



## Reviews Of Progress

### SOLEHRING : SAFE, EASY AND EFFECTIVE DISPOSABLE CIRCUMCISION DEVICE IN CHILDREN; A PILOT CLINICAL STUDY IN MALAYSIA AND INDONESIA.

Dr. Mohamad Salleh Bin Abdul Aziz<sup>1</sup>, Dr. Abdul Latiff Bin Mohamed<sup>2</sup> and Dr. P.Thamilselvam<sup>3</sup>

<sup>1</sup>General Surgeon and Senior Lecturer, Faculty of medicine ,  
Cyberjaya University college of medical Sciences , Malaysia.

<sup>2</sup>Professor , Deputy President and Consultant Cardiologist ,  
(Academic & International Affairs and Research & Commercialisation).  
Cyberjaya University College Of Medical Sciences , Malaysia.

<sup>3</sup>Professor, General Surgeon and Professor,  
Faculty of medicine and health defense(FPKP),  
National Defense University Malaysia (UPNM), Malaysia.

#### ABSTRACT

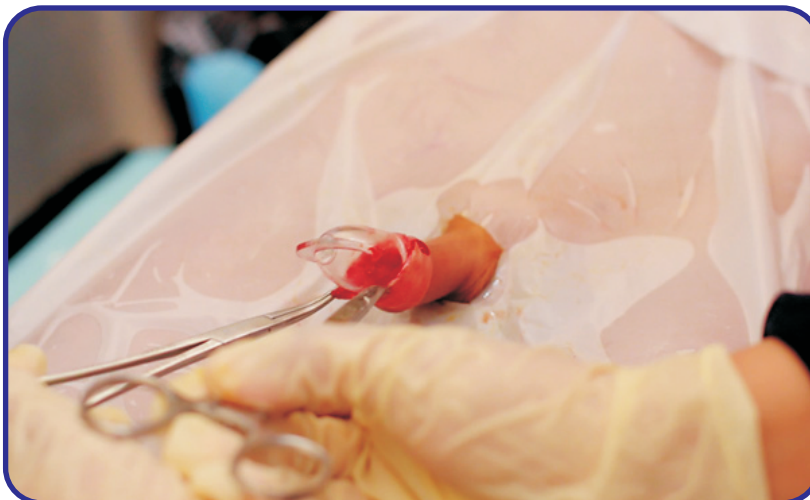
##### Background:

Solehring™ is a newly created disposable circumcision device. The concept and design are similar to Plastibell™ using surgical suture to tie and compress the blood vessel followed by cutting of the skin using surgical scissors.(1) It consists of two component which is called “The Cap” and “The Ring”. Both of them are separable. After the circumcision procedure, the ring will stay with patient to protect the glans penis while the

cap would be disposed. The ring will fall off from the skin within 10 to 14 days. Both of them are made by special polycarbonate which is safe for human and is approved by FDA. The design is in the form of a “bullet” to enhance safety and user-friendliness. It is also colourless to aid the circumcision operator to visualize the glans penis and to avoid injury during the procedure

##### Methods:

Pilot clinical studies were successfully conducted in Malaysia and Indonesia . The primary objective of the studies was to assess the safety of Solehring devices when conducted in children 7 to 12 years-old with the following end points: adverse events , pain-score measured using visual analog score, pain and swelling related with



allergic reaction, bleeding post circumcision, infection rate and drop-off day.

##### Results:

Out of 19 subjects who were offered solehring circumcision procedure, 15 were able to be completed technically. No adverse event was reported in all the children. The drop-off day was reported at day 10 (46.67%). The latest was at day 14 (13.33%). Average pain score was recorded as minimum at 2 (

26.67%). Only in one subject the pain score was 5.

#### **Discussion:**

The study result from 3 different area showed no adverse event reported from the 15 subjects. The sample size was insufficient to conclude the device as safe and effective disposable circumcision device. Further studies are required to elicit the safety and effectiveness of the device.

