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A new airway spiral stent designed to maintain airway architecture with an atraumatic removal after full epithelization—Research of feasibility and viability in canine patients with tracheomalacia

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Abstract

Objective: Surgical management of tracheomalacia is a challenge, with current treatments still presenting numerous complications. In the field of veterinary medicine, this same pathology is present in a significant number of dogs. For this reason, we present an experimental clinical trial performed on canines with tracheobronchomalacia, using a new atraumatic removable tracheal spiral stent (SS). Both implantation procedure and clinical improvement have been analyzed in this study.

Methods: In this study, four small dogs, a mean weight of 4.89 kg and body condition scores IV-V, were included. SS was implanted by two different surgical approaches. Image and clinical follow-up have been performed during 90 days. Symptoms were evaluated from 1 to 10 every week.

Results: This study achieved 100% technical and clinical success. Median tracheal diameters were as follows: cervical 10.85 (3.3), inlet 7.75 (2.1), and carina 7.75 (1.9) mm, and length was 77.5 (26) mm. A 12 × 10 × 100-mm SS was implanted in all cases. Goose honk cough punctuation improved from 8 to 1; also, there were important changes in exercise intolerance, a mean weight loss of 8.76%. The values of modified Karnofsky scale varied from 50 (20) before surgery to 90 (10) after 30 days of surgery. Neither granuloma tissue nor fractures of the prosthesis was observed.

Conclusion: The results in dogs are promising, and a new therapeutic alternative seems to be available for veterinarian field. The similarity of this disease between dogs and newborns suggests that this SS design can also be useful for human trials.

KEYWORDS

animal model, pediatrics, removable, stent, tracheomalacia

Abbreviations: BCS, body condition score; KS, modified Karnofsky scale; LL X-ray, laterolateral radiography; SS, spiral stent.

1 | INTRODUCTION

Airway collapse is an important cause of respiratory distress in children with malacia of the airway, especially in cases of tracheomalacia.[1-3]

Malacia refers to "softness" of a tissue, typically bone or cartilage. The term tracheomalacia refers to softness of the trachea, frequently due to a widened and lax pars muscular, and/or an impaired cartilage integrity, which result in a weakness of airway architecture with high collapsibility, preventing a normal airflow from the atmosphere to the lungs.[4-8]

Airway collapse normally occurs when more air is required, such as while crying or doing exercise. Congenital airway malacia includes tracheomalacia, bronchomalacia, and tracheobronchomalacia. In primary tracheomalacia, the pathology is caused by the abnormal trachea itself or secondary to external compression surrounding the airway. True secondary tracheomalacia is resolved by treating the main pathology such as mediastinal mass.[5]

Primary congenital tracheomalacia is generally produced due to the abnormal development or maturation of the airway in embryonic stages. In most cases, it is associated with other malacia disorders as part of a syndrome (e.g., Down´s syndrome and Ehlers-Danlos syndrome) or accompanied by other malformations of the digestive system (e.g., tracheoesophageal fistula).[9-11]

Tracheomalacia is regularly associated with common respiratory symptoms. The main symptoms are wheezing, persistent cough (caused by expiratory collapse and vibration of the floppy membrane), and dyspnea.[1,4] These symptoms overlap with other respiratory diseases; therefore, it is not surprising that the diagnosis is delayed with a suboptimal initial treatment.[11]

Tracheomalacia management includes medication or interventions that improve airway caliber (stents, aortopexy, and continuous airway pressure), enhance mucociliary clearance, avoid infection, and reduce intraluminal inflammation.[8,11-13]

Airway stenting has significant advantages as compared with conventional surgery. It is a minimally invasive technique that requires short anesthetic time with a fast recovery.[3,13] Several types of stents have been used. Currently, silicon stents and self-expandable covered stents are being used, but mucosal obstruction, migration, and granuloma tissue development at the ends of the prosthesis are common complications.[14-16] Metallic stents, both balloon-expandable and self-expandable, reduce the likelihood of migration and improve mucus clearance; however, they can be fully epithelized and cannot be retrieved.[17-19] Recently, bioabsorbable airway stents have been implanted in children with tracheomalacia, and the results are promising.[8,20] The patency of the airway is recovered, but stent fragmentation must be taken into account as a possible complication.[20-22] Nevertheless, more studies are needed to assess safety and efficacy in pediatric patients.

