Research Square

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The role of Sacral TENS in Improving Continence and Quality of Life in Children with Anorectal Malformations: A six-year Follow-up

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Abstract

PURPOSE

Anorectal malformations are congenital defects of the posterior intestinal development, leading to structural and functional abnormalities of the rectum and/or anal canal. Typically, these patients develop long-term constipation or fecal incontinence, which can be challenging to manage. Sacral transcutaneous electrical nerve stimulation (TENS) is a non-invasive technical alternative initially studied for bladder elimination disorders and has been increasingly established as a tool for treating intestinal dysfunctions. This study aims to observe outcomes in patients who underwent surgery for anorectal malformations and received TENS therapy. METHODS: A longitudinal and retrospective observational study (2018 to 2024). Included children with corrected anorectal malformation, aged 4 to 15 years who underwent TENS therapy. The analysis considered medication use, quality of life through the Paulista Continence Score, and anorectal manometry at three time points: before TENS application, four weeks and six years post TENS. RESULTS: Eleven children were included, 6 had low anorectal malformations and 5 had high anorectal malformations. Among these patients, 81.81% used some type of laxative or bowel management before application, and six years after the treatment, the immediate post-results remained, only 27.27% of patients used some type of laxative or bowel management. Applying São Paulo Continence Score 36.36% were classified as a continent before TENS, increasing to 75% continence six years after TENS. The number of Paulista score had shown improvement through time ($\chi^2_{(2)} = 29.7$, $p < 0.001$). Post-TENS and late follow-up scores were significantly lower than pre-TENS scores (post vs. pre: $p = 0.005$; late vs. pre: $p < 0.001$), and late follow-up scores were also significantly lower than post-TENS scores (late vs. post: $p = 0.012$). Manometric evaluation did not show statistical significance when analyzing resting pressure and average contraction pressure, neither intra-rectal volumes across the three time points. CONCLUSION: patients with anorectal malformation improved clinical outcomes with TENS therapy and can be used for treating elimination disorders.

Introduction

Anorectal malformations (ARMs) are congenital developmental defects of the hindgut, resulting in structural and functional abnormalities of the rectum and/or anal canal. In these cases, the hindgut fails to terminate in the correct position within the perineum and the muscular complex. In about 95% of cases, a fistula is present either opening to the perineum or the genitourinary tract—or the intestine ends in a blind pouch, creating a broad spectrum of clinical presentations. The condition affects approximately 1 in every 5,000 live births and is often associated with other congenital anomalies. Early diagnosis of ARM allows for appropriate surgical planning and optimal management during the neonatal period. The goal of definitive surgery is to restore normal anatomy and provide complete anatomical reconstruction. However, the greatest challenge following surgical correction lies in restoring normal function, particularly in terms of fecal and urinary continence [1] .

Several classification systems have been proposed to describe ARMs. These are similar for both sexes and are generally based on the position of the terminal hindgut [1]. The traditional Wingspread classification categorizes malformations as low, intermediate, or high, but it does not effectively predict the required surgical approach or clinical outcomes. The Krickenbeck classification has become more widely used, as it is based on anatomical features. This classification encompasses the full spectrum of fistulas and imperforate anus, distinguishing between male and female patients, and includes complex or atypical malformations [2] .

Clinically, patients with ARM often experience defecation dysfunction. It is estimated that around 45% of children who undergo surgery for ARMs develop fecal elimination disorders [3]. Low-type ARMs are more commonly associated with constipation, whereas high-type ARMs are typically associated with fecal incontinence [4]. Posterior sagittal anorectoplasty (PSARP) aims to correctly position the colon within the muscle complex, thereby improving fecal continence and voluntary control. In high-type ARMs, underdevelopment of the striated muscle complex and the external anal sphincter makes patients more susceptible to these dysfunctions[5] .

