

# + Evidence in focus

A collection of evidence

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**Smith+Nephew**

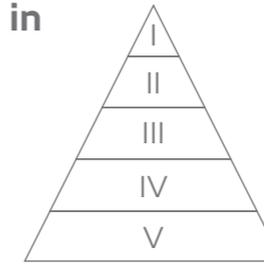
ENTACT<sup>®</sup>  
Septal Stapler



# ENTACT<sup>®</sup> Septal Stapler clinical collection: Contents

Please select a study of interest to see further information about the design and key results.

## Levels of evidence in clinical studies



Randomised controlled trials/systematic reviews

Prospective studies

Retrospective studies

Case series

Expert opinion

## Clinical studies

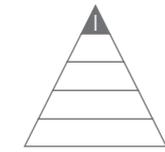
Sowerby, 2013: ENTACT Septal Stapler significantly reduced operating time compared to quilting sutures for septal flap closure

Tami, 2009: ENTACT Septal Stapler safe and effective for septal flap closure following septoplasty

Yıldırım, 2013: ENTACT Septal Stapler demonstrated comparable outcomes to nasal packing and trans-septal suturing

Sainio, 2019: Significantly fewer follow-up visits after septoplasty with the ENTACT Septal Stapler compared with other techniques

# ENTACT<sup>◇</sup> Septal Stapler significantly reduced operating time compared to quilting sutures for septal flap closure



Sowerby LJ, et al. *Int Forum Allergy Rhinol* (2013)<sup>1</sup>

## Overview

- Prospective, single-blind randomised controlled trial comparing operating time and postoperative outcomes in patients undergoing septal flap closure with ENTACT Septal Stapler (n=8) or quilting sutures (n=8) following septoplasty
- Primary outcome was operating time; secondary outcomes included NOSE scores and complication rates 3 weeks postoperatively

## Results

- Significant reduction in mean time to closure with ENTACT Septal Stapler compared to suture closure (35 vs 420 sec, respectively;  $p < 0.0001$ ; Figure)
- Significant reduction in mean total operating time with ENTACT Septal Stapler compared to suture closure (28 vs 43 min, respectively;  $p = 0.014$ ; Figure)
- No differences between groups in postoperative complications, mucosal healing or improvements in NOSE scores

## Conclusions

ENTACT Septal Stapler offers significant time savings compared to suture closure, with comparable outcomes and no difference in postoperative complications.

