Manual for early infant male circumcision under local anaesthesia

World Health Organization

innovating to save lives

Jhpiego

an affiliate of Johns Hopkins University

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Contents

Abbreviations

AIDS	acquired immunodeficiency syndrome
ANC	antenatal care
EMLA	eutectic mixture of local anaesthetics
HIV	human immunodeficiency virus
HPV	human papillomavirus
HSV	herpes simplex virus
M&E	monitoring and evaluation
MNCH	maternal, neonatal and child health
PEP	post-exposure prophylaxis
PMTCT	prevention of mother-to-child transmission
PNC	postnatal care
PPE	personal protective equipment
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund.
USAID	United States Agency for International Development
WHO	World Health Organization

Definitions

early infant	less than 60 days of age
preterm	less than 37 completed weeks of gestational age
low birth weight	less than 2500 g or 5 lb 9oz

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Photo credits

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Purpose

This manual builds on the World Health Organization's *Manual for male circumcision under local anaesthesia* and focuses entirely on early infant male circumcision. It has been developed by WHO in collaboration with Jhpiego to help providers and programme managers deliver high-quality safe infant male circumcision services for the purposes of HIV prevention and other health benefits.

The manual draws from experiences with service provision in Africa, the Eastern Mediterranean and developed countries and was reviewed by actual and potential providers of male circumcision services representing a range of health care and cultural settings where demand for male circumcision services is high.

Preface

Male circumcision is one of the oldest known surgical procedures. Egyptian records show that male circumcision was being performed as early as 2300 BC. The procedure has been adopted independently by different cultures all over the world for various medical and non-medical reasons.[1]

Since the mid-1980s, data from cross-sectional epidemiological studies have shown that circumcised men have a lower prevalence of HIV infection than uncircumcised men. And, over the past 5 years, three randomized controlled trials have convincingly demonstrated that male circumcision is effective in reducing female to male transmission of HIV.[2, 3, 4] This opportunity for disease prevention has resulted in an increased demand for male circumcision in several countries of high HIV incidence. Guidance for adolescent and adult male circumcision services has been developed, but technical guidance is lacking on how early infant services can be safely expanded.

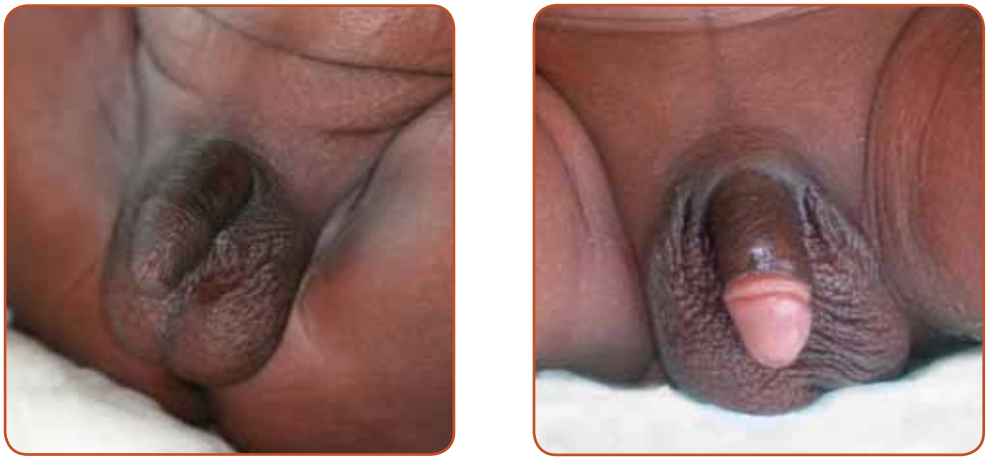
There are significant benefits in performing male circumcision in early infancy, and programmes that promote early infant male circumcision are likely to have lower morbidity rates and lower costs than programmes targeting adolescent boys and men.

Chapter 1: Male circumcision introduction

Summary

Male circumcision is the surgical removal of all or part of the foreskin tissue (prepuce) that typically covers the tip or head of the penis. Derived from the Latin word *circumcido*, circumcision means, "cutting around". During male circumcision, the foreskin is freed from the head of the penis (glans) and the foreskin is surgically excised.

Figure 1.1. An uncircumcised infant penis (left) and the same penis two weeks after male circumcision (right).



Male circumcision is widely practised for religious and traditional reasons, often within the first two weeks after birth or at the beginning of adolescence as a rite of passage into adulthood.[5, 6, 7] As a medical procedure, it is performed to treat problems involving the foreskin and as a means to help prevent some diseases. Recently, three randomized controlled trials have convincingly demonstrated that male circumcision reduces female to male heterosexual transmission of HIV. [8,9,10]

The decision to have a newborn male circumcised is very personal and should be made after careful consideration of the risks and benefits and cultural, religious, and personal preferences.

The following information is provided to help families, caregivers, and health-care workers make an informed decision about male circumcision.

Timing of male circumcision – infancy versus adolescence/adulthood

Male circumcision can be performed at any age. Several factors should be considered when determining its timing.

One important advantage of infant male circumcision is that the procedure is simpler than that performed on older boys and men because the penis is less developed and the foreskin is thinner and less vascular. Healing is quicker and complication rates are lower. The period of superficial wound healing after infant male circumcision is generally 5–7 days and most wounds heal completely within 14 days. Performing circumcision in infancy provides several other advantages:

- the wound typically does not need to be sutured;
- the procedure is not complicated by erections, which can be problematic in adolescent boys and men;
- infant male circumcision ensures that the wound will be healed before sexual activity begins; sexual activity can complicate circumcision in adolescents and adult males and can put older patients who engage in such activity before the wound has healed at higher risk for HIV transmission.

Another advantage of early infant male circumcision is the reduced risk of urinary tract infections in the first 6 months of life.[11] These infections typically present with signs and symptoms of systemic involvement and can be associated with significant complications, including sepsis and renal scarring. The benefit of male circumcision in preventing urinary tract infections in the first 6 months of life cannot be realized if the procedure is delayed until after infancy. This is especially pertinent if there is an underlying uropathy, such as vesicoureteral reflux or urinary tract obstruction.

A concern about early infant male circumcision is that the child cannot give informed consent for the procedure. Moreover, some of the health benefits, including reducing the risk of HIV infection, will not be realized until many years later when the person becomes sexually active. If circumcision is postponed until an older age the patient can evaluate the risks and benefits and consent to the procedure himself.

Programmes that promote male circumcision in early infancy are likely to have lower morbidity rates and lower costs than programmes targeting adolescent boys and men. However, these considerations must be balanced by concerns about consent.

Timing of male circumcision during infancy

No ideal time has been identified for performing male circumcision during infancy. Data exist showing that the procedure can be safely performed even immediately after birth.[12] A WHO expert review meeting on neonatal male circumcision held October 2009 in Geneva Switzerland concluded that the procedure is easier to perform and associated with less pain and fewer complications when performed within the first two months of life.

The American Academy of Family Physicians recommends that male circumcision should not be performed until at least 12 to 24 hours after birth to ensure the infant is stable. This time allows providers to perform neonatal care and treatment, to completely assess the neonate and to identify abnormalities or contraindications.[13] Other considerations prior to circumcision are allowing initiation of breastfeeding (according to mother's choice) and allowing the infant to void.

Data also suggest that male infants of low birth weight (less than 2500 g or 5 lb 9 oz) should undergo delayed outpatient circumcision[14] and that circumcision should be delayed in infants whose penile shaft length is less than 1 cm.[15] Early infant male circumcision is also not recommended in preterm infants (less than 37 completed weeks gestational age) or any infant with a medical contraindication (see Chapter 4).

Early infant male circumcision should only be performed on full/term infants weighing more than 2500 g without a medical contraindication. Until stronger evidence is available the timing of male circumcision in early infancy should be based on the assessment and care of each individual infant.

Benefits and risks of male circumcision

Benefits

If infant male circumcision is being performed for reasons other than the treatment of a specific medical problem, the health benefits are primarily preventive and may only be realized long after the procedure has been carried out. Circumcision may reduce the risk of acquiring some infections and related complications but does not guarantee complete protection. Some of these conditions are not as common as others, and the degree of risk may depend on the behaviours of the individual and the community to which he belongs. The benefits of male circumcision include the following.

- Decreased risk of HIV infection – male circumcision has been proved to help prevent female to male transmission of HIV, reducing the risk of transmission by 60–70%.[16, 17, 18]
- Decreased risk of urinary tract infections – male circumcision decreases the risk of such infections in infants[19] and adult men.[20] Uncircumcised male infants are estimated to have a 1% chance of acquiring a urinary tract infection. This type of infection is 10 times less common in circumcised male infants, who have an estimated 0.1% chance of developing such an infection.[21]
- Prevention of phimosis – this condition results from scar tissue that makes a tight opening in the foreskin and prevents exposure of the head of the penis and the normal retraction of the foreskin.[22]
- Prevention of paraphimosis – this is an extremely rare condition that occurs when the foreskin is pulled back or down and trapped in the retracted position below the glans. The tissue can become swollen and obstruct the blood flow to the tip of the penis, requiring urgent surgery to correct the problem. Male circumcision can prevent this complication.[23, 24]
- Prevention of balanitis and posthitis – under certain circumstances, dirt, sand and other irritants can collect under the foreskin and cause inflammation of the glans (balanitis) and foreskin (posthitis). Male circumcision helps to prevent these conditions by making it easier to keep the head of the penis clear of possible irritants.[25, 26]
- Decreased risk of other sexually transmitted infections – male circumcision has been shown to help protect against contracting genital herpes simplex virus (HSV) and human papillomavirus (HPV).[27, 28]
- Decreased risk of cancer of the penis, which, in some populations, occurs in 1 per 100 000 people and is much more common in men who are uncircumcised. Male circumcision markedly reduces the risk of developing this type of cancer.[29,30]
- Decreased risk of cancer of the cervix in female sexual partners – cervical cancer occurs less commonly in women with male sexual partners who are circumcised. Sex with either uncircumcised men or men circumcised after infancy increases a women's risk of cervical cancer.[31]
- Decreased vaginal infections caused by *Trichomonas vaginalis* and decreased bacterial vaginosis in female sexual partners.[32]

Male circumcision provides several medical benefits. In 2007, UNAIDS and WHO concluded that the efficacy of male circumcision in reducing female to male transmission of HIV had been proved beyond reasonable doubt.[33]

Risks

As with any surgical procedure there are risks associated with male circumcision. While the benefits of circumcision may be wide-ranging and long-term, most problems which arise from this surgery generally occur during or soon after the procedure. Risks associated with male circumcision include:

- pain, which can be minimized through the use of anaesthesia;
- bleeding, including the risk associated with a blood transfusion in the extremely rare case of life-threatening bleeding, most often associated with an underlying bleeding disorder;
- infection, including the risk of systemic spread and the need for intravenous antibiotics;
- injury to the penis and surrounding structures, including the urethra, glans and scrotum;
- poor cosmetic outcomes, i.e. general dissatisfaction with the appearance of the wound, adhesions, buried/concealed penis, removing an excess or an insufficient amount of foreskin, preputial-glandular fusion, and skin bridges;
- meatitis – inflammation of the opening of the urethra;
- meatal stenosis – scar formation over the outlet of the urethra;
- reactions to the anaesthetic agent.

When male circumcision is performed by well-trained, adequately equipped and experienced health-care personnel, these complications are minor and rare, occurring in 1 of every 250 to 500 cases.[34, 35] Most of the complications can be easily and rapidly addressed and do not result in significant morbidity or mortality.

Where there is a lack of formal training programmes, uniform policy and adequate equipment and resources, complication rates as high as 20% have been reported.[36,37] These data highlight the importance of education, training and establishing a uniform standard of care. Evidence suggests that this approach can be very effective in optimizing male circumcision outcomes.[38, 39]

Complications during male circumcision are rare when performed by well-trained, adequately equipped and experienced providers. Unbiased information must be provided to families and legal guardians on the benefits and risks of this procedure so that they can make informed decisions for their infants.

Male circumcision and the effect on sexual satisfaction

Many adults and parents are concerned that male circumcision will diminish male and possibly female sexual enjoyment and satisfaction later in life. Recent studies show no evidence of this. A randomized controlled trial evaluated the question in 4456 sexually experienced adult males and found that male circumcision did not adversely affect sexual satisfaction or clinically significant function in men.[40] These findings were confirmed in another large randomized controlled trial that found adult male circumcision was not associated with sexual dysfunction and that circumcised men reported increased penile sensitivity and enhanced ease of reaching orgasm.[41] Another study showed that male circumcision had no deleterious effect on female sexual satisfaction.

The existing evidence indicates that male circumcision is unlikely to adversely affect male sexual function or female sexual satisfaction.[42]

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Chapter 2: Overview of facility and equipment requirements

Facility requirements

The following criteria should be considered when evaluating a facility for early infant male circumcision:

- preferably close to maternal, neonatal and child health (MNCH) services;
- facility meets standards for universal precautions;
- facilities to wash/clean hands;
- a clean room with good lighting (a theatre setting is not required);
- ability to perform postoperative processing;
- resources for contaminated waste disposal;
- health-care workers trained to perform early infant male circumcision;
- health-care workers trained in caring for postoperative circumcision wounds and recognizing and treating complications of early infant male circumcision;
- access to care for routine follow-up and post-procedure emergencies.

Equipment requirements and necessary supplies

The following items must be immediately available and routinely checked before beginning any case in order to optimize safety during standard early infant male circumcision. (A sample equipment checklist is provided in Annex 1.)

Equipment

- Secure work surface (table or infant warmer) – height should be such that the surgeon does not have to stoop or bend
- Assistant or mechanism to restrain/position infant
- Hand-washing/cleaning facilities
- Light source

Supplies

- Infant padding, blankets and towels
- Clean nappies/diapers and wipes
- Sterile gloves
- Sterile drape with small opening in the centre (fenestrated)
- Betadyne or other skin-sterilizing preparation

- Sterile marking pen or gentian violet
- Sterile 2 x 2 or 4 x 4 gauze pads
- White petrolatum (Vaseline) or white petrolatum gauze

Instruments

- Instrument tray wrapped with sterile drape
- One 7.5-cm to 12.5-cm (3-inch to 5-inch) flexible probe
- Three small mosquito haemostats, two curved and one straight
- Small straight scissors
- Desired male circumcision device (Mogen, Gomco, Plastibell) and all appropriate parts
- Scalpel – no. 10 blade or similar

Anaesthesia administration

- 1% lidocaine **(WITHOUT EPINEPHRINE)**
- 1-ml sterile syringe with small 27-gauge or similar needle
- Alcohol wipes

Post-circumcision bleeding

- Topical epinephrine
- Gelfoam or equivalent
- Adson forceps
- 5-0 or 6-0 absorbable suture (chromic or catgut) on a needle (6-0 chromic on PC-1 needle or equivalent)
- Needle-holder
- Petrolatum-coated gauze

Postoperative processing

- Check sterilizing and reprocessing equipment
- Check that means are available to handle and dispose of contaminated sharps
- Check that means are available to handle and dispose of contaminated supplies

Surgical instruments wear out with use and repeated disinfection and sterilization. Each clinic should therefore carry out a periodic review of surgical instruments (see Annex 1 for sample equipment checklist). Failure to maintain instruments in good working condition can result in operative difficulties and complications. Haemostats, scissors, needle-holders and clamps should be checked routinely to ensure that they are in working order. This is particularly important for clinics using Mogen and Gomco devices.

Researchers have shown that the foreskin is enriched with HIV-1 target cells, providing evidence of a biological explanation for the protective effect of male circumcision against HIV transmission.[43, 44] This susceptibility of the foreskin means that extra vigilance is required when delivering male circumcision care, particularly in settings with a high prevalence of HIV infection. Instruments, needles, clamps and supplies must be sterile and meticulous sterile technique must be maintained to ensure that each patient is protected from HIV exposure.

Before any infant male circumcision programme can be considered, an effective comprehensive infection prevention programme must be established to ensure that patients are protected from HIV exposure during the procedure.

Chapter 3: Group education and individual counselling

Group education of parents and/or guardians on early infant male circumcision

Purpose of group education

Health education increases awareness and favourably influences attitudes and knowledge related to the improvement of health on a personal basis. Group education is used to support individual counselling services. It allows clients to be given basic information about male circumcision before an individual counselling session. It also allows the first counselling session to be shorter, which is an advantage in busy clinics. Counsellors can then work with clients and/or their parents on specific concerns related to infant male circumcision. Consideration should be given to the local cultural context when providing group education.

Opportunities for group education on infant male circumcision services

There are many possible opportunities to provide education about male circumcision. No opportunity should be missed. Once infant services are available, each clinic should decide the best services into which early infant male circumcision could be incorporated, such as the following.

Antenatal care clinics

The circumcision of male infants should form an integral part of the basic information that is given to pregnant women, so that they can start thinking about it, discuss it with their spouse or partner or the father of the child and have any questions clarified.

Postpartum services

The presence of the neonate provides the most timely opportunity to discuss male circumcision. The package of care at this time should include neonatal circumcision services. Information should be given to women/parents before discharge and also at the follow-up postpartum visits.

Well-child and immunization services

Parent or guardians should be receiving information about male circumcision during the well-child clinics and immunization visits (at 6 weeks postpartum visit) to help them make a decision if they have not already done so.

Home-based services

Information on early infant male circumcision can be offered to a family that is at an appropriate life stage during domiciliary visits or at any other time when the health-care provider visits the home of the client.

Adult outpatient clinics

Information on early infant male circumcision can be provided as part of other routine group education sessions while parents are waiting to see the provider for other reasons.

Adult male medical circumcision services

As men of reproductive age present for male circumcision for themselves the possibility of infant male circumcision for their potential future neonates should be shared.

Content of group education for parents or guardians

The information given to parents or guardians during an education session may differ slightly from site to site. Counsellors should be familiar with the standard education on early infant male circumcision offered at the place where they work, so that the messages and information given are consistent. In conducting group education on early infant male circumcision the following should be included.

What is male circumcision?

Male circumcision is the surgical removal of the foreskin of the penis (also called the prepuce). It is one of the oldest surgical procedures in history.

What are the benefits of infant male circumcision?

Infant male circumcision has been shown to have several health benefits including:

- reducing the risk of acquisition of HIV;
- decreasing the risk of urinary tract infections in children;
- reducing the risk of some of the sexually transmitted diseases, e.g. herpes, in the future;
- giving some protection against cancer of the penis;
- reducing the risk of cervical cancer in female sexual partners;
- preventing several medical problems of the penis and the foreskin, e.g. inflammation, scarring and swelling of the foreskin (balanitis, phimosis and paraphimosis).

What are the risks of infant male circumcision?

As with any surgical procedure, complications may sometimes follow the operation, even though everything possible has been done to reduce the risk. Possible problems include pain, bleeding, swelling of the penis caused by bleeding under the skin (haematoma), injury to the surrounding structures and infection of the surgical wound.

How is the procedure performed?

Describe the technique used in the specific clinic. Infants can go home shortly after the procedure. Local anaesthesia will be used to help take away the pain of the procedure.

Characteristics or skills needed to conduct a good group education session

Group education on early infant circumcision may be given by volunteers, staff (counsellors, nurses) or students who provide group education on a regular basis. It should be relatively consistent across sessions and standard content should provide parents or guardians with the same information about early infant male circumcision. When educators/counsellors are well skilled they can adapt the content to the group and avoid repeating information that parents or guardians already know, or can clarify misunderstandings.

Tips for conducting an effective group education session

- It is best to use a guide / job aid to help provide group education. A sample infant male circumcision information sheet is provided in Annex 2.
- Encourage all parents or guardians to participate in the session. Make participants feel welcome and be open to discussion.
- Introduce the topic clearly and state the objectives.
- Consider local cultural needs. Use appropriate topics and choose words that the group can understand.
- Ask questions to find out what the group knows before providing all the information. It is pointless to give information the group already possesses.
- Use an interactive approach. Ask and answer questions and encourage group members to ask questions.
- Provide positive feedback to group members when they participate.
- Use education materials as appropriate.
- Maintain eye contact or appropriate cultural non-verbal communication with the group.
- Speak loudly enough to allow everyone to hear.
- Summarize key points.
- Always ensure that parents or guardians with very ill babies receive immediate care.

Parent/guardian individual counselling for early infant male circumcision

Definition of counselling and basic facts about counselling

Health education and counselling are closely linked. Counselling is a two-way interactive process between client and provider. It is an interpersonal, dynamic communication process used to help people examine personal issues and make decisions and plans for taking action. Health-care providers have an important role to play in counselling women and men to adopt effective prevention strategies. In counselling for infant male circumcision the provider ensures that parents or guardians have all the information they need and that they can discuss their concerns in more depth than in group education sessions in order to make a decision about their infants undergoing the procedure. Counselling involves a kind of contract between client and counsellor, the latter being bound by a code of ethics and practice. (See also Annex 3.)

Counselling is not:

- **telling parents or guardians what to do;**
- **criticizing parents or guardians;**
- **forcing ideas or values on parents or guardians;**
- **taking responsibility for parents' or guardians' actions or decisions.**

Characteristics and basic skills of a good counsellor

- Listening to parents or guardians so as to understand their concerns and reasons for or against infant male circumcision.
- Respecting parents' or guardians' needs, values, culture, religion, lifestyles and choices.
- Providing information about the risks and benefits of the male circumcision service and discussing options for timing the procedure.
- Answering questions about the circumcision procedure and correcting any false information.
- Allowing parents or guardians to make their own informed decision on whether to choose male circumcision for their infant.
- Asking parents or guardians questions that help them to identify behaviours that may put their children at risk of HIV infection, or may do so after circumcision, e.g. for an HIV-positive mother there is continued risk of the early infant acquiring the HIV infection while the child is on mixed feeding or breastfeeding.
- Helping parents or guardians to understand their children's HIV test results when necessary.
- Helping parents or guardians to obtain other services for their children or themselves.

Informed consent for surgery

General

Education and counselling followed by a positive choice for infant male circumcision leads to the need for informed consent. The goal of this consent process is to ensure that parents or guardians understand the surgical procedure. Parents or guardians should make the decision according to the best interests of the children and indicate verbally and in writing their decisions for their infants.

Parents and/or guardians should give informed consent before infant male circumcisions are performed. They must give written consent for the procedure in line with national guidelines. Health-care providers should give all the information needed to make a fully informed decision. The following elements should be included:

- an explanation, in plain language, of male circumcision and the nature of the surgery;
- the risks and benefits of infant male circumcision (short-term and potential longer-term).

Only parents or guardians who have appropriate decision-making capacity and legal status can give informed consent to surgical care. The provider has to assess:

- whether the parent or guardian understands the information provided;
- the capacity of the parent or guardian to make the necessary decisions.

Providers should assure the parent or guardian that they are free to choose whether or not to have their infant circumcised. If there is any suggestion that the parent or guardian is not ready to provide consent, advise her or him to reflect on it for a few days. Ask the parent or guardian who decides that infant male circumcision should be performed to sign a consent document.

The goal of this consent process is to ensure that the parent or guardian understands the surgical procedure. Some of the information to be contained in the consent form is:

- the definition of male circumcision;
- the benefits of infant male circumcision;
- the risks of male circumcision;
- the care of the circumcised penis.

Details are explained in Chapters 1 and 9.

Components of early infant male circumcision session

A protocol is a plan or process that helps people to do a task correctly. The early infant counselling protocol helps counsellors by listing the main tasks that they have to complete during interaction with parents or guardians. The following components are involved.

- Welcome parents or guardians.
- Explain the counselling process.
- Assure privacy and confidentiality.
- Assess parents'/clients' understanding and knowledge of circumcision services.
- Provide information on:
  - the nature of male circumcision;
  - health benefits of early infant male circumcision;
  - risks associated with early infant male circumcision;
  - how early infant male circumcision is performed;
  - the male circumcision devices;
  - pain and how it can be controlled;
  - preoperative and postoperative procedures;
  - follow-up visits;
  - signs and symptoms requiring return for assessment and further management.

Record-keeping

It is not the role of a counsellor or health-care provider to develop a functional monitoring system for a facility. However, the counsellor should record data accurately and reliably, and should know how, to whom and when to report information about the service and the client. A counsellor with knowledge about infant male circumcision might also be able to help those responsible for the information system by providing feedback on how the system is working, how information about the system is shared with health-care providers, and the ease of use of monitoring tools by health-care providers. In this way health-care providers can help to refine and improve the monitoring system. (See Chapter 12.)

Basic information must be recorded during infant male circumcision counselling sessions. (Annex 4 provides a sample client record form.)

Education and counselling on infant male circumcision must be done in a culturally acceptable manner.

Chapter 4: Screening for early infant male circumcision

The screening procedure for infants is aimed at ensuring that they are eligible for surgery. If there is any doubt, surgery should be deferred and the clients should be referred to a specialist centre.

Circumcision providers should conduct a thorough health history and physical assessment of the early infant. In the case of very young babies, enquiries should be made about whether the pregnancy and delivery were normal. Early infant circumcision should be undertaken only if the infant is healthy, full-term and weighs more than 2500 g. Only babies with a normal physical examination and an intact penis of completely normal appearance should be considered for male circumcision.[45, 46]

Contraindications for early infant male circumcision include any known haematological disorders and jaundice. Thus any infant with yellow sclera or purpuric skin lesions should not be accepted for clinic-based circumcision. Any congenital abnormality of the genitalia is a contraindication. If an abnormality exists the foreskin should be left intact because the tissue may be required to repair the defect.

Routine early infant male circumcision should only be undertaken if the infant is healthy, full-term, weighs more than 2500 g, has a normal physical examination, and has an intact penis and scrotum of completely normal appearance.

The following photographs are examples of congenital abnormalities that are contraindications to early infant male circumcision.

