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·Original Article·

Clinical application of a new device for minimally invasive circumcision

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Abstract

Aim: To study the clinical effects of a disposable circumcision device in treatment of male patients of different ages with either phimosis or excess foreskin. **Methods:** One thousand two hundred patients between the age of 5 and 95 years underwent circumcision using this procedure in the 2-year period between October 2005 and September 2007. Of these cases, 904 had excess foreskin and 296 were cases of phimosis. **Results:** In 96.33% of the cases the incision healed, leaving a minimal amount of the inner foreskin with no scarring and producing good cosmetic results. There were no incidents of device dislocation or damage to the frenulum. The average operative time was 2.5 min for excess foreskin, and 3.5 min for phimosis. During the 7 days of wearing the device, mild to moderate edema occurred in 10.08 % of cases with excess foreskin and in 2.58 % of those with phimosis. Edema in the frenulum was seen in 1.67% of patients, and only 0.67% had an infection of the incision. A total of 86.25% of patients reported pain due to penile erection. After removal of the device, 0.58% of the cases had minimal bleeding around the incision, and 2.42% had wound dehiscence. **Conclusion:** The new device can be applied to an overwhelming majority of patients with phimosis and excess foreskin. This technique is relatively simple to perform, and patients who underwent this surgery had very few complications. Antibiotics were not required and patients reported less pain than those who were circumcised using conventional methods. Circumcision with this device requires minimal tissue manipulation, and is quicker and safer than circumcision using conventional techniques. *(Asian J Andro 2008 May; 10: 447–454)*

Keywords: excess foreskin; phimosis; circumcision device

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1 Introduction

Male circumcision has been practiced on a large scale for more than 5 000 years [1] as a way to remove the redundant foreskin in order to expose the glans. The

benefits of circumcision include easier urination, improved penile topical hygiene, and increased sexual pleasure. In addition, a World Health Organization/Joint United Nations Programme on HIV/AIDS (UNAIDS) evaluation of recent research, conducted in Africa, concluded that circumcision can reduce the risk of men becoming infected with HIV by approximately 60% [2]. Male circumcision is practiced worldwide for medical, cultural, and religious reasons. Regardless of why it is carried out, circumcision should be done in a way that reduces unnecessary suffering. Although circumcision is easy to perform [3], complications may result if the procedure is not done properly. The introduction of new, easy-to-use circumcision devices has made it possible to improve the results of the operation, prevent infection, and reduce pain in patients. Along with our colleagues from hospitals on the Chinese mainland, we have been using a newly invented disposable circumcision device (Shenghuan Disposable Minimally Invasive Circumcision Anastomosis Device; China Wuhu Snnda Medical Treatment Application Technology Co. Ltd., Wuhu, China) for treating patients with phimosis and excess foreskin, and have achieved satisfactory results.

2 Materials and methods

2.1 Clinical data

One thousand two hundred patients with phimosis or excess foreskin underwent circumcision using this new disposable device. The group included children between the ages of 5 and 12 years (n = 160), teenagers aged 13 to 17 years (n = 440), adults between the ages of 18 and 60 years (n = 534), and elderly patients between the ages of 61 and 95 years (n = 66). According to medical records, 296 out of the 1 200 cases were phimotic and 904 had excess foreskin. In the phimosis group, there were 120 children, 128 teenagers, 32 adults, and 16 elderly patients. In children with phimosis, 93 had experienced concretions beneath the foreskin. All participants were provided with information about the benefits and risks associated with the procedure, and were required to sign an informed consent form before being enrolled in the study.

2.2 Circumcision device

The Shenghuan Disposable Minimally Invasive Circumcision Anastomosis Device was invented by Shang Jianzhong (China Wuhu Snnda Medical Treatment Application Technology Co. Ltd.) and was granted domestic patent approval (Patent No. ZL200320124901.9; PCT/CN2003/000903). International patents are pending. The device is made of medical grade polymers imported from the USA. Weighing from 2.8 g to 8 g, the device consists of an inner and outer ring, a silicon rubber gasket, and a fastener (Figure 1). The inner ring serves as a frame for the device, which comes in 13 sizes, based on its inside diameter. The sizes are as follows: A2 (40 mm), A1 (37 mm), A (34 mm), B (32 mm), C (30 mm), D (28 mm), E (26 mm), F (24 mm), G (22 mm), H (20 mm), I (18 mm), J (16 mm), and K (13 mm). The outer ring is made of two linked semicircular pieces with cutting blades attached to the inner surfaces. The devices are hermetically sealed in a foil-covered paper bag and sterilized by γ-ray radiation.