Several alternatives have been proposed and there is a continuous development on this topic. Studies on pathological animals are a good alternative to analyze and improve new surgical alternatives. Tracheobronchomalacia is a well-known disease in the field of veterinary medicine, which mainly affects small and toy dog breeds.[23,24] Similar characteristics are present between dogs and pediatric patients regarding this disease; hence, pathological canines could be a good alternative as an animal model for tracheal stenting.

The aim of this study is to assess the feasibility and viability of a new spiral airway stent (SS) in dogs with tracheomalacia or tracheobronchomalacia. We hypothesize that this prosthesis in a near future could be an alternative therapy for the treatment of tracheomalacia or tracheobronchomalacia in pediatric patients.

2 | MATERIAL AND METHODS

The study presented is a prospective, nonrandomized, monocentric clinical trial on pathological dogs. It was approved by the ethics committee (Code PI50/18), supported by a grant of the University of Zaragoza, Spain, and elaborated according to Animal Research: Reporting of In Vivo Experiments guidelines.[25] All owners of the dogs accepted and signed the participation agreement.

2.1 | Spiral stent

The design of the current stent is a type of SS (patent number ES2725273) that pretends to solve the currently described complications of tracheal stents, improving the mucociliary clearance due to the resembling of the tracheal architecture, and to reduce the proportion of contact between the tissue and prosthesis.

The helical prostheses implanted were manufactured in superelastic memory shape NiTi (Nitinol) with a wire diameter of 0.3 mm and a gap of 5 mm between loops. NiTi was chosen due to its elasticity and biocompatibility.

One conical-shaped device was used: 12 mm × 10 mm diameter and 100 mm length. The conic diameter was chosen, because it resembled dog's tracheal architecture. Both tips of the SS were specially manufactured; the cranial part (largest diameter) had a small loop to fix the stent to the trachea, and the caudal part (smallest diameter) was rounded and soft to avoid tracheal damage during the introduction (Figure 1).

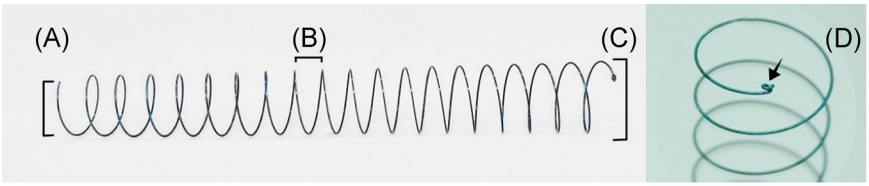

FIGURE 1 Device design. A, Caudal part of the SS, rounded and soft. B, Distance between SS loops. C, Cranial part, largest diameter. D, Small loop to fix the stent. SS, spiral stent [Color figure can be viewed at wileyonlinelibrary.com]

2.2 | Surgical procedures

The dogs were premedicated with a combination of acepromazine (0.04 mg/kg intramuscular [IM]) and butorphanol (0.3 mg/kg IM), enough to place an intravenous catheter, and they were induced with alfaxalone intravenously, whose effect lasted until endotracheal intubation was allowed. Under fluoroscopy guidance, the endotracheal tube was repositioned at the level of the first tracheal cartilage, and the animals were ventilated during the procedure. Under general anesthesia, they were positioned in dorsal recumbence with slight hyperextension of the neck. By palpation, the cricoid cartilage was located, and surrounding it, a square of 4 × 4 cm was shaved and prepared surgically.

A skin incision of 2 cm was performed one centimeter caudal to the cricoid cartilage, and dissection of the subcutaneous tissue and muscular planes were performed until the exposure of the trachea. To obtain the best vision, a small separator was placed.

