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Research Article

Revolutionizing GERD Treatment: The Breakthrough GEST Procedure Using Endosuture - A Landmark 12-Month Study with Perfect Feasibility and Safety Record

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Abstract

Background and Aim: Gastrofundoplication with endosuture technique (GEST) represents an innovative approach to managing gastroesophageal reflux disease (GERD). This minimally invasive procedure utilizes the GEN-2 apollo endosuture device to perform a partial fundoplication by strategically placing of sutures around the gastroesophageal junction (GOJ). The technique aims to enhance the function of the lower esophageal sphincter (LES) by creating a comprehensive and circumferential plication, thereby improving the barrier against reflux without requiring invasive surgery.

Methods: Data was recorded on a dedicated microsoft excel sheet and analyzed using SPSS Ver. 27 (IBM Corp, New York). Categorical variables were presented as frequencies along with percentages while continuous variables including age and quality of life (QOL) scores were presented as mean values with standard deviation. The ANOVA was used to find any statistically significant differences between QOL (50), QOL (30), and De Meester scores at the time of the procedure, at 6 months, and at 12 months. Pearson's Chi-square test was used to find any statistically significant differences between categorical variables (QOL assessments, GERD on endoscopy, use of anti-GERD medications) recorded at the time of the procedure, at 6 months, and at 12 months. A p-value of < 0.05 was deemed statistically significant for all analyses.

Results: A total of 18 participants were enrolled in the study, most of whom were males (n = 11). The mean age was just over 35 years, and over 70% of the participants had initially revisited the Hill grade of IIb. Only one adverse event was recorded following the procedure, and only one patient underwent valve reinforcement at 12 months. Comparison of GERD QOL (50) scores at the time of procedure vs. at six months and 12 months revealed that the mean QOL (50) score was markedly high at the time of procedure (39.9 ± 4.0) and lower at six months and 12 months with statistical significance ($p < .001$). However, the score was slightly higher at 12 months than at six months. A comparison of QOL (30) scores revealed a high mean score at procedure, a lower score at six months, and an even lower score at 12 months, with statistical significance ($p < .001$). A similar trend was noted for mean De Meester scores, again with statistical significance ($p < .001$).

Conclusion: GEST offers promising results as a minimally invasive alternative to traditional surgical interventions and other endoscopic techniques for managing GERD. Further research is warranted to validate its long-term efficacy, durability, and comparative effectiveness against existing treatments, ensuring broader adoption and optimization of patient outcomes in clinical practice.

Keywords: *Gastrofundoplication with Endosuture Technique (GEST); Gastroesophageal Reflux Disease (GERD); Gastroesophageal Junction (GOJ); Lower Esophageal Sphincter (LES); Quality of Life (QOL)*

Introduction

Gastroesophageal reflux disease (GERD) remains one of the most frequently encountered conditions by gastroenterologists, surgeons and primary care physicians. GERD is a common chronic condition, affecting about 20% of the Western population and significantly impacting quality of life. GERD occurs when stomach contents reflux into the esophagus, causing symptoms such as heartburn, regurgitation, and chest pain. Long-term GERD can result in serious complications, including esophagitis, stricture formation, Barrett's esophagus, and, most concerning, esophageal adenocarcinoma [1,2].

Initial management of GERD generally includes lifestyle changes and pharmacological treatments. Proton pump inhibitors (PPIs) are the mainstay of medical therapy, effectively reducing acid production and alleviating symptoms. Recently, vonoprazan, a potassium-competitive acid blocker, has been introduced as a powerful alternative, providing rapid and sustained acid suppression. Nevertheless, some patients do not respond to these medical treatments or prefer alternatives due to concerns about prolonged medication use [1,3].

For those needing a more definitive intervention, surgical options such as Nissen fundoplication have been widely utilized. Although these procedures are effective, they come with inherent surgical risks and longer recovery periods, underscoring the need for less invasive solutions. As a result, endoscopic techniques have gained traction, offering effective GERD management with reduced morbidity [1,4].

Transoral Incisionless Fundoplication (TIF) is an innovative endoscopic technique that utilizes the EsophyX device to reconstruct the gastroesophageal valve, offering an incisionless alternative to traditional surgery. While TIF has demonstrated clinical success, it is associated with high procedural costs and is less suitable for individuals with previous bariatric surgeries due to the size constraints of the device [5]. In addition to TIF, another endoscopic option is the GERDx™ procedure. GERDx™ involves the use of a flexible endoscopic stapler to create a partial fundoplication by placing a series of transmural staples at the gastroesophageal junction. This technique helps to enhance the anti-reflux barrier without the need for incisions, providing a minimally invasive alternative to traditional surgical methods [6].