Figure 4.1. Bilateral hydroceles

Figure 4.2. Curvature with penile torsion

Figure 4.3. Penile torsion

Figure 4.4. Absence of ventral foreskin

Figure 4.5. Concealed penis (left) trapping urine beneath the foreskin (right)

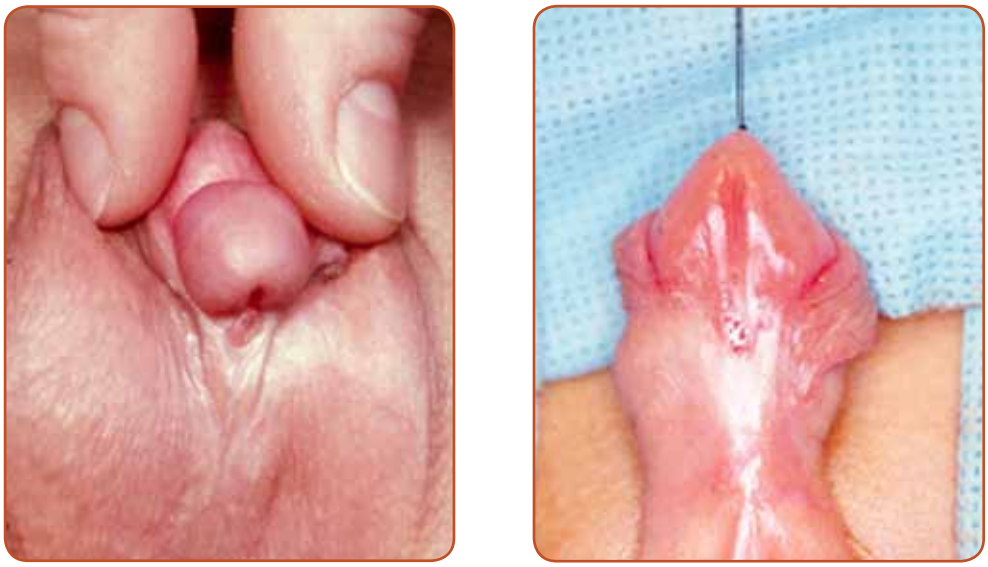
Figure 4.6. Concealed penis on inspection (left) and during exam (right)

Figure 4.7. Megalourethra with deficiency of corpus spongiosum

Figure 4.8. Penoscrotal webbing on inspection (left) and during exam (right)

Figure 4.9. Epispadias and dorsal curvature on inspection (left) and during exam (right)

Figure 4.10. Hypospadias during exam (left) and prior to repair (right)



Chapter 5: Overview of anaesthesia

Anaesthesia is recommended for early infant male circumcision. A review of studies has shown that infants react to pain and that local anaesthesia can be effectively provided by a dorsal penile nerve block.[47] The maximum safe dose of lidocaine in infants is 3 mg/kg of body weight. For a 3-kg infant, this corresponds to 0.9 ml of 1% solution or 1.8 ml of 0.5% solution. Anaesthetic solutions containing epinephrine (adrenaline) should **never** be used.

For most neonates and young infants, 1 ml of 1% lidocaine without epinephrine can be used by injecting 0.5 ml at the 10 o'clock site and 0.5 ml at the 2 o'clock site at the base of the penis.

Providing pain relief during infant male circumcision is a priority but it must be done in a way that does not endanger the long-term well-being of the infant. Local anaesthesia alone should be used for most infants (under 1 year of age), who can be held still during the procedure. There are serious risks associated with sedation, which is not recommended for clinic-based circumcision. If sedation is required for the safe performance of the procedure the patient should be referred to an appropriate clinic capable of providing sedation safely.

Safe injection of local anaesthetic

The risks and benefits of providing anaesthesia in any given health-care environment must be evaluated before choosing a particular method. Significant morbidity and mortality can occur if appropriate precautions are not taken during the delivery of any form of anaesthesia.

The injection of a local anaesthetic should only be considered in settings where there is reliable access to sterile needles and where institutional protocols have been established to ensure the safe handling and disposal of contaminated sharps.

Circumcision will probably be delivered in some areas with a high incidence of HIV infection. In these environments a contaminated hollow-bore needle could present a far greater risk of HIV to the patient than any risk identified in the existing literature evaluating the safety of anaesthesia.

The data supporting the safety of the penile dorsal nerve and ring block relate to strict study protocols and almost ideal circumstances in developed countries. The applicability of these data to other health-care settings in other parts of the world should be considered when the risks versus the benefits of anaesthesia given by injection are being evaluated.

In environments where the injection of local anaesthetics can be done safely it is the surgeon's responsibility to check the vial of anaesthetic, including the expiry date, and to ensure the sterility of the needle and syringe and that the correct agent and concentration have been selected. It is important to verify that the anaesthetic is clear and that there are no visible particles, which may suggest that the vial is contaminated. The use of single-dose vials has also been recommended as a measure to prevent surgical site infections.[48]

The surgeon should gently aspirate once the needle is in place but before injecting any local anaesthetic so that no blood enters the syringe, in order to ensure that no anaesthetic is injected into a blood vessel. This precaution should be repeated each time the needle is moved and before any additional local anaesthetic is injected.

Dorsal penile nerve block

A 1-ml syringe is used with a 27-gauge or a 30-gauge needle and inserted at the 2 o'clock position at the base of the penis in a posteromedial direction and to a depth of 0.3 and 0.5 cm into the subcutaneous tissue.[49, 50] Once aspiration demonstrates no blood, 0.5 ml of 1% lidocaine without epinephrine is injected. The needle is withdrawn and this step is repeated at the 10 o'clock position.

Figure 5.1. Cross-section of the shaft of an infant penis. The dorsal nerve, artery and vein run along the dorsal midline. To avoid these vessels, the injection is made laterally at the 10 o'clock and 2 o'clock positions at the base of the shaft of the penis

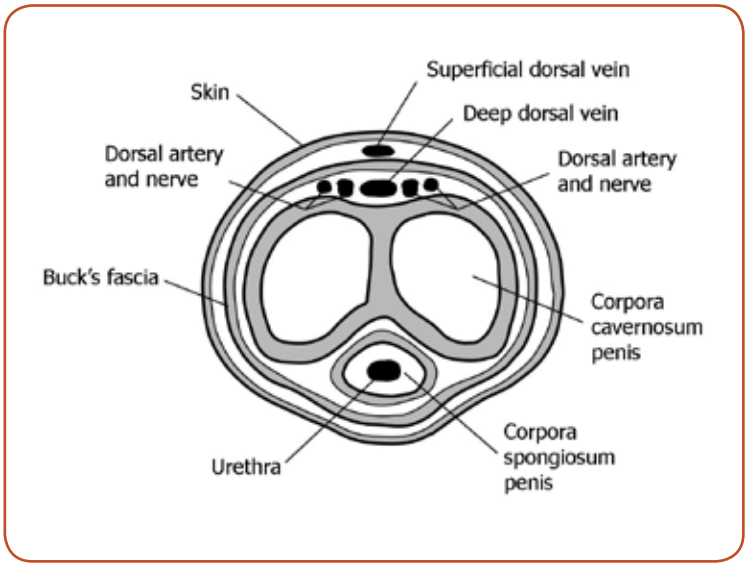
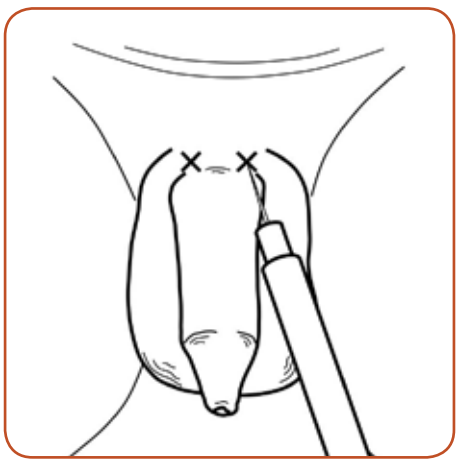


Figure 5.2. Injection of local anaesthetic for a dorsal penile nerve block at the 2 o'clock and 10 o'clock positions at the base of the penis



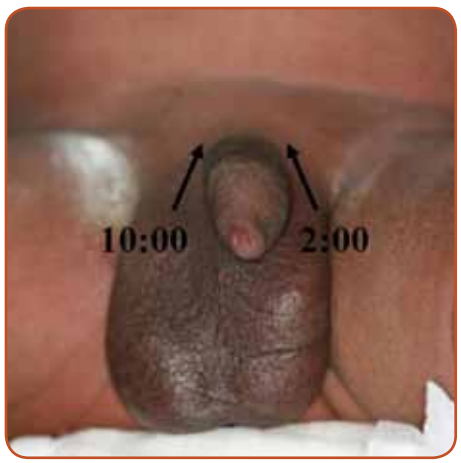


Figure 5.3. Injection of anaesthetic at the base of the penis

The most common complications of dorsal penile nerve blocks are bleeding, bruising, inadequate analgesia and small haematomas. Lidocaine toxicity can be avoided by aspirating before injection. Injection should not be done in the midline so as to avoid injecting directly into a vessel.

The dorsal penile nerve block is the best-described and best-studied technique and has a low rate of minor complications.[51] The ring block has been more recently described but takes longer and requires more needle sticks.[52] In the only randomized controlled trial comparing the two techniques, 14 infants were enrolled in each arm, and no significant difference in pain perception was noted between the two techniques during activation of the clamp, the step that creates the most significant tissue injury and likely pain.[53] There are insufficient data to determine if one technique is truly superior to the other.

An advantage of the dorsal penile nerve block is that the injection is made at the base of the penis. With a ring block, anaesthetic is injected along the shaft of the penis and can cause distortion of the anatomy, making it difficult for the surgeon to identify the coronal margin and appropriately mark the location of the incision. This is particularly problematic in patients with a short penile shaft.

EMLA cream

EMLA 5% cream (eutectic mixture of local anaesthetics, containing 2.5% lidocaine and 2.5% prilocaine) has been extensively used for Plastibell circumcision in children of all ages.[54] If used correctly it is safe and provides effective anaesthesia.[55] It must be applied with care in neonates, because of the potential risk of methaemoglobinaemia from prilocaine metabolites, which can oxidize haemoglobin (see Annex 5). Care must be taken to ensure that the cream is not rubbed on to a large area of the infant's body, as a result of the hands and feet wriggling during the procedure. This can be done by covering the penis with a small piece of polythene held in place with a sticking plaster. It has been shown that, provided the cream is applied only to the penis, EMLA cream is safe for both term and preterm infants. Possible minor adverse events include transient local skin reactions, such as blanching and redness.

EMLA cream should be applied to the whole penis 60 to 80 minutes before the procedure. Depending on local circumstances, it is often possible for the parent to apply the cream at home before coming to the clinic. If this is done the clinic staff should ensure that the cream has been applied properly.

The maximum recommended doses and duration of exposure to EMLA cream are summarized below in Table 5.1.

Table 5.1. Recommended maximum exposures to EMLA cream in early infancy[56]

Age group	Maximum dose	Period of application
0–3 months	1 g	60–80 minutes

Other options for comfort

Breast milk is a natural and economical way to comfort the baby.[57, 58] Expressed milk may be applied to a fingered glove or gauze for suckling. Just providing a clean finger to the baby for sucking may also be an effective option for comfort. Data indicate that neonates can be comforted by oral sucrose at 0.05 to 0.5 ml of 24% solution (sugar water) administered 2 minutes before the painful procedure.[59] Glucose administration may not be justified in areas of the world where successful breastfeeding is essential for survival.

Risks of not using anaesthesia

Although providing anaesthesia should be a priority the anticipated risks and benefits must be weighed.

In many parts of Nigeria, infant male circumcision is routinely performed without anaesthesia, and as recently as 12 years ago in the USA more then half of the physicians performing neonatal male circumcision reported that they did not use any form of local anaesthesia.[60] There is very little scientific evidence indicating that this results in any long-term complications. On the other hand, serious complications have been reported, although rarely, from the use of anaesthesia.[61, 62]

The true risks and benefits of providing anaesthesia depend on many factors, including the provider's experience, the location, the health-care setting, family preference and available resources.

Because of these variables the decision to use anaesthesia, and the specific type, must ultimately be made by the surgeon in close consultation with the infant's family / legal guardian. The decision to have anaesthesia available and the infrastructure required to support it should be incorporated into the standard operating procedure for every early infant male circumcision clinic.

Sedation

There are serious risks associated with sedation, which is not recommended for clinic-based circumcision. If sedation is required in order to perform the procedure safely the patient should be referred to an appropriate clinic capable of providing safe sedation.

In early infancy (<60 days of age), sedation should not be required for the performance of male circumcision and should be avoided because of the serious complications that can develop.

Chapter 6: Procedure preparation

General preparation

To help improve outcomes and avoid complications, providers should follow a standard procedure.[63] Annex 6 gives an example of a procedural checklist for early infant male circumcision. This should be posted and reviewed before beginning the procedure. The following items are included in this checklist and should be addressed before considering any patient for male circumcision.

Ensure availability of appropriate equipment and supplies

Check equipment and supplies. Annex 1 gives an early infant male circumcision equipment checklist. This should be regularly reviewed.

Provide information to parents / legal guardians

As outlined above, parents and legal guardians must be informed of the risks and benefits of male circumcision. Annex 2 gives an early infant male circumcision information sheet that can be reviewed with the parents / legal guardians.

Obtain informed consent

As outlined above, informed consent must be obtained. Annex 7 gives an early infant male circumcision consent form that should be reviewed and signed.

Thoroughly wash/clean hands

Before proceeding with male circumcision the patient must be closely examined. This should only be done after thorough washing and cleaning of the hands.

Screen patient

As outlined above, the patient should be screened to determine eligibility for undergoing the procedure. Annex 8 provides a sample client record form that can be used to document patient screening. A thorough history should be obtained and the patient should be closely examined. Only healthy, vigorous babies with an intact foreskin of normal appearance should be considered for early infant male circumcision. Infants with a family history of a bleeding disorder, illness or any urological abnormality should be excluded and referred to the appropriate specialist.

Feeding restrictions

Although it is a standard surgical precaution to restrict oral intake before surgery because of the risk of regurgitation and aspiration, this typically does not apply to minor outpatient surgeries performed under local anaesthesia and should not be considered a necessity for early infant male circumcision.

Safety check

Ensure that the correct patient is brought to the procedure room and that he remains a suitable candidate for male circumcision.

Preparing the patient and the prepuce

Three male circumcision techniques are described in this manual. The following steps are common to all early infant male circumcision techniques. These steps describe how to prepare the infant and the prepuce for the procedure.

Determine device and appropriate size

The advantages and disadvantages of each device are outlined in Chapter 7. Providers should use the device which is nationally recommended or with which they are most comfortable. The Mogen, Gomco and Plastibell devices are available in multiple sizes. A single infant-sized Mogen clamp exists which is adequate for most infants, but the device is available in larger sizes for other patients. These larger clamps have a larger gap (to accommodate more tissue) and can increase the likelihood of penile amputation when used on infants. The gap size of the Mogen clamp should be checked before each use. To ensure reliable operation of the device the appropriate size should be used. Determining which size to use is discussed below under the description of each surgical technique. This should be determined before initiating the procedure, so as to ensure availability of the appropriate size.

Determine and prepare the most appropriate anaesthesia

The anaesthetic agent should be inspected and prepared as previously indicated in Chapter 5.

Position the infant

Clean gloves should be worn when positioning the infant in a well-lit warm area on a soft surface. The infant should be restrained by an assistant or a circumcision board. Other means of restraint are to swaddle the arms and chest with a blanket or towel or to have another health-care worker gently holding the arms and chest of the infant. The patient's head and mouth should never be covered and the patient should be continually monitored to minimize any discomfort during restraint. If a restraint board is used, it can be helpful to prop up the top so that the infant is not lying flat on his back. A blanket can be placed between the infant and the restraint board for comfort and soft velcro straps can be used to gently restrain the infant.

The nappy should be removed and the perineum cleaned with moist wipes. A fresh nappy can be tucked under the patient and left open.

Figure 6.1. Two methods to restrain infants during male circumcision

Prepare the surgical area

Using clean gloves, a 2.5-cm area of skin around the penis should be thoroughly cleaned with at least three applications of swabs soaked in providone iodine or an equivalent antiseptic agent.

Figure 6.2. Preparing the surgical area with swabs soaked in providone iodine

Apply sterile gloves and proceed using sterile technique

Sterile gloves should be worn and the procedure should be completed using sterile technique.

Figure 6.3. Sterile surgical gloves

Inspect/assemble device

The sterile device and instruments required should be closely inspected to ensure they are in working order. In the case of the Gomco clamp the parts should be fully assembled to ensure all the parts match.

Drape the surgical area

A sterile drape with a small hole (fenestration) should be applied, exposing the penis. Care should be taken to ensure that the infant's face is not covered by the drape.

Figure 6.4. Apply fenestrated drape to the surgical area

Clean and dry the shaft of the penis

Excess antiseptic should be wiped off with sterile gauze to allow better application of the surgical mark.

Palpate and examine penis to determine location of corona

In most infant males the corona is prominent and can be visualized beneath the foreskin. In some, however, the location of the corona may not be obvious. In all cases the penis should be palpated to determine and/or confirm the location of the corona. In some cases it may be helpful to pinch the foreskin on one side of the penis, pushing the corona to the other side, making it more visible beneath the foreskin.

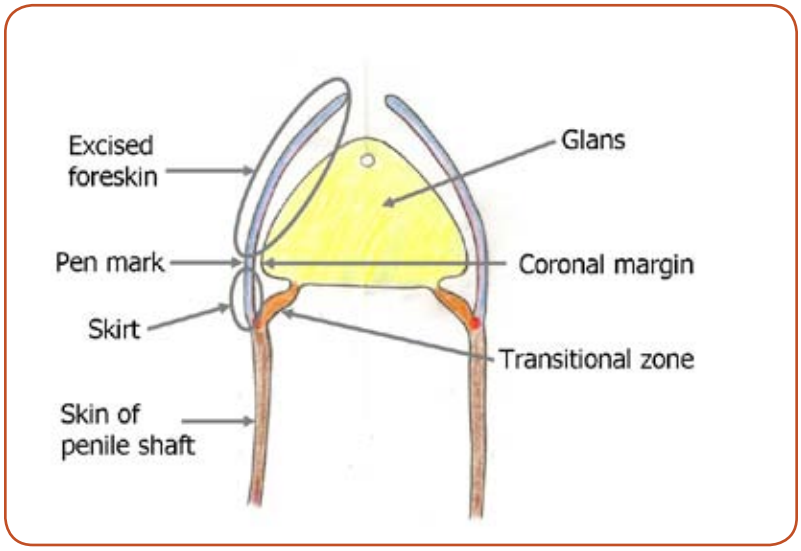
Figure 6.5. Identifying the corona (arrow)

Mark the location of the incision

Errors made in removing excessive or insufficient amounts of foreskin can be prevented by marking the incision site at the corona.[64, 65]

Marking and making the incision at the level of the corona helps to ensure that the penile shaft skin is not inadvertently removed and leaves a small amount of tissue in place to allow the wound to contract without foreshortening the penis.

Figure 6.6. Anatomy of the infant penis



Below are examples of outcomes following early infant male circumcision using the three most common devices after making a surgical pen mark at the corona to guide the incision.

Figure 6.7. Mogen immediately postoperative (left) and at 2 weeks postoperative (right), demonstrating how the wound contracts.

The skirt that remains immediately following the procedure contracts and the final scar can be seen at the proximal border of the transitional zone.

Figure 6.8. Gomco immediately after excision and removing baseplate (left) and at 2 weeks postoperative (right), demonstrating how the wound contracts following circumcision

Figure 6.9. Plastibell immediately following the procedure (left) and at 2 weeks postoperative (right)

At 2 weeks postoperative the skirt is gone and the well-healed scar is adjacent to the proximal edge of the transitional zone.

A sterile marking pen or gentian violet should be used to mark the line of the circumcision over the corona, with no tension on the foreskin. Using a surgical mark helps to ensure the accuracy of the incision.

In most neonates and young infant males the foreskin adheres to the glans. For this reason the most appropriate time to determine the natural lie of the foreskin over the corona is before removing any adhesions. In infants with a prominent suprapubic fat pad, slight pressure over the base of the penis may help to identify the most anatomically appropriate orientation of the penis and foreskin. After thorough inspection and palpation the provider should mark the most appropriate location for the incision. After the surgical mark is made, the foreskin should be palpated again to confirm that the pen mark is at the level of the corona.

Figure 6.10. Marking the line of the circumcision at the level of the corona

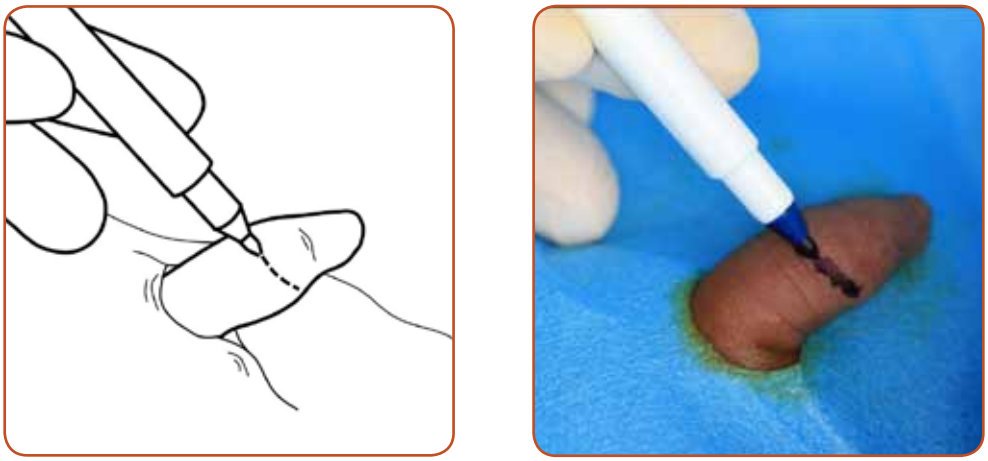
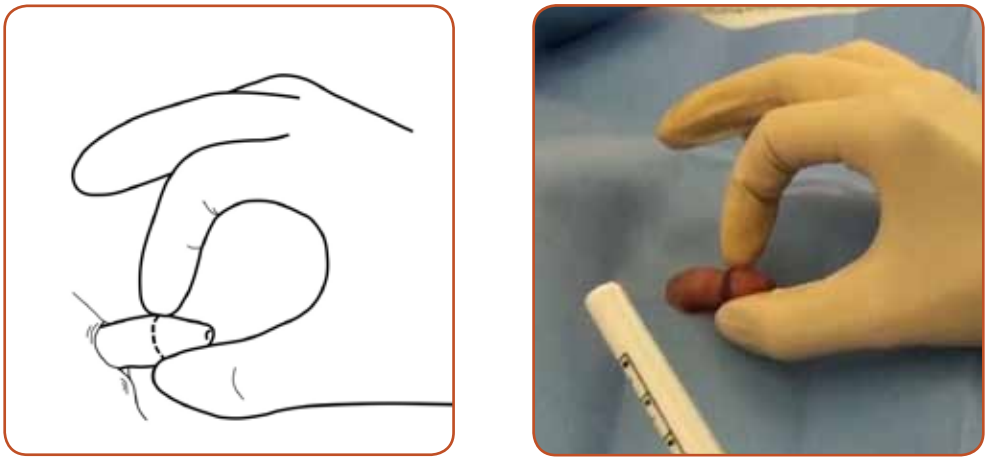


Figure 6.11. Palpating the corona to ensure the mark is accurate



Administer anaesthesia and wait for effectiveness

Administer anaesthesia as described in Chapter 5. The timing of anaesthesia delivery can vary, depending on the preference of the provider. Because delivery of the anaesthestic agent can alter the normal anatomy, it is preferable to delay delivery until the location of the incision has been marked.

The one disadvantage of this approach is that the surgeon will be using sterile technique and will require an assistant to hold the vial while drawing up the anaesthetic solution using a sterile syringe. The advantages are that only a single preparation is required and that the injection is made under true sterile conditions.

An alternative technique that can be used if an assistant is not available is for the surgeon to use clean gloves and a sterile syringe and needle. The surgeon, before donning surgical gloves, draws up the anaesthetic, uses an alcohol wipe to sterilize the skin and performs the injection before preparing and draping the patient. This allows the surgeon to draw up and deliver the anaesthetic without an assistant before donning surgical gloves.

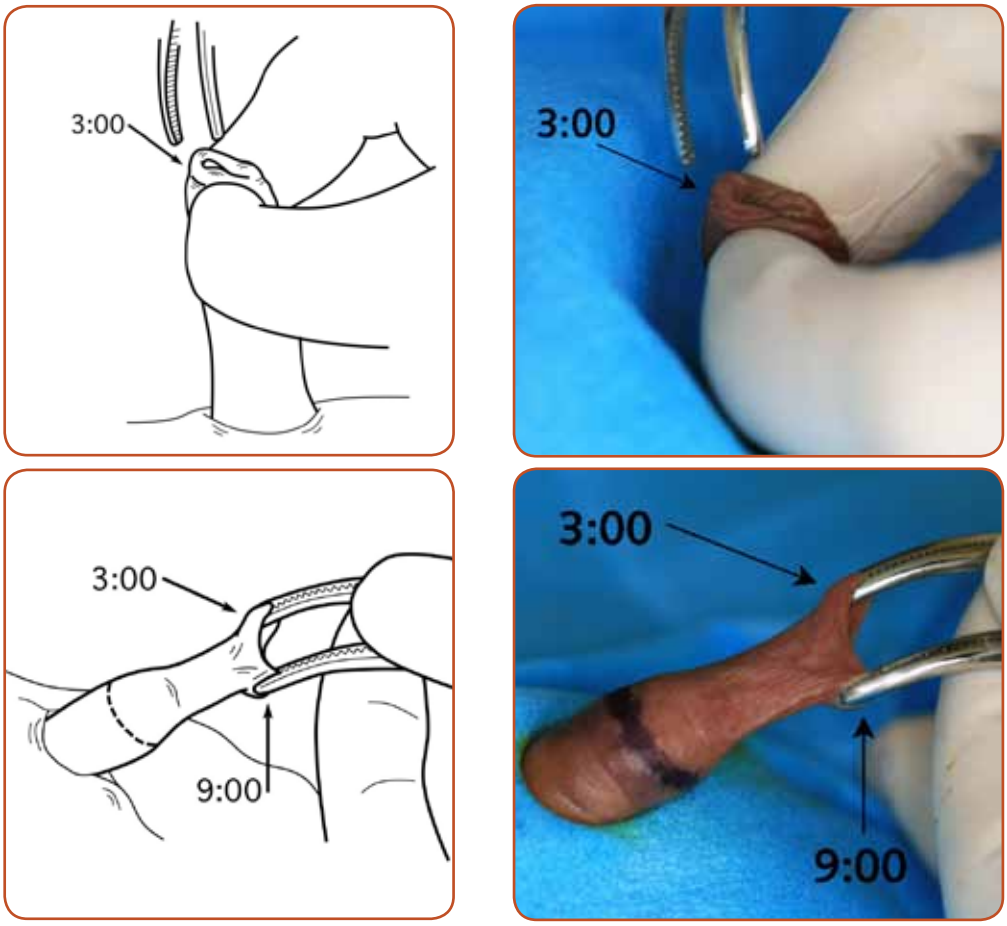
In the United States there are multiple reports of neonatal methicillin-resistant *Staphylococcus aureus* skin and soft tissue infections in well-infant nurseries associated with male circumcision and injectable anaesthesia. A better approach may be to deliver the injection after the patient has been fully prepared and the surgeon has donned sterile gloves and is meticulously using sterile technique.[66]

If a dorsal penile nerve block is used the procedure should be delayed at least 2 minutes until the anaesthetic has taken affect. If anaesthesia is used, the procedure should not start until the first haemostat can be placed without the infant crying or without a change in the cry or grimace being noticed. To help distribute the anaesthesia the area at the base of the penis can be massaged. In rare cases another injection may be required to achieve adequate anaesthesia.

Grasp foreskin

The surgical procedure begins by grasping the foreskin with two curved haemostats (straight haemostats are also acceptable). In some infants the opening of the foreskin may not be obvious. To help guide placement of the haemostats the foreskin can be pinched, pushing the glans down for protection and creating a fold in the foreskin at the 3 o'clock and 9 o'clock positions, where the haemostats can be attached.

Figure 6.12. While pinching the tip of the foreskin, haemostats are placed at the 3 o'clock and 9 o'clock positions



Ensure that the haemostats have a firm grasp on the foreskin without applying their full length. At least three or four teeth of each haemostat should be used to hold the tissue in order to prevent the haemostats from slipping off. The teeth of the haemostats are sharp and can tear the tissue if not securely attached.

