WHITE PAPER

CIRCUMPLAST® INFANT MALE CIRCUMCISION DEVICE: A CASE SERIES
Circumplast Infant Male Circumcision Device: A Case Series

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Abstract

Objective: To conduct a service evaluation of the Circumplast infant male circumcision device in routine service delivery at Newcastle Private Hospital in Australia.

Methods: 51 patients’ parents were asked if they were willing to participate in a service evaluation being conducted on the use of the Circumplast circumcision device. Parents that agreed to participate were provided with a link to an online survey where a list of questions were to be answered. The answers were then gathered and analysed.

Results: 51 parents (one per infant) responded to the survey. The mean age of the patients ± SD was 44.0 ± 14.6 days. The mean number of days the Circumplast device was in place ± SD was 6.3 ± 1.6 days. No complications were recorded including infection requiring antibiotics, glans protruding through the Circumplast device (proximal migration), and bleeding.

Conclusions: The Circumplast circumcision device provides a safe and effective circumcision that is similar in use to the Plastibell method. No complications were recorded and in particular no cases of proximal migration were recorded.

Introduction

Male circumcision is one of the oldest and most commonly performed surgical procedures in the world today [1,2]. In 2007 the World Health Organisation (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS) released a policy statement recommending male circumcision be incorporated as a tool to reduce heterosexually-acquired HIV infection [3]. In 2012 the American Academy of Pediatrics (AAP) released an evidence-based policy statement on infant male circumcision (IMC) stating that the benefits of circumcision outweigh the risks and recommended access to safe affordable medical circumcision and parental education early in a pregnancy [4]. The Centers for Disease Control and Prevention (CDC) in the United States
released its draft recommendations in Nov 2014 further supporting the benefits of infant male circumcision and also recommending circumcision at later ages [5], which are outlined below. Research has shown that the optimal time at which circumcision should be performed is in early infancy using local anaesthesia since risks are lowest, the procedure is quick, simple, convenient, cheaper and cosmetic outcome is optimal. Infant male circumcision (IMC) bestows immediate protection against urinary tract infections, which extends over their lifetime.[6]. IMC also reduces the risk of childhood and lifelong inflammatory foreskin conditions such as balanitis and balanoposthitis, as well as phimosis, paraphimosis, and foreskin injuries [7]. The benefits of circumcision once the male becomes sexually active are substantial and include protection against HIV and other viral sexually transmitted infections such as oncogenic human papillomavirus and genital herpes [7,8,9,10]. IMC also protects against genital cancers (penile, prostate and cervical) [11]. A risk-benefit analysis showed that benefits exceed risks by 100 to 1 and that over their lifetime 1 in 2 uncircumcised males will develop a medical condition caused by the foreskin [12].

There are various devices used for IMC. The most common are the Gomco clamp, the Mogen clamp, and the Plastibell® [13,14]. Of these three devices, only the Plastibell® is a sterile disposable IMC device. The Gomco and Mogen clamps are multiple use devices that require sterilization prior to use. The Plastibell® is also the only device of the three to rely on ischaemic necrosis of the foreskin using a ligature. The Plastibell® has been in use for more than 50 years, has been studied extensively and has known risks associated with its use [15]. There are several complications that may arise from the use of the Plastibell® circumcision device. One of the more serious of which relates to proximal migration of the device up the penile shaft [15]. Proximal migration leading to glans extrusion is an inherent design flaw in the Plastibell® device due to the distal opening being smaller in diameter than the proximal opening (Figure 1).
The Plastibell® is inserted over the glans and the foreskin is pulled over the device, the ligature is then secured in the groove labelled as “A”. There are several scenarios which lead to proximal migration, mainly an incorrect choice of size, and inducing tension into the foreskin when it is being pulled over the device. The incorrect choice of the Plastibell® device can cause proximal migration as the distal opening would be large enough to allow the glans to pass through the opening, resulting in complications such as urethral obstruction once the device slides proximally up the glans [16]. Inducing tension into the foreskin occurs when the surgeon attempts to remove more foreskin than the Plastibell® device allows by pulling the foreskin distally until the required position is reached. The foreskin tension induced by the pulling action forces the Plastibell® device to migrate proximally resulting in the glans being forced against the distal opening. Another inherent design flaw in the Plastibell® is the fact that not all the inner foreskin can be removed due to the section between the proximal opening and groove “A”. The inner foreskin has been shown to be rich in Langerhans cells which plays a key role in HIV transmission. Therefore the inability of the Plastibell® device to remove more of the inner (mucosal layer of the) foreskin may result in a lower level of protection from HIV [17].

Rates of complication associated with the use of the Plastibell® device vary significantly based on what is considered to be a complication and are suspected to be higher than reported [18,19]. Serious complications are rare, however. Complications can be categorized as either early or late.
complications. Early complications include bleeding, inadequate skin removal, pain and infection of the surgical site and are minor and easily treatable. There are however several serious early complications such as chordae, glanular necrosis, iatrogenic hypospadias and glanular amputation which require immediate surgical intervention. Late complications include chordae, epidermal inclusion cysts, inadequate foreskin removal resulting in redundant foreskin, suture sinus tracts, phimosis, penile adhesions, buried penis, meatalitis, urethrocystaneous fistulæ and meatal stenosis [10]. Late complications are usually treated in an outpatient setting.

The Circumplast® (Figure 2) is a new single use infant male circumcision device aimed at circumventing the risks associated with the use of the Plastibell®.

![Figure 2: Circumplast® circumcision device](image)

The main features of Circumplast® are numbered in Figure 2 and are described as follows:

1- The proximal lip acts as the location where the ligature can be secured to remove the maximum amount of foreskin. This location is generally close to the coronal sulcus of the glans.