**Key words:** Solehring, disposable circumcision device, circumcision in children.

#### **BACKGROUND**

Circumcision is one the commonest surgical procedure among the malay It routinely done among the children between 7 to 12 years old.(2) In Malaysia, there are several method of circumcision. One the method is using disposable circumcision device. (3)

Throught out the years, more than 1000 children circumcised using those disposable device. Lots of complication related with these disposable devices which includes bleeding, unable to pass urine , infection and incomplete circumcision. Many of the parents have puts on voice because of these complication and deliver their unhappiness to the doctors. Concerning of these complication , the idea of creating solehring have raised. (4)

Solehring is bullet-look plastic device made up by material called PC Macrolone which had been approved by FDA as safe for human contact as long as 30 days. It consists of two parts. The ring and the cap. On the ring parts, its have anti-slip effect which prevent the string to slip proximally. The ring also have a grip which can be fitted easily on the finger to enhance twisting movement for unlocking the cap. It is transparent, so that can easily visualize the glans penis and it so light, so that it will not put burden on the shaft.

The string provided is made up by non-absorbable synthetic cotton which very soft and safe for human contact. It also provides adequate tension and grip to the performer. Very less likely to have allergic reaction to the patient.

Because of these features, material , design and concept, it helps in reducing the complication like bleeding as the string will give adequate tension. Infection can be reduce because the design is so light and easy to handle it after the procedure. It provides enough spaces for glans penis to be dilated during micturition. This prevent retaining of urine in the devices which helps in preventing infection.

#### **METHODS**

##### **Study Design**

The study was conducted in two different countries, Malaysia and Indonesia. In Malaysia The study was held in Puchong and Selayang. Whereas, in indonesia the study was conducted in Rumpet, Aceh at different time. The study was conducted by single performer to make sure the efficacy of the device.

A total of 19 children was circumcised in this study. However, four children were excluded because varies reason. The first children because of having different size, another two children were excluded due to different performer and last children was excluded due to rejected by parents. All four of them was circumcised by conventional method.

Four children were successful circumcised by solehring in Aceh. The age ranges between 7 to 10 years old. Another four children were also successfully circumcised by solehring in Puchong, Selangor area. The age ranges between 9 to 10 years old. The rest of children were successful circumcised in Selayang, which involved Rohingya Community. One of them was excluded due to

rejected by parents. The youngest is 7 years old and the eldest was 10 years old.

## OUTCOME MEASURES

### Outcome measures included:

- Frequency and percentage of adverse events (AEs). Per WHO recommendations, we measured the rate of moderate and severe AEs. AEs included average pain score during the solehring process; measured using a visual analog score with a range of 0–10, where 0 corresponds to “no pain at all” and 10 to “worst pain imaginable.” The pain assessments were made at specified time points throughout the study.
- Bleeding is the crucial complication happen during the procedure. So we recorded any event of bleeding during or immediate post placement of the device.
- Any evident of infection consider not safe for the device. We recorded any evident of pus discharge, purulent swelling mainly at shaft of the penis.
- ‘Drop-off’ day is the term use to explain about the device has fall off from the penis. It varies from person to person. Therefore, we recorded the drop-off day for every patient,

### Inclusion and Exclusion Criteria

The following inclusion and exclusion criteria were used.

#### Inclusion Criteria

Children aged 7 – 12 years old, uncircumcised, consents/assents to the Solehring circumcision procedure, in good general health, provides contact information, agrees to active follow-up, providing location information and a cell phone number.

#### Exclusion Criteria

Unconsented, Glans Penis did not fit any of the 3 Solehring sizes; medical contraindication, cognitive, or psychiatric impairment as determined by staff, genital anatomic abnormalities or/and active genital disease/infections, evidence of partial circumcision, or scarification.

## RESULTS

### Safety

#### Adverse Events

The adverse event was elicited among the children using solehring. The adverse event were mortality, severe pain and swelling due to allergic reaction, bleeding and sign of heavy infection like purulent discharge. No adverse event was recorded among the children using solehring.

