

# ***Now and Future – a Scalable Surgery Solution offered for the Obesity and T2D Pandemics***

Keynote Presentation by Peter S. Harris, Session Chair  
Bariatric Surgery

—  
**International Conference on  
Surgery and  
Anaesthesia, 2018. Tokyo, Japan**

Peter S. Harris  
CEO, Longevity Surgical Inc.,  
Seattle, WA ,USA  
[www.longevitysurgical.com](http://www.longevitysurgical.com)  
[p.harris@longevitysurgical.com](mailto:p.harris@longevitysurgical.com)

# New Solution – LGP/LapProx™

Laparoscopic Gastric Plication - Invented concurrently and separately by Peter Harris and M. Talebpour, MD.

US Patent Office ruled no interference by Talebpour. Thus Harris and co-patentee Rabin awarded a total of 9 issued patents, with the earliest patent dates for LGP Method and Device.

The patents now available for an asset sale. We both have other interests and do not intend to commercialize the LGP/LapProx ourselves.

Pro-forma Plans for 510K, Financial, Sales and Marketing – available upon request – [p.harris@longevitysurgical.com](mailto:p.harris@longevitysurgical.com).

## Overriding Issue – Adoption Resistance

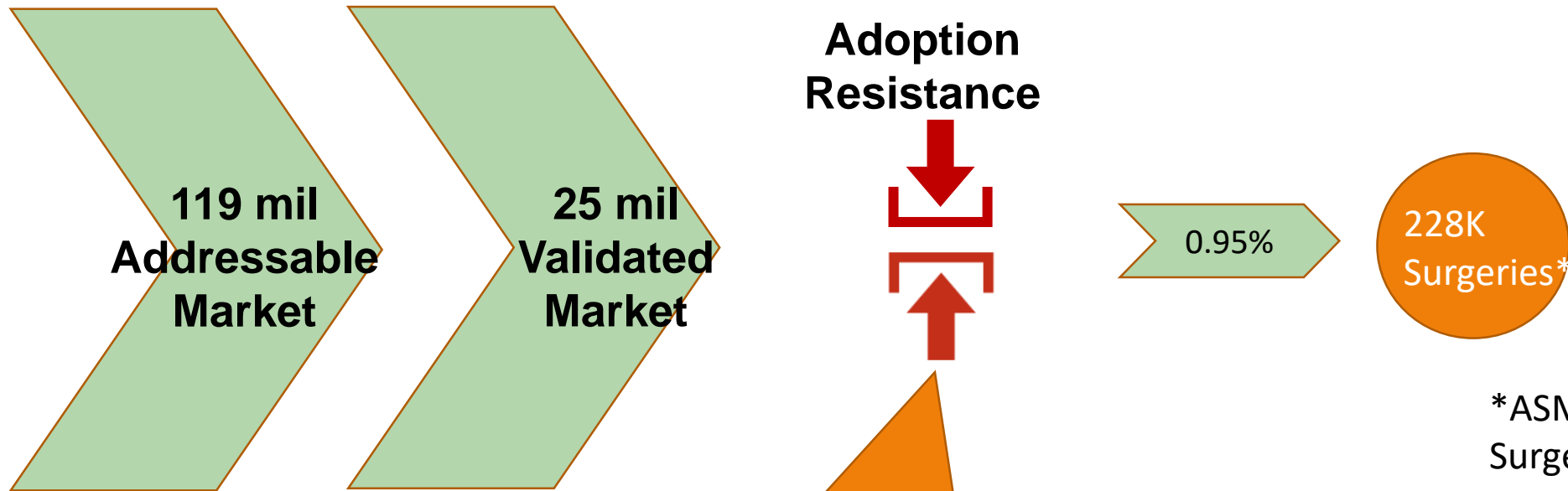
The current low adoption (<1%) of surgery as a treatment, meaning that people don't want, can't afford, can't access the surgery.\*

### **We Offer:**

A surgical procedure and enabling tool, designed with the intent that it can be scaled up to serve the obesity and T2D pandemic.

