Use of Improved Nitinol SEMS(Self Expandable Metal Stent) for Tracheal Collapse in small breed dogs.

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[Introduction]

Collapsing trachea is a common disorder in middle-aged toy and small breed dogs. The airway becomes dorso-ventrally flattened beginning with laxity of the trachealis dorsalis muscle, followed by progressive cartilage collapse. (Figure 1).

Several treatments for tracheal collapse have been well documented elsewhere. Described surgical corrections include plication of the dorsal tracheal membrane, tracheal ring chondrotomy, and intra- and extraluminal stabilization with polypropylene rings. Generally, only extraluminal polypropylene stabilization gives a favorable outcome. Despite the known success of extraluminal stabilization, the method requires open surgery that may lead to additional complications, such as persistent coughing, iatrogenic laryngeal paralysis, and dyspnea. To date, however, its etiology and most effective management are still controversial.

Intra-luminal tracheal stenting originated with application of stents designed for use within the biliary, vascular, gastrointestinal, and respiratory systems in people. Advantages of intraluminal stents include short anesthetic time, immediate improvement in clinical signs related to tracheal collapse, and the ability to noninvasively place the stent within the cervical or thoracic regions. Available stents have differing characteristics for use as airway prostheses. Shape memory alloys, such as nitinol, an alloy of nickel and titanium, have thermal shape memory, super elasticity, and force hysteresis properties. These alloys are advantageous because they can accommodate substantial strain before reaching irreversible plastic deformation. Fauna Stent™ by M.I.Tech (Pyeongtaek, KOREA), a nitinol stent designed specifically for use in dogs and cats is a woven nitinol material, classified as a reconstrainable, foreshortening stent.

The advent of super-elastic self-expanding stents has provided another advance in airway stents. Stainless steel can resist deformation of 0.3%, whereas super-elastic materials such as nitinol can sustain alterations of up to 10% and still return to their original form. This characteristic is ideal for the dynamic conditions in the tracheobronchial tree. However, previous stents (old stents) have other problems with migration and fracture of stents.

The purpose of the retrospective study was to evaluate efficacy of this technique and to the long-term outcome associated with the use of improved intra-luminal stents (new stent) in small breed dogs and to identify common complications.

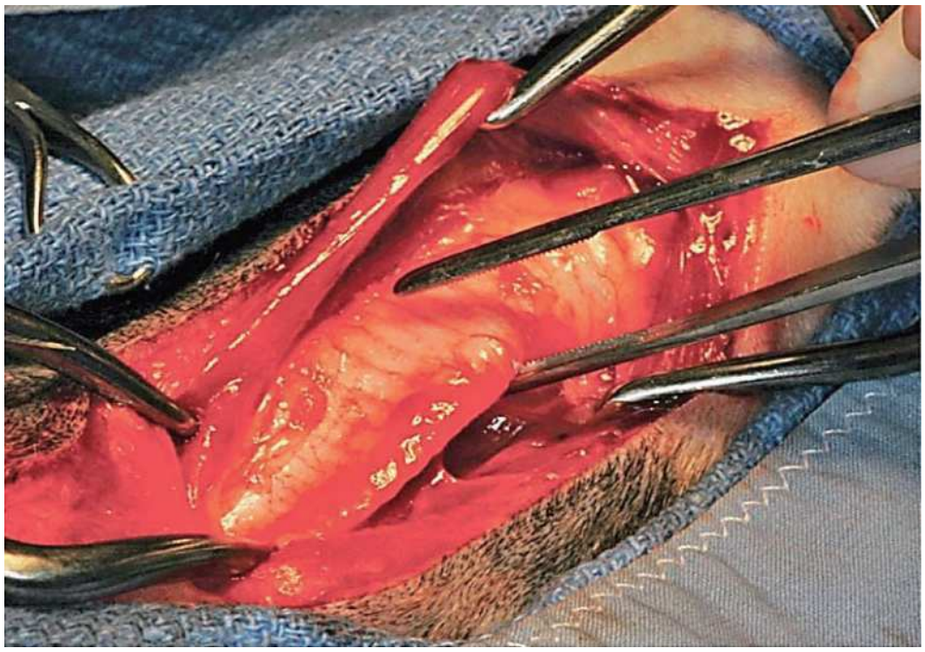

Figure 1. Grade III or IV cervical tracheal collapse in dog.

