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ORIGINAL RESEARCH

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A new office-based procedure for treatment of snoring: The S.I.Le.N.C.E. study

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Abstract

Objective: Demonstrate the safety and effectiveness of palatal foreshortening and stiffening in reducing snoring severity in nonobstructive sleep apnea (non-OSA) patients complaining of chronic disruptive snoring.

Methods: In a US-based 8-center, open-label, prospective, single-arm cohort study, 52 consenting adults with chronic disruptive snoring (snoring impacting a patient's life and causing patient or bed partner to seek medical intervention) were treated via office-based placement of resorbable, bidirectional, barbed suture implants into the soft palate under local anesthesia. Prior to intervention, home sleep tests (HSTs) were performed to rule out OSA and to document snoring noise level. Both subject and their bed/sleep partners (also consented) completed questionnaires including: bed/sleep partner's scored visual analog scale (VAS) for subjects' snoring severity, and subject scoring for Epworth Sleepiness Scale (ESS) and Pittsburgh Sleep Quality Index (PSQI). Following intervention, HSTs, VAS, ESS and PSQI were repeated at 30, 90 and 180 days.

Results: Mean baseline bed/sleep partner VAS was 7.81 ± 1.59. Mean postimplant VAS scores decreased significantly at each measured interval; to 5.77±2.35 ($P < .001$) at 30 days, 4.48 ± 1.81 ($P < .001$) at 90 days, and 5.40 ± 2.28 ($P < .001$) at 180 days. Post treatment improvements in daytime sleepiness and QOL were also observed. Two partial extrusions were reported. No further adverse events were identified.

Conclusion: The current study demonstrates the safety and efficacy of the Elevoplasty procedure in reducing snoring severity over a follow-up period of 6 months.

Level of Evidence: 2b

KEYWORDS

palatal stiffening, sleep-disordered breathing, snoring, snoring treatment

1 | INTRODUCTION

Chronic and disruptive snoring is a common sleeping disorder affecting more than 37 million people in the United States.[1] Snoring is more

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frequent in adults, males, in the overweight and usually worsens with age. Often, snoring is glossed over as an entity and attention diverts to its relationship to obstructive sleep apnea (OSA). However, snoring can have significant bothersome, if not serious consequences to the individual and to others sharing a common sleeping space. Snoring disrupts sleep and may lead to excessive daytime sleepiness and decreases in performance and productivity, lack of concentration, irritability, and decreased libido.[2-5] Night-time snoring almost certainly disrupts the sleep of those in close proximity, leading to similar consequences of sleep deprivation, as well as the associated social discord and even estrangement.[6-9]

Whether primary or related to OSA, snoring is the result of vibration of oro- and/or nasopharynx tissue caused by turbulent airflow through the relaxed airway during sleep. Thus, virtually all current treatments involve methods to open the airway. Life-style modifications include weight loss, smoking cessation, limiting alcohol consumption, and improved sleep hygiene.[10-12] Over-the-counter treatment options include nasal sprays, nasal strips or dilators, lubricating sprays, and "anti-snore" clothing and pillows. Surgical correction is usually reserved for patients with associated moderate to severe OSA. Non-surgical snoring treatment often focuses on palate stiffening. Methods include injection sclerotherapy, laser therapy, cautery procedures, radiofrequency ablation and palatal implants.[13-19] These procedures usually result in palatal stiffening without significant palatal shortening and all have met limited success in selected patients. To improve success rate and reduce morbidity, an office-based procedure that would both stiffen and foreshorten the palate was tested. The Elevoplasty procedure demonstrated effectiveness and safety in a single-center pilot study employing a prototype device.[20] Based on these results a multicenter, prospective study was designed for the United States. The objective of the **S**noring **I**ntervention via E**le**voplasty in a **N**on-surgical **C**linical **E**nvironment (S.I.Le.N.C.E.) trial was to evaluate the safety and effectiveness of a minimally invasive implant of fully resorbable, bidirectional barbed sutures into the soft palate for the treatment of chronic, disruptive, primary snoring using the Elevo kit (Zelegent, Inc, Irvine, California) and the Elevoplasty procedure.

