

# Burst Pressures in Gastric Closure – A NOTES® Study of the Lock-It® System with the Padlock-G® in the Explanted Porcine Stomach

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## BACKGROUND:

A reliable, secure closure of the gastrotomy remains a fundamental challenge in transgastric NOTES® procedures. Gastrotomy closure using endoscopic clips is unreliable, technically difficult, and expensive. While much of early NOTES® device development has focused on gastrotomy closure, few tests of the integrity of these techniques have been published. We assessed burst pressures in gastric explants utilizing a proprietary endoscopic clip for closure.

## METHODS:

In eight explanted porcine stomachs in an Erlangen Model, we made a gastrotomy in each stomach on the greater curvature near the gastrocolic ligament. The gastrotomy was created with a wire-guided, endoscopic balloon dilatation catheter, and was enlarged to 18-mm. Prior to creation of the gastrotomy, two T-tags were placed on either side of the opening to facilitate closure. The gastrotomy was closed by pulling the T-tags into the endoscope and then deploying the Padlock-G® clip (Aponos Medical, Kingston, NH) via a stainless-steel, endoscopic-mounted delivery pod (the Lock-It® system) affixed to the endoscope. Integrity of the closures was assessed by submerging each explant under water and inflating until gas leakage occurred. Pressure gradients across the gastric wall were recorded using a manometer. Leak pressure and site of leak were then recorded. An *in vivo* test was also done, and the stomach was harvested at necropsy, and tested as an additional gastric explant.



Padlock-G® Clip.



Lock-It® System.



Gastrotomy closed with Padlock-G®.



Burst testing closed gastrotomy.

## RESULTS:

The mean transmural pressure gradients (mm Hg) at failure are shown here:

*Ex vivo* Padlock-G® closures: **57, 107, 45, 72, 69, 62, 66, 66, Mean = 68**

*In vivo* Padlock-G® closure: **98**

Comparison of these mean closing pressures is comparable to sutured and stapled closure. Interestingly, in the one Padlock-G® closure that exceeded 100 mm Hg pressure, the gastric leak occurred secondary to rupture of the stomach at a site away from the gastrotomy, while the Padlock-G® remained intact. All of the other closures in both series leaked at the original gastrotomy site.

## CONCLUSION:

Gastrotomy closure with the Lock-It® system and Padlock-G® clip is a safe and reliable gastric closure method, with results comparable to published burst pressures in explants closed with different techniques. *In-vivo* studies to assess the safety and longer-term efficacy of the clip are necessary prior to human trials.

