TOPICAL STEROIDS, AN ALTERNATIVE TO CIRCUMCISION FOR TREATMENT OF PHIMOSIS AT THE UNIVERSITY TEACHING HOSPITAL, LUSAKA.

BY

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I hereby declare that the work presented in this study for the Degree of Master of Medicine (Surgery) represents my work and has not been presented either wholly or in part for any other degree and is not currently being submitted for any other degree at University of Zambia or any other University.

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Dr Kachimba (Consultant Surgeon, Consultant Urologist) proofread my draft.

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* Mentioned in the acknowledgement. Page Vi
ABBREVIATIONS

BXO : Balanitis Xerotica Obliterans
E.g. : Example
EMLA : Eutectic Mixture of Local Anesthetic cream
Fig. : Figure
i.e. : “id est” (Latin) : it is the same
NOHARMM : National Organisation to Halt the Abuse and Routine Mutilation of Males
NORM : National Organisation of Restoring Men
P : Page
S2-S4 : Sacral vertebra number 2 to sacral vertebra number 4
T11-L2 : Thoracic vertebra number 11 to lumbar vertebra number 2
UNR : Universite Nationale du Rwanda (National University of Rwanda)
UNZA : University of Zambia
UTH : University Teaching Hospital
UTI : Urinary tract infection
TERMINOLOGIES

Circumcision : Surgical operation that consists of a total excision of the foreskin of the penis

Impare : A Kinyarwanda (Rwandese national/official language) word to mean penis with uncovered glans (due to lack of the prepuce).

New case : In our study, it was the patient who presented to the clinic for phimosis for the first time and no other form of treatment for this condition has ever been attempted on him.

Phimosis : Non retractable penile foreskin /prepuce.

Mild phimosis : Non-retractable penile foreskin and passes urine with no discomfort.

Moderate Phimosis : Non-retractable foreskin, tight opening, with some evidence of difficulties in passing urine but no evidence of pain. E G: Ballooning

Severe Phimosis : Non-retractable foreskin, tight opening, with or without ballooning, associated with pain/ crying on passing urine but with no evidence of urine retention per se.

Posthetomy : Synonymous to circumcision

Preputioplasty : Surgical operation aiming at treating pathological foreskin without getting rid of it

Recurrent case : In our study, it was a patient who presented to the clinic for phimosis for which he has had treatment in from of dilatation or steroid cream and the prepuce became retractable and the condition has reappeared again
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A prospective study to evaluate the effectiveness of topical steroid as a treatment option for phimosis and its economical benefits compared to circumcision has been conducted from December 2003 to February 2005 at The University Teaching Hospital. A total of 365 patients with phimosis were referred to the Paediatric Surgical Clinic from December 2003 to December 2004. For the recruitment period of first 8 months, 262 patients were seen. Of these 43 had physiological phimosis and parents understood that there was no need for any intervention, 6 were scheduled for circumcision (5 of them due to parents wish and the other one had a very severe phimosis associated with urine retention and recurrent infection), 31 were recruited in another study and all these were excluded. The remaining 182 participated in our study.

Two groups were compared: Group 1 of 125 patients who opted for conservative management by a topical steroid namely betamethasone cream of 0.1 %. Of these 125 patients, 85 (68.0%) received topical steroid therapy as primary treatment and they were termed” new cases”, while 40 (32.0%) were “recurrent” phimosis some weeks after dilatation before the commencement of this study. Group 2 of 57 (31.3%) were the patients who, at presentation, had dilatation of the phimotic prepuce as means of treatment. This group acted as a control. The age ranged between 1 to 13 years with an average of 23.37 months (median of 16 months); both groups included.

The follow up was of 6 months from the commencement of the treatment for both groups. Of all patients, 141 (77.5%) successfully completed the follow up period, 92 (65.2%) in Group1 and 49 (34.8%) in Group2. In Group1, 80 (86.9%) had a successful outcome and 12 (13.1%) failed to achieve full foreskin retraction while in Group 2 only 17(34.0%) had a good outcome, 32 (66.6%) failed to maintain the retraction after dilatation and had recurrences. One child (0.01%) of Group 1 developed acute severe paraphimosis that he required general anaesthesia for reduction. The average number of betamethasone tube cream (15gr) used, was 1.7 while the average price for each tube was K4000.00. The overall economical saving was estimated at about 90% compared to the cost of the circumcision.
The study shows that topical steroid, betamethasone 0.1%, is efficient, safe and cost effective in treating phimosis. We highly recommend this conservative method to become the standard and initial measure for the treatment of phimosis particularly in upcountry hospitals and health centers.
2. INTRODUCTION

Phimosis or non-retractile prepuce is one the commonest condition encountered in the paediatric surgical clinic at University Teaching Hospital [UTH] (1) and circumcision has been the traditional mode of treatment. This surgical treatment is associated with not only long waiting theatre lists but also a number of complications in some patients. (2)

The effectiveness of topical steroid therapy of phimosis and its economical benefits compared to circumcision has been advocated in many western publications mostly since the last decade. (3, 4)

This method of treatment does not require any special training, it is safe, cost-effective and efficient (3, 4, 5). In our region, particularly in our country where poor financial resources and shortage of Surgeons for safe circumcision are far from being mere problems; similar study has not yet been documented, in best of my knowledge.
3. OBJECTIVES OF STUDY

- To study the efficacy, short term outcome and cost consideration of topical steroid in phimosis therapy
- To study the complications of topical steroid in phimosis therapy
- To determine the effect of this method, in case of its failure, to circumcision
- To identify and recommend the most suitable type of patients for this method

4. RATIONALE

Topical steroid, as a method of treatment of phimosis is technically simple, non-invasive, safe and cost-effective. It has proved to be efficient and giving lasting results (3, 4, and 5). It will be of benefit both to the clinicians/surgeons and hospital management on one hand and to the patient and parents on the other hand. If effective, hen it may be the most suitable line of management particularly in our environment.

5. LITERATURE REVIEW

A. Introduction

Phimosis or non-retractile foreskin (8) is a congenital or acquired preputial stenosis (3, 9, 10) It is also defined as a clinically verifiable, pathological, cicatricial stenosis of the prepuce (4). It is one of the most frequent problems encountered in the department of surgery at UTH (1). Circumcision remains the most frequently adopted treatment (1, 8, 11).

An estimated one sixth of men in the world is circumcised (14) and 120 circumcisions are being done every 5-min over the world (15). The procedure is performed first for religious practice and cultural “rite of passage “; second as a prophylactic measure against future ailment, “routine circumcision” and third for immediate medical indication (14, 16). Ninety percent of medically indicated circumcision are for phimosis, 9% for balanoposthitis and 1% for other reasons (16) Although these values are almost certainly exaggerated (17, 16) the
proportion performed for phimosis, by any reckoning, constitutes the commonest reason for circumcising boys (16, 18)

Circumcision operation entails the sacrifice of the prepuce and frenulum; the penis looses its natural protection (11). It is also defined as the amputation of the prepuce from the rest of the penis, resulting in permanent alteration of the anatomy, histology and function of the penis (13, 16, 19, 20). However, before considering theoretical justifications for circumcision, its complications and different attempts to overcome or avoid them, a complete understanding of the normal anatomy and function of the prepuce is required.

B. Anatomy and physiology of the prepuce

The prepuce is the hairless skin; prolonged forwards in fold overlaps in the glans and double back to be attached to the neck of the glans. (41) It is an integral, normal part of the external genitalia that forms the anatomical covering of the glans penis and clitoris (clitoral prepuce or clitoral hood) (20, 42, 43). For obvious reasons this review will limit itself to male anatomy.

The prepuce has the protective function of covering the glans, urethral meatus and the inner preputial epithelium, thus decreasing external irritation or contamination. The prepuce is a specialized, junctional mucocutaneous tissue, which marks the boundary between mucosa and skin; it is similar to the eyelids, labia minora, anus and lips (41). The adulthood inner and outer surfaces of the prepuce constitute 65-90cm² (51%) of the penile skin (24, 44). The male prepuce also provides adequate mucosa and skin to cover the entire penis during erection. The unique innervation of the prepuce establishes its function as an erogenous tissue (20, 44).

1. Embryology

The male prepuce is formed by a midline collision of ectoderm, neuroectoderm and mesenchyme, resulting in a pentalaminar structure composed of a squamous mucosal epithelium, lamina propria (corion), dartos muscle, dermis, and outer glabrous skin (45).

