Innovación y seguridad en cirugía mínimamente invasiva.

Grapadoras Motorizadas: Seguridad, ergonomía y eficiencia.

Dr. A García Muñoz-Najar

[redacted]

2 Empresas líder que acaparan 80% del mercado

Estudios preclínicos Laboratorio

Empresa A:

-Least tissue during firing of any endocutter, 4X less tissue slipage compared to Empresa B technology. (tejido porcino gatrico)

-“Infographic of slipping out of the end of the gun”, “5 mm more targeted tissue transected”

- “Superior Grip”

- ” Reloads with gripping surface technology have a propietary ridged surface to provide an atraumatic grip on tissue to hold in place during firing”, based on 10-15 second clamp and reléase testing on anímate preclinical lung and vasulature

- “88% les movement at the end effector”

Estudios preclínicos Laboratorio :

Empresa B:

1. Based on internal test report #R2146-151-0, Powered stapling firing speed DOE analysis and ASA parameters. 2015.

2. Based on internal test report #R2146-173-0, ASA verification testing with slow speed force limit evaluation. 2015.

3. Drew S, Tarek T, Donald P. UCONN biodynamics final report on results focusing on biomechanical exposures related to laparoscopic stapler use. Report #RE00022065. 2012.

4. Based on internal test report #RE00024826, Signia™ stapling system summative usability report, Rev A. January 2016.

5. Based on internal test report #RE00027558, Signia™ powered stapler center of Mass. 2015.

6. Based on internal test report #PCG-007 rev 1, When compared to Echelon Flex™* green reloads as part of an analysis comparing different stapler designs and their performance and impact on tissues under compression using two-dimensional finite element analysis. Sept. 2, 2011.

7. Based on internal test report #2128-002-2, Final analysis of staple line vascularity using MicroCT. April 27, 2015.

8. Signia™ stapler [package insert]. Minneapolis, MN: Medtronic, 2016.

9. Hasegawa S, Nakayama S, Hida K, Kawada K, Sakai Y. Effect of Tri-Staple™ technology and slow firing on secure stapling using an endoscopic linear stapler. *Dig Surg*. 2015;32:353–360.

Disparo “CONTROLADO”: menor velocidad, menos deformidad de las grapas, mayor consistencia de la línea de corte.
Resistencia a las fugas, resistencia de la línea de grapado.
Mayor hemostasia.

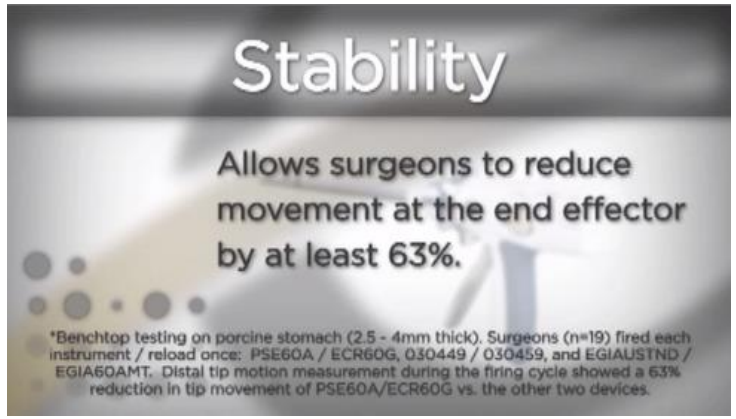
- Pre-clínica: especimen animal:

  - ✓ Kimura M. Superior staple formation with powered stapling devices. SOARD 2016; 12: 668-72

  - ✓ Matsuzawa F. Serosal Laceration During Firing of Powered Linear Stapler Is a Predictor of Staple Malformation Surg Innov 2017. (Epub ahead of print)

  - ✓ Hasegawa S. Effect of Tri-Staple Technology and Slow Firing on Secure Stapling Using an Endoscopic Linear Stapler. Dig Surg 2015;32(5):353-60.