	Sample size	Average pain score	Drop-off day
Acheh children	4	2.75	11.75 day
Puchong Children	4	2.5	11.25 day
Rohingya	7	3.75	11.71 day

### Acheh

Only 5 children were offered for solehringcircumscsion procedure, however only four ( 26.67%) children are includes in the study. The exclusion happened due to inappropriate size of solehring. Among four children, average pain score was elicited from the children using visual analog score at day 1, day 3, day 7 and day 10 post procedure using phone call, message, email and whatsapp application. The average pain score was recorded as 3, 2, 4 and 2. So the average pain score form the Acheh children was 2.75. However, the drop-off day was recorded at day 10, day 12, 13, and day 10. So make it the average drop-off day is at 11.75 days.

### Puchong

The circumcision procedure was done earlier at this area. A total of 6 children was offered for solehring circumcision procedure. However, only 4 children ( 26.67%) were successful using solehring procedure. The reason of exclusion are due to inappropriate size and inappropriate performer. All the four children was followed up at day 1 , day 3, day 7 and day 10 to elicit information regarding average pain score and drop-off day. Pain score was elicit using visual analogue score and the data were 2,3,2 and 2 score. Make it the average of pain score is 2.5. The drop-off day was recorded at day 10, 10 , 12, and day 13. The average drop-off day was 11.25 days.

### Selayang( Rohingya)

Community Rohingya in Malaysia was offered for circumcision for age between 7 to 12 years. A total of 8 patients were offered for solehring procedure and only 7 children ( 46.67%) were successful completion solehring procedure. The one was excluded due to parents are not well informed and they refuse on the last minute. Among the 7 children, the pain score was recorded as follows : 4,3,4,3,5,4 and 3. The average pain score was 3.7. The average pain score was slightly higher Rohingya community group. The drop-off day was recorded as follow: Day 10, 12, 14, 12, 10, 14 and day 10. So the average drop-off day was at day 11.71

## DISCUSSION

Circumcision is the oldest surgical procedure practiced until now. It was first described by ancient Egyptian on written wall of the pyramid.(7) Male circumcision consists of the surgical removal of some, or all, of the foreskin (or prepuce) from the penis. It is one of the most common procedures in the world. Elective circumcision regularly performed soon after the newborn period till adolescent. In a large retrospective review of Nationwide Inpatient Sample, estimated rates of newborn circumcision have risen from 48.3% nationwide in this period 1988-1991 to 61.1% of male newborn from 1997 – 2001. (5) This represent an increases in incidence of approximately 6.8% per year. (6)

Solehring is bullet-look plastic device made up by material called PC Macrolone which had been approved by FDA as safe for human contact as long as 30 days. It consists of two parts. The ring and the cap. On the ring parts, its have anti-slip effect which prevent the string to slip proximally. The ring also have a grip which can be fitted easily on the finger to enhance twisting movement for unlocking the cap. It is transparent, so that can easily visualize the glans penis and it so light, so that it will not put burden on the shaft.

During the solehring procedure 19 children was offered for circumcision, however only 15 children eligible or includes in the study. Four children ( 26.67%) was come from Acheh, another four was from Puchong , Selangor ( 26.67%) and the rest 7 children ( 46.67%) from Rohingya community in Selayang. All the children age ranges between 7 to 10 years old. Children ages 8 years old was the

minimum participant which was only 3 children ( 20%) of the participant. The rest were 7 years old ( 26.67%), 9 years old ( 26.67%) and 10 years old ( 26.67%). Weight of the patient ranges between 14kg to 25kg. However no direct relation between weight and other parameter measured.

The pain score was measured and elicited from the patient at day 1, day 3, day 7 and day 10 post procedure. The information was gathered by using handphone, message, email and whatsapp application. The Average pain score measured and recorded ranges between 2 to 5 pain score. The minimum average pain score was 2 which were 26.27% of the children. 6 children was giving information of average pain as 6 which were the majority that carries 40% of the children. Only one children was giving information pain score as 5 which is 6.67% .

The drop-off day was measured and recorded from all children using solehring. Majority of the children was giving information that solehring drop-off day at day 10 post procedure which was 46.67%. No children was informed to have drop-off day at day 11 post procedure. 4 children having day 12 post procedure which was 26.67%, 2 children at day 13 post procedure and only 2 children at day 14 which carries 13.33%.