Materializing at 8 weeks' gestation as a ridge of thickened epidermis, the prepuce grows forward over the developing glans penis, more quickly dorsally than ventrally. Preputial construction is complete by 16 weeks' gestation although, at this stage, the epithelia lining the prepuce and surfaced glans are contiguous, with no plane of separation between them, so that
'preputial adhesions' represent a feature of normal development, not a pathological process. (16) Glenister confirmed Retterer work (1885-1915) the first to show that it is formed by a combination of preputial folding and the ingrowth of a cellular lamella. This ingrowth creates the prepuce, glans, corona and coronal sulcus mucosa. This results in a common mucosal epithelium of the glans penis and the inner mucosal lining of the prepuce (46).

Spontaneous separation, usually proceeding proximally, occurs by desquamation whereby in certain areas cells arrange in whorls to form cell nests, the centers of which, in degenerating, result in a series of spaces that ultimately enlarge and coalesce to form a continuous preputial sac. This process commences late in gestation and, after birth, proceeds at a rate varying among individuals, uninfluenced by environmental or genetic factors. It may sometimes be accompanied by mild inflammatory episodes, possibly as a result of infection of retained smegma (16).

The squamous mucosa of the glans penis, coronal sulcus and prepuce should be considered as one tissue compartment with a common cytokeratin polypeptide pattern (20, 45, 47).

2. Mucosal epithelium (inner plate of the prepuce)

The mucosal epithelium of the male prepuce is the same as the squamous mucosal epithelium that covers the glans penis (45). The glans penis and the inner prepuce share a common, fused mucosal epithelium at birth in 96% of the boys (57). Regardless of the embryological explanation, this common epithelium does not separate until the proper hormonal and growth factors are present. The fused inner plate of the prepuce/glans in male embryo has also been reported to have intraepithelial nerves (59, 61). The mucosal epithelium also contains Langerhan's cells, but does not contain Melanocytes. (20)

3. Lamina propria of preputial mucosa

The lamina propria of prepuce is very vascular, which explains the common haemorrhagic complications associated with circumcision. The male prepuce has looser collagen than the dense collagenous lamina propria of the glans penis. The ridged band of the prepuce is near the mucocutaneous tip (acroposthion) of the male prepuce and, in the unretracted prepuce, usually
lies against the glans penis (20, 19). The mucosal lamina propria (corion) is devoid of lanugo hair follicles, sweat and sebaceous glands (19).

Even in modern textbooks, Tyson's glands are often described as the source of smegma (64); however, no evidence of Tyson's glands has ever been described outside of Cowper's macroscopic description of these glands in 1694 (65). This may be one of the longest held myths in medicine (65, 66). Cowper's description of Tyson's glands in the human is actually of hirsutoid papillomas of the glans penis, which are fibroepithelial structures and not glandular structures (65).

Although other mammals have true clitoral and penile preputial glands that secrete sex pheromones, there is no current evidence of these glands in humans (67).

4. Dartos muscle

The dartos muscle consists of smooth muscle cells invested with elastic fibres. From the prepuce, the delicate, attenuated penile dartos muscle surrounds the shaft of the penis and is continuous with the scrotal dartos muscle. The penile dartos muscle is temperature-dependent and allows for the volume changes required for erection (68). The function of the dartos muscle has been well described by Jefferson, and its loss to circumcision explains the altered response of the circumcised penis to temperature changes. In the infant, the muscle fibres are intertwined and arranged in a mosaic-like pattern, causing the distal prepuce to pucker and close like a one-way valve (69, 70). When comparing the dartos muscle layer of the prepuce in males before and after puberty, the ratio of muscle fibres to elastic fibres decreases. This may explain why on gross inspection the distal prepuce is puckered in the infant and appears more relaxed in the adult.

While the aetiology of this transformation is unknown, steroid hormones may have an influence, as their topical application can accelerate the retractability of the prepuce in prepubescent boys (35-38). Nerve bundles of the prepuce run alongside the dartos muscle (20).

5. Dermis of the prepuce

It consists of connective tissue, blood vessels, nerve trunks, Meissner corpuscles within the papillae, and scattered sebaceous glands. The dermis of the male prepuce appears to have more elastic fibres than the lamina propria of the prepuce (20). This difference may also help form-the
"muzzle" configuration around the glans penis. The elastic tissue of the prepuce dermis, along with the dartos muscle and frenulum, tether the prepuce and help return it to its anatomically correct position after deployment during erection or after manual retraction (20, 41).

6. Outer epithelium (glabrous skin of the prepuce)

The outer epithelium of the prepuce consists of stratified squamous cells that are keratinized. Melanocytes are present in the basal layers. Langerhans cells and Merkel cells are also present. The Langerhans cells are the first line of the body's immune defence system and are required for normal immune function. Merkel cells are specialized neuroendocrine cells that mediate tactile sensations but the function and concentration of Merkel cells within the external genitalia has not been extensively studied (45, 81).

7. The preputial sac

The preputial space is formed by patchy desquamation of the epithelial cells, which were contiguous between the glans and the prepuce (41, 57). Urine is not a normal component of subpreputial wetness. The preputial sac is moistened by secretions from the prostate, seminal vesicle and urethral glands of Littré (66) and the rich vascular plexus of the prepuce mucosa may facilitate production of a fluid transudate similar to that of the vaginal/vulva mucosa (72). The moist, lubricated male preputial sac provides for atraumatic vaginal intercourse.

The preputial sac is colonized by Corynbacterium, Gram-negative anaerobes (especially Bacteroides melaninogenicus), Enterococci, Enterobacteria and coagulase-positive Staphylococci (73). Although Mycobacterium smegmatis is reported in a modern textbook as a possible factor in penile carcinogenesis (74), attempts to show that M. smegmatis produces carcinogens or procarcinogens have been unsuccessful (75,76). In the study by Neubert and Lentze (73), acid-fast bacteria could be seen on the Ziehl-Nielsen smears, but nothing could be cultured in Lowenstein-Jensen medium. Therefore, the acid-fast organisms found in the preputial sac by Neubert and Lentze could have been mycobacterial contaminants from soil and water, such as M. gordonae (77). Although M. smegmatis may be a commensal organism within the preputial sac it does not cause genital tract disease. However, it can cause non-genital soft-tissue infections after trauma or surgery (78). Of interest, one study found M. smegmatis more commonly in female labial smears (46%) than in male urethral smears (4.5%).
Furthermore, this study showed that circumcision had no effect on the recovery of acid-fast bacteria from the male urethra, and the presence of acid-fast bacteria did not cause urethritis (79). These data support the contention that M. smegmatis is a benign commensal organism within the external genital tract.

The preputial sac contains desquamated squamous epithelial cells similar to other mucosal cavities such as the oral cavity or vagina. This white, creamy material may collect under the prepuce of the clitoris (smegma clitoridis) or penis (smegma preputii). Male smegma has been shown to contain squalene, beta-cholesterol, sterols and long-chain fatty acids (75, 76, 80).

In men over 35 years old, 9,10-methyleneoctadecanoic acid is present, but it is not found in younger (17-20-year-old) males (80). The function of the steroids, sterols and fatty acids produced within the human prepuce are unknown, but are considered to be protective elsewhere on the skin.

8. Innervation of the prepuce

The male prepuce has somatosensory innervation by the dorsal nerve of the penis and branches of the perineal nerve (including the posterior scrotal nerves) (82, 83). Autonomic innervation of the prepuce arises from the pelvic plexus. The parasympathetic visceral efferent and afferent fibres arise from the sacral centre (S2-S4), and sympathetic preganglionic afferent and visceral afferent fibres from the thoracolumbar centre (T11-L2). The parasympathetic nerves run adjacent to and through the wall of the membranous urethra (82). Although most neonatal and childhood circumcisions are performed with no anaesthesia (84), the complicated innervation of the penis explains why a dorsal penile nerve block provides incomplete pain relief for neonatal male circumcision (84, 85). Likewise, a penile ring block cannot block the visceral afferent fibres from the cavernosal nerve nor the posterior scrotal somatosensory branches of the perineal nerve (85).