Remove preputial glandular adhesions

One of the most important steps of male circumcision is ensuring that the foreskin is completely free from the glans to a level below the surgical mark. This tissue must be free and clear in order to be safely excised. Many providers are reluctant to remove adhesions on the ventral surface near the frenulum. Although minimizing trauma to this area is important in order to avoid frenular artery bleeding, this ventral foreskin tissue must still be separated from the glans to ensure that it can be safely removed. The best way to avoid frenular bleeding is to remove the adhesions by using an up-and-down motion. The frenulum runs parallel to the penis. By passing a probe parallel to this structure, injury is less likely. In the ventral area, opening the haemostats should be avoided as this is more likely to tear the structures and cause frenular bleeding.

The two haemostats should be used to apply traction to the foreskin while using a flexible probe to remove the adhesions between the glans and the inner mucosal layer of the foreskin. The urethral meatus should be avoided by tenting the foreskin up with the probe tip. The probe should be moved in an up-and-down motion and worked around the full circumference of the foreskin. The probe should be used to ensure that the foreskin is completely free and clear to a level below the surgical mark.

Using a haemostat, straight or curved, is an acceptable alternative. The advantage of a flexible probe is that it bends and minimizes the amount of force that can be applied to the tissue, minimizing the risk of injury and enabling providers to confidently and more adequately remove the adhesions.

The application of lubrication (Surgilube) to the blunt probe will also help to facilitate breaking down the adhesions.

Figure 6.13. An example of a flexible probe

The flexible nature of the probe helps to protect tissue from injury during removal of the adhesions.

Figure 6.14. Using a flexible probe to remove the adhesions between the foreskin and the glans to a level below the surgical mark

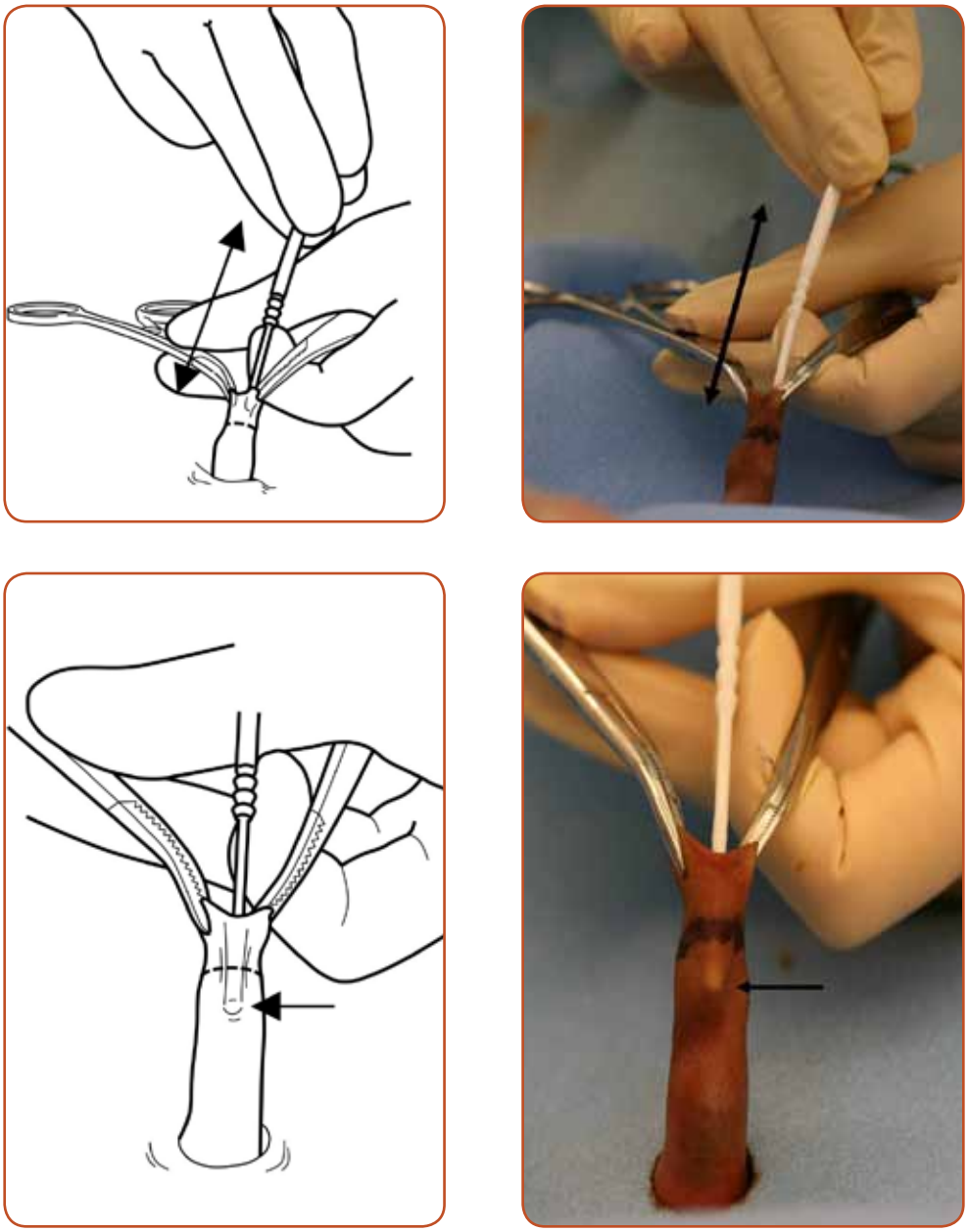
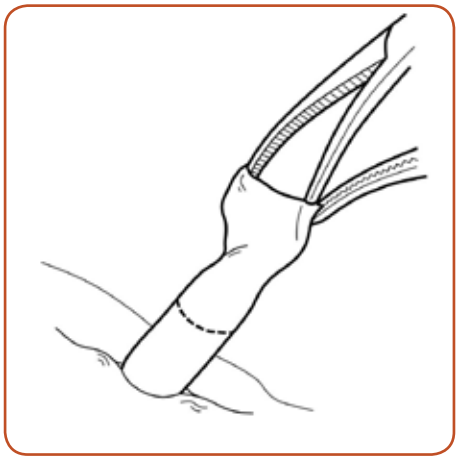


Figure 6.15. A straight haemostat can also be used to remove adhesions

Dilate foreskin opening

During the process of removing adhesions the foreskin opening will naturally dilate. In the Gomco and Plastibell techniques the foreskin will probably have to be stretched even more to accommodate the shield. To accomplish this, one of the curved haemostats is removed and used to firmly stretch the foreskin opening.

Figure 6.16. A curved haemostat is removed and used to dilate the foreskin opening

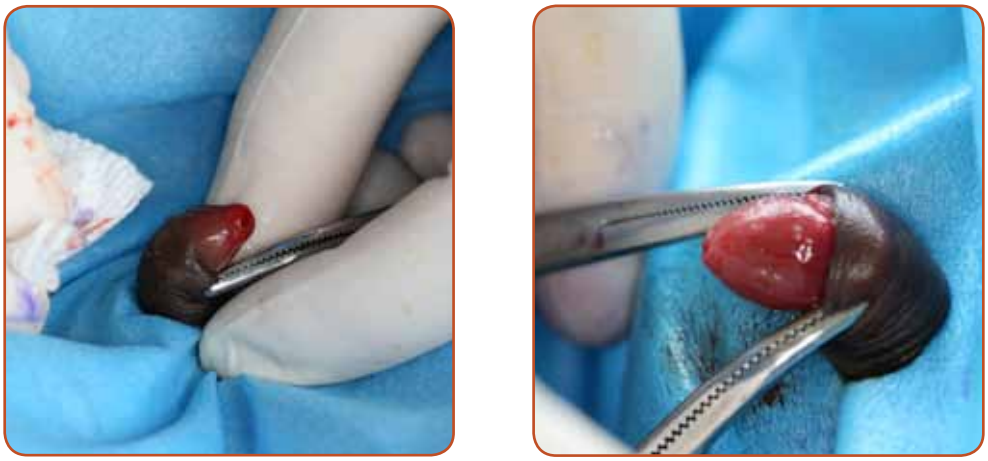


Stretching the foreskin is associated with less bleeding than making a dorsal slit and avoids the risk of urethral injury associated with using the required scissors.

Retract foreskin

After the opening has been firmly dilated the foreskin can be pulled down while the glans is pushed up through the foreskin opening to expose the corona. This allows inspection of the glans. Any residual adhesions can be removed with a blunt instrument or a gauze pad. This step can ensure that all the adhesions have been adequately removed from the glans and that the foreskin is ready for excision.

Figure 6.17. Foreskin being retracted to expose the glans



Many Mogen, Plastibell and Gomco users do not perform this step and never fully expose the glans before applying the clamp. This can shorten the procedure time and avoid swelling that may occur in the foreskin during the manipulation required to expose the glans. At present there are insufficient data to support recommending one method over another. In cases where the surgeon is unsure if the adhesions have been adequately removed, a prudent approach would be to expose the glans and ensure that the foreskin is truly ready for excision.

One argument for exposing the glans is the need to verify the absence of hypospadias. While rare, hypospadias can be present with a prepuce and penile shaft that are otherwise of normal appearance. On the basis of evidence obtained from Mogen users over the past 50 years who performed male circumcision without making a dorsal slit and visualizing the glans, it is evident that hypospadias recognized only after circumcision can be repaired without the foreskin. The overall outcome is unaffected by circumcision having been performed, as most concealed hypospadias are relatively mild deformities.

This has recently been substantiated by two studies concluding that prior circumcision did not complicate the subsequent repair of hypospadias in males whose urethral anomaly was concealed by an intact prepuce.[67, 68]

Male circumcision should only be considered in infants with a normal intact prepuce. Exposing and visualizing the glans can be left to the discretion of the surgeon.

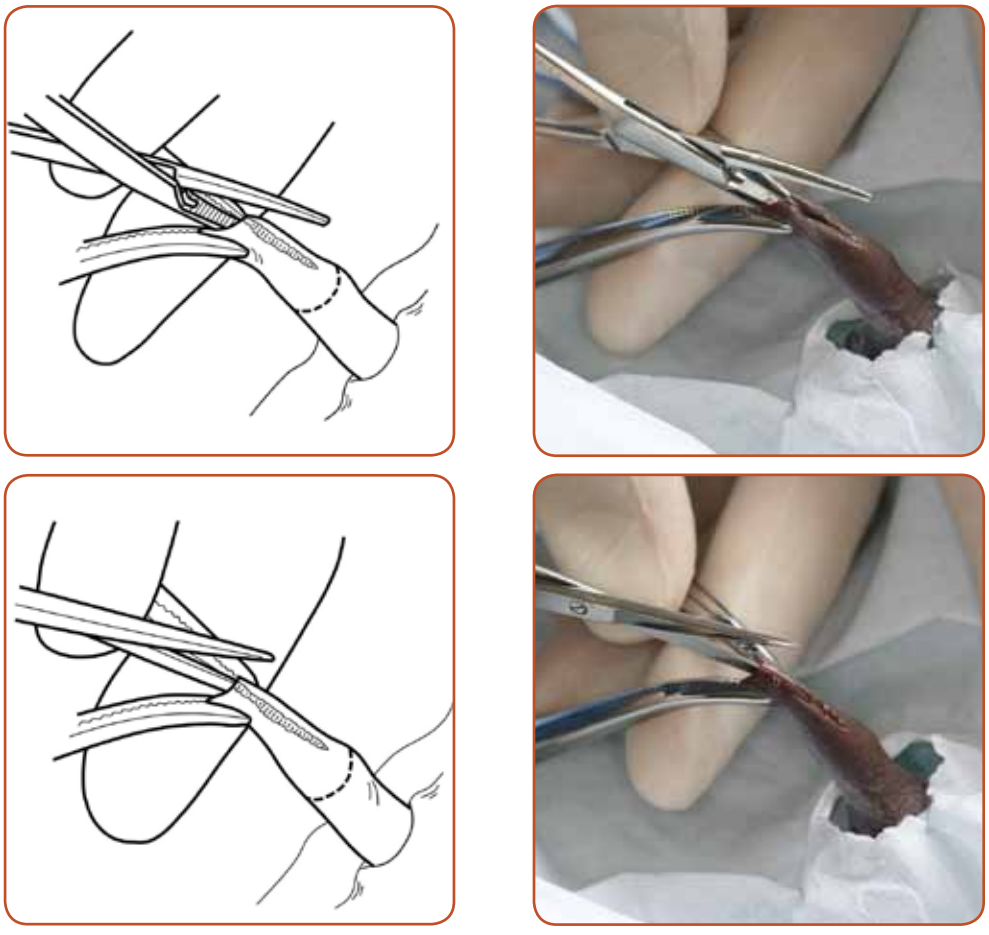
If necessary, create a dorsal slit

In cases where the surgeon cannot expose the glans to allow visual inspection or where the prepuce cannot be dilated sufficiently to place a shield, it may be necessary to make a dorsal slit.

This can be achieved by first making a dorsal crush. As the foreskin is retracted using the two curved haemostats, a straight haemostat is placed at the 12 o'clock position, taking care not to place the tip of the clamp beyond the previously marked circumcision line and to avoid the urethra (Figure 5.12). Close the clamp to crush the skin and leave in place for one minute. This will reduce bleeding when the skin is incised.

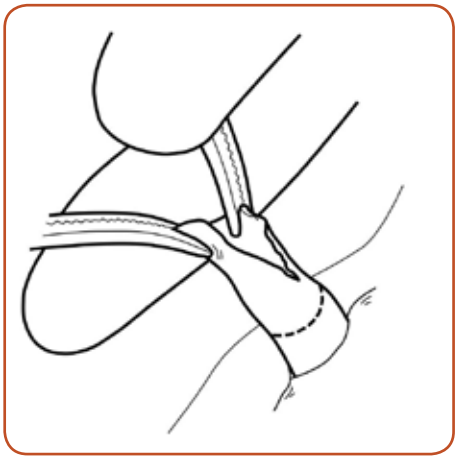
The foreskin is held with haemostats on each side of the crushed area and scissors are used to make a cut at the 12 o'clock position, through the crushed skin, taking special care not to insert the scissors into the urethra.

Figure 6.18. Making a dorsal crush and dorsal slit



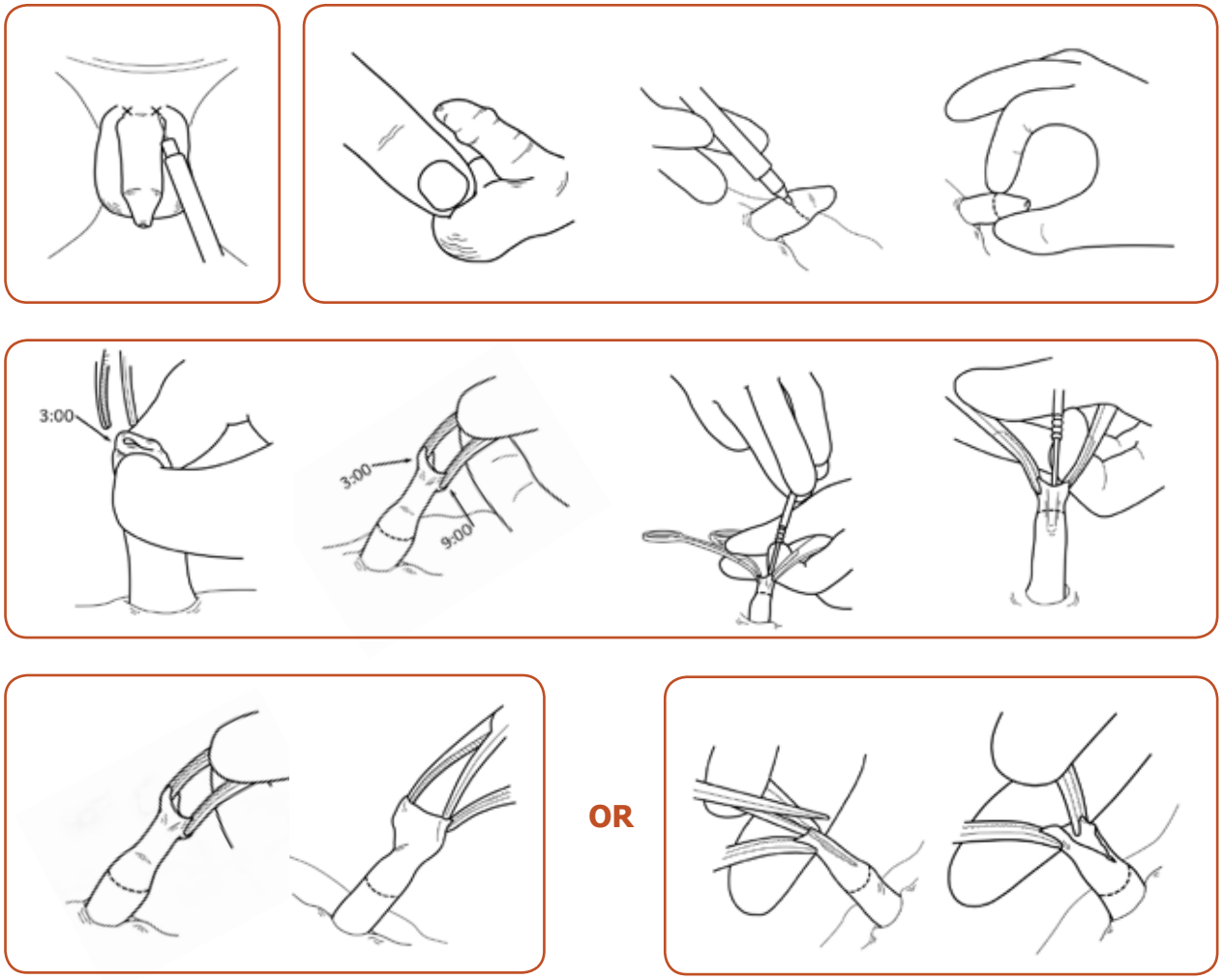
Before the dorsal slit is made the surgeon must ensure that only the foreskin is being incised and that the scissors have not been inadvertently placed inside the urethra. This is best achieved by tenting the foreskin up with the tip of the scissors (Figure 6.18).

Figure 6.19. The dorsal slit, which should not extend below the corona



Many Mogen users do not make a dorsal slit, as no shield is required over the glans. Likewise, many Gomco and Plastibell users do not make a dorsal slit and instead insert the shield through the dilated opening of the foreskin. Eliminating the dorsal slit avoids the associated risk of urethral injury and probably reduces bleeding by eliminating an incision. The decision to make a dorsal slit can be left to the discretion of the surgeon but may be required in some cases to safely complete the procedure.

Figure 6.20. Preparing the prepuce for infant male circumcision



1. Administer anaesthesia. **2.** Identify and mark the foreskin over the corona and palpate to ensure correct position of the mark. **3.** Grasp foreskin with two haemostats at the 3 o'clock and 9 o'clock positions and remove adhesions using a flexible probe. **4.** For devices that use a shield, either stretch the foreskin or create a dorsal crush and slit.

Chapter 7: Overview of surgical devices

Three widely used surgical techniques for early infant male circumcision are described in this manual. The recommended techniques are shown in detail so that they can be referred to in the context of a training course. After the initial training, they can be used to reinforce what has been learnt.

Figure 7.1. The three male circumcision devices described in this manual: Mogen (left), Gomco (centre), and Plastibell (right)



Surgeons (nurse specialists, clinical or medical officers) should become experts in the nationally recommended technique most suited to the circumstances of their practice. It is not recommended that a surgeon learn all the techniques. It is best to become a master of one technique. This will produce the best results with the least complications.

Mogen (Bronstein-style) clamp: introduction

The Mogen clamp was introduced by Dr Bronstein in 1955.[69, 70] The word Mogen is derived from the Hebrew word for "shield". Long before the advent of the Mogen clamp, providers used a simple shield with a narrow gap that protected the glans while the foreskin was pulled through and excised. Providers modified this simple shield and began using instruments that produced a crushing action. Still used in many parts of the world, bone cutters are used to shield the glans, crush the foreskin tissue and guide the scalpel for a clean incision.[71] The Mogen clamp is only a refinement of these age-old techniques.

The Mogen clamp is now widely used around the world. There have been several studies comparing it with the Gomco clamp, another widely used device. The Mogen clamp compares favourably, because it is easy to use and has no parts to assemble. Because the Mogen clamp is reusable, careful precautions have to be taken to ensure that the device is properly cleaned and sterilized between procedures. There is a risk that the glans can be pulled into the slit and crushed or partially severed.[72]

Figure 7.2. Before the advent of the Mogen clamp and still in use today, a simple shield was used to protect the glans (left); providers began using clamping devices like these bone cutters (right) to crush the foreskin and help guide the incision

Figure 7.3. The Mogen clamp as originally described by Dr Bronstein

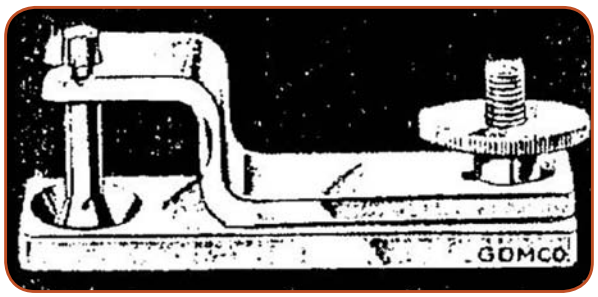
Great care must be exercised to ensure that the clamp is properly sterilized before each use and that the glans is not inadvertently pulled into the clamp and partially severed.

Gomco (Yellen-style) clamp: introduction

Dr Hiram Yellen, an obstetrician and a veteran of both the First World War and the Second World War, invented the Gomco clamp on the basis of his experience of using a Ford motor tyre lever.[73, 74]

Figure 7.4. Dr Yellen's invention of the Gomco clamp was inspired by a car tyre lever, similar to the one pictured here

Figure 7.5. The original clamp described by Dr Yellen and produced by the Goldstein Manufacturing Company (Gomco)[75]



When used as directed with matching non-defective parts the Gomco clamp has an impeccable safety record, as the stainless steel bell protects the glans from the risk of amputation. In the USA, where it is estimated that well over 1 million neonates are circumcised each year, the Gomco clamp has become the leading instrument used to perform non-ritual male circumcision.[76, 77]

One of the limitations of this clamp is that it is made up of four different parts and exists in many different sizes. In order for the clamp to work properly the surgeon must use the correctly sized parts when assembling the device.

Figure 7.6. The various parts of the Gomco clamp: assembled device (A), rocker arm (B), nut (C), baseplate (D) and bell/shield (E)

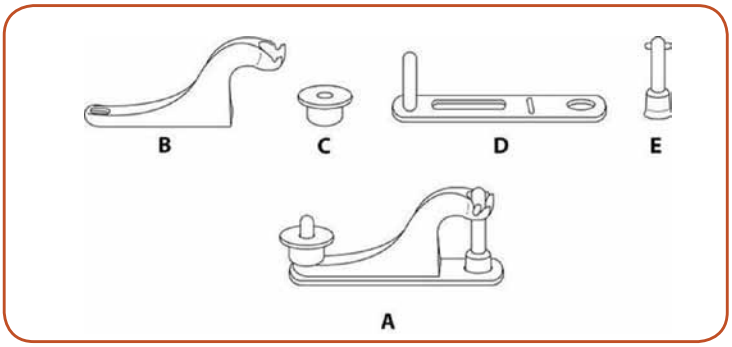


Figure 7.7. Photograph of a 1.1-cm Gomco clamp (left) and a 1.3-cm clamp (right)

The parts look almost identical, making it easy to inadvertently mismatch them.

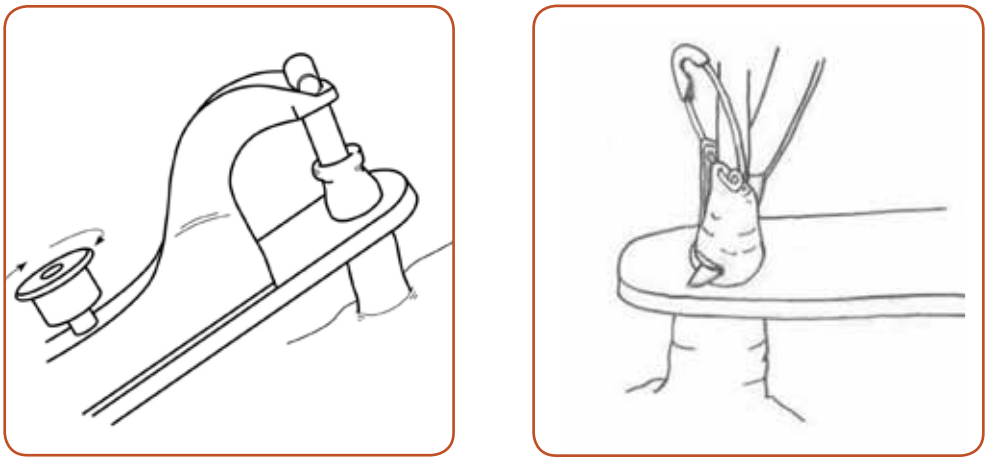
Because of the many parts and multiple manufacturers there is a risk of non-matching parts being used during the procedure. This is a problem because if a small bell is inadvertently used with a larger baseplate, the device can still be assembled but it will neither crush the foreskin nor protect the glans, resulting in penile laceration and haemorrhage. It is not unusual for device parts to be mislaid, lost or mixed during cleaning and sterilization, further complicating the problem of mismatching parts. The surgeon must check that all the parts of the Gomco clamp and the necessary bell sizes are available and that they fit correctly before any anaesthetic is given and the procedure begins.

Component parts from different Gomco clamps are not always interchangeable. Parts from different clamp manufacturers should not be substituted and care must be taken to ensure that the clamp is assembled only from its original set of parts.

Most surgeons routinely assemble the Gomco clamp before the procedure in order to ensure that the parts match and are in working order. This can be an effective safety measure but can fail when a surgeon needs to switch device sizes in the middle of the procedure. The following factors contribute to injuries associated with mismatching device parts.

1. During the procedure the provider may be forced to change to a smaller clamp, creating the possibility of mismatching device parts.
2. In the middle of the procedure the provider may not take the time or forget to check that the new clamp parts are compatible or remove the parts from the clamp that was initially being used, creating the potential to mismatch parts.
3. If a smaller bell is being used with a larger baseplate the error is hidden by the foreskin, preventing the provider from recognizing the error.
4. If a smaller bell is being used with a larger baseplate the clamp can be assembled and the nut can be tightened, creating the deception that the foreskin has been crushed and the glans is being protected. Because the bell is smaller and passes through the baseplate, neither of these things has been achieved.
5. If the provider expects the steel bell to protect the penis and makes an aggressive incision, mismatching parts result in the scalpel passing under the bell and lacerating the glans, producing haemorrhage and penile laceration.

Figure 7.8. Schematic diagram showing the complication that occurs when a small Gomco bell/shield is used with a larger baseplate



The bell does not fit and passes cleanly through the larger baseplate. The foreskin hides the error and the provider is further deceived because the clamp can be assembled and the nut fully tightened (left). When the provider makes the incision, the scalpel passes under the bell, lacerating the unprotected penis and causing haemorrhage.