[Material and Methods]

Evaluate patients were classified into two groups by old and new stents (old group-12 dogs, new group-10 dogs). All dogs were selected for stent placement on the basis of the severity of clinical signs and failure of medical management. Endoscopic evaluation was used to grade the severity of collapse for the cervical and thoracic portions of the trachea and mainstem bronchi, as described elsewhere (Figure 2). All evaluations were performed by use of a bronchoscope with a 120º field of view and 575-mm working length. Location and length of the most severe collapse (> 50% luminal compromise) was measured with the bronchoscope. Radiography was then performed. The endotracheal tube was extracted until the cuff was at the level of the larynx. The cuff was inflated to maintain an airway pressure of 20 cm H2O. The lungs were inflated to a pressure of 20 cm H2O while a lateral thoracic radiograph that included the cervical portion of the trachea was obtained. This radiograph was used to calculate maximal tracheal diameter as well as confirm length of the collapsed portion (Figure 3). Radiographic magnification was corrected through use of an endotracheal tube of known diameter. The diameter of stent chosen was approximately 10% to 20% larger than the trachea at its largest diameter during maximal inflation. Length was calculated to include the area of collapse as well as a 1- to 2-cm margin of trachea cranial and caudal to the collapse. Appropriate stents were ordered for each dog and subsequently placed during a separate anesthetic episode. Stent placement was performed under fluoroscopic guidance. Anesthesia was induced and maintained by IV administration of propofol. Each dog was placed in left lateral recumbency and a 22-gauge needle was percutaneously inserted into the tissues overlying the fourth rib to approximate the level of the carina. During manufacture, the self-expanding stent was collapsed over a delivery catheter and held in place with a tightly wound cord. Real-time fluoroscopy was used to introduce and advance the stent delivery system to the level of the carina. Controlled deployment was achieved by traction on the cord. Paralytics were not used to suspend respiration of the dogs during stent deployment. Fluoroscopic and endoscopic evaluations of stent placement were performed prior to recovery from anesthesia. Post deployment radiographs were also obtained (Figure 4-A, B)