2.3 Methods

2.3.1 Examination of foreskin

The area under and around the foreskin was examined for inflammation and warts and assessed to see whether it could be pulled over and stretched. Surgical contraindications were defined as the presence of acute inflammation, uncontrolled diabetes mellitus, and concealed penile phimosis related to balanitis xerotica obliterans. Males born with penile anomalies (hypospadias, epispadias, or megalourethra) and children with ammonia dermatitis were also excluded from the study. Caution is required for indications for circumcision, especially in children, as the protective role of the foreskin is not always understood. Excess foreskin is only a surgical indication for children's circumcision when the foreskin is long enough

Figure 1. Shenghuan Disposable Minimally Invasive Circumcision Anastomosis Device consists of an inner and outer ring, a silicon rubber gasket and a fastener. The outer ring is made up of two linked semi-circular pieces with cutting-blades attached to the inner surfaces.

to lead to recurrent irritation and discomfort from retention of urine inside the sac.

2.3.2 Measurement of circumference

A specially prepared measuring tape was used to measure the circumference of the penis at the level of the coronal sulcus in order to select the appropriate device size. For instance, if penile circumference at the coronal sulcus was at the C point on the measuring tape (Figure 2), device model type C was used.

2.3.3 Disinfection and anesthesia

Disinfection was accomplished by applying disinfectant iodophor or 0.05% chlorhexidine acetic solution around the penis and involved tissues and by covering the operative site with a surgical drape. The dorsal penile nerve was blocked by a local anesthetic solution of 1% lidocaine using a 24-gauge needle. The recommended anesthetic dose varied from 3 mL to 5 mL.

Figure 2. A specially prepared measuring tape is used to measure the circumference of the penis at the level of the coronal sulcus.

2.3.4 Placement of device and fixation

Once the penis was completely anesthetized, the inner ring was placed on the shaft (Figure 3). Next, the rim of the foreskin was clamped with blood vessel forceps at the 3, 6, 9 and 12 o'clock points (Figure 4). A urologist and an assistant each held two clamps to widen the opening of the foreskin, and pulled it over the inner ring (Figure 5). After the inner and outer layers of the foreskin and the frenulum were symmetrically positioned, the assistant installed the outer ring over the foreskin and gently screwed it together. Finally, they verified that 0.5 cm of the inner foreskin lining and an adequate frenulum were preserved (Figure 6). In cases with phimosis, a dorsal slit of the foreskin must be made after binding the root of penis with a rubber band. The dorsal foreskin should be cut deep enough to be pulled over the inner ring (except in the case of phimosis related to balanitis xerotica obliterans, where the procedure would be contraindicated). The procedure can then be carried out as described above.

2.3.5 Removal of excess foreskin

Excess foreskin is then cut by stretching the foreskin to just below the circumcision device with the aid of blood vessel forceps. Four or five relieving incisions must be made with a sharp knife at the end of the re-

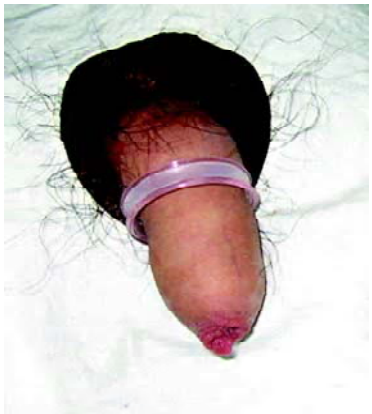

Figure 3. The inner ring was placed on the shaft after the penis was completely anesthetized.

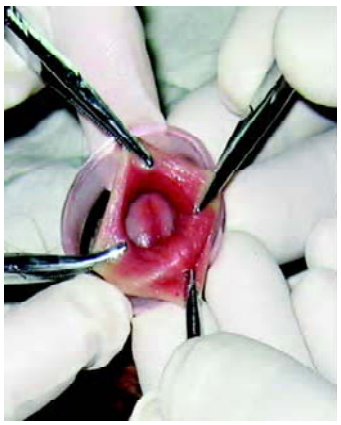

Figure 4. The rim of the foreskin was clamped with blood vessel forceps at the 3, 6, 9 and 12 o'clock points.

maining foreskin (Figure 7).

