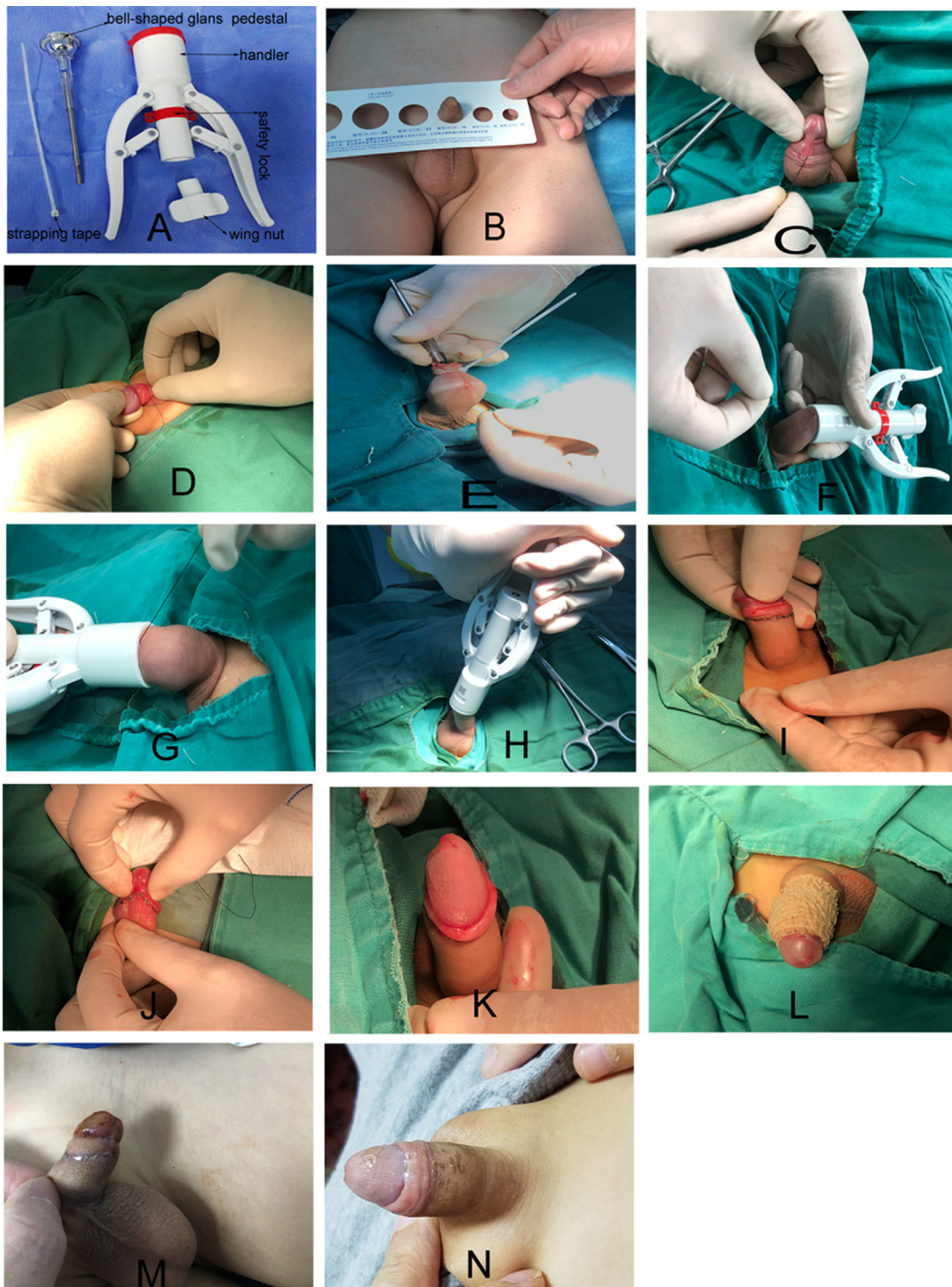
Statistical analysis was performed using the SPSS 20 software package. Data were presented as mean  $\pm$  standard deviation, absolute values or percentages. Mann-Whitney *U* test was used for comparison of continuous variables of both groups. The chi-square test or Fisher's exact test was used for categorical variables. All tests were 2-sided, and differences were considered significant at  $P < .05$ .

## RESULTS

Two hundred eighty-four eligible patients were randomly assigned to either device group ( $n = 144$ ) or conventional group ( $n = 140$ ). Two hundred seventy-seven patients completed the 4 weeks follow-up and were evaluated: 139 of 144 in the device group and 138 of 140 in the conventional group. The reason for dropouts was unwillingness to follow-up by 3 patients and phone or address change for 4 patients.