Children who develop fecal elimination disorders may also experience psychosocial issues [6]. These problems can significantly impact quality of life and social development [4]. Children may face socially embarrassing situations that negatively affect their emotional well-being and motivation, leading to decreased self-esteem and withdrawal from social, family, and school environments [3] .

Anorectal manometry, the gold standard for evaluating anorectal function in adults, is gradually being introduced into pediatric diagnostic routines. It provides valuable insights into anorectal physiology and helps clarify the underlying pathophysiology, thereby guiding treatment strategies for better outcomes. It is increasingly being used to manage patients with chronic constipation, defecation disorders, and fecal incontinence [6] .

The management of constipation and fecal incontinence involves multiple steps and various treatment options. Each patient may respond differently, and some may not respond to any conventional methods. Recently, neuromodulation therapies have gained attention as adjunct treatments for refractory constipation. These therapies involve applying electrical currents to elicit physiological responses, depending on the intensity, frequency, and pulse width [7]. Transcutaneous Electrical Nerve Stimulation (TENS) has emerged as a promising alternative because it is non-invasive and more cost-effective compared to other techniques.

TENS was initially developed for pain management. Later, transcutaneous tibial nerve stimulation (TPTNS) demonstrated efficacy in treating urge incontinence and overactive bladder. Encouraged by these promising outcomes, researchers proposed its use for fecal incontinence, with a reported success rate of 78% [8] .

Although the exact neurophysiological mechanism behind its effectiveness remains unclear, it is believed that neuromodulation induces physiological reconditioning. Electrical stimulation promotes

synaptic remodeling and long-term neural reconditioning, especially through afferent pathways. These effects are thought to occur via neuroplasticity mechanisms, enhancing integrative neural functions [9] .

The non-invasive TENS technique is applied over the sacral forame region and is notable for its simplicity and good tolerance among children [10]. TPTNS works similarly to TENS, utilizing the same sacral reflex arc to influence the rectal and anal sphincter pathways. These nerve branches contain both sensory and motor fibers, stimulating pelvic floor contraction and improving intestinal transit time. Peripheral stimulation of the tibial nerve at the ankle transmits impulses to the sacral nerves, thereby creating a reflex arc. For this reason, parasacral TENS is proposed as it shortens the reflex pathway [11] .

Anorectal malformations represent a group of congenital anatomical anomalies which, despite early surgical correction, may lead to persistent fecal elimination disorders. These children require careful outpatient follow-up to manage constipation and prevent long-term functional and psychological sequelae [1]. Currently, sacral TENS is being proposed as an adjunctive therapy for intractable constipation. This study aims to evaluate the response of patients with ARM who underwent TENS treatment for fecal incontinence due to chronic constipation and true incontinence.

Objective

Observe epidemiologic data and outcomes in patients who underwent surgery for anorectal malformation and received TENS therapy .

Methods

This is a longitudinal, retrospective observational study aimed at evaluating the clinical outcomes of patients born with anorectal malformations, followed at the pediatric proctology outpatient clinic of the Pediatric Surgery Department at Hospital Estadual Mário Covas. The study involved a review of medical records of patients who underwent transcutaneous electrical nerve stimulation (TENS) therapy, in accordance with the institution’s protocol. All data and patient identities were kept confidential. The study was approved by the Research Ethics Committee under protocol number CAAE 87912524000000082 and was conducted in accordance with the ethical principles of the Declaration of Helsinki. For individuals younger than the age of 18, parents and/or legal guardians provided a written informed consent form, and informed consent for publication of clinical details and/or clinical images of the patient.

Patients included in the study had surgically corrected anorectal malformations with the rectum positioned within the center of the sphincter complex. Postoperative follow-up after posterior sagittal anorectoplasty revealed fecal elimination dysfunctions, either constipation or fecal incontinence—indicating the need for TENS therapy. Patients with additional organic conditions that could contribute to these symptoms, including spinal dysraphism or central neurological disorders, were excluded, as were those who failed to complete the full TENS protocol or did not respond to the follow-up questionnaire.