An eutectic mixture of local anaesthetic cream (EMLA) does not relieve the pain associated with circumcision because of the complexity of penile innervation and the multiple layers that would have to be penetrated by the topical cream in the newborn penis (86). Amazingly, some modern urology textbooks even recommend wine as an anaesthetic for newborn circumcision (20 55). Researchers have documented that women with complete spinal cord injury may achieve orgasm with self-stimulation, suggesting that some sensory pathways of the genital tract may
bypass the spinal cord by way of the vagus nerve (87). Whether the external genitalia, including the prepuce, are innervated by the vagus nerve has yet to be determined.

Although the sensory and autonomic innervation of the penis and clitoris are similar, there is a remarkable difference in their encapsulated somatosensory receptors.

Sensory receptors can be classified as mechanoreceptors, e.g. Meissner's corpuscles, Vater-Pacinian corpuscles and Merkel cells, and nociceptors (free nerve endings) (88). A multitude of names have been used to describe these encapsulated receptors, e.g. Krause, Dogiel, genital corpuscles, Endkalpsen and mucocutaneous end-organs (20, 89), but the term corpuscular (encapsulated) receptors will be used here to include all of these mechanoreceptors. Most of the encapsulated receptors of the prepuce are Meissner corpuscles, as they contact the epithelial basement membrane (20).

The glans penis is primarily innervated by free nerve endings and has primarily protopathic sensitivity (95). Protopathic sensitivity refers to cruder, poorly localized feelings (including pain, some temperature sensations and certain perceptions of mechanical contact) (96). In the glans penis, encapsulated end-organs are sparse, and found mainly along the glans corona and the frenulum (95). The only portion of the body with less fine-touch discrimination than the glans penis is the heel of the foot (97). In contrast, the male prepuce ridged band at the mucocutaneous junction has a high concentration of encapsulated receptors (19). The innervation difference between the protopathic sensitivity of the glans penis and the corpuscular receptor-rich ridged band of the prepuce is part of the normal complement of penile erogenous tissue (20, 95).

9. Immunological aspects of the prepuce

The study of the immunological function of the prepuce is in its infancy and the role of subpreputial flora in preventing infection has yet to be explored (90). Circumcision has been justified by some because it removes the Langerhans' cells of the prepuce and therefore supposedly decreases the risk of HIV infections (91). This theory is flawed, as even after circumcision, there is residual penile mucosa of the glans, and there are Langerhans' cells in the penile shaft epidermis. Surgical removal of the Langerhans' cells in all mucosa and skin to prevent infections is not rational, nor feasible. In addition, the aggressive circumcision campaign in the USA has not prevented sexually transmitted infections, including HIV.
Furthermore, it is only recently that it was discovered that squamous epithelial cells, with no Langerhans' cells, can secrete cytokines and interleukin-1 that stimulate the immune response of T cells (93), otherwise secreted by the Langerhans' cells (93). Weiss et al. were unable to document Langerhans' cells in the mucosal surface of newborn foreskins, but in the adult prepuce (94) This can be explained by the fusion of the preputial mucosa to the glanular mucosa in the sterile intrauterine environment. Langerhans' cells would not be expected in the fused prepuce/glans penile mucosa until later in life, when the prepuce becomes retractable and the mucosa is exposed to antigens. Therefore, Langerhans' cells of the prepuce should be understood as normal mucosal immune cells, rather than a pathological entity requiring excision (20, 90).

The cytokines released by the preputial mucosa and skin are still being carefully studied (20, 91). More advanced research states that the prepuce is an androgen dependant structure (20, 56) with complex intradermal enzyme systems, which confer upon it on wide range of metabolism of various prostaglandins that are copiously produced throughout the male and female genitals tract (60). It is also known as good accessible and ready source of live human fibroblasts and it has become a favourite tissue reservoir for cell culture biologists and hence basic scientific research (14).

Certainly it is not a vestigial dangerous structure like older documentation suggested (63, 98, 114). It can be anticipated that many other biochemical functions will be defined with time (113).

C. Phimosis pathogenesis / pathophysiology

Literally the word “Phimosis” means “muzzling” and implies the existence of pathology. In true phimosis, the preputial orifice proper is scarred and indurated. Presenting symptoms comprise secondary unretractability of the foreskin, irritation at or bleeding from the preputial orifice, dysuria, acute urinary retention and, rarely, chronic retention, which may in turn be complicated by secondary enuresis or, exceptionally, by obstructive changes in the upper urinary tracts. (16).

At birth, the prepuce is almost always completely unretractable and, with few exceptions, there is also some degree of preputial adherence. Attempted retraction results in a blanched and apparently constricting ring of skin appearing a few millimeters proximal to the preputial meatus.
No abnormal histological features are found in this area in cases where circumcision has been performed and the phenomenon does not therefore represent phimosis in the pathological sense; it is better termed 'physiological phimosis' or, more simply, 'nonretractile foreskin'. A few boys have no symptoms at all and the finding is made incidentally during the course of an examination for some other purpose. Otherwise the fused mucosa of the glans penis and the inner lining of the prepuce separate gradually over years, as a spontaneous biological process.

In male monkeys exposed to intrauterine diethyl-stilbestrol, the normal separation of the glans/prepuce is delayed from a normal age of 2.5-3 years to 4.5-5.5 years. Despite this research, the hormones and/or growth factors responsible for this separation of the glans-prepuce are poorly understood. It has been observed that the formation of the prepuce space occurs by patchy desquamation of the epithelial cells which were contiguous between the glans and the prepuce. A process not necessary complete at birth.

Douglas Gairdner supported by Oster and much later by larger Chinese studies reported that at birth only 4% of boys have retractable foreskin, by the age of three years 90% have retractable foreskin while at 17 years of age only 1% remains unretractable. Recent work by Kayaba et al. verified that the preputial orifice may be tight in young boys, but resolves over time. Interestingly topical steroid and non steroid anti-inflammatory ointments are now known to accelerate the glans-prepuce separation. This being the subject of the whole study, is reserved more details in subsequent pages.

Without knowledge of the normal development of the penis, some physicians advocate childhood circumcision as a surgical treatment of normal anatomy. A tight preputial orifice with normal histology is not pathological in young boys, but should be considered a normal stage of penile development. Neonatal circumcision, before the prepuce has naturally separated, involves tearing the common prepuce/glans penis mucosa apart, with the concomitant risk of glanular excoriation and injury. Manipulation and retraction of the immature prepuce must be avoided to prevent bleeding, scarring, phimosis and psychological trauma. Other causes of true phimosis are histologically confirmed like balanitis xerotica obliterans 9% (105,108), Lichen sclerosis et atrophicus about 4.3% in one study and 10% in another.
D. History and indications of circumcision

An estimated one sixth of world’s men is circumcised (14) and 120 circumcisions are done every 5-min over the world (15) still, the anthropologists do not agree on when and where originates circumcision (14) and many meanings are attributed to the procedure. Sir Graston Elliot Smith English Egyptologist suggested that it is traced back in some 15000 years ago (14) the earliest Egyptian mummies (2300 BCE) were circumcised (14,100,101). Many natives that Columbus found in the “New World” were circumcised. It is also known that circumcision has been practiced in Near East, patchily through out tribal Africa, among the Moslem People of India and south East Asia. It was also found in Australian Aborigines (14)

The procedure was performed at different timings (age of the male to be circumcised) and for different reasons that have been evolving over time. Firstly, for religious practice and cultural “rite of passage“, the timing of circumcision varies from birth (e.g.: in some African tribes) and 8th day after birth (e.g.: in Judaic communities) to at early adult life like in Moslems and many tribal cultures. Secondly, it is performed as a prophylactic measure against future ailment, “routine circumcision” and thirdly for immediate medical indication at any time of life (14,16)

i. Many theories as to why circumcision and different significances of circumcision

Historians (19th century) suggested that circumcision is an ancient ritual, form of social control. Penile pain and bleeding is to remind the man of the power of the community/ church i.e. we have control over your distinction to be man, your pleasure and your right to produce (14).

The ritual is a warning and the timing dictates who is warned. For the newborn it is the parents who accede to the church: “mark your son, who belongs to us not to you” (14,115)

For the young, adolescent circumcision is “a rite of passage” the warning accompanies the “aggrandisement “of puberty (14, 116).

Others think that circumcision arose as a mark of slavery or defilement (117, 118). In ancient Egypt, captured warriors were often mutilated (amputation of digits and castration mainly) before being condemned to slavery but morbidity was high and their value as a slave was reduced. Thereafter, circumcision was just as degrading and evolved as sufficiently humiliating
compromise. Eventually all male descendants of these slaves were circumcised. Both Phoenicians and Jews, who were largely enslaved, adopted and ritualised circumcision (14).