Two implantation procedures (twining or packing implantation) were performed, depending on four factors: tracheal collapse morphology, collapsed extension, location, and the elasticity of the malacia.

Patients with lower elasticity, lateral collapse, and shorter extension of the collapse were implanted with the "packing" method. The decision was taken through a consensus of four professionals to check which procedure was the best for each patient.

2.2.1 | Implantation method 1: Twining implantation

The material used for the implantation was an 18-G needle. A hole between two tracheal rings (caudal to the cricoid) was made using the needle.

Through this hole, the stent was introduced with a rotatory movement. The smallest diameter of the SS was introduced first, and the cranial part of the stent (biggest diameter) was fixed to the cranial tracheal ring. The fixation was done with a nonabsorbable monofilament suture that was introduced through the loop of the stent and stitched to the trachea. The implantation of the stent (twining) was always performed in collaboration with the anesthetist veterinarian, who did a ventilation with a positive pressure of 20 cm H_2O to obtain the maximum diameter of the trachea while performing the rotatory movement.

2.2.2 | Implantation method 2: Packing implantation

This procedure was performed by introducing the SS though a 4-Fr peel-away dilator. The dilator length was adapted to the patient, enough to advance 1 cm into the intrathoracic trachea. A minimum incision was made between two tracheal rings (at the desired level of implantation) with an 11 scalpel to introduce the dilator. Under fluoroscopic guidance, the position of the dilator was then checked, and the SS was introduced through the dilator lumen, rotating from outside until the stent advanced into the intrathoracic trachea. Once the SS reached the carina, it was kept outside and the dilator was removed slowly, using the maneuver of "pinch and pull." When the SS was inside the trachea, it was fixed as previously explained (Figure 2).

2.3 | Animals: Inclusion and exclusion criteria

In this study, four dogs of three different breeds were involved. Their weights ranged from 3.5 to 7.5 kg, the body condition score was IV-V (BCS-classified I-V), and the age ranged from 4.5 to 16 years.

Inclusion criteria were as follows: presence and persistence of symptoms, tracheal collapse grade II-IV, at least one radiological imaging for diagnosis, and owner's acceptance of the participation agreement.

Exclusion criteria were as follows: nonpersistent symptoms, tracheal collapse less than grade II, the impossibility of follow-up, another life-threatening disease, and nonparticipation agreement signed.

All animals were referred to the Minimally Invasive Department of the Veterinarian School of the University of Zaragoza.

Measurements of the tracheas were performed according to the protocol for tracheal stenting[23,26]: under fluoroscopic guidance, with 20 cm H_2O of positive pressure, the diameter elected was at least 20% larger than the tracheal diameter. Areas measured were taken at three levels: cervical, inlet, and at the level of the carina.

Patient 1: A 4.5-year-old Pomeranian female was diagnosed of tracheomalacia 2 years ago. The collapse seemed refractory to medical management (corticosteroids, antitussives, and bronchodilators). She suffered from exercise intolerance, continuous cough episodes, dyspnea, panting, and persistent cyanosis (bluish tongue).

Patient 2: A 16-year-old Chihuahua spayed female was presented with a dyspnea episode. At emergency service, a generalized tracheobronchomalacia was observed. Initially, the treatment with corticosteroids passified the symptoms. After 2 months, cough and exercise intolerance were uncontrollable without high corticosteroids doses (1 mg/kg each 12 hours).

Patient 3: A 12-year-old Yorkshire Terrier female was referred to the hospital with the classical presentation of chronic tracheal collapse.

She suffered from cardiac remodeling, pulmonary hypertension, constant tachypnea, exercise intolerance, hepatomegaly, and persistent cough.

Patient 4: A 7-year-old Pomeranian male was presented in the last three summer seasons to the emergency service due to uncontrollable respiratory distress and cough episodes. He did better in winter, but the last year, his lifestyle was pretty compromised by the disease.