Clinical data of 2 groups are shown in Table 1. There was no difference in patient age or indications between the groups ( $P > .05$ ). The mean operative time in the device group ( $7.4 \pm 3.3$  minutes) was significantly less than the conventional group ( $21.3 \pm 6.4$  minutes) ( $P < .001$ ). The mean blood loss was significantly more in the conventional group ( $5.6 \pm 4.2$  ml) than device group ( $2.6 \pm 2.1$  ml) ( $P < .001$ ). Compared with conventional group, intraoperative and postoperative (24 hours postoperatively) pain score was significantly less in the device group ( $P < .001$ ).

In general, a lower complication rate was showed in the device group than conventional group (4.3% vs 12.3%,  $P < .05$ ). Similarly, severe edema was observed less frequently in the device group than conventional group (0.7% vs 5.8%,  $P < .05$ ). The edema could be treated conservatively since it would disappear gradually with time. There were no differences in the rates of bleeding, infection or wound dehiscence in 2 groups. Bleeding



**Figure 1.** (A), disposable circumcision suture device (DCSD) is mainly composed of strapping tape, wing nut, safety lock, bell-shaped glans pedestal and handler. (B), a proper DCSD was determined using a measure when the penis was in the flaccid state. (C) and (D), the incision was marked at 0.5-1.0 cm proximal to the coronal sulcus using a suture at 6 o'clock and 12 o'clock positions. (E), (F), and (G), the foreskin was fixed onto bell-shaped glans pedestal with strapping tape; the bell-shaped glans pedestal was adjusted to an appropriate position where its edges did not exceed the position of the marked incision. (H) after removing the safety lock on the handler, the operators squeezed and held the handle for 20 seconds, resulting in removal of the prepuce removed while the incision was simultaneously reapproximated with staples. (I), (J), and (K), the penile cosmetic appearance was showed after DCSD circumcision. L, the incision was covered with the self-adhesive elastic bandage. (M) and (N), penile cosmetic result was showed 1 week and 4 weeks after DCSD circumcision. (Color version available online.)

**Table 1.** Clinical data of the device group and conventional group

| Variables                    | Device Group | Conventional Group | P Value |
|------------------------------|--------------|--------------------|---------|
| No. pts                      | 139          | 138                |         |
| Age (y)                      | 9.8 ± 2.8    | 9.6 ± 2.7          | .359    |
| Indications for circumcision |              |                    |         |
| Phimosis                     | 105 (75.5%)  | 102 (73.9%)        | .097    |
| Recurrent balanoposthitis    | 25 (18.0%)   | 26 (18.8%)         | .854    |
| Redundant prepuce            | 9 (6.5%)     | 10 (7.2%)          | .799    |
| Operative time (min)         | 7.4 ± 3.3    | 21.3 ± 6.4         | .000    |
| Blood loss (ml)              | 2.6 ± 2.1    | 5.6 ± 4.2          | .000    |
| Pain score                   |              |                    |         |
| Intraoperative               | 2.4 ± 2.1    | 6.4 ± 2.3          | .000    |
| Postoperative                | 1.8 ± 1.7    | 3.4 ± 2.3          | .000    |
| Complication (%)             | 6 (4.3%)     | 17 (12.3%)         | .016    |
| Bleeding (%)                 | 2 (1.4%)     | 4 (2.9%)           | .447    |
| Severe edema (%)             | 1 (0.7%)     | 8 (5.8%)           | .019    |
| Infection (%)                | 1 (0.7%)     | 2 (1.4%)           | .622    |
| Wound dehiscence (%)         | 2 (1.4%)     | 3 (2.2%)           | .684    |
| Healing time (d)             | 12.2 ± 2.6   | 14.2 ± 2.6         | .000    |
| Cost (Dollars)               | 279.9 ± 63.4 | 187.7 ± 69.1       | .000    |
| No. satisfaction (%)         | 138 (99.3)   | 128 (92.8)         | .005    |

occurred in 6 patients and can usually be controlled by local compression-using the self-adhesive elastic bandages to cover bleeding wounds immediately (Fig. 1L). During the follow-up, 3 patients experienced infection that usually occurred in the bandages or wounds being wet by urination, but this resolved with oral antibiotics and a bandage change. Five patients complained of wound dehiscence. Wound dehiscence usually did not need suturing if there was no bleeding. Moreover, Patients in the device group healed significantly faster than conventional group (12.2 ± 2.6 vs 14.2 ± 2.6 days,  $P < .001$ ). Similarly, the satisfaction rate was also higher in the device group than conventional group (99.3% vs 92.8%,  $P < .001$ ). But total cost was considerably higher in the device group.