The endosuture device developed by Apollo Endosurgery is widely recognized for its effectiveness and safety in performing endoscopic suturing procedures. Clinical studies have shown that it provides favorable outcomes and maintains a strong safety profile, making it a reliable choice for endoscopic sleeve gastroplasty and other suturing applications. Systematic reviews and meta-analyses further support its safety and efficacy, underscoring its suitability for these medical procedures [7,8].

Given the challenges associated with current GERD treatments, we have introduced a new endoscopic technique known as gastrofundoplication with endosuture technique (GEST). Utilizing the endosuture device, GEST offers a unique approach compared to the TIF procedure by endogastric solutions. This innovative technique broadens the range of therapeutic options available for GERD patients and addresses some of the limitations of existing endoscopic methods, especially for those who have undergone prior bariatric surgeries. The capability of GEST to offer a more accessible and effective treatment for a wider patient population signifies a major advancement in the field of gastroenterology [7,8].

This publication details the methodology, clinical outcomes, and implications of GEST, highlighting its transformative potential in managing GERD and setting a new standard in treatment efficacy and patient safety.

Methods

A prospective study was conducted with patients who underwent GEST. Data collected included age, gender, GERD presence at initial and subsequent endoscopies (6 and 12 months), health-related quality of life (HQOL) scores, DeMeester scores at the procedure and follow-up visits, and the use of anti-GERD medication. These were assessed using a 24-hour impedance-pH monitoring device.

The indications for GEST align with those established for TIF, utilizing the endoscopic treatment classification system known as Hill revisited, created by Dr. Abu-Dayyed. This classification system stratifies patients based on the anatomical and functional integrity of the gastroesophageal junction. For our study, only patients classified as Hill revisited IIa and IIb were included, indicating a moderate level of gastroesophageal junction competence, suitable for endoscopic intervention. Patients classified as Hill revisited IIa and IIb typically possess sufficient anatomical structure to benefit from endoscopic techniques like GEST, without the severe anatomical distortions seen in more advanced classifications. This targeted approach ensures that the selected patients are likely to derive maximum benefit from the procedure, enhancing the overall efficacy and safety profile of GEST [9-13].

In this study, we recruited 38 patients, including 7 from Mesteri clinic and 11 from angioskope. Of the total recruited, 26 patients completed the procedure. Exclusions included 8 patients who declined to repeat impedance-pH monitoring, 4 who failed to attend their appointments, and 1 who was lost to follow-up due to refusal to repeat manometry tests. None of the patients had a hiatal hernia. A

second-generation cephalosporin was administered during the procedure. Post-procedure medications included paracetamol for pain management, and sucralfate and vonoprazan (1 gram twice a day/40 mg daily) for the first two weeks.

The post-procedure diet regimen was structured as follows: a liquid normocaloric protein-enriched diet in the first week, a liquified diet in the second week, a mashed diet in the third week, and a regular diet from the fourth week onward. The health-related quality of life scale for GERD (GERD-HRQL Scale) was used to measure outcomes, as referenced in Sanchez, C.E. (2022) [14].

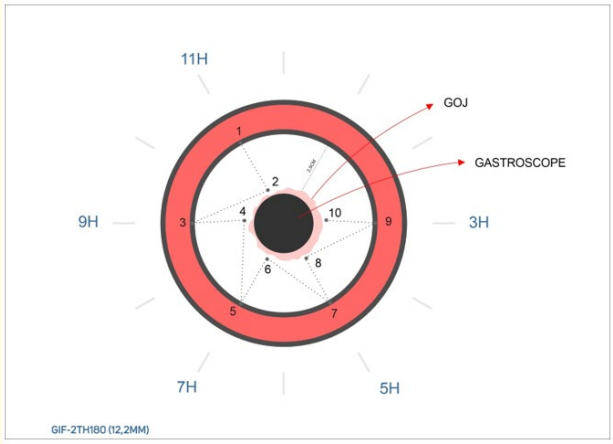
All patients provided informed consent for the procedure, and the study was approved by the ethics committee at angioskope (approval number AN 00172-3). All pH-metries and manometries were conducted using a 36-channel high-resolution impedanciometry by ALACER-multiplex (24+12) [15].

