Circumcision

Historical Background

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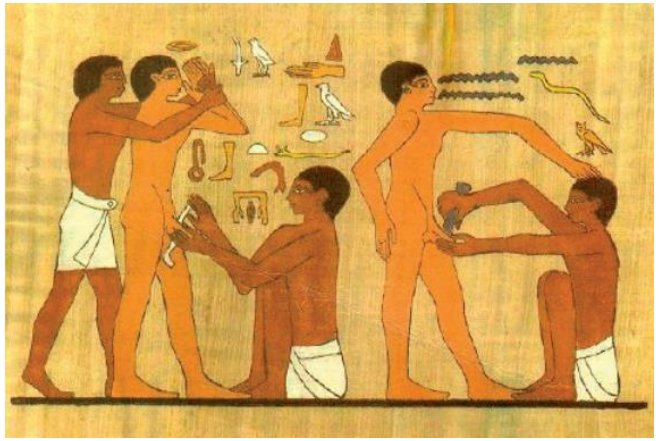
- Male circumcision is one of the oldest surgical operations in human history.
- Historically, male circumcision has always been related to religious practice and ethnic identity. A symbol of cultural identity or religious importance.
- In ancient times, human beings began to cut the foreskin with stone, fishbone and other sharp hard objects.
- The earliest circumcision was carried out in the ancient Semitic people, including the ancient Egyptians and the Jews, the earliest records of the fresco in the Egyptian tombs around 2300 BC.



Circumcision In The World

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- At present, about 700 million men around the world have performed circumcision, mostly in the Asian countries that believe in Islam, as well as in the United States, Canada, and most of the African countries.

- According to WHO's 2006 data, about 2/3 of the 30% men circumcised around the world believe in Islam.

- In a country that believes in Islam, circumcision is an important event in the Islamic law. It is necessary for a boy to be circumcised within a hundred days. The Jewish bo circumcised on the eighth day of his birth.

Global Circumcision Rate

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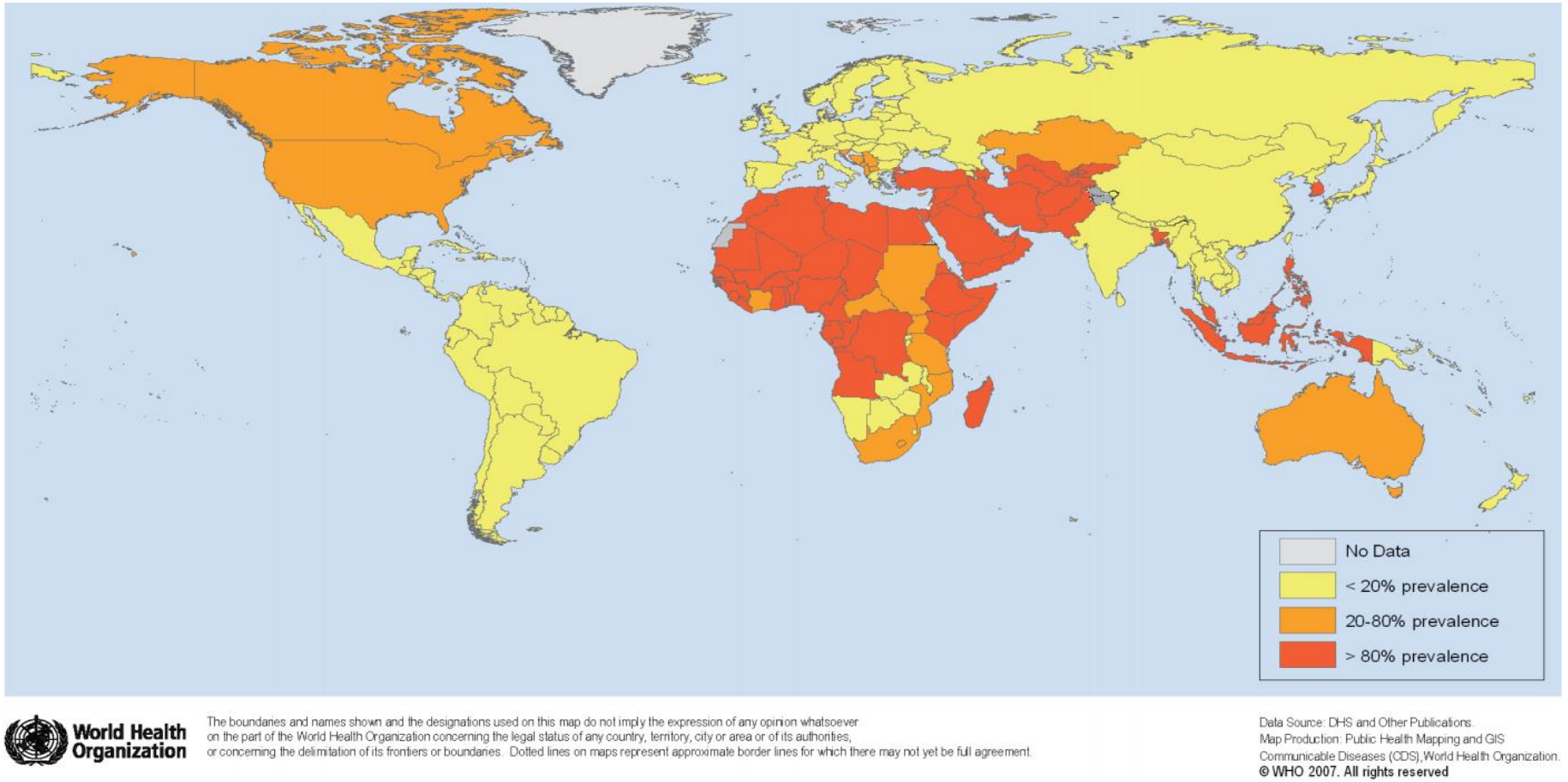

Worldwide male circumcision distribution map by December 2006

WHO 2007, http://data.unaids.org/pub/informationnote/2007/mc_briefing_pack2_en.pdf

The Health Benefits Of Male Circumcision

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- Male circumcision can significantly reduce the risk of male acquired HIV infection by about 60%, and has been recommended by the WHO and UNAIDS as an important intervention in the HIV defense strategy. It can be called as a live vaccine for surgical operation.

- Circumcision prevents HIV infection, it was named the top ten medical breakthroughs in 2007 by the Time Magazine of the United States. Since then, the importance of circumcision has been greatly increased in medical circles.

- In recent years, more and more studies have shown that male circumcision has potential health benefits for male and female spouses.

World Health Organization

UNAIDS
JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS
UNHCR UNICEF WFP UNDP UNFPA
UNODC ILO UNESCO WHO WORLD BANK

The Benefits Of Male Reproductive Health

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Benefits	Protective Effect	Reference
Improvement of reproductive health	remarkable	Morris（2007,2008）
Reduce the risk of HIV infection	Reduce 50%-60%	WHO, UNAIDS（2007）
Reduce the risk of HPV infection	Reduce 72%	Castllsague, etc.（2002）
Reduce the risk of urinary tract infection	Reduce 90%	Morris（2007,2008）
Reduce the incidence of Balanoposthitis and penile cancer	Significantly reduced	Morris（2008）
Reduce the incidence of Chancroid	Significantly reduced	Morris（2008）
The risk of syphilis infection	Significantly reduced	Weiss, etc.（2006）
Incidence of gonorrhea	Significantly reduced	Tobian, etc.（2009）
Children's penis second growth	Phimosis constrains the development of glans and penis,	
Improve the quality of sperm	Repeated infection of the urinary tract can cause prostatitis, hyperplasia of prostate, and decrease of sperm quality, leading to infertility.	

The Benefits Of Female Reproductive Health

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Benefits	Protective Effect	Reference
Improvement of reproductive health	Significantly reduced	Morris（2008）
Reducing the incidence of cervical cancer.	Moderate reduction in general population, a significant reduction in high risk population	Castellsague, etc.（2002）
Reduction of bacterial vaginitis	Reduce 18%	Gray, etc.（2009）
Reducing ulcerative disease in female genital tract	Reduce 22%	Gray, etc.（2009）
Chlamydia trachomatis	Reduce 82%	Castellsague, etc.（2002）
Infection rate of trichomonas vaginalis	Reduce 45%	Gray, etc.（2009）

Prepuce Medicine

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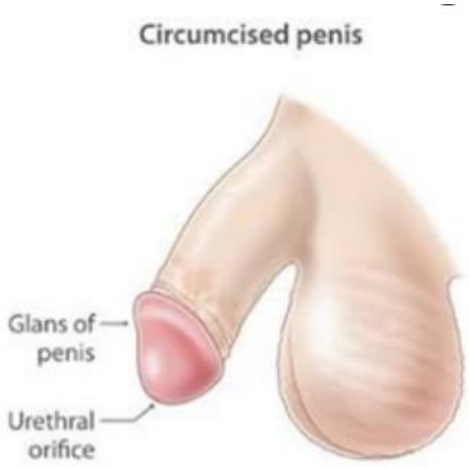
Phimosis

Redundant Prepuce



The Clinical Manifestation Of Phimosis

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- Phimosis: The foreskin ostium is narrow, and the foreskin can not be turned over to reveal all the glans.
- Taxonomy of phimosis (EAU, Children's Department of Urology Guide, 2014)
- Physiological Phimosis
- Secondary Phimosis
- Paraphimosis;

The Clinical Manifestation Of Redundant Prepuce

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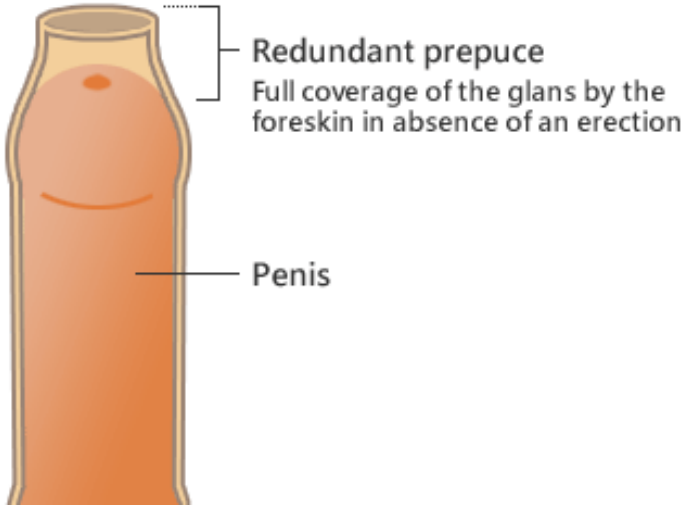
- The prepuce covers all the glans and urethral orifice, but it can still turn upside down to expose the glans.
- Clinical Observation Method: When the penis is in soft state, the glans is completely wrapped by the foreskin, and the glans can not be shown while erecting. But can open the glans by hand.