The study was conducted at three time points: prior to TENS therapy, four weeks after completion of therapy, and six years post-treatment. At each stage, assessments included use of laxative medication or bowel management strategies, quality of life evaluation using the São Paulo Score of Continence, and anorectal manometry.

TENS therapy was applied following the institutional protocol. Four self-adhesive electrodes were positioned in the presacral region at vertebral levels L5-S1 and S1-S2. Devices used included the FesVif 995 Dual Quark and Neurodyn II. Stimulation intensity was set to the maximum level tolerated by each child, with a pulse amplitude of 200 μs and a pulse frequency of 10 Hz. Each session lasted 30 minutes and was performed twice weekly for eight weeks, totaling 16 sessions.

Anorectal Manometry Protocol:

Manometry was conducted using the Alacer Biomédica BP 108 system, without prior preparation or sedation, and with full cooperation from the children. A polyethylene catheter with eight pressure channels and a perfusion rate of 21 mL/min was used. Pressures were recorded in mmHg after identifying the location of the internal anal sphincter. Sensory thresholds were measured using a latex balloon affixed to the catheter tip, inflated with air through the central channel until the maximum tolerable volume was reached or the balloon's limit of 350 mL. Parameters evaluated included maximum squeeze pressure, mean squeeze pressure, resting pressure, first sensation volume, urge-to-defecate volume, and maximum tolerable volume.

Quality of Life Assessment:

Quality of life was assessed at all three time points using the São Paulo Score of Continence (Fig. 1), a validated scale developed to assess the of fecal continence in children. The score incorporates physiological parameters, dependence on enemas, and the impact on daily life. Scores below 8 indicate continence; higher scores reflect increasing severity of incontinence (mild, moderate, or severe), depending on the total score [12] .

Statistical Analysis

Statistical analyses were conducted using Jamovi version 2.4.11 (https://www.jamovi.org/). For the repeated measures of the Paulista score, a Generalized Linear Mixed Model (GLMM)[13] with a gamma distribution and identity link function was used to compare scores across the pre-TENS, post-TENS, and late follow-up periods. Time was treated as a fixed factor, and subject as a random factor. When a significant effect was detected, Bonferroni post-hoc tests were applied. The graphs were constructed using Prism GraphPad 8.0.2.

Results

A total of eleven patients (four females) with corrected anorectal malformation, aged 4 to 15 years (8.78 ± 4.32), underwent TENS therapy. Using the Wingspread classification of anorectal anomalies, four patients had low anorectal anomalies, and five had high anorectal anomalies. According to the Krickenbeck classification, two patients presented with perineal fistula, two with rectovestibular fistula, one with rectourethral fistula, three with rectoprostatic fistula, and one with rectovesical fistula. All patients underwent posterior sagittal anorectoplasty for the surgical treatment of the anorectal anomaly.

Regarding medication use (Fig. 2), we observed that in Pre-TENS therapy, only two patients were not using medication for constipation treatment, as their constipation was managed through toilet habits. For constipation treatment, seven patients used only medication for constipation treatment, one only use enemas for bowel management, and one used medication and bowel management. In the second phase, Post-TENS, nine patients did not use medication for constipation treatment and maintained their toilet habits, while two patients continued using medication for constipation treatment, and only one patient managed their bowel management. In the late follow-up, during the third phase of the protocol, nine patients remained without medication use, two patients were using medication for constipation treatment, and one patient continued managing their bowel management.

Analyzing the quality of life of patients undergoing TENS therapy using the São Paulo Continence Score, it was observed that before TENS application, only 36.36% (four patients) were continent. Four weeks after the completion of TENS, 72.72% of the patients were considered continent, with 75% of the patients remaining continent. It was identified that one patient, who was considered continent immediately after TENS application, was classified as moderately incontinent six years after the therapy.