TABLE 1 The S.I.Le.N.C.E. prospectively-defined study endpoints

Primary endpoint
Change between baseline and 30-day bed/sleep partner snoring severity VAS
Secondary endpoints
1. Change between baseline and 90-day bed/sleep partner snoring severity VAS
2. Change between baseline and 30-day HST snoring noise ratio measure #1
3. Change between baseline and 30-day HST snoring noise ratio measure #2
4. Change between baseline and 90-day HST snoring noise ratio measure #1
5. Change between baseline and 90-day HST snoring noise ratio measure #2
6. Change between baseline and 30-day Pittsburgh Sleep Quality Index (PSQI) Score
7. Change between baseline and 30-day Epworth Sleepiness Scale (ESS)
8. Change between baseline and 90-day PSQI score
9. Change between baseline and 90-day ESS
10. Change between baseline and 180-day bed/sleep partner snoring VAS
11. Change between baseline and 180-day PSQI score
12. Change between baseline and 180-day ESS
13. Change between baseline and 180-day HST snoring noise ratio measure #1
14. Change between baseline and 180-day HST snoring noise ratio measure #2

Abbreviations: HST, home sleep test; VAS, visual analog scale.

2 | MATERIALS AND METHODS

2.1 | Study design and outcome measures

This prospective, multicenter, single-arm study was initiated at eight sites in the United States (ClinicalTrials.gov ID: NCT03083106). It was designed to evaluate the technical safety and effectiveness of the Elevo minimally invasive, barbed, absorbable suture implant in the reduction of simple snoring through subjective evaluation of snoring and objective snoring sound analysis. The protocol and potential sites and investigators were reviewed and approved by the Western Institutional Review Board (WIRB, Puyallup, Washington) or by a site's institutional ethics/review board when a local IRB maintained jurisdiction.

The safety endpoint was assessed by documenting and analysis of all adverse events (AEs) that occurred during the trial. The primary efficacy endpoint was the mean within-subject change of snoring visual analog scale (VAS) from baseline (prior to implant) to Day 30 postimplant as completed by the study subject's bed/sleep partner. There were multiple secondary endpoints as noted in Table 1 ranked in order of relevance to the study.

2.2 | Selection or screening

Prospective subjects presented to the study centers with complaints of chronic, disruptive snoring and negative screening for OSA. Subjects deemed qualified to participate were informed about the trial, the proposed implant procedure and follow-up requirements and provided with IRB-approved reading material and copies of the informed consent forms for both subject and bed/sleep partner. Identified prospective subjects (and their bed/sleep partners) were invited to a baseline visit where full informed consent was provided and informed consent forms were signed, and inclusion/exclusion criteria (Table 2) were reviewed.

At enrollment, investigators documented demography, medical and surgical history, and performed a physical examination—including awake fiberoptic nasopharyngeal, hypopharyngeal endoscopy and oral cavity

TABLE 2 The S.I.Le.N.C.E inclusion and exclusion criteria

Inclusion criteria
1. Age > 22 years (no maximum age)
2. Has consistent bed/sleep partner willing to provide co-participant informed consent
3. Has basic computer literacy (eg, email) and home internet access or smartphone
4. Chronic, simple snoring (bed/sleep partner-verified)
5. No prior surgical treatment for snoring
6. Willing and capable of providing Informed Consent
Exclusion criteria
1. Age < 22 years
2. Has no consistent bed/sleep partner
3. Intermittent or occasional snoring
4. Body mass index >32 kg/m^2
5. Friedman tongue position 3 or 4
6. Tonsil Grade 3 or 4
7. Significant nasal obstruction
8. Previous palatal surgery
9. Current cigarette smoker
10. Known history of coronary artery disease or stroke
11. Chronic obstructive pulmonary disease
12. Diabetes
13. Major depression or noncontrolled psychiatric illness
14. Drug or alcohol abuse
15. Untreated or poorly controlled hypertension
16. Anticoagulation therapy
17. History of bleeding or clotting disorder
18. Epworth Sleepiness Score > 10, indicative of obstructive sleep apnea

