



Now a part
of Stryker

Entellus Medical Announces Publication of The 1-Year Results of a Randomized Controlled Trial Comparing Balloon Dilation with Medical Therapy For Treatment of Persistent Eustachian Tube Dysfunction

PLYMOUTH, MN. (June 19, 2018) -- Otolaryngology and Neurotology today published results from a study that compares balloon dilation with ongoing medical therapy for the treatment of persistent Eustachian tube dysfunction (ETD). Over 7.3 million people have symptoms of Eustachian tube dysfunction, including ear pain and pressure, ear fullness, muffled hearing, and pain or discomfort with barometric changes. Balloon dilation has recently emerged as a treatment option for ETD that has the potential to provide more durable relief than traditional alternatives.

The results of "Randomized Controlled Trial of Balloon Dilation as a Treatment for Persistent Eustachian Tube Dysfunction with 1-Year Follow-Up" demonstrate that balloon dilation with XprESS ENT Dilation System is superior to ongoing medical management, and is safe and effective for the treatment of persistent ETD. Statistically significant improvements in ETD symptoms and middle ear functional assessments were demonstrated at 1-year follow-up.

According to lead author Dr. Ted Meyer, from the Medical University of South Carolina, "Traditional treatments for patients with Eustachian tube dysfunction do not address the underlying disease pathology and are considered temporary options. The results of this study offer new hope to appropriate patients that balloon dilation can provide durable symptom relief of their Eustachian tube dysfunction."

"The results of this randomized controlled trial are an important affirmation of balloon dilation as an effective treatment option for Eustachian tube dysfunction," said Robert White, CEO of Entellus Medical, Inc. "This study demonstrates our ongoing commitment to deliver technologies backed by clinical evidence to serve the needs of our ENT physician partners and their patients."

Patients included in the study had to be 18 years and older, diagnosed with ETD for 12 months or more, have three or more ETD symptoms, and have failed medical therapy. Patients were required to have moderate severe symptoms, as indicated by an overall Eustachian Tube Dysfunction Questionnaire (ETDQ-7). Sixty qualified patients were randomized 1:1 to either balloon dilation with the XprESS ENT Dilation System or ongoing medical therapy (control). Follow-up was conducted and outcomes compared at 6 weeks for all randomized patients. Control patients who had continuing symptoms at 6 weeks were offered treatment with balloon dilation. Long-term follow-up was conducted at 3, 6 and 12 months for all patients who underwent balloon dilation. A majority of study procedures (72%) were performed under local anesthesia in the office point-of-care.

Participants in the balloon dilation arm reported a mean reduction (improvement) of 2.9 in overall ETDQ-7 score, versus 0.6 for those in the control arm of the study – a significant difference demonstrating balloon dilation's superiority in reducing symptoms ($p < 0.0001$). Significant symptom improvement was maintained through 3-, 6-, and 12-month follow-up ($p < 0.0001$). The participants with abnormal middle ear functional assessments at baseline experienced significant improvements in these

assessments at 12 months. Normalization of the tympanic membrane position was experienced by 79.2% (19/24; $p < 0.001$), positive Valsalva maneuver by 62.5% (20/32; $p < 0.0001$), and improvement in tympanogram type by 55.0% (11/20; $p = 0.006$). No complications were reported, demonstrating the safety of balloon dilation with XprESS for treatment of ETD.

About XprESS ENT Dilation System

XprESS ENT Dilation System is a versatile balloon dilation system that can be used by ENT physicians to treat the frontal, maxillary, and sphenoid sinuses in adult and pediatric patients with chronic or recurrent sinusitis, and Eustachian tubes in adult patients suffering from Eustachian tube dysfunction.

XprESS is based on a traditional sinus seeker, providing a familiar experience to physicians, with an atraumatic ball tip and malleable shaft that can be shaped to appropriate angles to gently access the sinus or Eustachian tube targeted for treatment through the nasal cavity. Upon placement, the physician gently advances and inflates the balloon, and, after an appropriate treatment duration, the balloon is deflated and the device removed. XprESS can be used in a traditional OR setting or in a physician's office.

More information about XprESS can be found at sinussurgeryoptions.com.

About Eustachian tube dysfunction (ETD)

Over 7.3 million people have symptoms of Eustachian tube dysfunction in the United States. Patients with ETD may experience a range of symptoms, including ear pain and pressure, ear fullness, muffled hearing, and pain or discomfort with barometric changes. Traditional approaches to treatment consist of medical therapy, including oral or topically applied nasal steroids, and pressure equalization (PE) tubes. Both treatment options are considered temporary solutions that do not address the underlying pathology.

About Entellus Medical, Now a Part of Stryker

Entellus is a medical technology company focused on delivering superior patient and physician experiences through products designed for less invasive treatment. Entellus products are used for the treatment of adult and pediatric patients with chronic and recurrent sinusitis, patients with nasal airway obstruction, as well as adult patients with persistent Eustachian tube dysfunction, and combine to enable ENT physicians to conveniently and comfortably perform a broad range of procedures in the most cost effective and efficient site of care. Entellus was acquired by Stryker in February of 2018.

About Stryker

Stryker is one of the world's leading medical technology companies and, together with its customers, is driven to make healthcare better. The company offers innovative products and services in Orthopaedics, Medical and Surgical, and Neurotechnology and Spine that help improve patient and hospital outcomes.