2.3.6 Postoperative management

Oral painkillers were recommended for postoperative pain. Oral use of diethylstilbestrol at a dose of 2 mg per night can prevent nocturnal erection of the penis.

2.3.7 Removal of circumcision device

The circumcision device was removed 7 days after the procedure. Its position and the edges of the wound were checked. To remove the device, the following steps were taken: 1) the screw was gently unfastened and the outer rings removed (Figure 8); 2) the inner ring by the rim of incision was pushed carefully backward; and 3) the ring was cut with special sulcate scissors and removed (Figure 9).

2.3.8 Protective dressing

A specially prepared wound dressing (Figure 10) is recommended to keep the necrotic skin tissues from rubbing against the scrotum.

3 Results

In a total of 1 200 cases of circumcision in male patients with phimosis or excess foreskin, 96.33% had primary wound healing of the incision with a straight margin. The frenulum remained flexible and intact, and a minimal layer of the inner foreskin was left, producing good cosmetic results (Figure 11). There were no incidents of device dislocation or injury to the frenulum in any of the cases. The average duration of the procedure for cases with excess foreskin was 2.5 min compared

Figure 5. Pulling the foreskin over around the inner ring.

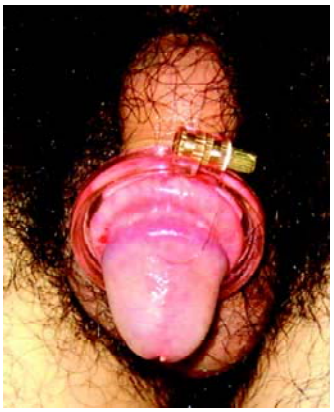

Figure 6. The outer ring was installed over the foreskin and fastened the screw of the outer ring.

Figure 7. After excess foreskin was snipped, four or five relieving incisions must be made with a sharp knife at the foreskin stump between the inner and out ring.

Figure 8. The outer ring was removed at day 7 post-operation.

with 3.5 min for cases with phimosis. Although the patients suffered pain from wearing the device on the day of the procedure, it was relieved by oral painkillers and subsided within 24 h.

Complications that occurred while the patients were required to wear the device are listed in Table 1. Most men reported pain at night associated with nocturnal erections despite, the suggested use of an anti-androgen. However, the pain was tolerable and no devices needed to be removed for this reason. Table 2 shows the complications that occurred after the device was removed.

4 Discussion

Conventional circumcision may result in complications due to postoperative disturbance of circulation of the inner foreskin layer. This can result in edema that could delay the healing of the wound [4]. Hemostasis by ligation is necessary to treat subcutaneous bleeding. Furthermore, sutures might cause pain or dyspareunia, and potential intra-operative or postoperative bleeding could cause secondary infections. Because the wounds are close to the urethral orifice, the dressings are likely to be wet by urination. These damp conditions are favorable to bacterial infection around the wounds, chiefly at the junction of the frenulum and the urethral orifice, and hematomas and hydrops are likely to cause local inflammation.

Technicians in medical instrument research and development have invented a new circumcision device that can reduce morbidity associated with this procedure. The Shenghuan Disposable Minimally Invasive Circumcision Anastomosis Device is superior to other recently invented devices because of its unique structure. The uniform force from both outer rings created by this device can

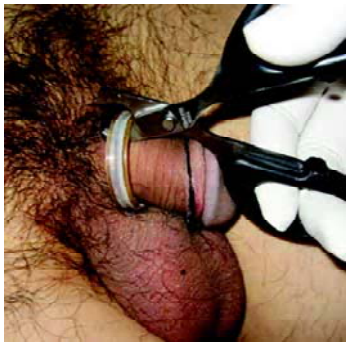

Figure 9. Cutting off the inner ring with the special sulcate scissors.

Figure 11. Non-symptomatic penis with cosmetic results exhibited an even linear rim and uniform inner and outer preputial laminas after the scab falls off.

Figure 10. Special adhesive tape dressing for disinfection and to keep the necrotic skin tissues from rubbing against the scrotum after removal of the device.

