Redefining staple loading pressures for adequate tissue apposition in laparoscopic sleeve gastrectomy

Eujin Yeo BA[1], Jonathan Thompson MD[1,2,3], Dennis Hanseman PhD[1], Erica Langan[1], Adam Dunki-Jacobs BS[3], Ben Thompson BS[3], Tayyab Diwan MD[1]

[1]Department of Surgery, University of Cincinnati College of Medicine, Cincinnati, OH, [2]The Thompson Center, University of Cincinnati Research Institute, Cincinnati, OH, [3]Standard Bariatrics, Inc. Blue Ash, OH

University of CINCINNATI

Introduction

Laparoscopic sleeve gastrectomy (LSG) has been shown to achieve more substantial weight reduction than medical regimen alone, with improved or eliminated comorbidities associated with obesity, such as hypertension, diabetes, and hyperlipidemia.[1] In LSG, the lateral portion of the stomach is resected, sealing the remaining portion with a line of staples. For optimal tissue apposition that prevents bleeding and leakage, the surgeon-selected closed staple height (CSH) must be appropriate for the stomach tissue thickness (TT). Most modern surgical staples are designed to exert a pressure of 8g/mm^2, a pressure reported to be adequate by Astrafiev et al. in 1967 using canine models and human cadaver tissue.[2,3] Prior attempts to characterize compressed stomach TT under stapling conditions have also used this loading pressure of 8g/mm^2.[4-6] The purpose of this project is to investigate the pressure applied to achieve CSH in LSG, which has implications on TT measurement and surgeon staple cartridge selection.

Hypothesis: We hypothesize that 8g/mm^2 is an inadequate loading pressure for measuring stomach TT.

Methods

Freshly excised stomach specimens from 39 patients between the ages 18 and 75 undergoing LSG performed by two surgeons at UC Health West Chester Hospital between June 16 and August 11, 2017 were included.

Measurements recorded:

- Total staple line length,
- Cartridge zone locations (CSH), and
- TT adjacent to staple line at sequential pressures.

Figure 1. Tissue measuring device (TMD).

TT measurements were recorded on a tissue measuring device (TMD) using the following protocol:

- Measurements were taken every 10mm along staple line, 5mm perpendicularly from staple line.
- At each location, TT was recorded at sequential pressures, using 100g weights.
- Tissue was allowed to equilibrate under constant load for 15 seconds before TT was recorded.
- Pressure applied was increased until TT recorded was smaller than CSH.

Median pressure to achieve CSH was derived and TT maps at 8g/mm^2 and at the median pressure were compared via T-test.

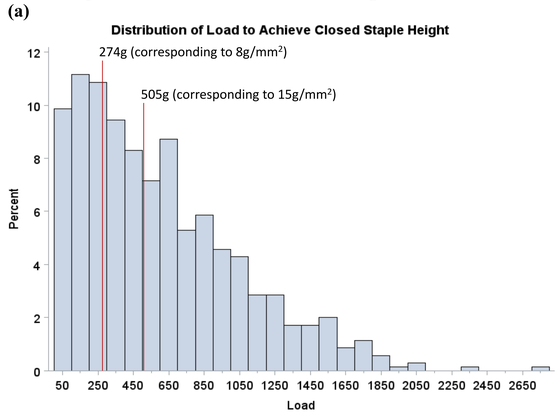
Results

Demographic data.

Stomach specimens from 39 patients were studied. 32 were female. Mean age was 42.0years (range 20-70years) and mean BMI was 49.0 (range 36.9-71.0).

Median pressure to achieve CSH is 15g/mm^2.

(a)



(b)

Median pressure to achieve CSH (g/mm^2)	Standard deviation (g/mm^2)
15	13

Figure 2. Load and pressure required to achieve closed staple height (CSH). **(a)** Distribution of load required to achieve CSH. Exact load values that would lead to CSH were calculated by interpolation. Vertical lines denote loads corresponding to previous reported 8g/mm^2 (274g) and median pressure of 15g/mm^2 (505g). **(b)** Median pressure to achieve CSH and standard deviation. Median pressure to achieve CSH was calculated by dividing the median load required to achieve CSH (505g) by the surface area of contact between TMD and stomach tissue (34.2mm^2). Standard deviation of pressure required to achieve CSH was calculated similarly from standard deviation of load to achieve CSH (452g).

TT maps at 8g/mm^2 and 15g/mm^2.

