The Open Urology & Nephrology Journal

Content list available at: https://openurologyandnephrologyjournal.com

RESEARCH ARTICLE

Does Circumplast Ring Offer Safe Alternative to Standard Plastibell Ring for Infant Male Circumcision?

Muhammad Moazzam[1,*] and Aibak Khwaja[1]

[1]*Queen's Hospital, University Hospital of Derby & Burton NHS Trust, Belvedere Rd, Burton-on-Trent, DE13 0RB, United Kingdom*

Abstract:

Purpose:

This study evaluated the early postoperative complications in Circumplast® and Plastibell® techniques for infant male circumcision in two community clinics.

Materials and Methods:

We retrospectively reviewed the outcome of infant male circumcision (n=649) over 1 year (Jan 2021 to Feb 2022) performed under local anaesthesia by a single urologist. The technique was non-randomly selected. Data were collected retrospectively, and early postoperative complications were compared between Circumplast® and Plastibell® circumcisions. Both parents consented to the procedure. The 24-telephone support and follow-up were provided if required.

Results:

All records of infants were reviewed with Circumplast® circumcision (CC) n=302 and Plastibell® circumcision (PC) n=347 during this period. The mean age was 52.33 +/- 44.16 days in CC and 38.64 ± SD 30.39 days in PC. Three infants were excluded. There was no major complication and minor complications were lower in CC (0.99% n=3/302) *versus* PC (2.9% n=10/347). Delayed ring separation happened in PC (2.3% n=8/347), which was separated by a bone cutter in the clinic and no ring impaction occurred in CC. One infant in CC had bleeding after 24 hours, which was managed by removal of the ring and revision of circumcision. Two infants required separation of coronal adhesions in CC and two required revisions of circumcision in PC.

Discussion:

This is the first study to report the results of early experience involving the use of Circumplast® ring to perform pediatric circumcision. Our findings reflect the use of this device as a safe alternative to Plastibell®. A randomised controlled trial (RCT) would be required to document the relative superiority of either device. The reduced number of ring impactions among CC may be attributed to its unique design.

Conclusion:

Infant male circumcision by the Circumplast® device has a lower risk of early postoperative minor complications especially migration/impaction and may offer a safe alternative.

Keywords: Infant male circumcision, Circumplast, Plastibell, Complications.

Article History	Received: April 26, 2023	Revised: July 14, 2023	Accepted: August 01, 2023

1. INTRODUCTION

Male circumcision is a common surgical procedure in the world, mostly performed for medical and religious reasons. It originated in ancient Egypt over 5,000 years ago to remove the foreskin to expose the glans penis. The estimated global male circumcision prevalence is around 38.7% of the total male population in the world [1]. Over 60% of male newborns were circumcised in the USA in 1992. There are an estimated 30,000 ritual circumcisions performed in Great Britain every year. The National Health Service (NHS) in the UK does not provide religious or cultural circumcisions in England and Wales [2]. Non-therapeutic infant male circumcision (IMC) is practised in

* Address correspondence to this author at the Queen's Hospital, University Hospital of Derby & Burton NHS Trust, Belvedere Rd, Burton-on-Trent, DE13 0RB, United Kingdom; Tel No: +44-1283 566333;
E-mail: muhammad.moazzam@yahoo.com

the UK and Europe by many community clinics and religious venues [3]. Circumcision is a procedure with a high success rate and is relatively safe, with few complications reported in the literature [4]. The British Association of Paediatric Urologists (BAPU) and the British Medical Association (BMA) recommended that the standards of care relating to the practice of religious circumcision should be identical to those for any other surgical procedure [5]. There are many methods for circumcision described in the literature; traditional surgery or using clamp devices are a few of the methods most frequently used for circumcision. The Gomco®, Mogen® and Plastibell® clamp devices have been mostly used in the USA and have been pre-qualified by WHO for use in IMC [1]. The Gomco® and Mogen® clamps are multiple-use devices that require re-sterilisation before use. The Plastibell® is a disposable device that relies on ischaemic necrosis of the foreskin using a ligature [6]. Circumplast® device is based on the same principle and was approved by the FDA in 2015. Circumplast® offers additional features like a choice for multiple levels of foreskin division and protection of the glans penis due to its cylindrical design and multiple groves [7]. It may also offer possible prevention of risk for proximal migration of ring (Fig. **1a**).

This study aimed to compare the early postoperative complications of two methods Plastibell® circumcision (PC) and Circumplast® circumcision (CC) in our two community clinics by a consultant urologist. This is the first report to look at the experience of the new innovative Circumplast® device in IMC.