**\*Even though the ASMBS has long stated that surgery is the most successful treatment for morbid obesity.**

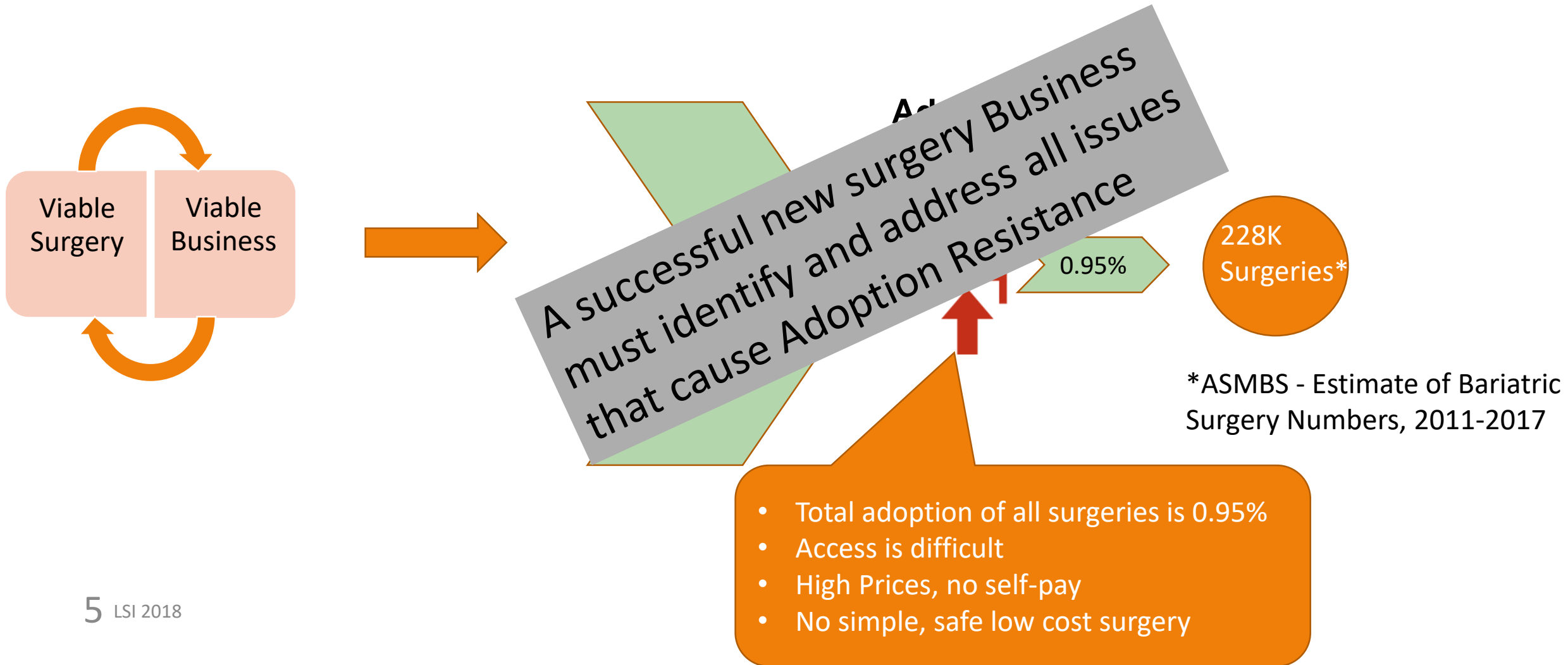
# Understand Adoption Resistance. In the US:



\*ASMBS - Estimate of Bariatric Surgery Numbers, 2011-2017

- Total adoption of all surgeries is 0.95%
- Access is difficult
- High Prices, no self-pay
- No simple, safe low cost surgery

# Avoid Adoption Resistance by Design Intent (later is too late!)



# When considering or designing a new bariatric surgery/device:

Two possible types -

**Type 1.** For limited distribution (access) to patients. Examples

- LASG, LARNY - (needs high surgeon skill; high risk to patient).
- ESG (Esophageal Sleeve Gastroplasty) – same.

**Type 2.** A surgery for many patients – **currently there is one ready to be commercialized: LGP/LapProx™**.

- Goal/vision: safe, quick, easy, standardized, low cost, and offered at urban facilities world wide for multimorbid pts.

# Wasted Resources

**20%-40% Global Health Resources wasted by inefficient, uncoordinated care every year.**

Medtronic website

Example: Medicare paid \$470 million for laparoscopic gastric band associated procedures, of which \$224 million [1/4 Billion] (47.6%) of the payments were for reoperations.

JAMA Surg. 2017 Sep 1;152(9):835-842. doi: 10.1001/jamasurg.2017.1093.  
Reoperation and Medicare Expenditures After Laparoscopic Gastric Band Surgery.  
Ibrahim AM et al.

