TEKNO KLEM: NEW DISPOSABLE DEVICE FOR PEDIATRIC CIRCUMCISION– A CASE REPORT

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ABSTRACT

Objective: *This case report aimed to present the use of Tekno Klem, a new disposable circumcision device. Unlike existing devices, Tekno Klem allows immediate clamp removal, potentially reducing the risk of postoperative complications.* ***Case(s) Presentation:*** *A 6-year-old boy presented to the Urology Outpatient Clinic with difficulty in retracting the foreskin of the penis. Physical examination revealed a non-retractable foreskin with a constrictive ring, classified as grade 3 phimosis. Elective dorsal slit surgery using Tekno Klem device was scheduled. The circumcision procedure using the Tekno Klem device began with measuring the glans size to ensure appropriate device selection. The appropriate Tekno Klem clamp size was selected from the available options: 12 mm, 14 mm, 16 mm, 18 mm, 22 mm, and 27 mm. The preputial skin was marked to define the excision area. The safety tube was then carefully positioned around the glans. Subsequently, the clamp frame was inserted. Once the desired positioning was confirmed, the screw cap was applied, locking the clamp securely in place through its serrated and threaded mechanism. The preputial skin was excised using thermal cautery. After clamp removal, N-butyl cyanoacrylate ointment was applied to protect the wound. The procedure lasted 15 minutes.* ***Discussion:*** *Postoperative pediatric penile perception scored 10, indicating improved penile appearance, while voiding satisfaction scored 5, reflecting favorable functional outcomes. No complications, including bleeding, hematoma, infection, glans injury, meatal stenosis, or delayed healing, were observed. The circumcision site healed properly with satisfactory cosmetic and functional results.* ***Conclusion:*** *Tekno Klem offers enhanced precision, safety, and ease of use over conventional devices, with the potential to reduce complications and optimize outcomes, particularly in settings prioritizing surgical accuracy and patient safety.*

Keywords: *Tekno Klem, circumcision, disposable, pediatric, clamp.*

ABSTRAK

Tujuan: *Laporan kasus ini bertujuan untuk menyajikan penggunaan Tekno Klem, sebuah alat sirkumsisi disposable yang inovatif terbaru. Berbeda dengan alat yang sudah ada, Tekno Klem memungkinkan pelepasan klem secara langsung, yang berpotensi mengurangi risiko komplikasi pascaoperasi.* ***Presentasi Kasus:*** *Seorang anak laki-laki berusia 6 tahun datang ke Klinik Rawat Jalan Urologi dengan kesulitan menarik kembali preputium penis. Pemeriksaan fisik menunjukkan preputium yang tidak dapat ditarik kembali dengan cincin penyempitan, diklasifikasikan sebagai fimosis derajat 3. Operasi sayatan dorsal elektif menggunakan alat Tekno Klem dijadwalkan. Prosedur sirkumsisi menggunakan alat Tekno Klem dimulai dengan mengukur ukuran kelenjar untuk memastikan pemilihan alat yang tepat. Ukuran penjepit Tekno Klem yang sesuai dipilih dari pilihan yang tersedia: 12 mm, 14 mm, 16 mm, 18 mm, 22 mm, dan 27 mm. Kulit preputium ditandai untuk menentukan area eksisi. Tabung pengaman kemudian diposisikan dengan hati-hati di sekitar kelenjar. Selanjutnya, rangka penjepit dimasukkan. Setelah posisi yang diinginkan dikonfirmasi, tutup sekrup dipasang, mengunci penjepit dengan aman di tempatnya melalui mekanisme bergerigi dan berulir. Kulit preputium dieksisi menggunakan kauter termal. Setelah klem dilepas, salep N-butil sianoakrilat dioleskan untuk melindungi luka. Prosedur ini berlangsung selama 15 menit.* ***Diskusi:*** *Skor persepsi penis pediatri pascaoperasi adalah 10, menunjukkan peningkatan penampilan penis, sedangkan kepuasan buang air kecil mendapat skor 5, mencerminkan hasil fungsional yang baik. Tidak ada komplikasi, termasuk perdarahan, hematoma, infeksi, cedera kelenjar, stenosis meatus, atau penyembuhan yang tertunda,*