examinations to rule out any pathology and to identify Friedman tongue position (FTP) and tonsil size. Finally, each subject was provided with and trained to use a home sleep test (HST) device. The HST device was sent home with the understanding that the subject would self-conduct a two-night HST and return the device for data analysis. This HST functioned to confirm the presence of chronic, disruptive snoring and rule out moderate/severe OSA (apnea/hypopnea index >15). Following confirmation of both snoring and negative OSA status, the subject and bed/sleep partner received individual e-mails inviting them to complete online baseline questionnaires. The bed/sleep partner rated the subject's snoring severity (via 0-10 VAS). The subject assessed daytime somnolence via the Epworth Sleepiness Index (ESS) and sleep quality via the Pittsburgh Sleep Quality Index (PSQI). In addition, the subject was scheduled for the Elevoplasty procedure.

2.3 | Elevoplasty procedure

Each subject was treated with an in-office Elevoplasty procedure whereby three, fully resorbable (polydioxanone), barbed suture implants

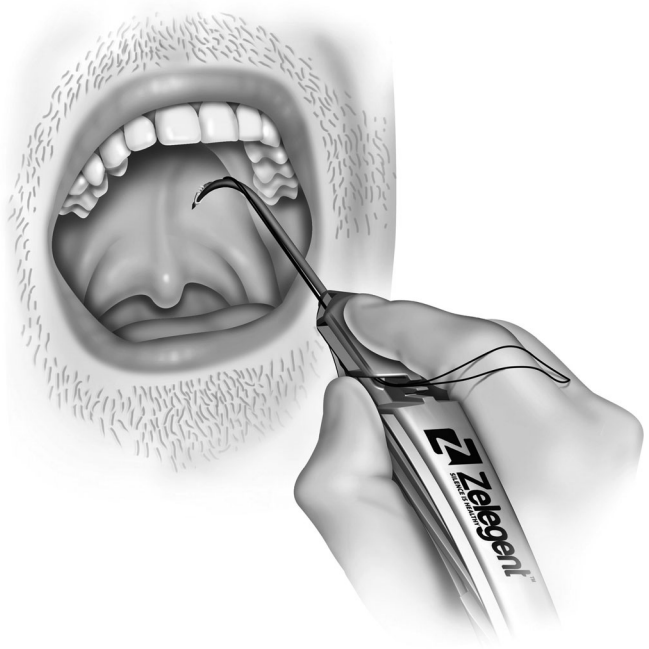

FIGURE 1 The Elevo suture implant is provided preloaded into a specialized suturing needle delivery device

were inserted into the soft palate under topical and local infiltration anesthesia. The bidirectional, self-anchoring suture configuration incorporates tiny barbs spaced evenly in a helical array on either side of a nonbarbed midsegment. Developed originally used for soft-tissue approximation to produce lift in facelift procedures,[21,22] the barb configuration and the implant length were optimized for the present study to provide tissue apposition in the soft palate. The net result is stiffening and shortening of the soft palate without the need for surgical knots or swaged needles. Each implant was provided preloaded into a specialized suturing needle delivery device (Figure 1).

The entry points for these implants are approximately 2 to 3 mm distal (posterior) to the hard/soft palate junction. Applying gentle pressure on the handle, the tip delivery needle was advanced in a gentle arch motion through the levator palatine muscles toward the posterior end of the soft palate (the uvula). Some investigators found it helpful to create three initial or "pilot" holes before deploying the Elevo implants, to ease insertion. A depth insertion marker located on the needle shaft was used for visual reference. As a general rule, the tip was advanced 25 to 30 mm distally through the soft palate to an area approximately 8 to 10 mm from the distal edge of the soft palate (Figure 2). When insertion depth was deemed acceptable, a reversal of the arced motion of the handle uncoupled the implant and enabled the needle to be withdrawn, leaving the implant in place with both sets of barbs engaged in tissue and the tension suture protruding out of the subject's palate and mouth. This process was repeated for the each of the implants.