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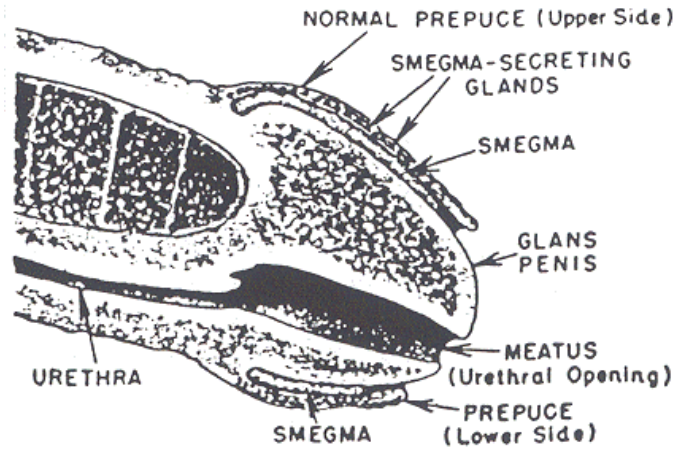
Smegma: phimosis and redundant prepuce make the foreskin cannot turn upwards, the secretion of sebaceous glands in the foreskin can not be excreted, and urine will also permeate to form a chemical reaction with sebaceous glands. Smegma are suitable for bacteria growth and cause inflammation and other diseases.

There is an enzyme in the Smegma

that is one of the target cells of HIV.



Traditional Circumcision Complications:

- Excess Bleeding
- Infection
- Excessive Foreskin Removed
- Adhesions
- Skin Bridges
- Inclusion Cysts
- Abnormal Healing
- Meatitis
- Meatal Stenosis
- Chordee
- Hypospadias
- Epispadias
- Urethrocutaneous Fistula
- Necrosis Of The Penis
- Amputation Of The Glans/Penis
- Death
- Dressing Too Tight
- Unable To Pass Urine
- Sepsis
- Penile Hematoma
- Migration Of Plastibell To Midshaft

Circumcision Device

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The Last Generation Of Circumcision

Celticsmed

Comparison of Different Surgical Methods

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Item	Traditonal	Clamp& Ligation	Celticsmed Circumcision Stapler
Operation Time	30-45 minutes	about 15 minutes	about 5 minutes
Blood loss during operation	Many	Less	Very less or no bleeding
Pain after operation	About 3-5 days	About 5-7 days	After anesthesia,a slight pain after waking up
Postoperative hematoma	Easy to appear	Rare	Rare
Incision	Not smooth, slow healing	Smooth, slow healing	Very smooth, quick healing
Suture removal	Back to hospital after 10 days	Back to hospital after 7 days	No need to return to hospital,the staples will fall off automatically by itself
postoperative infection	Not easy to be infected	Easy to be infected	Not easy to be infected
Will to accept	Adults easy to accept,children difficult to accept	Adults and children difficult to accept	Adults and children easy to accept

Advantages and Benefits of Circumcision Stapler

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Advantages:

- Simple and quick, standard and safe
- Minimal tissue injury and little bleeding
- Shorter operation time
- Fewer post-operative complications
- Faster recovery
- Neat and perfect cutting edge
- Slight post-operative edema
- Replacing tradtional and ligation necrosis technique

Benefits:

- Improve personal hygiene
- Reduce the risk of urinary tract infections
- Reduce the risk of sexually transmitted diseases and infections.
- Lower the risk of penile cancer.
- Improve sexual life.
- Prevent future penile problems.

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- Standardized operation
- Safety
- No need remove the suture;
- Glans can be protected completely
- Easy to control
- No need stay at bed after circumcision
- Shorter operation time
- Less pain during & post operation
- Less bleeding during & post operation
- Less post-operative complications
- Shorter healing time

Indications and contraindications

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Indications

Medical reasons:

Phimosis: Tight foreskin that cannot be pulled back.

Paraphimosis: the foreskin can be retracted but cannot be moved back to its original position.

Balanoposthitis: A condition which causes irritation, itching, and swelling of the foreskin and glans.

Balanitis: An inflammatory condition with redness, soreness, and swelling of the glans of the penis.

Balanitis Xerotica Obliterans: A chronic condition that causes phimosis and in some cases, also affects the glans causing inflammation.

Personal hygiene & preventive healthcare

Non medical reasons: Religious or cultural tradition

Contraindications

1.Prepuce, glans and penis malformations (including tight adhesion of the prepuce and glans, scar phimosis, typical occult penis).

2. Hypospadias.

3. prepuce and glans infection, edema.

4. Patients with penile cancer.

5. Patients with systemic diseases (such as bleeding tendency, hypoproteinemia, serious cardiovascular disease, etc.)

Surgical Method

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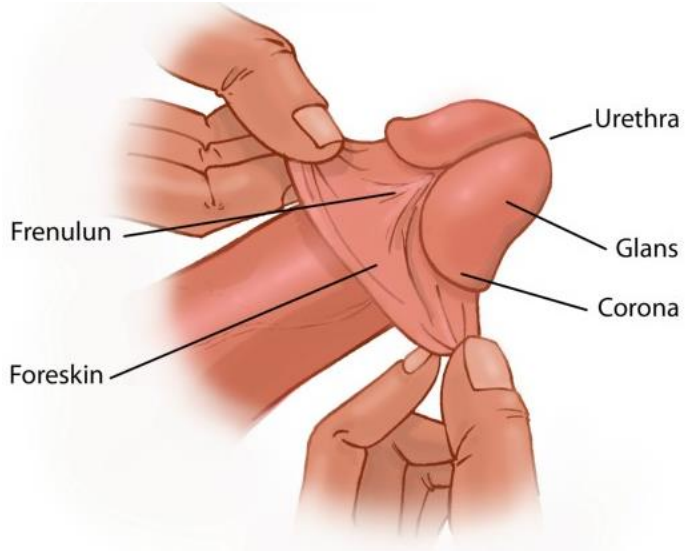
- For a long time, the circumcision is a minor operation for Urology physicians, but it is a small operation that has a certain challenge to personal manipulation.

- The key of is this surgery is difficult to standardize, and a slight negligence will leave unsightly post-operative wounds to the patient. Therefore, doctors are not willing to do this operation, although circumcision is a minor operation, poor surgical results can cause serious adverse consequences.

- Only small organs, But no small surgery!



Surgical Method

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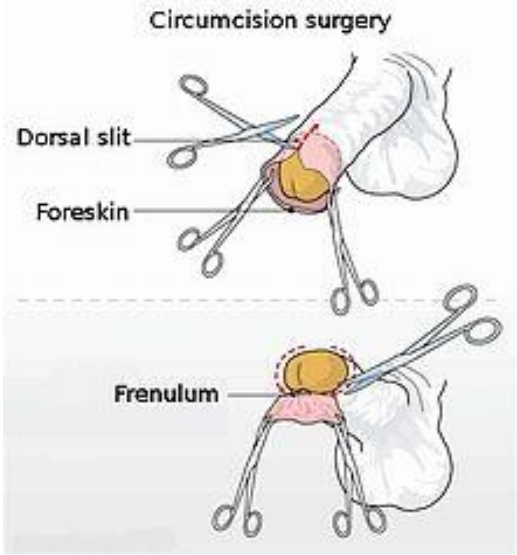

1st Generation:
Conventional Circumcision Method: Manual Operation & Laser Surgery.

2nd Generation:
Clamp and Ligation Method.

3rd Generation:
Anastomosis Method.

Surgical Method

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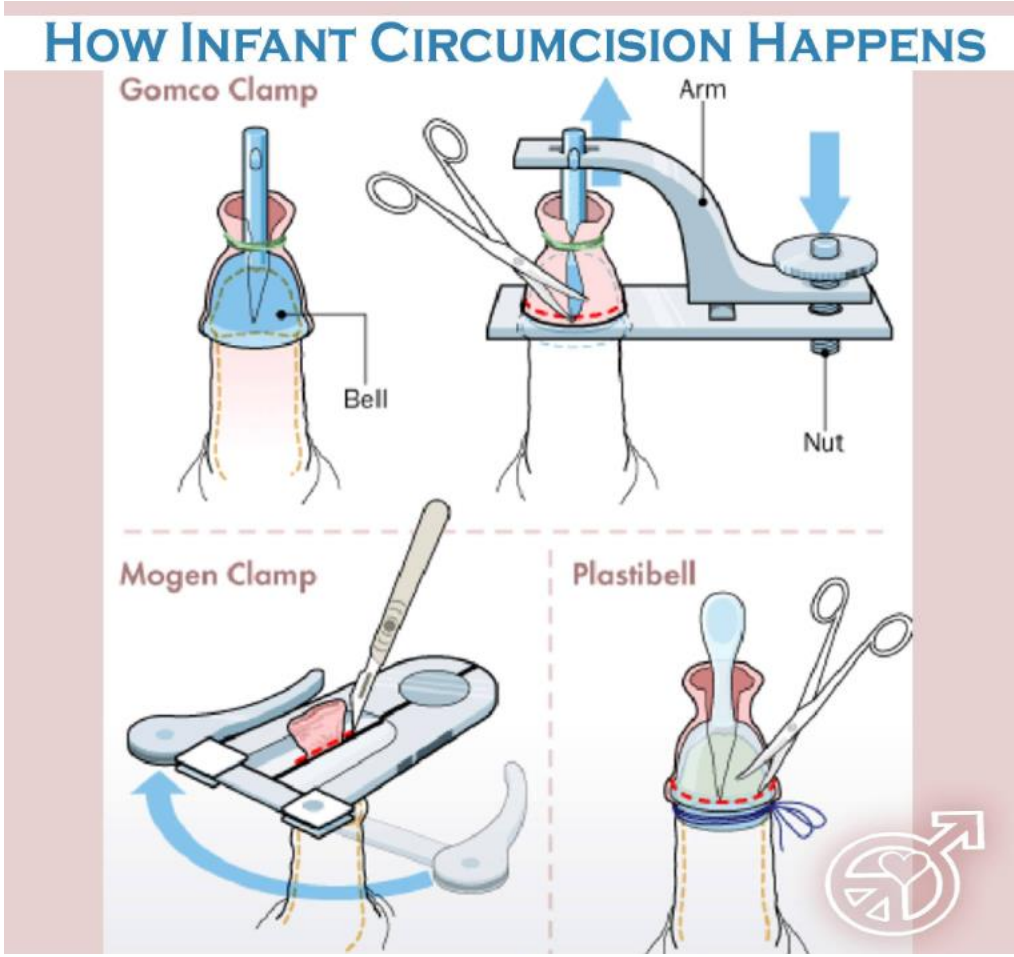
- 2nd Generation Clamp and Ligation Method have two major categories:

1) Clamp Type

2) Ring Type



Surgical Method – Clamp Type

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- Mogen Clamp (America invented in 1954) commonly used in neonates and children, is currently the most widely used circumcision device.

- Plastibell (America invented in 1935) about 60% of infants in the United States use Plastibell for circumcision.

- Gomco Clam mcision between neo

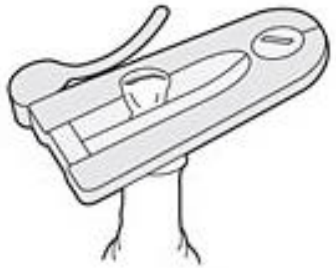

FIGURE 1:
THE MOGEN CLAMP

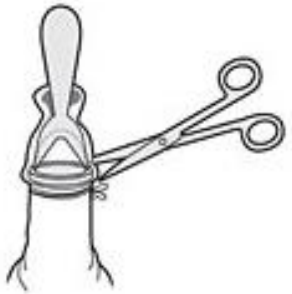

FIGURE 2:
THE PLASTIBELL

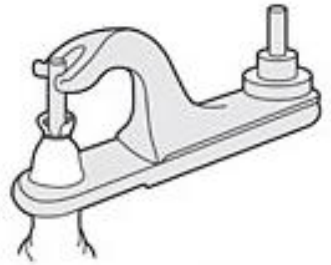

FIGURE 3:
THE GOMCO CLAMP

Surgical Method – Ring Type

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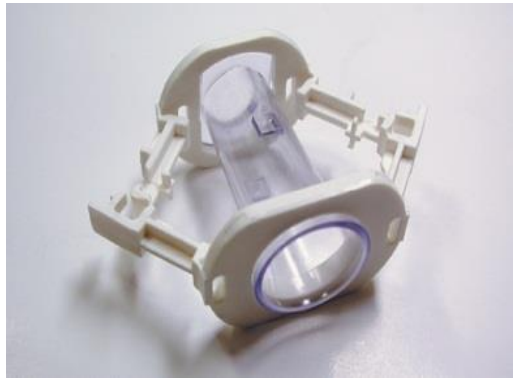
- Smart Klamp (Malaysia invented in 1990) used in Southeast Asian countries only for infants and early puberty males.

- AlisKlamp (Turkey invented in 2007) Widely used Middle East, South East Asia and other countries.

- ShangRing (China invented in 2002) Use in China and African countries



Surgical Method – Anastomosis Method

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The creative inventions of China.

Patent products with independent intellectual property

Inventor： Celtics Medical

TWO MILLION CASES VERIFICATION

CE ISO 13485 ISO ISO9001 SGS GMP

Surgical Contrast

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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 ± 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.

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

http://www.ajandrology.com/article.asp?issn=1008-682X;year=2014;volume=16;issue=3;spage=453;epage=456;aulast=Lv

Surgical Contrast

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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 ± 2.3 and 7.6 ± 4.5 *vs* 21.4 ± 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 ± 2.3 and 3.8 ± 2.6 *vs* 16.5 ± 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 ± 4.3 *vs* 23.6 ± 9.3 and 19.5 ± 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.

http://www.ajandrology.com/article.asp?issn=1008-682X;year=2014;volume=16;issue=3;spage=453;epage=456;aulast=Lv

Surgical Contrast

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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 ± 1.3 *vs* 6.2 ± 2.2 and 5.8 ± 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 ± 0.9 and 3.3 ± 0.8 *vs* 6.4 ± 2.0, $P < 0.001$). There was no difference between the modified and conventional circumcision groups.

http://www.ajandrology.com/article.asp?issn=1008-682X;year=2014;volume=16;issue=3;spage=453;epage=456;aulast=Lv

Surgical Contrast

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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

http://www.ajandrology.com/article.asp?issn=1008-682X;year=2014;volume=16;issue=3;spage=453;epage=456;aulast=Lv

Surgical Contrast

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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.

http://www.ajandrology.com/article.asp?issn=1008-682X;year=2014;volume=16;issue=3;spage=453;epage=456;aulast=Lv

Surgical Contrast

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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

http://www.ajandrology.com/article.asp?issn=1008-

Surgical Contrast

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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, $P < 0.005$).

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Surgical Contrast

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	Conventional Manual Surgery	Clamp/Ring Method	CircCurer™ Anastomosis Method
Operation Time	about 30-45 min	about 15 min	about 5 min
Intraoperative Bleeding	excessive bleeding	little bleeding	little bleeding
Postoperative Pain	about 3 days	about 7 days	only a slight pain in the day of surgery
Incision	unsightly	smoothly	cosmetically
Postoperative Caring	return hospital to change dressing and remove stitches	return hospital to change dressing and remove ring	no need return to hospital, suturing staples drop automatically
Complications	bleeding & edema	hematoma, edema, pain, wound dehiscence	incidental bleeding and edema

Advantages

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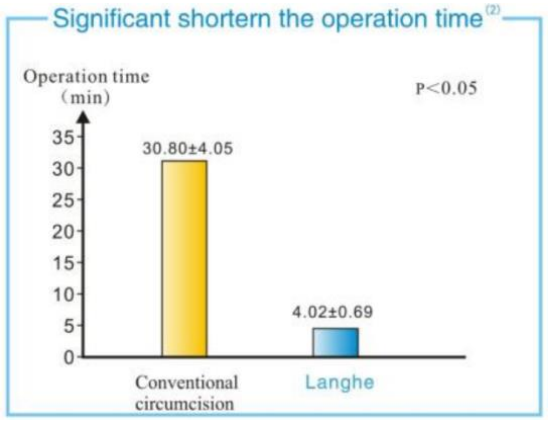
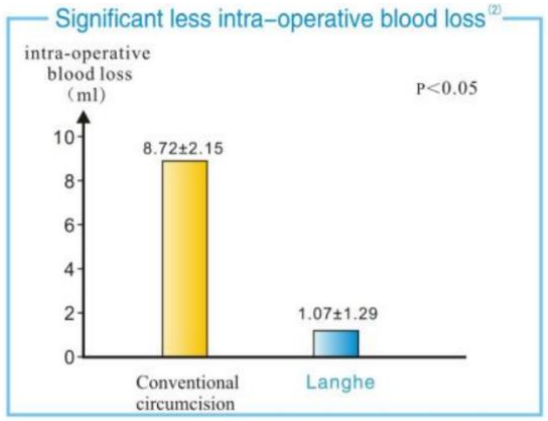
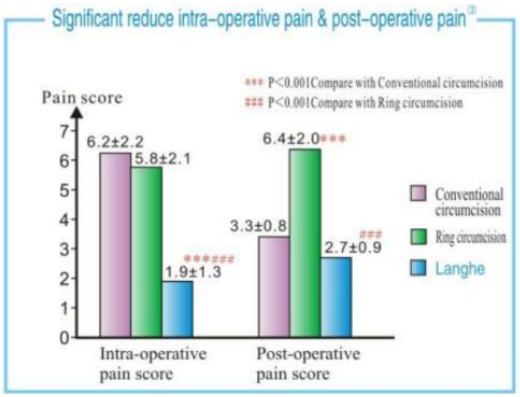
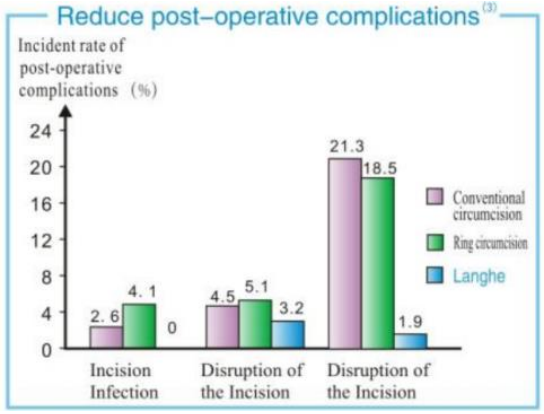
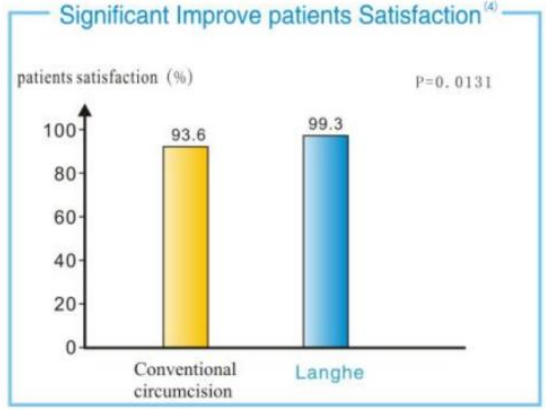
- Standardized operation, safe, easy to control.
- Short operation time (3-5 min).
- Automatic suturing, less painful.
- Less bleeding and complications.