Meticulous care must be taken to avoid mismatching device parts. If a small bell is used with a larger baseplate the device will not crush the foreskin or protect the glans, resulting in haemorrhage and penile laceration. Correctly matched and sized parts must be used.

Unfortunately, even in developed countries with excellent training programmes, this complication continues to occur.[78, 79] Education alone will probably not entirely prevent the problem and strict hospital protocols should be developed and instituted to help protect providers from making this simple and unfortunate mistake.

A new, modified, Yellen-style (Gomco) clamp has been developed that can prevent surgeons from assembling mismatching device parts under any circumstance. When available, this device will also help to prevent this complication.[80]

The Gomco clamp should be thoroughly checked and should not be used if it has stripped threads, a warped or bent baseplate, a bent arm, twisted forks on the rocker arm, or a scored or nicked bell. Defects in the parts can lead to device malfunction and poor contact between the crushing surfaces, causing unnecessary bleeding.

Plastibell (Ross-style) tourniquet technique: introduction

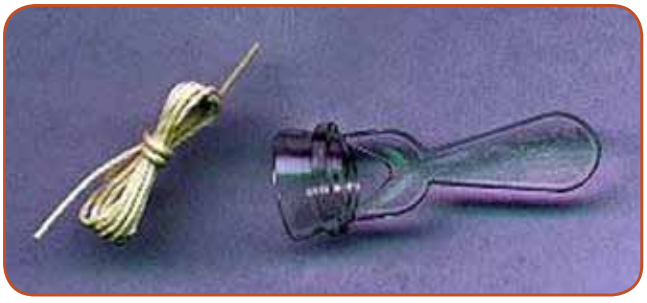
Dr Cecil J. Ross is credited with being the first to describe the tourniquet male circumcision technique after his experience using a tourniquet to remove an extra digit in an infant.[81, 82, 83]

Figure 7.9. Using a tourniquet to remove an extra digit, as shown in this picture, inspired Dr Ross to develop a tourniquet approach to male circumcision

Figure 7.10. Original set of Ross stainless steel male circumcision rings

Dr Ross's design was adopted by Dr Kariher, who was the first to describe a plastic ring with a removable handle.[84, 85] Manufactured by the Hollister Company, this simple device is available under the trade name Plastibell and comes in a sterile package with a single ligature.

Figure 7.11. The Plastibell, as first described by Dr Kariher, is made of plastic and has a removable handle



The Plastibell (Ross-style) technique is widely used around the world and has been shown to be acceptable and practical in developing countries. In addition to being used in infants, it can be used in children up to the age of 10–12 years and has been used extensively with EMLA anaesthetic cream.

As with the other surgical methods, incorrect technique can result in complications. Any clinic offering Plastibell circumcision should have in stock the full range of bell sizes. If the bell used is too small it may cause pressure necrosis and injury to the glans. If the bell is too large, it may slip over the glans on to the shaft of the penis and cause skin loss.

For these reasons the Plastibell technique is only recommended for use in clinics that regularly perform paediatric circumcisions and have all the appropriate sizes. It is not recommended for occasional use.

The Plastibell is manufactured by the Hollister Company and comes in a sterile package (Hollister Inc., 2000 Hollister Drive, Libertyville, Illinois 60048, USA).

Figure 7.12. The Plastibell device, showing sterile package, ligature, plastic shield, manner in which handle can be removed and ligature (left), with an enlarged view of bell (right)

Following the procedure, the Plastibell ring remains in place, providing a tourniquet. This ring is typically released when the skin distal to the string necroses and separates. In rare cases, the glans can become swollen and herniate through the ring, causing it not to release and become retained. The retained ring causes oedema to build in the glans and can disrupt blood and urine flow, resulting in late catastrophic complications, including glandular necrosis and complete urinary obstruction.

The serious complications that can occur with the use of this device are caused from the retained ring. For this reason the Plastibell should only be used in situations where access to follow-up can be assured.[86, 87, 88]

Device summary

The following two tables summarize these devices and the complications associated with them.

Table 7.1. Considerations for selecting among the three most commonly used infant male circumcision devices

The shaded areas represent undesirable features that should be taken into account when each technique is being considered for programme introduction.

Consideration	Mogen	Gomco	Plastibell
Single or multiple sizes	Single infant size can be used for all infant males	Various sizes must be available	Various sizes must be available
Number of parts	Single part simplifies inventory	Various sizes and multiple parts complicate inventory	Multiple sizes but a single part simplifies inventory
Sizing errors	Reduced risk One size for all infants (slot size must be checked)	Increased risk (related to mismatching device parts)	Increased risk (complications associated with bell of wrong size)
Duration of procedure	Requires the least amount of time to perform	Requires more time	Requires more time
Use in older infant males and young boys without suturing[1]	Routinely requires closure of the wound in infants >60 days of age	Routinely requires closure of the wound in infants >60 days of age	Routinely does not require closure of the wound, regardless of age
Disposable/ reusable	Reusable Requires reprocessing[2]	Reusable Requires reprocessing[2]	Device itself is disposable (Instruments may require reprocessing)

[1] **This manual addresses early infant male circumcision. For more information on male circumcision later in life refer to the WHO *Manual for male circumcision under local anaesthesia*.**

[2] **The Mogen and Gomco clamps are reusable. This could be a benefit if the infrastructure is available to reprocess the instruments and the cost of sterilization is less than that of purchasing a disposable device.**

In early infancy (<60 days of age), regardless of which technique is used, closure of the wound is typically not necessary. Beyond early infancy (>60 days), better cosmetic outcomes may be achieved if the wound is closed with simple interrupted sutures. An overview of suturing and wound closure is provided in Annex 9. The Plastibell provides a unique benefit over the other techniques in that it can be used outside the early infant period without regularly requiring surgical closure.

Extremely rare catastrophic complications such as necrosis of the glans, urinary retention and bladder rupture have been reported with the use of the Plastibell device, as a result of retained parts, particularly if a bell of the wrong size is used. The Plastibell should only be considered in areas where follow-up is both reliable and easily available.[89]

The Plastibell is a disposable device, whereas the Mogen and Gomco clamps are reusable. The choice between the different techniques may depend on the cost of the Plastibell, the need to sterilize the Mogen and Gomco clamps, patient age, access to follow-up, carer reliability and the possible need for suturing skills.

None of these devices has been proved truly superior and each has its advantages and disadvantages. The purpose of this manual is to help providers to obtain optimal results regardless of which technique is employed.

Table 7.2. Potential complications of the three most commonly used infant male circumcision devices

The shaded areas represent undesirable features that must be considered.

Consideration	Mogen	Gomco	Plastibell
Bleeding	Similar risk (1.0%)	Similar risk (1.0%)	Similar risk (1.0%) Associated with injury to the frenulum during application of the bell and/or loose ligature
Urethral injury	Reduced risk (dorsal slit is not routinely required)	Increased risk (dorsal slit routinely required)	Increased risk (dorsal slit routinely required)
Penile laceration/ amputation	Increased risk (glans may not be protected)	Increased risk (related to mismatching device parts)	Reduced risk
Urinary retention, bladder rupture, injury from retained parts	No risk (no retained parts)	No risk (no retained parts)	Increased risk if bell of wrong size is used, as it can slip back on to shaft of penis, causing gangrene, urinary retention and bladder rupture
Buried glans	Increased risk if surgeon does not free glans	Similar risk	Similar risk
Other comment	Penile amputations can occur even under ideal circumstances	When matching non-defective parts are used there is essentially no risk of injury to the glans	Complications from retained parts can occur even under ideal circumstances

Chapter 8: Surgical techniques

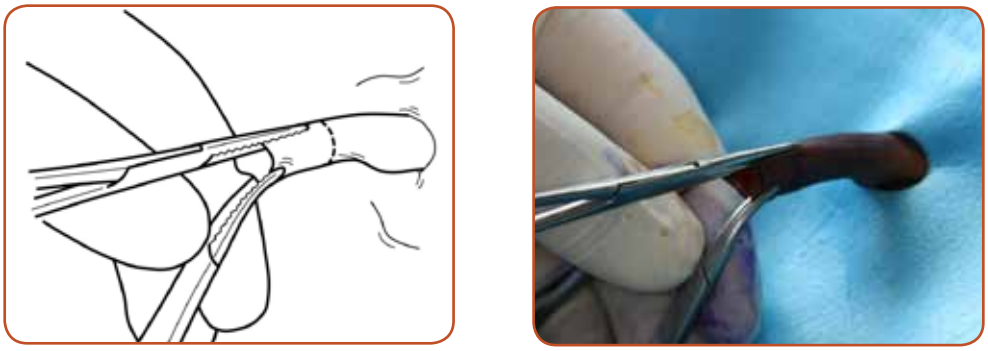
Mogen (Bronstein style) clamp: technique

Step 1: Ensure that the clamp is the correct size and in good working order. Although there is only one standard infant size, Mogen clamps exist in different sizes with varying gap distances to accommodate older males with thicker foreskins. The Mogen clamp with a gap distance of 2.5 mm is designed for infants. Clamps of larger size with a gap distance greater than 2.5 mm have been associated with more frequent penile amputations in infants and should be removed from any area that performs infant male circumcision so that they cannot be inadvertently used by an unsuspecting provider.[90, 91] The edges of the jaws should be routinely inspected to ensure that they are not dented or chipped. Because the clamp is rigid, any defect that prevents approximation of the edges will prevent adequate crushing.

Step 2: Ensure that the foreskin is free from the glans. This is particularly important with the Mogen clamp because, if the glans is inadvertently pulled into the clamp, it will be amputated when the incision is made.

Step 3: A straight haemostat is used to grasp the dorsal foreskin at the 12 o'clock position as shown below. It is not unusual for the penile shaft to have some degree of rotation. The ventral raphe should be identified and the haemostat placed directly opposite this landmark.

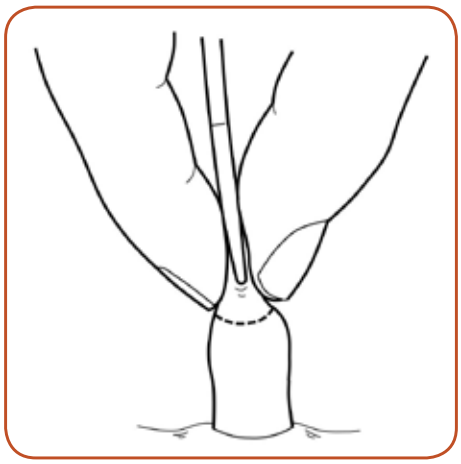
Figure 8.1. Applying a haemostat to the dorsal foreskin at the 12 o'clock position



Step 4: Put traction on the foreskin, and introduce it into the slit in the device, guided by the dorsal haemostat, with the concavity facing the glans and the flat surface facing the provider. It is important to ensure that the glans is not pulled into the slit. If there is any doubt, remove the clamp, inspect the glans for any sign of crushing injury and reapply the clamp. Many providers place the long axis of the clamp parallel to the frenulum along the dorsal-ventral axis of the penis.[92]

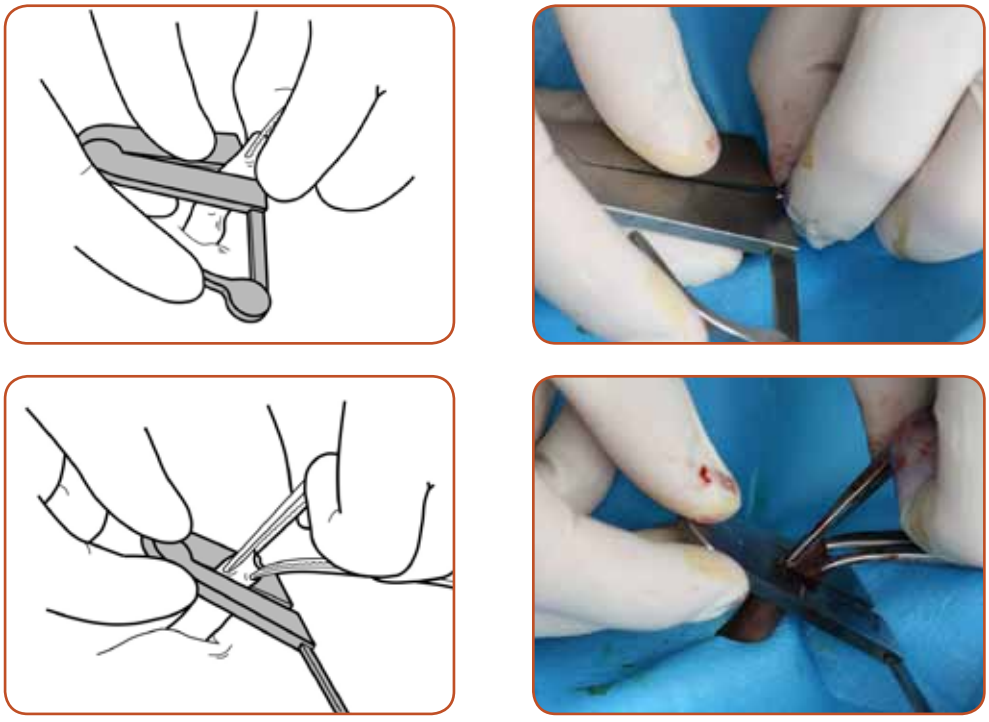
Other providers place the clamp horizontally. Both methods are acceptable, as neither has been proved to provide a better outcome.

Figure 8.2. Pinching the foreskin between the index finger and thumb, pushing the glans down and out of the way in preparation for aligning the foreskin tissue in the Mogen clamp



To ensure that the glans is protected the non-dominant index finger and thumb are used to pinch the foreskin together from the ventral side to the dorsal haemostat, the handle of which is held in the palm (Figure 8.2). Traction is then applied along the axis of the penis. The first manoeuvre retracts the glans out of the way. The Mogen clamp is then slid across the foreskin, starting at the tip of the haemostat and angling distally as it approaches the ventral side. The foreskin that remains above the clamp should be wedge-shaped, with more length dorsally than ventrally.[93]

Figure 8.3. Application of the Mogen device

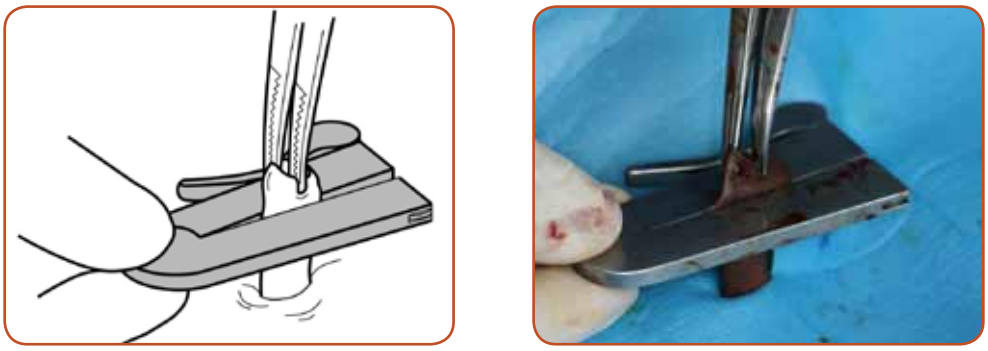


Step 5: Align the foreskin. Using the surgical mark as a guide, the foreskin should be aligned in the clamp. It has been suggested that, before the clamp is activated, the provider should attempt to palpate and mobilize the glans in order to ensure that it is free and clear beneath the clamp. This can be difficult with small infants and providers with large fingers. Others have suggested that the foreskin be transilluminated so as to ensure that the glans is not trapped. This can also be problematic and none of these techniques have been proved to reduce the incidence of penile amputation.

To help avoid this complication the foreskin should be carefully removed from the glans before applying the clamp. In addition the foreskin should be carefully pinched to ensure that the glans is beneath the level of the provider's fingertips when the clamp is applied.

Step 6: Once the provider is sure that the glans is safely below the clamp, it is closed and activated using the lever arm, crushing the foreskin. To reduce the risk of bleeding, the clamp should remain closed for 5 minutes.

Figure 8.4. Activation of the Mogen device



Step 7: The foreskin is incised with a scalpel by using the outer flat side of the clamp as a guide. After allowing a 5-minute crush time, release the lever arm, open the device, and remove.

Figure 8.5. The foreskin is cut flush with the clamp using a scalpel. The Mogen clamp is designed to protect the glans, which remains below the clamp

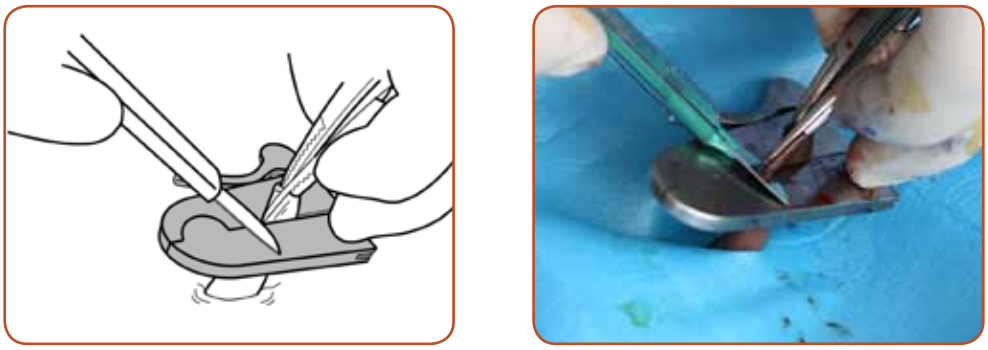


Figure 8.6. The Mogen device in the clamped position, showing the concave part of the clamp that faces the patient

Step 8: Manipulate the penis, using gentle pressure from the side, to allow the glans to emerge from under the crushed foreskin. This is an important step to ensure that the foreskin heals below the level of the corona.

Figure 8.7. Liberating the glans after removing the Mogen clamp

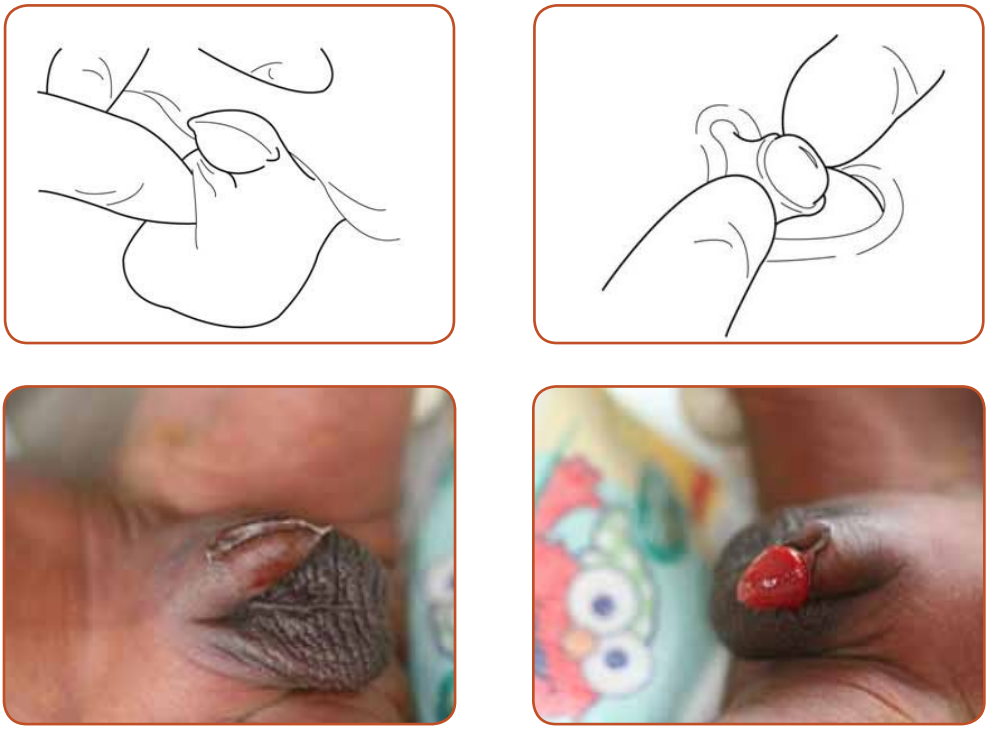
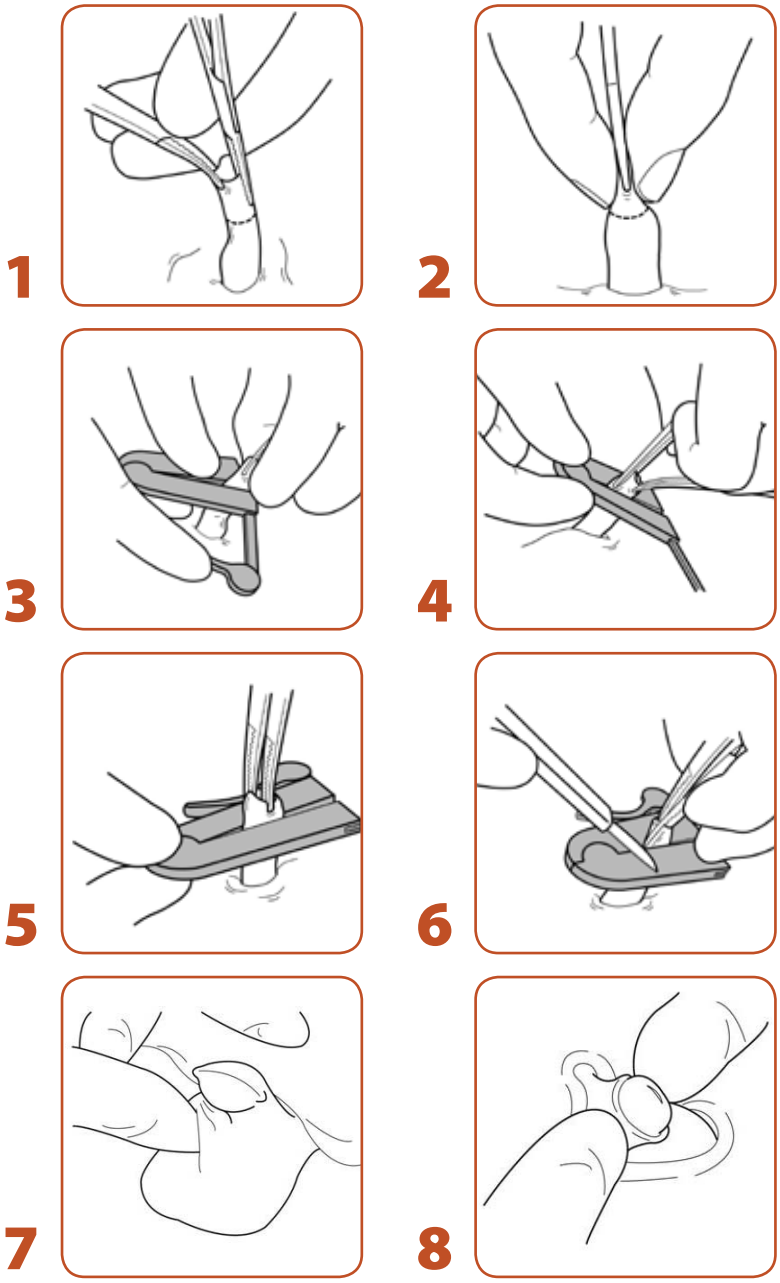


Figure 8.8. Mogen circumcision two weeks postoperatively

Figure 8.9. Mogen surgical technique overview



1. Place dorsal haemostat. **2.** Pinch foreskin, pushing glans down and out of the way. **3.** Apply clamp. **4.** Align foreskin. **5.** Activate clamp, maintain 5-minute crush time. **6.** Excise foreskin. **7.** Remove clamp. **8.** Liberate the glans by pushing foreskin down beneath corona.

Mogen (Bronstein-style) clamp: device-specific complications

The most significant device-related complication associated with the Mogen clamp is distal tip penile amputation.

Figure 8.10. Partial glandular amputation following infant male circumcision

This extremely rare complication can be minimized by using good surgical technique but is unlikely to be eliminated. Unfortunately, even under ideal circumstances and with experienced surgeons this complication continues to occur.[94, 95]

Risks associated with this device can be minimized by exercising the following precautions:

- ☐ **the clamp must be properly sterilized before each use;**
- ☐ **the clamp should be inspected for any defects and the gap distance should not be greater than 2.5 mm;**
- ☐ **the clamp should only be applied if the foreskin can be freely separated from the glans. If the glans is not separated from the foreskin it can be inadvertently pulled into the clamp and excised;**
- ☐ **use a surgical mark and ensure that the foreskin is symmetrically aligned before activating the clamp.**

Gomco (Yellen-style) clamp: technique

Step 1: Select a Gomco clamp of the correct size. The size of both the Gomco clamp and the Plastibell device correspond to the outside diameter of the bell or shield. The correct size depends on the outside diameter of the corona, not the length of the penis. The bell should completely cover the glans penis without distending the foreskin excessively.

To help determine the correct size, surgeons can use their little finger as a gauge. Once the surgeon knows the size of her or his little finger, she or he will always be able to measure/gauge the size of the penis. The following Gomco infant sizes are available: 1.1, 1.3, 1.45 and 1.46 cm. Larger sizes are available for older boys and men, viz. 2.6, 2.9, 3.2 and 3.5 cm.

Figure 8.11. Surgeons may use their little finger to gauge the size of the penis and help determine the correct size Gomco clamp

A bell size of either 1.1 or 1.3 cm is usually appropriate for early infant male circumcision.

In the USA there are several large unpublished ongoing case series where a 1.1-cm Gomco device is being used universally on all neonate male circumcisions, regardless of the true penile shaft size of the patient. This is similar to the Mogen clamp, where only a single neonate-size clamp is used. There are few published data indicating that using an undersized Gomco clamp poses any risk or adversely affects outcome.

If an undersized Gomco clamp is used it becomes more important to rely on a surgical pen mark for determining the amount of skin to remove, instead of relying on the fit of the bell. And, as with the Mogen device, it is important to ensure that the foreskin is free of adhesions before placing the clamp. There is no compelling mechanical or physiological reason why a 1.1-cm Gomco device could not be used in the same manner as the Mogen clamp, where one size is used universally in all neonates. The full length of the crushing surface of an infant Mogen device is 3.5 cm. The length of the crushing surface for the 1.1-cm Gomco bell, the circumference of the bell, is the same, 3.5 cm. So whether an infant Mogen device or a 1.1-cm Gomco clamp is used, the crushing surface for any given foreskin is the same, one being linear and the other circular.