The three implants were deployed within the width of the subject's soft palate. One implant was inserted along the subject's midline. The remaining two implants were generally inserted approximately 5 to 10 mm laterally on each side and advanced in a slight radiating pattern

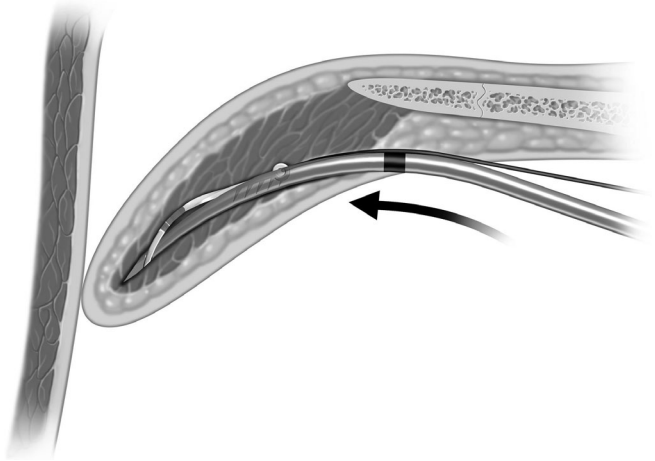

FIGURE 2 Gentle pressure is applied on the handle as the tip of the needle is advanced in an arched motion through the uvular and levetor palatine muscles of the soft palate

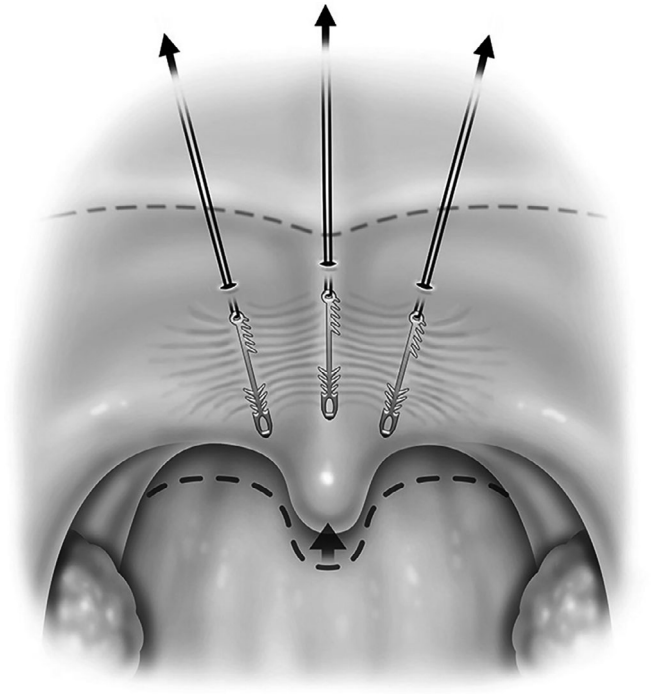

FIGURE 3 Gently traction on the silk sutures causes mild tissue apposition ("accordion-ing") and results in elevaton, shorten, and stiffen the soft palate. The proximal barbs engage with tissue to maintain the tension

so that the tip of the suture implant resides approximately 10 to 15 mm lateral to the distal end of the fully advanced middle suture implant. Once all implants were placed, the black silk sutures protruding from the subject's palate were each manually retracted causing a mild tissue apposition ("accordion-ing") of the soft palate tissue (Figure 3). This action was meant to slightly raise, shorten, and stiffen the soft palate, with the proximal barb row engaging with tissue to gently ratchet tension. After an approximately 1 to 4 mm of soft palate lift was achieved, the silk sutures were cut and withdrawn.

On the following day, subjects were contacted via telephone/text message to query postprocedure complications, pain, and pain medication usage. Subjects were scheduled to return in 1 month (or earlier if necessary) for a standard postprocedure follow-up.