## Formally included in the design of LGP/LapProx™:

- ❑ Value based
- ❑ Excellent Value Proposition for Patient
- ❑ Frictionless delivery to the marketplace



# “Value based” means Value as in:

$$\text{Value} = \frac{\text{Outcomes beneficial to the System}}{\text{Cost to the System}}$$

Example of a low Value to the system:

From 2006 to 2013, reoperations increased from 16.4% to 77.3% of their annual spending on the LAGB.

JAMA Surg. 2017 Sep 1;152(9):835-842. doi: 10.1001/jamasurg.2017.1093.  
Reoperation and Medicare Expenditures After Laparoscopic Gastric Band Surgery.  
Ibrahim AM et al.

## Value Proposition for Patient

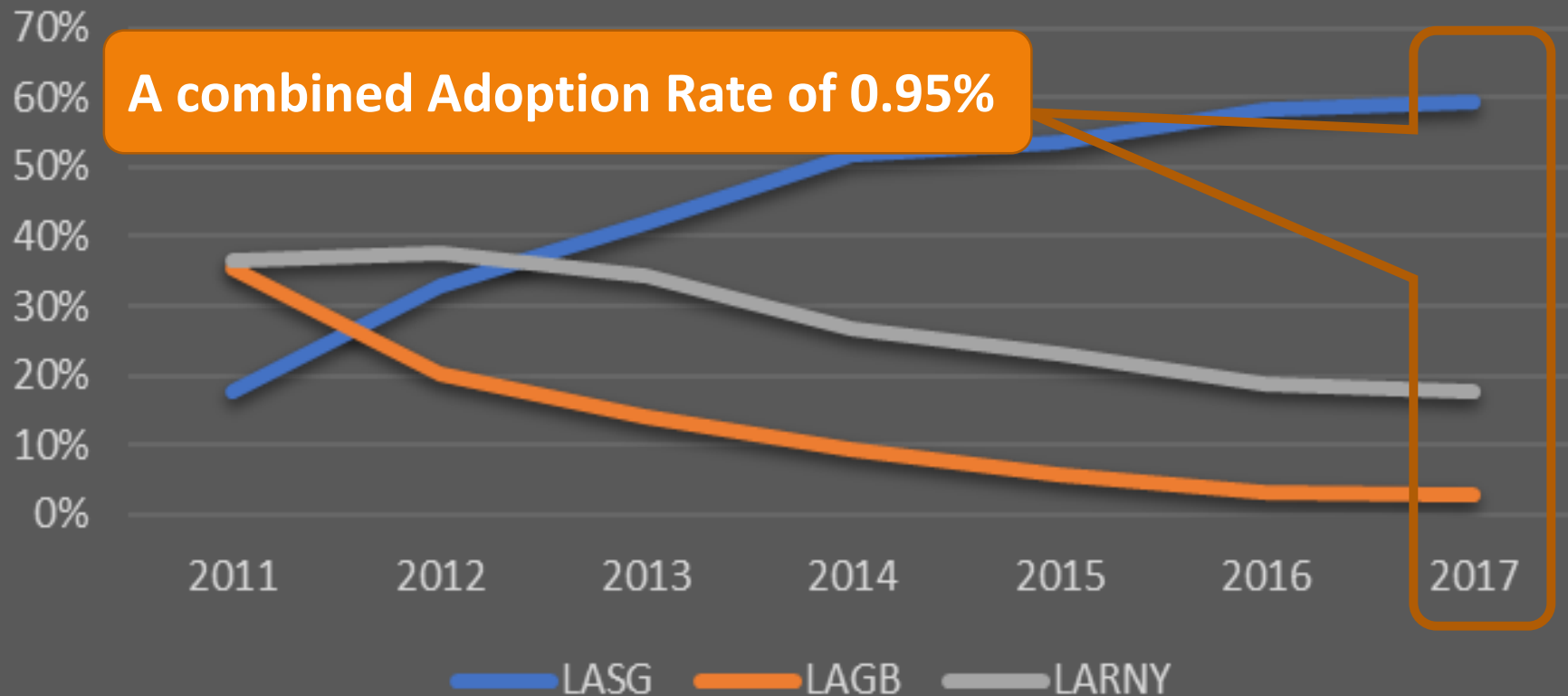
$$\text{VP for Patient} = \frac{\text{Satisfaction the Patient Receives}}{\text{Cost to Patient}}$$

Example of a low VP:

Revision of primary bariatric surgeries on average ranges from 2.5% to 18.4%, costing between \$14,000 and \$50,000 USD per patient.