yang diamati. Lokasi sirkumsisi sembuh dengan baik dengan hasil kosmetik dan fungsional yang memuaskan. ***Simpulan:*** *Tekno Klem menawarkan peningkatan presisi, keamanan, dan kemudahan penggunaan dibandingkan perangkat konvensional, dengan potensi untuk mengurangi komplikasi dan mengoptimalkan hasil, terutama dalam lingkungan yang memprioritaskan akurasi bedah dan keselamatan pasien.*

Kata kunci: *Tekno Klem, sirkumsisi, disposable, pediatri, klem.*

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INTRODUCTION

Male circumcision is one of the most commonly performed surgical procedures worldwide, with an estimated prevalence of approximately 37–39% of males globally undergoing the procedure for religious and cultural reasons.[1] The procedure involves the removal of the preputial skin and has been associated with various health benefits, including reduced risks of urinary tract infections, balanitis, penile cancer, and sexually transmitted infections such as human immunodeficiency virus (HIV) and human papillomavirus (HPV).[2] While the procedure is generally safe when performed by trained practitioners, complications such as bleeding, infection, and poor cosmetic outcomes can occur, particularly in non-sterile or inexperienced settings.[3-5]

The conventional scalpel and suture technique is considered the gold standard for circumcision, involving excision of the preputial skin with a scalpel, hemostasis through ligation or electrocautery, and wound closure with sutures to facilitate healing.[6-7] However, this method is time-consuming and requires a high level of surgical skill to ensure precise excision and proper hemostasis.[8] Inadequate technique can lead to complications such as excessive bleeding, hematoma formation, infection, postoperative pain, and suboptimal cosmetic outcomes.[3] Additionally, the prolonged operative time and need for meticulous postoperative wound care contribute to patient discomfort and extended recovery periods.[2,3,6] These challenges highlight the need for alternative approaches that improve procedural efficiency, safety, and outcomes while minimizing complications.

To address these challenges, device-assisted circumcision techniques have been widely adopted due to their efficiency, safety, and improved cosmetic outcomes.[9] The most commonly used devices include the Gomco clamp, Mogen clamp, and Plastibell device.[9-16] These techniques have significantly contributed to the standardization of circumcision procedures, reducing operative time and postoperative complications.[10,13,14] However, despite their advantages, each of these devices has inherent limitations.[11,15] The Gomco clamp is regarded as one of the safest methods in terms of infection risk and provides excellent cosmetic results.[9-11] However, its use is technically demanding, requiring precise placement and careful handling.[10] It also necessitates suturing and carries a risk of bleeding, making it less ideal for settings requiring rapid procedures.[11] The Mogen clamp, on the other hand, is a faster technique that requires minimal instrumentation and does not require suturing.[13] However, it has a higher risk of bleeding and carries the potential for iatrogenic injury if applied too proximally.[13-14] The Plastibell device is commonly used in neonates and has advantages such as minimal bleeding and ease of use.[12,16] However, it requires the presence of a foreign body on the penis for several days, which may increase the risk of infection and prolong healing time.[15,17]

Given these drawbacks, there is a growing need for a disposable circumcision device that ensures safety, ease of use, and improved patient outcomes.[17-19] Previous studies have introduced disposable circumcision devices; however, these devices require prolonged placement, which may increase the risk of complications.[17-23] This case report aimed to present the use of Tekno Klem, a new disposable circumcision device designed to enhance procedural efficiency, safety, and precision while minimizing complications and improving cosmetic outcomes. To the best of our knowledge, Tekno Klem is the first disposable circumcision device that does not require the clamp to remain in place immediately after the procedure, potentially reducing the risk of complications. By documenting its clinical application and postoperative outcomes, this report aims to contribute valuable insights into the advancement of circumcision techniques and the role of disposable devices in contemporary urological practice. This case report was prepared in accordance with the CAse REport (CARE) guideline[24] and the Surgical CAse REport (SCARE) guideline.[25]