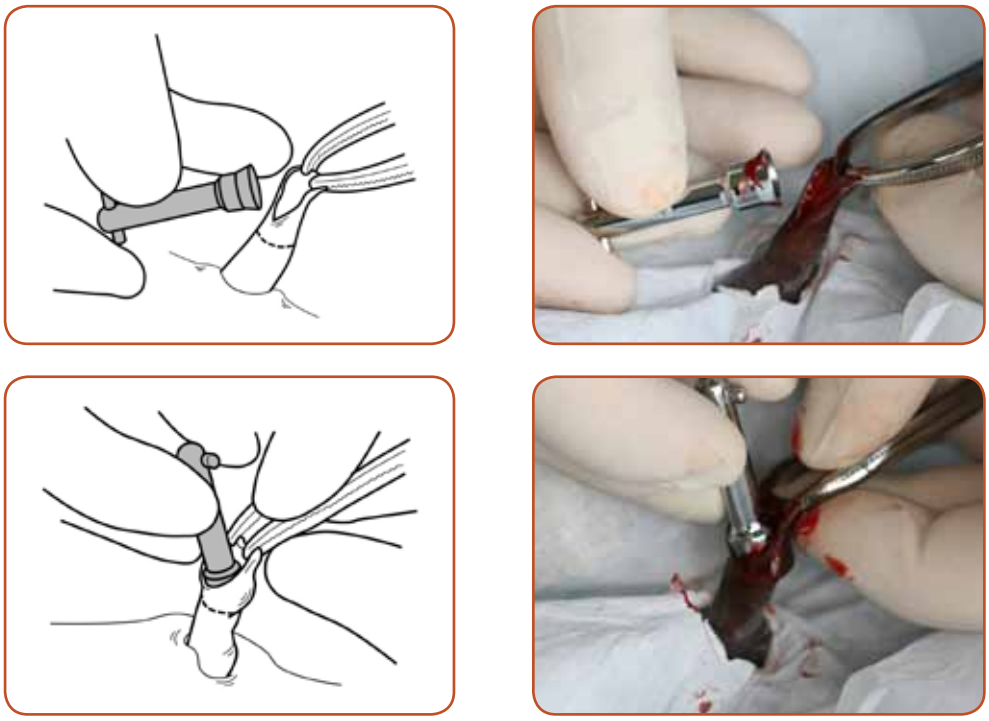
The advantages of adopting a single-size device are that providers no longer need to determine size, inventory is simplified and complications associated with mismatching parts are eliminated. Unfortunately, at present, there are no published outcome data on this approach.

When clamps of different sizes are used, and, for some reason during the procedure, it is determined that the Gomco clamp initially selected is too big and another smaller-sized device is requested, it is essential that the larger clamp and all of its parts are removed from the surgical sterile field and that the new device is fully assembled and inspected before being used.

To minimize the risk of mismatching device parts a surgeon should never have two clamps of different sizes in the sterile field at one time.

Step 2: Place the shield/bell over the glans. If required, a dorsal slit can be made to allow for a larger opening to insert the shield, as previously described. In one method the foreskin is stretched with two haemostats and the bell is inserted directly into the opening of the foreskin (Figure 8.12). In another method the foreskin is pulled down, completely exposing the glans, the bell is placed on top of the glans and the foreskin is pulled up and over the bell.

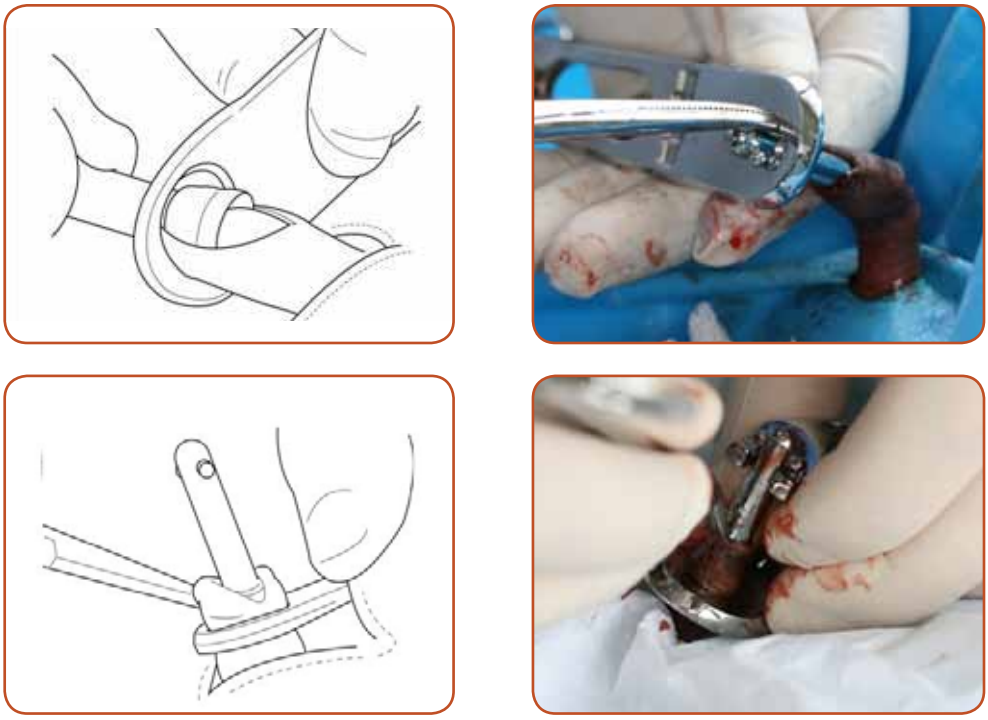
Figure 8.12. The Gomco bell/shield is placed into the preputial space through the opening of the foreskin and over the glans



A dorsal slit has been made to help accommodate the bell/shield.

Step 3: The stem of the bell and the foreskin are manoeuvred through the hole in the matching baseplate. Two techniques can be used to accomplish this. The first uses a haemostat to reach through the hole in the baseplate to grasp the foreskin and tease it up through the hole (Figure 8.13).

Figure 8.13. The stem of the bell and the foreskin are fed through the bottom of the matching Gomco baseplate by means of a haemostat.



The second uses a small safety pin to bring the edges of the dorsal slit together over the flare of the bell. The stem of the bell is then fed through the hole of the matching base plate along with the safety pin, which is used to pull through the foreskin (Figure 8.14). If a safety pin is used, caution must be exercised so that the sharp point does not injure the surgeon or the patient. To achieve optimal results the safety pin should be pierced through the full thickness of the foreskin.

Figure 8.14. The foreskin is closed over the Gomco bell by means of a small safety pin (left); the stem of the bell and the safety pin are then fed through the bottom of the matching baseplate so that the foreskin can be pulled through and aligned (right)

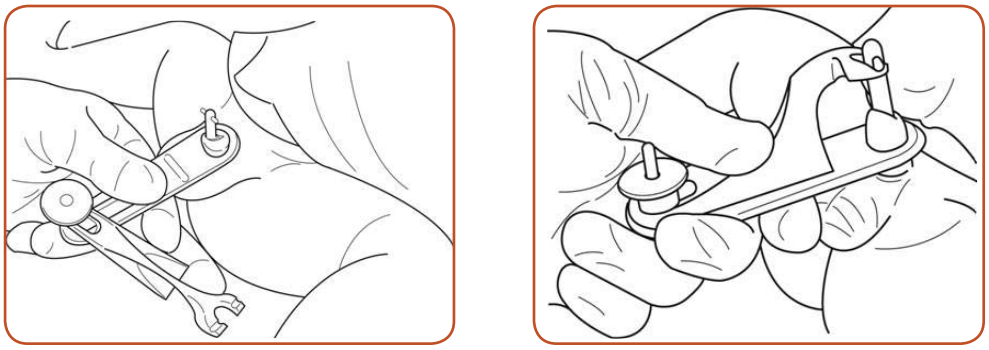
The full thickness of the foreskin has to be adjusted symmetrically in the clamp. This should only be done when the bell and baseplate are loose. Pulling the foreskin into a tightly held or fully assembled clamp can cause asymmetry of the tissue and adversely affect the outcome.

In difficult cases some providers find it helpful to close the foreskin over the flare of the bell with a haemostat and to use this haemostat to tease the foreskin up through the baseplate hole from the bottom. Once the foreskin is sticking through the hole, another haemostat can be attached to the foreskin from the top of the hole. This haemostat can then be used to help align the foreskin.

Step 4: Align the foreskin by using the surgical mark. The apex of the dorsal slit (if made) can also help to guide alignment. With the bell and baseplate being loosely held, the foreskin can be adjusted for length and symmetry. If a dorsal slit has been made the apex should be visible above the baseplate. At this time the amount of penile shaft skin that remains below the clamp should be assessed. It should be symmetrical and not stretched too tight.

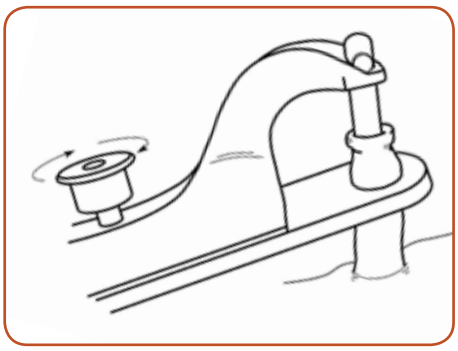
Step 5: The rocker arm (top plate) is attached and aligned with the base plate. The crossbar (arms) on the stem of the bell are settled into the recess on the yoke of the rocker arm (top plate) as shown below (Figure 8.15). The crossbar at the top of the bell should sit squarely in the yoke of the clamp; otherwise there can be uneven crushing and a risk of bleeding.

Figure 8.15. The rocker arm of the Gomco clamp is put into position over the baseplate and the crosspiece of the bell is pulled up into position on the yoke of the rocker arm (top plate)



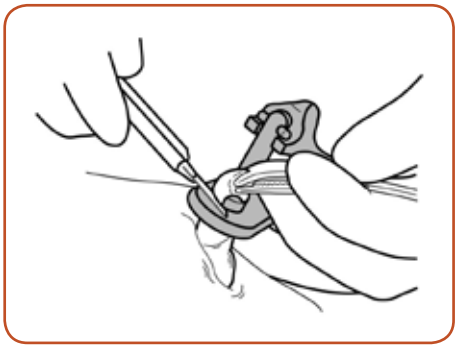
Step 6: Once the surgeon is sure that the clamp and foreskin are in the optimal position, the nut is tightened, activating the crushing action.

Figure 8.16. The Gomco clamp is activated by turning the nut, creating the lever action that crushes the foreskin tissue



Step 7: Excise the foreskin with a scalpel circumferentially around the bell, distal to the clamp. The bell, securely clamped against a matching baseplate, protects the glans.

Figure 8.17. The foreskin is excised using a scalpel



The incision should always be made with a scalpel. One should NEVER use an electric current when performing circumcision with a metal Gomco clamp.[97] The metal bell of the Gomco can concentrate heat, causing complete tissue destruction. The use of electrocautery with the Gomco device has resulted in total ablation of the penis during male circumcision.[96] To avoid this devastating complication, surgeons must be educated that electrocautery has to be strictly avoided when using a Gomco clamp.

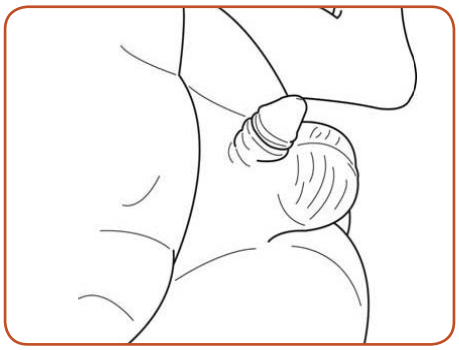
Step 8: As initially described by Dr Yellen, the clamp should be left on for 5 minutes to ensure adequate haemostasis.[98] Many providers remove the clamp immediately after they excise the foreskin, with the result that the crush time is less than 1 minute. This practice runs the risk of bleeding and it is therefore better to use the technique described by Dr Yellen.

In order to minimize bleeding and avoid possible surgical intervention and other subsequent complications, a 5-minute clamp time is recommended.

Figure 8.18. Once the foreskin has been excised the Gomco device should remain clamped for at least 5 minutes to ensure haemostasis

Step 9: The nut is loosened and the clamp is disassembled and removed. Gauze can be used to separate the foreskin from the bell and ensure that the foreskin is pushed below the level of the corona. Any residual adhesions can be removed with a blunt probe or gauze pad.

Figure 8.19. Immediate postoperative outcome following a Gomco neonatal male circumcision



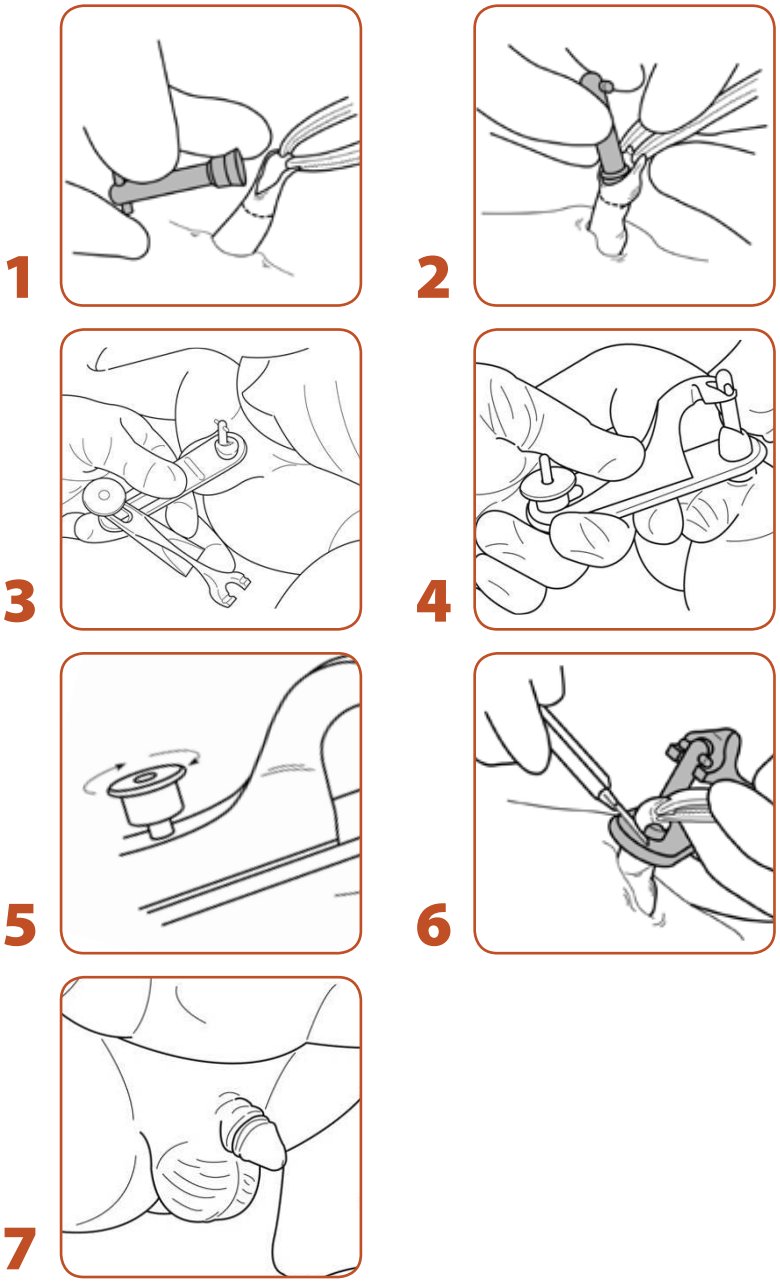
Once the clamp has been removed the crushed skin edge will typically provide haemostasis and tissue alignment. No sutures are required normally in early infancy. Because the clamp crushes the edge of the foreskin, bleeding is rare.

Figure 8.20. Two-week postoperative outcome following a Gomco neonatal male circumcision

To ensure the reliable operation of the Gomco clamp it is important to remember the following points.

- ☐ **The clamp must be properly sterilized before each use.**
- ☐ **Matching device parts must be used; no two different clamps should be in the sterile field at the same time.**
- ☐ **The dorsal slit should not be cut too long. The apex of the dorsal slit should be above the baseplate before the clamp is activated.**
- ☐ **The crossbar of the bell must be placed evenly in the yoke of the rocker arm to ensure an even distribution of the crushing force.**
- ☐ **Ensure that the foreskin is symmetrically aligned before the clamp is activated.**

Figure 8.21. Gomco surgical technique overview



1. Insert the bell/shield. **2.** Ensure the shield covers and protects the glans.
3. Apply clamp by inserting bell and foreskin through hole in the base plate.
4. Loosely assemble clamp and align foreskin. **5.** Tighten nut and maintain 5-minute crush time.
6. Excise foreskin. **7.** Remove clamp and liberate the glans by pushing foreskin down beneath corona.

Gomco (Yellen style) clamp: device-specific complications

The most common device-related complications associated with the Gomco clamp are penile laceration and haemorrhage. These occur when wrong-sized parts are inadvertently assembled by the surgeon and the device fails to crush the tissue and protect the patient.

Figure 8.22. Penile laceration following infant male circumcision

Figure 8.23. Penile laceration with a urethrocutaneous fistula following infant male circumcision

These complications can be prevented through education, training and the adoption of strict procedural guidelines. The injuries should prompt immediate specialist consultation.

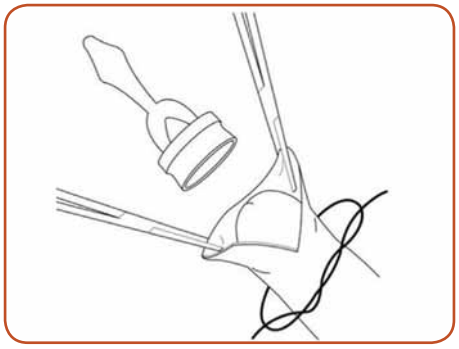
Plastibell (Ross-style) tourniquet: technique

Step 1: Select the correct size of Plastibell. The device size corresponds to the outside diameter of the shield in centimetres for both the Plastibell and the Gomco and should roughly correlate with the outside diameter of the patient's glans, not the length of the penis. To help determine the correct size of device to use, surgeons can use their little finger as a gauge. Once the surgeon knows the size of her or his little finger, she or he will always be able to measure/gauge the size of the penis. The following sizes are available: 1.1, 1.2, 1.3, 1.4, 1.5, 1.6 and 1.7 cm.

Figure 8.24. The surgeon may use her or his little finger to gauge the size of the penis and help determine the correct size of Plastibell device

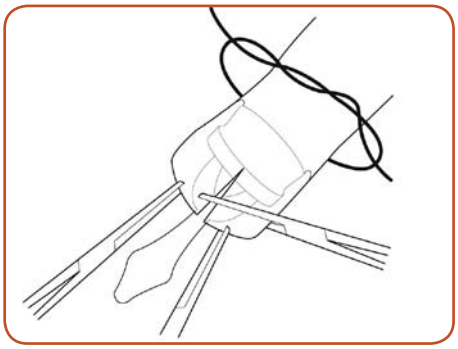
Step 2: The Plastibell is placed over the glans. If necessary, a dorsal slit can be made to enlarge the foreskin opening and allow placement (as described in Chapter 6). The slit needs only to be sufficiently long to allow the Plastibell to be placed over the glans. Each Plastibell is supplied in a sterile packet with a ligature (the Plastibell tie). The procedure is easier if, after opening the Plastibell package, the Plastibell tie is placed loosely around the shaft of the penis before the dorsal slit is made (Figure 8.25).

Figure 8.25. The ligature may be loosely tied around the base of the penis before beginning the procedure (left); the Plastibell is then inserted into the foreskin opening and placed over the glans



Step 3: Align the foreskin. Pull the foreskin up and over the Plastibell. The surgical mark should be positioned over the ridge of the Plastibell, where the ligature will be secured. Once the desired alignment has been achieved, it can be helpful to hold the foreskin in position by cross-clamping the foreskin over the Plastibell handle with a haemostat (Figure 8.26).

Figure 8.26. Haemostats are used to secure the foreskin to the handle of the Plastibell

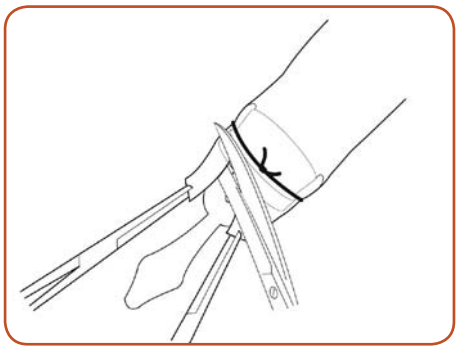


Step 4: Apply the tourniquet. Before doing so the surgeon must be satisfied with the alignment of the foreskin on the Plastibell. The foreskin should be symmetrical but not taut, and the alignment should be guided by the surgical mark. To adjust alignment, the haemostats must be unclamped and the Plastibell repositioned. Once alignment has been achieved, carefully place the ligature over the groove of the Plastibell. Ensure that it is in the correct position, then pull it tight and tie (Figure 8.27).

Figure 8.27. The ligature is secured over the groove of the Plastibell

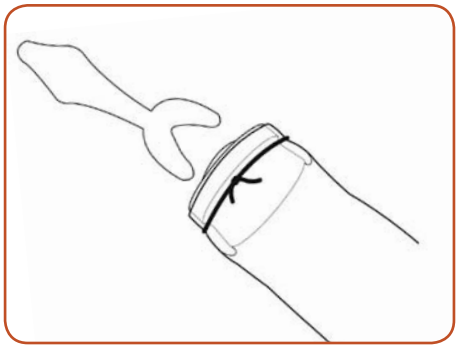
Step 5: Excise the foreskin using scissors, leaving 1–2 mm of cuff to prevent the ligature from slipping off (Figure 8.28). The wound will contract, and, if the tissue is excised too close to the ligature, haematomas and bleeding can result. Dr Ross, in his original description of the tourniquet technique, did not advocate that the skin be removed distal to the ligature. In fact there are still providers in the USA and Nigeria who routinely leave the foreskin in place after applying the ligature. Which approach is better has never been studied.

Figure 8.28. The foreskin is excised, leaving 1–2 mm of tissue to prevent the ligature from slipping



Step 6: Snap off the handle of the Plastibell. The index finger and thumb of one hand are used to hold the body of the Plastibell, the other hand is used to grasp the handle and snap it off. The handle is designed to snap off at the base of the wishbone.

Figure 8.29. Snapping off the Plastibell handle

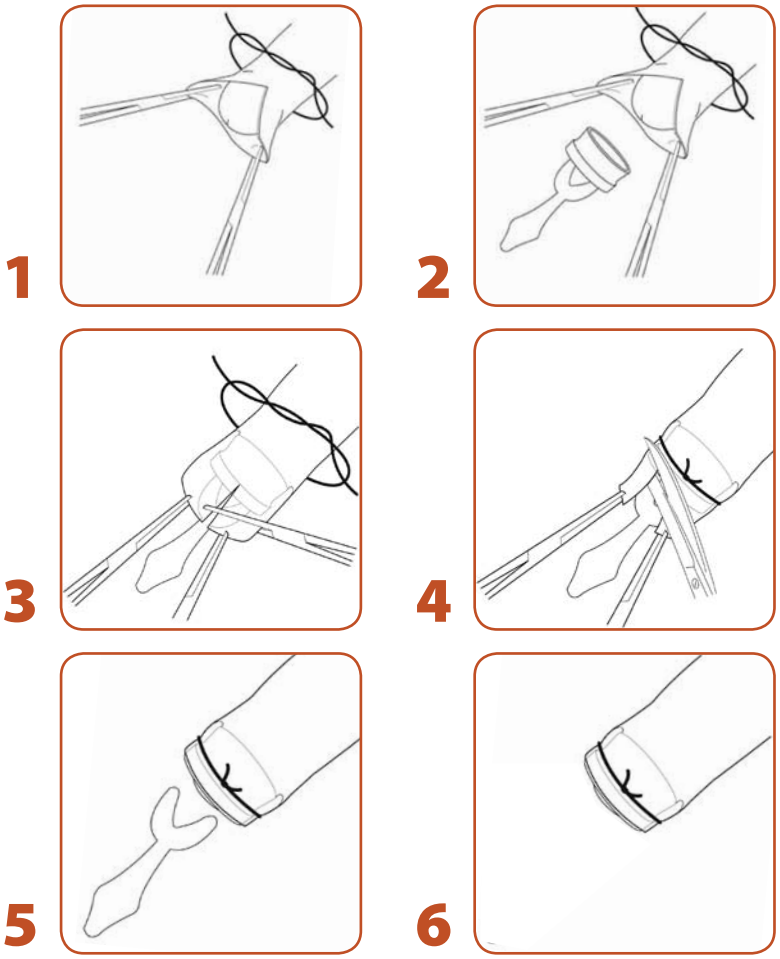


Step 7: Check that there is no bleeding. If there is no bleeding the child can be sent home and looked after in the normal way, including normal washing and use of nappies. A dressing is typically not used with the Plastibell, but the use of Vaseline / petroleum jelly should be encouraged to keep the raw skin edges from sticking to the nappy/diaper. The rim of tissue distal to the ligature should become necrotic and the Plastibell should drop off after 5–8 days. Alternatively, the infant can be checked after 36–48 hours, the ligature cut and the Plastibell removed. It should be emphasized to the family that the Plastibell does not always fall off and that after 8 days, if the bell is still attached, it should be removed.

Figure 8.30. Two-week postoperative outcome following a neonatal Plastibell male circumcision

Some of the most serious complications ever seen from male circumcision have resulted from retained Plastibells. Educating the family to closely monitor the wound and the infant's urine output is paramount with the use of this device.

Figure 8.31. Plastibell surgical technique overview



1. Loosely apply tourniquet around base of penis. **2.** Insert bell/shield to cover and protect the glans. **3.** Align foreskin and apply haemostat across Plastibell handle to secure. **4.** Tie tourniquet and use scissors to excise foreskin. **5.** Snap off handle of Plastibell. **6.** Review precautions with family concerning retained parts.

Plastibell (Ross-style) tourniquet: device-specific complications

Bleeding from the skin edge

If bleeding occurs at the site of the freshly cut skin edge another ligature can be tied over the existing one. This ligature should be tied securely to achieve a complete tourniquet.

Bleeding from beneath the Plastibell

Many people believe the Plastibell is associated with less bleeding than the clamping and cutting devices because a tourniquet is used. In terms of bleeding at the skin edge, this is probably true. However, circumcision bleeding can come from other places, specifically the area around the frenulum. Because the Plastibell can hinder the ability to apply direct pressure in the frenular area, some of these cases will require removal of the Plastibell in order to control the bleeding.

Regardless of the technique or the skill of the operator, frenular bleeding can occur, particularly when a rigid bell is placed into the preputial space. With a rigid Plastibell secured by a tourniquet, it is difficult to evaluate and manage this type of bleeding. In several recent large Plastibell case series the reported rate of bleeding was higher than those reported for the clamping and cutting devices.[99, 100, 101] This higher rate of bleeding may only be attributable to the fact that frenular artery bleeding following a Plastibell circumcision cannot always be managed effectively.

In the event of bleeding occurring from within the ring, before the Plastibell is removed, an attempt should be made to control it with directed pressure using a cotton-tip swab through the hole of the Plastibell. Topical epinephrine can also be used. These interventions may be of limited use if the specific location of the source of bleeding cannot be identified.