From the bible’s view, circumcision was incorporated into Judaic religious practice and viewed as an outward sign of a covenant between God and man. [Genesis 17: 11-21, 34: 6-24, Acts 15: 1-21 (esp. 1-11)]

Many other meanings of circumcision may have evolved: e.g. it is a mark of culture identity akin to a tattoo or body piecing (100). It is a ritual evolved as fertility for others: in some tribal cultures apportion the “seasons” for circumcision and support the view that it developed as a sacrifice to gods, an offering in exchanged for good harvest, etc... This seems to be reasonable as the penis is inhabited by powers that produce life (101, 117). Its connections with harvest is also found in Nicaragua were blood from this operation is mixed with maize to be eaten during the ceremony (63).

Psychologists explain it to incorporate notions of pain imprinting by encoding violence on the brain, child-maternal bonding and sense of betrayal is instilled in the infant to enhance the child’s ability for survival in later life (14, 120).

The earliest documentation found on circumcision on medical ground is in 1267: Theodoric suggests the need for removal of the end part of the penis, in the “black warts and tubercles”.

It is presumed he was describing circumcision in the context of some penile pathology (14, 16). It is believed that doctors did not widely perform circumcision until later half of 19th century.

Brief description of adult circumcision for phimosis start to appear in early 19th century textbook (14) but again, the surgical technique tends not to be described in detail.

In 1828, Abernethy reported the use of bistourey (knife) to achieve circumcision in men with gonococcal phimosis and bleeding should be “stanch” with iodoform and boric, possibly indicating that no suturing was done (102). He also warns against immediate circumcision in presences of a morbidly sensible surface, but the posthitis (inflammation of the foreskin) should be allowed to resolve before surgical intervention (14). Sir Everard Homé and M Baillie (1833) agree with Abernethy on the above (103).
In 1865 the first circumcision was reported in surgical accounts of Saint Bartholomew’s Hospital but it was only one in 417 operations performed that year (14). It is clear that circumcision was not taken lightly at that time and so far none of the authors mentions circumcision in neonates.

**ii. Drive, control and dynamics of circumcision**

Miller suggested that circumcised man is bound to “avenge himself “unless his subsequent life allows “old wound to heal in love” which is seldom the case, adding children who were once injured will later injure their own children maintaining that their behaviour does not harm because their own loving parents did the same (122).

We note from other analysts that as circumcision is often not a voluntary commitment to a group identity but imposed to children by adults, it suggests that circumcision is a form of social control. It was a primitive effort to produce a male who is less sexually excitable, less distracted by individual goals of amorous exchanges and hence more amenable to group authority figures (14). They describe it again as “a low grade neurological castration” (57) and religious commentators assert that it controls male lust (51, 57, 58).

However diminishing sexual satisfaction does not reduce sexual drive but can lead to compensatory, quite opposite, behaviour including altered sexual practices (124) compulsivity (123) and other unforeseen personal /societal consequences (125).

Denial that circumcision damages the body or sexuality may cause some victims to react sceptically towards others who report their own harm / mischief from circumcision. Hence many circumcised persons avoid any discussion of circumcision, others can discuss it only humorously, others trivialise it or get angry when circumcision is challenged (16). Circumcised fathers when requesting their son to be circumcised for family / social conformity, may be projecting their own anxieties about feeling inferior to intact son (125).

In other circles, currently 'hygiene' and 'presumed preventive medicine' are frequently given as reasons for continuing the practice (121). Especially the new theory that circumcision decreases the risk of HIV infections by removing the Langerhans' cells of the prepuce (91) Systematic researches are still going on in Zambia, Uganda, Kenya and South Africa (129,130).
E. Medical indications for circumcision

By far, 'phimosis' constitutes the commonest reason for circumcising boys. The statistics are clear. In the former Mersey Region (England), 90% of medically indicated circumcisions are coded as being for 'phimosis', 9% for balanoposthitis and 1% for other reasons. In England as a whole, 'phimosis' counts 89% of boyhood circumcisions (122).

The validity, or otherwise, of 'phimosis' as an indication for circumcision hinges crucially upon the extent to which this represents a genuine pathological entity and which, in turn, demands some understanding of normal development of the prepuce, both before and after birth; as seen above.

In an other study, pathological phimosis due to Balanitis Xerotica Obliterans that may be an absolute indication for circumcision, affects 0.8-1.5% of boys (51,123) and the one common relative indication, recurrent balanoposthitis, 1% of boys (124), so that by a generous estimate <2.5% of boys require circumcision (16). Paraphimosis, accounting for <1% of emergency surgical admissions, is not necessarily treated by circumcision (16, 58).

Because preputial cysts, very rare, do not resolve spontaneously, surgical intervention, i.e. enucleation is necessary, for localized lesions and circumcision for those that are more diffuse.

Redundant foreskin has at time been recorded as reason for circumcision otherwise except, sadly, when constituting a self-fulfilling prophecy at the hands of some surgeons, the 'redundant foreskin' does not exist and the term should be discarded. Penile lymphoedema, acute balanoposthitis, ammonia dermatitis are any longer genuine indication for circumcision (16).

F. Methods of circumcision

Sir Fredrick Treves described in 1903 in a comprehensible account the basic surgical principles of circumcision that remain valid today (126)

- Removal of the prepuce using a scissors and mandatory ligation of frenular vessels
- Necessity to live adequate cut-off inner skin or else there is risk of synechium (skin bridges between residual prepuce and glans) formation
- Warning against the excess removal of the skin to avoid the risk of chordee
- Suturing the skin edges with interrupted "fine catgut "Horse-hair or silk have also been documented. Few other surgeons like E.Doyen (Institut Doyen, Paris), Master Technician, advocate an antihaemorrhagic triradiate continuous circumcision suture line with ends of each suture not tied so as to allow expansion of the space between the two layers if necessary (14) (Fig.1, p.35)

- A compressing piece of sterilised muslin is then wrapped over the entire distal penis with a snug hole to allow passage of the glans. The dressing and sutures are removed after 3-5 days.

Charles Chetwood recommended in 1921 to leave long interrupted horsehair sutures so that compressive strips of idoforms and petroleum gauze could be securely tied down over the suture line (14,126) (Fig. 2, p. 35)

In 1920 Doyen developed his "ecraseur" for neonatal circumcision. The foreskin is crushed and cut in 4 separate manoeuvres with very little concomitant bleeding (Fig.3, p.35)

Many other circumcision clamps were developed thereafter e.g.: Winkelman circumcision clamp (in 1935) and Thomson Walker warn of the dangers of injury to the glans when such clamps are used (Fig.4, p.36). Due to the dangers of these circumcision clamp coupled with the risks of neonatal anaesthesia, "Plastibell" device was first used in 1956 and still used today. Many other types with integral steel cutting blades- such as the Glansguards® device - have been introduced (127) (Fig.5, p.36')

To prevent erection hence reduce the risk of haemorrhage within the 1st 24hrs of surgery, administration of stilboestrol or the use of bromide and chloral, was advocated by Sir Alec Badenoch in 1953 but was no longer included in 1974 edition of Badenoch's manual of Urology (14)

G. Complications of circumcision

"Often poor surgical results are not recognised until year after the event" T. Hammond (21)

Circumcision has an appreciable morbidity. Even though many factors come into play, the rate of complications, especially physical immediate and intermediate ones, depends mainly on who performs the operation while the psychosocial ones may not (2).
In Muslim countries, e.g. Pakistan, Turkey 85-95% of circumcisions are performed by traditional/unqualified circumcisers (22). With them, most the complications often go unreported and data that are available are from developed countries or city setting where the rate of complications is low. Nevertheless just as an example, a study conducted in Pakistan over 330 circumcisions showed the following immediate and intermediate complications (23): primary haemorrhage 170 (52%), infection 27(8.2%), meatal stenosis 24 (7.2%), incomplete circumcision 21 (6.3%), penile oedema 16 (4.8%), circumcision in hypospadias 11(3.3%), glanular injury 9 (2.9%), slipped plastibell 4 (1.3%) , urinary retention 4 (1.3%), necrotising fasciitis/gangrene of the penis 6 (1.8%) (Fig 6, p.36), Fournier’s gangrene 2 (0.6%), buried Penis 2 (0.6%), sloughing of glans 1 (0.3%), death in haemophilic patient 2 (0.6) and death from sepsis 2 (0.6%).