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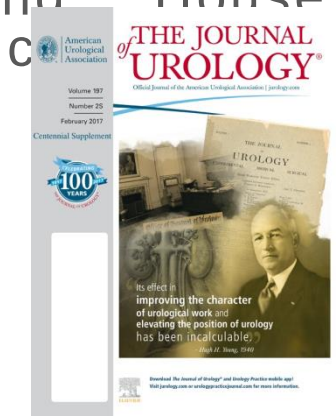
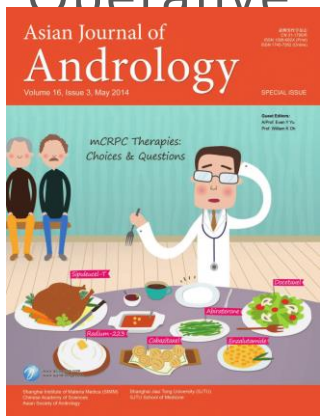
Academic Recognition

- International professional academic journals.
- The Journal of Urology.
- Asian Journal of Andrology.
- National Surgical Guide & Expert Consensus.
- Chinese Medical Association Andrology branch Guidelines and Expert Consensus on Diagnosis and Treatment of Chinese Andrology Diseases.
- People's Medical Publishing House: Operative techni[illegible]rac[illegible]mc[illegible]e d[illegible]





Academic Papers

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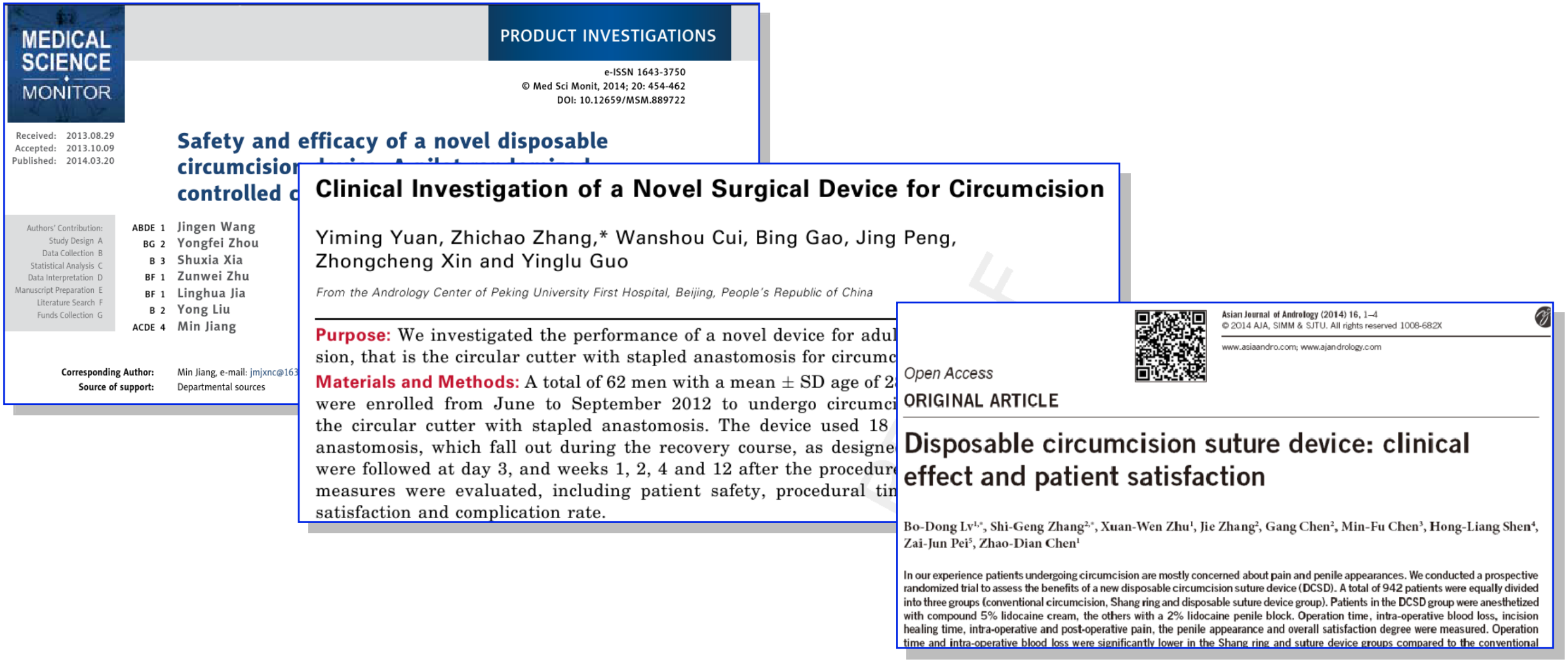

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Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

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Clinical Investigation of a Novel Surgical Device for Circumcision

Yiming Yuan, Zhichao Zhang,* Wanshou Cui, Bing Gao, Jing Peng, Zhongcheng Xin and Yinglu Guo

From the Andrology Center of Peking University First Hospital, Beijing, People's Republic of China

Purpose: We investigated the performance of a novel device for adul
sion, that is the circular cutter with stapled anastomosis for circumc
Materials and Methods: A total of 62 men with a mean ± SD age of 2
were enrolled from June to September 2012 to undergo circumci
the circular cutter with stapled anastomosis. The device used 18
anastomosis, which fall out during the recovery course, as designe
were followed at day 3, and weeks 1, 2, 4 and 12 after the procedur
measures were evaluated, including patient safety, procedural tin
satisfaction and complication rate.

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ORIGINAL ARTICLE

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

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3965290/ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4023377/

Operation Principle

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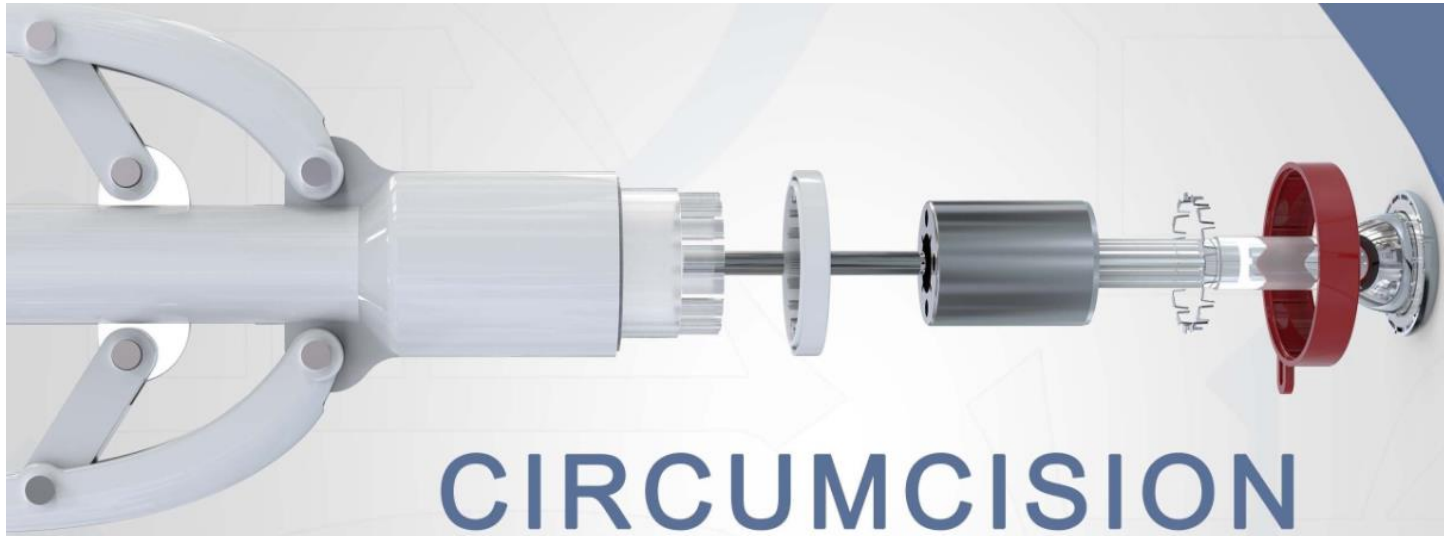
- Four principles were applied: Dynamic, Anorectal Anastomosis, Circular Cutting and Automatic Suturing. It is the perfect combination of advanced principles in the history of surgery.
- Main components are Glans Bell, Circular Scalpel, Suturing Staple, Triggering Handle, Safety clasp, Adjusting Knob, etc.