The GEST technique utilized the GEN-2 apollo endosuture device and the olympus H2T180 gastroscope. General anesthesia was administered to all patients. An initial endoscopy was performed to map and identify anatomical structures before the procedure began. All patients were placed under general anesthesia, and ample lubrication was applied to the gastroscope and working channel. The gastroscope was then advanced through the oropharynx into the esophagus and stomach. Upon reaching the stomach, both devices were independently retroflexed under direct vision. The apollo endosuture device was rotated to the 11 o'clock position, slightly opened, and the helical retractor advanced into the gastroesophageal junction (GOJ) on the esophageal side. Using traction on the helical retractor, the apollo endosuture was closed, and prolene 2-0 sutures were placed to attach the fundus to the esophagus. Four additional sutures were placed at this location. The helical retractor was then detached, and the endosuture device was rotated to the 7, 1, and 3 o'clock positions, where four sutures were placed at each position, creating a 2 - 3 cm partial fundoplication. The devices were then straightened and removed under direct visualization.

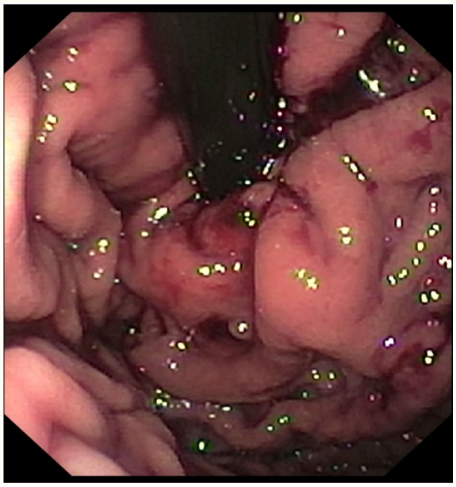
The TIF procedure inspired the feasibility principle, aiming to mimic the same valve using a similar device but employing prolene 2-0 for full-thickness sutures instead of plastic clips. All cinching was performed in retroflexion using the gastroscope olympus H2T180 and the GEN-2 apollo endosuture device to calibrate the valve. After the GEST procedure, the apollo GEN-2 device was detached, and an upper endoscopy with the olympus H2T180 was conducted to assess the valve; no difficulties at the GOJ were observed. A vascular surgeon was always present in the OR to assist in case of adverse events, following the same protocol used during TIF procedures [5,17,18].

Data was recorded on a dedicated Microsoft Excel sheet and analyzed using SPSS Ver. 27 (IBM Corp, New York). Categorical variables were presented as frequencies and percentages, while continuous variables (including age and QOL scores) were presented as mean values with standard deviation. The ANOVA was used to find any statistically significant differences between QOL (50), QOL (30), and De Meester scores at the time of the procedure, at six months and 12 months. Pearson's Chi-square test was used to find any statistically significant differences between categorical variables (QOL assessments, GERD on endoscopy, use of anti-GERD medications) recorded at the time of the procedure, at six months and 12 months. A p-value of < 0.05 was deemed statistically significant for all analyses.

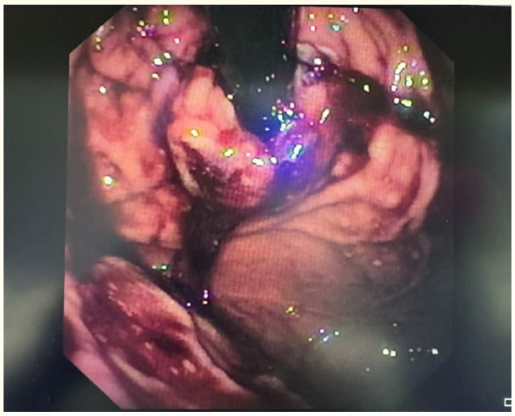
This prospective study was conducted between January and July 2024 in Brazil. Ethical approval for the study was sought and subsequently registered under Angioskope number AN00172-3.