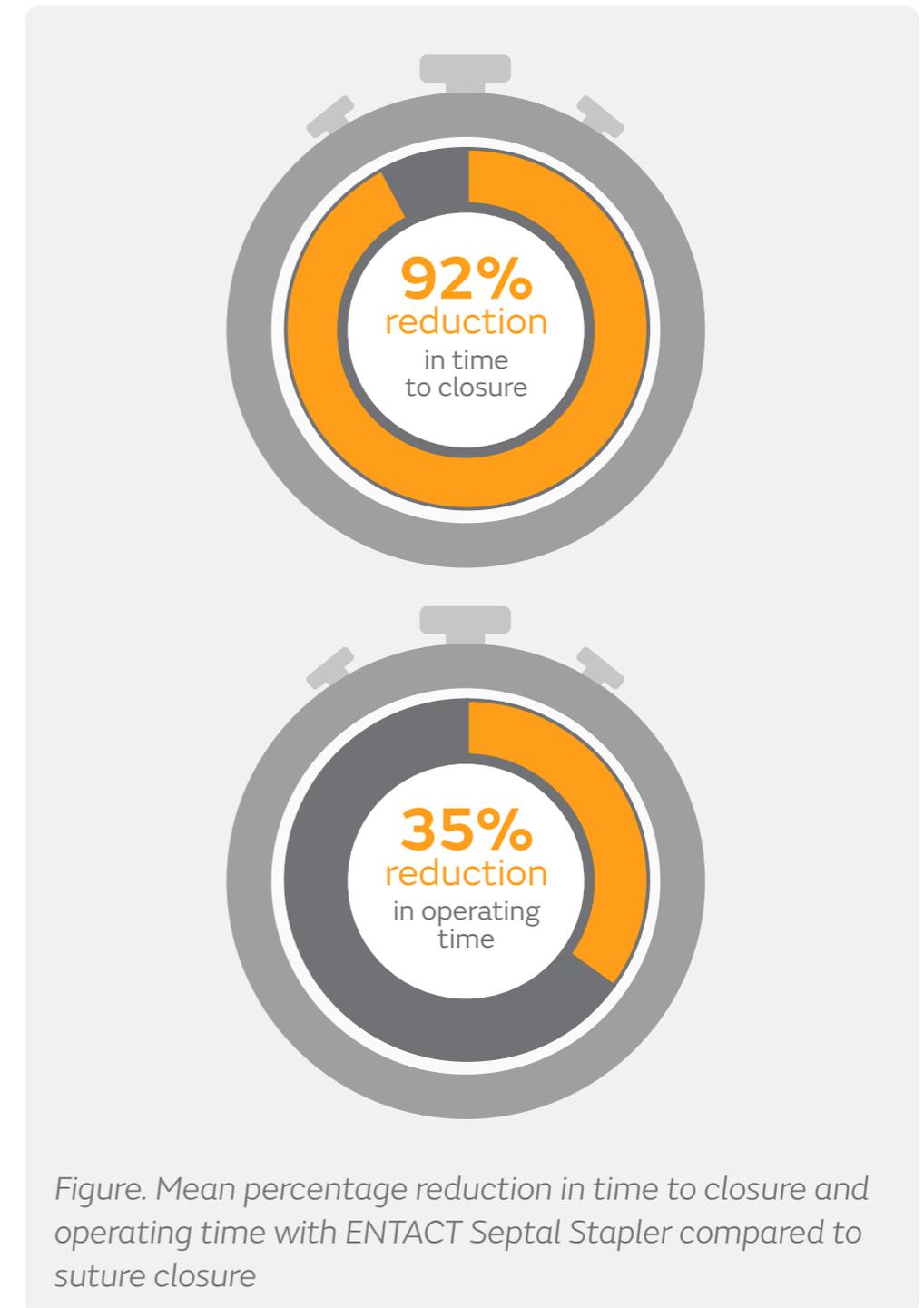


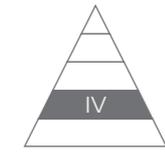
Figure. Mean percentage reduction in time to closure and operating time with ENTACT Septal Stapler compared to suture closure

NOSE = Nasal Obstruction Symptom Evaluation

1. Sowerby LJ, Wright ED. A comparison of septal stapler to suture closure in septoplasty: a prospective, randomized trial evaluating the effect on operative time. *Int Forum Allergy Rhinol*. 2013;3:911-914.