2. METHODS

We reviewed the infant male circumcisions in infants retrospectively (n=649) over 1 year (1st Jan 2021 to 1st Feb 2022) and data of age, methods (Circumplast® or Plastibell®), incidence and interventions to deal with complications (Clavien-Dindo grading/classification) [8] were collected. All procedures were performed under local anaesthesia by a single urologist.

Informed consent was obtained from both parents and procedures were explained using visual aids. A preoperative assessment with a detailed history and clinical examination was carried out to exclude any congenital abnormalities like hypospadias or congenital deformities like penile chordae. Circumcision was performed under local anaesthesia by the consultant urologist, who has more than 20-year experience working as a urologist in NHS and performing circumcisions at the community clinics, using both disposable devices. Procedures were performed using a disposable sterile circumcision pack (Cat No: RMT4002-MASTER, Rocialle Wales UK). The infant was held securely and safely in a specially designed tray (Olympic Circumstraint ™) in the supine position. Following all aseptic measures and cleaning (Chlorhexidine gluconate 0.5mg/ml) penile block was administered using 1% Lidocaine (Lidocaine 20mg/2ml 1% solution for injection ampoules, A A H Pharmaceuticals Ltd, UK), according to the weight of infant using a 30-gauge needle. The foreskin was held laterally with two pairs of artery forceps at 3 and 9 o'clock positions and the adhesions inside the foreskin were gently separated with the third pair of artery forceps. The dorsal slit of the prepuce was performed after a few seconds of crushing the foreskin by artery forceps at the 12 o'clock position, which helped to avoid bleeding from the edges. Any bleeding from the frenular area was secured using a disposable diathermy pen (Disposable Cautry pen 28mm Cat No: FS499B, Four Square Healthcare Ltd, UK). Size of Plastibell® device (1.1cm -1.7cm) was selected according to the size of the exposed glans and would snugly fit over two-third of glans. Size of Circumplast® ring (9.5mm-13mm) was also selected according to Glans size, which would loosely fit on glans and no preputial lining visible inside the ring, following its insertion inside the prepuce. The Circumplast or Plastibell device was then inserted over the glans inside the foreskin following an assessment of the correct size of the device (Fig. **1b**). The ligature was placed firmly and securely at the desired level using a cotton thread provided with the device. The excess foreskin was cut distal to the edge of the ligature and checked again for any bleeding. The technique was non-randomly selected depending on the availability of devices and the parent's choice. Post-operatively, written instructions (as well as an instructional/demonstrative video) were given to the parents regarding local care and maintenance of hygiene. Oral paracetamol suspension was provided and advised for pain relief according to the weight of the child. Safety advice was given to inform the clinic if the ring has not fallen off by the end of 14 days. An on-demand 24-hour telephone support line was provided along with telephone follow-up at 4 weeks. Child was reviewed in the clinic if there was any concern raised by parents.

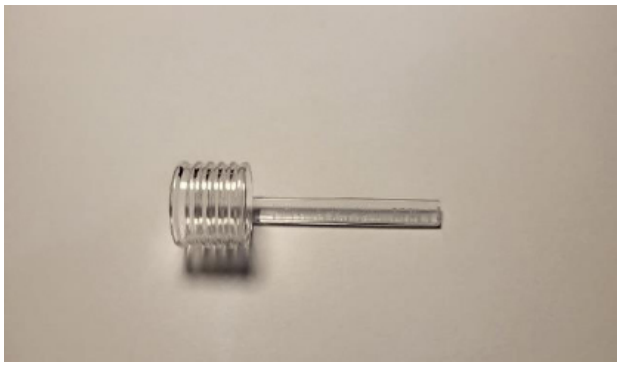

Fig. (1a). Circumplast® device.

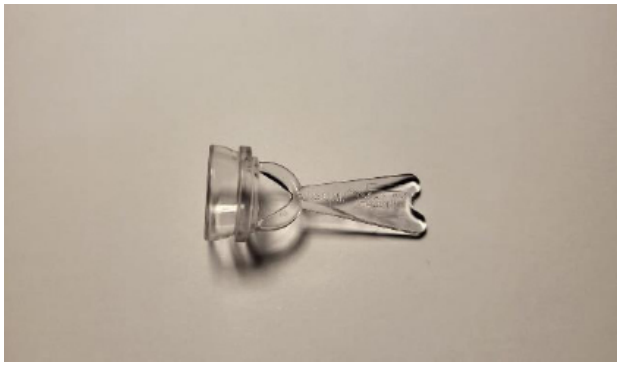

Fig. (1b). Plastibell® device.