2.4 | Diagnosis and follow-up

2.4.1 | Pathology diagnosis

Diagnosis confirmation was performed by three different methods: right laterolateral radiography (LL X-ray) in expiration and inspiration, fluoroscopy examination (awake and under sedation), and

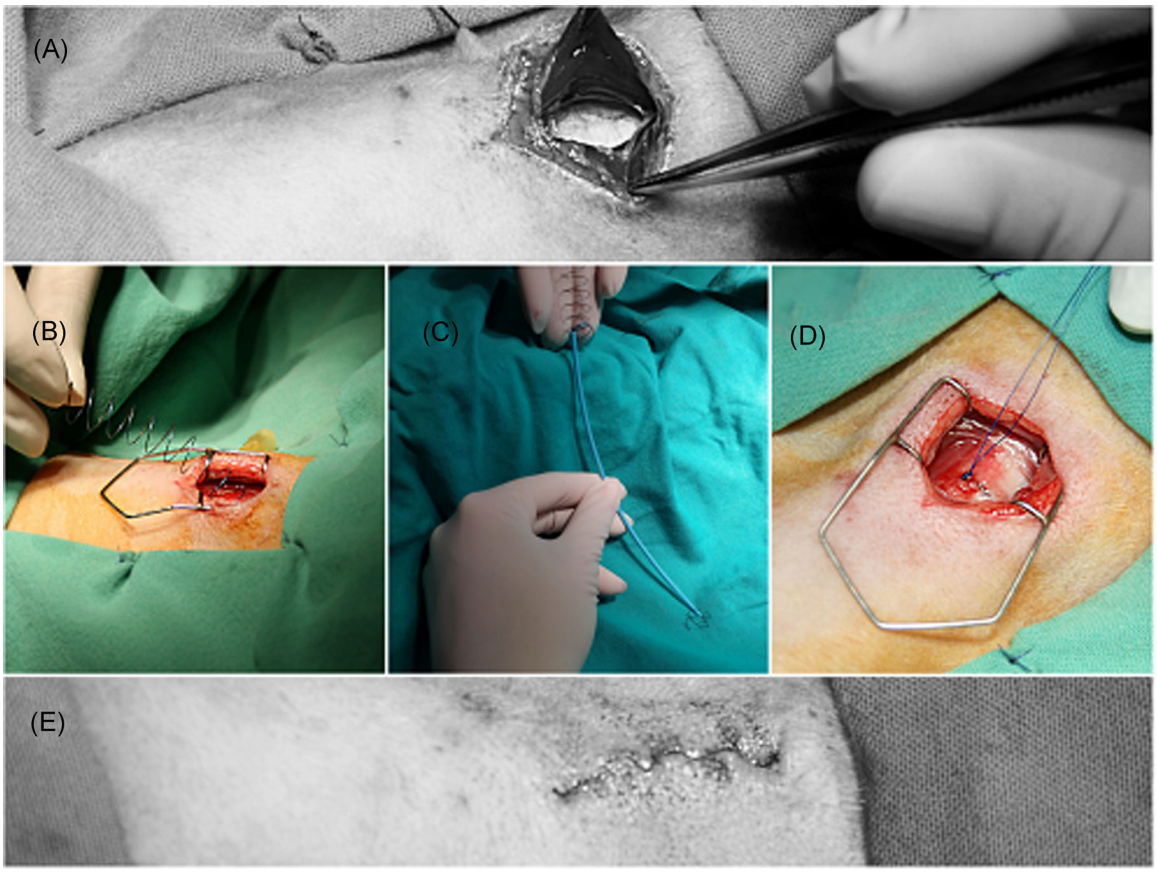

FIGURE 2 Surgical procedure. A, 2-cm dissection. B, Twining the SS. C, SS compressed inside the dilator. D, Fixation point of the tracheal ring. E, Incision suture. SS, spiral stent [Color figure can be viewed at wileyonlinelibrary.com]

endoscopic examination to classify tracheal collapse grade and bronchial affectation.