  - ✓ Ng CS. Novel narrow profile articulating powered vascular stapler provides superior access and haemostasis equivalent to conventional devices. Eur J Cardiothorac Surg. 2016; 49: S1 73-78



Retos de los cirujanos Endoscópicos:

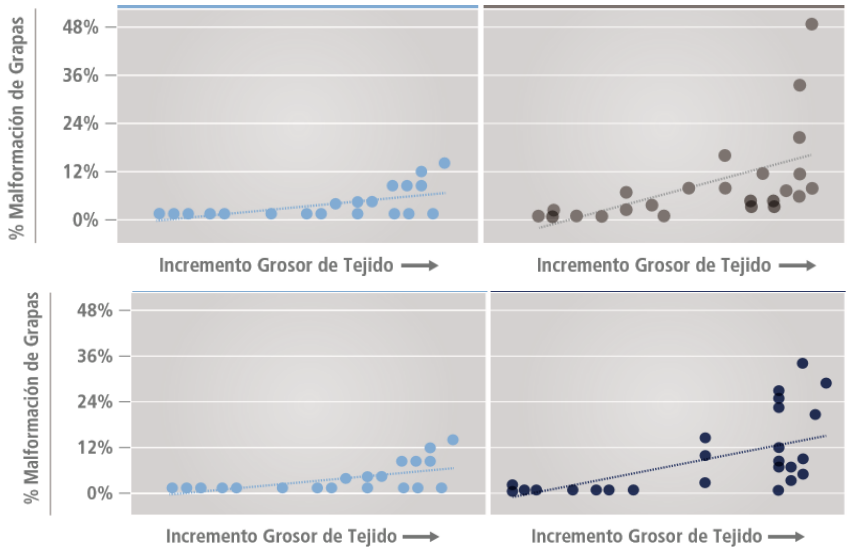
- Tejido grueso o denso
- Diseño de las endocortadoras actuales

→ Problema más común: Movimiento del tejido entre las mandíbulas durante el disparo

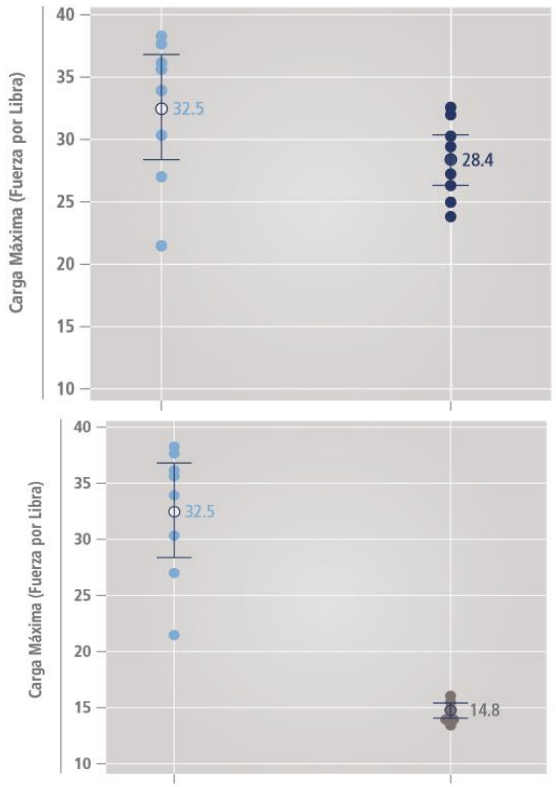
- Mala formación de grapas
- Desplazamiento del tejido fuera de las mandibulas

Alineación del canal de carga con el yunque además de minimizando efecto de desplazamiento (sistema GST)