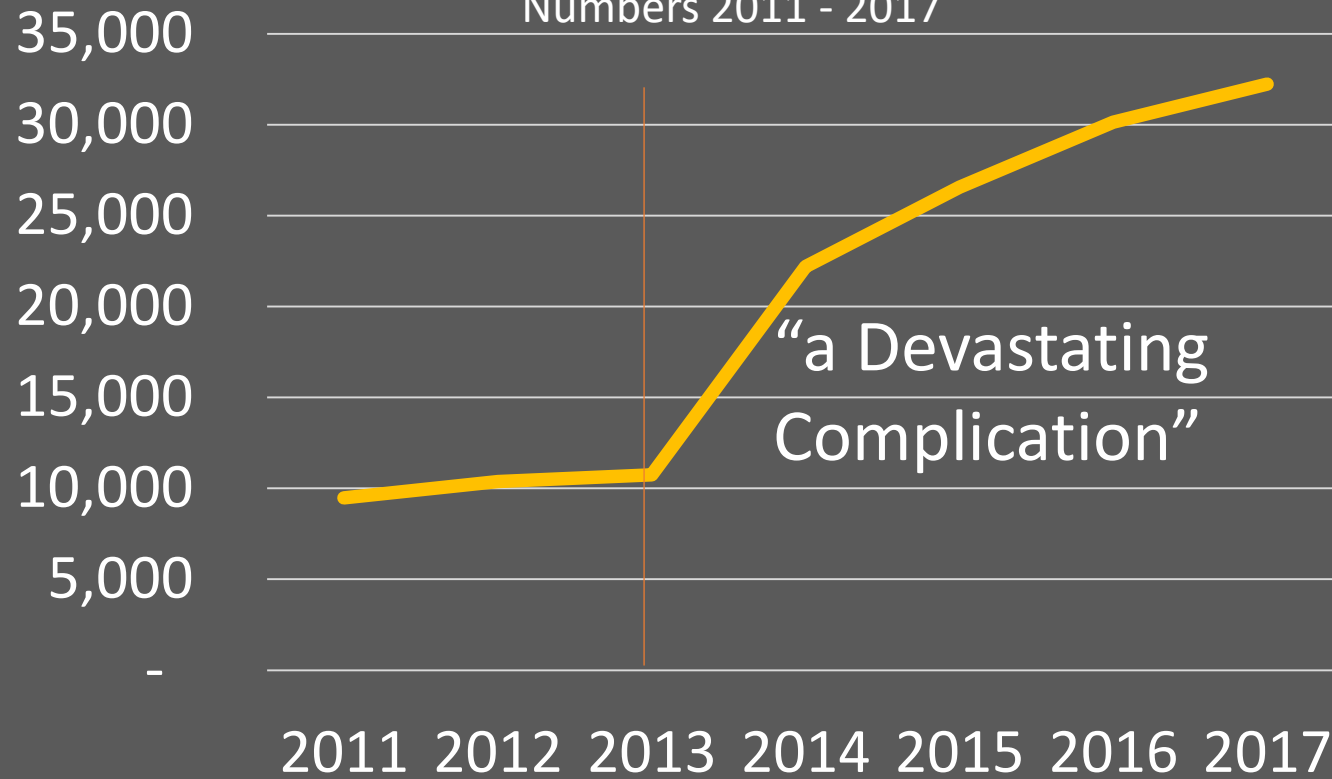
Gastroenterology Research and Practice

# Share of annual Total - This is what a failed Value Proposition looks like - Derived from ASMBS Estimate of Bariatric Suregery Numbers 2011-2017



# Revision Surgery Count - What happened in 2013?

Derived from ASMBS Estimate Of Bariatric Surgery Numbers 2011 - 2017



Reoperation after Bariatric Surgery: Still a Devastating Complication

J. Amer. College of Surgeons. October 2015 Volume 221, Issue 4, Supplement 1, Pages S16–S17. Mark H. Hanna et al.

# A New Solution – LGP/LapProx™

## Frictionless Clinical Solution

- Safe and effective, can be standardized
- Same surgery for T2D patients
- Easy for the surgeon
- In a review of 11 studies<sup>1</sup> EWL is “comparable to LASG”, re-op 3%, conversion 0.2%
- Does not cause or exacerbate GERD<sup>2,3</sup>

