

Clinical Evaluation to Confirm SAfety and Efficacy of Sinusotomy in the PaRanasal Sinuses (CLEAR)

A summary of 2-year data published in *Otolaryngology - Head and Neck Surgery*
September 2008, Vol. 139

Overview

This study is an international, multi-center, prospective evaluation designed to confirm the long-term safety of balloon catheters as well as objective and subjective efficacy of balloon catheter sinusotomy.

Methodology

The CLEAR study enrolled patients that failed medical therapy and for whom endoscopic sinus surgery was recommended.

At two years, 65 patients were available for follow-up and were asked to have a CT scan, complete a validated quality-of-life questionnaire, and to complete a structured patient satisfaction questionnaire.

Summary of Results

Multi-Year Safety:

- 0% serious adverse event rate out to 2 years

Multi-Year Efficacy and Patient Outcomes:

- 2 year follow-up revision rate of 3.6% of sinuses and 9.2% of patients is comparable to previously published revision data
- Statistically significant improvement in CT scores out to 2 years (decrease in average Lund-MacKay scores from 9.66 to 2.69), with no change between 1 and 2 year scores
- Clinically and statistically significant improvement in patient symptoms out to 2 years, with no change between 1 and 2 year outcomes

Multi-Year Patient Satisfaction:

- Patient satisfaction remains high at 2 year follow-up
 - > 85% of patients report sinus symptoms have improved, 0% report sinus symptoms have worsened

The results of this study confirm other published peer-reviewed studies showing that use of *Relieva Balloon Sinuplasty*[™] instruments in sinus surgery is safe and effective and improves patients' quality of life. Patient satisfaction with this minimally invasive technology is consistently positive across the two years after surgery.