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ORIGINAL ARTICLE

Male Health

Circumcision with “no-flip Shang Ring” and “Dorsal Slit” methods for adult males: a single-centered, prospective, clinical study

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This paper was aimed to compare the clinical effectiveness and safety of adult male circumcision using the Shang Ring™ (SR) with the no-flip technique compared with Dorsal Slit (DS) surgical method. A single-centered, prospective study was conducted at the West China Hospital, where patients were circumcised using the no-flip SR ($n = 408$) or the DS ($n = 94$) procedure. The adverse events (AEs) and satisfaction were recorded for both groups, and ring-removal time and percentage of delayed removals were recorded for the SR group. Finally, complete follow-up data were collected for 76.1% of patients (SR: $n = 306$; DS: $n = 76$). The average ring-removal time for the SR group was 17.62 ± 6.30 days. The operation time ($P < 0.001$), pain scores during the procedure ($P < 0.001$) and at 24 h postoperatively ($P < 0.001$), bleeding ($P = 0.001$), infection ($P = 0.034$), and satisfaction with penile appearance ($P < 0.001$) in the SR group were superior to those in the DS group. After two postoperative weeks, the percentage of patients with edema in the SR group ($P = 0.029$) was higher but no differences were found at 4 weeks ($P = 0.185$) between the two groups. In conclusions, the no-flip SR method was found to be superior to the DS method for its short operation time (<5 min), involving less pain, bleeding, infection, and resulting in a satisfactory appearance. However, the time for recovery from edema took longer, and patients may wear device for 2–3 weeks after the procedure.

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Keywords: Chinese Shang Ring; circumcision; Dorsal Slit; phimosis; redundant prepuce

INTRODUCTION

Circumcision is one of the most ancient and common urinary surgeries dating back more than 5000 years.¹ To date, there have been hundreds of derivatives of the circumcision surgery, and the most common forms are the World Health Organization (WHO)-recommended forceps-guided, Dorsal Slit (DS), and sleeve resection methods.² In these traditional surgeries, it is necessary to cut-off the excess foreskin and suture the incision; this procedure is cumbersome and time-consuming, creating a longer learning curve for the surgeon. Among the above-mentioned methods, the DS method is the most widely used worldwide;² however, it requires superior surgical skill to avoid asymmetric removal of the foreskin on both sides, which, if not achieved, may result in an imperfect postoperative appearance. Therefore, there is an urgent need to reform the circumcision surgery to simplify the surgical process, shorten the operative time, reduce the adverse events (AEs) rate, and achieve a more acceptable appearance.

In 2008, Peng *et al.*³ first reported clinical data after applying a type of disposable circumcision device, the Chinese Shang Ring™ (SR), which was invented by Mr. Shang JZ from China. The study showed that compared with traditional circumcision, the novel device had a

substantial advantage: circumcision using SR is easier to perform and takes less time; it does not require cumbersome procedures such as these traditional surgeries. For the procedure, an inner and outer ring are squeezed together to achieve necrosis on the distal foreskin. It causes slight pain and results in less bleeding, a low incidence of postoperative infection, and a satisfactory appearance; thus, it is commonly accepted by patients. In 2009, Cheng *et al.*⁴ established a standardized surgical protocol for circumcision using SR, which has been widely applied by urologists.⁵ In addition to the benefits mentioned above, during the surgery, the foreskin is completely flipped to expose the corona, which may be easily cleaned after the surgery, thereby producing a cleaner surface and a lower risk of infection. Therefore, this surgical method has been widely used during the SR procedure of circumcision (the so-called “flip SR” or “outward placement” procedure).

Meanwhile, based on Xie *et al.*⁶ and our previous data,⁷ we have found that circumcision using SR during a “no-flip SR” procedure (also called an “inward placement” procedure) can result in excellent outcomes. The main difference between the flip and no-flip SR methods is that during the former, the foreskin needs to be turned over to cover the inner ring, which is placed at the outer plate of prepuce; the latter just requires the foreskin to be pulled and the inner ring placed in

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the corona without turning over the foreskin. This single-centered, prospective clinical study was conducted to compare the clinical efficacy and AEs between the "no-flip SR" and "DS" procedures for adult males with redundant prepuce or phimosis.