2.4 | Data collection

Prior to the procedure, each subject and bed/sleep partner were trained on the use of an online outcomes-tracking database (Trials.ai, San Diego, California). Online questionnaire assessments were prompted by e-mails to both the subject and the bed/sleep partner at the following four intervals: (a) before the procedure (baseline), (b) 30 days after the procedure, (c) 90 days after the procedure, and (d) 180 days after the procedure. Assessments included ESS and PSQI for the subjects and a VAS 0 to 10 score assessment of the study subject's snoring severity entered by the bed/sleep partner.

In addition, each subject was provided with an HST device (SNAP Diagnostics, LLC, Wheeling, IL, Model 8) at each interval for two-night sleep studies. This device uses sound energy measurements and oximetry to screen for OSA.[23,24] HST testing provided detailed, acoustical analysis of snoring by quantifying snoring index (snore events/hour), average snoring loudness, maximal snoring loudness, and average snoring frequency.[25] The HST recordings (minimum 4 hours recording) were analyzed independently. The snoring events were classified into five predefined types: (a) type I: mostly palatal; (b) type II: mostly palatal + tongue; (c) type III: sound, but no particular pattern, can originate in lungs, or upper airway; (d) type IV: high pitch, more diffuse, similar to asthma; and (e) type WL: wheezing-like. As derivatives of these outcome measures, noise ratios were calculated using the algorithms below to compute the percentage of snoring believed to be of palatal origin (measure #1) and ratio of loudness of palatal snoring vs background noise (measure #2).

1. Measure #1: percent (%) of snoring events comprised of types (I + II)/(I + II + III + IV + WL); and
2. Measure #2: average loudness ratio of events: (loudest 15% of type I and II)/(average loudness nonsnoring breathing events loudness) on Base 10 log.

Since inclusion criteria did not restrict enrollment to patients with a predominance of a specific snoring type, the study assessed the pre- and post-treatment measures to detect a change in palatal snoring vs other breathing sounds. In total, the endpoints the trial consisted of 1 primary endpoint and 14 secondary endpoints (Table 1).

2.5 | Statistical analysis

Sample size was selected based on the potential of the lower bound of a two-sided 95% confidence interval to exceed 50%, if the patient selection criteria were appropriate. Given that no p redetermined multiple comparison rule was defined a priori, all probability values

provided are nominal. Continuous variables are presented as mean ± SD and categorical variable data as frequencies and percentages. Multiple paired t-tests were used to assess statistical differences between measures collected at baseline and compared to 30-day, 90-day, and 180-days postprocedure. Probability values <.05 are considered statistically significant. All statistical analyses were conducted in SAS version 9.3 (SAS Institute, Cary, North Carolina).

3 | RESULTS

Fifty-two study subjects were treated across seven of the eight centers that gained IRB approval to enroll subjects. Enrollment included 33 males, 19 females, and their bed/sleep partners.

Prior to treatment (baseline), the subject's mean VAS score for snoring severity as assessed by the bed/sleep partner was 7.81 ± 1.59. At 30-days postprocedure, the VAS score (*Primary Endpoint*) decreased significantly to 5.77 ± 2.35 ($t(51) = 6.390$, $P < .001$). At 90-days postprocedure, the snoring severity mean VAS score (*Secondary Endpoint #1*) was 4.48 ± 1.81 ($t(47) = 7.141$, $P < .001$). The 180-days mean VAS score (*Secondary Endpoint #10*) was 5.40 ± 2.28 ($t(44) = 7.097$, $P < .001$). The mean within-subject ESS (0-24) at baseline was 6.63 ± 4.00 and decreased to 5.38 + 3.21 ($P < .05$) at 30 days postprocedure. This decrease in ESS was sustained at 90-days (5.06 ± 3.03 [$P < .01$]) and 180-days postprocedure (4.63 ± 2.54 [$P < .01$]), These results comprise the prospectively-defined secondary endpoints #7, #9, and #12.