Owing to the fact that wound healing after Solehring procedure is by secondary intention, the time required for complete healing across the 3 studies was at least about 2 weeks. The studies provide better understanding of some of the reported advantages of the method, including ease of task shifting to nonphysician cadres of providers; increased efficiency due to reduced procedure time; and lower risk of bleeding and infection. It is important to note that backup surgery by an experienced provider proficient in the dorsal slit or sleeve method needs to be available because of the risk of device displacement and self-removal by the children.

#### **We note the following study limitations:**

Interpretation of complete healing and pain scores was subjective. This explains the high variability for the average pain score 3 areas. The most important weakness of the study was the insufficient of number of study and improper follow-up of study participants across all studies. Follow-up of each participant was intended until complete healing could be confirmed, but a high percentage of the children were either lost to follow-up after drop-off day or exited the study without certification of complete healing.

#### **REFERENCES**

- (1) Aaron J. Krill, Lane S. Palmer, Jeffrey S. Palmer, " Complication of circumcision"; *TheScientificWorld of journal*; Vol. 11, pp 2458-2468, 2011
- (2) Helen A Weiss , natashaLarke, Daniel Halperin , InonSchenker, " Complication of circumcision in male neonates , infants and children : a systemic review ", *BMC Urol*. Vol. ; 10:2, 2010
- (3) C.P.Nelson, R. Dunn, J. Wan and J.T.Wei, " The increasing incidence of newborn circumcision : data from the nationwide inpatient sample," Vol. 173, no. 3 pp. 978-981, 2005
- (4) C. M. Lammon , A. G. D. Bailey, A.R. Fleischman et al., " Circumcision policy statement. American Academy of paediatrics. Task force on circumcision ". *Pediatrics*, Vol. 103, no. 3 pp686-693, 1999
- (5) H.G. Gray, G. Kigozi, D. Serwadda et. Al., " Male circumcision for HIV prevention in men in Rakai, Uganda : a randomized trial" *The Lancet*, vol. 369, no. 9562, pp643-666, 2007
- (6) R.C. Bailey , S. Moses, C.B. Parker et al , " Male circumcision for HIV prevention in young men in Kisumu, Kenya : a randomized control trial" *The Lancet*, vol. 369, no. 9562 pp 643 – 656, 2007
- (7) Al-Samarrai AYI, Moifti AB, Crankson SJ, Jawad A, Haque K, al-Meshari A. A review of a Plastibell device in neonatal circumcision in 2,000 instances. *SurgGynecolObstet* 1988; 167 (4):341-3