MATERIALS AND METHODS

Clinical data

Patients attended the Department of Urology, West China Hospital, Chengdu, China, between October 2012 and April 2014. In total, 502 adult males aged 18–76 years (mean 25.4 years), 56 with phimosis and 446 with redundant prepuces, underwent the no-flip SR ($n = 408$) or DS ($n = 94$) procedures, respectively. Patients were given freedom to choose their procedure. However, the patients were sufficiently informed of the merits and costs of the two methods before deciding on which one to choose and providing written informed consent. The average cost of the SR procedure was 2–3 times higher than that of the DS procedure. Males with severe active balanitis, hypospadias, or a concealed penis were surgery taboos and were excluded. YCZ performed all these procedures. The study was approved by the Ethics Committee of the West China Hospital of Sichuan University.

Surgical instruments

For contents of the circumcision special surgical package in detail, please refer to the paper of Cheng *et al.*⁴ The common SR sizes in China are C (34 mm), D (33 mm), E (32 mm), F (31 mm), G (30 mm), H (29 mm), and I (28 mm) (Wuhu Santa Medical Equipment Technology Co., Ltd.; Wuhu; China). If required, a special opener and scissors were used during ring-removal.⁴

Preoperative preparation

A routine blood test, the coagulation function test, was conducted on each patient to rule out infection, circulatory disease, and dysfunction of blood coagulation. With the foreskin returned to a natural "resting" position at 20°C room temperature, the circumference of the penis was measured just below the corona, following which the corresponding size of SR was chosen. If the reading was just between two sizes, the larger one was selected.⁴ When measuring the circumference of the penis, the special SR tape should not be too tight or too loose. The measurement process should be quick to decrease the chance of erection, which could result in a measurement error.

Surgical method

The patient lay supine and was disinfected from the level of navel to mid-thigh. Approximately, 1 ml of lidocaine (2%, 2 g ml⁻¹) was subcutaneously injected at the 12 o'clock position near the base of the penis. Following this, without withdrawing, the needle was advanced into the layer of dorsal nerves. At this point, 1 ml of lidocaine was injected, followed by further 5 ml on both the sides to block the dorsal nerves. Lidocaine (1 ml) was also injected for the frenum position. The injection from both sides was planned to converge at the 6 o'clock position. Before injecting any anesthetic, the surgeon gently withdrew the plunger of the syringe to ensure that no blood was drawn. The foreskin was grasped at the 3, 6, and 9 o'clock positions with mosquito clamps to expose the opening of the foreskin. Any adhesions were separated, and the smegma was cleaned away. The glans and corona were disinfected again. An inner ring of the appropriate model size was placed between the corona and the inner plate of the foreskin, the length of the inner and outer plates were adjusted to the proper extent, and the outer ring was gently placed onto the inner ring. The outer ring was tightened to the first fixing buckle. Approximately, 0.5 cm of the inner plate of the prepuce was conserved with the ring positioned higher at

the front and lower at the back, forming a 30°–45° angle with the axis of the penis. The positions of the inner and outer rings were adjusted; the outer ring was tightened to the second fixing buckle. Dissection scissors were used to cut the redundant foreskin. The blade was used to perform an open relaxation incision at the 2, 5, 8, and 11 o'clock positions of the incisal edge.⁴ The incisal edge was disinfected and the wound covered with gauze (Figures 1–4). Patients were requested to take more rest and to avoid sexual stimulation and strenuous exercise during the first postoperative week for preventing penile erection, SR slip, or hemorrhage.

If the foreskin could not be fully retracted because of phimosis, a dorsal incision was performed. The incision position was clamped with a medium artery forceps for 1 min, and the dissection scissors were then used to cut the foreskin for reducing bleeding. Following this, the proximal incision was clamped to prevent tearing the inner plate when turning over the foreskin.

For details of the DS procedure, please refer to the guidelines of the DS method of circumcision under local anesthesia.² The local block procedure was just the same between the two groups.

Observational indexes

Time-related indexes

The operation time was defined as the duration from disinfecting the operative area to covering the surgical incision with gauze. The ring-removal time was defined as the number of days between SR placement and spontaneous ring-removal. Delayed ring-removal was defined as the lack of spontaneous ring-removal during 3 weeks after placement.