However, when the Paulista score was analyzed as a quantitative variable, a significant time (before vs. after TENS) effect was observed ($\chi^2_{(2)} = 29.7$, $p = 0.001$). Post-TENS and late follow-up scores were significantly lower than pre-TENS scores (post vs. pre: $p = 0.005$; late vs. pre: $p < 0.001$), and late follow-up scores were also significantly lower than post-TENS scores (late vs. post: $p = 0.012$) (Fig. 3). The descriptive values could be observed in Table 1.

Table 1
São Paulo Continence Score

					Percents				
		n	mean	standard deviation	min	25th	median	75th	max
São Paulo Continence	**pre**	11	9.64	2.01	7	8	10	11.5	12
	post	11	7.64	2.11	5	6	8	8.5	12
	six years	8	7	3.34	4	4.75	6	8	13

The resting pressure values before TENS application had a minimum value of 5 mmHg, a maximum value of 51.9 mmHg, and an average value of 26.19 mmHg. The values remained similar immediately

after TENS application and six years after TENS. The detailed pressure values can be observed in Table 2.

Table 2
Manometric values: maximum, mean, and resting pressure.

					Percents				
		n	mean	standard deviation	min	25th	median	75th	max
max pressure	**pre**	11	82.8	43.1	40.4	45.5	70.5	108	175.1
	post	11	85.8	35.8	34	64.5	81	101.4	158
	six years	8	67.7	45.3	28.3	37.9	45.9	90.5	161
mean pressure	**pre**	11	54.4	32.9	26.2	31.6	46	64.5	138.4
	post	8	82.3	47.4	32.8	57.7	74.2	84.2	190
	six years	7	38	17.5	20	28.6	29.6	44.3	70.6
resting pressure	**pre**	11	26.2	14.5	5	16.9	20.2	36.1	51.9
	post	11	34.4	18.4	12	23.3	30	43.4	70
	six years	8	19.4	17.5	4.4	11.8	13.7	18.2	60.5

The first sensitivity estimated by anorectal manometry found minimum values of 10 ml, maximum values of 40 ml, and an average of 23.33 ml before TENS. The values remained similar immediately after TENS application and six years after TENS. The first defecatory urge before TENS, the minimum values were 30 ml, the maximum values were 160 ml, and the average was 84 ml. The values remained similar immediately after TENS application and six years after TENS. The detailed pressure values can be observed in Table 3.

significant effect of time was observed on rest pressure ($\chi^2_{(2)} = 15.6$, $p < 0.01$), the post-TENS resting pressure was significantly higher than pre-TENS values (post vs. pre: $p = 0.019$), and the late follow-up-TENS period (late vs. post: $p < 0.001$). A significant effect of time on average squeeze pressure ($\chi^2_{(2)} = 6.43$, $p = 0.04$), the late follow-up average squeeze pressure was significantly lower than the post-TENS average squeeze pressure (late vs. post: $p = 0.036$). No effects were observed for maximum squeeze pressure ($\chi^2_{(2)} = 5.48$, $p = 0.065$) (Figure 4A). No significant time effects were observed for first sensation ($\chi^2_{(2)} = 4.58$, $p = 0.101$), first urge to defecate ($\chi^2_{(2)} = 0.38$, $p = 0.824$), or maximum urge to defecate ($\chi^2_{(2)} = 0.71$, $p = 0.70$) (Figure 4 B).

Table 3

Manometric values: first sensitivity, first defecatory urge and maximum defecatory urge..