In dogs, tracheal collapse is classified in four degrees, with I denoting near normality and IV denoting a lumen reduction greater than 90%.[27]

2.5 | Clinical and image follow-up

Before the intervention, the owners were asked to score the symptoms between 0 (total absence) and 10 (maximum frequency), and every week during the first month, they completed it to assess the clinical evolution. Moreover, owners evaluated their pets according to a modified Karnofsky Scale (KS) for dogs[28,29] (0: death and 100: normal activities of daily living, non-disease evidence).

Medical management was provided to all patients 21 days after surgery, which included corticosteroids, antitussives, and antibiotics.

An LL X-ray examination was performed to check the position of the SS, its shortening, and abnormal tissue obstructions. It was performed at three controls: 12 hours, 30 days, and 90 days after the surgery. The endoscopic evaluation was performed just after twine placement to determine the position and the patency of the airway (Figure 3).

2.6 | Data analysis

Data were processed and analyzed using a computer software program for statistical analyses with SPSS (IBM SPSS Statistics for Macintosh, Version 21.0; IBM Corp, Armonk, NY). $P < .05$ was considered to indicate statistical significance. Qualitative variables were expressed as frequencies and compared using Fisher´s exact test and the likelihood ratio.

Quantitative parametric variables were expressed as mean ± SD, and nonparametric variables were expressed as median (range). Previously, the normality was calculated using Shapiro-Wilk test. Paired samples were analyzed using Student's *t*-test for parametric samples and Wilcoxon test for nonparametric variables.

3 | RESULTS

Both implantation procedures achieved 100% technical success and feasibility. The two procedures required the same incision length, but procedure 1 produced a minimum aggression of the trachea. The total elapsed surgery time during the procedure-2 was 20.5 minutes less than procedure 1, with a mean of 90.3 minutes. Stent replacement was performed without complications during the intervention

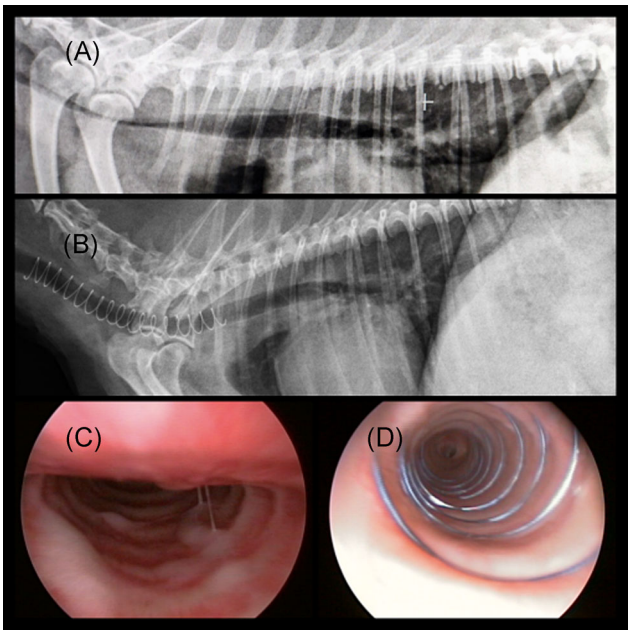

FIGURE 3 Patient number 2. A, Radiographic diagnosis, collapse of cervical trachea. B, SS implanted, clean luminogram. C, Endoscopic diagnosis, collapse grade V. D, SS implanted, patency of the trachea. SS, spiral stent [Color figure can be viewed at wileyonlinelibrary.com]

in patient 1 three times, until the caudal tip of the SS was inside the carina. Postsurgical analgesia was not necessary and medical treatment was discontinued after 21 days in any case.

The four animals presented BCS IV-V; with marked fat accumulation surrounding the neck, both Pomerania dogs presented shorter neck and the worse body weight conditions. All clinical data recorded are presented in Table 1.

Median diameter measurements were as follows: cervical 10.85 (3.3) mm, inlet 7.75 (2.1) mm, and carina 7.75 (1.9) mm, and the length was 77.5 (26) mm. The SS implanted in all cases had the following measurements: 12-mm cranial, 10-mm caudal, and 100-mm length.