## Frictionless Delivery Solution

- Self-pay, often day surgery
- Not limited by the scarcity of qualified surgeons
- Not limited by high costs/no reimbursement
- Profitable for Surgeons/Centers

**\*All LGP to date has been done by manual lap suturing, on an estimated 2,000+ patients outside the US. Many published papers.**

1. Michael Kourkoulos et al. Laparoscopic Gastric Plication for the Treatment of Morbid Obesity: A Review.

Minimally Invasive Surgery Volume 2012, Article ID 696348.

2. Altieri MS, Yang J, Nie L, et al, "Rate of revisions or conversion after bariatric surgery over 10 years in the state of New York," Surg Obes Relat Dis, vol. 14(4), pp. 500-507, 2018 Apr.

3. Khidir N, Al Dhaheri W, Ansari W, et al, "Outcomes of Laparoscopic Gastric Greater Curvature Plication in Morbidly Obese Patients," Journal of Obesity, vol. 2017, 2017.

# Now a new dimension is possible - Surgery for T2D

## Primary Intent

Surgery to **reduce T2D**

**LAGP:** “in 92% of patients resulted in **remission** of T2D, and significantly decreased fasting blood sugar. Mean HbA1c for the entire cohort decreased from 9.8% to 6.6%”<sup>1</sup>  
[LASG is comparatively low at only “more than 60%”<sup>2</sup>, and 37%<sup>3</sup>]

Bariatric Surgery for T2D is **cost effective**<sup>2</sup>

Surgery for T2D **recommended** for BMI as low as 27.5 – 30 dep. on ancestry: New American Diab. Assn. Guidelines formally endorsed by over 50 worldwide medical and scientific societies<sup>4</sup>.

## Secondary Intent

Surgery to **reduce obesity**

1. Effects of laparoscopic gastric plication (LGP) in patients with type 2 diabetes, one year follow-up. Journal of Diabetes and Metabolic Disorders 14(1) · July 2015. DOI: 10.1186/s40200-015-0188-4. Mohammad Talebpour et al.
2. ASMBS Surgery for Diabetes.
3. J Biomed Res. 2015 Apr; 29(2): 105–111. Table 2. Published online 2015 Mar 3. doi: 10.7555/JBR.29.20140127. PMID: 25859264. Metabolic bariatric surgery and type 2 diabetes mellitus: an endocrinologist's perspective. Sonali Ganguly et al.
4. Surgical Treatment for Type 2 Diabetes. Diabetes Surgery Summit (DSSII).

A video of the LGP surgery and LapProx™ enabling tool:  
providing a scalable surgery. Difficulty viewing? Go to  
[https://youtu.be/cifum\\_G3SMQ](https://youtu.be/cifum_G3SMQ)

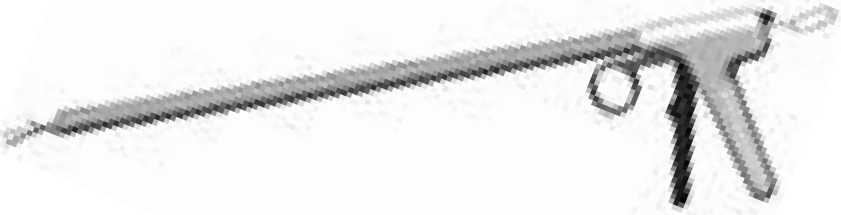
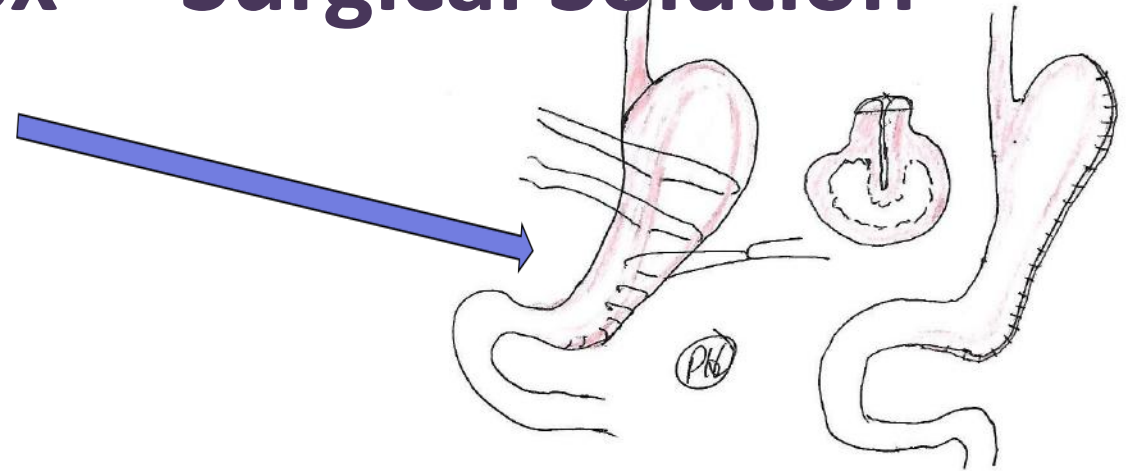