CASE(S) PRESENTATION

A 6-year-old boy presented to the Urology Outpatient Clinic, with difficulty in retracting the foreskin of the penis. There was no history of previous genital trauma, urinary tract infection, or prior interventions. The patient had no significant past medical history, and developmental milestones were appropriate for age. The patient's vital signs, including heart rate, blood pressure, respiratory rate, and body temperature, were within normal physiological ranges. Physical examination revealed a non-retractable foreskin with a constrictive ring, classified as grade 3 phimosis. There were no signs of erythema, edema, or purulent discharge. The external genitalia were otherwise normal. Urinalysis and urine culture were performed to rule out underlying infection, both of which yielded normal results. The diagnosis of grade 3 phimosis was established based on clinical examination.

Elective dorsal slit surgery using the Tekno Klem device was scheduled. The procedure was performed under a combination of local anesthetic cream and nerve block anesthesia. The Tekno Klem device consisted of three components: (1) a safety tube, (2) a clamper frame, and (3) a screw cap (Figure 1). The circumcision procedure using the Tekno Klem device began with measuring the glans size to ensure appropriate device selection, which was crucial for a secure fit and optimal surgical outcome (Figure 2). Following glans measurement, the appropriate Tekno Klem clamp size was selected from the available options: 12 mm, 14 mm, 16 mm, 18 mm, 22 mm, and 27 mm, ensuring an optimal fit for the patient. The preputial skin was marked to define the excision area, facilitating precise tissue removal. The safety tube was then carefully positioned around the glans, serving as a protective barrier while allowing for adequate air circulation.

Subsequently, the clamper frame was inserted, securing the preputial tissue in place while permitting adjustments to the skin and mucosal length as needed (Figure 2). Once the desired positioning was confirmed, the screw cap was applied, locking the clamp securely in place through its serrated and threaded mechanism. The preputial skin was excised using thermal cautery, ensuring hemostasis while minimizing tissue trauma. After clamp removal, the wound was evaluated to assess healing progression and the absence of complications. Finally, N-butyl cyanoacrylate ointment was applied topically in a thin layer over the surgical site to protect the urethral orifice and promote optimal recovery (Figure 2). The procedure lasted approximately 15 minutes. Ibuprofen was administered orally at a dose of 10

mg/kg, given every 8 hours as needed to manage pain, inflammation, and swelling.

Cosmetic outcomes were evaluated 14 days after surgery using the pediatric penile perception score (PPPS), which assesses meatal position and shape, glans shape, penile skin configuration, and overall appearance. The scoring ranged from 0 (very dissatisfied) to 3 (very satisfied). Voiding satisfaction was assessed 14 days postoperatively based on a five-point scale (1=very unsatisfactory to 5=very satisfactory), as reported by the patient's parents. The postoperative PPPS assessment yielded a score of 10, indicating an improvement in penile appearance from the patient's perspective. Voiding satisfaction received a score of 5, reflecting positive functional outcomes. No complications were noted during the procedure or follow-up period on days 3, 7, and 14. There were no reports of excessive bleeding, hematoma, infection, glans injury, meatal stenosis, or delayed wound healing. The circumcision site healed properly, with favorable cosmetic and functional results (Figure 3). This case report was approved by medical and health research ethics committee (MHREC), faculty of medicine, public health and nursing, Universitas Gadjah Mada, Sardjito Hospital (KE/FK/1031/EC/2024).