In an other survey, D M Griffiths et al. (21) noted that the morbidity of the procedure include 2.8% patients required acute readmission postoperatively, 46% vomited, 36% oozed, 19% did not pass urine for more than 12 h and 26% could not wear pants for more than 7 days and a 2.8% developed meatal stenosis, requiring a formal meatoectomy. Jacobsen (164) reports on 4 cases of Jewish infants who died from haemorrhage after circumcision. June 2005, most of the Canadian media reported a child who died of complications of circumcision.

A 3 years study in 546 circumcised participants revealed the following physical consequences of circumcision: prominent scarring (33%), insufficient penile skin for comfortable erection (27%), erectile curvature from uneven skin loss (16%), pain and bleeding of an erection/manipulation (17%), painful skin bridges (12%) and 20% had other complications like: bevelling deformities of glans, meatal stenosis, recurrent non specific urethritis.

Sexual consequences include progressive sensory deficit in the preputial remnant and glans (61%) causing sexual dysfunction, erectile problems ejaculatory and/or anorgasmia. Sensual responsiveness and sexual well being is also greatly affected by the loss of 51% (65-90) cm² of the penile skin through circumcision (19).

Money and Davison findings concur with the above and add loss of proprioceptive stretch receptors of the prepuce, increased penile pain and changes in masturbatory behaviour and may affect the entire sense of well being, work capability included as well as erotosexual bonding and family life. The constantly exposed glans keratinizes to varying degrees, causing desensitisation, which is alleged to prolong intercourse (39).
The subtle pleasures of genital foreplay afforded respondent negligible enjoyment hence often abandoned or bypassed it favouring immediate coitus hoping to achieve sufficient stimulation for both pleasure and orgasm. But again many respondents state that vaginal sex offered inadequate simulation for pleasure and/or orgasm. Extraordinary 40% stimulation is required for orgasm (24). Other reports suggest some circumcised individuals compensate for a diminished sexual response with either compulsive sexual behaviour (123), or those offering greater stimulation (masturbation, oral, anal sex) (124), others needing to resort to extraordinary, often violent, thrusting during intercourse—with some respondents or their wives reporting genital abrasions, pain and bleeding. (24, 95)

Psychological consequences potentially altering brain development, function and behaviour start at the time of infants’ circumcision with exposure to stress hormones in an extreme pain (24, 62). They then proceed in recognising the loss of body parts that can produce grief for loss of body image, function or both. Emotion suffering to variable extent was described in all adult respondents (24): Intrusive thoughts about one’s circumcision, including: feeling of mutilation (60%), self esteem/ inferiority to intact men (50%), genital dysmorphia (55%), rage (52%), resentment/ depression (59%), violation (46%), parental betrayal (30%).

Physical/ emotional suffering impeded emotional intimacy with partner with resulting sexual dysfunction in 41% of respondents and dependence on substances or behaviours to relieve their sufferings (tobacco, alcohol, drugs/food and/or sexual compulsivity) was in 30% but 51% of these had not sought help for their problem with different reasons like thinking that no recourse available (41%), embarrassment (19%), fear of ridicule (17%) and mistrust of doctors (11%).

In 1993 P. Boyton (24) surveyed on 197 intact and circumcised American men. Of intact men 80%, 17% and 3% were satisfied, ambivalent and dissatisfied respectively with their condition. Of the circumcised the respective values were 38%, 41% and 20%

Another report (1996) revealed that 50% of the respondents circumcised as infant were unhappy about it while only 3% were happy to be so.

Following a number of valuable randomised studies, both the British Medical Association and the American Academy of Pediatrics recommend that circumcision should only be performed for medical reasons (21). In legal circles, heated debates are still going on as to whether child
circumcision should be regarded as a child’s right or in deed is child abuse! It appears in some states of the USA, it is a matter of law interpretation on what is harmful and what is beneficial for the child while in Queensland (Australia) the law reform commission concluded that on a strict interpretation of the assault provisions of the criminal code as that routine circumcision could be regarded as a criminal act (6, 13)

H. Preputial restoration

Non-circumcision as a measure to offset the oppression of Jews like in Old Testament, 1 Maccabees 1: 14-15 and many more documentation tell about prepuce restoration (14, 99). In the Roman Empire, the Greek practice of public nudity was adopted at the bathhouses and gymasia for all exercises and sports activities. To have a glans without a preputial covering was considered socially unacceptable and ugly. It was also unacceptable for uncircumcised foreskin was allowed to retract in public. The judeum pendum was an instrument funnel-shaped copper tube used during the roman times. It was placed around the penile shaft hoping that the heavy copper stretches the shaft skin to cover the glands and would eventually stay in place and create a new prepuce (71).

It is not again without importance to note that Celsus who was the first to describe in details the operative technique of uncircumcision used specific terminology like “decircumcision“ or prepuce“ restoration “ for those who were circumcised and prepuce “reconstruction” for those with congenital deficiency of the foreskin (absent or undeveloped)

During the Second World War, clandestine prepuce restorations and reconstructions were done in a desperate attempt by Jewish men to avoid internment. Because circumcision was rarely practiced among any European ethnic group except Jews, being circumcised was a physical characteristic that could expose and identify a Jew. In Nazi occupied Poland, several Warsaw Doctors had busy practices by performing surgery to restore the prepuce. In early Renaissance, Europe operations to “stretch” the circumcised foreskin are recorded (71).

Currently, an international net work of non-governmental and children’s advocate organisations like NORM (National Organisation of Restoring Men) or NOHARMM (National Organisation to Halt the Abuse and Routine Mutilation of Males), among other things, offer circumcised men moral and technical support to regain genital integrity (24)
I. Alternatives to circumcision

As circumcision is contraindicated in some cases (e.g., paraphimosis with severe balanoposthitis), moreover as, it is becoming progressively less popular, an alternative treatment ought to be found for medical conditions for which it has been otherwise the only means of relieve.

Cloquet’s “V” excision of the foreskin became popular means of treating phimosis without circumcision around 1900. The “dorsal slit”, was traditionally and still occasionally performed, but is rarely to be recommended now as the cosmetic result is unsatisfactory and hence formal circumcision almost always ensues (16). 26 years later Young & Davis described a 'preputioplasty' where by the constricting band was incised in 2 -3 points and closed transversally (Heinecke- Mikulicz principle) (14,128)

Welshman (1903) described a method whereby acute division of the paraphimotic band is all tat is required, i.e.with preservation of the foreskin. Other many different techniques have been proposed as an alternative to circumcision e.g. which may take the form either of a limited dorsal slit, with transverse suture or longitudinal incision of the 'constricting ring' proximal to the preputial meatus, again with transverse suture (14, 16, 109)

More recently, late 1990’s, it has been claimed that topical application of steroid creams, is the ideal treatment for 'phimosis' (3-5, 16, 33, 37, 110, 111, 112) The last category represents the subject of this work hence a particular attention in reviewed literature.

J. Topical steroids as an alternative to circumcision

“A good surgeon knows how to operate,  
A better surgeon knows when to operate  
The best surgeon knows when not to operate” (119)

Treatment of phimosis with topical steroids that avoids any form of surgery and its associated risks is now becoming the most favored choice and standard measure for treating this condition (3). This is due to its numerous and strong advantages like: safe, simple, cost effective, non-invasive (conservative) and efficient with no side effect (3, 4, 5, 33, 35, 36, 38). Topical steroid creams used vary: clobetasol propionate 0.05% twice daily (30), betamethasone cream 0.1%, 0.05% (5, 111), betamethasone valerate 0.06% (a highly potent steroid) or clobetasone butyrate 0.05% (a
The application is almost invariably twice daily for a month (5, 33-38, 110-112) or more, to 6 weeks (39, 110). Prepucial retraction is well observed in about 50% only after 2 weeks of treatment. While the overall results vary from 86% to 97% (5, 33-38, 110-112).

The advantage with highly to moderately potent steroid creams like betamethasone valerate 0.06% and clobetasone butyrate 0.05% respectively is evaluated at about 5% of higher response to treatment; otherwise they are both of comparable effectiveness in treating phimosis (110). The recurrence rate was observed at around 7.7% (110) in a follow up extending from 4 months to 4 years. There has been no adverse effect noted all studies reviewed.

