First Clinical Experience with the TransPyloric Shuttle® (TPS®) Device, a Non-Surgical Endoscopic Treatment for Obesity: Results from a 3-Month and 6-Month Study

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Objective: The TransPyloric Shuttle® (TPS®) is a non-surgical device that is delivered endoscopically to the stomach and is intended to enable significant weight loss for obese patients.

Description: The TransPyloric Shuttle has a functional shape consisting of a large spherical bulb connected to a smaller cylindrical bulb by a flexible tether and is composed primarily of medical grade silicone. In its functional, constructed state, the larger bulb assumes a shape of sufficient diameter to prevent migration from the stomach. The smaller bulb passes freely into the duodenum during normal peristalsis, allowing the device to self-orient and assume transpyloric positioning. Once transpyloric, the compliant base of the larger bulb engages the pylorus directly to create an intermittent seal intended to reduce the rate of gastric outflow, enabling an overall reduction in caloric intake and weight loss.

Method: TPS delivery and removal procedures are performed in outpatient endoscopic settings using a standard gastric overtube for access and esophageal protection. The device is preloaded in a delivery catheter as a low-profile, single-helical coil elongated to 65 cm for transoral delivery. During deployment, the delivery catheter is inserted through a pre-placed overtube, and the helical coil is dispensed into the stomach where the coil assumes its functional shape. Delivery is complete when the delivery system locks and releases the formed TPS. The device then resides in the stomach for the desired treatment period. During removal, an endoscope is inserted into the stomach through an overtube and standard endoscopic instruments are used to unlock, capture and remove the deconstructed TPS through the overtube.

A prospective, open-label, non-randomized, single-center study was approved and conducted to evaluate the safety and efficacy of the procedure and device. Twenty subjects with a mean body mass index (BMI) of 36.0 kg/m2 ± 5.4 kg/m2 were enrolled. Subjects were serially assigned to three-month and six-month treatment cohorts. Throughout the study, surveillance endoscopies were performed to evaluate the device and gastric tissues. Primary outcomes measured included percentage of excess weight loss (EWL) using the BMI method, total weight loss (WL), and adverse events.

Results: All devices were deployed and retrieved in 20 patients without complication. Mean procedure times for delivery and retrieval were 10.3 minutes ± 3.9 minutes and 12.9 minutes ± 6.4 minutes, respectively. Patients demonstrated minimal transient intolerance to the TPS and were able to quickly return to normal daily activity. Three-month patients demonstrated a mean EWL of 31.3% ± 15.7% and a mean WL of 8.9 kg ± 5.2 kg. Six-month patients achieved a mean EWL of 50.0% ± 26.4% and a mean WL of 14.6 kg ± 5.7 kg. Observations of persistent gastric ulceration in two patients resulted in the decision to remove both devices approximately one to two weeks prior to their scheduled removal dates. Both patients recovered fully with no residual adverse effects.

Conclusions: The TPS provides a safe and reliable non-surgical method for weight loss with exceptional patient tolerance compared to surgical weight loss interventions.

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