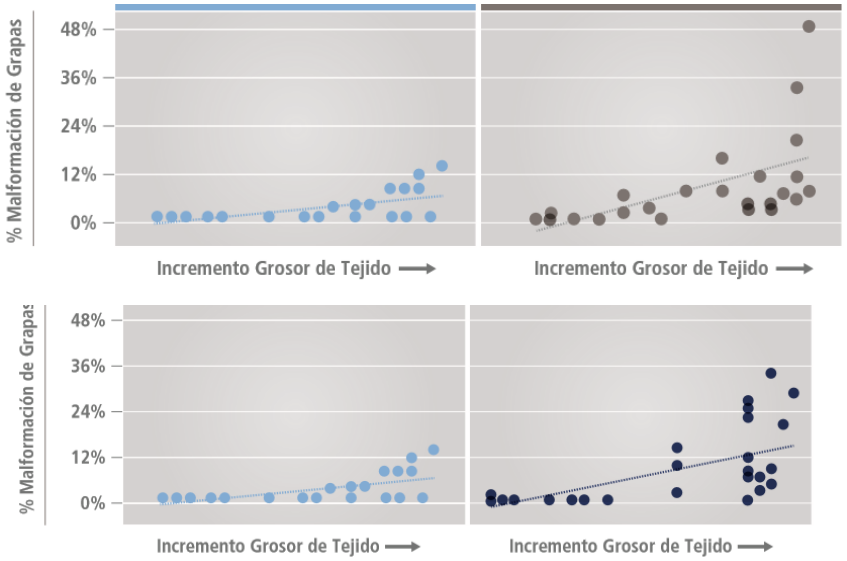
% grapas malformadas



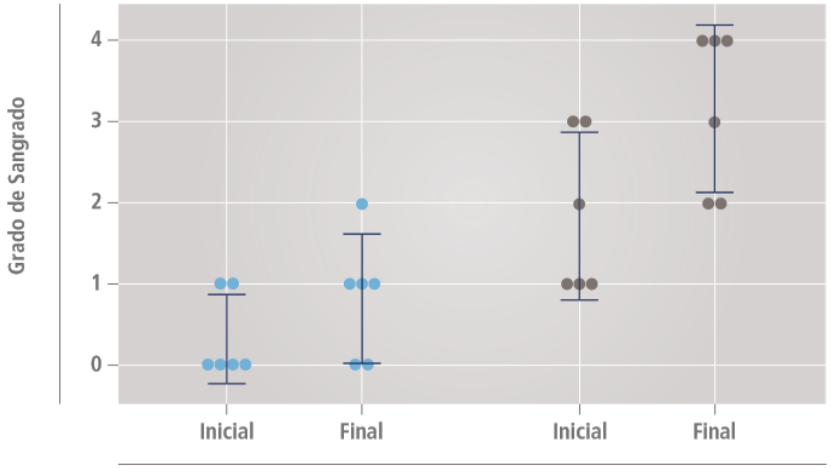
Resistencia de la línea de grapado



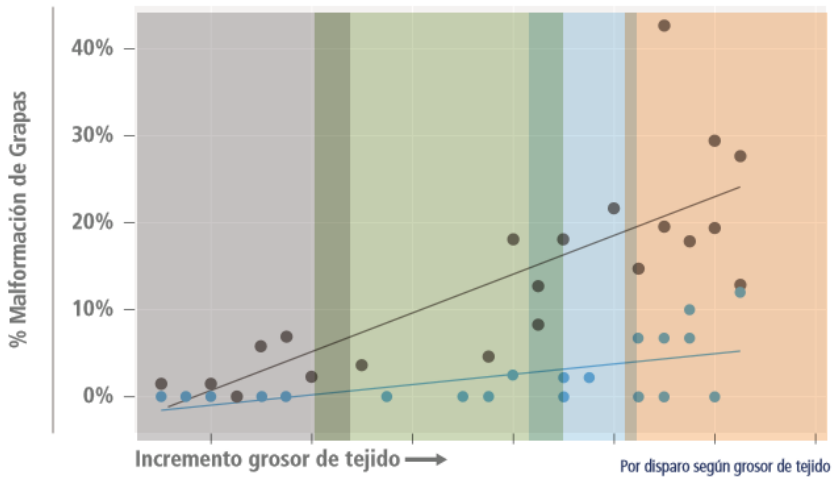
Valor medio espacio entre grapas

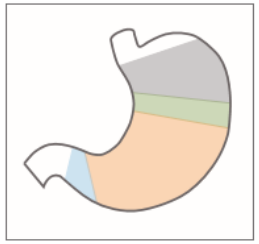


Grado de Sangrado Agudo in Vivo:



Comparación de Endograpadora Inteligente vs Eléctrica y Porcentaje de Malformación de Grapas



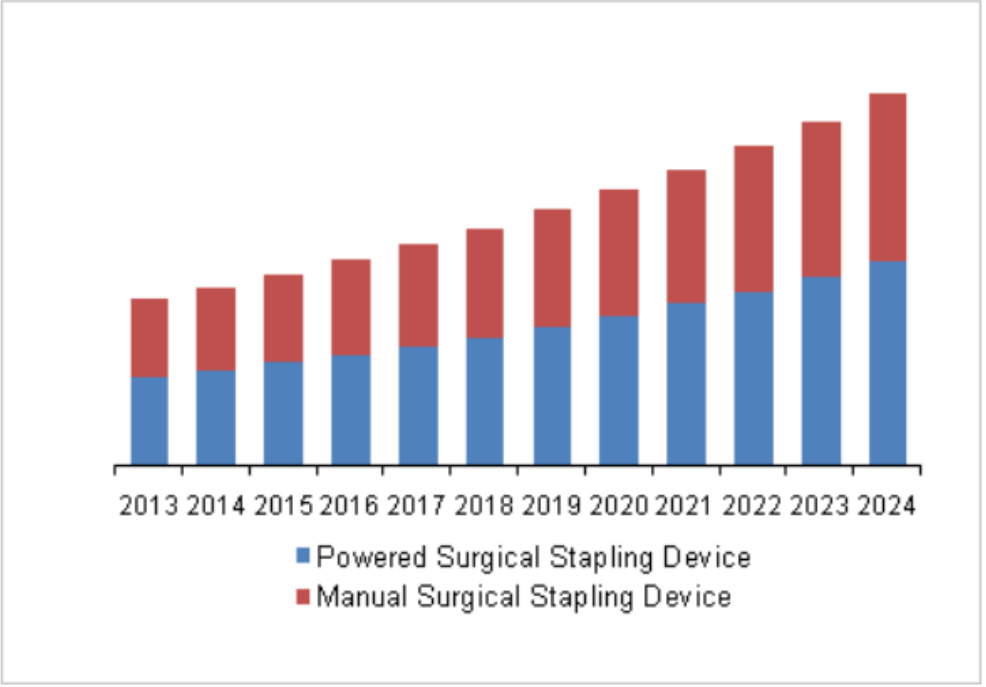


EXPERIENCIA CLINICA

- Licht PB. *Prospective Clinical Study to Evaluate Clinical Performance of a Powered Surgical Stapler in Video-assisted Thoracoscopic Lung Resections*. Surg Technol Int. 2015 Nov;27:67-75.
- Satoh Y. *Ultra powered stapling system for general lung surgery.* Kyobu Geka 2014; 67 (3): 225-8
- Akil A. *Use of a Powered Stapling System for Minimally Invasive Lung Volume Reduction Surgery: Results of a Prospective Double-Blind Single-Center Randomized Trial.* Thorac Cardiovasc Surg 2017 (Epub ahead of print)
- Qiu B. *A multi-center evaluation of a powered surgical stapler in video-assisted thoracoscopic lung resection procedures in China.* Thorac Cardiovasc Surg. 2017 Sep 13. [Epub ahead of print]
- Yoshimaru K. *Graft reduction using a powered stapler in pediatric living donor liver transplantation.* Pediatr Transplant. 2017 Sept;21(6).
- Vargün R. *En-bloc stapling of the splenic hilum in laparoscopic splenectomy*. Minim Invasive Ther Allied Technol. 2007;16(6):360-2

¿Pero qué ventajas aportan las endograpadoras eléctricas para nuestros pacientes respecto a las endograpadoras manuales?

U.S. surgical stapling market, by product, 2013 - 2024 (USD Million)



$2 billion worth of surgical stapling devices were sold in the world 2016, and revenues are expected to double by the end of 2026.