If directed pressure is not effective or significant bleeding is occurring the Plastibell must be removed and the bleeding addressed. This can lead to other problems, namely an uncrushed and somewhat unsightly skin edge without a tourniquet to help control the bleeding or ensure an optimal cosmetic outcome. With so little tissue remaining, reapplication of the Plastibell or any other device is discouraged. In these very rare cases the bleeding must be controlled with direct pressure (now unhindered by the rigid bell) and/or surgical closure. Depending on the complexity of the situation and the experience of the surgeon, immediate specialist consultation may be warranted.

Several techniques have been evaluated to help prevent this type of bleeding during Plastibell circumcision but have proved ineffective for various reasons.[102] If a Plastibell male circumcision is going to be performed regularly, this complication must be anticipated and the resources must be available to manage it appropriately.

Incomplete separation of the ring

During wound-healing, incomplete separation of the bell can occur. In most such cases the bell and the necrotic tissue can be gently separated and removed. In some rare circumstances, when the ligature is not tied tightly enough, the tourniquet can be incomplete and some distal foreskin may remain viable. In these cases, the Plastibell should be removed and any remaining viable foreskin that was distal to the tourniquet should be surgically removed. Depending on the complexity of the situation and the experience of the surgeon, specialist consultation may be warranted.

Infection

Remarkably, despite the fact a foreign body is retained for several days, the Plastibell is associated with only a slightly increased rate of infection.[103, 104] Because the Plastibell is retained, it is easier for providers to identify and report infections associated with this device than with any of the others. In addition, even if another factor leads to the infection, unrelated to the device itself, the retained Plastibell will always be implicated.

If an infection is identified before the Plastibell has been released, it must be removed urgently. This can be achieved by cutting the ligature and carefully removing the bell. If significant oedema and/or a partially necrosed skin edge complicates removal, a penile dorsal nerve block should be considered to help alleviate pain during the procedure.

Figure 8.32. Local redness and oedema associated with a retained ring following male circumcision using a Plastibell; the infant presented with fever and poor feeding, suggesting possible systemic involvement (left); the wound following the removal of the Plastibell ring (right)[105]

In addition to removing the ring, an appropriate workup should be performed to evaluate for sepsis and other complications. Prompt treatment should be initiated, and, for severe infections, appropriate specialist consultation should be considered.

Urinary retention

Urinary retention can complicate Plastibell male circumcision by obstructing outflow at the urethral opening or by causing tense oedema that can obstruct the urethra as it passes through the shaft of the penis. This oedema can occur because of proximal migration of the bell or herniation/ballooning of the glans through the ring.

Figure 8.33. Wound of normal appearance following Plastibell circumcision (left); abnormal wound following Plastibell circumcision, showing a retained ring and significant oedema distal to the ring (right)

In severe cases this can lead to complete outlet obstruction, renal failure and bladder rupture. In addition to obstructing the urethra, such significant oedema can also obstruct arterial supply and venous return, resulting in tissue ischaemia and even necrosis.

Figure 8.34. Penile necrosis and urinary obstruction following Plastibell circumcision complicated by a retained ring

Figure 8.35. Partial penile necrosis following Plastibell circumcision complicated by a retained ring

Tissue injury

In addition to causing urinary retention and necrosis, a retained Plastibell ring can cause considerable tissue injury. Such injury can result from pulling too much skin on to the bell or from migration of the bell during wound-healing.

Figure 8.36. Tissue injury following a Plastibell circumcision complicated by a retained ring

Depending on the severity of the injury, immediate specialist consultation may be necessary.

The following precautions can be adopted to help minimize these types of complications: training and attention to the correct surgical technique, detailed and well-understood precautions for the carers, easy access to urgent follow-up care, a patient population with carers willing and able to seek follow-up care, and provider education aimed at recognizing and appropriately managing these complications.

At present it is unclear if the severity and type of late postoperative complications could affect acceptability of the procedure and/or the success of a new male circumcision programme. Because the Plastibell is associated with more serious complications and because preventing them depends largely on the family and not the immediate health-care team, caution should be used before adopting this technique in areas where male circumcision is poorly understood. The significant complications that result from the Mogen and Gomco techniques occur immediately and can be typically managed and resolved by the health-care team at the time the injury occurs. The catastrophic Plastibell complications occur late and may not be recognized or managed correctly. The difference in timing and severity of the complications of each surgical technique should be considered in the context of developing a male circumcision programme.

Although catastrophic late postoperative complications can occur with the Plastibell, many of these can be prevented, and the low rate of intraoperative complications, the simplicity of the device, disposability, cost and ease of use must also be considered when critically evaluating this technique.

Chapter 9: Postoperative care

Good postoperative care is extremely important for ensuring the best outcome.

Postoperative dressing

One of the complications of male circumcision is the possibility of developing a surgical site infection. There has been an increasing number of reports in the USA of infections associated with methicillin-resistant *Staphylococcus aureus* in well-infant nurseries.[106]

Strong evidence exists that protecting a postoperative incision with a sterile dressing for 24 to 48 hours can help to prevent surgical site infections.[107, 108] The WHO guidelines for safe surgery also recommend that a sterile dressing be applied over a surgical wound for the first 24 to 48 hours to help prevent surgical site infections.[109]

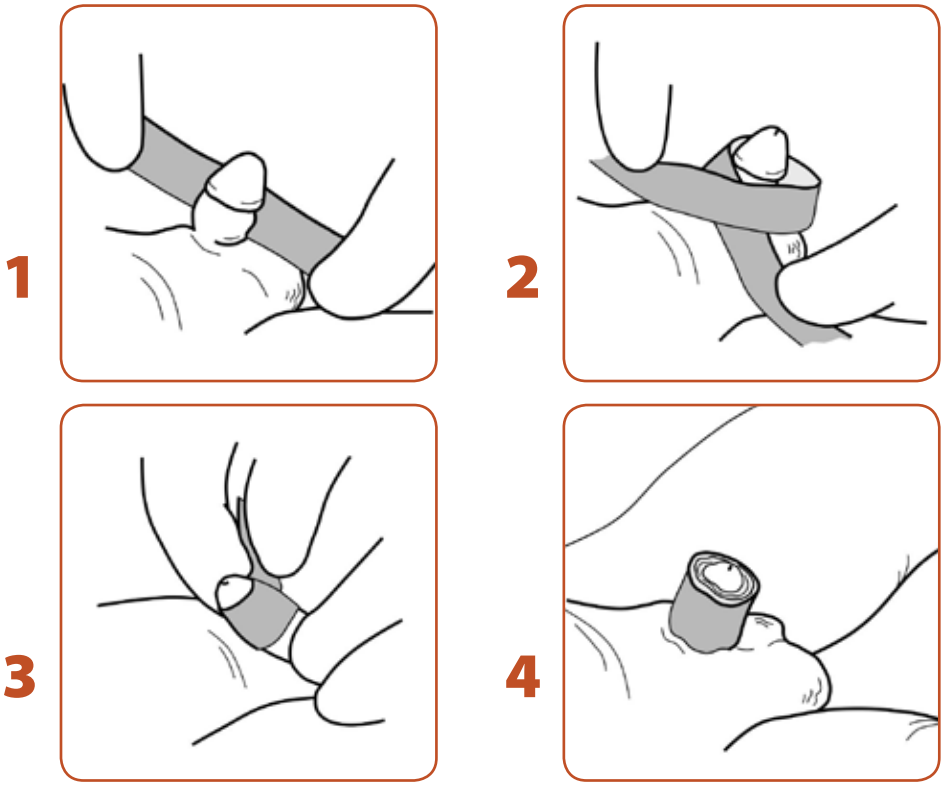
Various methods of dressing a circumcision wound have been described.[110, 111] The most important elements of a circumcision dressing are to protect the wound, help control bleeding and oedema, allow for monitoring of bleeding, and allow the passage of urine.

Figure 9.1. Examples of a poorly applied dressing (left) and an acceptable dressing (right)

The dressing on the left may obstruct urine flow and is poorly applied to the wound. The dressing on the right allows visualization of the glans, does not obstruct urine and is well applied to the wound, protecting it from contamination and reducing oedema and bleeding risk.

The method of applying this type of dressing is illustrated below. More detailed instructions, including photographs showing each step, are provided in Annex 10. These more detailed instructions can be used as a poster and should be prominently displayed in all circumcision care areas.

Figure 9.2. Method of applying a postsurgical infant male circumcision dressing



Step 1: Fold gauze to create long narrow dressing and impregnate with petrolatum (Vaseline).
Step 2: Wrap gauze around the penis, crossing the two ends.
Step 3: Pull gauze ends until dressing is snugly applied to the wound.
Step 4: Wrap the remainder of the dressing neatly around the penis.

To ensure that the dressing is not too tight, the penis should be squeezed to check that it is still compressible. The dressing should be applied snugly but should not restrict the flow of blood and urine through the penis.

One of the advantages of this dressing is its ability to help control bleeding and minimize the need for more aggressive surgical intervention. The dressing should remain in place for 48 hours, during which time bleeding and urine output should be closely monitored. If the dressing falls off and there is no significant bleeding, another dressing does not need to be applied and petrolatum should be applied to help protect the wound and keep it from sticking to the nappy/diaper.

There have been isolated case reports in the literature describing urinary obstruction from dressings that have been left in place for more than 7 days.[112] Clear instructions must be provided to monitor bleeding and urine output and to remove the dressing 48 hours after its application. To remove the dressing it should be moistened and gently unwrapped. Some minor bleeding that can occur when the dressing is removed should be managed with simple direct pressure.

Postoperative care instructions

A postoperative information sheet is provided in Annex 10. This can be used as a handout for family or carers. The general precautions indicated below are provided in this handout. They should be reviewed in detail with the family of the infant before discharge from the clinic or hospital. The family should be instructed to return to the health clinic for any of the following reasons.

General precautions

- The infant appears to be distressed or in pain.
- The infant is inconsolable.
- The infant is lethargic.
- The infant has fever.
- The infant does not wake for feeding in accordance with his usual pattern.
- There is any separation of the skin edges.
- There is any unusual swelling or bleeding.
- The infant has any difficulties with urination.
- The family has any other concerns.

Gomco/Mogen-specific precautions

- The dressing must not be left on for longer than 48 hours.

Plastibell-specific precautions

- The plastic ring slips on to the shaft of the penis.
- The tip of the penis becomes swollen or changes colour.
- A part of the foreskin beyond the ligature remains alive or has not shrivelled after 48 hours.
- The plastic ring has not fallen off within 8 days.

Postoperative healing

The following pictures demonstrate typical wound-healing after male circumcision involving the use of each of the devices described in this manual. Male circumcision providers must become adept at identifying normal male circumcision wound-healing.

Figure 9.3. Normal wound-healing following Mogen circumcision

Figure 9.4. Normal wound-healing following Gomco circumcision

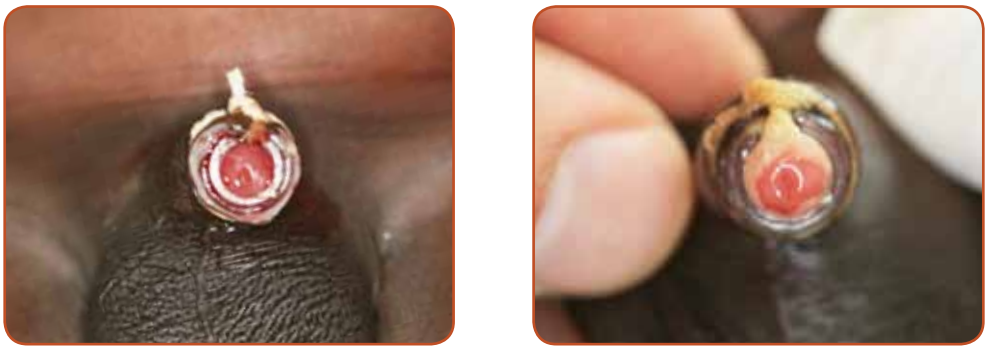
Figure 9.5. Normal wound-healing following Plastibell circumcision

During the healing process a shiny white or yellowish film may cover part of the penis as shown in the figures below. This coating is part of the normal healing process and it cannot be easily removed with a moist wipe. However, if a yellowish discharge forms that can easily be wiped away, has a foul odour and is causing increasing redness and swelling, immediate specialist referral should be considered.

Below are examples of normal wound-healing after early infant male circumcision.

Figure 9.6. Normal male circumcision wound-healing after Gomco male circumcision at 72 hours postoperative (left) and at 2 weeks (right)

Figure 9.7. Normal male circumcision wound-healing after Plastibell male circumcision immediately postoperative (left) and at 48 hours (right)



As a general rule the healing area will have some swelling and redness but should start to look better 24 to 48 hours after the procedure. If ever the area starts to look worse or the infant develops a fever, stops having wet diapers, stops eating, becomes inconsolable or the area appears to be infected or not healing, specialist care should be considered.

Lubricants (petroleum jelly, Vaseline, petrolatum) have been shown to significantly reduce infant male circumcision complications. Petrolatum helps to protect the wound, creates a barrier between the healing surfaces of the foreskin and denuded areas of the glans, and keeps the wound from sticking to the nappy/diaper. Petrolatum should be applied immediately after surgery, before the dressing is applied, and regularly once the dressing is removed (with each diaper change) until the wound has healed. Petrolatum should be applied liberally to cover the circumcision wound and the glans.[113]

Chapter 10: Postoperative complications

Providers and families must be able to recognize and address postoperative complications.

Immediate postoperative complications

Post-circumcision bleeding

Most episodes of post-circumcision bleeding can be addressed by simply applying an appropriate dressing as described in Annex 11. In the event of continued bleeding, direct pressure should be applied with the dressing in place. After 5 minutes of pressure the dressing can be released and the patient observed.

If bleeding persists the dressing should be removed and the wound closely inspected. Other causes of bleeding, including a clotting disorder and/or an occult injury, should be considered. If the bleeding is minor and localized another dressing can be applied and accompanied by 10 minutes of direct pressure, measured by the clock.

If bleeding persists despite these measures, surgical and medical consultation should be considered. A post-circumcision bleeding protocol is provided in Annex 12. It should be posted on the wall in the procedure room and in units caring for infants with a circumcision wound. Such a protocol will minimize the need for surgical intervention and its associated complications. The protocol focuses on direct pressure and patience, representing the most effective, least expensive and universally available intervention.

Vitamin K at a dose of 1 mg given intramuscularly shortly after birth has been shown to reduce bleeding after neonatal circumcision.[114, 115] In some countries this is routinely given to all neonates to prevent bleeding attributable to vitamin K deficiency. Routine administration of Vitamin K should be considered when a neonatal male circumcision programme is being developed and should be consistent with national policy, in order to help prevent bleeding after male circumcision

Application of simple direct pressure and an appropriate dressing should be the mainstay for treatment of bleeding after infant male circumcision.

In extremely rare circumstances during infant male circumcision the need for suturing may be required. The rarity of this complication means that, for some providers, surgical consultation should be obtained without attempting to suture or close the wound. An overview of suturing and wound closure is provided in Annex 9 but is suggested only for those providers who have experience of suturing and closing wounds. All other providers should obtain immediate specialist consultation.

Too little skin is removed

There will inevitably be cases where an error is made in determining the amount of foreskin to remove. This is one of the least serious complications, as more tissue can always be removed later. In these cases the wound should be cared for in the usual manner and the family should be reassured that once the wound heals the procedure can be redone if necessary. The body has a remarkable propensity to heal: frequently, by the time the wound has healed, the outcome is satisfactory. If a revision is necessary the procedure should be delayed (if possible) until after 6 months of age and scheduled with a provider skilled in performing infant male circumcision revisions.

If insufficient foreskin is removed the wound should be allowed to heal before any further intervention. An immediate secondary procedure to remove more foreskin tissue can be complicated and is strongly discouraged.

Too much skin is removed (degloving)

In mild cases and without significant bleeding the wound can be managed conservatively and will heal reasonably well through secondary intention. Another reasonable approach would be to close the wound with sutures as described in Chapter 5.

Figure 10.1. An example of degloving immediately following male circumcision (left), and the same wound three weeks postoperative with healing occurring through secondary intention (right)

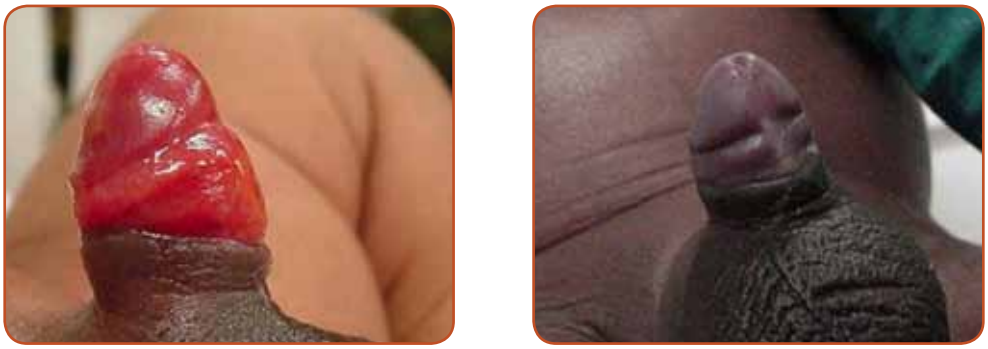


Figure 10.2. An example of degloving immediately following a Mogen male circumcision

The severity of this injury warrants specialist consultation.

Figure 10.3. An example of degloving following male circumcision

The wound is being closed with simple interrupted sutures.

In severe cases, or if the surgeon has any concerns, the patient should be referred for immediate specialist consultation.

Injury to penis or surrounding structure

Don't panic and don't try to hide the injury. Most injuries can be successfully repaired without any significant long-term consequences. However, the injuries must be addressed early. Basic first aid should be administered. Once the injury is identified the bleeding should be controlled by applying direct pressure on the wound, using a moist dressing. Any injury to the penis or a surrounding structure should be evaluated by a specialist. While consultation is being arranged the infant should be made comfortable and the wound should be closely monitored for bleeding.

If an injury occurs to the penis or to a surrounding structure, immediate specialist consultation should be obtained.

A thin mucosal layer is not excised

In the early infant foreskin the outer keratinized skin is tightly adhered to the very thin inner mucosal tissue.

Figure 10.4. A piece of removed foreskin showing the inner mucosal membrane

In the infant penis this thin membrane is tightly adhered to the outer keratinized skin and cannot be easily dissected and separated from the outer tissue.

Under unusual circumstances this thin membrane can be separated from the outer skin. This may occur more commonly when a dorsal slit is made, allowing a point of entry between these two tissue planes. If a shielding device is placed in this potential space the possibility exists that, following excision and removal of the clamp, the thin mucosal membrane remains intact. In most of these cases the mucosal layer will be tightly adhered to the glans. The thin membrane can be teased away from the glans with gauze or a blunt instrument. In many cases, during this blunt dissection alone, the thin connective tissue will retract and no further intervention will be required. In some cases this membrane may be thick and require excision. Because this mucosal tissue avoids being crushed, special attention should be given to any bleeding after its excision.

Other postoperative complications

Reactions to anaesthetic agent

If an infant appears to be having a reaction to the anaesthetic agent, immediate specialist consultation should be obtained to help manage the problem.

Pain

Acetaminophen or paracetamol has been suggested for treating postoperative pain associated with infant male circumcision.

Infection

Normal wound-healing must be understood so that a true infection can be identified and treated. To the untrained eye a completely normal circumcision wound could look infected. It is normal for a circumcision wound to have a thin yellow film, which can easily be mistaken for pus. One distinct difference is that this yellow film cannot be easily removed. Pus, which is not normal, can typically be easily wiped away with a moist wipe.

During the first 48 hours, infection is rare and the wound looks its worst, with inflammation, redness and tenderness. This is normal. After 48 hours the wound should look better, but if it starts to look worse and is accompanied by more swelling, redness, pain or frank pus, a wound infection should be seriously considered. Fever, poor feeding, decreased urine output (reduced number of wet nappies/diapers) or an infant that is inconsolable or lethargic should immediately raise concern for systemic involvement.

In the event of a wound infection the infant should be evaluated for possible sepsis and other complications and treatment should begin immediately.

Urine obstruction

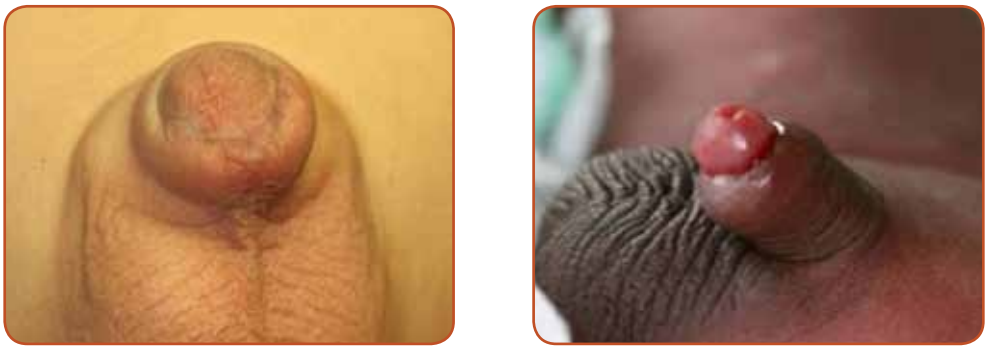
For any suspicion of urine obstruction the dressing should be removed immediately. If a Plastibell was used and the ring has not been released, it should be removed urgently. Another cause of urine obstruction following male circumcision is the placement of ventral sutures, which may penetrate the shallow urethra and cause occlusion. Specialist consultation should be considered.

Adhesions

Adhesions that form between any residual foreskin and the glans can be reduced over time by carefully wiping and pushing the foreskin back away from the glans. Without any intervention, most of these adhesions will resolve spontaneously during adolescence under the influence of androgens. Only rarely will adhesions involve the circumcision wound and require subsequent surgical intervention.[116]

To help avoid adhesions the family can be instructed to gently retract the penile skin at each nappy/diaper change to ensure that no adhesions develop on to the glans or corona. Many providers also suggest the liberal use of petrolatum to create a barrier between the two surfaces.

Figure 10.5. Adhesions following infant male circumcision



Preputial glandular fusion

To help prevent preputial glandular fusion it is important to maintain a barrier between the circumcision wound and the de-epithelialized areas on the glans where adhesions were removed. This can be achieved through the use of a dressing or the liberal application of petrolatum.

Trapped penis

The complication of a trapped penis can occur even if the perfect amount of foreskin is removed. To help prevent this complication it is important to ensure that the healing wound stays beneath the level of the corona.[117, 118] If the wound begins to contract above the level of the corona the glans can be pushed down beneath the contracting scar and appear to be buried. This complication can frequently be managed with the application of topical steroids, which can help to reduce the scar and allow the glans to resume its normal anatomical position.[119]

Figure 10.6. Trapped penis in an infant following male circumcision

The healing wound has contracted over the glans, causing it to become hidden.

Figure 10.7. Trapped penis in an adolescent male following circumcision

The healing wound has contracted over the glans, causing it to become hidden.

Figure 10.8. Redundant skin in an infant following male circumcision

This can be difficult to differentiate from a buried/concealed penis and should be evaluated with specialist consultation.

The glans is partially covered by the foreskin

During the first year of life it is common for the glans to become partially covered with penile skin as a result of a prominent suprapubic fat pad. This may be disconcerting to family members but typically resolves during normal development after the first year of life. Appropriate education must be provided at the time of surgery to avoid inappropriate post-procedural expectations and disappointment.

Meatal stenosis

Figure 10.9. Meatal stenosis

A fibrotic scar forms over the urethral opening.

Skin bridge

Figure 10.10. Skin bridge

During healing it is important to isolate the surgical wound from wounds on the glans, where the epithelial layer may have been disrupted during the removal of adhesions.

Chapter 11: Standard precautions and instrument processing

Overview

- Health-care workers should follow recommended practices for preventing infection in order to protect themselves, other health-care workers and their patients from exposure to HIV and other infections.
- Hand hygiene greatly reduces the number of disease-causing microorganisms on hands and arms. It is the most important way of limiting the spread of infection. The hands should be washed with soap and water after each patient/client has been seen; otherwise, an alcohol-based handrub should be used.
- Appropriate personal protective equipment should be worn to protect both clients and staff from infectious microorganisms.
- Sterile gloves should be worn during early infant circumcision procedures or when performing any invasive procedure. A new pair of gloves should be worn for each new client contact in order to avoid spreading infection from person to person.
- All staff should be trained in the proper handling of sharp instruments. Hypodermic (hollow-bore) needles can cause injuries to clinic staff at all levels: workers can be stuck by hypodermic needles during patient care, cleaning and housekeeping. Staff may be exposed to needle-stick and sharps injuries when washing soiled instruments and disposing of infectious waste material.
- Clean or heavy-duty gloves should be worn by staff when handling contaminated items.
- Instruments and other reusable items can transmit disease if not properly decontaminated, cleaned, sterilized or subjected to high-level disinfection.
- High-level disinfection destroys all microorganisms, except some bacterial endospores. Sterilization destroys all microorganisms, including bacterial endospores.
- Proper waste management is important for preventing accidental injury to people who handle waste items and for preventing the spread of infection to health-care workers and the local community.
- Post-exposure prophylaxis for HIV with antiretroviral drugs may reduce the risk of infection after exposure to HIV. It will be effective only if it is started as soon as possible within 72 hours after exposure and if the full course of treatment is adhered to.
- Post-exposure prophylaxis for hepatitis B with immune globulin can reduce the risk of hepatitis B infection. Consideration should be given to vaccinating all workers against hepatitis B.

Basic concepts

Measures to prevent infection in male circumcision programmes have the following primary objectives.

- To prevent infections in people having surgery.
- To minimize the risk of transmitting HIV and other infections to clients and health-care staff, including cleaning and housekeeping staff.

In male circumcision programmes a major concern is the potential transmission of bloodborne pathogens, such as HIV and hepatitis B virus, to health-care workers or patients. The risk of acquiring HIV from an HIV-infected person through a needle-stick injury is estimated at 0.3% (3 HIV infections for every 1000 injuries). The risk of acquiring hepatitis B virus infection, after being stuck with a needle that has been used on a person with hepatitis B infection, ranges from 6% to 37%, with an average of 18%. Finally, the risk of acquiring hepatitis C infection after being stuck with a needle that has been used on a person infected with hepatitis C is 1.8%. Most instances of transmission of infection in health-care facilities can be prevented through the application of standard precautions. In the circumcision clinic, standard precautions, as described below, should be applied to all clients at all times, regardless of their infection status.

Standard precautions

Standard precautions are practices aimed at preventing and controlling infection. They include the use of personal protective equipment, designed to protect health-care workers and patients from contact with infectious agents.

Remember the following points.

- The minimum requirement is that providers should wash their hands with soap and water or use a handrub after each patient has been seen.
- Alcohol-based handrubs do not remove soil or organic matter. Washing with soap and water is recommended between the use of handrubs.
- Staff who frequently wash their hands or use an alcohol-based handrub should use hand lotions and creams regularly in order to minimize drying of the skin and reduce the risk of irritant contact dermatitis. Staff with an allergy or adverse reaction to alcohol-based handrubs should use other handrubs or soap and water. If potentially infectious blood or other body fluid is splashed on to non-intact skin, or if there is a potentially infective percutaneous injury, do not use alcohol-based solutions or strong disinfectants but wash the affected part with water and soap, and seek advice on the need for post-exposure prophylaxis.

