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Help for Patients with Barrett's Esophagus July 2006

A study in the January issue of Surgical Endoscopy tested the **HALO360 System** to determine the optimal energy density and treatment parameters to achieve the complete removal of human esophageal epithelium. The study was designed as a pilot trial leading up to the use of this bipolar radiofrequency balloon device in patients with Barrett's esophagus, a premalignant disease of the esophageal epithelium.

Thirteen male patients aged 49 to 85, all diagnosed with esophageal adenocarcinoma, were enrolled in this study. The study patients underwent randomization into three groups, with each group receiving slightly different energy doses when treated with the HALO360 System. Endoscopy was performed, followed by positioning of the HALO360 ablation catheter within the esophagus. The ablation catheter was inflated and a short burst of heat energy was delivered to the thin epithelial lining of the esophagus. This was followed by a total esophagectomy (removal of the esophagus) as indicated by the cancer diagnosis. Pathological evaluation was performed on the ablated segments to determine the ablation depth and completeness of epithelial removal.

The study results confirm that the HALO360 System is capable of removing the esophageal epithelium without causing untoward injury to the delicate underlying structures. These data have been used to identify the appropriate treatment parameters for the use of the HALO360 System in subsequent clinical trials for patients with the diagnosis of Barrett's esophagus who haven't yet progressed to esophageal cancer.