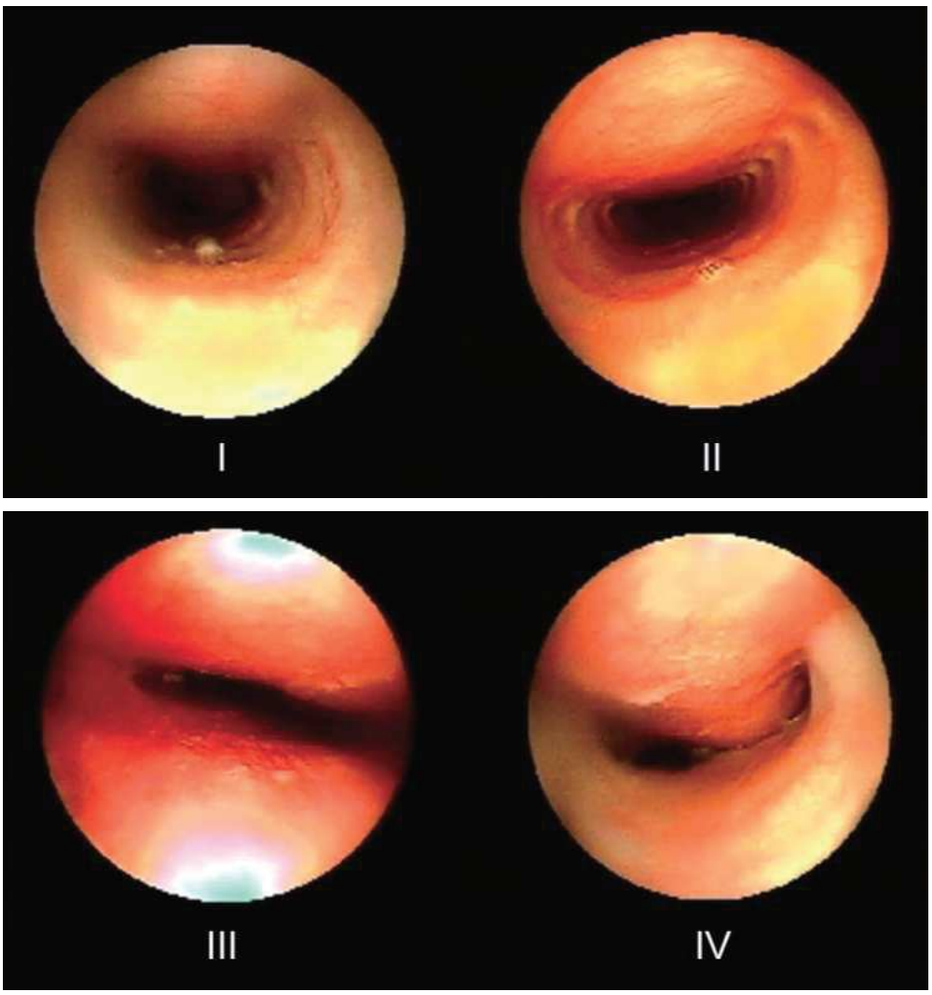

Figure 2. Bronchoscopic appearance of tracheal collapse in dogs

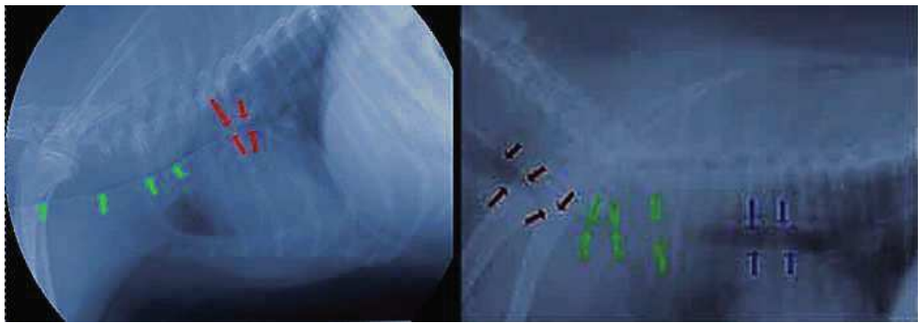

Figure 3. Lateral thoracic radiographic view revealing measurements used to determine appropriate size of a stent in a dog with tracheal collapse.

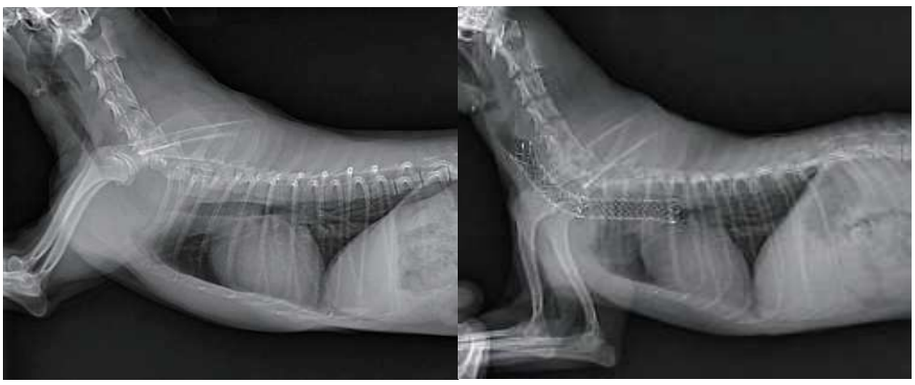

Figure 4-A. Stents application of tracheal collapse with previous stent (old stent).