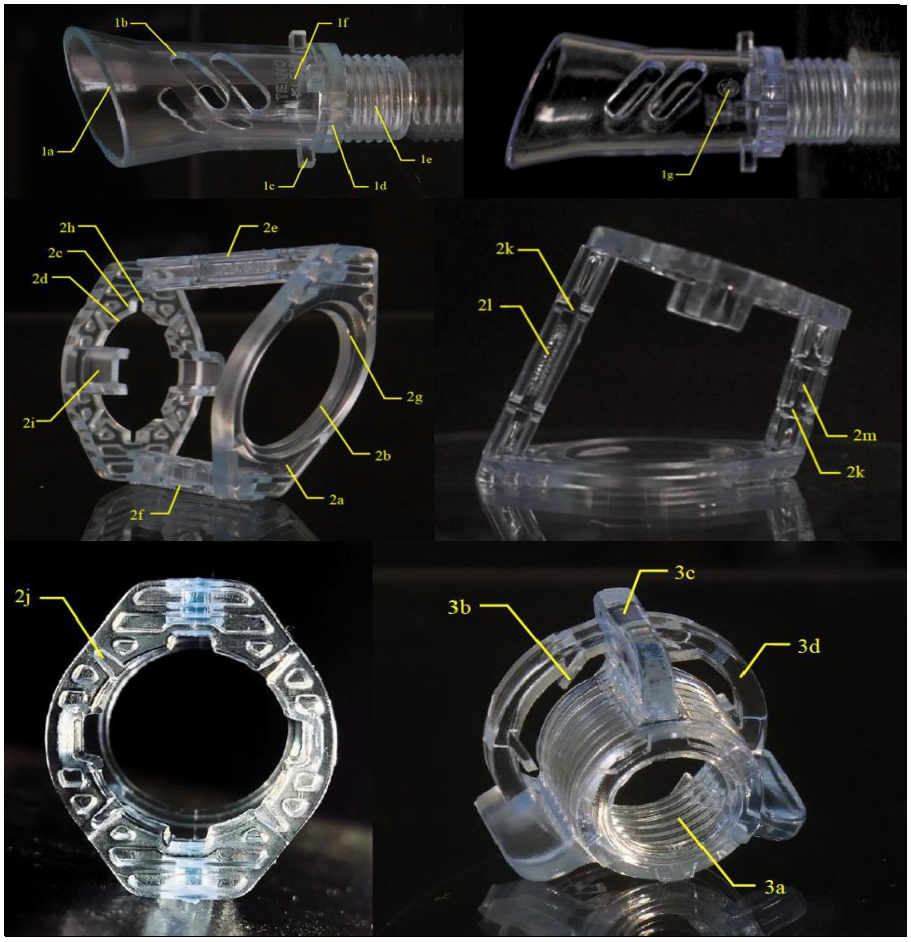

Figure 1. Components of the Tekno Klem device. The device consists of three main components: (1) the safety tube, which protects the glans, allows air circulation, facilitates cleaning, and features four ear tubes (3, 6, 9, and 12 o'clock) for secure positioning of the clamper frame; (2) the clamper frame, which stabilizes the prepuce against the safety tube, includes front and rear flanges, connecting rods, an ear tube slot to prevent movement, a safety notch for precise placement, and designated cutting areas for removal; and (3) the screw cap, which locks the device using a serrated and threaded system, ensuring secure attachment to the safety tube, with a handle for precise tightening and a retaining ring to prevent loosening.

