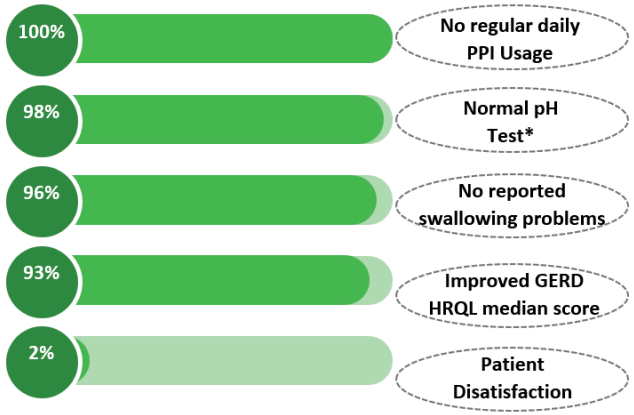
RefluxStop™ clinical trial

The RefluxStop™ CE-mark trial

The RefluxStop™ CE-mark trial is a prospective, open label, multicentre, single arm trial to evaluate the safety and effectiveness of RefluxStop™ for the treatment of GERD. Chronic GERD patients were operated using a standardized surgical technique between December 2016 and September 2017. They were followed up after one, two and three years so far and the CE-mark was granted after six months. The primary safety outcome was prevalence of serious adverse events related to the device, and the primary effectiveness outcome was reduction of GERD symptoms based on the GERD-HRQL score. Secondary outcomes were prevalence of adverse events other than serious adverse events, reduction of total acid exposure time in 24-h pH monitoring and reduction in average daily PPI usage and patient satisfaction.

Three-year follow-up data from the trial cohort were available showing exceptional results with consistent efficacy and safety profile. None of the 47 participating patients were in need of regular daily PPIs, which were taken by all before surgery and there were no serious adverse events reported since the trial's 1-year data was published. Consistency of these results are truly remarkable and stand in stark contrast to other forms of treatment.

RefluxStop Patient Outcomes at 3-Years: Potential to Transform Current Treatment Pathways and Become a New Standard of Care



* After 6 month test only potential failures such as Questionnaire failures or PPI users performed another pH test and only one patient (2%) had a pathologic pH test.

LNF, Laparoscopic Nissen Fundoplication, is the original fundoplication procedure developed by Dr. Nissen in 1956 and considered the current Gold Standard surgical treatment alternative for GERD. In LNF, the top part of the stomach (fundus) is wrapped around the LES with the intention to reinforce and to support and compress a weak LES.

LNF is used as a comparison for safety and performance of the RefluxStop. The literature review by Karolinska Institute identified and summarized safety events and performance outcomes reported in relation to the LNF. This literature review and meta-analysis comprising 983 articles and all 59 randomised articles was used for this meta-analysis, which makes it a strong and valid platform for a comparison with the standard-of-care surgical treatment for acid reflux. See Figure 1 and Table 1 provided below.

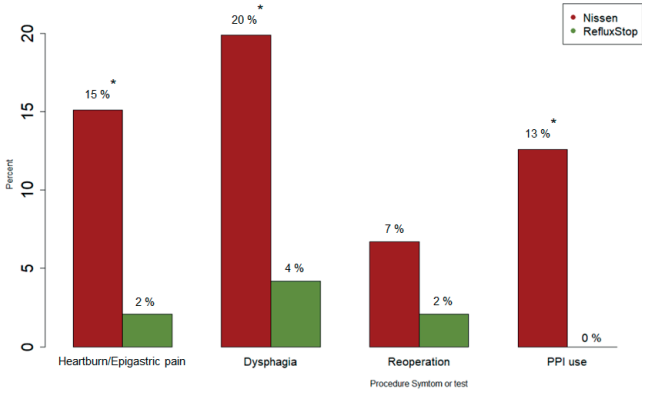


Figure 1. Comparison of safety and performance parameters following RefluxStop and LNF

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RefluxStop™ treating GERD

Comparing the RefluxStop™ CE-mark trial results to the main device competitor's FDA clinical trial results

When controlling the objective standard of care measurement, pH in the lower esophagus over a 24-hour period, RefluxStop™ presents normal pH values in 96 percent of patients while LINX, the main device competitor, presents normal pH values in 58 percent of patients.

This means the main device competitor in its FDA trial have tenfold as many failures 42% compared to 4% in the RefluxStop™ CE trial.

What is GERD?

GERD happens when the stomach acid regurgitates back up into the esophagus. This acid reflux irritates and damages the tissue in the esophagus and leads to heartburn, trouble swallowing and general chest pain. Unfortunately, acid reflux is also associated with cancer due to acid repeatedly damaging esophageal tissue. The incidence of esophageal cancer, or esophageal adenocarcinoma, has significantly increased in the last 40 years and is growing rapidly in the western world with approximately 48,000 deaths annually in the EU and US alone. The major risk factors are GERD causing Barrett's esophagus, which is a pre-cancerous condition.

GERD is among the top two most widespread chronic diseases in the world, impacting 17% of the EU and 19% of the US population with over six percent of the population – over 400 million people – having daily symptoms. The high prevalence of GERD presents a significant financial burden for the world's healthcare system and employers.

The American College of Gastroenterology reported that GERD symptoms cost the US nearly USD 2 billion per week in lost productivity. In the US alone, GERD accounts for direct and indirect costs of approximately USD 15-20 billion.

Current treatment of GERD

The most common way to treat GERD is through pharmacological treatment. Proton pump inhibitors, or PPI drugs, are considered to be the most efficient non-surgical treatment for GERD, even though they only treat the symptoms and not the cause – reflux with lower acidity is still present. Also, 59 percent of the drug users experience heartburn now and then and almost 40 percent of GERD patients continue to experience 24-hour pH measurable reflux episodes despite daily PPI use. (Becker V et al. 20007). This is probably the reason why it has not been possible to show that the cancer risk with Barrett's esophagus is reduced by drug therapy.

Also, in recent years several observational studies pointed out association between chronic PPI use and development of different serious adverse conditions, such as; chronic kidney disease, acute kidney disease, osteoporosis, stomach cancer, small bowel injury, intestinal infections etc. It has been estimated that prescribed medications for GERD, PPI drugs, account for over 50 percent of prescriptions for all digestive diseases, resulting in around USD 10 billion in annual direct healthcare costs, excluding indirect costs such as those resulting from reduced work productivity.

Surgical treatment of GERD has been around since the 1950s and one relatively new treatment is the Magnetic Sphincter Augmentation, which is a band that compresses the muscles at the end of the esophagus to support the closing. These surgical methods, however, have one major drawback – they all compress the food passageway – thereby causing swallowing problems and the inability to burp and vomit. Recent clinical opinion has questioned this technology for its complication and adverse events that are often a concern in relation to the benefits it provides.[1]

[1] Bortolotti M. Magnetic challenge against gastroesophageal reflux . World J Gastroenterol 2021; 27(48: 8227-8241
[PMID: 35068867 DOI: 10.3748/wjg.v27.i48.8227]