		Percents							
		n	mean	standard deviation	min	25th	median	75th	max
first sensitivity	**pre**	7	22.9	10.75	10	17.5	20	27.5	40
	post	11	29.5	31.42	10	12.5	20	30	120
	six years	6	19.2	6.65	10	16.3	20	20	30
first defecatory urge	**pre**	11	84.5	45.47	30	45	80	115	160
	post	11	66.4	43.59	30	37.5	50	82.5	180
	six years	8	79.4	52.54	25	47.5	55	112.5	180
max defecatory urge	**pre**	11	172.7	90.01	60	100	150	235	330
	post	11	147.7	78.08	85	95	110	160	310
	six years	8	165	76.16	50	117.5	165	197.5	300

Discussion

This study has a limited sample size but although study population was diverse in terms of malformation types and patient ages, the number of participants was insufficient to detect meaningful associations. Despite our clinic receiving a considerable number of patients with anorectal malformations, socioeconomic challenges, particularly financial constraints, impacted treatment adherence, as the protocol required 16 hospital visits over two months [14, 15] .

Neuromodulation in Review

A systematic reviewed sacral neuromodulation most through implanted devices. Despite reporting complications in invasive treatment, it is advocated for its use in managing treatment-resistant constipation and fecal incontinence. However, they cautioned against its use in patients with improperly positioned anus, recommending surgical revision and anatomical correction before initiating neuromodulation therapy [16] .

Non-invasive neuromodulation methods such as transcutaneous electrical nerve stimulation (TENS) and transcutaneous posterior tibial nerve stimulation (TPTNS) have shown effectiveness in improving both constipation and fecal incontinence across different age groups. These therapies are advantageous due to their minimal invasiveness, low cost, and good patient tolerability [8, 16–18] .

TENS has demonstrated promising results in the treatment of neurogenic bladder in systematic reviews [19]. In the context of constipation, studies have reported symptom improvement in children compared to laxative use, and have also noted effects on gut microbiota and neurotransmitter activity [11, 20, 21]. Veiga reported that 60% of patients with neurogenic bladder experienced improvement in constipation following TENS therapy [21]. Similarly, in our study, 67% of patients reported reduced reliance on laxatives after treatment.

The São Paulo Score of Continence is a validated Portuguese-language tool for evaluating quality of life in patients with involuntary fecal loss. It considers physiological function, the need for enemas, social embarrassment, isolation, and overall patient satisfaction [12] .

Chronic constipation has a profound impact on quality of life due to its prolonged symptoms and poor response to conventional treatment. Coelho demonstrated clinically significant improvements in overall quality of life—covering physical, psychosocial, and bowel habit dimensions—following TENS therapy, with sustained benefits observed four weeks after treatment [22] .

Velasco-Benítez et al.[23] reported significant improvements in stool consistency and bowel movement frequency following TPTNS, with 75% of patients achieving normal defecation patterns and a 96.7% satisfaction rate. Rego et al. observed improvements in quality of life and bowel function after four weeks of TPTNS, but noted that the effect did not accumulate further after eight weeks, suggesting the benefits may be temporary[4] .

In our study, we observed significant improvement in the São Paulo Score of Continence both immediately after TENS therapy and at the six-year follow-up. It is well established that constipation in patients with anorectal malformations tends to improve with age. This is thought to result from gastrointestinal tract maturation and better adherence to treatment strategies in adolescence and adulthood [24]. These factors may have contributed to the sustained or even enhanced quality of life over the long term. However, this improvement could not be clearly explained by manometric data, which revealed a decline in pressure parameters at the six-year follow-up, despite improved continence scores

Our manometric analysis also suggests that the beneficial effects of sacral TENS were not sustained over the long term. Resting pressure increased shortly after TENS therapy but returned to levels consistent with sphincter hypotonia six years later. A similar trend was seen in voluntary squeeze pressure, which initially doubled post-TENS but diminished over time. These findings imply that without ongoing therapy, the anal sphincter reverts to a low-tone state, compromising continence [25, 26]. The main limitations of this study include the small sample size and clinical heterogeneity of the subgroups, which may have limited our ability to detect significant associations. Future research with larger cohorts, standardized follow-up protocols, and well-defined rehabilitation strategies is needed to clarify the optimal duration and cumulative effects of sacral neuromodulation in this population.

Conclusion

Patients with anorectal malformation improved clinical outcomes with TENS therapy and can be used for treating elimination disorders.