Evaluation of AEs

Bleeding, edema, pain, infection, wound dehiscence, and delayed ring-removal were observed. The official criteria⁸ were applied to evaluate if those AEs occurred. The severity of each AE was graded to three levels: mild (if no intervention was needed), moderate (if nonsurgical intervention was indicated), and severity (if surgical intervention or hospitalization was required).⁹ A visual analog scale (VAS) was used to evaluate the pain¹⁰ on a scale of 0 to 10, with 0 representing no pain and 10 representing sharp pain. We recorded the pain scores during the procedure and at 24 h postoperatively.

Follow-up

We phoned the patients 24 h after surgery for postoperative pain scores. We recommended a hospital check-up 2 and 4 weeks after surgery; at this second-time point, data regarding AEs were collected. Telephone follow-ups were used for the patients who could not return. We instructed each patient to return to the hospital for surgical ring-removal if spontaneous ring-removal had not occurred in 3 weeks. The satisfaction with penile appearance was followed-up at 4 weeks after surgery. If purulence, cracking, or bleeding of the wound occurred, patients were strongly recommended to return to the hospital. All the follow-up data were collected by WBX.

Statistical analysis

SPSS 13.0 (International Business Machines Co., Ltd.; Armonk; USA) was used for statistical analyses. Discrete variables and continuous variables were compared with the χ^2 and *t*-test, respectively. $P < 0.05$ was considered to reflect a significant difference. Two authors (LRL and LY) conducted the statistical analysis independently, and any disagreements were solved by discussion within the study group.

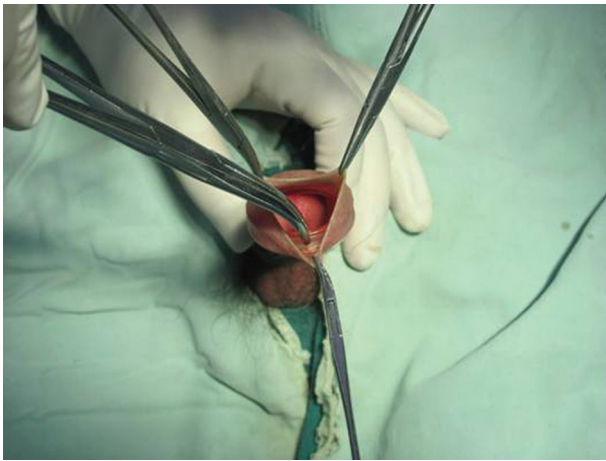


Figure 1: Placing the inner ring between the inner plate and sulcus.

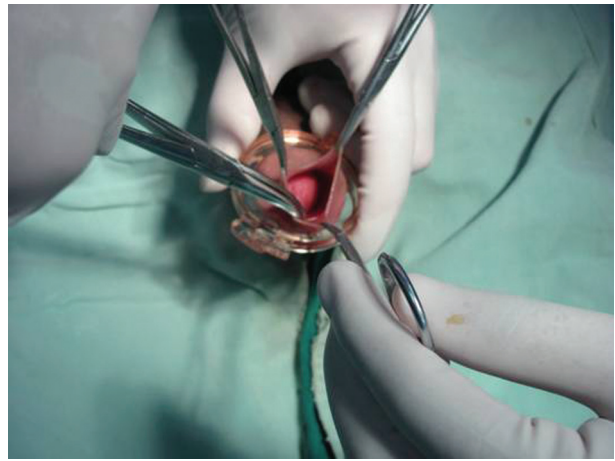


Figure 2: Trapping the outer ring over the inner ring.

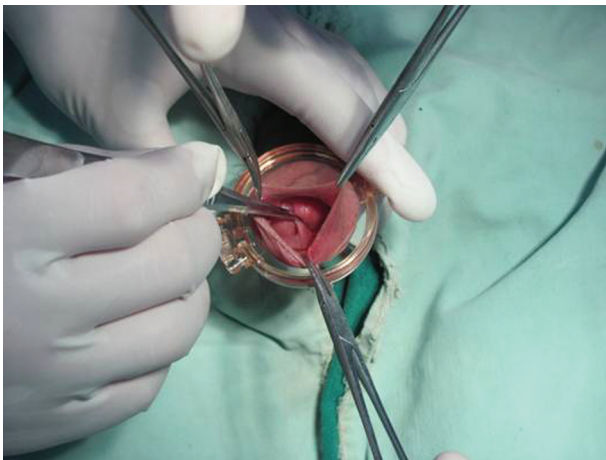


Figure 3: Adjusting the frenulum length, and tightening up the outer ring.