## DISCUSSION

The traditional circumcisions are generally considered the gold-standard surgery in most MC programs.<sup>1,9,10</sup> However, these procedures are time-consuming, and have some drawbacks, including bleeding, wound infection, pain, and unsatisfactory cosmetic results.<sup>10,11</sup> In order to overcome these problems, many newer devices for MC have been developed.

Shang Ring was proved to be effective and safe in adults and children MC, with shorter operative time, lower complications and satisfactory appearance.<sup>9,13,16-19,23,25,26</sup> It obtained the World Health Organization prequalification for use in men 13 years and older.<sup>26</sup> However, it also has its disadvantages, including longer wound healing time, prolonged postoperative pain, and higher edema rate due to the obstruction of lymphatic return.<sup>12-17,19,25</sup> Thus, DCSD is devised for MC based on bowel anastomotic stapler principles that removes the prepuce and makes the stapled anastomosis simultaneously.<sup>12-17</sup> According to results from randomized controlled trial comparing Shang Ring to DCSD, DCSD was as safe and effective as Shang Ring.<sup>13,16,19</sup> Several authors also confirmed that DCSD can improve the foregoing Shang Ring disadvantages.<sup>12-14,16-19</sup>

In a landmark study, Yuan et al<sup>12</sup> retrospectively evaluated the 3-month results of 62 patients treated with DCSD. Average operative time was 7.7 ± 2.6 minutes. Patients returned to full physical activity 3 days postoperatively. All patients had the satisfactory postoperative penile cosmesis, and had fewer complications. Compared to the conventional circumcision, DCSD had shorter operation time, lower pain score and a higher satisfaction rate of penile cosmetic appearance, with minimal complications and rapid postoperative recovery.<sup>13-15,17,18</sup> However, the condition of inner foreskin layer could not be observed by operators when removal of foreskin is performed (Fig. 1H), which may result in either too much or too little skin removed, especially for beginners.<sup>20,21</sup> For the reason, operators should improve the DCSD circumcision to reduce these complications and improve the cosmetic penile appearance. To our knowledge, some studies have investigated DCSD used for adults,<sup>12-17</sup> but randomized trials of DCSD vs traditional DS circumcision for children are scanty. In this study, we modified the DCSD circumcision for children and present the initial outcomes compared to conventional DS method in a randomized controlled study.

Our study showed DCSD circumcision can be successfully, simply, quickly and safely performed using the modified technique in 7-16 years old boys. The satisfaction rate was higher in the device group (99.3%) than conventional group (92.8%) ( $P < .05$ ). This might be mainly because we redesigned the operating procedures for circumcision by combining the advantages of traditional DS method and DCSD technique. Before the prepuce was removed by DCSD, the inner foreskin layer incision was marked at 0.5-1.0 cm proximal to the coronal sulcus using a suture at the 6 o'clock and 12 o'clock positions (Fig. 1C, D). In this way, the DCSD made an even and symmetrical incision and avoided too much or too little skin removed, keeping the lengths of the edges on the inner and outer skin of the prepuce consistent, thereby improving the

penile cosmetic appearance (Fig. 1N). As can be seen in our study, the device group had a shorter mean surgical time than conventional group (7.4 vs 21.3 minutes,  $P < .001$ ). In addition to simple procedure with fewer steps, this might be partly because the inner foreskin layer incision had been marked before circumcision, saving the surgical time required to identify the plane of incision in order to avoid complications. This also helps alleviate the stress for the family waiting for child to return from the operation room, reduce surgery cost and decrease surgical complication.<sup>23</sup> The present study showed intraoperative blood loss was much lower in the device group than conventional group ( $2.6 \pm 2.1$  ml vs  $5.6 \pm 4.2$  ml,  $P < .001$ ). On the one hand, we believe that this difference is at least partly because DCSD removes the prepuce and makes the stapled anastomosis simultaneously. On the other hand, different from the conventional circumcision using ligature or electrocoagulation to hemostasis, causing a relatively large amount of intraoperative bleeding, DCSD has a bell-shaped glans pedestal and handler equivalent to the inner and outer ring of Shang Ring, which can prevent bleeding by physically occluding blood vessels between device rings.<sup>12-18</sup> Besides, we have improved the operating procedures for DCSD circumcision, also avoiding bleeding caused by the tearing of frenulum (Fig. 1C).