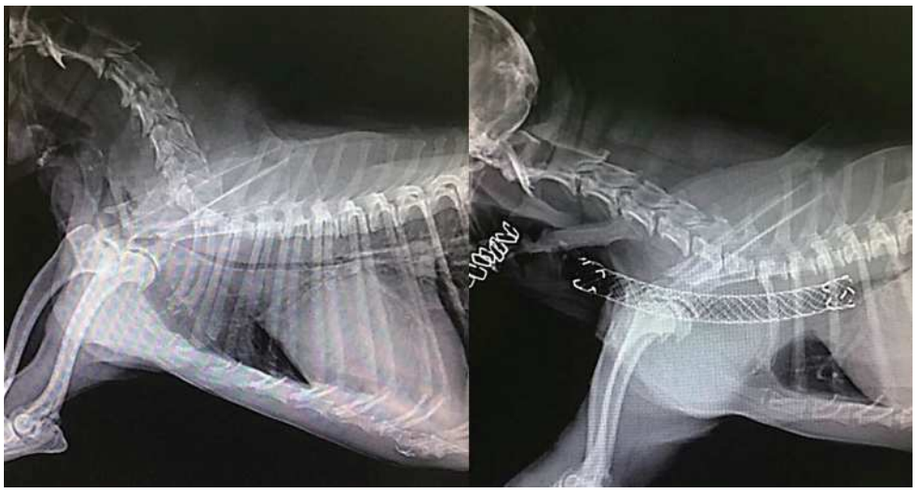

Figure 4-B. Stents application of tracheal collapse with improved stent (new stent).

[Results]

Stents used in the study were available in predetermined sizes; therefore, it was sometimes necessary to use > 1 stent to span the collapse. All stents were placed by 1 surgeon. Number, size, and location of stent placement and results of immediate post deployment endoscopy-fluoroscopy were determined.

No complications were recorded during the anesthetic recovery period after endoscopy used to obtain stent, measurements or the separate anesthetic episode for stent placement. Stent location within the trachea was considered ideal in 6 dogs of old stent group. In 1 dog, an error in placement was attributed to a manufacturing defect because the caudal aspect of the stent did not expand. This non-expanded end fractured within 1 month after placement. Malpositioning in 5 dogs of old stent group (including extension into the mainstem bronchi), gaps between stents, and inadequate spanning of collapsed regions were attributed to surgeon error. Overt stent migration was detected in 1 dog of old stent group at 1 month after placement of 2 stents of differing diameters (Figure 5). Medical history and clinical signs at the time of reevaluation included acute onset of intractable cough and hemoptysis. Migration of the caudal stent within the lumen of the cranial stent was evident during examination of thoracic radiographs. During endoscopic evaluation, the cranial stent was securely embedded into the mucosa and the caudal stent was located within its lumen. The caudal stent was freely movable and was removed with grasping forceps. This stent was not replaced because the collapse in the previously stented area was only classified as grade II at the time of stent removal.