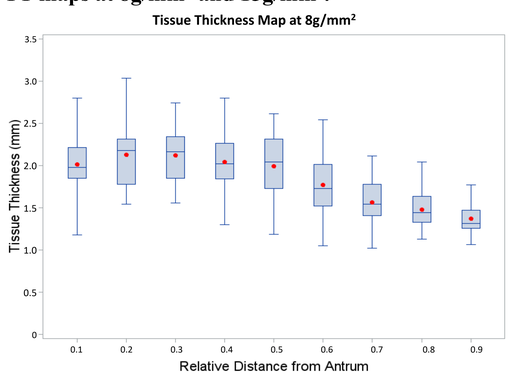


Figure 3. TT map at 8g/mm^2. Red dots indicate mean values. Relative distance from antrum was calculated in relation to total staple line length of each sample. TTs at these relative distances were calculated by interpolation. Mean TTs were 2.13mm at the antrum, 1.99mm at the body, and 1.37mm at the fundus.

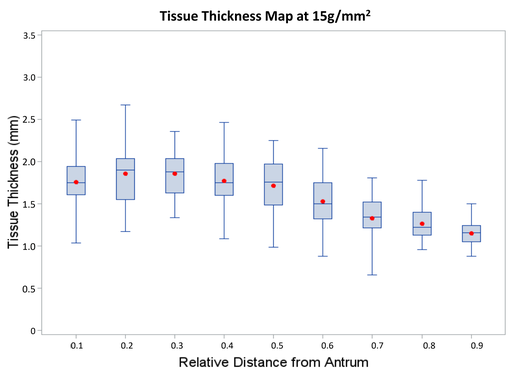


Figure 4. TT map at 15g/mm^2. Red dots indicate mean values. Relative distance from antrum was calculated in relation to total staple line length of each sample. TT at these relative distances were calculated by interpolation. Mean TTs were 1.86mm at the antrum, 1.71mm at the body, and 1.15mm at the fundus.

TT under a pressure of 15g/mm^2 is significantly smaller than under 8g/mm^2 at all locations along the staple line.

Relative distance from antrum	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9
Mean TT at 8g/mm^2	2.01	2.13	2.13	2.04	1.99	1.77	1.57	1.48	1.37
Mean TT at 15g/mm^2	1.76	1.86	1.86	1.77	1.71	1.53	1.33	1.27	1.15
p value	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001	<.0001

Table 1. T-test results for comparing mean TTs at 8g/mm^2 and 15g/mm^2 at 9 locations along the staple line. Relative distance from antrum was calculated in relation to total staple line length of each sample. p values were less than 0.01 at all locations.

Conclusion

We have shown that the pressure exerted on the stomach under stapling conditions is significantly greater than 8g/mm^2 that was reported by Astafiev et al.[3] Our results indicate that the use of smaller staple heights is biomechanically acceptable in LSG. The new loading pressure of 15g/mm^2 should be used in future studies to mimic stapling conditions and for development of new stapling devices

Discussion

This project is the first to examine freshly excised stomach TT at pressures beyond 8g/mm^2. The results provide a better understanding of the true relationship between TT and CSH. Application of our results in future studies will help achieve better tissue apposition in LSG, reducing the incidence of both intraoperative and postoperative bleeding and leakage.

Acknowledgements

This project was supported in part by NIH grant T35DK060444. Measurement equipment was supplied by Standard Bariatrics, Inc.

References

[1]Maggard MA, Shugarman LR, Suttorp M, et al. Meta-analysis: surgical treatment of obesity. *Ann Intern Med.* 2005;142(7):547-59.

[2]Echelon Flex Product Brochure. *Ethicon.com*. Ethicon US. LLC., updated 2014, accessed February 2017. http://www.ethicon.com/sites/default/files/managed-documents/030233-150225_gst-product-brochure.pdf

[3]Astafiev G. A study on tissue compressing processes under stitching instruments. *Chirurgicheskiey Shivayushiye Apparaty*. 1967;7:22–31.

[4]Elariny H, Gonzalez H, Wang B. Tissue thickness of human stomach measured on excised gastricc specimens from obese patients. *Sure Technol Int.* 2005;14:119-24.

[5]Rawlins L, Rawlins MP, Teel D. Human tissue thickness measurements from excised sleeve gastrectomy specimens. *Sure Endosc*. 2014;28:811-814.

[6]Huang R, Gagner M. A thickness calibration device is needed to determine staple height and avoid leaks in laparoscopic sleeve gastrectomy. *Obese Surg*. 2015;25:2360-2367.