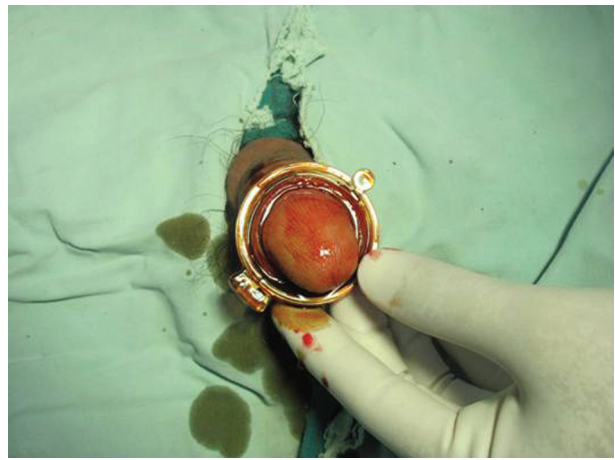


Figure 4: Removing the redundant foreskin and sterilizing the edge.

RESULTS

Comparison of operation results and AEs

The baseline data were comparable between two groups in age and number of the phimosis/redundant prepuce ($P > 0.05$). In total, 502 adult males received successful circumcision. The operation time of the SR group was 4.76 ± 0.82 min, and that of the DS group was 24.02 ± 4.55 min. The patients with a redundant prepuce rarely bled during the surgery, whereas others with phimosis bled no more than 5 ml when separating adhesions and exposing the opening of the foreskin. Until 4 weeks postoperatively, the complete follow-up data of 76.1% (382/502) of patients (306 in the SR group and 76 in the DS group) were obtained by phone (24.6%, 94/382) or during postoperative hospital follow-ups (75.4%, 288/382). The average ring-removal time of the SR group was 17.62 ± 6.30 days. Data between groups showed no difference in age, redundant prepuce, or phimosis. The operation time ($P < 0.001$, *t*-test), pain scores during the procedure ($P < 0.001$, *t*-test) and at 24 h postoperatively ($P < 0.001$, paired *t*-test), bleeding ($P = 0.001$, χ^2 test), infection ($P = 0.034$, χ^2 test), and satisfaction with penile appearance ($P < 0.001$, χ^2 test) in the SR group were superior to those in the DS group. The percentage of edema present in the SR group ($P = 0.029$, χ^2 test) at 2 weeks after surgery was more serious; however, no differences were found at 4 weeks ($P = 0.185$) between the two groups. Detailed data are shown in **Tables 1 and 2**.

Table 1: The baseline data and outcomes of male circumcision when compared “no-flip SR” with “DS” methods

Items	SR (n=306) (%)	DS (n=76) (%)	P (two-sided/tailed)
Baseline data			
Age (year)			
18–44	229 (74.84)	53 (69.74)	0.448
45–59	61 (19.94)	19 (25.00)	0.416
60–76	16 (5.22)	4 (5.26)	1.000*
Redundant prepuce	281 (91.83)	65 (85.53)	0.143
Phimosis	25 (8.17)	11 (14.47)	0.143
Surgical and follow-up data			
Operation time (min)	4.81 ± 0.86	23.39 ± 4.31	< 0.001
Pain scores			
During the procedure	1.78 ± 1.27	3.12 ± 1.43	< 0.001
At 24 h postoperatively	4.02 ± 1.16	5.82 ± 1.44	< 0.001
Satisfaction with penis appearance	295 (96.41)	55 (72.37)	< 0.001
Ring-removal time [‡] (day)	17.62 ± 6.30	NA	NA
Spontaneous removal (%)	79.17 (323/408)	NA	NA
Delayed ring-removal (%)	20.83 (85/408)	NA	NA

*It was calculated by Fisher’s exact test because one cell (25%) had expected count < 5 .