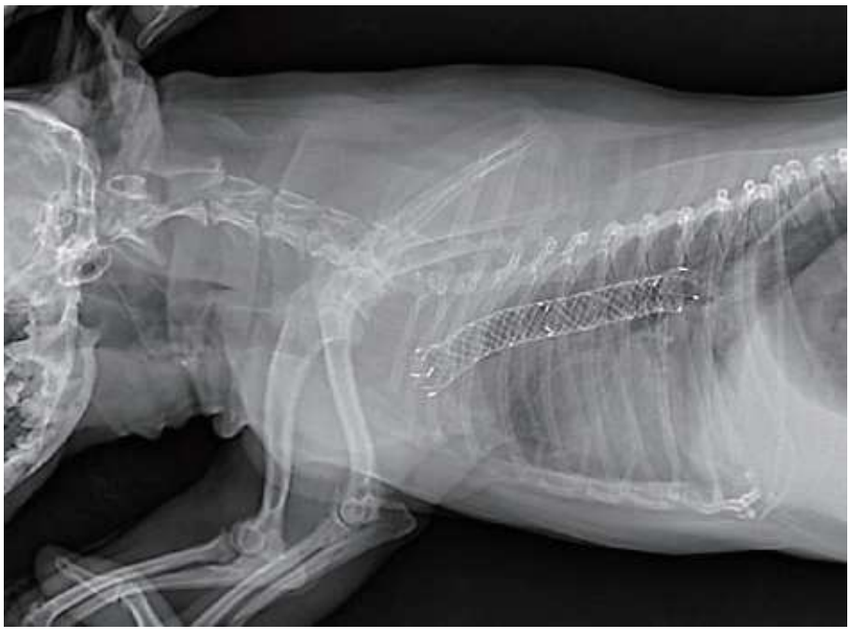

Figure 5. complication, migration of stents with old stents.

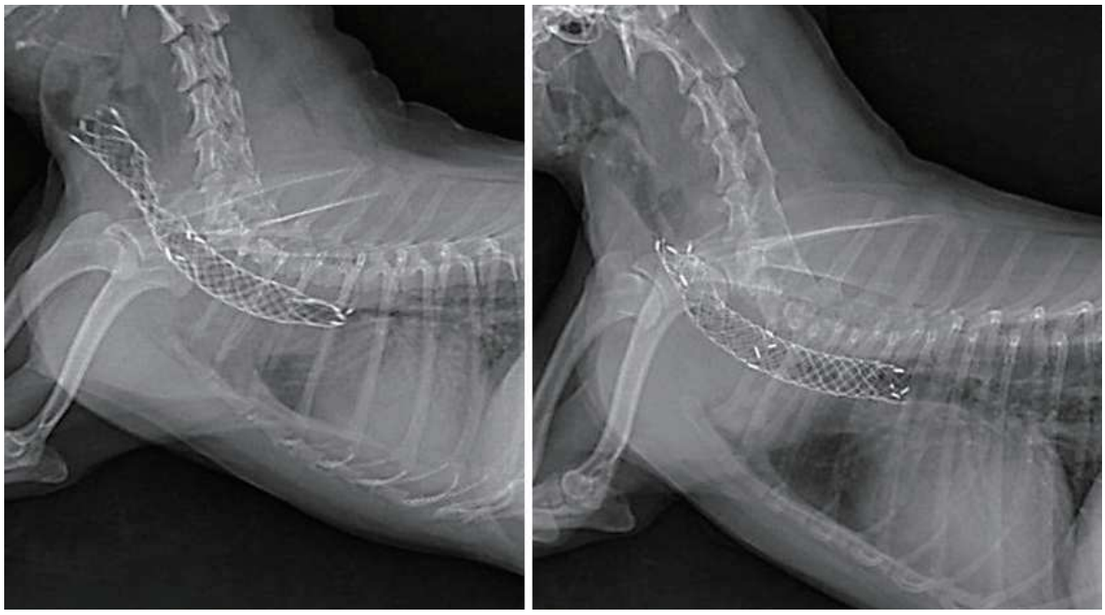

Figure 6. complication, Fracture of stents with old stents.

Material failure (stent fracture) was the second most commonly recorded complication(Figure 6). The majority of stent fractures were cranial to or at the level of the thoracic inlet. Stent fracture was detected in 4 dogs of old stent group at the time of their first reevaluation appointment (ranging from 1 month to 3 months after stent placement). The fifth dog had an intact stent (as determined by endoscopy at 1 month after stent placement), but that stent fractured by 6 months after surgery. This dog had infrequent coughing at the time of reevaluation that had worsened during the month prior to evaluation and was receiving a codeine-based cough suppressant.