Surgical hand scrub

The use of surgical hand scrub is recommended at the beginning of the first procedure of the day and whenever the provider comes back to the procedure room after leaving, e.g. after lunch or after use of the bathroom.

Personal protective equipment

Personal protective equipment (PPE) provides a physical barrier against microorganisms, helping providers to prevent the contamination of hands, eyes, clothing, hair and shoes, and the transmission of infections to patients and other staff. PPE includes gloves, masks, protective eyewear (face shield or goggles), cap or hair cover, apron, gown and footwear (boot or shoe covers). PPE should be used by health-care workers who provide direct care to patients, support staff including medical aides, cleaners, laundry staff and family members who provide care to patients. The ensemble of PPE worn by staff should be appropriate to the level of potential exposure (to both staff and patients). Reusable PPE (e.g. plastic aprons) should be decontaminated according to the manufacturer's instructions or laundered according to the protocol of the health-care facility.

For early infant male circumcision procedure the following PPE is recommended.

Gloves: The use of gloves does not replace the need for hand hygiene by either hand-rubbing or hand-washing. Gloves should be worn during and after caring for a patient. Gloves should not be reused to provide care to more than one patient.

Masks (optional): Masks protect the mucous membranes of the mouth and nose from possible infections, as well as reducing the risks of transmission of infections from the health-care worker. They should be worn by anyone undertaking a procedure that is likely to generate splashes of blood, blood products and body fluids. Surgical masks are designed to resist fluids, and are preferable to cotton or gauze masks. The use of masks is optional as their benefit during minor procedures is questionable.

Aprons and the surgeon's gown: Aprons made of rubber or plastic provide a waterproof barrier to keep contaminated fluids off the health worker's clothing and skin. Staff should wear aprons when cleaning instruments and other items used for patient care.

Immunizations

Certain vaccines, e.g. hepatitis B vaccine, can be useful in protecting health-care workers against diseases that they may be exposed to during their work. Follow the protocols of health facilities' regulations on immunization.

Safe handling of hypodermic needles and syringes

All clinic staff should be trained in the safe handling of sharp instruments. Hypodermic (hollow-bore) needles are the most common cause of injuries to all types of clinic workers.

- Health-care workers are most often stuck by hypodermic needles during patient care.
- Cleaning staff are most often stuck by needles when washing soiled instruments.
- Housekeeping staff are most often stuck by needles when disposing of infectious waste material.

- Tips for the safe use of hypodermic needles and syringes:
  - disposable needles and syringes must be used only once;
  - do not disassemble the needle and syringe after use;
  - do not bend or break needles before disposal;
  - dispose of needles and syringes together in a puncture-resistant container.

In general, it is safer to dispose of a needle and syringe directly into a sharps container without recapping. If a needle must be recapped, use the one-handed recapping method as follows.

- Place the needle cap on a firm flat surface.
- Holding the syringe with one hand, use the needle to scoop up the cap.
- With the cap over the needle tip, turn the syringe upright (vertical) so that the needle is pointing towards the ceiling.
- With the forefinger and thumb of your other hand, grasp the cap just above its open end and push it firmly down on to the hub (the place where the needle joins the syringe).

Sharps containers

Clearly labelled, puncture-proof and tamper-proof sharps safety boxes or containers are a key component in efforts to keep injuries from disposable sharps to a minimum.

- Place sharps containers as close to the point of use as possible and practical (ideally within arm's reach), but away from busy areas. Avoid placing containers near light switches, overhead fans or thermostat controls, where people might accidentally put their hands into them.
- Attach containers to walls or other surfaces, if possible, at a convenient height, so that staff can use and replace them easily.
- Mark the containers clearly so that people will not mistakenly use them as rubbish bins.
- Mark the fill line (at the three-quarters-full level). Do not shake the container to settle its contents to make room for more sharps. Never fill the containers more than three-quarters.
- Never attempt to empty a sharps container.

Processing of instruments, environmental cleaning and management of spills

Soiled instruments and other reusable items can transmit infection if they are not properly reprocessed. Effective and safe reprocessing includes decontamination of instruments and equipment immediately after use, cleaning to remove all organic matter and chemicals, and high-level disinfection or sterilization of instruments used in normally sterile critical sites, i.e. within the body, in sterile tissue, cavities or the bloodstream. Before sterilization, all equipment must be decontaminated and then cleaned to remove debris. Sterilization is intended to kill living organisms.

Disinfectant solutions are used to inactivate any infectious agents that may be present in blood or other body fluids. They must always be available for cleaning working surfaces, equipment that cannot be autoclaved and non-disposable items, and for dealing with any spillages involving pathological specimens or other known infectious material.

For decontamination, used instruments should routinely be soaked in a chemical solution (0.5% chlorine) for 10 minutes before cleaning. Decontamination decreases the viral and bacterial burden of an instrument but does not clean debris from the instrument or sterilize it. The purpose of decontamination is to reduce the risk to those who have to handle the instruments during further cleaning. Decontamination is not a sterilizing process and must not be used as a substitute for sterilization.

There are many disinfectant solutions and their effectiveness varies. In most countries the most widely available disinfectant is sodium hypochlorite solution (commonly known as bleach or chloros), which is a particularly effective antiviral agent.

For cleaning, all used instruments and equipment must be treated with detergent and water before being subjected to high-level disinfection or sterilized. Otherwise, organic matter may prevent adequate contact with the disinfectant or sterilizing agent. Organic matter may also bind and inactivate chemical disinfectants.

Instructions for manual cleaning

- Wear thick household or utility gloves.
- Wear protective eyewear, mask and plastic apron, if available, to prevent contaminated fluids from splashing into your eyes or on to your body.
- Use liquid soap, if available. Do not use abrasive cleaners or steel wool, especially on metal (they cause scratches and increase the risk of rusting).
- Using a soft brush, scrub instruments under the surface of the water to prevent splashing, paying particular attention to any teeth, joints or screws.
- Rinse the instruments with clean water.
- Dry the instruments with a towel or allow them to air-dry.

High-level disinfection

High-level disinfection destroys all microorganisms except some bacterial endospores. It is usually used for heat-sensitive instruments and equipment that is used in critical sites but cannot be sterilized. High-level disinfection is the only acceptable alternative to sterilization for heat-sensitive surgical instruments. There is no single ideal disinfectant. Different grades of disinfectant are used for different purposes. However, glutaral (glutaraldehyde) is generally the most appropriate chemical for high-level disinfection. It must be used under very strictly controlled conditions, in a safe working environment, and the manufacturer's handling instructions must be strictly followed. In situations where sterilization is not possible for equipment used for circumcision, high-level disinfection is the next best acceptable method of instrument processing.

Sterilization

Sterilization is the destruction of all microorganisms, including bacterial endospores. Sterilization can be achieved by either physical or chemical methods. It is necessary for medical devices that will be used in sterile body sites and can be achieved using:

- high-pressure steam (autoclave) or dry heat (oven);
- chemicals, such as ethylene oxide or formaldehyde, or glutaraldehyde if left for 10 hours;[120]
- radiation.

Sterilization of all surgical instruments and supplies is crucial in preventing HIV transmission. All viruses, including HIV, are inactivated by high-pressure steam sterilization (autoclaving) for 20 minutes at 121–132 °C, or for 30 minutes if the instruments are in wrapped packs. Items that have been sterilized must be properly stored in order to ensure that they do not become recontaminated.

- The storage area should be clean, dry and free of dust and lint.
- The temperature should be kept at approximately 24 °C and the relative humidity at less than 70%, if possible.
- Sterile packs and containers should be stored 20–25 cm off the floor, 45–50 cm from the ceiling and 15–20 cm from an outside wall.
- Do not use cardboard boxes for storage of sterile items, as they shed dust and debris and may harbour insects.
- Mark the date of sterilization on the package and use the oldest packages first (i.e. first in, first out). Dates serve as an indicator of when packs should be used, but they do not guarantee the sterility of the packs. It is therefore necessary to examine the general condition of packs.

Safe disposal of infectious waste materials

Waste management

The purpose of waste management is to:

- protect people who handle waste items from accidental injury;
- prevent the spread of infection to health-care workers and the local community.

Tips for safe handling and disposal of infectious waste

- Place waste in plastic or galvanized metal containers with tightly fitting colour-coded covers that differentiate infectious from noninfectious waste.
- Place all disposable sharps in designated puncture-resistant containers.
- Place waste containers close to where the waste is generated in a position convenient for users.
- Ensure that equipment used to hold and transport waste is not used for any other purpose.
- Regularly clean all waste containers with a disinfectant (0.5% chlorine solution), then wash with water and soap, rinse with water only, and allow to air-dry.
- When possible, use separate containers for waste that will be treated or that will be disposed of in a particular manner. In this way, workers will not have to handle and separate waste by hand.

Disposing of sharp items

Disposable sharp items, such as hypodermic needles, require special handling. They are the items most likely to injure the health-care workers who handle them. If these items are disposed of in a municipal landfill they become a danger to people in the community.

Burning waste containers

Burning destroys waste, kills any microorganisms, and is the best method of disposing of contaminated waste. It reduces the bulk volume of waste and also ensures that items cannot be scavenged and reused.

Encapsulating waste containers

Encapsulation is the easiest way to safely dispose of sharps containers. When a container is three-quarters full, pour cement (mortar), plastic foam, clay or other similar material into it until it is completely full. After the material has hardened, seal the container and dispose of it in a landfill or bury it.

Burying waste

In health-care facilities with limited resources the burial of waste (such as excised foreskins) near the facility may be the only practical option for waste disposal. To limit health risks and environmental pollution, the following basic rules should be followed.

- Restrict access to the disposal site. Build a fence around the site to keep animals and children away.
- Line the burial site with a material of low permeability (e.g. clay), if available.
- Select a site at least 50 metres away from any water source to prevent contamination of the water table.
- Ensure that the site has proper drainage, is located downhill from any wells, is free of standing water and is not in an area that floods.

Post-exposure prophylaxis

Health-care workers may be accidentally exposed to blood and other body fluids that are potentially infected with HIV, hepatitis virus or other bloodborne pathogens. Occupational exposure may occur through direct contact of non-intact skin with potentially infected blood or body fluids, from splashes into the eyes or mouth, or through injury with a used needle or sharp instrument. PEP can help to prevent the transmission of pathogens after such an exposure.

Managing occupational exposure to hepatitis B, hepatitis C and HIV

The immediate response to exposure to blood or other fluids that are potentially infected with hepatitis B virus (HBV), hepatitis C virus (HCV) or HIV are summarized here (more details should be available in routine standard protocols in a facility).

Step 1. Provide immediate first-aid care to the exposure site.

- If a splash or a spill occurs on the skin, wash the area immediately with soap and water. Do not use caustic agents, alcohol or bleach, because they will irritate the skin and may increase the risk of infection. Do not apply a dressing.
- If a splash or a spill occurs in the eyes, the nose, the mouth or on any mucous membrane, rinse the area with clean water for at least 10 minutes.
- If an injury has been caused by a potentially contaminated sharp, wash the area with soapy water and allow the wound to bleed freely (do not squeeze) for a while. Then give normal first aid.

Step 2. Evaluate the risk by determining the type of fluid (blood, visibly bloody fluid, or other potentially infectious fluid), the severity and type of exposure (percutaneous or needle-stick, mucous membranes, intact or non-intact skin) and the source of infection.

Step 3. If the source person is identified it is important to obtain information on her or his hepatitis and HIV serostatus, and, if positive, to conduct an evaluation of the clinical status and treatment history.

- Assess the risk of infection, using available information.
- The source person may be tested only with her or his informed consent.
- Do not test discarded needles or syringes for virus contamination.
- After the result, refer the health-care worker to receive PEP if available in the same facility (according to national guidelines). The client should be linked to care and treatment services if this is the first time.

Chapter 12: Introduction to monitoring and evaluation

Background

Early infant male circumcision services are envisioned to be integrated into countries' MNCH service delivery models. As with many other health programmes, their expansion and/or initiation has to be assessed on the basis of their overall benefits.

Definition: Monitoring is the routine process of data collection and reporting for the measurement of progress toward programme objectives.

- Monitoring involves counting what is being done.
- Monitoring involves routinely looking at the data collected to inform the services and programme delivery.

Definition: Evaluation is the use of social research methods to systematically investigate a programme's effectiveness. It is more rigorous than monitoring and involves special studies.

Goals and objectives

The core of any monitoring and evaluation (M&E) system is the goals and objectives of the programme to be monitored and evaluated. If the goals and objectives are written so that they can be easily distinguished from one another and measured, the M&E work will be much easier. Unfortunately, goals and objectives are often not written so that they can be easily monitored or evaluated.

Goal: General statement that describes the hoped-for result of a programme (e.g. increased circumcision prevalence amongst children age 0–1 year, integration of early infant circumcision into MNCH care services). Goals are achieved over the long term (5–10 years) and through the combined efforts of multiple programmes.

Objective: Specific and operationalized statement detailing the desired accomplishment of the programme. A properly stated objective is action-oriented, starts with the word "To", and is followed by an action verb. Objectives address questions of "what" and "when" but not of "why" or "how". Objectives are stated in terms of results to be achieved, not processes or activities to be performed.

Global, national, and health facility indicators

Indicators are clues, signs and markers as to how close we are to our path and how much things are changing. They point to or indicate possible changes in the situation that may lead to improved health status. An analogy: in a motor car the fuel gauge shows how much fuel there is; one does not look at the fuel itself but at an indicator of the amount remaining.

Examples of indicators for HIV programmes are:

- the number of adult circumcision sites/clinics set up in the past year;
- the number of clinicians trained in syndromic management of sexually transmitted infections in the last 6 months;
- the percentage of men who have developed side-effects while on a first-line regimen;
- the number of HIV-infected pregnant women started on zidovudine and nevirapine.

Indicators for early infant male circumcision programmes

Global indicators

Global indicators are generally limited to the final step of the programme cycle and a few key outcomes. Based on national indicators, they:

- reflect, in a few summary numbers, the current worldwide situation regarding infant circumcision efforts;
- provide a picture of how countries, on average, are addressing infant circumcision;
- help donors to understand how to assess the results of past spending and to prioritize future funding.

Example of a global indicator: Number of male circumcisions performed by age.

National indicators

National indicators usually address several steps of the programme cycle. Obtained from information provided at the local level, they:

- reflect the goals, objectives and activities of the national programme;
- assess the safety and effectiveness of the national response to scaling up neonatal circumcision.

Example of a national indicator: Number of health-care facilities delivering early infant male circumcision services.

Health-care facility indicators

Health-care facility indicators (information collected at health-care facilities) are essential to monitoring and evaluation and to the provision of quality health-care services to patients. National and global indicators are often based on health-care facility indicators.

Health-care facility indicators:

- help staff to set targets and track progress towards reaching goals, e.g. coverage for neonates in need of circumcision services;
- help to identify progress, problems and challenges;
- help to find solutions to the problems of increasing coverage/scale-up and improving the quality of care.

Example of a health-care facility indicator: Number and percentage of males experiencing at least one moderate or severe adverse event during or following the procedure.

Selecting indicators

One of the critical steps in designing and conducting an M&E system is selecting the most appropriate indicators. Indicators should always be directly related to the project or programme objective, so the process of selecting indicators can be fairly straightforward if the programme objectives have been presented clearly and in terms that define the quantity, quality and time frame of a particular aspect of the programme. Selecting indicators and setting targets is usually done during programme planning, preferably with input from key stakeholders such as the ministry of health, implementing agencies, etc.

Even with well-defined objectives, however, selecting evaluation indicators requires careful thought on both the theoretical and practical elements. The following questions can be helpful in selecting indicators.

- Have the definitions of the indicators been tested and can objectives be measured accurately (**operational**) and **reliably**?
- Will the indicators measure only what they are supposed to measure (**valid**)?
- Are there areas of overlap in the content of the indicator with that of other indicators; is it **specific** or is it too general?
- Will the indicators be able to measure changes over time (**sensitivity**)?
- What resources (human and financial) do the indicators require (**affordable, feasible**)?
- Are there alternative measures that should be considered?
- Will multiple indicators be able to help clarify the results of the primary objective?

Tools for monitoring and evaluation of early infant male circumcision

Whereas a method refers to the scientific design or approach to monitoring, evaluation or research activity, a data collection tool refers to the instrument used to record the information that will be gathered by a particular method.

Some common quantitative M&E tools include:

- sign-in (registration) logs;
- registration (enrolment, intake) forms;
- checklists;
- programme activity forms;
- logs and tally sheets;
- early infant charts;
- structured questionnaires.

Since the goal of an early infant male circumcision programme is to integrate circumcision into MNCH services, current reporting tools should be reviewed and updated to accommodate the data needs of the programme.

Sample: Early infant male circumcision sample registration form (Annex 13).

Sample: Early infant male circumcision assessment form and procedure form (Annexes 4 and 6).

Sample: Early infant male circumcision monthly report form (Annex 14).

Chapter 13: Early infant male circumcision service delivery and programme management

To be effective an early infant male circumcision programme has to have strong coordination at both the management and service delivery levels. This helps public facilities to provide for a safe male circumcision service of high quality, integrated with the MNCH services and other circumcision service delivery outlets.

Service delivery planning and management

The decision to provide an early infant male circumcision service depends on available resources, including human resources, supplies, client load and infrastructure. The key elements of planning and management are:

- human capacity development
  - staff performance and motivation
  - sufficient staff available to provide safe effective care
- management of equipment, supplies and drugs
- community involvement
- assessment and monitoring
- organization of services, including referral
- assuring safe services of high quality.

Human capacity development

The training requirements for each category of care provider are based on the skills needed to perform the job. It is recommended that early Infant male circumcision be a primary task of non-physician health-care workers. However, this should be in line with national regulations.

Non-physician health-care workers include, but are not limited to, nurses, midwives, clinical officers, health officers and assistant medical officers. Moreover, countries may opt to use physicians and specialists for the male circumcision programme if there are adequate numbers of them for other health-care needs in the country concerned.

The ministry of health can implement an approach to the training of health-care providers in line with its existing capacity-building activities, with reference to both in-service and pre-service aspects. A multidisciplinary team approach is recommended in training courses. Initially, it is important to adopt an in-service training approach that considers the case-load available for early infant procedures.

Management of equipment, supplies and drugs

The procurement, distribution, storage and utilization of equipment and drugs related to early infant circumcision must comply with the management systems of specific national supply chains. Programme managers should make the people in charge of such systems aware of the newer needs of scaling up HIV/AIDS prevention programmes. Managers at programme and facility levels should incorporate the required equipment, supplies and drugs into the routine logistics and procurement systems.

Ensuring community involvement

Understanding the community perspective is essential in planning national early infant male circumcision programmes. It is important to understand the family dynamics of decision-making for early infant male circumcision and the preferred timing of the procedure. Depending on the acceptability of programme roll-out, countries may opt to make early-infant-friendly circumcision services available at more than one location in the community. Education and demand creation for the circumcision of male babies may be carried out at various service delivery points and referral may be made to facilities where the services are being offered. The services for male circumcision should be ready before demand is generated.

Assessment and monitoring

Managers should assess the current state of MNCH services and minor surgical care. They can explore how the services are perceived by clients and the community, how they can help to focus efforts where critical changes are needed, and how to assist managers in establishing efficient services that infants and their parents/guardians will use. (See Chapter 12 for monitoring indicators and questions.)

Programme managers in areas where baseline infant mortality is high should anticipate that, after the implementation of an early infant male circumcision programme, some infant deaths may be inappropriately associated with the procedure. It is important for programme managers to understand baseline mortality rates and monitor them closely so as to appropriately assess the impact of male circumcision on overall infant mortality.

Organization of services

Safe clinical early infant male circumcision programmes should target male infants up to the age of 2 months. Many parents return to health facilities for either immunization or family planning counselling and services within 45 days postpartum. The additional 2 weeks after the usually recommended 6-week postpartum visit helps to accommodate carers who cannot bring an infant within the first week or by the first postpartum visit. Careful clinical and programmatic consideration and skill proficiency are needed in relation to circumcision services after 2 months of life, as the rate of device-related complications increases with age after this time.

Issues to consider in determining when and where services will be offered include the following.

- Integration and linkages: For the provision of male circumcision it is necessary to carefully consider essential neonatal care services (See Annex 15). Every early infant and/or guardian of an early infant coming for male circumcision should have access to all recommended elements of essential neonatal and early infant care, preferably in a single visit.[121] Male circumcision services should also be integrated into routine education and care in antenatal care and into maternity/postnatal care, family planning and immunization care services. The needs of the parents should also be considered and this opportunity should be used to promote good health and provide them with education on HIV prevention.
- Multiple contacts: Parent/guardian education and counselling on safe and clinical early infant circumcision should be available at every antenatal visit and at postnatal visits.
- Convenience: Early infant circumcision services should preferably be located as close to the above service entry points as possible. If this is not feasible, however, the parent/infant is assisted/escorted to the appropriate clean procedure room in the facility so that the service can be provided during the same visit.
- Remove barriers: Assess whether services are early-infant/parent/guardian-friendly. Change processes and procedures that discourage their use (e.g. burdensome or duplicative administrative requirements, cost, long waits, perception that culture is not respected, multiple visits required, not all decision-makers have been informed, perception that the procedure is more risky for babies than adults, lack of transport, cultural barriers such as desire for ritual circumcision later in life, religious beliefs, concerns about infant's pain/discomfort, other risks).
- Comprehensive approach: Provide comprehensive care for the infant, including: intake, physical assessment, history-taking, education/counselling, appropriate care based on these steps, return visits, identification and referral for other health-care needs.
- Exclusion criteria: In order for providers to rule out the presence of any other neonatal conditions, circumcision should not be performed until at least 12 to 24 hours after birth.[122] This recommendation is based on the projected time needed for providers of neonatal care and treatment to perform a complete assessment of the neonate and ensure that the infant is stable.

Possible exclusion criteria for early infant male circumcision include:

- family history of bleeding disorder
- estimated infant gestational age <37 weeks
- infant delivery weight <2500 g
- infant receipt of methaemoglobin-inducing agents (for EMLA cream precaution) (Annex 5)
- neonatal sepsis or other severe illness requiring infant hospitalization
- penile abnormality that might require reconstructive surgery in the future or other abnormality that is a contraindication for circumcision:
  - penile torsion / median raphe not midline
  - hypospadias / blind urethral pit
  - buried penis
  - penile-scrotal web
  - hydrocoele
  - dorsal hood / ventral foreskin missing
  - lack of scrotal ruggae suggesting lack of testicles bilaterally as could be karyotypic XX gene
  - megameatus
  - any other abnormality that may require consultation with urologist.

Quality assurance

Quality assurance is the assessment or measurement of the quality of care and services and the implementation of any necessary changes to either maintain or improve the quality of care rendered. The quality of male circumcision services can be defined through the development and communication of standards. WHO has developed a comprehensive guide to quality assurance for male circumcision programmes.[123] It outlines the process of quality assessment and includes guidance for facility managers and staff. The guide defines ten service standards that each programme should meet (Box 1) and includes the essential competences for the provision of male circumcision services. All relevant staff members should be familiar with these standards.

Box 1. WHO-recommended standards for male circumcision services

Standard 1. An effective management system is established to oversee the provision of male circumcision services.

Standard 2*. A minimum package of male circumcision services is provided.

Standard 3. The facility has the necessary medicines, supplies, equipment and environment for providing safe male circumcision services of high quality.

Standard 4. Providers are qualified and competent.

Standard 5. Clients are provided with information, education and counsellng for HIV prevention and male circumcision.

Standard 6. Assessments are performed to determine the client's condition.

Standard 7. Male circumcision surgical care is delivered according to evidence-based guidelines.

Standard 8. Infection prevention and control measures are practised.

Standard 9. Continuity of care is provided.

Standard 10. A system for monitoring and evaluation is established.

**The minimum package of services that are not directly relevant for the infant (e.g. management of sexually transmitted infections, condom promotion and risk reduction counselling) should, as far as possible, still be available to offer to parents. To the extent possible, staff should be trained to provide integrated services for parents and infants. Direct linkages should be established with other sites offering these services to allow for easy referral.*

Referrals

Standing referral and feedback arrangements should be put in place that address key needs around the early infant male circumcision service and opportunities, such as:

- protocol in place for potential referrals related to conditions identified as contraindications, emergencies and serious complications of male circumcision procedures;
- encouragement of HIV counselling and testing for couples among parents who present with an infant, and provision of referral to the service;
- referral of all HIV-exposed infants to care and support, prophylaxis and, if necessary, treatment;
- referral for family planning follow-up, especially for parents/guardians who do not seek routine health services / follow-up in the facility where they delivered;
- referral for appropriate education and support relating to infant feeding options.

Annex 1: Sample checklist for early infant male circumcision equipment

Equipment

☐	Secure work surface (table or infant warmer) with sufficient height for provider.
☐	Assistant or mechanism to restrain/position infant.
☐	Check handwashing/cleaning facilities.
☐	Check light source.

Supplies

☐	Infant padding, blankets and towels.
☐	Clean nappies/diapers and wipes.
☐	Sterile gloves.
☐	Sterile drapes with small opening in the centre (fenestration).
☐	Betadyne or other skin-sterilizing preparations.
☐	Sterile marking pen or gentian violet.
☐	Sterile 2 x 2 or 4 x 4 gauze pads.
☐	White petrolatum (Vaseline) or white petrolatum gauze.

Instruments

☐	Instrument trays, wrapped and sterile.
☐	One 7.5-cm to 12.5-inch flexible probe.
☐	Three small mosquito haemostats, two curved and one straight.
☐	Small straight scissors.
☐	Desired male circumcision device (Mogen, Gomco or Plastibell).
☐	Scalpel (no. 10 blade or similar).

Anaesthesia administration

☐	1% lidocaine (**WITHOUT EPINEPHRINE**).
☐	1-ml sterile syringes with small 27-gauge or similar needle.
☐	Alcohol wipes.

Post-circumcision bleeding

☐	Topical epinephrine.
☐	Gel foam or equivalent.
☐	Adson forceps.
☐	5-0 absorbable suture (chromic or catgut) on a needle.
☐	Needle holder.
☐	Petroleum-coated gauze.

Annex 2: Sample information sheet for early infant male circumcision

Circumcision is the surgical removal of all or part of the foreskin covering the end of the penis. The decision to have an infant male circumcised is very personal and should only be made after careful consideration. The following information is provided to help you make an informed decision. We encourage you to discuss any questions or concerns with your health-care providers.