The trial results also achieved significance in the mean within-subject change in subject-reported PSQI results. The mean PSQI score (0-21) at baseline was 7.04 ± 3.53. The mean PSQI score at 30-days postprocedure had decreased to 5.51 ± 2.58 ($P < .001$). This decreased persisted through 180-days; at 90-days 5.47 ± 2.76 ($P < .001$) and at 180-days postprocedure 5.51 ± 2.99 ($P < .001$). These results comprise the prospectively-defined secondary endpoints #6, #8, and #11.

Table 3 displays comparative data collected from the two prospectively-defined HST snoring noise ratio measurement (secondary endpoints #2, #3, #4, #5, #13, and #14). The trial results achieved some numerical improvement, but not statistical significance in either percentage of snoring event types (HST measure #1) or average event loudness ratio (HST measure #2).

Safety outcomes from the trial indicate low risk of harm to patients. There were no reported adverse events. Two subjects reported being able to palpate an implant with their tongues after discharge. In both those cases, an extruding section of the implant was discovered and treated with a simple trimming of the protruding portion of the implant in a brief follow-up office visit. This trimming with scissors involved no anesthesia, bleeding, or pain.

All subjects were contacted on the evening of postprocedure day 1 to elicit peak pain VAS on both the evening of procedure and on postprocedure day 1. Peak postprocedure pain VAS, collected on the evening of the procedure was as reported on a 0 to 10 VAS was 3.85 ± 2.69 and. 24 hours later (postprocedure day 1) was 2.90 ± 2.21. Only 3 out of 52 (5.8%) reported using an opioid for postprocedure pain control on the evening of or day after the procedure.

4 | DISCUSSION

The present study was conducted in selected adult patients suffering from chronic, disruptive snoring based on their bed/sleep partner reporting, the subject's own assessment of sleep quality and confirmed by HST snoring sound recordings. Snoring is often linked to OSA and admittedly, the anatomic causes of snoring may also contribute to the OSA syndrome. However, the airway obstruction in OSA is often multilevel in origin. Since the focus of this study dealt with treatment of snoring at the level of the soft palate, patients with coexisting moderate to severe OSA were specifically excluded to more clearly discern any improvement in sleep quality without the background of OSA. The objectives of the other inclusion and exclusion criteria (Table 2) were similarly aimed to recruit those patients who could potentially most benefit from palatal stiffening and in whom demonstrable clinical improvement might be clearly recognizable.[17,26]

The results of the multi-institutional trial demonstrated a statistically significant and prolonged decrease in mean snoring severity VAS as assessed by the bed/sleep partner and thus, confirmed the prospectively-defined primary and several secondary endpoints. The mean decrease at the 30-day interval was 25% and decreasing further still to an approximately 30% at 90- and 180-days post treatment. In addition, significant and prolonged improvements in subject-reported

TABLE 3 Data summary of primary and secondary study outcome measures

	Baseline	30-Day (n = 52)	90-Day (n = 48)	180-Day (n = 45)
Snoring VAS 1° and 2° endpoints #1 and #10	7.81 ± 1.59	5.77 ± 2.35 ($P < .001$)	4.48 ± 1.81 ($P < .001$)	5.40 ± 2.28 ($P < .001$)
ESS 2° endpoints #7, #9, and #12	6.63 ± 4.00	5.38 + 3.21 ($P < .5$)	5.06 + 3.03 ($P < .1$)	4.63 + 2.54 ($P < .1$)
PSQI 2° endpoints #6, #8, and #11	7.04 ± 3.53	5.51 ± 2.58 ($P < .001$)	5.47 ± 2.76 ($P < .001$)	5.51 ± 2.99 ($P < .001$)
HST measure #1 (%) 2° endpoints #2, #4, and #13	11.75 ± 8.93	12.23 ± 8.94 (NS)	12.00 ± 12.21 (NS)	10.19 ± 10.59 (NS)
HST measure #2 (dB) 2° endpoints #3, #5, and #14	18.50 ± 7.08	19.90 ± 6.90 (NS)	19.54 ± 9.98 (NS)	17.24 ± 8.78 (NS)