Advantages – Shorter Operation Time

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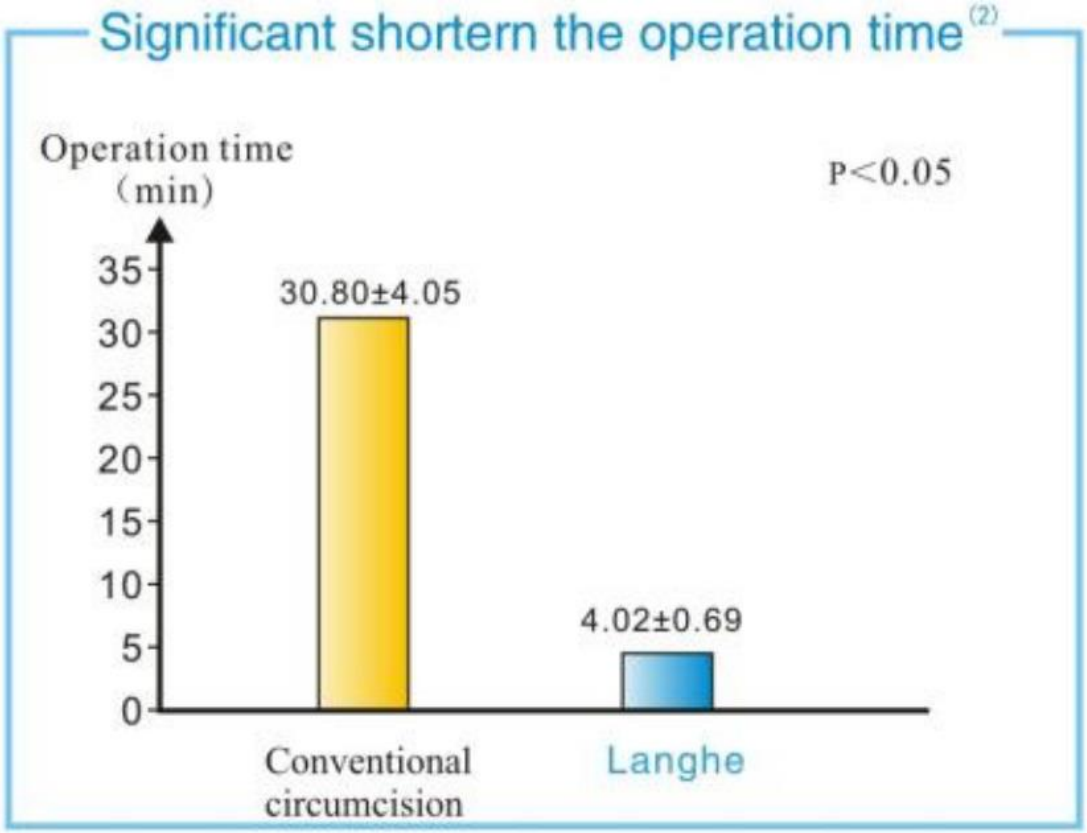

（2）Li Sheng, Zhang Lei, Wang Dawen, Yang Sen, Mu Haiqi, Nan Cunjin, Wu Tielin, Zhu Shijian, Chen Yinghe. Clinical application of the disposable circumcision suture device in the male circumcision. Natl J Androl, 2014,20(9): 816–819.

Advantages – Lesser Bleeding

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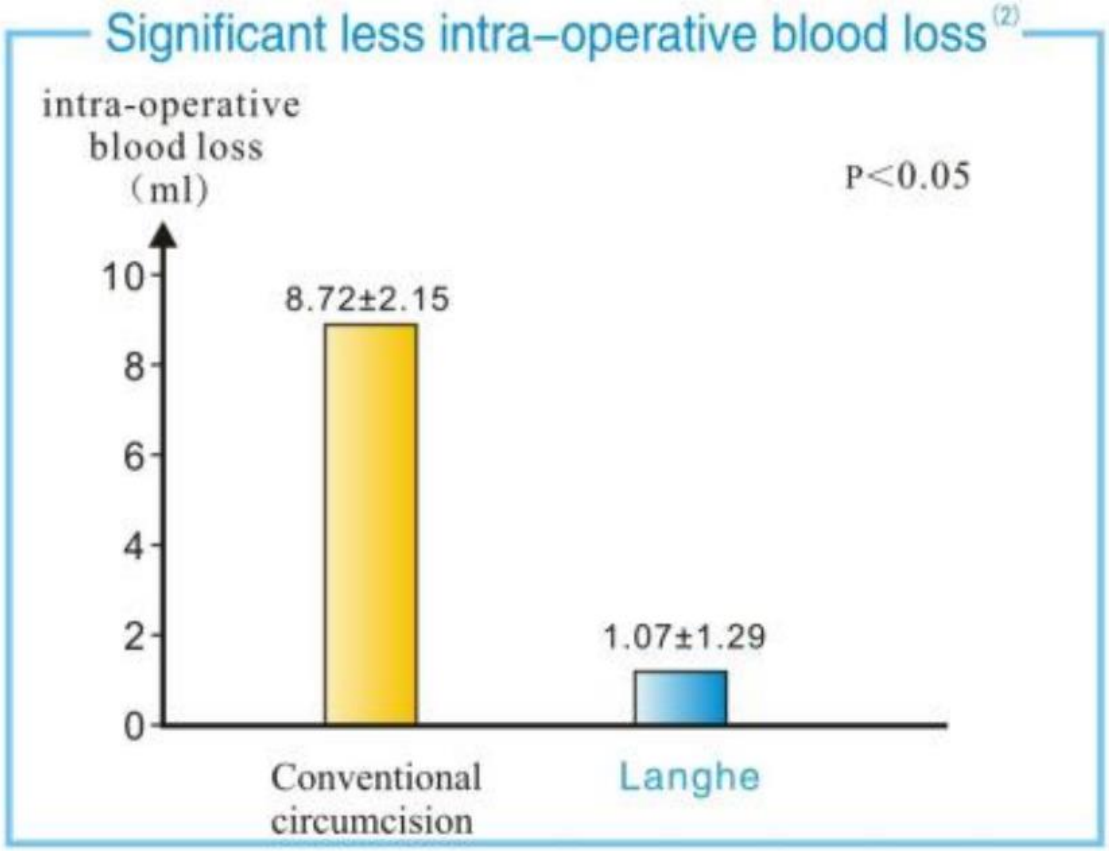

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Advantage – Lesser Pain

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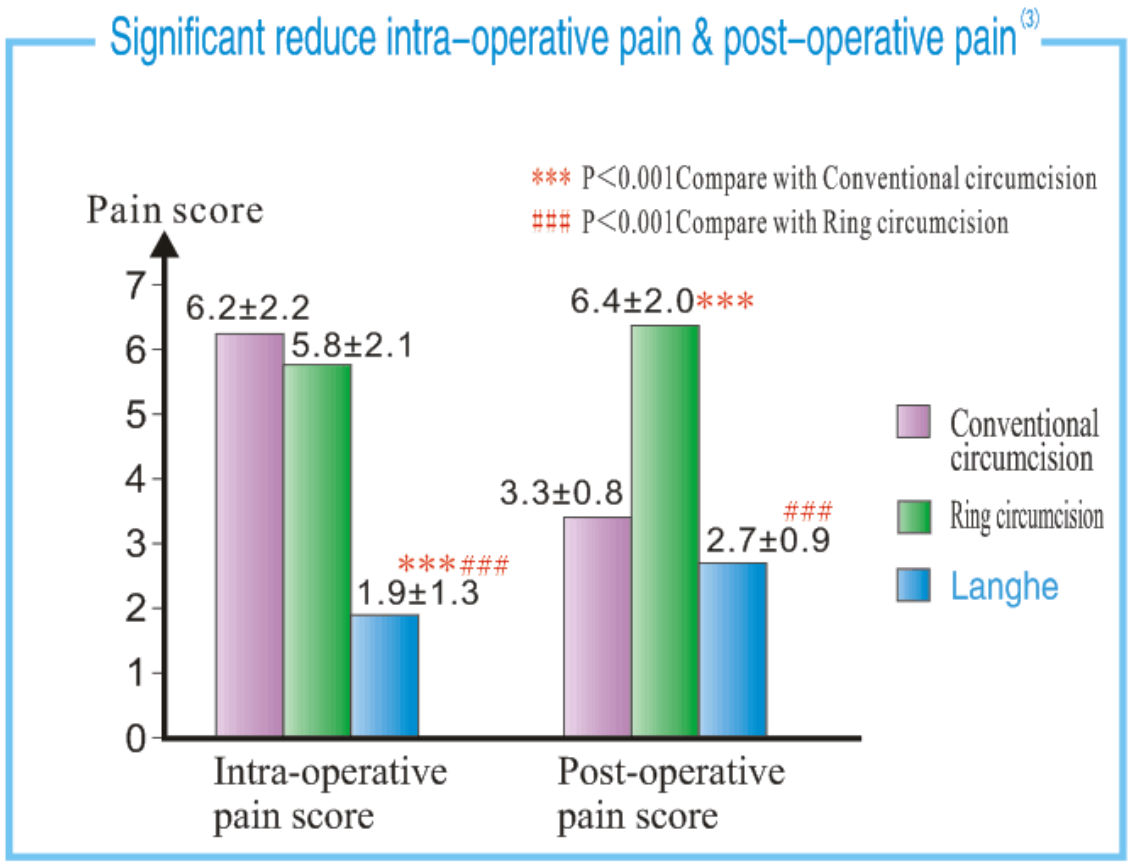

(3) LvBD, Zhang SG, Zhu XW, Zhang J, Chen G, Chen MF, Shen HL Pei ZJ, Chen ZD. Disposable circumcision suture device: clinical effect and patient satisfaction. Asian J Androl (11 April 2014) 16: 453–456 . doi: 10.4103/1008–682X. 127816