Benefits of male circumcision

1. Cleanliness – Under certain circumstances, dirt, sand, lint and other irritants can collect under the foreskin and cause inflammation and infection. Male circumcision helps to prevent this type of irritation and makes it easier to clean the head of the penis.
2. Prevention of paraphimosis, an extremely rare condition that occurs when the foreskin becomes retracted or pulled down below the tip of the penis and becomes stuck. The tissue can become swollen and can decrease the blood flow to the tip of the penis, requiring urgent surgery to correct the problem. Circumcision prevents this complication from occurring.
3. Decreased risk of urinary tract infections. Circumcision decreases the risk of urinary tract infections in males, both infants and adults. Uncircumcised infants have a 1% chance of acquiring a urinary tract infection. This type of infection is 10 times less common in circumcised infants, for whom there is only a 0.1% chance of developing a urinary tract infection.
4. Decreased risk of HIV infection. Circumcision has been proved to help prevent female to male transmission of HIV, reducing the risk of transmission by 60–70%.
5. Decreased risk of other sexually transmitted diseases. Circumcision has been proved to help protect against contracting genital herpes and some other sexually transmitted diseases.
6. Prevention of cancer of the penis. Cancer of the penis is extremely rare but occurs much more commonly in men who are uncircumcised than in those who are circumcised.
7. Prevention of cervical cancer in female sexual partners. Cervical cancer is less common in women who have sexual partners who are circumcised. Sex with either uncircumcised men or men circumcised after infancy increases a women's risk of cervical cancer.
8. Avoiding the need for circumcision later in life. Some uncircumcised males will require circumcision later in life for medical reasons.

Risks of male circumcision

1. Lack of informed consent. An infant cannot consent to the procedure. The decision must be made by the family. The procedure is considered permanent and there is a risk that when the child is older he will be unhappy he was circumcised as an infant.
2. Pain. This can be reduced and even eliminated with the use of safe and effective medications. Please discuss the use of pain medication with your health-care team.
3. Surgical risk. Complications during male circumcision are rare, being estimated to occur in 1 of every 500 procedures. These complications, which can be severe, include poor cosmetic outcome, bleeding, infection, injury to the penis and the removal of too much or too little skin.
4. Expense. There may be a cost associated with the procedure.
5. Change in sexual satisfaction. Some people believe that circumcision leads to decreased sexual pleasure later in life. Data recently collected from a large group of adult males who underwent circumcision later in life suggest that there is no change in sexual satisfaction between circumcised and uncircumcised men and their partners. However, some patients may be unhappy that they were circumcised.

Annex 3: Overview of counselling skills

All counsellors need certain basic counselling skills in order to talk with parents and guardians in a helpful way. Some of these skills are explained below.

Empathizing

Empathy is the ability to see the world through another person's eyes and understand how that person feels. Counsellors should listen to parents or guardians carefully and show them that they understand without judging. Empathy is not sympathy. It is not feeling sorry for the client but understanding the parent's or guardian's feelings.

Active listening

Active listening involves paying attention to what a guardian or parent says and does, in a way that shows respect, interest and empathy. Active listening is more than just hearing what parents or guardians say. It is paying attention to the content of the message as well as to the feelings and worries that show through movements, tone of voice, facial expressions and posture.

Open questioning

Open questions require more than a one-word, "Yes/No" type of answer. They usually begin with words such as "How", "What" or "Why". Open questions encourage parents or guardians to express their feelings and share information about their situation.

Probing

Probing involves using questions to help parents or guardians express themselves more clearly. It is necessary when the counsellor needs more information about the parent's or guardian's feelings or situation. Asking a probing question is a good way to follow up on a question that has been answered by "Yes" or "No".

Focusing

Focusing allows the patient to share concerns and worries more easily. Parents or guardians are often overwhelmed by emotional or personal problems related to their particular child's needs or health problems. They may want to address all the issues at once. If parents or guardians start to talk about problems or situations that will be discussed later in the session, the counsellor may want to bring the topic of discussion back to the current issue.

Affirming

Affirming is congratulating or complimenting parents or guardians on the positive actions that they have taken. It is important to encourage success. Complimenting parents or guardians helps them to feel respected and valued and encourages them to try to make other changes to enhance good health choices for their children. It may also make them more willing to share information about other actions they have taken.

Clarifying

Counsellors clarify in order to make sure that they understand parents' or guardians' statements or questions. Clarifying also helps parents or guardians to understand their own situation or feelings better and to identify uncertainty or conflict between their thoughts and behaviour.

Pointing out a conflict may help a parent or guardian to identify which of two issues is more important to them. This is better than the counsellor telling the parent or guardian to do something that he or she is not ready to accept. Clarifying also helps parents or guardians to make their own choices and draw their own conclusions. Saying "Help me to understand this" is a good way to begin this type of discussion

Correcting false information

It is important to provide correct information to parents or guardians and to correct any myths and false information. There are many incorrect rumours about male circumcision. These should be corrected. However, this needs to be done in a sensitive way, without making the parent or guardian feel belittled or defensive. Counsellors should acknowledge false information and then correct it quickly. It is not necessary to give detailed explanations.

Summarizing

Counsellors summarize in order to present the main points of the conversation to parents or guardians. Summarizing can be useful when moving to another topic or ending the session, and to make sure that counsellor and parent or guardian have understood each other correctly. Summarizing also helps parents or guardians see the whole picture and understand the situation better.

Confidentiality

Confidentiality is an important characteristic of all health services. Counsellors should keep all information private and allow parents or guardians to decide when and with whom to discuss the infant male circumcision issues and other health problems. Parents or guardians will feel more comfortable about sharing personal information with counsellors if they know that it will remain private. An atmosphere of trust will encourage parents or guardians to discuss other health needs of their children.

Annex 4: Sample client record form for early infant male circumcision

NAME OF PATIENT (BLOCK CAPITALS)	
DATE OF PROCEDURE	DATE OF BIRTH

General information

Name of parent/guardian:				
Address Line 1:				
Address Line 2:				
Card ID number:				
Place of delivery:	☐ Same facility	☐ Different facility	☐ Home	
	☐ Other _____ (specify)			
Ethnicity:				
Religion of parent/guardian:				
Primary reason for MC:				
HIV test/exposure status:	HIV test performed for mother	☐ Yes	☐ No	
	HIV test result of mother	☐ n/a	☐ -ve	☐+ve
	HIV test performed for father	☐ Yes	☐ No	
	HIV test result for father	☐ n/a	☐ -ve	☐+ve

Medical history

Bleeding disorder:	☐ No	☐ Yes	Convulsions:	☐ No	☐ Yes
Premature delivery:	☐ No	☐ Yes	Hospitalization:	☐ No	☐ Yes
Fever:	☐ No	☐ Yes	Swelling of scrotum:	☐ No	☐ Yes
Other (specify):	_____				

Physical examination

Birth weight <2.5 kg:	☐ No	☐ Yes	Normal cardiac examination:	☐ Yes	☐ No
Growth <5th centile:	☐ No	☐ Yes	Normal pulmonary examination:	☐ Yes	☐ No
Specify abnormal findings:	_____				
Penile torsion	☐ No	☐ Yes	Median raphe not midline	☐ No	☐ Yes
Hypospadias	☐ No	☐ Yes	Abnormal urethra	☐ No	☐ Yes
Buried penis	☐ No	☐ Yes	Penile scrotal web	☐ No	☐ Yes
Hydrocele	☐ No	☐ Yes	Dorsal hood	☐ No	☐ Yes
Buried penis	☐ No	☐ Yes	Penile scrotal web	☐ No	☐ Yes
Abnormal scrotal ruggae	☐ No	☐ Yes	Abnormal ventral foreskin	☐ No	☐ Yes
Abnormal findings:	_____				

Suitable for male circumcision

Is infant suitable for male circumcision at this clinic?	☐ Yes	☐ No
Is infant in good general health?	☐ Yes	☐ No
Have infant's parents/guardians given informed consent?	☐ Yes	☐ No

If there is any question about suitability, male circumcision should be delayed.

Annex 5: Reported inducers of methaemoglobinaemia

The following exposures should be considered when using EMLA cream to reduce the risk of methaemoglobinaemia.

Reported inducers of methaemoglobinaemia	
Agent	**Sources/drugs**
Inorganic nitrates/nitrites	Contaminated well water Meat preservatives Vegetables, i.e. carrot juice, spinach Silver nitrate burn therapy Industrial salts Contaminants of nitrous oxide canisters for anaesthesia
Butyl/isobutyl nitrite	Room deodorizer propellants
Amyl nitrite	Inhalant in cyanide antidote kit
Nitroglycerin	Pharmaceuticals for treatment of angina
Aniline/aminophenols	Laundry ink
Nitrobenzene	Industrial solvents; gun-cleaning products
Sulfonamides	Antibacterial drugs
Phenazopyridine	Pyridium
Antimalarials	Chloroquine; primaquine
Sulfones	Dapsone
p-aminosalicylic acid	Bactericide (tuberculostatic)
Naphthalene	Mothballs
Copper sulfate	Fungicides for plants, seed treatments
Resorcinol	Antiseborrheic, antipruritic, antiseptic
Chlorates	Matches, explosives, pyrotechnics
Combustion products	Fires
Local anaesthetics	Benzocaine; lidocaine; propitocaine; prilocaine

Annex 6: Sample checklist for early infant male circumcision procedure

Procedure preparation, education and screening

☐	Ensure availability of appropriate instruments and supplies	Review *Male circumcision equipment checklist*
☐	Provide information to parents / legal guardians as to risks and benefits of MC	Review *Male circumcision information handout*
☐	Determine if the parents / legal guardians want their child to undergo MC	Review *Male circumcision consent form* and sign
☐	Thoroughly wash/clean hands	
☐	Screen patient to determine eligibility for early infant male circumcision (history and physical)	Review *Male circumcision client record form*
☐	Ensure identity of infant	Safe surgery 'time out' (safety check)

Patient preparation

☐	Determine device and appropriate size. Ensure device has been properly sterilized.
☐	Determine and prepare most appropriate form of anaesthesia.
☐	Position patient.
☐	Prepare the surgical area with providone iodine or equivalent antiseptic agent.
☐	Put on sterile gloves and proceed using sterile technique.
☐	Inspect/assemble device, ensure size and that the Gomco has matching device parts.
☐	Drape the surgical area.

Prepuce preparation

☐	Mark the location of the incision at the corona. The penis should be clean and dry.
☐	Administer anaesthesia. Wait for effectiveness.
☐	Grasp foreskin with two curved haemostats at 3:00 and 9:00.
☐	Remove adhesions using blunt, flexible probe.
☐	Dilate foreskin opening or, if necessary, create dorsal slit (optional for Mogen clamp).
☐	Retract foreskin (optional for all devices).

Mogen		Gomco		Plastibell	
☐	Apply dorsal haemostat.	☐	Insert bell/shield.	☐	Loosely apply ligature.
☐	Approximate foreskin.	☐	Apply Gomco clamp.	☐	Insert bell/shield.
☐	Apply Mogen clamp.	☐	Align foreskin.	☐	Align foreskin.
☐	Align foreskin.	☐	Activate clamp.	☐	Tightly apply ligature.
☐	Activate clamp.	☐	Incise foreskin.	☐	Excise extra foreskin.
☐	Incise foreskin.	☐	5-minute clamp time.		
☐	5-minute clamp time.				

Immediately postoperative

☐	Inspect for any injury to surrounding structures.
☐	Remove any residual adhesions, optional (Gomco/Mogen).
☐	Reduce foreskin below corona (Gomco/Mogen).
☐	Apply petroleum-coated ribbon dressing (Gomco/Mogen). Instructions should be posted in procedure room.
☐	Monitor bleeding and urine output – all devices. Bleeding protocol should be posted in procedure room.

Post-procedure documentation and education

☐	Complete procedure note.
☐	Review post-circumcision care instruction.
☐	Review post-circumcision precautions.
☐	Review emergency contact information.

Postoperative processing

☐	Check sterilization and reprocessing equipment.
☐	Check sharps container (way to handle / dispose of contaminated sharps).
☐	Check waste container (way to handle / dispose of contaminated supplies).

Annex 7: Sample consent form for early infant male circumcision

NAME OF PATIENT (BLOCK CAPITALS)	
DATE OF PROCEDURE	DATE OF BIRTH

Parent / legal guardian's name: _____

Relation to patient/child: _____

I am the boy's parent / legal guardian.

I am asking you to do a circumcision operation (removal of the foreskin) on my son/ward and I give you permission to do this operation.

Signed .....
(Parent or legal guardian)

Name of counsellor/surgeon: _____ (BLOCK CAPITALS)

I am the counsellor/surgeon who has given information to the parent or guardian of the above-mentioned boy.

I have given information about:

- what circumcision is;
- the benefits of circumcision;
- how circumcision is done;
- the risks of circumcision;
- what to do before circumcision;
- what to do after circumcision;
- what to do if there are any complications or problems after circumcision;
- an emergency contact number and where to go in an emergency.

I have given the client an opportunity to ask me questions about all the above.

I have asked the parent or guardian some questions to make sure that he or she understands the information I have given.

To the best of my belief the client is capable of giving consent and has enough information to make a proper decision about whether to proceed with the operation of circumcision.

Signed .....
(Clinic counsellor or surgeon)

Annex 8: Sample documentation form for early infant male circumcision procedure

NAME OF PATIENT (BLOCK CAPITALS)	
DATE OF PROCEDURE	DATE OF BIRTH

Infant

☐	Term
☐	Informed consent has been obtained and documented
☐	No family history of bleeding was reported
☐	Patient examined and no urological/anatomical abnormalities were noted
☐	Patient identity checked and vital signs reviewed
☐	Safety pause
☐	Patient positioned and prepared and procedure completed using sterile technique

Anaesthesia

☐	Lidocaine 1% without epinephrine ☐ 1 ml sc ☐ _____*(dose and route)*
☐	Dorsal penile nerve block ☐ Penile ring block
☐	Oral sucrose administration ☐ EMLA cream

Procedure

Device used: ☐ Gomco ☐ Mogen ☐ Plastibell _____*(device size)*	
Haemostasis was obtained using: ☐ No intervention ☐ Direct pressure ☐ Liquid epinephrine ☐ Surgical ☐ Suture _____*(type and number)*	
☐	Patient tolerated procedure well
☐	No complications were observed and good cosmetic outcome was obtained
☐	Blood loss was minimal
☐	Vaseline-impregnated sterile gauze dressing applied
Notes:	

Postoperative care

☐	Patient returned to parent/guardian in excellent condition
☐	Postoperative care instructions reviewed with parent/guardian
☐	Postoperative precautions reviewed with parent/guardian
☐	Emergency contact information/procedures reviewed with parent/guardian

Surgeon's signature: _____

Surgeon's name: _____

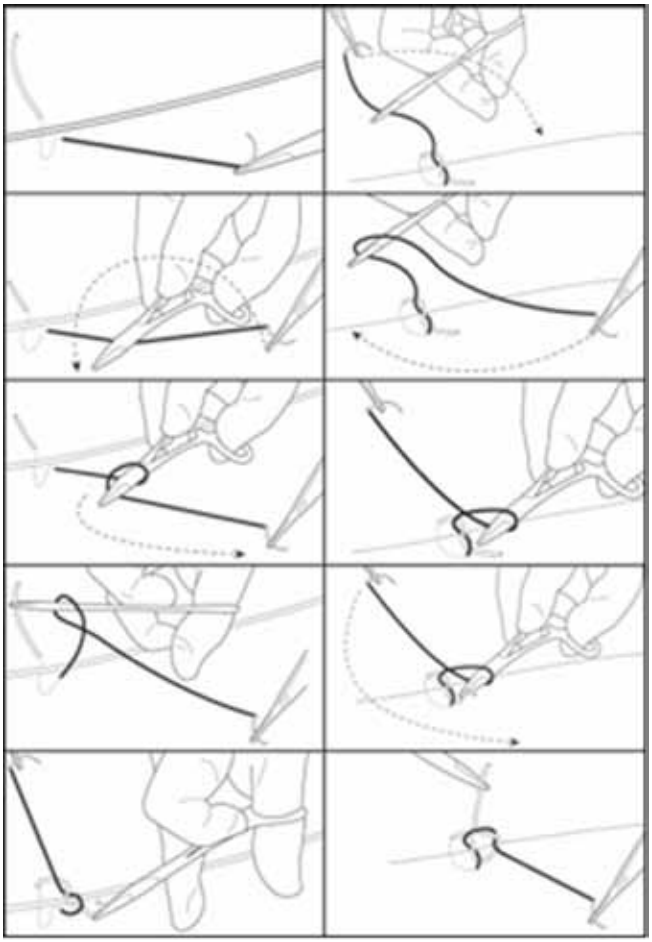
Annex 9: Overview of suturing and wound closure

Most early infant male circumcisions will not require any type of suturing or wound closure. Once the incision is made and the clamp is released, the wound is managed conservatively without primary closure. In very rare cases, however, the need may arise to close the wound and/or use a suture to ligate a vessel for haemostasis.

To close a circumcision wound the edges of the foreskin are sutured together with 5/0 or 6/0 vicryl or chromic catgut sutures and a round-bodied needle. Cutting needles should not be used. The suture size is a compromise between ensuring adequate tensile strength and keeping the amount of foreign material to a minimum.

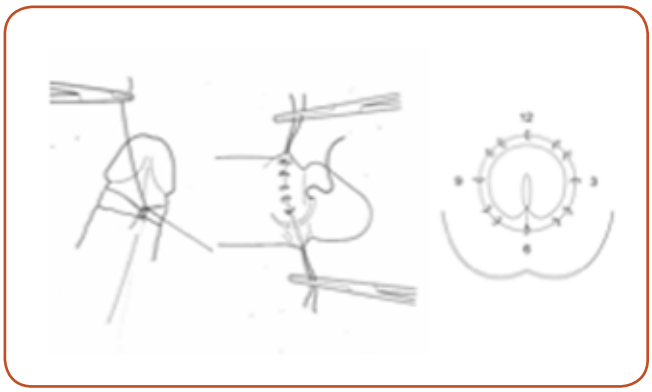
Approximate the skin edges using simple sutures, as shown below. More complex mattress sutures are not necessary.

Figure. A.1. Technique for applying a simple suture



Before approximating the skin, ensure that the frenulum is aligned at the 6 o'clock position. Take great care in this area, because the urethra is near the ventral surface and can easily be injured by too deep a stitch bite. Place all sutures approximately 1 mm from the skin edge. Place the first two sutures at the 12 o'clock and 6 o'clock positions, leaving them long and temporarily held with forceps (Figure A.2). This keeps the penis stable while the remaining sutures are completed. In infants, only two further stitches may be needed on each side.

Figure A.2. Suturing the circumcision wound



Annex 10: Sample postoperative information sheet for early infant male circumcision

1. My child has gauze wrapped around his penis. When should this come off?

If it does not fall off on its own the gauze should be removed in 48 hours. To remove the gauze it should be soaked with warm water and then carefully unwrapped. If bleeding occurs follow the instructions below.

2. What do I need to do to take care of the area that is healing?

No special care is needed except placing petroleum jelly (Vaseline/A&D ointment) on the penis. Apply a lot, this will protect the area that is healing and prevent the penis from sticking to the nappy/diaper. Apply this with every nappy change for the first 3–5 days following the circumcision or longer if the penis still looks as if it is healing and may stick to the nappy. If an absorbable nappy is not available the infant may be left bare and the healing area should be kept as clean and dry as possible.

3. What if there is bleeding?

A small amount of blood on the gauze or nappy is almost always present and is normal. If you see blood soaking the nappy or making a spot greater in size then your two thumbs, you should seek medical attention. If an area begins to bleed when you are changing the nappy, hold direct pressure with gauze on the site for 5 minutes. This should stop the bleeding but if it does not do so you should continue holding pressure on the area and seek medical attention.

4. There is something on the penis that looks like pus. Should I be worried?

During the healing process a shiny white or yellowish film may cover part of the penis. This coating is part of the healing process and cannot be easily removed with a moist wipe. This is normal. However, if you see a yellowish discharge that you can wipe away, has a foul odour and is causing increasing redness and swelling, seek medical attention. A general rule is that the healing area will have some swelling and redness but should start to look better 48 hours after the procedure. Subsequently, the healing area should continue to look better every day. If your infant ever develops a fever, stops having wet nappies/diapers, stops eating or becomes inconsolable, or if the area appears to be infected or not healing, seek medical attention.

5. How long does it take to heal?

It may take several days to a week for a circumcision to heal completely. During this time you should be gentle around the area and try to keep the area clean until it has completely healed. Most circumcisions will be fully healed by 2 weeks.

6. The foreskin looks as if it is coming back over the head of the penis. Is that OK?

Most babies develop a small area of fat at the base of the penis during the first year of life. This is normal and can cause some of the skin of the penis to get pushed up and cover part of the head of the penis. The penis may look buried or uncircumcised. It is important to gently retract the skin to the base of the head of the penis several times a day to prevent the foreskin from reattaching to the head of the penis. As your infant grows, this should get better with more of the tip of the penis showing all the time. Not all babies have this fat pad and so the look of the circumcision is not always the same in different children, even when the correct amount of skin is removed during the circumcision.

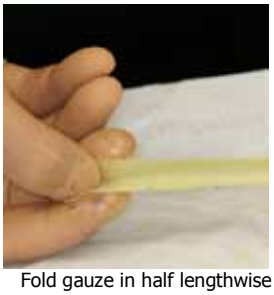
7. If you have any questions about the circumcision wound or the care of your infant, please call your local health-care provider.

Annex 11: Sample wound-dressing poster for early infant male circumcision

Ensure foreskin is reduced below the glans

Open xeroform gauze pack

Stretch gauze until it is straight



Fold gauze in half lengthwise

Flaten with your finger

Apply liberal amount of petrolatum (Vaseline/A&D ointment)

Wrap gauze around the shaft of the penis

Ensure the glans can be visualized to observe for bleeding and allow for the passage of urine

Pull gauze until the dressing is snugly applied to the wound

Wrap the remainder of the dressing neatly around the penis

Apply liberal amount of petrolatum to the tip of the penis and apply diaper

If dressing is tightly applied monitor urine output closely

Alternative to xeroform gauze

Unfold 2 x 2 or 4 x 4 gauze pad

Fold gauze pad into 1-inch strip and apply a liberal amount of petrolatum

Fold dressing in half lengthwise, impregnating the gauze with petrolatum

Apply liberal amount of petrolatum and apply as above

Note: If bleeding occurs, direct pressure should be applied over the dressing. The dressing can be left on for 24 to 48 hours and should be removed only after being thoroughly soaked with warm water during bathing. While the dressing is on, bleeding and urine output should be closely monitored.

Annex 12: Sample postoperative bleeding protocol for early infant male circumcision

Prevention

1. Enquire about a family history of bleeding disorders.
2. Use a flexible probe to remove adhesions in place of a haemostat to avoid injuring the frenular artery.
3. Move the flexible probe up and down, ensuring that the adhesions have been adequately removed, before application of the clamp and incising the foreskin.
4. If subcoronal adhesions exist following the procedure, gently reduce these by using gauze to separate the foreskin from the glans. Try to avoid disrupting the wound.
5. Use a 5-minute clamp time (by the clock) as originally described by Dr Yellen, the inventor of the Gomco clamp.
6. Use a dressing that is well applied to the wound and not just placed on top of the penis.

How to manage bleeding with clamping devices

1. Don't panic. During many traditional circumcisions, the foreskin is never crushed before making the incision, yet, even under these extreme circumstances, severe complications from bleeding are rare.
2. Closely inspect the penis to ensure that there has been no injury to the glans or other surrounding structures.
3. Using gauze, apply temporary direct pressure to the wound while carefully applying a firm circumcision dressing.
4. If bleeding continues through or around the dressing, leave the dressing in place and apply direct pressure over it for 5 minutes by the clock.
5. If bleeding continues the dressing should be removed and the wound reinspected. Frenular artery bleeding comes from a small area on the ventral side. If the bleeding is diffuse and rapid, consider the possibility of a bleeding disorder and seek immediate medical and surgical consultation.
6. If the bleeding appears to be minor, reapply a compression dressing and apply direct pressure over the dressing for 10 minutes by the clock. If bleeding continues despite these conservative measures, medical and surgical intervention should be considered while continuing to hold direct pressure.

How to manage bleeding with the Plastibell device

1. Ensure that the ligature is tied tightly. If necessary, retie the tourniquet with a new ligature.
2. During placement of the Plastibell, the frenular artery can be injured, resulting in bleeding. This bleeding will not originate from the skin edge, but from beneath the plastic bell. Cotton-tip applicators can be used to apply pressure in the area of the bleeding through the hole of the Plastibell device.
3. If bleeding cannot be controlled by these means the ligature should be cut and the Plastibell removed. The steps outlined above for clamping devices can then be followed.

Annex 13: Sample register for early infant male circumcision

Name of facility: _____

Type of facility: _____

Region/province: _____

Country: _____

Infant card no.	Infant name	Date of delivery	Place of delivery 1 = This facility 2 = Another facility: Specify 3 = home	Mode of delivery 1= SVD 2= C-sec 3= Instr	Mother's and father's or guardian's name		Parent(s)/ guardian counselled? If Yes, where? 1, 2, 3, 4, 5		Parent(s) HIV result	Parent(s) and/or infant referred to ART clinic (Yes or No)		Remarks
					Mother's	Father's	Yes	No		Parent(s)	Iinfant	

Annex 14: Sample monthly site summary form for early infant male circumcision

Site name: _____

Month of report: _____

Name of person completing report: _____

Contact of person completing report:_____

Indicator		Total
Number of male babies circumcised for age group	Less than 7 days	
	7–28 days of age 1–2 months	
	2 months and older	
	Total	
Number of parents/guardians counselled and tested for HIV		
Number of HIV-exposed babies circumcised		
Number of babies circumcised who experienced one or more adverse events		
Number of circumcised male babies brought back at least once for postoperative follow-up care (routine or emergency) within 2 weeks of the procedure		
Referred from:		
Self-referral (parents/guardians)		
Antenatal care		
Family planning		
Maternity and labour/delivery		
Paediatric ward and outpatient department		
Other		
Total referred from all settings		
Referred to:		
Paediatric HIV care and treatment centre		
Paediatric outpatient department and/or ward		
Other clinical surgical services		

Annex 15: Essential neonatal and infant care

Interventions at home/community level

Promotion and support for:

- Exclusive breastfeeding
- Thermal protection
- Infection prevention: general hygiene, hand-washing, cord care and safe disposal of baby's faeces
- Care of a small baby without breathing and feeding problems: frequent breastfeeding, skin-to-skin contact
- Prevention of indoor air pollution
- Neonate stimulation and play
- Recognition of problems, illness and timely care-seeking
- Support for routine care and follow-up visits
- Birth registration

Situational:

- Promotion and provision of insecticide-treated bednets
- Adherence to antiretrovirals for PMTCT

Interventions at first-level health facilities

All of the above plus:

- Rooming in
- Promotion, protection and support for exclusive breastfeeding
- Eye infection prophylaxis
- Immunization
- Presumptive treatment of congenital syphilis
- Monitoring and assessment of well-being and response to maternal concerns
- Additional follow-up for at-risk babies
- Treatment of local infections (skin, cord, eye, mouth)
- Identification, initial management and referral of a neonate with any sign of severe illness, injury or malformation

- Care of preterm / low-birth-weight infants without breathing problems: support for breast(-milk)feeding, Kangaroo Mother Care
- Recording and reporting

Situational:

- All of the above plus:
- Antiretroviral regimens for PMTCT including antiretroviral therapy
- Support for safer infant feeding options

Interventions at referral facilities

All of the above plus:

- Management of a neonate with severe problems: general care of a sick neonate and specific care for:
  - preterm babies with breathing problem or unable to feed orally (includes provision of Kangaroo Mother Care)
  - severe infection
  - severe birth asphyxia
  - other: severe jaundice, malformations

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