**Introducing LapProx™**  
**Soft Tissue Approximation & Fastening Devices**

# Difference between Talebpour and Harris: The LGP/LapProx™ Surgical Solution

**Talebpour - Operation time 72-152 min**

Annals of Surgical Innovation  
and Research 2012:6:7  
N=800; Twelve Year  
Experience. Talebpour, M.



**Harris - Operation stapling  
time approx. 25 min** - live  
animal lab, regular-skilled  
surgeon, does not need very  
high laparoscopic skills. Easy,  
one-handed operation.



# Standardization – Scaling into the Pandemic



- Scaling a surgery into the pandemic is impossible without **Standardization** to maintain surgical quality.
- This tool can be in different sizes, and with calibration marks, to allow for standardized bites of fold as determined empirically and by training.
- The staple always grips with the same pressure, removing any need for surgical skill in the fastening of the fold.



## Value Proposition Index (VPI) for Patient and Surgeon

	Barriers eg Insurance	Low-priced for Self-pay	High Risk/Failure EWL or T2D	Easy Access for Patients	Durable or needs follow up	Index Sub Total
LASG	1	0	1	0	2	4
LAGB	1	0	0	1	0	2
LARNY	1	0	1	0	1	3
LAGP/LapProx™	3	3	3	3	3	15

## Value Proposition Index (VPI) for a New Bariatric Surgeon

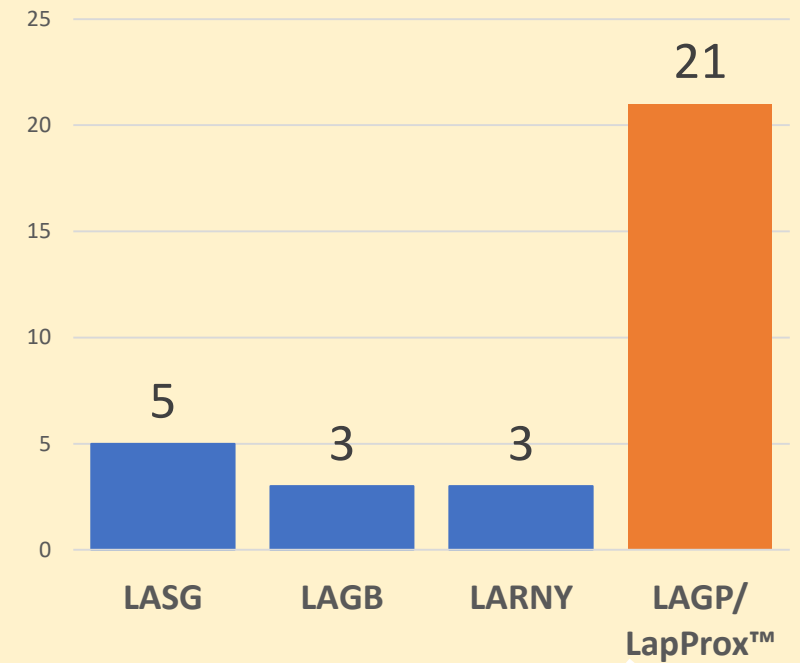
	Training Needed	Skill level Needed	Index Sub Total
LASG	0	1	1
LAGB	0	1	1
LARNY	0	0	0
LAGP/LapProx™	3*	3	6

\*1-5 cases (for an experienced Lap surgeon, as shown in LSI animal Lab)