[‡]It was defined as the number of days between SR placement and spontaneous ring-removal. NA: not available; DS: dorsal slit; SR: shang ring

Table 2: The severity grading of main AEs[§]

AEs items	SR			DS			P* (two-sided/tailed)
	Mild	Moderate	Severity	Mild	Moderate	Severity	
Bleeding (n=13)	3	0	0	8	0	2	0.001
Edema							
At 2 weeks (n=123)	107	0	0	16	0	0	0.029
At 4 weeks (n=32)	29	0	0	3	0	0	0.185
Infection (n=16)	0	9	0	0	7	0	0.034
Wound dehiscence (n=3)	1	0	2	0	0	0	NA

[§]The severity of each AE was graded to three levels: mild (if no intervention was needed), moderate (if nonsurgical intervention was indicated), and severity (if surgical intervention or hospitalization was required); *The P value was applied to the comparison between the total events of SR arm and the total events of DS arm. NA: not available; AEs: adverse events; DS: dorsal slit; SR: shang ring

Specific adverse events and their treatment

There were three cases in which part of the outer ring slipped in the first 7 days after surgery because of frequent penile erection. For patients with over 1 cm of wound dehiscence (2 of the 3), we sutured the inner and outer plates where the dehiscence occurred and asked them to avoid sexual stimulation and to cover the penis with a cold towel if erection occurred. Meanwhile, they were asked to disinfect the wound and the slipping position with 5% povidone iodine 3 times a day. SR fell off by itself in 3 weeks, and the wound healed well after stitch removal in the hospital for all three cases. Hemorrhage occurred in 13 patients within the first 3 days; however, they recovered after disinfection, binding and suturing when necessary. A further six cases in the SR group had serious edema beyond 4 weeks. We asked these patients to steep the penis in strong brine for 5 min (3 times a day), following which the edema faded within an additional 2 weeks. There were 16 cases of infection after surgery. They all resolved after the application of antibiotics for 1 week and a routine of washing the penis with 5% povidone iodine every day. For the SR arm, spontaneous ring-removal occurred in 323 cases and delayed removal of the ring occurred in the residual 85 cases. Using special equipment in our department, the rings were successfully removed.

DISCUSSION

Previous studies have shown that male circumcision can reduce the human immunodeficiency virus (HIV) infection rate in men by 60% and reduce urinary tract infections, penile cancer, and the female partners’ incidence of cervical cancer.¹¹⁻¹⁴ In 2008, the WHO published three methods of adult male circumcision using local anesthesia: forceps-guided, DS, and sleeve resection methods; all three require cutting and suturing, and the operation time is rather long.²

Circumcision using SR is an innovative circumcision surgery because it abandons the complex surgical procedures during traditional circumcision surgery. Because of the pressure between the inner and outer ring blocks, blood supply to the distal foreskin is stopped, resulting in necrosis and eventual shedding of the dead tissue. SR simplifies the surgical procedure, shortens the learning curve, reduces the operation time and difficulty, and substantially reduces the rate of AEs such as pain and infection. However, if choosing the method of waiting for spontaneous ring-removal, patients must wear the device for 2-3 weeks after the procedure, which is a major drawback.

To our knowledge, this was the first study to compare the clinical efficacy and AEs of the “no-flip SR” and “DS” procedures for males with a redundant prepuce or phimosis. Most published clinical data on circumcision using SR are based on the so-called “standard program” (flip SR method).⁴ The study by Xie *et al.*⁶ shows that the pain score of the no-flip SR method is lower than that of the flip method at day 3 after surgery (2.23 ± 0.24 vs 4.92 ± 1.21, P < 0.05).

This study showed that most patients can tolerate surgery after taking nonsteroidal analgesics orally 1 h before surgery. The pain scores during the procedure and at 24 h for the no-flip SR method were 1.78 ± 1.27 and 4.02 ± 1.16, respectively, which were lower than those for the DS method (P < 0.001 for both time points). We noted that the no-flip method left the foreskin in a more natural state, reducing the stretching on the foreskin by the ring, leading to less pain and discomfort. In contrast, the drawback of the long duration and complex and invasive procedure of the DS method may cause more pain to patients.

However, because the inner ring of the no-flip method was located in the inner foreskin, forming a narrow space between the corona and the inner ring, depositions of smegma and residual urine were more common using the no-flip method than using the flip method; the latter were subsequently more likely to result in infection. This study found that the infection rate was 2.94%, which was higher than that using the flip method as reported by Cheng *et al.* and Xie *et al.* (0.6% and 1.5%, respectively) but still lower than that using the DS method (P = 0.034).^{4,6} In addition, Yang *et al.*¹⁵ reported that the incidence of infection for no-flip adult SR was 0.56% (3/528), which is lower than that detected in our study (2.94%, 29/306). They did not report the complete follow-up data of how many cases were available among the 528 cases; they may assume that no AEs occurred for cases lost to follow-up. In contrast, because the patients subjected to the DS method underwent a complex, invasive, and open procedure, they suffered a higher chance of being infected. Therefore, we suggested that each patient should wash his penis with 5% povidone iodine and clean the narrow space and the incision with povidone iodine swabs.