Symptoms scored before the surgery were recorded during 90 days (Figure 4). Previous exercise intolerance median was 6 (5) points, being reduced until 1 (2), after 90 days, it increased to 6 (7) due to other nonassociated pathologies (gastritis and hips dysplasia). Dyspnea was reduced to 0 (0) 15 days postimplantation.

Goose honk cough varied substantially between patients during the first 21 days, and it was more stable after 30 and 90 days, with values 2 (1) and 1 (1), respectively.

The analysis of the KS scale revealed a median initial punctuation of 50 (20) and the improvement to 90 (10) after 30 days of the surgery. It was not evaluated after 90 days because two patients suffered from other nonassociated pathologies, and in patient 4, it was necessary to remove the SS because it was too small for him.

The weight reduction was not statistically significant ($P = .102$), but the average percentage was 8.87%.

During radiographic imaging, the shortening of SS occurred in two cases 12 hours postimplantation; the percentage reduced was 20% and 40% in each case, without clinical significance with KS and without statistical significance ($P = 1.000$), respectively (Figure 5). In any case, neither dislocation nor intraluminal tissue was evident. The endoscopic evaluation after surgery demonstrated the patency of the trachea in all cases.

4 | DISCUSSION

Airway malacia is a benign pathology that presents many difficulties for its management. Talking about pediatric tracheomalacia, the challenge is still greater due to the reduced diameter of the

TABLE 1 Patient's clinical record

	Patient 1	Patient 2	Patient 3	Patient 4
Breed	Pomeranian	Chihuahua	Yorkshire terrier	Pomeranian
Sex	Female	Female	Female	Male
Age, y	4.5	14	12	5
Weight, kg	5.2	3.35	3.5	7.5
Symptoms' evolution	Slow	Moderate	Slow	Moderate
Medical Tx, mo	24	6	none	36
Collapse grade	Grade V	Grade III	Grade IV	Grade V
Affected area	Entire trachea	Entire trachea	Entire trachea	Entire trachea
Bronchial affectation	Left and right	Left	Left and right	Left
Cardiac affectation	HRWCS	HRPH + M	HRWCS	HRWCS
Surgical procedure	Packing	Twining	Twining	Packing

Note: Symptoms' evolution: slow >5 y, moderate 5-2 y, and severe <1 y symptoms began. Medical Tx, time of medical management/corticosteroids' administration.
Abbreviations: HRPH, heart remodeling and pulmonary hypertension; HRWCS, heart remodeling without clinical significance; M, murmur; Tx, treatment.