2- The plurality of locations where the ligature can be secured based on the surgeon’s preference.

3- The distal lip is equivalent to the location where the Plastibell® device requires the surgeon to place the ligature. It would not be used routinely with the Circumplast® device.

4- The handle, which is used to insert the Circumplast® device over the glans, and is removed at the end of the procedure.
The method for using the Circumplast® circumcision device is similar to that used for placement and completion of the Plastibell® method.

The present study is the first case series study aimed at evaluating the efficacy of the Circumplast® circumcision device.

**Materials and Methods**

Ethics approval was received by the Hunter New England Human Research Ethics Committee (authorisation number AU201504-6). Written informed consent was gathered from all parents of patients who volunteered to participate in the study.

The research was undertaken by a single General Practitioner who has performed ring-based circumcisions for 32 years. The Circumplast® circumcision procedure had been performed over a 12 month period, during which over 300 procedures had been completed with this method. Prior to that the Plastibell® ring had been used.

The study was carried out over a period of 3 months in 2014. All patients who were to have a Circumplast® circumcision by Dr Milton Sales were offered an opportunity to participate in a post-operative survey that assessed the occurrence of complications and the post-operative course of the procedure. Consent to take part was obtained from parents of the boys that underwent circumcision.

All babies were assessed and examined by Dr Sales prior to surgery. Parents were required to view information on the website [www.circumcisions.com.au](http://www.circumcisions.com.au) prior to attending for preoperative assessment. This website also contains postoperative photographs to assist parents in decision making relating to management of complications.

All boys were post-neonatal with a minimum of 28 days old owing to administrative requirements of the hospital’s licence. Premature babies were older than their due date, and all babies weighed > 3 kg at the time of the procedure.
The procedures were all performed in an operating theatre at Newcastle Private Hospital. A premedication of oral Paracetamol 15 mg per kg and EMLA cream for 90 minutes were given.

The following is an outline of the procedure:

a) A dorsal penile nerve and ring block using 1% lignocaine were performed 5 minutes prior to the start of surgery (Figure 3)

b) Separate the adhesions between the glans and the foreskin. Cut open the foreskin to allow enough space for the Circumplast® device (Figure 4, Figure 5)

c) Insert the Circumplast® device until the coronal sulcus is reached. Use forceps to secure the foreskin to the distal lip of Circumplast® (Figure 6)

d) Tightly secure the ligature provided with the Circumplast® device at the desired location (Figure 7, Figure 8)

e) Cut off excess foreskin and break off handle (Figure 9)

f) Figure 10 is day 4

g) Figure 11 is day 7

h) Figure 12 is day 14

A survey using the SurveyMonkey online system was developed. This had an internet link (https://www.surveymonkey.com/s/circumplast). Parents who consented to take part were emailed the link and chose to log in and respond.
Questions in the survey included the age of the patient, the number of days that the ring was in place prior to it separating, the occurrence of complications (possible specific adverse events being listed) and whether the parents communicated with the surgeon about the postoperative course, with either photos or text.

**Results**

A total of 51 parents (one per infant) responded to the survey of postoperative care of the Circumplast® procedure.

The mean age of the patients was $44.0 \pm 14.6$ SD days.
The mean number of days that the Circumplast® was in place before naturally falling off was 6.3±1.6 days.

None of the 51 parents reported a complication.

22% of parents communicated with the surgeon using photographs and all were able to be reassured that the progress was within normal limits.

Specifically, there were no postoperative infections, or bleeds after leaving the operating theatre. One baby had a minimal ooze immediately post procedure and this was successfully managed by cotton wool and Tinc Benz Co prior to leaving the operating theatre complex.

**Discussion**

The present survey of postoperative experience of the Circumplast® device confirms that the device is safe, and has a similar postoperative course to the Plastibell® device.

As with all ring methods of circumcision, the process of ring separation occurs by the effect of a tight ligature surrounding the ring, causing ischaemic necrosis of the tissue under the tie and resultant degeneration and separation of the tissue. The ring, tie and residual ischaemic foreskin tissue slough off together without assistance being required.

This process is associated with an inflammatory response causing some erythema of the penile shaft.

The difference between the Plastibell® and Circumplast® during surgery relates to the position of the tie on the ring, and the shape of the rings. In a Plastibell® circumcision the shaft skin is drawn distally and the ligature tie is applied at the distal end in a groove. The ring is conical with a narrowed end and the glans is held against the distal ring opening. This design can lead to the tip of the glans extruding through the ring and becoming oedematous. Occasionally this will require the string being cut and the ring removed prior to its natural separation process. This complication can be associated with urethral obstruction.
In contrast, the Circumplast® involves placement of the tie proximally in a groove with the string being applied at the resting position of the skin. The glans is not pulled to the end of the ring. As the Circumplast® ring is cylindrical, if the glans swells and moves to the end of the ring, there is no restriction in the ring, and the glans can not be caught beyond the ring. The shape of the Circumplast® enables easy access to the glans and frenulum, should there be any bleeding in the postoperative period. The application of cotton wool and Tinc Benz Co, or cellulose polymer (e.g., Surgicel) is facilitated because the distal end of the ring is wide open and the glans is visible.

**Conclusion**

The present study has confirmed that the Circumplast® ring method of circumcision is a safe procedure. The design of the Circumplast®, being cylindrical, is safer than the Plastibell®, so removing a significant potential complication. The ring falls off in the same time frame as the Plastibell®.

**Acknowledgements**

We thank Professor Emeritus, School of Medical Sciences, University of Sydney, for suggestions and editing of a draft of the manuscript.
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