Figure 12. Circumcision of the foreskin of a child (the best preserve the frenulum of glans) using the Shenghuan Disposable Minimally Invasive Circumcision Anastomosis Device.

Table 1. Complications in 1 200 male patients while wearing the Shenghuan Disposable Minimally Invasive Circumcision Anastomosis Device.

Symptoms	Children (Aged 5–12 years) (n = 160)	Teenagers (Aged 13–17 years) (n = 440)	Adults (Aged 18–60 years) (n = 534)	Elderly (Aged 61–95 years) (n = 66)	Total of cases (%)
Mild edema (inner preputial lamina)	16	46	53	6	121 (10.08)
Moderate edema (inner preputial lamina)	5	11	14	1	31 (2.58)
Edema of the frenulum	5	6	8	1	20 (1.67)
Infection of incision	2	3	3	0	8 (0.67)
Swelling pain from nocturnal erection	70	386	459	21	936 (78)

Table 2. Complications in 1 200 male patients after removal of the Shenghuan Disposable Minimally Invasive Circumcision Anastomosis Device.

Symptoms	Children (Aged 5–12 years) (n = 160)	Teenagers (Aged 13–17 years) (n = 440)	Adults (Aged 18–60 years) (n = 534)	Elderly (Aged 61–95 years) (n = 66)	Total of cases (%)
Bleeding of the incision	0	2	5	0	7 (0.58)
Wound dehiscence of the incision	1	11	16	1	29 (2.42)

result in ischemic necrosis of the tissues clamped between the inner and outer rings and spontaneous anastomosis of the incised rim with no injury to the frenulum. Sutures and antibiotics are not required because there is no bleeding during the procedure and very few complications have been reported. Patients can follow their normal daily routines, and can even bathe while the device is still attached. Recovery time is approximately 1 week. The cosmetic results were good, with an even linear rim and uniform inner and outer foreskin layers after the scab fell off 10–14 days after the removal of the device. Considering the tender condition of the frenulum in children, conventional circumcision tends to result in bleeding, segmentation, hematoma, or sclerosis of penile frenulum if it is improperly managed. Fortunately, this new device can provide children with a safer circumcision (Figure 12). Our device is superior to the Korean style of circumcision (Korea Good Man CDS-8; Korea GM Medical Corp.; Seoul, Korea). The Korean device locates the inner ring around the coronal sulcus under the foreskin, making it difficult to precisely measure the length of the frenulum. Having an unexposed coronal sulcus after the procedure can create warm and humid conditions that could encourage bacterial growth. Inflammation around the sutures might also lead to the growth of bacteria. Antibiotics are often required to prevent postoperative infection, because the incision is so close to the external orifice of the urethra that it is easily infected by urine.

Together with health providers from different hospitals, we have performed circumcisions using the Shenghuan Disposable Minimally Invasive Circumcision Anastomosis Device in 1 200 cases, and no incidents of significant bleeding or device dislocation have occured. Both the silicon rubber gasket on the inner ring and the cutting blade attached to the inner side of the outer ring can exert moderate and persistent force on the clamped tissues. This ensures that the tissues will not be cut off due to excessive force from the outer rings, and that the wound margin tissues of both inner and outer foreskin layers will not slip. Bleeding control and blockage and apposition of both inner and outer foreskin layers are carried out once the device has been set. All patients underwent local anesthesia for the procedure. The data show that this device can be used for circumcision in male patients aged 5–95 years. In cases of children, the procedure can be carried out if the child can tolerate a local anesthesia. A dose of 3 mL of 1% lidocaine will

facilitate the procedure, but 5 mL of 1% lidocaine is recommended for teenagers, young adults and elderly patients. Dorsal penile nerve block requires a minimum of 0.5 mL of anesthetic without additional epinephrine 1:1 000. Not a single case of ischemic glans penis was seen in our clinical experience, as reported by Tzeng *et al*. [5] when the dorsal penile nerve block was introduced. The average duration of the procedure was 2.5 min for patients with excess foreskin, and 3.5 min for phimotic cases. In contrast, it took Zhao *et al*. [6] an average of 9 min to perform a circumcision using the Korean device. Circumcisions done without the aid of a device commonly take as long as 20–30 min [7].