- El aumento global de las cirugías laparoscópicas, especialmente las bariátricas, está llevando a una mayor dependencia de las grapas quirúrgicas, según un informe sobre el mercado de dispositivos de grapado quirúrgico de Future Markets Insight:
    - Envejecimiento de la población
    - Aumento de enfermedades
    - Creciente demanda de tecnología médica avanzada

Surgical Stapling Devices Market by Product Type (millions)		
Product	**2016**	**2026**
Powered	1,182	2,558
Manual	774	1,499

Surgical Stapling Devices Market by Usage Type (millions)		
Product	**2016**	**2026**
Disposable	1,294	2,824
Reusable	662	1,233

JOURNAL OF MEDICAL ECONOMICS, 2017
VOL. 20, NO. 4, 423–433
http://dx.doi.org/10.1080/13696998.2017.1296453
Article 0174.R1/1296453

Taylor & Francis
Taylor & Francis Group

ORIGINAL RESEARCH

Comparison of economic and clinical outcomes between patients undergoing laparoscopic bariatric surgery with powered versus manual endoscopic surgical staplers

Sanjoy Roy[a], Andrew Yoo[b], Sashi Yadalam[b], Elliott J. Fegelman[c], Iftekhar Kalsekar[b] and Stephen S. Johnston[b]

[a]Ethicon, Somerville, NJ, USA; [b]Johnson & Johnson; New Brunswick, NJ, USA; [c]Global Medical Affairs, Johnson & Johnson Medical Devices, Cincinnati, OH, USA

ABSTRACT

Aims: To compare economic and clinical outcomes between patients undergoing laparoscopic Roux-en-Y gastric bypass (LRY) or laparoscopic sleeve gastrectomy (LSG) with use of powered vs manual endoscopic surgical staplers.

Materials and methods: Patients (aged ≥21 years) who underwent LRY or LSG during a hospital admission (January 1, 2012–September 30, 2015) were identified from the Premier Perspective Hospital Database. Use of powered vs manual staplers was identified from hospital administrative billing records. Multivariable analyses were used to compare the following outcomes between the powered and manual stapler groups, adjusting for patient and hospital characteristics and hospital-level clustering: hospital length of stay (LOS), total hospital costs, medical/surgical supply costs, room and board costs, operating room costs, operating room time, discharge status, bleeding/transfusion during the hospital admission, and 30, 60, and 90-day all-cause readmissions.

Results: The powered and manual stapler groups comprised 9,851 patients (mean age = 44.6 years; 79.3% female) and 21,558 patients (mean age = 45.0 years; 78.0% female), respectively. In the multivariable analyses, adjusted mean hospital LOS was 2.1 days for both the powered and manual stapler groups ($p = .981$). Adjusted mean total hospital costs ($12,415 vs $13,547, $p = .003$), adjusted mean supply costs ($4,629 vs $5,217, $p = .011$), and adjusted mean operating room costs ($4,126 vs $4,413, $p = .009$) were significantly lower in the powered vs manual stapler group. The adjusted rate of bleeding and/or transfusion during the hospital admission (2.46% vs 3.22%, $p = .025$) was significantly lower in the powered vs manual stapler group. The adjusted rates of 30, 60, and 90-day all-cause readmissions were similar between the groups (all $p > .05$). Sub-analysis by manufacturer showed similar results.

Limitations: This observational study cannot establish causal linkages.

Conclusions: In this analysis of patients who underwent LRY or LSG, the use of powered staplers was associated with better economic outcomes, and a lower rate of bleeding/transfusion vs manual staplers in the real-world setting.

ARTICLE HISTORY
Received 13 December 2016
Revised 13 February 2017
Accepted 14 February 2017

KEYWORDS
Laparoscopic roux-en-Y gastric bypass; laparoscopic sleeve gastrectomy; Bariatric surgery; endoscopic surgical staplers; costs

Table 5. Multivariable-adjusted outcomes.[a]