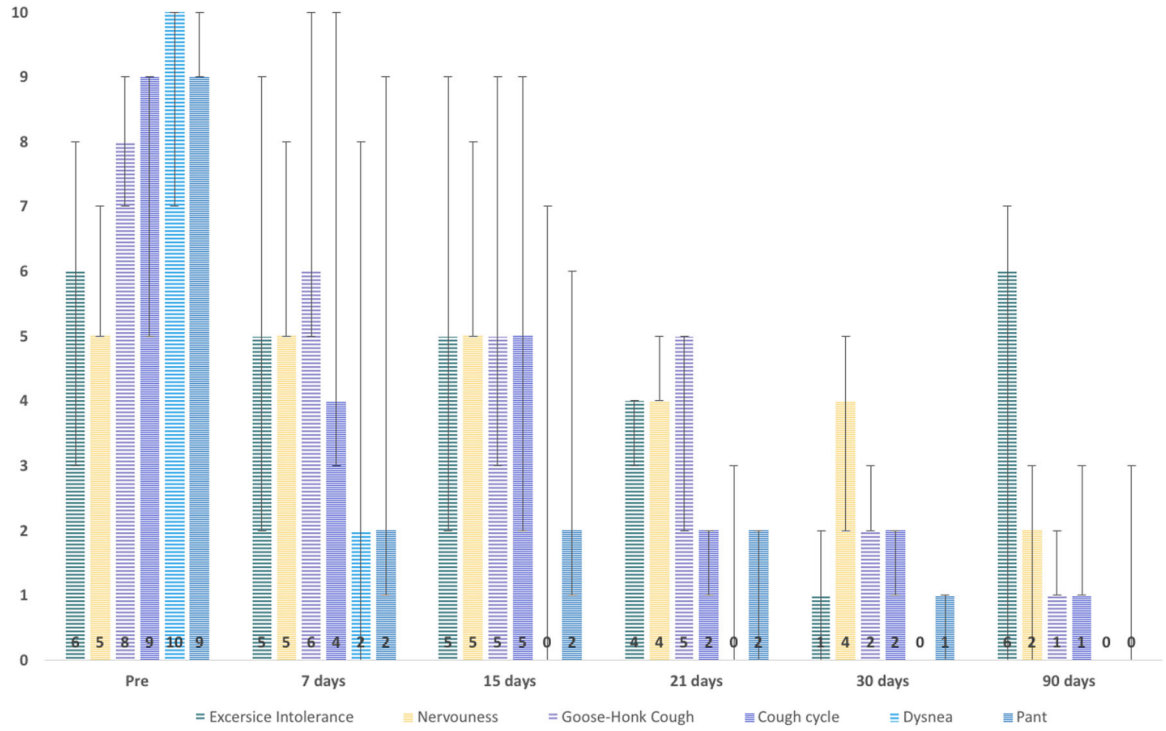

FIGURE 4 Clinical follow-up answered by the owner. Each parameter was graduated between 0 (minimum frequency) and 10 (maximum frequency), with median and statistical bar error (the maximum and minimum values) [Color figure can be viewed at wileyonlinelibrary.com]

respiratory tree and the rapid growth of the patient.[30] The study presented is a research on pathological dogs of three different small/toy breeds, with a reduced tracheal diameter. Canine tracheomalacia characteristics are pretty similar to pediatric patients, regarding the cartilage degeneration and the hyperlaxity in the pars muscularis. The main difference is the age of presentation, as in dogs, it is a degenerative progressive disease in middle-aged canines.[27,31,32]

In cases of pediatric congenital diffuse tracheomalacia, it is necessary to give support to the entire trachea; also, it is essential to adapt the support to the growing patient.[3] Numerous surgical alternatives have been described for severe tracheobronchial obstruction in children, with limitations in many cases.[3,8,9,11,13,18,19] Stenting aims to recover the airway architecture, giving support to the structure, and to maintain the permeability of the trachea.[30]

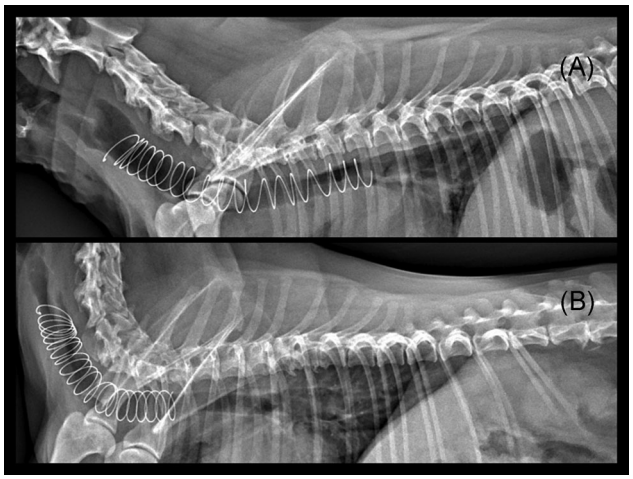

FIGURE 5 Patient 3, stent shortened. A, SS after implantation. B, SS shortened 90 days postimplantation. SS, spiral stent

In our clinical research experience with airway stents in animals, we have tested numerous stents such as steel stain, nitinol, drug-eluting, and biodegradable stents. Each stent has pros and cons, but complications are always present.[33,34] The "ideal airway stent" should allow a perfect mucous flow, reduce foreign body reaction, and give enough support to maintain permeability of trachea and main bronchus. In pediatric patients, the device must allow an atraumatic placement as well as the exchange.[35] For this reason, we have developed a new shape stent with the same characteristics of the classical devices, avoiding its complications.