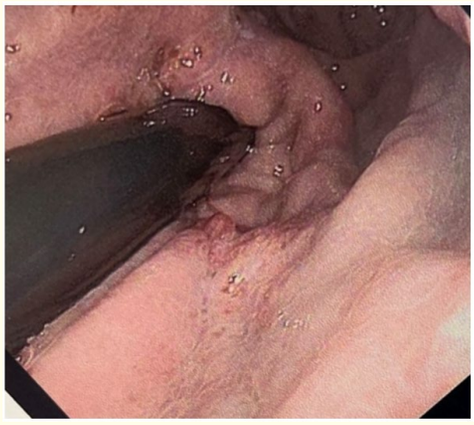


Picture 1: *Diagram of the GEST procedure.*

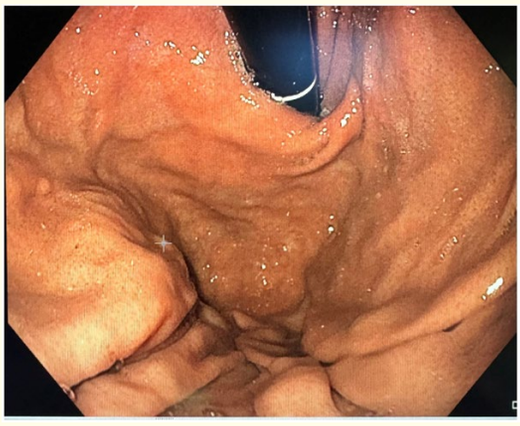


Picture 2: *Right after GEST.*





Picture 3 and 4: *One month after GEST.*



Picture 5: *One year after GEST.*

Results

Patient characteristics

A total of 18 participants were enrolled in the study, most of whom were males (n = 11). The mean age was just over 35 years, and over 70% of the participants had initially revisited the Hill grade of IIb. Only one adverse event was recorded following the procedure (oozing at the 11 o'clock position), and only one patient underwent valve reinforcement at 12 months (Table 1).

Characteristic	Value
Gender (n, %) Males Females	 11, 61.1 7, 38.9
Mean age in years ± SD	35.4 ± 5.4
Initial revisited Hill grade (n, %) IIa IIb	 4, 22.2 14, 77.8
Adverse events (n, %)	1, 5.6
Reinforcement of valve at 12 months (n, %)	1, 5.6

Table 1: *Patient characteristics.*

Acid reflux scores and quality of life measures

Comparison of GERD QOL (50) scores at the time of procedure vs. at six months and 12 months revealed that the mean QOL (50) score was markedly high at the time of procedure (39.9 ± 4.0) and lower at six months and 12 months with statistical significance ($p < .001$) (Table 2). However, the score was slightly higher at 12 months than at six months (Figure 1). A comparison of QOL (30) scores revealed a high mean score at procedure, a lower score at six months, and an even lower score at 12 months, with statistical significance ($p < .001$) (Figure 2). A similar trend was noted for mean De Meester scores, again with statistical significance ($p < .001$) (Figure 3 and table 2).

Score	At procedure	At six months	At 12 months	p-value
GERD QOL (50)	39.9 ± 4.0	8.4 ± 4.7	8.7 ± 5.0	<.001*
GERD QOL (30)	21.8 ± 2.2	2.9 ± 3.3	2.5 ± 2.7	<.001*
De Meester	27.0 ± 6.5	10.6 ± 2.5	9.6 ± 2.4	<.001*

Table 2: *Comparison of QOL and De Meester scores at procedure vs. six months and 12 months.*

**Statistically significant result.*

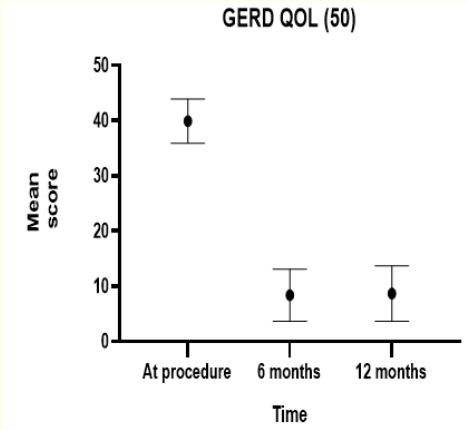


Figure 1: *Illustration of mean GERD QOL (50) scores at procedure vs six months and 12 months ($p < .001$).*

