

A Novel Duodenal-Release Formulation of Caraway Oil and L-Menthol is a Safe, Effective and Well Tolerated Therapy for Functional Dyspepsia

Brian E. Lacy, MD, PhD; William D. Chey, MD; Michael Epstein, MD; Syed Shah, PhD; Patrick Corsino, PhD; Linda R. Zeitzoff, MSN, CRNP; Brooks D. Cash, MD

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FULL ARTICLE: <https://pubmed.ncbi.nlm.nih.gov/35255832/>

Background:

Functional dyspepsia (FD) is a disorder of gut-brain interaction (DGBI) that affects the upper portion of the gastrointestinal tract. While the prevalence of FD varies among countries and regions, it is estimated that the disorder affects up to 16% of otherwise healthy individuals in the general population. While no medication is approved for the treatment of FD, physicians prescribe a variety of treatments in off-label fashion to patients with FD to improve their symptoms. This approach has met with varying degrees of success. As an alternative to using off-label prescription drugs, non-prescription therapies, including herbal-based treatments, have been used by patients and health care providers to address the multiple symptoms of FD. The combination of peppermint oil and caraway oil has been studied in a number of clinical trials and has consistently been shown to be effective at treating FD symptoms.

A randomized, placebo-controlled clinical trial (FDREST) of a novel formulation of caraway oil and L-menthol (COLM-SST) demonstrated symptom relief in patients with functional dyspepsia (FD).

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6493684/>. Two follow-up studies were conducted to evaluate patient satisfaction, self-regulated dosing, and long-term safety data: FDACT, Functional Dyspepsia Adherence and Compliance Trial, and FDSU36, Functional Dyspepsia Safety Update at 36 months.

FDACT: Functional Dyspepsia Adherence and Compliance Trial is an open label patient reported outcomes survey of 600 COLM-SST® users reporting on frequency of use, symptom improvement and patient satisfaction. Participants were recruited either through distribution of samples from their HCP office or purchase of COLM-SST at the pharmacy. Participants answered survey questions online and upon completion and received a \$3.00 off coupon for a future purchase upon completion of the survey.

Key findings:

Symptoms and Usage Data:

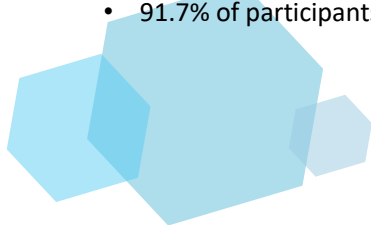
- 75.5% of participants reported suffering from symptoms daily
- More than 56% of users took COLM-SST before a meal; 27.5% took it after the meal
- Participants reported taking 1-2 capsules per day (47.5%) or 3-4 capsules per day (43.7%)

After COLM-SST Use:

- 95% of participants indicated a major or moderate improvement in the FD symptoms
- 92% of participants indicated a major or moderate improvement in their upper abdominal pain
- 86.5% of participants indicated a major or moderate improvement in their symptom of epigastric fullness
- 86.4% of participants reported feeling achievement of relief from indigestion between 1-2 hrs

Quality of Life and Satisfaction:

- 97.7% of participants indicated – likely or very likely to continue use for their FD symptoms
- 95.3% of participants indicated – likely or very likely to recommend to family or friends
- 91.7% of participants indicated – major or moderate improvement in their quality of life



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FDSU36: Functional Dyspepsia Safety Update at 36 months is a voluntarily reported safety surveillance program of COLM-SST users who accessed the call center to report adverse events.

Key findings:

- An estimated 1 million individuals used COLM-SST over the 3-year monitoring period
- A total of 205 adverse events were reported; 74 were considered unrelated to COLM-SST
- No serious adverse events were reported
- The 3 most common AEs reported were dyspepsia, diarrhea and nausea

Conclusion: COLM-SST is effective at addressing multiple symptoms of FD and is also safe and well- tolerated. COLM-SST provides a viable option for individuals with FD.

For more information regarding COLM-SST or questions regarding the studies: Contact us | Nestlé Medical Hub | Nestlé Health Science Portal for Healthcare Professionals (www.nestlemedicalhub.com).

COLM-SST is marketed as FDgard®. FDgard® capsules are a dietary supplement intended to help meal-triggered indigestion. Support of these symptoms are addressed in several studies. This information is intended for use by licensed health care practitioners only and is not intended as medical advice.