3. RESULTS

The medical records of all infants reviewed who had circumcision in two community clinics over 1 year (Jan 2021 to Feb 2022). A total of 649 procedures were recorded using Circumplast® (n=302) and Plastibell® (n=347) devices, during this period. The indications for circumcisions were religious in all our patients. Out of these 86.1% infants had Muslim and 13.9% had Christian background. Complications of CC and PC are shown in Tables **1** and **2**. The mean age was 38.64 ± SD 30.39 days (range: 5-205days) in PC (Table **3**). A mean volume of local anaesthetic used was 1.42mls +/- 0.28mls (range 1-2mls). Frequency of different sizes of Plastibell® devices used were 1.1cm (3, 0.9%), 1.2cm (30, 8.6%), 1.3cm (94, 27.1%), 1.4cm (118, 34%), 1.5cm (85, 24.5%) and 1.7cm (17, 4.9%). In CC group, the mean age was 52.33 +/- 44.16 days (range 4-254 days). A mean volume of local anaesthetic used in CC group was 1.40 mls +/- 0.28 mls (range 1-2mls). Frequency of different sizes of Circumplast® devices used included 9.5mm (24, 7.9%), 11mm (3, 1%), 12mm (126, 41.7%) and 13mm (149, 49.3%). There was no major complication in our cohort and minor complications were noted. These complications were lower in CC (0.99%, n=3/302) *versus* PC (2.9% n=10/347). Delayed ring separation/impaction (Clavien-Dindo Grade-3a) happened in Plastibell® (2.3% n=8/347) which was separated by a bone cutter in the clinic. There was no ring impaction/migration occurred in CC group. One infant in CC had bleeding after 24 hours which was managed by removal of the ring, and revision of circumcision with excision of remaining foreskin beyond the level of ligature and reconstruction of the muco-cutaneous junction with stitches, using absorbable suture (Clavien-Dindo Grade-3a). Two infants required separation of coronal adhesions in CC group (Clavien-Dindo Grade-1). Two infants required revisions of circumcision in Plastibell (Clavien-Dindo Grade-3a). Face to face follow-up appointments were required in those children who required interventions (3 infants in CC and 10 infants in PC).

Neonatal complications (circumcision performed within the age of 30 days) were fewer in CC as compared to PC. Only one neonate had minor coronal adhesions with CC (for which no intervention was required and separated on clinical examination) as compared to the 3 neonates who had complications with PC (one requiring revision of circumcision due to scar tissue, the other 2 needed removal of the impacted ring by division with the help of bone cutter).

Similarly, complications in the infant group (circumcision performed at the age of one to 12 months) were fewer in CC as compared to PC. Of the 2 complications in CC, 1 infant had coronal adhesions for which no intervention was required, and adhesions were separated in the clinic along with parental education to prevent them in the future. One infant had bleeding after 24 hours which was managed by removal of the ring, and revision of circumcision as described before. Seven infants had complications in the PC group. One infant had delayed separation of the Plastibell ring which was easily removed in the clinic and required no additional intervention. One infant appeared to have incomplete excision of the foreskin which was managed by revision of circumcision by excision of excess skin and suturing under the penile block. Five infants had impacted rings which required removal following division with the help of a bone cutter. No infection-related complications were reported.

Table 1. Complications following Circumplast circumcision (CC).

Patient	Age at Operation (days)	Follow-up (days)	Complications	Clavien-Dindo's Grade	Intervention Required
1	25	114	Coronal adhesions	1	none
2	73	1	Bleeding	3a	ring removed and redo circumcision after stopping bleeding at the frenulum
3	35	100	Coronal adhesions	1	none

Table 2. Complications following Plastibell circumcision (PC).

Case	Age at Operation (days)	Follow-up (days)	Complications	Clavien-Dindo's grade	Intervention Required
1	35	14	Plastibell delayed separation	3a	Removed in the clinic
2	25	49	Scar tissues	3a	Excision of scar due to cosmetic reason
3	20	10	Plastibell Impaction	3a	Removed by bone cutter
4	97	16	Plastibell Impaction	3a	Removed by bone cutter
5	14	17	Plastibell Impaction	3a	Removed by bone cutter
6	122	12	Plastibell Impaction	3a	Removed by bone cutter
7	33	200	Incomplete circumcision	3a	Redo circumcision
8	37	16	Plastibell Impaction	3a	Removed by bone cutter
9	90	11	Plastibell Impaction	3a	Removed by bone cutter
10	106	11	Plastibell Impaction	3a	Removed in the clinic

Table 3. Distribution of procedures among two age groups.