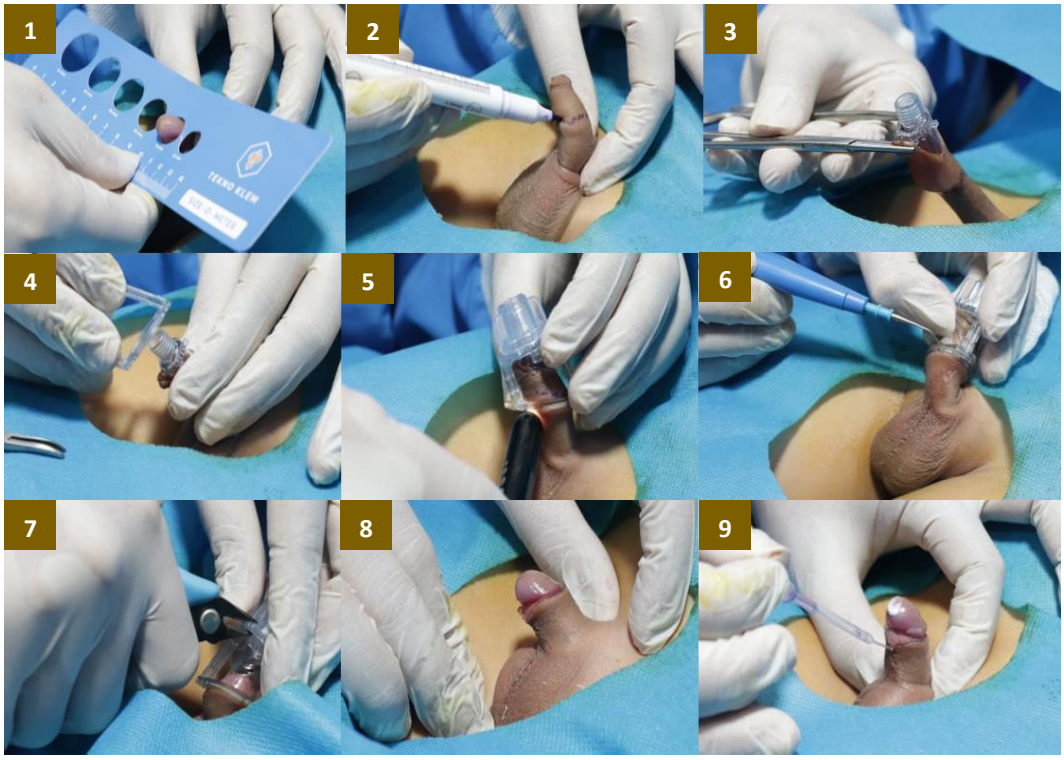

Figure 2. Step-by-step procedure of circumcision using the Tekno Klem device: (1) measurement of glans size to determine appropriate device selection; (2) preputial skin marking for precise excision; (3) insertion of the safety tube to protect the glans and stabilize the prepuce; (4) placement of the clamper frame, allowing adjustment of the preputial and mucosal length; (5) securing the clamp by locking the screw cap; (6) excision of the preputial skin using the designated cutting area; (7) the clamp is removed immediately by excising the designated cutting points; (8) post-removal evaluation of wound healing; (9) application of ointment to protect the urethral orifice and promote recovery.

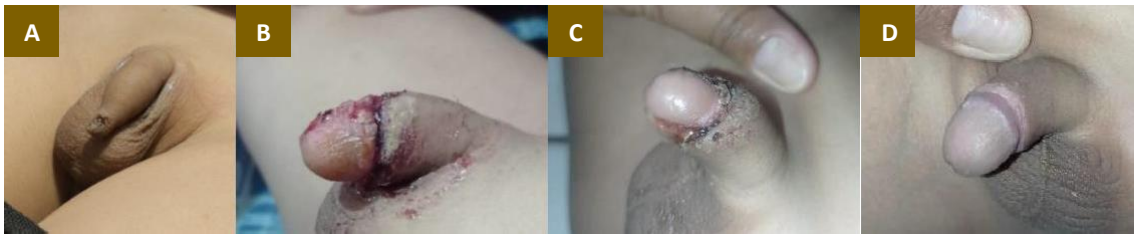

Figure 3. Pre- and postoperative penile appearance: (A) prior to circumcision; (B) postoperative day 3; (C) postoperative day 7; and (D) Postoperative day 14.