Discomfort in the intraoperative and postoperative period was measured by pain score. In our study, the mean intraoperative pain score was significantly lower in the device group than conventional group ( $2.4 \pm 2.1$  vs  $6.4 \pm 2.3$ ,  $P < .001$ ). This might be mainly because shorter operative time ensures the satisfactory effects of local administration.<sup>13-15</sup> Similarly, the mean pain score was also significantly lower in the device group than conventional group 24 hours postoperatively ( $1.8 \pm 1.7$  vs  $3.4 \pm 2.3$ ,  $P < .001$ ). This might be due to DCSD circumcision has less damage to superficial fascia of penis, resulting in less postoperative pain.<sup>13-15,27</sup> Moreover, patients with less postoperative pain might also be because they had less of local acute inflammatory response in the wounds created by DCSD.<sup>13-15,18,19</sup> However, many factors (anesthetic effects, parent's anxiety, children's psychological involvement), may affect the patient's intraoperative and postoperative pain.<sup>14,23</sup> So we think that the results could be altered and more studies are needed to further confirm these results.

Selecting an appropriate DCSD size is very important for preventing the intraoperative and postoperative complications. DCSD was chosen properly based on the penis circumference in the flaccid state and should abide by the principle of "larger rather than smaller." If DCSD is too small, the prepuce fixed onto the bell-shaped glans pedestal with strapping tape (Fig. 1E), is easy to stack together, which is similar to a thick foreskin, resulting in staples detachment and wound bleeding due to the limited stapling power of the small staples.<sup>12</sup> With increased experience, we have observed a slightly larger DCSD maintains a certain tension of the foreskin and avoids incision poor alignment, ensuring better aesthetic results postoperatively. If DCSD is too large, too much foreskin will be removed.

The modified DCSD circumcision had lower postoperative complication rates than conventional circumcision (4.3% vs 12.3%,  $P < .05$ ), which is an obvious advantage of the modified DCSD circumcision. Bleeding is the most common early complication of circumcision and usually from the frenulum blood vessels but can be also from the cut edges of the foreskin.<sup>1</sup> In the device group, bleeding may occur in the residual skin gap that was not covered by staples, and severe bleeding may result in hematoma, particularly during the early stage of the application of technique. With increased experience, we have observed it can usually be controlled by local compression-using the self-adhesive elastic bandages to cover bleeding wounds immediately postoperatively (Fig. 1L). Severe edema was less frequent in the device group than conventional group (0.7% vs 5.8%,  $P < .05$ ). This might be partly because more superficial fascia was removed in the conventional surgery, resulting in the local circulation to be influenced.<sup>27</sup> When the lymphatic circulation has been reconstructed, the edema gradually disappeared. The infection usually occurred in the bandages or wounds being wet by urination. These damp environments could encourage bacterial growth around the wounds. Therefore, we recommend patients return to our clinic for a bandage change in time after the bandage or wound was wet by urination. Wound dehiscence rate was lower in the device group than conventional group, but it did not differ significantly between 2 groups ( $P > .05$ ). This might be attributable to DCSD circumcision that has the reduced edema and better blood supply.<sup>13</sup> The use of the DCSD significantly decreased incision healing time. This probably resulted from the less damage to superficial fascia of penis, which helped the reconstruction of the suturing site and its blood and lymphatic systems.<sup>18,27</sup>

The cost of DCSD circumcision ( $279.9 \pm 63.4$  dollars) was higher than that of conventional circumcision ( $187.7 \pm 69.1$  dollars) ( $P < .05$ ). Patients needed to exclusively pay about 147 dollars for DCSD cost in DCSD group. However, actual cost of producing DCSD is much lower. It may be possible to negotiate with manufacturer to determine a lower, more acceptable price to facilitate widespread promotion of modified DCSD circumcision. Besides, if DCSD that can be re-sterilized and re-used was developed, it could also reduce cost of DCSD circumcision.

From these findings, modified DCSD circumcision can be successfully, simply, quickly and safely performed with fewer postoperative complications and favorable results. In China, neonates and infants circumcision was rarely indicated and most children were operated at an older age based on medical indications.<sup>23,25</sup> Therefore, such good results were needed to further confirmed in larger, multi-centric, randomized studies including neonates and infants in the future.

## CONCLUSIONS

The modified DCSD circumcision is a simple, safe, faster, and effective procedure and may become the attractive

alternative to the conventional technique for the children, with a relatively lower complication rate and better cosmetic results. With the improvement of DCSD, modified DCSD circumcision has the potential to be widely used in the world.

## SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.urology.2020.06.018>.

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