- (8) WD Dansmuir, EM Gordon. The history of circumcision. *BJU International* 1999;83: 1-12
- (9) Fraser ID, Tjoe J. Circumcision using bipolar diathermy scissors: a simple, safe and acceptable new technique. *Ann R CollSurgEngl* 2000; 82: 190-191
- (10) Fearne. Bloodless circumcision. *BJU International* 2001; 83(6): 717
- (11) Kaplan GW. Complications of circumcision. *Urologic Clinics of North America* 1983;10: 543-549
- (12) Subramaniam R, Jacobsen AS. Sutureless circumcision: a prospective randomised controlled study. *Pediatr Surg Int* 2004;20: 783-785
- (13) Arunachalam P, King PA, Orford J. A prospective comparison of tissue glue versus sutures for circumcision. *PediatrSurgInt* 2003; 19: 18-19
- (14) Ozkan KU, Gonen M, Sahinkanat T, et al. Wound approximation with tissue glue in circumcision. *Int Journal of Urology* 2005; 12(4): 374-377
- (15) Cheng W, Saing H. A prospective randomized study of wound approximation with tissue glue in circumcision in children. *Journal of Paediatrics& Child Health* 1997; 33(6): 515-516
- (16) Petratos P, Rucker GB, Soslow RA et al. Evaluation of octylcyanoacrylate for wound repair of clinical circumcision and human skin incisional healing in a nude rat model. *The Journal of Urology* 2002;167: 677-679
- (17) Sharma P. Sutureless circumcision: Wound closure after circumcision with cyanoacrylate glue – A preliminary Indian study. *Indian J Surg* 2004;66: 286-8
- (18) Elmore J, Smith E, Kirsch A. Sutureless circumcision using 2-octyl cyanoacrylate (Dermabond): Appraisal after 18-month experience. *Urology* 2007;70: 803-806
- (19) Fraser ID, Goede AC. Sutureless circumcision. *BJU International* 2002;90(4): 467-468
- (20) Schmitz RF et al. Results of group-circumcision of Muslim boys in Malaysia with a new type of disposable clamp. *Trop Doct.* 2001; 31(3):152-154
- (21) Kulkarni SS, Chava KK. Comparison of cyanoacrylate and silk sutures on healing of oral wounds- an animal study. *Indian J Dental Res.* 2003;14(4): 254-258
- (22) Toriumi DM, Watson D. Cyanoacrylate tissue adhesives for superficial skin closure. *Current Opinion in Otolaryngology & Head and Neck Surgery.* 1999;7(4): 214
- (23) Pelissier P et al. Internal use of n-butyl 2-cyanoacrylate (Indermil) for wound closure: an experimental study. *Plastic and Reconstructive Surgery.* 2001;108(6): 1661-1666
- (24) Civjan S, Margetis P, Reddick R. Properties of n-Butyl-alpha-cyanoacrylate mixtures. *J Dent Res* July-August 1969, Vol 48 No 4
- (25) Nitsch A, PabykAet al. Cellular, histomorphologic, and clinical characteristic of a new octyl-2-cyanoacrylate skin adhesive. *AesthPlast Surg.* 2005;29: 53-58
- (26) Mattamal G. US FDA perspective on regulation of cyanoacrylate polymer tissue adhesives in clinical applications. *Material Science Forum* Vols. 539-543 (2007): 692-697
- (27) Barnett P, et al. Randomised trial of histoacryl blue tissue adhesive glue versus suturing in the repair of paediatric lacerations. *Journal of Paediatrics and Child Health,* 2002,34(6): 548-550
- (28) Tissue Seal LLC. Summary of safety and effectiveness data. February 2007. [www.tissueseal.com](http://www.tissueseal.com)
- (29) Wilkinson JN et al. The antimicrobial effect of Histoacryl® skin adhesive. *Anaesthesia* 2008;63(12): 1382-84
- (30) Hollander J et al. Wound Registry: Development and Validation. *Annals of Emergency Medicine* 1995; 25 :5
- (31) Fadaizadeh L et al. Comparison of Visual Analogue Scale and Faces Rating Scale in Measuring Acute Postoperative Pain. *Arch Iranian Med* 2009;12(1): 73-75
- (32) Hartrick C et al. The Numeric Rating Scale for Clinical Pain Measurement: A Ratio Measure? *Pain*

Practice 2003;3(4): 310-316

(33) Amiel GE, Sukhotnik I, Kawar B, Siplovich L. Use of N-Butyl-2-cyanoacrylate in Elective Surgical Incisions- Longterm Outcomes. *J Am Coll Surg*. 1999;189: 21-25

(34) Bruns TB, Simon HK, McLario DJ et al. Laceration Repair Using a Tissue Adhesive in a Children's Emergency Department. *Paediatrics*. 1996;98: 673-675

(35) Llyod JD, Marque MJ, Kacprowicz RF. Closure Techniques. *Emerg Med Clin N Am*. 2007;25: 73-81

(36) Quinn JV, Osmond MH, Yurak JA et al. N-2-butylcyanoacrylate: Risk of bacterial contamination with an appraisal for its antimicrobial effects. *J Emerg Med* 1995;13:581-585

(37) Quinn J, Maw J, Ramortar K et al. Octylcyanoacrylate tissue adhesive versus suture wound repair in a contaminated wound model. *Surgery* 1997;122(1):69-72

(38) Singer AJ, Quinn JV, Hollander JE. The cyanoacrylate topical skin adhesives. *Am J Emerg Med* 2008;26:490