Pain might arise from the circumcised site when the anesthesia loses its effect after the procedure, but it can be relieved by an oral painkiller and will usually disappear on day 2 after the operation. The lightweight, smooth device is comfortable for the patient to wear and does not cause interference with urination or daily activities. The inner diameter of the device is larger than the penis, which should reduce or prevent nocturnal pain from erection. There was reported pain from nocturnal erections in 78% of patients, but pain can be lessened by oral use of diethylstilbestrol before bed-time.

Selecting the appropriate device size is very important in order to prevent postoperative complications. This selection is facilitated by using a measuring tape to measure the penis. If the inner ring is too large, it will be difficult to pull the foreskin over and around the inner ring and insufficient tissue will be resected. If the inner ring is too small, it will lead to constriction during nocturnal erection, producing disturbance of the blood flowing back to the glans. Although Cheng *et al*. [8] reported complications in a study of circumcision in adults using a plastic ring that compressed the external urethra and caused dysuresia and pain, this was attributable to a ring that was too tight, and these complications were not observed in our study.

In 10.08% of the cases, complications arose with mild edema of the inner layer of the foreskin, a condition that spontaneously disappeared shortly after the ring was removed. Incidents of moderate edema were seen in 2.58% cases and were drained with a needle. Mild edema in the frenulum was observed in 1.67% of cases, but the symptom subsided within 3 to 4 weeks of removal of the rings. In a study that used the Korean style of circumsion, Ge and Liu [9] reported complications in 50% of adult cases, with mild to moderate edema in the rim of the foreskin. Comparatively, the rate of edema in our study was significantly lower. We observed only 0.67% cases of infection around the incision. The infection involved phimotic chronic inflammation or inflammatory hyperplasia and the wounds were healed by oral antibiotics and by changing the dressings. The infection rate was lower than the 8.2% associated with the conventional procedure circumcision as reported by Rizvi *et al*. [10].

Adherence of the foreskin to the coronal sulcus of the glans, and effusion of slight yellowish fluid from the disjuncting layer was observed in some children with phimosis on the day the device was attached. Scab formation is regarded as a natural condition, and scabs will usually fall off from the surface of glans in 4–5 days after surgery.

Incision bleeding following the removal of the device was seen in two teenagers and five adults, accounting for 0.58% of the total cases. This was caused by repeated rubbing against underwear when walking, torn wounds due to incomplete healing, or the expansion of blood vessels during erection. Complete hemostasis was achieved by local compression with cotton swabs in two cases. One suture at the site of bleeding was required in five cases. In contrast, in a study of circumcision using the Plastibell device (Hollister Inc., Seattle, Washington, USA), Lazarus *et al*. [11] found bleeding to be the most common complication (7/16 cases or 44%) among cases presenting at the hospital after circumcisions done outside the hospital. Among 79 in-hospital cases, one had a significant bleeding complication.

Wound dehiscence of the incision, commonly seen during or following the night of device removal, was caused by nocturnal erection. Three consecutive days of medication by diethylstilbestrol, right after the removal of the device, can prevent dehiscence of the incision. Would dehiscence was observed in 2.24% of cases with this wound measuring from 3 to 5 mm wide. Sutures were not needed, and the wounds were treated by closing the incised rim with a butterfly adhesive plaster and topical disinfection, which healed the wound within a week.

Circumcision using a device like this one is an improvement on conventional surgical techniques. The essential purpose of using this device for circumcision is to improve the quality of the operation, make the procedure easier, prevent infection, and reduce pain. The Shenghuan Disposable Minimally Invasive Circumcision Anastomosis Device serves this purpose. Compared with conventional and Korean styles of circumcisions, this

device distinguishes itself because it is quick, relatively simple and safe. Fewer complications and less pain were observed than in conventional circumcision. Patients did not experience discomfort with the device, which is lightweight and smooth. The foreskin was folded back, so the layers were further from the external urethral meatus, thus reducing exposure to bacterial infection. The linear and even cut produced good cosmetic results as well as meeting requirements for circumcision with minimal tissue manipulation. Additional research is needed to: 1) better evaluate pain severity associated with nocturnal erections without the use of an anti-androgen, or with the use of other anti-androgens, as the use of diethylstilbesterol might not be acceptable in other settings; and 2) evaluate use of the device in African countries with high HIV prevalence. This device deserves wide clinical application and evaluation in other settings.

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