Advantage – Shorter Healing Time

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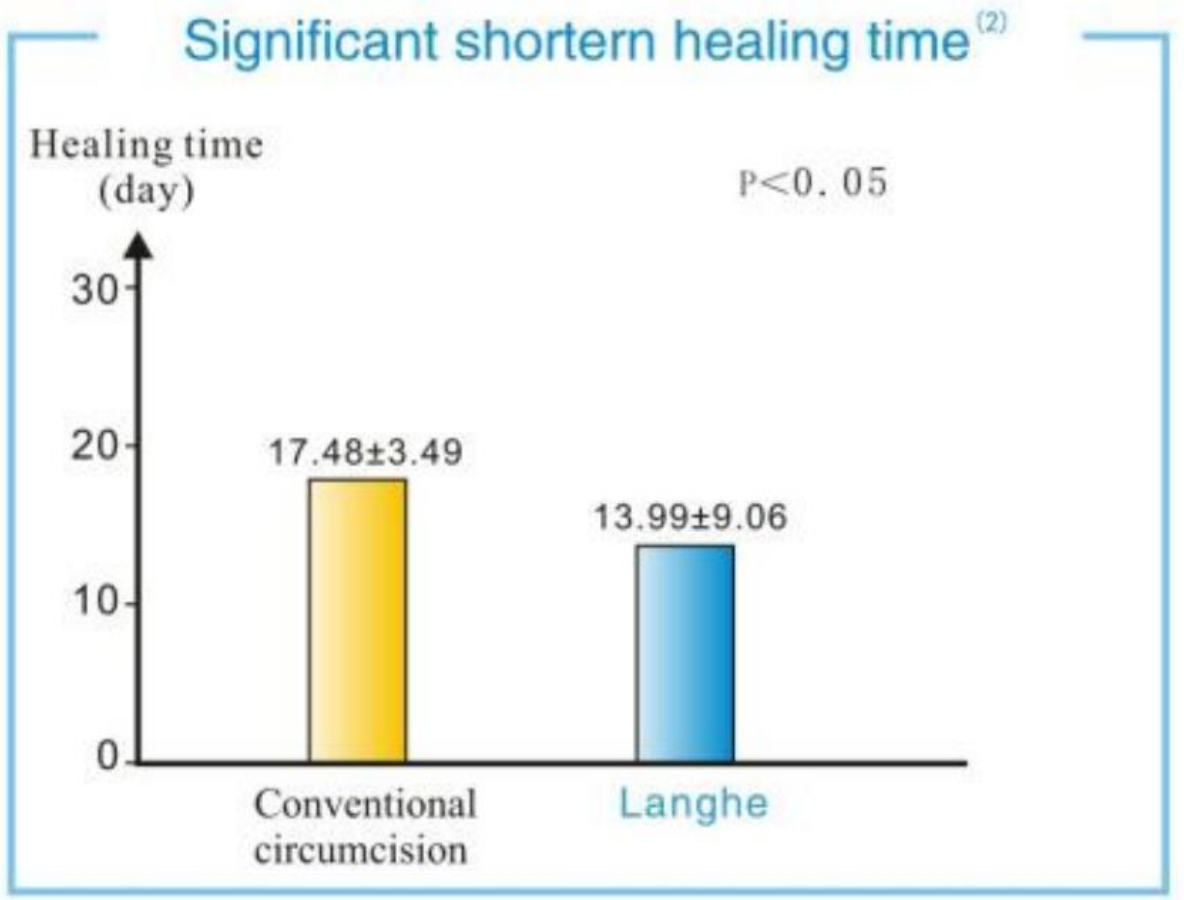

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Advantage – Lesser Complications

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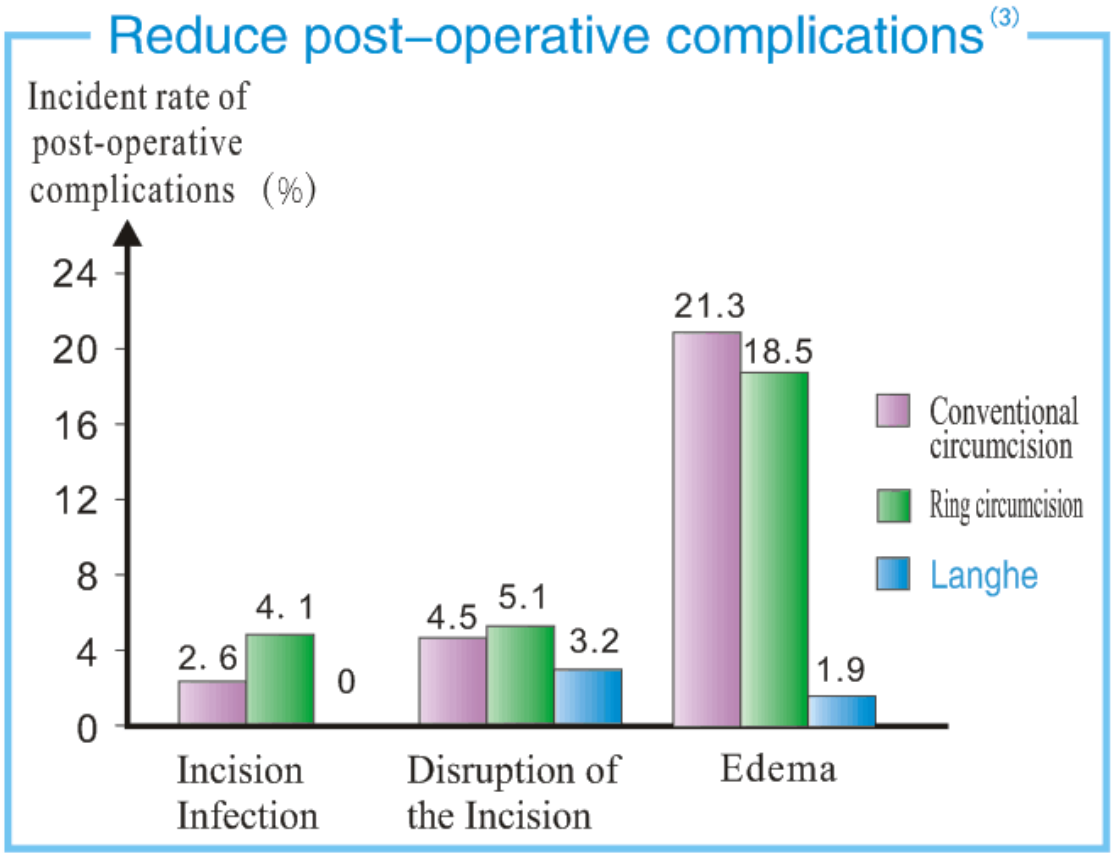

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Advantage – High Satisfaction

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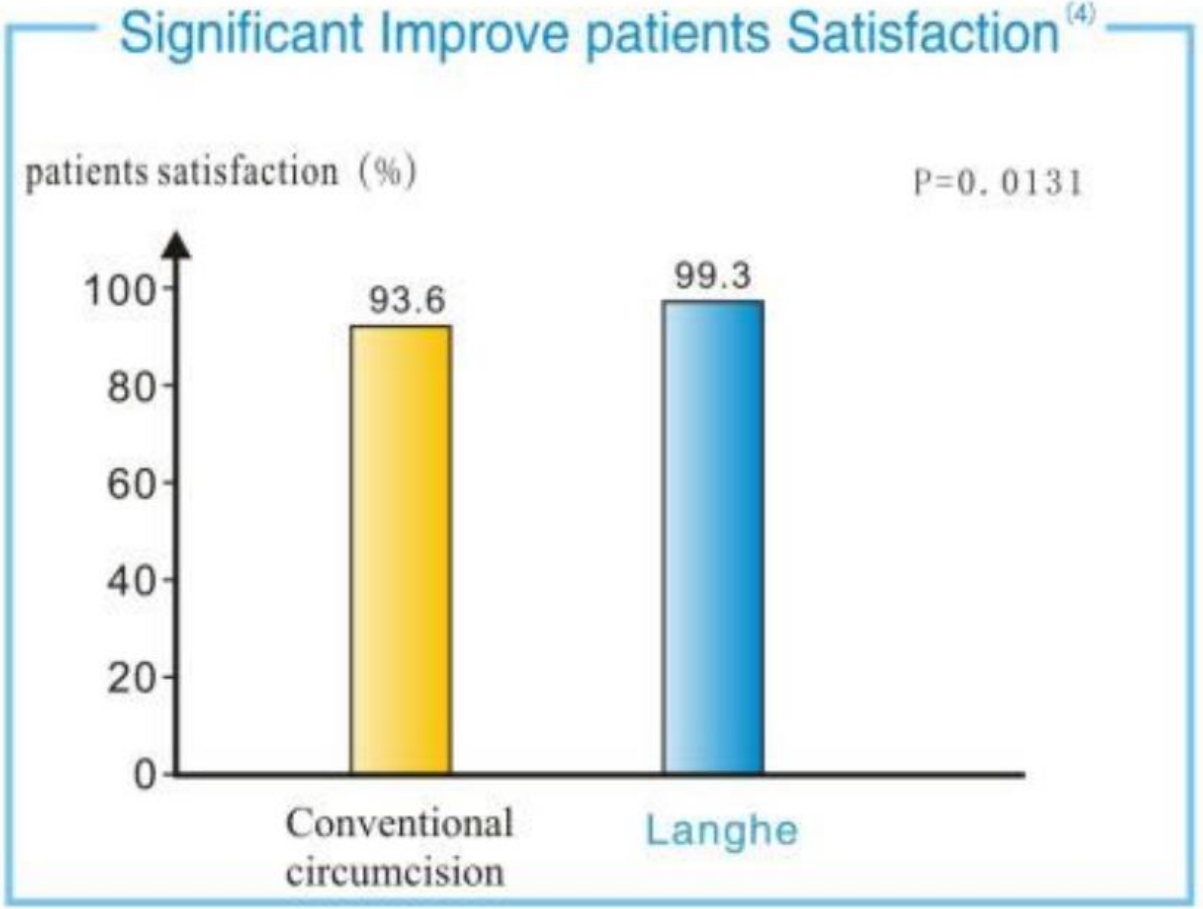

(4) Qi Jinchun, Xue Wenyong, Yang Caiyun, Yang Shuwen, Li Wei et al. Clinical efficiency analysis of peritomy anastomoses device and traditional way for circumcision. Chinese Journal of Andrology, 2014; 28(6):48–51.

Product Overview

Available size:
11,13,16,19,21,25,28,31,34mm

Safety Block
To prevent triggering of the handle accidentally

Ajusting knob
Unscrew it,take out the bellseat

Staples cartridge
Big cartridge volume to hold more tissue

Handle
Trigger the handle,cut and suture at the same time

Bell Seat

Protective Cap
Protect the staples and silicone ring

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Product Feature

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Pure metal integrated bellseat:
Offer more stability during surgery.

Red dotted indicator:
Better to know tightening status

Silicone Ring:
Minimize bleeding and promote healing.

Ergonomic Handle:
Non slip
more comfortable

Unique staple design:
Penetrates tissue well and better hemostasis.

Instructions for Use

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1

Step1:
Select the appropriate size of stapler by using the measuring scale.