Note: Data presented as mean ± SD. Statistical significance accepted when $P < .05$.
Abbreviations: dB, Decibels; ESS, Epworth Sleepiness Scale; HST, home sleep testing; NS, not significant; PSQI, Pittsburgh Sleep Quality Index; VAS, snoring severity visual analogue scale as recorded by bed/sleep partner.

sleep quality and daytime alertness represented an additional six secondary endpoints. It must be noted that although the primary and 8 of 14 secondary endpoints were achieved, all these were subjective endpoints. The remaining six secondary endpoints were based on SNAP Diagnostics sound adjudication algorithms for HST sound recordings of snoring. Statistical analysis found no improvement in the two calculated measures involving snoring type analysis or snoring volume analysis (Table 3). However, since the inclusion criteria did not limit enrollment to only those with snoring believed to be of palatal origin, the cohort included patients exhibiting little or no palatal (type 1 or type II) snoring and thus, changes in HST measures #1 and HST measures #2 might have been minimized.

This study was designed to establish the effectiveness of the Elevo implant and the Elevoplasty procedure in a population of non-OSA snoring patients and not just among a subset of patients with predominantly palatal snoring. Had HST measures #1 and #2 been used as inclusion criteria, we might have increased the magnitude of our efficacy indices. However, this also might have limited the applicability of the procedure to those prescreened for palatal snoring.

The S.I.Le.N.C.E protocol described the placement of three implants as optimal, although individual anatomic considerations might have necessitated only two or suggested that three would be inadequate. Factors such as FTP, palatal dimensions or pharyngometry may come into play in such decision making. These were not documented in the present study. However, the issue of optimal number of has not yet been clearly defined for the Elevo implant. Still, one may examine the literature for precedent. The only other minimally invasive soft palate implant to be studied in multicenter trials, the Pillar Palatal (Pilliar Patatal, LLC, Dallas, Texas) implant, has been studied in this way. A study successfully treated patients undergoing initial Pillar procedure for snoring reduction results and returning to their clinic dissatisfied with a fourth or fifth additional implant to improve outcome.[27] These results might support the reasonable assumption that additional Elevo implants may further improve upon the current study's outcome.

The Elevo suture implant is comprised of polydioxanone. Testing of such resorbable suture material has shown that by 6 weeks following implantation, a significant percentage of the original tensile strength is lost.[28] Notably, the duration of snoring severity reduction appears to exceed the resorption time of implants. This observation is consistent with the notion that the physical tissue apposition of the tissue caused by the pulling of the implant induces a secondary tissue remodeling and contraction process that persists after the implant has been replaced by scar tissue. Similar rational exists for other palatal stiffening such as radiofrequency ablation of the soft palate/volumetric reduction of the tongue base (RFTBR), cautery assisted palatal stiffening procedure (CAPSO), injection sclerotherapy (injection snoreplasty) and observation of persistent snoring reduction following extrusion or removal of Pillar implants.

The overall safety of the device is characterized by the fact that there were only two reported minor adverse events. On follow-up, some subjects were able to palpate the implant following sensory recovery from the local anesthesia, this strange feeling diminished over the next 24 hours. Two subjects required a return to office for partial extrusion of the implant. Partial extrusion was treated by simply cutting away the extruded segment. There were no complete extrusions. In addition, postprocedure pain was very minor in level and short in duration. No pain medication usage was specifically directed at postprocedure pain was reported after postprocedure day 1.

5 | CONCLUSIONS

Based on the results of the current study, we believe that this minimally invasive office procedure can be a safe tool in treating patients suffering from predominantly palatal snoring. The limited data on our selected group of patients indicates a moderate reduction in snoring.

CONFLICT OF INTEREST

Dr Friedman is a member of the Zelegent, Inc. advisory panel and is a (0.075%) shareholder of Zelegent, Inc. Dr Gillespie is a member of the Zelegent, Inc. advisory panel and is a recipient of a grant (or funding) from Zelegent, Inc. Dr Meyer is a recipient of a grant (or funding) from Zelegent, Inc. Drs Shabdiz, Hiltzik, Ahn and Catalano, and Mr Joseph have no financial declarations.

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