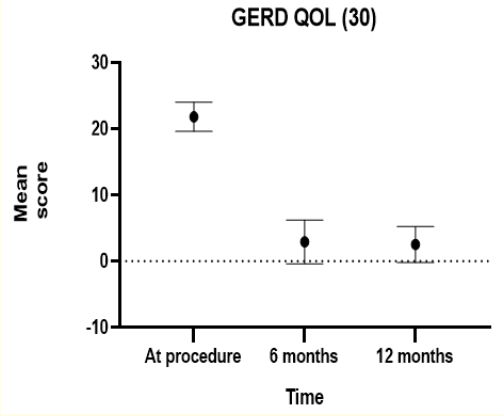


Figure 2: *Illustration of mean GERD QOL (30) scores at procedure vs six months and 12 months ($p < .001$).*

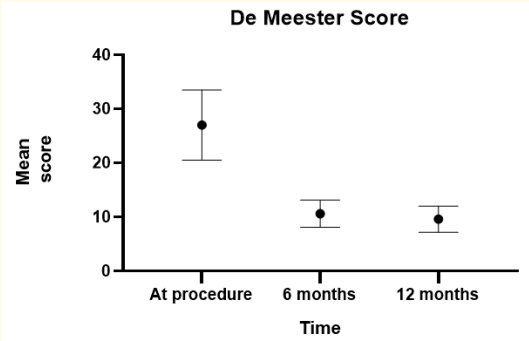


Figure 3: *Illustration of mean De Meester scores at procedure vs six months and 12 months (p < .001).*

Quality of life (QOL)

Comparison of GERD QOL assessments at procedure vs. at six months and 12 months revealed that patients' satisfaction increased at 6 and 12 months with statistical significance (p < .001). No patient was satisfied with QOL at the procedure and dissatisfied based on GERD QOL at 6 and 12 months (Figure 4 and table 3).

Assessment	At procedure	At six months	At 12 months	p-value
Satisfied (n)	0	17	17	<.001*
Neutral (n)	2	1	1	
Dissatisfied (n)	16	0	0	

Table 3: *Comparison of GERD QOL assessment at procedure vs. six months and 12 months.*

**Statistically significant result.*

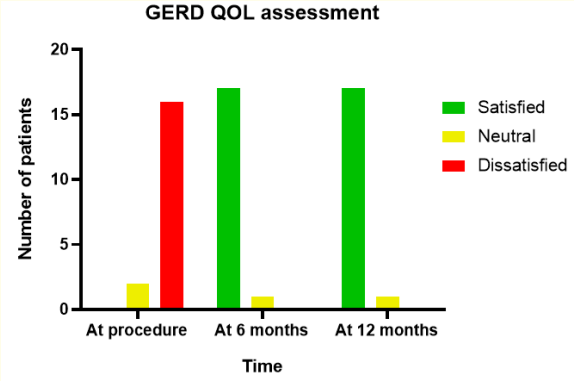


Figure 4: *Illustration showing the GERD QOL assessments at procedure vs. six months and 12 months (p < .001).*

Efficacy of treatment

A comparison of treatment efficacy with GFET revealed that GERD was detected in 13 patients at the time of the procedure, three patients at six months, and one at 12 months. This relationship of declining GERD detection was statistically significant ($p < .001$) (Figure 5). Meanwhile, at the time of the procedure, all the patients were on anti-GERD medications, and this number was reduced to 3 at six months and one at 12 months (Figure 6). This decline in anti-GERD medication use was also statistically significant ($p < .001$) (Table 4).

Score	At procedure	At six months	At 12 months	p-value
GERD on endoscopy (n)	13	3	1	<.001*
Anti-GERD medications (n)	18	3	1	<.001*

Table 4: *Comparison of efficacy of treatment with GFET.*

**Statistically significant result.*

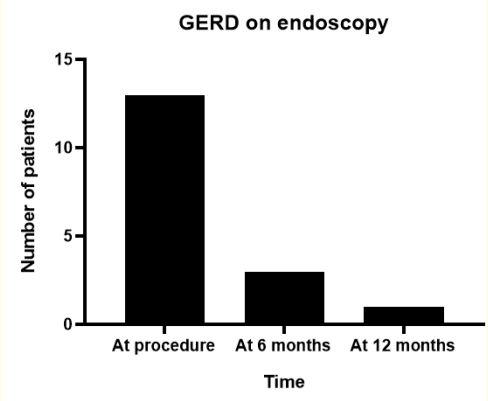


Figure 5: *Illustration showing the number of patients with GERD detected on endoscopy at procedure vs six months and 12 months ($p < .001$).*