DISCUSSION

Tekno Klem was developed as a new disposable circumcision device that integrates the advantages of existing suture-based circumcision devices while addressing their limitations. Unlike other disposable circumcision devices.[18-19] Tekno Klem features a disposable, adjustable mechanism that enables controlled excision of the preputial skin without requiring prolonged placement. Its clamping system ensures precise tissue removal while minimizing trauma to surrounding structures. The design specifically enhances glans protection, reducing the risk of intraoperative injury, a concern associated with other disposable circumcision devices. The Tekno Klem device comprises three main components: the safety tube, clamper frame, and screw cap, each designed to enhance procedural safety and efficacy.

The safety tube protects the glans penis during circumcision. Its hollow spade design provides shielding while allowing air circulation through a designated opening, which also facilitates post-procedure cleaning. Four ear tubes positioned at 3, 6, 9, and 12 o'clock secure the clamper frame in place. A serrated locking mechanism ensures a firm connection to the screw cap, while the threaded section aligns with the screw cap's thread. Each safety tube is labeled with the product name and size for proper selection.

All components of Tekno Klem are made from medical-grade polycarbonate, a durable, lightweight material commonly used in medical devices. Polycarbonate has high tensile (9500 psi) and compressive strength (12000–12500 psi), as well as impact resistance (12–16 ft-lbs/in), ensuring structural integrity. With a density of 1.2 g/cm³, it contributes to the device's lightweight design. The material withstands temperatures up to 150°C before density alterations occur and has a melting point of 300°C, making it highly heat-resistant. Additionally, polycarbonate is an effective electrical insulator, allowing compatibility with electrosurgical units (ESU) and other powered surgical instruments. Polycarbonate's resistance to chemicals, including alcohols, acids, bases, and oils, enhances its durability in medical settings. It supports multiple sterilization methods, such as autoclaving, gamma radiation, and ethylene oxide (EtO) gas sterilization, ensuring safe reuse. Its natural transparency, with a light transmission rate of nearly 90%, allows clear visualization during procedures, further supporting its clinical applicability.

The clamper frame functions as the primary clamping mechanism. It comprises a front and rear flange, which accommodate the safety tube at both the entry and exit points, ensuring structural integrity. The upper and lower connecting rods provide stability and serve as surfaces for compressing the prepuce against the outer wall of the safety tube. The frame also includes an ear tube slot, which restricts excessive movement of the safety tube during application. A safety notch is incorporated to enhance precision when mounting the clamper frame. Additionally, designated cutting areas on the frame and connecting rods allow for controlled removal of the clamp after the procedure. The product name is imprinted on the frame for identification purposes.

The screw cap acts as the locking component of the device. It features a serrated section that interlocks with the corresponding serration on the safety tube, ensuring a secure fit. The threaded design allows it to engage seamlessly with the safety tube's threading, facilitating controlled tightening. A dedicated handle provides an ergonomic grip for rotation, enabling precise application of pressure. Additionally, a retaining ring stabilizes the screw cap rotation and serves as a thread holder, preventing unintended loosening during the procedure. Together, these components contribute to the Tekno Klem's efficacy by providing a secure, controlled, and safe circumcision technique.

Previous studies have explored the use of disposable circumcision devices, utilizing a two- ring clamping system that remains in place for several days to facilitate preputial tissue necrosis and detachment.[17,20,23] While this method reduces intraoperative bleeding and eliminates the need for sutures, the prolonged retention of the device increases the risk of infection, discomfort, and delayed wound healing.[18,19] In contrast, Tekno Klem was developed to address these limitations by incorporating an adjustable clamping system that enables immediate excision of the preputial skin without requiring device retention. This design ensures precise tissue removal while minimizing trauma to surrounding structures. Additionally, its protective safety tube safeguards the glans penis, reducing the risk of intraoperative injury. By eliminating the need for prolonged placement, Tekno Klem potentially lowers

the risk of postoperative complications and promotes faster healing.