# ENTACT<sup>®</sup> Septal Stapler safe and effective for septal flap closure following septoplasty

Tami TA, et al. *Am J Rhinol Allergy* (2010)<sup>2</sup>



## Overview

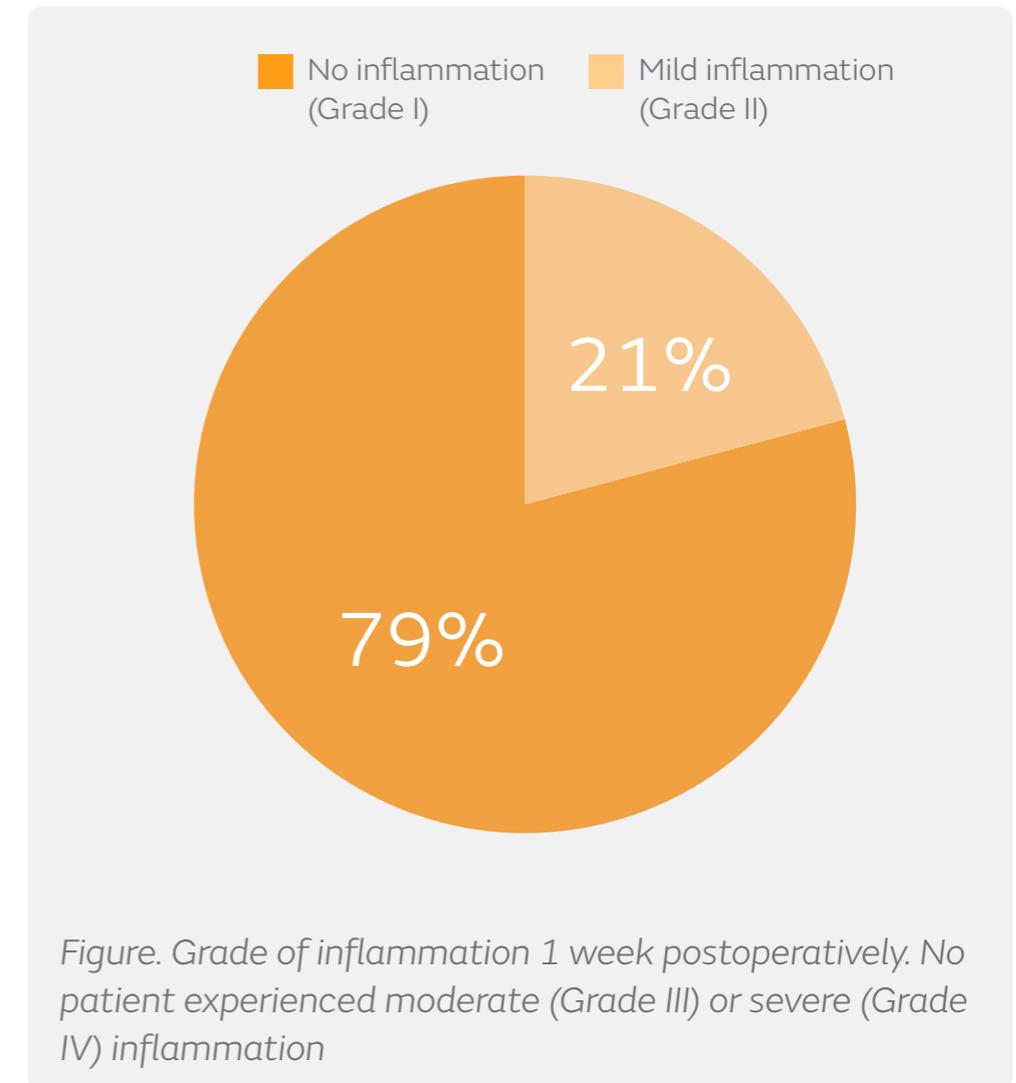
- Prospective, multicentre study evaluating outcomes following septal flap closure with ENTACT Septal Stapler (n=24) after septoplasty
- Primary outcome was successful septal flap closure 1 week postoperatively; secondary outcomes included tissue reaction 1 week postoperatively and intraoperative evaluation of device performance

## Results

- Septal flap closure was successfully accomplished in all patients
- Mild inflammation was observed in 21% of patients at 1 week, however, there were no occurrences of moderate or severe inflammation (Grades III or IV; Figure)
- No postoperative haematomas occurred
- The first batch of staplers failed to perform to device specifications. Following design modifications, no subsequent malfunctions occurred

## Conclusions

ENTACT Septal Stapler is safe, efficient and effective for septal flap closure following septoplasty.