Excessive granulation tissue surrounding the stent was a severe complication that resulted in differing degrees of airway obstruction in 2 dogs of old stent group. Both dogs responded well to treatment by administration of an anti-inflammatory dose of corticosteroids (tapered during a 6-week period) and treatment for associated bacterial tracheitis.

However, still now (after 6month of application), new stent group have not any complication specially migration and fracture of stents.

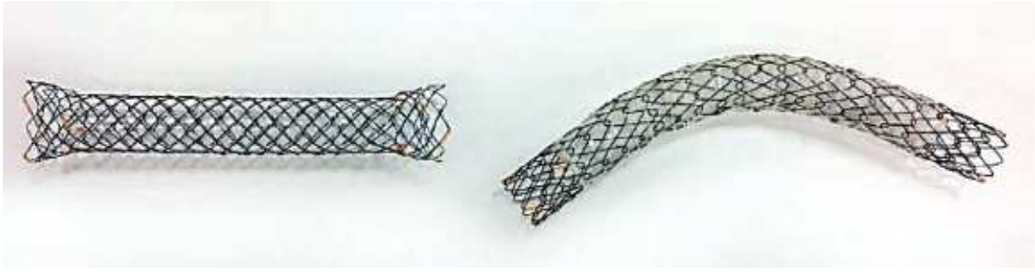

Figure 7. c— Comparison of stent for tracheal collapse. (Left: old stent, Right: new stent)

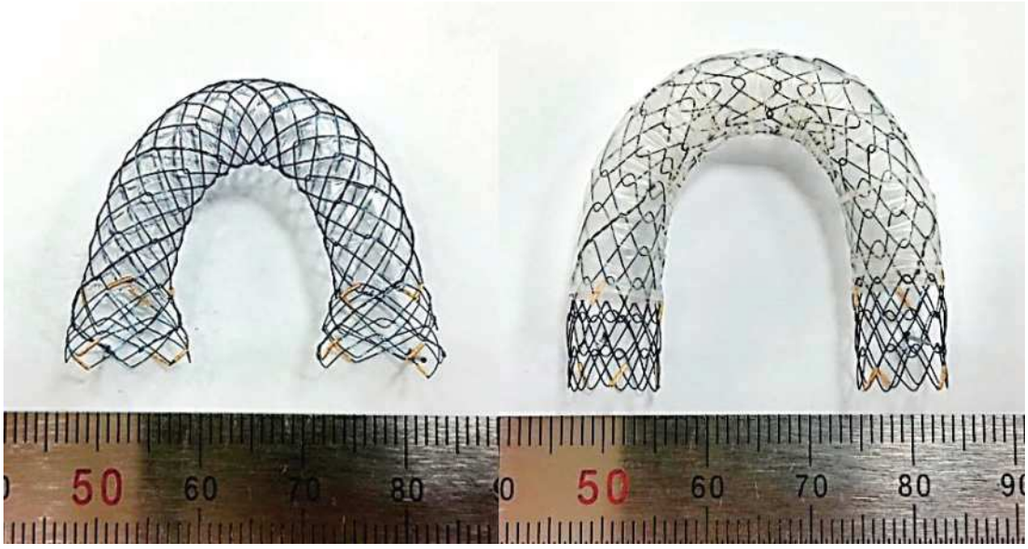

Figure 8. Comparison of stent for tracheal collapse.
(Left: old stent – subject stent, Right: new stent – predicate stent)