2

Step2:
Perform surgical disinfection and regular local anesthesia or other appropriate anesthesisa.

3

Step3:
Rotate the ajusting knob anti-clockwise ,take out the bellseat for later use.

Procedure 1:
Choose Appropriate Model

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- Measure glans size by measuring scale, select the appropriate model
- Model Selection Principle: select bigger one if glans size between two sizes.
- By age stage：

  Age 2-6 – 12mm
  Age 6-10 – 15mm
  Age 11-13 – 18mm
  Age 14-20 – 21/26mm
  Age 20+ – 30/36mm

- Mark the pre-cutting area

Procedure 2:
Skin Prep, Sterilize, Drape, Local Anaesthesia

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- Skin prep, Sterilize, Drape
- Local anesthesia is usually used (5ml lidocaine + 10ml or 20ml sodium chloride injection), Other appropriate anesthesia methods may selected for children: Lidocaine Cream was applied in half an hour before local anesthesia, 1ml syringe needle is recommended to reduce pain.
- Massaging penis after injection is conducive to the spread of anesthetic effect.

Procedure 3:
CircCurer™ Preparation

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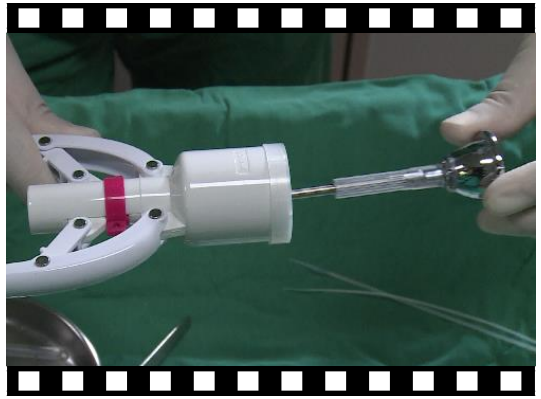
- Prepared surgical instrument, dismount CircCurer™, take out staple protection cap and glans bell.



Instructions for Use

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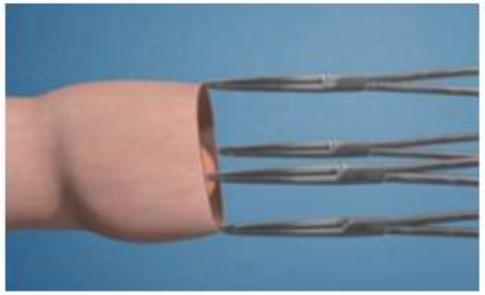
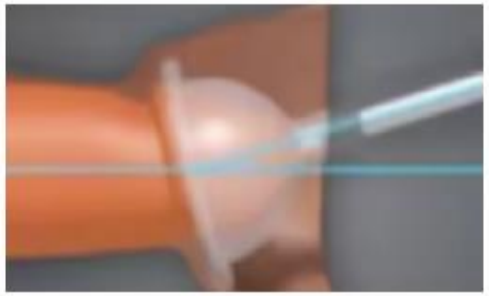


Step 4:

Pull up the foreskin with foreceps to expose the glans.
If People with adherent prepuce,shall separate it from the glans.
If People with phimosis need to enlarge the foreskin opening or cut a small opening with scissors to facilitate the insertion of bellseat.

5



Step 5:

Put the bellseat inside the foreskin to cover the glans at the frenulum position ; the edge of the bellseat is brought to the level of coronal sulcus.
And ensure the pre-cutting area is correct.

6

Step 6:

Fix the foreskin to the central rod of the bellseat by using ties or sutures,
Remove the lengthy foreskin in case of it is too much.
Don’t pull up the foreskin during circumcision, keep foreskin loose to avoide over cutting.
Re-check the pre-cutting area,ensure the foreskin is fixed properly,make sure the frenulum is remain loose to avoid frenulum hurt.

Instructions for Use

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7

Step 7:
Remover the protective cap, check if the silicone ring is in the staple groove, if not, put it back.
Place the stapler body over the bellseat, and tighten the adjusting knob till the red indicator can be touched.

8

Step 8:
Remove the safety block.

9

Step 9:
Hold the handles with both hands,trigger the handles of the stapler completely and hold for 15 seconds to ensure a clean cut of the foreskin and compression of blood vessels.

Procedure 4:
Insert Glans Bell

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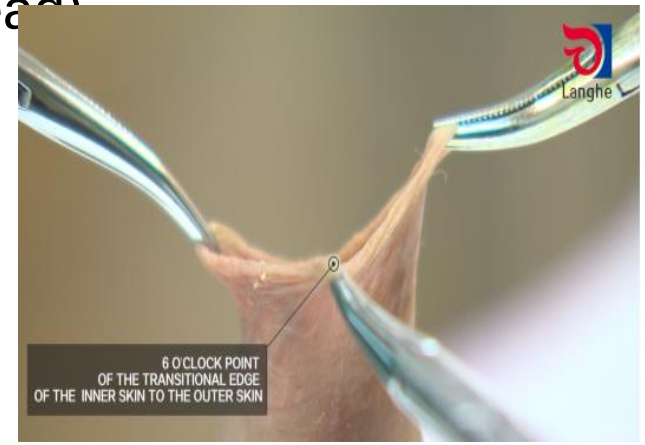
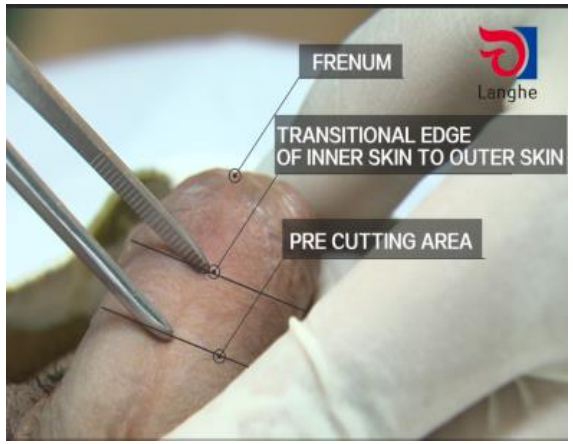
- Clip the foreskin with 3 mosquito forceps from the 2, 6, 10 o’clock point. The first forceps should clip on the dorsal frenulum, and clip on the junction edge between inner and outer layer.
- Pull open the foreskin to expose the glans. Mark the pre-cutting areas.
- Dip glans bell with iodophor, tilted insert the glans bell into the foreskin to empty the air and put the glans covered by the bell.
- If foreskin open not enough to insert the glans bell, cut dorsal frenulum to inset the bell.
- Tie the foreskin to the glans bell shaft with strapping tape (Children can be tied with silk thread)





Procedure 5:
Link the CircCurer™

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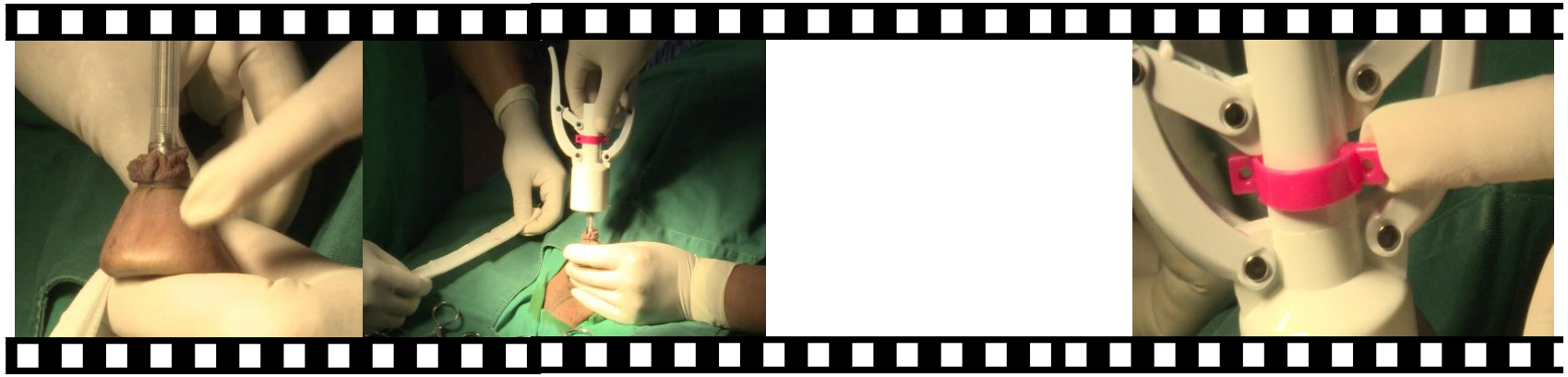
- Recheck the pre-cutting area and keep the axis of glands bell be 40-45 degree with the axis of the penis to keep the glans bell parallel to the coronary sulcus. Make sure the foreskin fixed on the glans bell shaft . Remove the lengthy foreskin in case it’s too much.
- Link the CircCurer™, clockwise screw the adjusting knob do not screw too tight, the screw rod have a little bulge on the surface of adjusting knob is ok.
- Hold the position of the frenulum with finger.
- Clockwise screw the adjusting knob to be vertical to the direction of the handle to avoid conflict while holding the handles.
- Take off the safety clasp before trigger the CircCurer™.