Declarations

Author Contributions

Conceptualization, V. C. S. R., A. D. S., and P. M. F.; Methodology, V. C. S. R., A. D. S. and R. P. F.; Data analysis, M. N. C.; Writing – Original Draft Preparation, V. C. S. R., A. D. S., R. P. F., and M. N. C.; Writing – Review & Editing, V. C. S. R. and M. N. C.; Supervision, P. M. F. All authors have read and agreed to the published version of the manuscript.

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Ethical approval

The study was conducted in accordance with the Declaration of Helsinki and the guidelines of the Brazilian National Council for Research Ethics and approved by the Ethics Committee of ABC University Medical School (protocol code CAAE 87912524000000082).

Informed Consent Statement

For individuals younger than the age of 18, parents and/or legal guardians provided a written informed consent form.

Consent for Publication

For individuals younger than the age of 18, parents and/or legal guardians provided a written informed consent for publication of clinical details and/or clinical images of the patient.

Data Availability Statement

The data presented in this study are available from the corresponding author upon reasonable request, in an edited form to exclude sensitive data and personal information, ensuring patient anonymity.

Conflicts of Interest

The authors declare no conflicts of interest.

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Figures

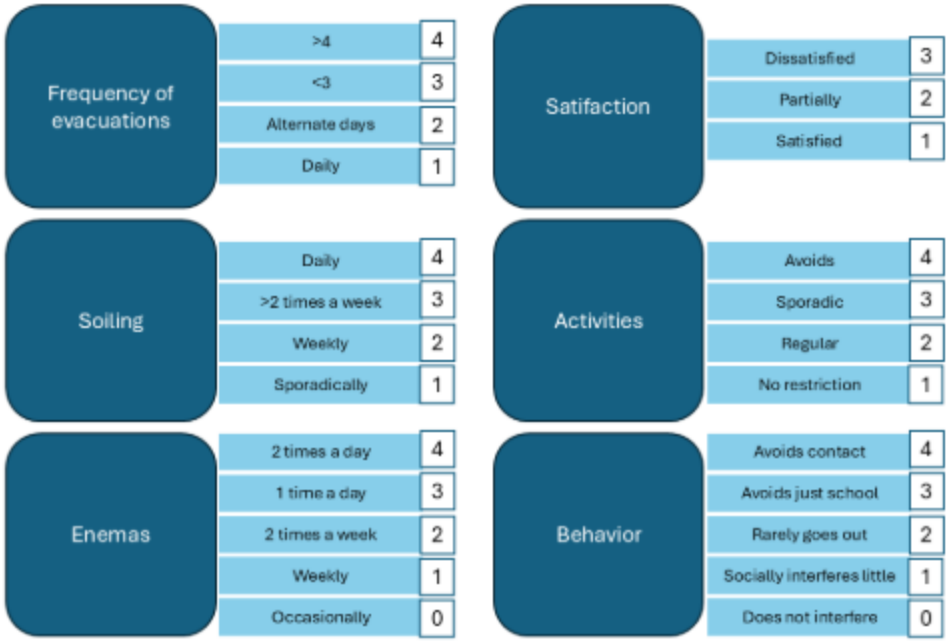


Figure 1

São Paulo Score of Continence: Figure adapted from Filho, H. S., Mastroti, R. A., & Klug, W. A. (2015). Quality-of-Life Assessment in Children With Fecal Incontinence. Diseases of the Colon & Rectum, 58(4), 463–468. [12] The sum of the values of each subgroup results in a number ranging from 4 to 23. Incontinence scale is as follows: severe = 17 to 23; moderate = 13 to 16; minimal = 9 to 12; and continent = 4 to 8.