Type of Device	Neonate (< 30 days)	Infants (> 30 days)	Total Numbers of Patients
Circumplast Ring	131	171	302
Plastibell	184	163	347
Total number of procedures	315	334	649

4. DISCUSSION

There were no major complications in our series and the overall minor complication rate is around 2% in circumcision under 7 months of age in our cohort. Although minor complications were lower in CC (0.99% n=3/302) *versus* PC (2.9% n=9/347). The difference between the Plastibell® and Circumplast® devices possibly relates to the position of the tie on the ring, and the shape of the rings. The complication rate in infants with Plastibell® is variable and ranges from 2.4 – 24% in the literature [9 - 11].

Bawazir *et al*. reviewed a cohort of 989 neonates and infants receiving Plastibell® circumcisions [6]. It included 633 neonates and 356 infants who have developed minor complications in 89 cases, 4.4% in neonates and 17% in infants ($P < 0.001$). The retained ring was the most common complication in 46 cases (4.6%), followed by excess skin in 21 cases (2%). In our cohort minor complications developed in 1.2% of neonates and 2.7% of infants.

Plastibell impaction/migration is a common complication following this method of circumcision in most of the previous publications and ranges from 1% - 20% [6, 9, 10, 12 - 15]. Possible underlying causes may include a choice of incorrect size, excessive pulling of penile skin, penile oedema or a natural erection which can potentially push the glans penis through the Plastibell® ring. Within the experienced surgeon's hands, the first two root causes are unlikely, however, we still had impaction of the conical side of Plastibell in our series, possibly due to penile oedema or natural erection. In a Plastibell circumcision, the penile shaft's skin is drawn distally, and the ligature tie is applied at the distal end in a groove. The ring is conical with a narrowed distal end and the glans is impacted at the narrowed end of the Plastibell®. This design can also lead to the tip of the glans extruding through the ring and becoming oedematous. This required the Plastibell to be cut and the ring removed as it caused hindrance to the natural separation process. This complication can be associated with a significant grove to the shaft, glans incarceration and sometimes 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 through 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 cannot be caught beyond the ring (Fig. **1**). The shape of the Circumplast® enables easy access to the glans to see the urethral opening and frenulum site. None of the patients had ring impaction with CC. Although the mean age within the CC group is 8 days older than compared to PC, the incidence of ring migration was more prevalent in PC. In most of the series, impaction is higher in older infants [9]. The Plastibell® impaction rate for over one year of age was reported to be more than seven times as compared to infants. Neonates appear to have the lowest rate of impaction for Plastibell® as compared to infants.

Other common complications are bleeding, infection, preputial adhesions, buried/trapped penis, and revision circumcision. In our cohort, there are a small number of adhesions and revisions. A recent systematic review of complications arising from male circumcision [16] showed that modern providers who practice in sterile and clean settings by trained and experienced doctors have better outcomes with fewer complications in circumcision. Parents should be counselled regarding all circumcision related complications and informed consent should be obtained. Another recent systemic review has interestingly pointed to a 2-fold increase in complications among therapeutic circumcisions as compared to nontherapeutic (7.47% and 3.34%, respectively). From this analysis, it appears that adhesions, meatal stenosis and infections were the most frequent complications among therapeutic circumcisions. Bleeding and device removals occurred more frequently in nontherapeutic circumcisions [17]. Our data lacks long term follow-up and complications can develop during long term follow-up, however, current study has concentrated on short term complications.

CONCLUSION

Infant male circumcision by the Circumplast® device appear to have a lower risk of early postoperative minor complications, especially migration/impaction of the ring, when compared to the standard Plastibell device in our practice at the community clinics. In the future, an RCT will be required to demonstrate the superiority of either device. Long term follow-up will be desirable to report any complications developing later in life.

LIST OF ABBREVIATIONS

CC	=	Circumplast Circumcision
PC	=	Plastibell Circumcision
IMC	=	Infantile Male Circumcision

LIMITATIONS OF STUDY

Retrospective study & lack of long-term data.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

No ethical approval/review requested as this review reflected the retrospective results of audit for current practice.

HUMAN AND ANIMAL RIGHTS

No animals were used in this research. All procedures performed in studies involving human participants were in accordance with the ethical standards of institutional and/or research committee and with the 1975 Declaration of Helsinki, as revised in 2013.

CONSENT FOR PUBLICATION

Informed consent was obtained from all participants.

STANDARDS OF REPORTING

STROBE guidelines were followed.

AVAILABILITY OF DATA AND MATERIALS

The data and supportive information is available within the article.

FUNDING

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

ACKNOWLEDGEMENTS

This paper would not have been possible without the exceptional support of my mentors Mr. Sikandar Khwaja and Mr. R A Khan.