Procedure 6:
Trigger the CircCurer™

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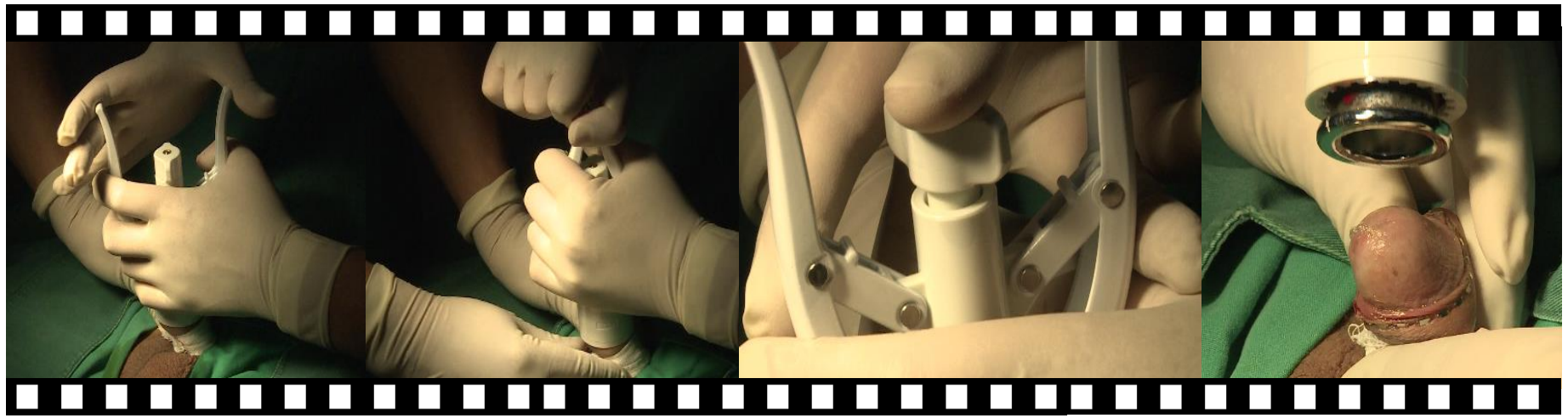
- Hold the front 2/3 of the handle with left hand, and right hand for the end 1/3. Squeeze and hold the handles to the end for 30 seconds (20 seconds for children). Keep the foreskin be in relaxed state when fire the trigger.
- Anticlockwise screw the adjusting knob to 5mm up, press down gently to take off the handler.
- Observe whether all foreskin be cut completely, if not, scissor it.
- Separate the glans bell from the penis.



Instructions for Use

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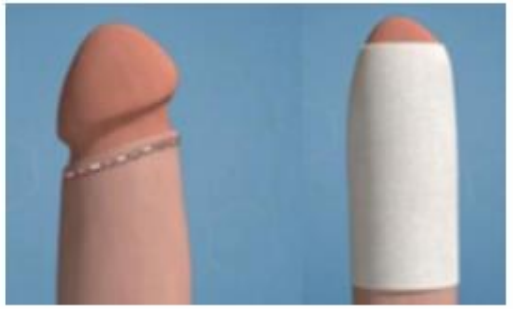
Step 10:
Rotate the adjusting knob anti-clockwise 3-5 circles, push the knob to separate the device.(if the foreskin is not cut completely, can use scissors to cut)

11



Step 11:
At this point, the procedure is considered complete.
Check the wound and press it with gauze for a minute or two to stop any bleeding,then cover the wound with bandage.

Procedure 7: Binding Up

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- Press the cutting area by dry gauze with fingers for 2-3 minutes. After loosen, little errhysis can be ignored and start binding up. For rare case of punctate blood ejection, make suture hemostasis.
- Cover the operative wound with Vaseline gauze as inner dressing. Iodophor gauze can be replacement if no Vaseline gauze. Dressing with dry gauze from penis distal to proximal. Use elastic bandage as final outer dressing. Double elastic bandage is recommended, inner one loose while outer one tight. The elastic bandage should be kept below the coronary sulcus and to penis distal.
- If no elas st

Post Operation Caring

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- In case the dressing be too tight to urinate, loose the outer elastic bandage 3 hours after operation.
- Sterilize with Iodophor by oneself if no obvious bleeding or hematoma 2-3 days after, change fresh dressing as well.
- Take off the dressing 3 days later and sterilize with Iodophor by oneself 4 times or more per day.
- Shower is allowed 3 days after operation. Condom can be use to protect the operation area during shower. Sterilize with Iodophor after shower.
- No heavy activities or sexual life in 50 days.
- Suturing staples can be dropped automatically from 1 week, and usually complete dropping within 1 month. For rare case of staple dropping in 2 months is also acceptable.

Surgery Effect

Conventional Methods

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before operation | post-operation | healed | before operation | post-operation | healed

Before Surgery

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Surgery Effect in Children

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Surgery Effect in Adult

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Key Points of Surgery

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- The adhesion of the foreskin and the glans should be fully separated: foreskin needs to be separated under the coronal sulcus.
- Clean smegma is a necessary step in the surgery.
- If foreskin have narrow ring, insert glans bell will have a sense of breakthroughs, cut the dorsal frenulum if foreskin open not enough to insert the glans bell.
- Pressurized dressing: The outer elastic bandage should be bind up from penis distal to proximal, elastic bandage should be covered the coronary sulcus to prevent bandage loosening.
- Pressurized dressing should be bind up appropriate, too tight may caused dysuria, too loose may caused bandage fall off earlier and lead to haemorrhage and hematoma. For short penis patients, 3M™Tegaderm™ can be use to reduce bandage loss.

Q & A

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- **Q: Screw adjusting knob to what extent is appropriate?**
- A: Adjust the screw rod to a slightly bulge on the knob, not too tight, and avoid conflict while holding the handles.

- **Q: How to deal with phimosis, adhesion and short frenulum?**
- A: Phimosis need to be cut from the middle of dorsal frenulum.

- Adhesion: clip and open foreskin, drop Iodophor to moist glans and the foreskin and then peel off to separate adhesion, clean smegma.

- Short Frenulum: more frenulum should be retained if it is too short, keep the axis of glands bell be 40-45 degree with the axis of the penis to keep the glans bell parallel to the coronary sulcus.

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- **Q: Does the bleeding need to make stitch?**
- A: Pressurized bind up for incisional bleeding, few bleeding no need to sutured. If there are still active bleeding required stitches.

- **Q: Is it painful after surgery?**
- A: After the effects of the anaesthetic, there will be half an hour to one hour of pain, but this pain is completely acceptable for patient.

- **Q: How to bind up to make better and quicker wound healing?**
- A: Bind up two layers of elastic bandage is suggested, internal loosing is tight, inner one loose, while outer one tight and bind up to the distal of penis.

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- **Q: How about suturing staple drop? How to do if suturing staple drop slowly?**
- A: Generally, staple start to drop one week after surgery, 20-30 days drop complete. The speed of staple removal is related to personal physique and erectile function of the patient. MEBO can be use to accelerate staple drop.

- **Q: How to prognosis of postoperative infection?**
- A: The main reason of incision infection are gauze was soaked by urine, wound effusion and improper care. Oral antibiotics for postoperative infection.

- **Q: How to accelerate the healing and suturing staple drop?**
- A: The daily application of MEBO after 3 days of surgery is beneficial to quickening the healing of incision.
- MEBO contains tissue regeneration and repair matrix, it has the characteristics of detoxifying, relieving pain, tissue regeneration and shortens healing time.

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- **Q: How to deal with edema and hematoma?**
- A: Causes of postoperative mainly due to inadequate dressing, pressurized bind up by elastic bandage again, after several days Edema will detumescence by itself.

- Hematoma in children is usually caused by pressurized dressing get loose earlier. The bandage should be removed after three days, and the hematoma can be absorbed within one week.

- **Q: The reason of intraoperative and postoperative bleeding**
- A: Possible reasons:
- 1) Improper use of equipment
- 2) Incision observation time is too long
- 3) Inflammation and edema of the foreskin
- 4) Incomplete anastomosis during operation
- 5) Blood vessel bleeding between the gap of two suturing staples
- 6) have no keep the foreskin be in relaxed state when fire the trigger or erection after operation.

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- **How to prevent and treat of intraoperative bleeding?**
- 1) Patients with inflammation and edema should be treated thoroughly before surgery.
- 2) If incomplete cutting occurs, spare scissors can be used.
- 3) Avoid excessive observation of blooding point.
- 4) Pressurized dressing from the proximal of incision to the distal of penis to avoid hematoma.
- 5) Stitching for the obvious bleeding points.

- **Q: How to prevent suturing staple embedded in tissue?**
- A: It is necessary to smooth the foreskin before dressing.
- All dressings need to removed 3 days after surgery to reduce the probability of suturing staple embedding by the folds of the foreskin.

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- **Q: How to deal with postoperative bleeding?**
- A: Check if the patient has intense exercise after operation and the history of disease. Whether there is coagulation dysfunction, take aspirin and anticoagulant drugs such as heparin injection recently. If so, use coagulant drugs.
- If the bleeding is serious, recall patient to hospital for observation. Remove the bandage and carefully check if the suturing staple is complete.

- **Q: How to stop intraoperative bleeding?**
- A: Press and hemostasis by compression, find out whether there is coagulation dysfunction.
- Ready to suture hemostasis.
- If the bleeding cannot be stopped, bipolar electrocoagulation is recommended.

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- **Exclusion criteria for patients with circumcision**
- 1) Frenulum deformity need correction.
- 2) With the blood coagulation dysfunction, diabetes and other non surgical indications.
- 3) Cicatricial constitution, webbed penis, concealed penis, aridity posthitis.
- 4) Severe adhesions of glans and foreskin and inseparable.
- 5) Suspected penis cancer.
- 6) patient with acute infection of the foreskin, glans and edema is needed anti - inflammatory treatment before surgery.

Risks and complications of Stapler Circumcision

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- **Bleeding:** Usually there is little bleeding after circumcision,this will generally stop on its own. Cases of excessive bleeding are rare but can still happen, then ask your urologist for help.

- **Edema:** Usually don't have to take action, Edema will disappear automatically. In case of serious edema,then ask your urologist for help.

- **Pain:** Usually there is some mild to moderate pain and discomfort after circumcision, in case of excessive pain,then ask your urologist for help.

- **Wound infection:** Any kind of surgical procedure carries some degree of risk of infection, while such cases are rare but can still happen,then ask your urologist for help.

- **Residual staples:** The staples are nailed together with a silicone ring, which starts to fall off automatically after one week, usually complete dropping in one month. if some staples may not fall after one month , then ask your urologist for help.

- **Wound dehiscence:** If the wound edges fail to close, the urologist may close the wound with sutures, although stapler circumcision is a sutureless technique.

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