1= Low, bad  
 3= High, good  
 0= very Low, Bad, fatal  
 Flaw for Scalability

## Value Proposition Worksheet: Patient and Surgeon

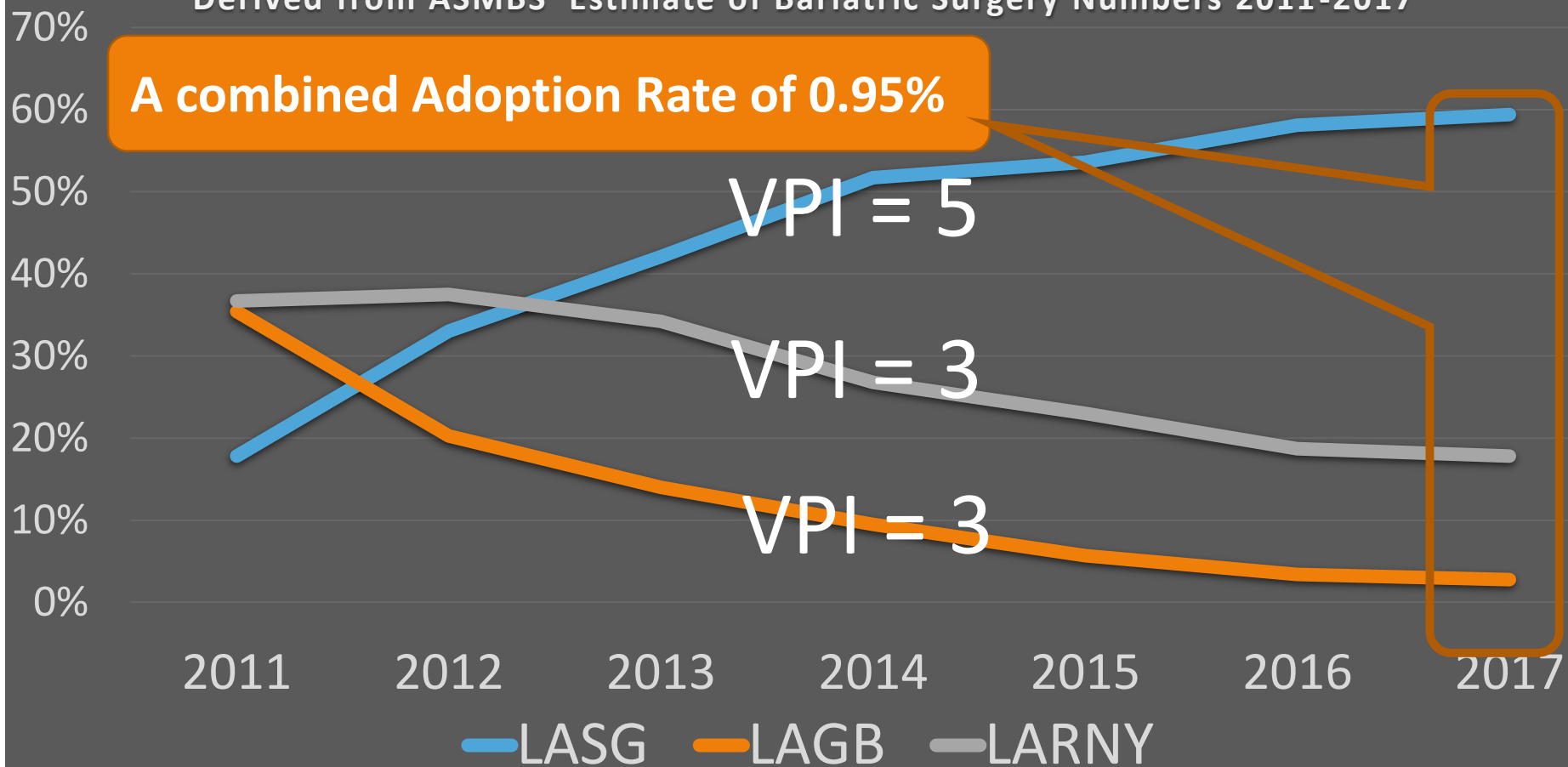
### Total Value Proposition Index (VPI) for Patient + Surgeon



**LAGP/LapProx™ is designed to outperform all conventional surgeries in Patient and Surgeon acceptance. LapProx™ not yet for human use.**

# Share of annual Total - This chart shows strong alignment to the VPI.

Derived from ASMBS Estimate of Bariatric Surgery Numbers 2011-2017



# The Future of Bariatric Surgery