Meanwhile, an obvious flaw of the SR procedure is the high incidence of edema. The incidence of edema at 2 weeks after surgery was higher than that in the DS group (P = 0.029) and was nearly 10% even at 4 weeks after surgery. This may be a result of some of the following factors: (i) lymphatic vessels could not be rebuilt in time, unlike after traditional surgery; (ii) a relatively narrow space between the corona and the inner ring increased the risk of infection, and infection could aggravate the edema; (iii) the inflammation reaction of the foreskin; or (iv) repeated erection of the penis after surgery. Therefore, it was advised to avoid sexual stimulation. Washing the penis with 5% povidone iodine mixed with 10% hypertonic saline during the early postoperative stage not only removed the secretion of the inner plate of the foreskin and the incision, thereby reducing the incidence of infection, but also relieved the foreskin edema.

The study by Cheng *et al.*⁴ shows that the pain score of manual ring-removal is the highest among the pain scores collected at different time points and that returning to the hospital for ring-removal increases the financial burden on patients. The randomized comparison in the study by Barone *et al.*¹⁶ confirmed that within the 3 weeks after surgery, the occurrence of spontaneous ring-removal was more likely when the

patients waited for longer. Therefore, we recommended the patients to come back to the hospital only in cases of delayed removal. We showed that the proportion of spontaneous ring-removal was 79.17 (323/408); this reduced the cost and avoided the pain of surgical ring-removal in most patients. For all patients in all cases of delayed removal, 2% lidocaine was applied to the surface to soften the scab, thereby reducing the pain and the occurrence of incision cracking and bleeding. For patients who are not willing to wait for SR to fall off on its own, the ring-removal procedure should be conducted at least 7 to 10 days postoperatively.⁴ Importantly, a randomized controlled trial (RCT)¹⁷ with circumcision intervention, which was performed at Uganda, demonstrated that among the couples with HIV+ females and HIV- males at baseline who resumed intercourse more than 5 days before the male partner's wound was certified as completely healed and within the 5 days before or any time after certified wound healing, 27.8% (5/18) and 9.5% (6/63) of males were confirmed with the seroconversion of HIV ($P = 0.06$), respectively. Therefore, it is necessary and important to remind the patients to delay resuming intercourse or to use condoms.

The most exciting result for the SR group was a near-perfect level of satisfaction with a penile appearance in comparison with the DS group (96.41%, $P < 0.001$). The inner ring of SR determined the edge of the residual prepuce; therefore, it could objectively produce an appropriate length of prepuce and frenula, bilateral symmetry appearance, and smooth edge. For the DS procedure, it may be difficult for surgeons to determine the prepuce edge and the ultimate appearance, largely depending on their surgical skill.

Finally, this study still had several limitations. First, although the prospective study provided evidence to support the use of the “Chinese SR,” the rate of follow-up was only 76.1%, thereby leading to potential bias, particularly for AEs. Further, RCTs with large-scale, multi-center, and rigorous design would provide more robust conclusions. Second, the self-reported data (24.6%) may result in reporting bias; therefore, the actual prevalence of AEs was higher than the current outcome. In addition, we failed to investigate their sex life quality after circumcision because most patients refused to answer related questions. A precise cost effectiveness of the two methods also was not assessed, which should have been considered, particularly in developing countries such as China.

CONCLUSION

In general, our study shows that circumcision using the no-flip SR method is superior to that using the DS method. The operation time was only approximately 5 min, with less pain and AEs such as bleeding and infection, producing a neat healing edge and a higher satisfaction with penile appearance. However, the edema recovery period was longer, and patients may wear the device for 2–3 weeks after the procedure.

AUTHOR CONTRIBUTIONS

JHL and LRL wrote the first edition of the paper. WBX and TRS

collected the data. SBY and LY analyzed the data. QW, YCZ and PH commented in detail on the drafts. All authors read and approved the final manuscript.

COMPETING INTERESTS

The authors declare that they have no competing interests.

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