	Adjusted outcome Powered	Adjusted outcome Manual	Difference (Powered - Manual)	% Difference (Powered – Manual)	*p*
Overall study population, n	9,851	21,558			
Hospital LOS (days)	2.05	2.05	0.0	0%	.981
Total hospital costs	$12,415	$13,547	−$1,132	−8%	.003
Supply costs	$4,629	$5,217	−$587	−11%	.011
Room and board costs	$1,845	$1,946	−$102	−5%	.379
Operating room costs	$4,126	$4,413	−$288	−7%	.009
Operating room time (min)[b]	135	151.4	−16.4	−11%	.066
Discharge status[c]	99.93%	99.91%	0.02%	0%	.575
Bleeding/transfusion	2.46%	3.22%	−0.76%	−24%	.025
30-day readmission	4.20%	4.08%	0.12%	3%	.749
60-day readmission	4.68%	4.86%	−0.18%	−4%	.679
90-day readmission	5.27%	5.55%	−0.28%	−5%	.569
LRY sub-group, n	4,057	9,613			
Hospital LOS (days)	2.31	2.26	0.05	2%	.635
Total hospital costs	$14,068	$14,644	−$576	−4%	.306
Supply costs	$5,555	$5,582	−$26	0%	.916
Room and board costs	$2,166	$2,240	−$74	−3%	.604
Operating room costs	$4,484	$4,959	−$475	−10%	.002
Operating room time (min)[b]	162.7	179.1	−16.4	−9%	.273
Discharge status[c]	99.82%	99.80%	0.02%	0%	.852
Bleeding/transfusion	3.70%	4.32%	−0.62%	−14%	.216
30-day readmission	6.16%	5.41%	0.75%	14%	.289
60-day readmission	6.62%	6.59%	0.03%	0%	.966
90-day readmission	7.62%	7.52%	0.10%	1%	.909
LSG sub-group, n	5,794	11,945			
Hospital LOS (days)	1.87	1.88	0.0	0%	.987
Total hospital costs	$10,708	$12,124	−$1,416	−12%	<.001
Supply costs	$3,875	$4,736	−$861	−18%	.001
Room and board costs	$1,798	$1,936	−$137	−7%	.219
Operating room costs	$3,631	$3,871	−$240	−6%	.015
Operating room time (min)[b]	121.6	130.5	−8.9	−7%	.092
Discharge status[c]	100.00%	99.99%	0.01%	0%	.712
Bleeding/transfusion	1.34%	2.31%	−0.97%	−42%	.013
30-day readmission	2.97%	3.13%	−0.16%	−5%	.692
60-day readmission	3.44%	3.68%	−0.24%	−7%	.579
90-day readmission	3.71%	4.11%	−0.40%	−10%	.398

LOS: length of stay; LRY: laparoscopic Roux-en-Y gastric bypass; LSG: laparoscopic sleeve gastrectomy; SD: standard deviation.

[a]Multivariable-adjusted outcomes were generated using the least squares means approach based on observed margins; costs are inflation-adjusted to 2015 US dollars using the Medical Care component of the US Bureau of Labor Statistics Consumer Price Index.

[b]Number of patients for whom operating room time data were available: Overall, powered $n = 9{,}136$, manual $n = 20{,}268$; LRY, powered $n = 3{,}704$, manual $n = 8{,}923$; LSG, powered $n = 5{,}432$, manual $n = 11{,}345$.

[c]Discharge to a home or home health organization vs other setting (e.g. skilled nursing facility).

> 31.000 pacientes

- RYGB y Gastrectomía vertical
- Tanto Empresa A como Empresa B

- Coste hospitalario total (p=0.003)
  - Coste de materiales (p=0.1)
  - Coste de quirófano (p=0.009)

13%
1777 USD

- Sangrado/necesidad de transfusión (p=0,025)

47%
menos

- Tiempo quirófano (entrada/salida) (n.e.s.)

14%
21 min.

Conclusiones:

- Las endocortadoras motorizadas o eléctricas
  - Menos sangrado y trasfusión
  - Menos coste hospitalario
  - Menos tiempo quirúrgico

  Podrían ser más seguras que las manuales en Cirugía Bariátrica e base a la bibliografía existente, aunque sin duda algo sesgada

- No existen suficientes estudios en la literatura médica de las ventajas reales de endocortadoras motorizadas en Cirugía Bariátrica

- Oportunidades de crecimiento para los fabricantes de dispositivos de grapado quirúrgico

Muchas Gracias