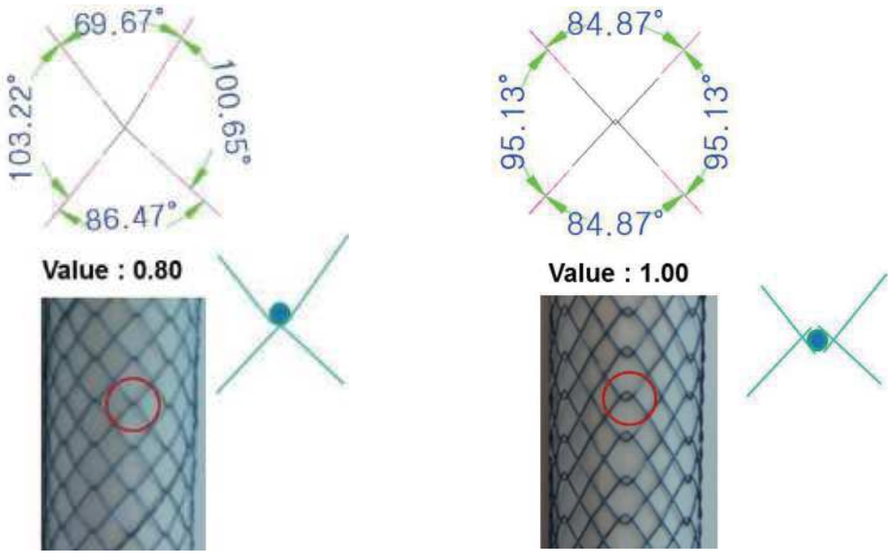

Figure 9. Comparison of stent for tracheal collapse.
(Left: old stent - asymmetric structure, Right: new stent - symmetric structure)

[Discussion]

We are unaware of long-term follow-up data in dogs after use of new Fauna Stent™ by M.I.Tech (Figure 7,8,9). Thus, our purpose was to describe an endoscopically assisted technique of intraluminal stent placement and report outcome after use of new Fauna Stent™ by M.I.Tech for relief of end-stage clinical signs associated with tracheal collapse. We also compared stent dimensions at follow up to determine the amount of foreshortening that can be expected and whether foreshortening had any clinical consequence. Our hypothesis was that the new Fauna Stent™ by M.I.Tech would result in improved clinical status with minimal complications

Complications are frequent and expected in patients with indwelling tracheal stents. A foreign body such as a stent within the windpipe predisposes patients to chronic and recurrent airway infections. Patients often require long-term antibiotic administration and repeated airway cultures. Chronic coughing in patients with an indwelling tracheal stent predisposes to fracture of the stent. If the fracture is severe enough, placement of a second stent within the first one may be attempted. Granuloma formation may also occur. This is a benign growth of inflammatory tissue within the airway. Intralesional injections of corticosteroids may help some of these cases.

We suspect that progressive bronchial collapse, differences in stent design, and irritation secondary to the presence of the stent were the primary reason for differences in our study when compared to the previously cited study.

Complications included stent fracture, aspiration pneumonia, rectal prolapse, and perineal hernia. Other reported complications include stent migration, stent collapse, breakage and deformation of the stent, excessive granulation tissue, coughing, pneumomediastinum, pneumonia, and death.

At this time there is no known prevention for tracheal collapse, although reducing weight or exposure to airway irritants such as smoke may help. About 70% of dogs that are treated with medical management alone will show some improvement. About 20% of dogs that undergo tracheal ring placement will require a tracheostomy- a temporary or permanent breathing hole in the neck. About 75% of dogs improve after surgical place

ment of rings. Dogs that are older than 6 years of age or that have laryngeal or bronchial disease have more complications and a poorer long-term outcome. Of dogs that receive stents, 95% are immediately improved and 90% are markedly improved at the time of recheck. Control of coughing is important for a good outcome, and dogs with bronchial collapse (and therefore continued coughing) are much more likely to have problems after stent or ring placement. Tracheoscopic placement of new Fauna Stent™ by M.I.Tech (Pyeongtaek, KOREA), as a therapy for tracheal collapse is associated with an overall fair to good outcome. Mortality and morbidity as a result of stent fracture and migration are infrequent with this type of improved nitinol stent, which appears to be effective in improving clinical signs of tracheal collapse. The significance of the increased shortening is unknown as no clinical signs could be attributed to shortening in this study. Further studies investigating the association of shortening with continued clinical signs and complications are warranted.

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