Evaluation conducted in France (2001), concluded that this treatment could reduce costs by 75%, which represents a potential annual saving of approximately F 150 million equivalent to 37,785,955.8 US $ (4). The common conclusion and recommendation is that it should be offered first instead of circumcision. Topical steroid therapy represents a potential alternative to circumcision regardless of the age of the patient, type of phimosis or relative indication for treatment (111)

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6. PATIENTS AND METHODS

This was a prospective study, conducted from December 2003 to February 2005 at the U.T.H., Paediatric Surgical Unit, D block. A special "phimosis clinic desk" was created and the clinic ran for one-hour 08:00 to 09:00 during the regular Tuesday out patient clinic. A total of 262 patients with phimosis were referred to the Paediatric clinic during the recruitment period of the first 8 months of the above period. Six were scheduled for circumcision due to parents wish or had very severe phimosis associated with urine retention and recurrent infection and were excluded. Parents with 43 young children with physiological phimosis were educated about this condition and understood that there was no intervention required and were also excluded. For those who definitely needed treatment, 31 were recruited in another study and were as well excluded from ours. The remaining 182 participated in our study. An informed consent (Appendix-1) was obtained from parent or guardian before including the patient in the study.

At presentation, each patient was to be qualified either "new" or "recurrent" and the severity of the phimosis was to be classified in one of the 3 groups "Mild, Moderate or Severe". These terms were defined as follow:

- **New case**: In our study, it was the patient who presented to the clinic for phimosis for the first time and no other form of treatment for this condition has ever been attempted on him.

- **Recurrent case**: In our study, it was a patient who presented to the clinic for phimosis for which he has had treatment in from of dilatation or steroid cream and the prepuce became retractable and the condition has reappeared again

- **Mild phimosis**: Non-retractable penile foreskin and passing urine with no discomfort.

- **Moderate Phimosis**: Non-retractable foreskin, tight opening, with or without ballooning, with some evidence of difficulties in passing urine but no evidence of pain. E G: Ballooning

- **Severe Phimosis**: Non-retractable foreskin, tight opening, with or without ballooning, associated with pain/ crying on passing urine but with no evidence of urine retention per se.
Chronological order of birth and number of the brothers for each individual patient were noted to see which born was most affected.

The education level of patients’ mothers was also recorded to study what part literacy played in developing phimosis and the outcome of the management.

Two groups were followed up. Group 1 was those patients with phimosis, new and recurrent cases, booked for Tuesday clinic and these were to be using the topical steroid cream.

After options were discussed with the parents or guardians, topical betamethasone ointment 0.1% was offered together with a protocol leaflet of written instructions of how to use the cream (Appendix -3).

Group 2 was those who were booked to the Thursday clinic and who were dilated. This group acted as a control and was compared to group 1 using the chi-square test (significance assigned with p<0.05)

The inclusion Criteria in the study were:

a) Patient aged up to 14 years,

b) Diagnosis of phimosis by a Consultant Surgeon

Exclusion Criteria were:

a) Above 14 years-aged patients,

b) Phimosis with evidence of acute urinary retention, infection

c) Other penile abnormality

d) Non-consent to participation in the study.

The author followed up each patient for six months from the time of treatment initiation otherwise he was qualified as lost for follow up. The data collection sheet (Appendix-2) and an EPI-Info database for information storage were used. The reviews were generally at 3 weeks but at 2 or 4 weeks depending on the case. The children were re-examined by the Paediatric surgeon before discharge.

Ethical approval was sought from the research ethics committee and confidentiality was observed throughout the study.
7. RESULTS

Introduction
The results are presented in three headings: Demographic data, Clinical factors and outcome. As mentioned earlier on in this study, two groups were followed up. Group 1: Those patients who used the topical steroid cream “betamethasone 0.1 %” as the only mode of treatment. They were 125. Group 2 of 57, were the patients who had dilatation of the phimotic prepuce as means of treatment during the study period.

Demographic data
A total of 182 males aged between 1 and 13 years with an average age of 2 years and a median of 16 months (Graph 2, p.28) were included in the study. Of 156 (85.7%) whose data is available, 108 (69.2%) were the first-born of their families, while 52(33.5%) and 45 (29.0%) had respectively no brothers and one brother (Graph 3 & 4, p.29).

The mother’s level of education was subdivided in (1) illiterate (with or without primary school) mothers, (2) literate and or completed their primary school, (3) those who did secondary school and (4) those who reached college or University level of education. Thirty two (29.9 %) are illiterates, 49 (32.0%) just literate, while 51(33.3%) have completed the secondary school and only 21 (13.3%) have gone as far as to college or University in education (Graph 5, p.30)

Clinical factors
We note that the ratio of new to recurrent cases was approximately 2:1 (exactly 2.25: 1) while for the severity level, mild cases are extremely few for meaningful statistical representation 8 (4.4%) as opposed to the severe ones who were far more than the majority 130 (71.4%) (Graph 6, 7, p.30 &31)

The patients with recurrence after dilatation, at presentation, were classified according to the number of dilatations they had undergone and the number of weeks after the last dilatation i.e. the number of weeks it took for the last recurrence to happen. The number of dilatations (recurrences) at presentation varied between 1 to 8 times but 1 to 3 times carried more than 90% (n=87) of the patients (Graph 8, p.31).
No patients with recurrence after topical steroid were to be restarted on the same treatment but referred to the consultant who most of the time booked them for circumcision. Only 11 were circumcised and followed up until discharge from the clinic. No peculiar appearance or complication that may be pertaining to the previous use of topical steroid was reported.

The number of weeks it took for the last recurrence to happen, varied from 1 to 14 weeks with more representation between 2 to 8 weeks cumulating 70.8% (n=96) (Graph 9, p.32)

Outcome

This was evaluated for “Group 1” in form of preputial full retractability as a good outcome and the opposite was a failure to achieve full retraction of the prepuce after consecutive 6 weeks of treatment. While in “Group 2” a good outcome was with those patients who did not have recurrence of phimosis after a full retraction achieved by means of a good dilatation while the recurrence was considered to be a failure or bad outcome.

Of all patients only 141 (77.5%) successfully completed the follow up period.

Group 1

Among 125 (68.7%) patients who used topical betamethasone, 92 (65.2%) patients were fully followed up. Of these, 80 (86.9%) had a successful and 12(13.1%) failed to achieve full foreskin retraction. (Graph10, p.32)

For the phimosis to respond well to topical steroid cream, it took from 1 to 7 weeks but 2, 3 and 4 weeks cumulate well above 82%. (Graph 12, p.33)

The number of cream tubes used by each patient is also from 1 to 4 in a decreasing percentage as follow: 42(47.7%), 28(31.8%), 15(17.0%), and 3(3.4%). (Graph 11, p.33) The average number of betamethasone 0.1% tube (15gr) used for each patient was 1.7 while the cost of such a tube varied between K3500.00 and K4500.00 in the local pharmacies [1$ (US) = K4635].
Group 2

Group 2 patients constitutes 49 (34.8%) of the cohort that completed the follow up period. Only 17(34.7%) of this group had a good outcome while 32(65.3%) failed to maintain the retraction after dilatation and had recurrences. (Table 1, p. 34)

More details are noted when the outcome is stratified by different criteria:

- By the type of patients: Full foreskin retraction was noted in 72(51.1%) among the new cases and 25(18.0) in the recurrent type of patients while the failure was respectfully 30(30.9%) and 14(10.0%). (Table 2, p.34).

- In relation to the mother’s level of education as shown in table 3, illiterate and primary school literate cumulate a count close to 70.0% of the failures in the study. The rate of successful outcome is proportionate to the total number of the patients within each education level group.

While on topical steroid cream, 1(0.01%) patient developed a paraphimosis, as the mother retracted and did not reduce the foreskin during a bath. The paraphimosis was reduced under general anaesthesia as an emergency at our casualty theatre. Otherwise there has been no other complication observed with this treatment.