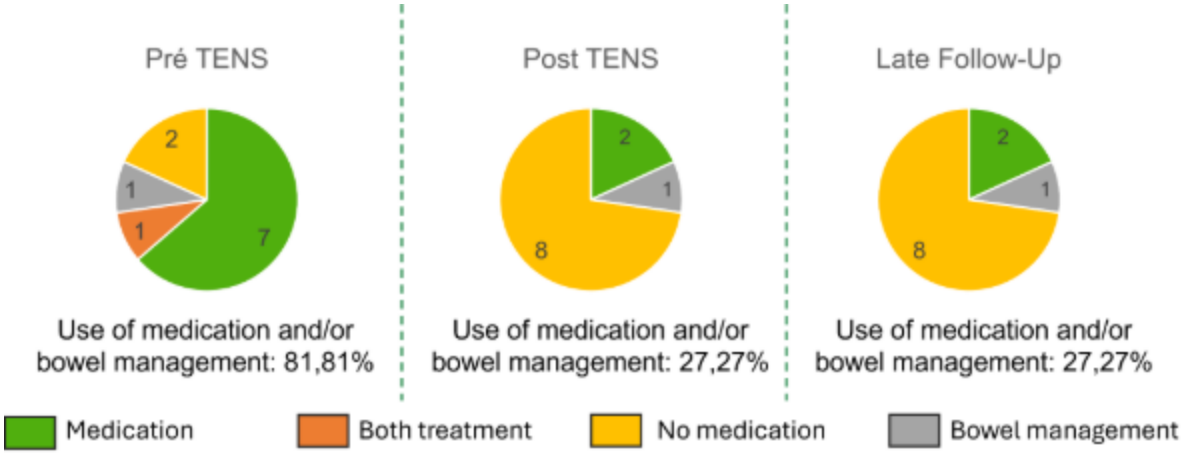


Figure 2

Use of medication and Bowel management. (A) Pre-TENS; (B) Post-TENS; and (C) Late Follow-up. The green represents the use of medication for constipation; the grey represents the Bowel management, the orage represents the intersection of both treatments, and the yellow represents those who did not use both treatments.