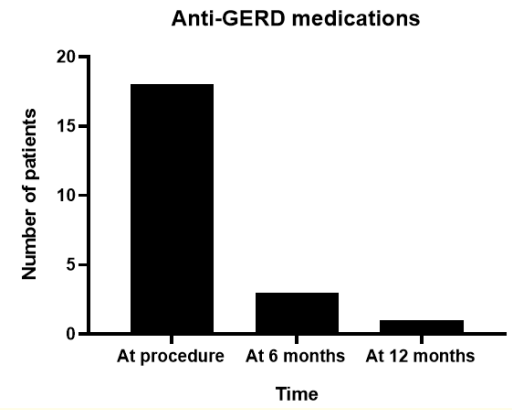


Figure 6: *Illustration showing the number of patients with Anti-GERD medications at procedure vs six months and 12 months ($p < .001$).*

Discussion

The overarching objective of this study was to assess the efficacy of gastrofundoplication with endosuture technique (GEST). The findings from our study demonstrate significant improvements in patient outcomes, comparable to those achieved with GERDX™ and TIF procedures. The GFET procedure showed marked improvements in GERD-related quality of life (QOL) scores, with substantial reductions in mean QOL (50) and QOL (30) scores at 6- and 12-months post-procedure. These improvements are statistically significant and align with the positive outcomes reported for GERDX™ and TIF, known for their effectiveness in enhancing patient quality of life and symptom relief [19].

Furthermore, the GEST technique resulted in a notable reduction in GERD symptoms, with endoscopic detection of GERD decreasing significantly from 13 patients at the time of the procedure to 1 patient at 12 months. This trend is consistent with the efficacy observed in GERDX™ and TIF procedures, which have significantly reduced GERD symptoms and esophageal acid exposure [20,21].

In comparing GEST to GERDX™, both procedures involve strategic placement of sutures around the gastroesophageal junction (GEJ) to create a stronger, more circumferential pressure barrier. However, GEST uses prolene 2-0 sutures placed at specific clock-face positions, potentially offering enhanced durability and effectiveness through full-thickness sutures, whereas GERDX™ employs a similar but distinct endoscopic suturing system [21]. The outcomes of our study suggest that GEST may offer comparable, if not superior, long-term symptom relief and durability. Moreover, when comparing GFET to TIF, notable differences include using prolene 2-0 sutures in GEFT versus plastic fasteners in TIF [19]. Both techniques aim to create a partial fundoplication, but GFET's use of full-thickness sutures may provide a more robust attachment and longer-lasting results [23].

This study indicates that GEST significantly improves QOL scores and reduces GERD symptoms and medication use, paralleling the positive outcomes reported for TIF. The minimally invasive nature and favorable safety profile of GEST, with low complication rates and only one adverse event recorded, are consistent with the outcomes seen in both GERDX™ and TIF procedures [22].

Additionally, the GEST procedure led to a substantial decrease in the use of anti-GERD medications, with all patients on medication at the time of the procedure and only one patient remaining on medication at 12 months. This reduction in medication use is similar to the outcomes seen with TIF, where patients often experience reduced dependence on proton pump inhibitors and other GERD treatments post-procedure. However, a study by Ebright., *et al*. found that only 63% of the patients stopped using PPIs. Seven grade 2 complications and one grade 3 complication were identified with aspiration pneumonia following TIF intervention, contrasting with our findings; only one complication was observed [19].

Overall, the GEST technique appears to be a viable and effective alternative to existing endoscopic methods for GERD treatment, offering significant improvements in patient outcomes with a minimally invasive approach. Further long-term studies are recommended to validate these findings and explore the potential advantages of GEST over GERDX™ and TIF procedures.

Limitations of the Study

Despite the positive outcomes, the study had limitations, including a small sample size and a single-center design, which may affect the generalizability of the results. Future studies with larger cohorts and multicenter involvement are needed to validate these findings further.

Conclusion

In conclusion, the gastrofundoplication with endosuture technique (GEST), employing the GEN-2 apollo endosuture device and precise suture placements, has demonstrated significant improvements in GERD-related quality of life, symptom reduction, and decreased reliance

on anti-GERD medications. These findings indicate that GEST is a promising, minimally invasive alternative for GERD management, potentially offering superior benefits compared to traditional surgical and other endoscopic approaches. However, this study is ongoing, and further research involving larger patient cohorts and extended follow-up periods is essential to verify the durability and long-term efficacy of the GEST method.

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