It was also noticed that 143 (90.5%), (n=158) of the mothers confirmed to have made many attempts with no improvement to overcome the non-retractability of their sons’ foreskin before deciding to take the child to the clinic.
TABLES AND GRAPHS

Graph key:
0 Phimosis
1 Hernia
2 Tongue tie
3 Hydrocephalus
4 Lymphadenopathy
5 Hydrocele
6 Polydactyly
7 Undescended testis
8 Lipoma
9 Cyst
10 Hypospadias

GRAPH 1: Phimosis compared to the 10 commonest conditions in Paediatric surgical clinic (UTH / Dec 2003- Dec 2004)

GRAPH 2: Age distribution of the patients in the study (n=182)
Graph 3: Chronological order of birth for an individual patient among the siblings

Showing that most of the patients were the first born in their families, hence young mothers

Graph 4: Number of brothers for an individual patient
GRAPH 5: Education level of the patients' mothers

Key: (1) have not been at school / illiterate (2): Primary school

GRAPH 6: Types of patients in Group 1.

New and recurrent cases among the topical steroid users (n=125)
GRAPH 7: Phimosis severity at presentation in our patients (n=182)

Showing that most of the patients were presented when the condition was becoming unbearable.

GRAPH 8: Number of dilatations among the recurrent type of patients
GRAPH 9: Number of weeks from the last dilatation among the recurrent type of patients

Showing the approximate time it takes for the recurrence to happen.

GRAPH 10: Group 1 and Group 2 outcome Comparison

Showing the percentage of patients (Pts) who achieved and/or maintained foreskin retraction and those who failed it among the two groups of treatment. **Group 1**: Betamethasone  
**Group 2**: Foreskin dilatation
GRAPH 11: Number of cream tubes used by patient among those who responded well to treatment

GRAPH 12: Number of patients and time (weeks) they took to respond well to the topical steroid cream
Table 1:
Outcome by mode of treatment

<table>
<thead>
<tr>
<th>Mode of treatment</th>
<th>Successful</th>
<th>Failure</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1</td>
<td>80 (86.9%)</td>
<td>12 (13.1%)</td>
<td>92 (65.2%)</td>
</tr>
<tr>
<td>Group 2</td>
<td>17 (34.7%)</td>
<td>32 (65.3%)</td>
<td>49 (34.8%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>97 (68.8%)</td>
<td>44 (31.2%)</td>
<td>141 (100%)</td>
</tr>
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</table>

**Group 1:** Betamethasone  
**Group 2:** Instant Dilatation / Expectant

Table 2
Outcome by type of patients

<table>
<thead>
<tr>
<th>Type of patients</th>
<th>outcome</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Successful</td>
<td>Failure</td>
</tr>
<tr>
<td>New</td>
<td>72 (51.1%)</td>
<td>30 (21.3%)</td>
</tr>
<tr>
<td>Recurrent</td>
<td>25 (17.7%)</td>
<td>14 (9.9%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>97 (68.8%)</td>
<td>44 (31.2%)</td>
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</table>

Table 3
Outcome related to the Mother's level of education

<table>
<thead>
<tr>
<th>Mother's education level</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Successful</td>
</tr>
<tr>
<td>1. No primary School/ illiterate</td>
<td>13 (10.2%)</td>
</tr>
<tr>
<td>2. Primary School</td>
<td>25 (19.5%)</td>
</tr>
<tr>
<td>3. Secondary School</td>
<td>35 (27.3%)</td>
</tr>
<tr>
<td>4. College/ University</td>
<td>16 (12.5%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>89 (69.5%)</td>
</tr>
</tbody>
</table>

34
Fig 1: The triradiate continuous suture of Doyen (1920)

Fig 2: Chetwood’s dressing secured with long sutures

Fig 3: The “Ecraseur” of Doyen. Used in crushing the foreskin along the excision line
Fig 4: The "Winkelman" circumcision clamp

Fig 5: The Glansguard device.

Fig 6: Penile gangrene after circumcision
8. DISCUSSION

The commonest reason to visit the paediatric surgical clinic at University Teaching Hospital [UTH] is phimosis. UTH statistics (Dec 2003 to December 2004) in Paediatric surgical out patient clinic, show that the highest number of patients present with phimosis (39.2%) followed by hernia (23.8%). Circumcision or dilatation in some cases to buy time has been the traditional mode of treatment. This surgical treatment is associated with not only long waiting theatre lists but also a high potential morbidity like wound pain and a number of complications in some patients such as: infection, scarring, excessive skin removal, glandular and urethral injuries, etc (2). Although these complications are relatively rare, other imperative reasons urge us to think wide for an effective, safe and more accommodating alternative mode of treatment. These include: the high number of patients compared to an excessively low number of trained staff for safe operations, the cost attached to each operation and the scarcity of resources in our setting, without forgetting the anaesthetic cost and its own set of risks and complications that it carries with it. Moreover, even if circumcision is an identification sign in some societies (Appendix-4), the appearance of circumcised penis may not be a tolerable outcome due to differences in cultural norms e.g.: Impare*. We also recall that even in the USA and Canada where the rates of neonatal circumcision once evaluated at 60% to 90% are now sensibly reducing (3) mainly due to the now realised need to preserve the foreskin. The introduction of topical steroid for treatment of phimosis solves most of the above problems.

One of the difficulties in studying phimosis is the lack of a clear definition to differentiate objectively pathological and physiological phimosis. Nevertheless, when a parent presents a child aged less than 3 to 4 years, with a complaint of non retractability of the foreskin alone it is not difficult to realise that it is in deed physiological and needs not to cause any worries but when it is associated with voiding problems with or without ballooning of the foreskin, it is agreed to be sufficient enough for the patient to require treatment.

We note that the average age of about 2.5 years in our sample brings about to wander why “pathological phimosis“ at this age! On the other hand we note that 69.2% of our population is the first born in their families, while about 62.5% cumulates the first and second boys of their

* See terminology p. ix

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families. Furthermore 90.5% of the mother confirms to have attempted forceful retraction of the foreskin, -to overcome the non retractability-, while bathing the baby. One would tentatively stipulate that the inexperienced young mothers might be causing repeated traumatic micro-crack into the prepuce. In attempt to heal the repeated micro injuries, a local reaction may then reduce further the already small outlet of urine through the foreskin, hence the physiological phimosis becoming progressively pathological. But this has still a large room for more elaborate research to be undeniably confirmed aetiology.

Using at least one the clinical factors, e.g.: "severity", we note that the two groups are some how comparable (p = 0.05) otherwise supposed to be < 0.05, bearing in mind that the major difference between them is their sample size 125 (68.7%) and 57 (31.3%) for Group 1 and 2 respectively. Nonetheless their success rate 80(86.9%) and 17(34.7%) for Group 1 and Group 2 (p= 0.001) respectively, are far from comparison. However in a series of 111 patients with phimosis treated with topical betamethasone Wright reported 80% success rate (34). Similarly, Ashfield et al (3), treated with topical betamethasone 194 patients with phimosis but 25 of them with coexisting balanitis, 4 with history of urinary tract infection and had an overall success rate of 87%. Monsour et al (33) did not find topical steroids this effective, only 16(67%) in a population of 24 boys with phimosis; while Golubovic et al observed a 95% success rate in 20 boys that were treated with topical steroid betamethasone. This is not far from the success rate of (90%) in 124 children treated by Orsola et al (5)

Webster et al (38) found an association between the scarring by balanitis xerotica obliterans (BXO) observed at presentation and the decrease in efficacy of the topical steroid treatment from 92% to 67%. He concluded that depending on the severity of the disease, BXO, the boys with should be considered for surgery primarily. In our series, any associated pathology other than phimosis was an exclusion criterion. Therefore we cannot comment on the efficacy of topical steroid in this condition. However we did not find any association with the severity of the phimosis itself, not even whether the phimosis is new or recurrent.(p=0.08 and 0.2). An association is observed with the number of dilatations (p=0.03)

On the other hand a statistical significance of a strong association was found between the mother’s level of education and the outcome (p=0.005). The reason may be no other than a clear understanding of the instructions and compliance increases with education. (Table 3, p.34)
Ashfield et al looked at 194 boys aged between 1 and 16 years. With a median age was 5 years, they found no association of their success/failure rate with the age of the patient (3). We did not also find any association of the outcome and the age but our sample age distribution (1 year to 13 years, with a mean age of 2 years) is not representative to make a valuable comment.