# ENTACT<sup>®</sup> Septal Stapler demonstrated comparable outcomes to nasal packing and trans-septal suturing



Yıldırım G, et al. *Eur Arch Otorhinolaryngol* (2013)<sup>3</sup>

## Overview

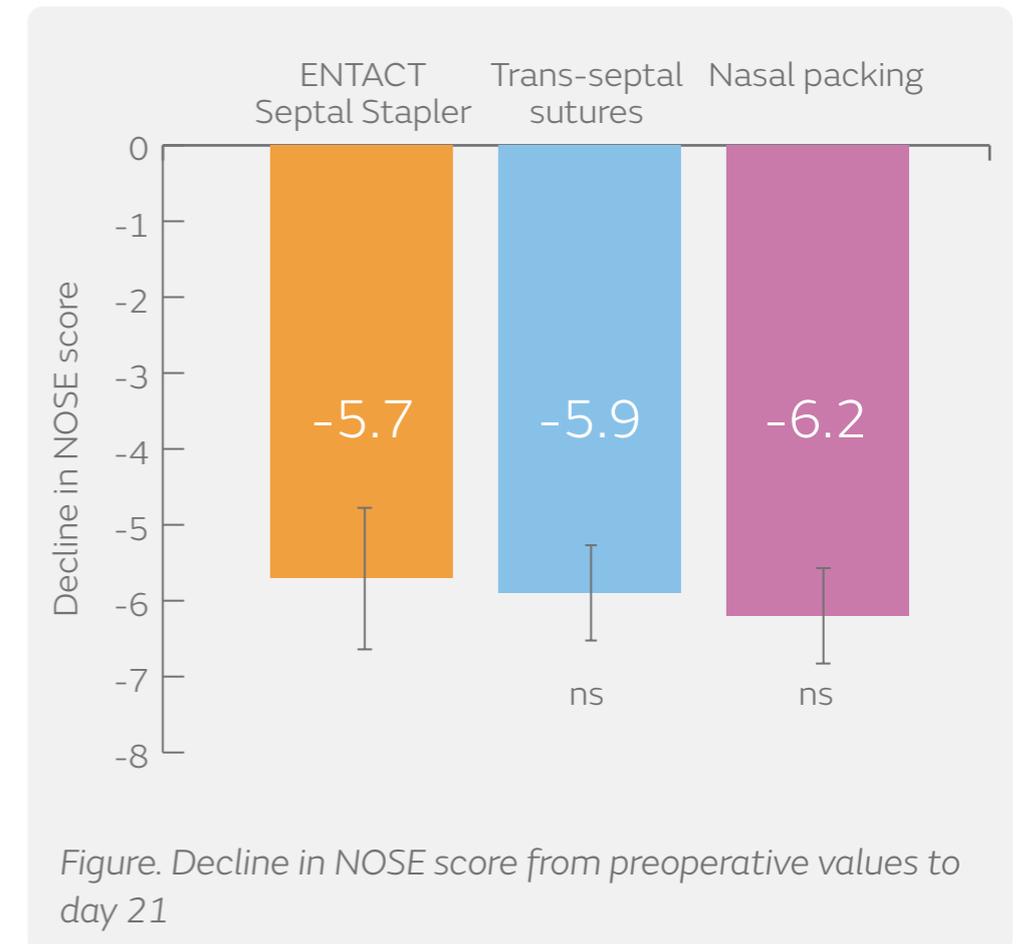
- Randomised trial comparing outcomes in patients receiving nasal packing (n=20), septal flap closure with trans-septal sutures (n=20) or septal flap closure with ENTACT Septal Stapler (n=20) following septoplasty
- Outcomes included nasal patency, NOSE and RQLQ scores at postoperative day 21

## Results

- Improvements in NOSE score from preoperative values were not significantly different between groups at day 21 (Figure)
- No significant difference between groups in nasal patency and RQLQ values at day 21
- Surgical outcomes were successful in all groups and no complications occurred

## Conclusions

Surgical outcomes were comparable for patients treated using ENTACT Septal Stapler, trans-septal suturing and nasal packing following septoplasty.



MCA = minimal cross-sectional area, NOSE = Nasal Obstruction Symptom Evaluation, ns = not significant, RQLQ = Rhinoconjunctivitis Quality of Life Questionnaire, VAS = visual analogue scale

3. Yıldırım G, Cingi C, Kaya E. Septal stapler use during septal surgery. *Eur Arch Otorhinolaryngol*. 2013;270:939-943.

# Significantly fewer follow-up visits after septoplasty with the ENTACT Septal Stapler compared with other techniques



Sainio S, et al. *Rhinology* (2019)

## Overview

- Single-centre retrospective study comparing outcomes after septoplasty with the ENTACT Septal Stapler (n=101) and all other septoplasty techniques at the institution (includes silicone splints, tamponade and sutures; n=356)

## Results

- Patients treated with the ENTACT Septal Stapler had significantly fewer postoperative follow-up visits compared with patients treated with other septoplasty techniques (Figure;  $p < 0.001$ )
- No significant difference in complication rate between ENTACT Septal Stapler and other septoplasty techniques (9.9 vs 9.0%;  $p = 0.80$ )
- Reoperation was required for one patient in each group

## Conclusions

Compared with other septoplasty techniques, the ENTACT Septal Stapler led to significantly fewer postoperative follow-up visits and had a similar rate of complications.