REFERENCES

[1] New data on male circumcision and HIV prevention: policy and programme implications. World Health Organization 2007.

[2] Atkin GK, Butler C, Broadhurst J, *et al.* Ritual circumcision: No longer a problem for health services in the British Isles. Ann R Coll Surg Engl 2009; 91(8): 693-6. [http://dx.doi.org/10.1308/003588409X12486167520957] [PMID: 19785945]

[3] Schmitz RF, Schulpen TWJ, Redjopawiro MS, Liem MSL, Madern GC, Van Der Werken C. Religious circumcision under local anaesthesia with a new disposable clamp. BJU Int 2001; 88(6): 581-5. [http://dx.doi.org/10.1046/j.1464-4096.2001.02399.x] [PMID: 11678755]

[4] Morris BJ, Moreton S, Krieger JN. Critical evaluation of arguments opposing male circumcision: A systematic review. J Evid Based Med 2019; 12(4): 263-90. [http://dx.doi.org/10.1111/jebm.12361] [PMID: 31496128]

[5] British Medical Association. The law and ethics of male circumcision: Guidance for doctors. J Med Ethics 2004; 30(3): 259-63. [http://dx.doi.org/10.1136/jme.2004.008540] [PMID: 15173359]

[6] Bawazir O, Alsaiari WS. Plastibell circumcision: Comparison between neonates and infants. Urol Ann 2020; 12(4): 347-51. [http://dx.doi.org/10.4103/UA.UA_146_19] [PMID: 33776331]

[7] Al-Salem AH. Male circumcision. In: An Illustrated Guide to Pediatric Urology. Cham: Springer 2017; p. 480. [http://dx.doi.org/10.1007/978-3-319-44182-5_22]

[8] Dindo D, Demartines N, Clavien PA. Classification of surgical complications: A new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004; 240(2): 205-13. [http://dx.doi.org/10.1097/01.sla.0000133083.54934.ae] [PMID: 15273542]

[9] Samad A, Khanzada TW, Kumar B. Plastibell circumcision: A minor surgical procedure of major importance. J Pediatr Urol 2010; 6(1): 28-31. [http://dx.doi.org/10.1016/j.jpurol.2009.05.006] [PMID: 19525148]

[10] Moosa FA, Khan FW, Rao MH. Comparison of complications of circumcision by 'Plastibell device technique' in male neonates and infants. J Pak Med Assoc 2010; 60(8): 664-7. [PMID: 20726200]

[11] Bawazir OA. A controlled trial of Gomco *versus* Plastibell for neonatal circumcisions in Saudi Arabia. Int J Pediatr Adolesc Med 2020; 7(3): 132-5. [http://dx.doi.org/10.1016/j.ijpam.2019.03.002] [PMID: 33094142]

[12] Palit V, Menebhi DK, Taylor I, Young M, Elmasry Y, Shah T. A unique service in UK delivering Plastibell® circumcision: Review of 9-year results. Pediatr Surg Int 2006; 23(1): 45-8. [http://dx.doi.org/10.1007/s00383-006-1805-6] [PMID: 17024296]

[13] Netto JMB, Araujo JG Jr, Noronha MFA, *et al.* A prospective evaluation of plastibell® circumcision in older children. Int Braz J Urol 2013; 39(4): 558-64. [http://dx.doi.org/10.1590/S1677-5538.IBJU.2013.04.14] [PMID: 24054384]

[14] Bode CO, Ikhisemojie S, Ademuyiwa AO. Penile injuries from proximal migration of the Plastibell circumcision ring. J Pediatr Urol 2010; 6(1): 23-7. [http://dx.doi.org/10.1016/j.jpurol.2009.05.011] [PMID: 19570722]

[15] Ekwunife O, Ugwu J, Okoli C, Modekwe V, Osuigwe A. Parental circumcision preferences and early outcome of plastibell circumcision in a Nigerian tertiary hospital. Afr J Paediatr Surg 2015; 12(4): 251-6. [http://dx.doi.org/10.4103/0189-6725.172565] [PMID: 26712290]

[16] Iacob SI, Feinn RS, Sardi L. Systematic review of complications arising from male circumcision. BJUI Compass 2022; 3(2): 99-123. [http://dx.doi.org/10.1002/bco2.123] [PMID: 35474726]

[17] Shabanzadeh DM, Clausen S, Maigaard K, Fode M. Male circumcision complications – a systematic review, meta-analysis and meta-regression. Urology 2021; 152: 25-34. [http://dx.doi.org/10.1016/j.urology.2021.01.041] [PMID: 33545206]