Initially, the SS was developed to find a therapeutic alternative for canine patients, but we observed benefits that could be also interesting for children under this condition.

The feasibility and viability of the procedures performed have been demonstrated, with a minimum aggression of the tissue and rapid recovery of the animals. Analgesic medication was not necessary in any case and the recovery period was 12 hours of hospitalization. However, classic stents do not require any incision for their implantation, thus making them more suitable to use.[13]

The first experience reported with metallic stents in children was in 1995 by Filler et al, and several cases have been published since then. Palmaz balloon-expandable metallic stents seemed to be the most acceptable for children.[17,36] They can be easily placed with precision, not interfering with mucous clearance.[11,13] Conversely, the rapid

epithelization and the tissue reaction are a matter that concerns many authors, and it is the reason why they consider these stents as permanent prostheses.[7,10,13,37] Management with self-expandable metallic stents have also been used, but their large diameter is a limitation for newborns; also, authors reported that their placement is less accurate, resulting in constant tension on the tracheal wall.[10,38] In this study, the spiral design allowed us to introduce it with precision in a small airway without any complications, and it was possible to reposition the SS anytime, as observed in another study with the same stent shape.[34,35] The new surgical approach has the drawback of being an open surgery, but screwing or unscrewing the SS enables to change the position until the precise situation is achieved. Furthermore, as with classic stents, we observed an early epithelization, but without signs of hyperinflammation or mucous accumulation.

Polydioxanone biodegradable stent is the newest therapeutic management used in children. The relatively rapid degradation of the stent requires repeated stenting, which limits its use for chronic pathologies. Some reports published lower complications, compared with other stents,[8] whereas other reports demonstrated important complications such as stent fragmentation and large sharp pieces' migration to lowest airway.[20]

Silicon stents or hybrid stents are also used generally in older children.[16] Granuloma tissue formation is one of the main complications arising due to metallic stents,[3,7,11,13] which is also observed with silicone devices.[18] In our experience, we did not achieve this phenomenon during the study, even though metallic material was used. We hypothesized that the similitude between the trachea structure and the spiral design reduces the foreign body reaction, and the radial force is concentrated in determined short areas.

Dislocation and mucous obstruction are probably the other major complications mostly present using silicon and hybrid stents.[12,14] The impossibility of being re-epithelizated makes it easier to remove them anytime, but recurrent infections caused by mucous accumulation and dislocation must be taken into account.[11]

Migration is a complication totally avoided with the SS design, as it has a fixation point in the tracheal ring, and it has not been observed in any case. An important improvement achieved is the option to remove the SS once fully epithelized without tissue damage, owing to the helical shape. The removal was performed in one animal, locating the fixation point and then unscrewing the SS. The fixation to the tracheal wall has a double function: to avoid migration and to locate and remove the stent. Stent shortening is a frequent phenomenon present in dogs.[26]

Patient's clinical improvement and the absence of disease signs are the main aim of the treatment. Immediate clinical improvement is normally observed after stenting.[8,13,23,39,40] However, our patients presented a high variety of symptoms during the first 2 weeks, substantially improving in the fourth week without medical treatment.

Currently, KS gives a median punctuation of 85, a great result in aged patients with this chronic pathology and with an initial scale of 40-60.

The main limitations of this study are the small number of patients studied, the short-term follow-up, and the differences between species compared.

Due to the similitude between the characteristics of the disease in dogs and children, we believe that the study on pathological canines can be used to assess a possible application of the SS in pediatric patients. Furthermore, the pathological dogs can be benefited from this treatment. The results obtained are really encouraging for veterinary professionals; the new SS shape is giving enough support to degenerated tracheas without the associated complications. The largest clinical research experience with animals would provide significant conclusions to extrapolate it to pediatric patients with tracheomalacia for a future consideration.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

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