Tekno Klem operates similarly to the SmartClamp and Alisklamp circumcision clamps by securing the preputial skin between the outer wall of the protective tube and the clamping frame.[26-28] It employs a permanent locking mechanism, preventing removal or reuse.[26-28] The key difference lies in the locking system. Tekno Klem utilizes an irreversible thread locking system, in which a threaded connection between the safety tube and screw cap secures the clamp. In contrast, Smart Klamp and Alisklamp use a snap-fit locking system integrated into the clamping frame.[26-28] The irreversible thread locking system in Tekno Klem provides superior clamping force compared to the snap-fit mechanism, which is critical for preventing bleeding during circumcision. This system relies on torque application, allowing the screw cap to be gradually tightened for controlled compression. The manual adjustment feature enables operators to fine-tune the clamping force as needed during the procedure. While the snap-fit locking mechanism offers quicker and simpler application, it generates lower clamping force due to its dependence on the elastic deformation of the hinge and the material's flexibility. Additionally, once locked, the snap-fit mechanism does not allow further adjustments. The irreversible thread locking system also ensures a more uniform distribution of force, reducing stress concentration at specific points. In contrast, the snap-fit mechanism localizes stress at critical areas, such as the hinge. The interlocking teeth on the screw cap and safety tube further enhance clamping stability and strength.

In this case, Tekno Klem was successfully used for circumcision in a 6-year-old boy with phimosis. The safety tube facilitated precise placement, while the clamping mechanism enabled accurate preputial excision with minimal tissue trauma. The use of thermal cautery further ensured hemostasis, and the application of a wound sealer allowed for immediate clamp removal. Postoperative assessment using PPPS yielded a score of 10, indicating improved penile appearance, while voiding satisfaction scored 5, reflecting positive functional outcomes. No complications, including excessive bleeding, hematoma, infection, glans injury, meatal stenosis, or delayed wound healing, were observed. The circumcision site healed properly, with favorable cosmetic and functional results, and follow-up assessments on days 3, 7, and 14 confirmed the absence of postoperative morbidity.

From a clinical perspective, Tekno Klem offers significant implications for improving circumcision outcomes. By enhancing procedural safety, reducing operative time, and minimizing postoperative complications, it may serve as a viable alternative to conventional devices, particularly in outpatient and primary care settings. Its disposable nature eliminates the need for repeated sterilization, which could be beneficial in resource-limited environments. Moreover, the potential reduction in infection and bleeding rates may contribute to lower healthcare costs associated with circumcision-related complications. Several factors must be considered when introducing a circumcision device, including ease of use, efficiency in preputial skin removal, cost-effectiveness, compliance with regulatory standards, and availability of high- quality clinical data. The procedure must also be appropriate for the specific age group and regional healthcare settings where it is to be implemented.

Despite these advantages, Tekno Klem is not without limitations. As with other device- assisted circumcision techniques, careful operator training is required to ensure proper device application and avoid complications such as excessive tissue removal. Additionally, further research is needed to compare Tekno Klem with existing circumcision devices in large-scale clinical studies. Future research

should focus on evaluating its long-term safety, healing time, patient satisfaction, and cost-effectiveness in various age groups and healthcare settings. Comparative trials assessing Tekno Klem against established techniques, including conventional surgical dissection and device-assisted circumcision techniques, would provide valuable insights into its efficacy.

CONCLUSION

Tekno Klem represents a promising advancement in circumcision technology, offering advantages over conventional devices, particularly in terms of precision, safety, and ease of use. Although its adoption is not yet as widespread as that of older devices, its design suggests potential for reducing complications and optimizing surgical outcomes, particularly in settings where precision and patient safety are critical. Further clinical studies comparing Tekno Klem with other circumcision devices are essential to establish its efficacy and role in modern urological practice.

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