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EFFICACY AND SAFETY OF TWO DISPOSABLE CIRCUMCISION SUTURE DEVICES FOR CIRCUMCISION IN ADULTS: A PROSPECTIVE COMPARATIVE MULTICENTER STUDY

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INTRODUCTION AND OBJECTIVE: Disposable circumcision suture devices have been developed to optimize outcomes of circumcision, one of the most common surgical procedures worldwide. The aim of this study is to evaluate the efficacy and safety of two different disposable circumcision suture devices (DCSDs) and compare their surgical outcomes.

METHODS: A prospective comparative multicenter study was performed between November 2019 and October 2021. Patients with congenital or acquired phimosis were included. Patients underwent circumcision using a DCSD (CircCurerTM or the ZSR[®] device) according to the surgeon preference and device availability. Postoperative follow-up was scheduled at 1 week and 2 months for all patients.

RESULTS: A total of 215 patients were enrolled, 120 underwent circumcision using CircCurerTM (Group A) and 95 patients using ZSR[®] (Group B). No differences were observed in baseline characteristics between the two groups (p>0.05). Mean (SD) operative time was 7.0 (2.5) minutes with no significant difference between the groups (p = 0.678). Seven patients (5.8%) in Group A and 2 (2.1%) in Group B required accessory stitches (p=0.156). Four subjects (3.3%) in Group A and 1 (1.1%) in group B presented hematoma (p=0.266). Surgical site infection occurred in 1 (0.8%) in Group A and 2 (2.1%) in Group B (p = 0.413). Metal clips fell out spontaneously in 39 patients (32.5%) of Group A and 47 (49.5%) of Group B (p<0.001). Median (IQR) Numeric Rating Scale (NRS) for postoperative pain was 2.5 (0-4) in Group A and 2.0 (0-4) in Group B (p=0.284). At 2 months, patients of both groups reported a median (IQR) satisfaction of 9 (8-9) points (p=0.469).

CONCLUSIONS: DCSDs appear to allow effective and safe circumcision, with short operative times, uncommon and mild complications, and high patient satisfaction; although there are several devices with some relevant differences on the market.

Table 1. Ba	seline charac	teristics of	patients and	perioperative	data

Group	Overall 215	Group A – <u>CircCurer</u> ™ 120	Group B – ZSR® 95	p-value
Subjects, n				
Age, years	21 (20-26)	21 (20-24)	21 (20-30)	0.758
median (IQR)				
Etiology of phimosis				0.082
Congenital, n (%)	168 (78.1)	99 (82.5)	69 (72.6)	
• Acquired, n (%)	47 (21.9)	21 (17.5)	26 (27.4)	
Diabetes mellitus, n (%)	23 (10.7)	12 (10.0)	11 (11.6)	0.709
Type of anesthesia				0.359
• Dorsal penile block, n (%)	180 (83.7)	98 (81.7%)	82 (86.3%)	
Dorsal penile block +	35 (16.3)	22 (26.4%)	13 (13.7%)	
Sedation, n (%)				
Operative time, min	7.0 (2.5)	7.1 (2.5)	6.8 (2.5)	0.327
Mean (SD)				
Need for dorsal incision, n (%)	68 (31.6%)	36 (30%)	32 (26.7%)	0.564
Accessory stitches, n (%)	9 (4.2)	7 (5.8)	2 (2.1)	0.156

IQR: Interquartile range; SD: standard deviation.

Table 2. Postoperative outcomes

	Overall	Group A – CircCurer™	Group B − ZSR®	p-value
Subjects, n	215	120	95	
Hematoma, n (%)	5 (2.3)	4 (3.3)	1 (1.1)	0.266
Edema, n (%)	15 (7.0%)	11 (13.2%)	4 (4.2%)	0.157
Surgical site infection, n (%)	3 (1.4)	1 (0.8)	2 (2.1)	0.413
Metal clips fall out				< 0.001
• Spontaneous, n (%)	86 (40.0)	39 (32.5)	47 (49.5)	
 Manual removal without anesthesia, n (%) 	78 (36.3)	48 (40.0)	40 (42.1)	
 Manual removal with anesthesia, n (%) 	51 (23.7)	33 (27.5)	8 (8.4)	
NRS for pain*, points	2.5 (0-4)	2.5 (0-4)	2.0 (0-4)	0.284
Median (IQR)				
Patient satisfaction**, points median (IQR)	9 (8-9)	9 (8-9)	9 (8-9)	0.469

NRS: Numeric rating scale; IQR: interquartile range * At 1 week.

** At 2 months

** At 2 months

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A NOVEL TECHNIQUE OF ADMINISTERING PRECISE PELVIC FLOOR TRIGGER POINT INJECTIONS WITH ELECTRICAL STIMULATION FEEDBACK

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INTRODUCTION AND OBJECTIVE: Pelvic floor trigger point injections (PFTPI) are an established therapy in the management of patients with myofascial pain. Commonly, botulinum toxin (BTA) is injected into the pelvic floor using digital palpation of the muscles. This is an imprecise method of delivery, as there is no objective confirmation of drug delivery to the desired location. We propose a technique using a peripheral nerve stimulator (PNS) to precisely isolate the muscles during PFTPI.

METHODS: We conducted a retrospective review of patients with myofascial pain who had PFTPI using a PNS (LifeTech NS-2CA DualStim Plus) between 9/1/2020-8/31/2022. 50-100u of BTA reconstituted with 20 mL saline was injected into the levator ani complex at 1, 3, 5, 7, 9, and 11 o'clock. A insulated needle was inserted into the muscle while connected to the PNS. Placement was confirmed when the muscle twitch was palpated. Motor response thresholds were obtained by reducing the PNS amplitude until the muscle twitch was no longer appreciated. We aim to describe the procedure and intraoperative characteristics of patients receiving TPI with PNS. Our secondary objective is to compare patients who did and did not receive subsequent injections.

RESULTS: A total of 15 patients underwent 27 injections. 8/15 (53%) received >1 injection. The mean age was 48 yr and 3 patients were male. 67% were non-Hispanic white. This procedure was always combined with another intraoperative procedure (cystoscopy n=3, intradetrusor BTA n=18, urethral sphincter or bladder neck BTA n=6). Mean operative time was 48 minutes (range 29-106). The average interval between injections was 163 days (range 98-364). In comparing those who did or did not undergo a repeat injection procedure, there was no difference in age (48 vs 47 years, p=0.95), BTA units (93.8 vs 71.4, p=0.30), concomitant procedure type, or the average threshold of injection sites (10.7 mA vs 9.8 mA, p=0.57). Among patients who had more than one injection, there was no relationship between average threshold over time (Figure 1).

CONCLUSIONS: In this pilot study we demonstrate that pelvic floor TPI with PNS is reliable and reproduceable. Though we lack standardized assessment of benefit, over 50% of patients returned for repeat injections. Further study is needed to compare outcomes of TPI with and without this technique.