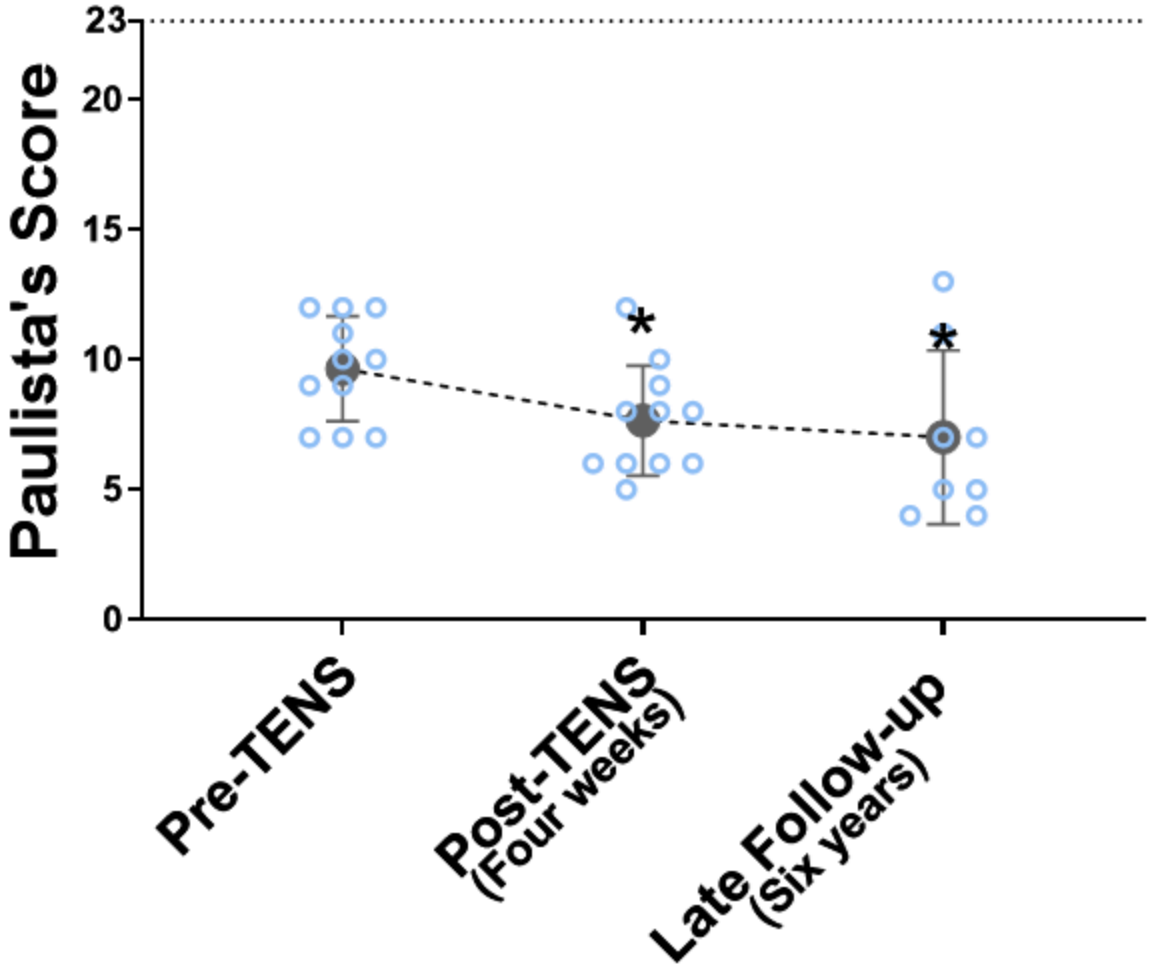


Figure 3

*Paulista's Score in Pre, Post and Follow-up. Dark grey dot: Mean with Standard Error. * p < 0,05. Blue circles: Individual values.*

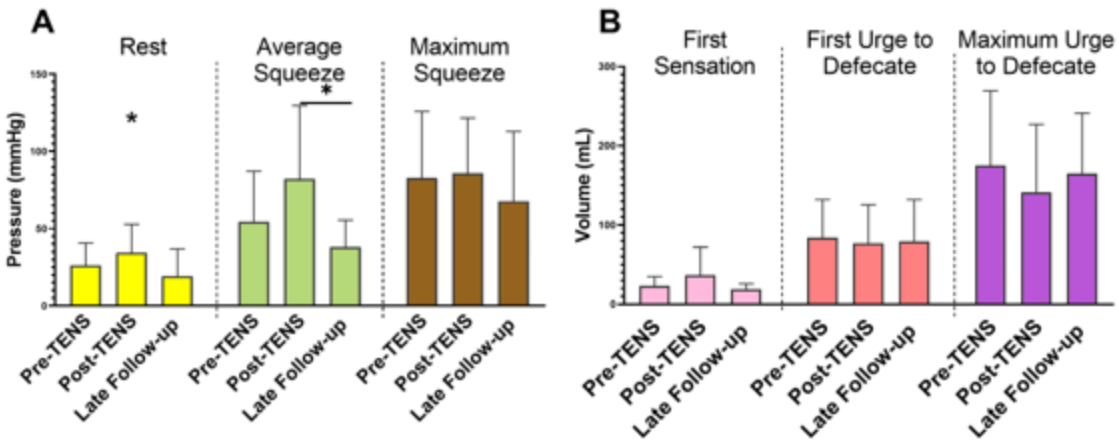


Figure 4

*Manometric Variables Across Time Points. (A) Pressure measures: Medium grey: Average Squeeze; Light grey: Rest; Dark grey: Maximum Squeeze. (B) Defecation sensation measure: Medium grey: First Sensation; Light grey: First Urge to Defecate; Dark grey: Maximum Urge to Defecate. Mean with Standard Deviation. * p < 0,05.*