(39) Bruns TB, Worthington JM. Using tissue adhesive for wound repair: a practical guide to Dermabond. *Am Fam Physician* 2000;61:1383

(40) Kaye JD, Kalisvaart JF, Cuda SP et al. Sutureless and scalpel-free circumcision – More rapid, less expensive and better? *J Urol* 2010;184(4):1758-1762

(41) Elemen L, Seyidov TH, Tugay M. The advantages of cyanoacrylate wound closure in circumcision. *PediatrSurgInt* 2010; Oct 13

(42) Ozturk H, Karaaslan K, Kocoglu H. *AdvClinExp Med* 2009;18(4):381-384

(43) Lane V, Vadja P, Subramaniam R. Paediatricsutureless circumcision: a systematic literature review. *PediatrSurgInt* 2010;26:141-144

(44) D'Arcy FT, Jaffry SQ. A review of 100 consecutive sutureless child and adult circumcision. *Ir J Med Sci* 2010 Aug 8

(45) Hasan Z, Gangopadhyay AN, Gupta DK et al. Sutureless skin closure with isoamyl 2-cyanoacrylate in pediatric day-care surgery. *PediatrSurgInt* 2009;25:1123-1125

(46) Chaim JB, Livne PM, Binyanmini J et al. Complications of circumcision in Israel: A one year multicenter survey. *IMAJ* 2005;7:368-370

(47) Maw J, Quinn J. Cyanoacrylate tissue adhesives. *Am J Cosmetic Surg* 14:413-416

(48) Gairdner D. The fate of the foreskin, a study of circumcision. *British Med Journal* 1949:1433-1437

(49) Mackenzie AR. Meatal ulcer following circumcision. *ObstetGynecol* 1966;28:221-223

(50) Bazmamoun H, Ghorbanpour M, Mousavi-Bahar SH. Lubrication of circumcision site for prevention of meatal stenosis in children younger than 2 years old. *Urol J* 2008;5(4):233-236

(51) Persad R, Sharma S, McTavish J et al. Clinical presentation and pathophysiology of meatal stenosis following circumcision. *Br J Urol* 1995;75(1):91-93

(52) O'Sullivan, DC Heal, MR Powell. Circumcision: how the urologist do it? *Br J Urol* 1996,78(2):265-270

(53) Williams, Kapila. Complications of circumcision. *Br J Surg* 1993;80:1231-1236

(54) Ong C, Jacobson, Joseph. Comparing wound closure using tissue glue versus subcuticular suture for paediatric surgical incisions: a prospective, randomized trial. *PaedtSurgInt* 2002;18:555-556



Figure 1.0) 3D image of solehring device



Figure 2.0) Multiple sizes available for solehring

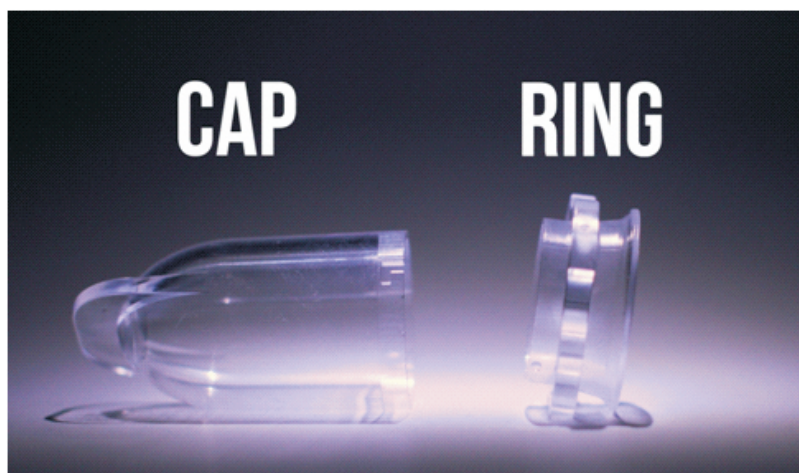


Figure 3.0) two parts of solehring: ring and cap