It is observed as well that our lost for follow rate 40 (21.9%) is relatively high, but again associated with the low level of education of the mothers (p=0.01). In an attempt to discover the reason 5 (12.5%) of these were visited at their homes and 4 (80%) saw no need to continue to come at the clinic as the child was "all right" when there was no transport money. The other mother was very sick and there was no body to bring the child who in deed had no" problem". This is coupled with a relatively long follow up period. There is no doubt that if finances were available and transport was paid for the patients, the drops out were to be minimal and the success rate would increase sensibly.

Throughout the entire reference list the authors who thought of the topical steroids adverse effect did confirm to have found none. This study did not find it otherwise but a low risk of paraphimosis (0.01%).

Berdeu et al (4) and Van Howe (35) estimated the savings by the topical steroid at 75% of the cost of circumcision. The trend in our series was that the saving were much higher than the above, more than 92%, as the average number of cream tubes used was 1.7 (mode 1, median 2) tubes and the price of one tube (15gr) K4000.00 at the local market against circumcision cost estimated at not less than K100, 000.00 in our local private hospitals.
9. CONCLUSION

The efficacy of the topical steroid betamethasone 0.1% as treatment of phimosis, documented elsewhere is similar to our findings, even though our conclusions are drawn from a short term study. With this therapy, 86.9% of the patients were saved from circumcision while dilatation could avoid it for 34.7% only. Eighty six point nine percent success rate is highly commendable and offers a valuable alternative option treatment of phimosis. No wonder the topical steroids are becoming the standard treatment of phimosis.

While the cost-effectiveness of this method of treatment is beyond discussion, it is also user friendly and requires no special training. The cream is readily available, hence appropriate to our environment.

It has no adverse effect per se if mother or guardian is cautioned about the risk of paraphimosis when the prepuce is not reduced after every retraction.

For those patients who did not respond well to the topical steroid and had circumcision, there was no complication.

This study did not find any significant difference in efficacy for different types of patients, being the severity, the newness or the recurrence of the phimosis.
10. RECOMMENDATIONS

This study is definitely supporting the shift from circumcising a young boy because of phimosis to conservative treatment by topical steroid e.g.: betamethasone 0.1% as a standard primary / initial measure for the treatment of phimosis but clear instructions good follow up are required to avoid complications.
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Appendix-1

RESEARCH CONSENT FORM

TOPICAL STEROIDS, AN ALTERNATIVE TO CIRCUMCISION FOR TREATMENT OF PHIMOSIS

1. Why are we giving you this form?
We are giving you this form, telling you what it means and giving you the chance to ask questions about the study. Then you can decide if you want to take part in the study that is trying to investigate the role of topical steroids as an alternative to circumcision for treatment of phimosis.

2. Who is carrying out this study?
Dr. J.Baptiste Nzayisenga is the principal investigator in this study. He is being supervised by Dr. Mohamed Labib and Prof. Lupando Munkonge who will advise and help him to monitor the progress of patients.

The study is being conducted in a special clinic: "Circumcision Clinic“ established in D block, Department of Surgery at the University Teaching Hospital in Lusaka, Zambia.

The official name of the study is: “Topical steroids, an alternative to circumcision for treatment of phimosis”.

3. Background Information
You are being asked to take part in a research study because your child has phimosis. We are trying a medical treatment of phimosis as an alternative to circumcision in view to avoid its complications that follow.

Some medical research suggests that this way of treating phimosis is efficient, safe, less costly and above all it non-invasive. It is recommended for the patients with this condition. We hope this study will show such benefits in patients being treated similarly in the University Teaching Hospital, in Lusaka.

4. What happens in this research?
Several things will take place:
A protocol form will be used to enter the child's personal details and the type of the phimosis and its severity. We will demonstrate how to apply the cream 0,1% betamethasone that will be used twice daily for the next 4 to 6 weeks. The child will be reviewed at regular intervals as per schedule and a series of observations will be recorded at the protocol form.

5. **Are there any possible Problems?**

So far there has been no side effect with 0,1 % betamethasone cream, the medicine we are going to use but it has not worked in a small proportion of patients who used it, which is a manageable risk. However the study may have risks that are not known now. We believe there will be none and the study will endeavour to follow you up closely.

6. **Benefits**

No theatre waiting list as treatment is initiated now,
No pain resulting in circumcision and no risk of anaesthetic problems,
No risk of wound infection and other circumcision complications,
A lot of funds are spared by avoiding the operation.
*You may not benefit from participating in the study.*

7. **Your rights to participate, not participate, or to withdraw from the study**

Taking part in this study is voluntary. You do not need to take part in this study – it is up to you. You may choose to either participate or not. If you choose to take part in the study, you can later change your mind and withdraw from the study. You will still receive the standard treatment.

You will suffer no penalty if you do not take part in the study. If you do not take part in this study you will not lose any benefits to which you are entitled as a patient of this hospital. Your present and future medical care at University Teaching Hospital; Lusaka will be the same whether or not you take part in this study.

If there are any new findings during the study that may affect whether you want to continue to take part in this study, you will be told about them as soon as possible.

The investigators may decide to discontinue your participation without your permission because they may decide that staying in the study will be bad for you.
8. Confidentiality

Your name will never be made public by the investigators. The medical record of your care will be treated the same as all medical records at the University Teaching Hospital, Lusaka.

Information from this study and from your medical record may be reviewed and copied by the study investigators and examiners that may be appointed by the University of Zambia. A code number that makes it very difficult for anyone to identify you will identify the research information gathered by the study. All information will be stored in a secure place. Information from this study and from your medical record may be used for research purposed and may be published; however, your name will not be made public by the investigators. It is possible that, after the study is over we may want to look again at the medical record data collected during the study to help us answer another question. If this happens, your name will not be made public by the investigators.

I………………………………. (Full Name + code) hereby give consent for inclusion in the study. I have understood the details of the study as explained to me by the investigator.

Signature: .................... Date: ......................

I have explained this research study to the subject. I am available to answer any questions now or in the future regarding the study and the subject’s rights.

The principal investigator Dr. J.Baptiste Nzayisenga and his supervisors can be reached at the Department of Surgery, University Teaching Hospital, Lusaka, Zambia.

Signature of Investigator and Printed Name
DATA COLLECTION FORM

ID

PERSONNAL DETAILS

Name

Age:

Address: ........................................

........................................

........................................

Number of siblings

Birth order among brothers

DATE (Visit 1): .........................

File number

Mother education level

Key (0) Illiterate

(1) Literate / Primary school

(2) Secondary school

(3) College / University

CLINICAL PRESENTATION (Visit 1)

TYPE OF PATIENT

(1) New

(2) Recurrent

Number of dilatation

Last Dilatation (weeks)

SEVERITY LEVEL

(1) Mild

(2) Moderate

(3) Severe

CURRENT MODE OF TREATMENT

(1) Dilatation

(2) Betamethasone
SUBSEQUENT VISITS

Date 2
Date 3
Date 4
Date 5
Date 6
Date 7
Date 8
Date 9
Date 10

Key to options

<table>
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<tr>
<th>Visit</th>
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<th>4</th>
<th>5</th>
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<td>2: Moderate foreskin retraction</td>
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<td>3: Full foreskin retraction</td>
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<td>4: Free full foreskin retraction</td>
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</table>

OUTCOME

(1) Retracting
(2) Circumcised / booked for circumcision
(3) Lost follow up

Time (weeks) it takes to reach full retraction

Total Number of tubes (Cream) used

REMARKS

55
Appendix-3

Protocol

TOPICAL STEROIDS AS A FIRST OPTION FOR TREATMENT OF PHIMOSIS.
HOW TO USE THE CREAM.

Introduction
★ Phimosis is non-retractile prepuce which is one the commonest conditions
★ Topical steroid, as a first treatment option of phimosis is technically simple, non-invasive, safe, cost-effective and efficient.

How is it done?
The application of topical steroids is done in the following way:

1. Before cream application, the prepuce should be thoroughly cleaned with water & bath soap.

2. The cream is applied to the prepuce from the inner most on gentle but firm retraction, twice daily for 6-8 weeks.

3. If there is no sign of prepucial retraction showing the tip of the meatus by the 3rd week, consult your doctor.

4. Do not stop treatment abruptly (suddenly) but gradually from the time it is noted to be retracting freely.

5. Hygiene is the most important factor after treatment to avoid recurrence of the problem.
Map of Zambia showing distribution of some tribes

Key:

Luvale: Name of tribe that practices traditional circumcision

Nsenga: Name of tribe that does not practice traditional circumcision