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Can a Fully Articulating Electromechanical Laparoscopic Needle Driver Compare with a Robotic Platform in Transabdominal Preperitoneal Inguinal Hernia Repair?

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Abstract

Background: Enhanced laparoscopic instruments are filling the gap between straight-stick laparoscopic equipment and robotic platforms. We sought to evaluate the performance and cost of the HandX™ device during mesh fixation and peritoneal flap closure of transabdominal preperitoneal (TAPP) inguinal hernia repairs.
Methods: The video recordings of a consecutive series of TAPP surgeries using the articulated needle driver device were compared with a series of surgeries on the DaVinci robotic platform by a single surgeon. Two critical steps of the procedure were analyzed: mesh fixation and peritoneal closure. A cost analysis between the two platforms was completed.
Results: We analyzed 27 cases using the new needle driver and 27 cases using the DaVinci Surgical Robotic system. To evaluate the learning curve (LC) with the HandX device, we created three groups (G1, G2, and G3). The two latter groups were combined and called after LC. Mean fixation time using the DaVinci system was 258.1 seconds (±100.4) compared with 391.5 (±95.9) using the articulating handheld laparoscopic needle driver after LC ($P < .001$). The average time for peritoneal closure was 418.6 (±192.1) seconds for DaVinci and 634.5 (±159.5) seconds for HandX ($P < .001$). When comparing the after-LC HandX cases and the DaVinci system stratified by side, there was no significant difference in peritoneal closure in the right side (520.1 seconds (84.3) with the HandX versus 444.2 seconds (229.7) using the DaVinci system ($P = .353$). When evaluating direct cost of the instruments, HandX cases had a lower cost (310 USD) when compared with the cost of using DaVinci (973 USD).
Conclusions: The new smart articulating needle driver may be a cost-effective means of bringing some of the benefits of the robotic platform to laparoscopy.

Keywords: inguinal hernia, laparoscopy, TAPP, articulating needle driver, robotic surgery

Introduction

The development of laparoscopic surgery revolutionized the field of general surgery. Over the years, the technology has evolved, adapted, and improved in a way that has allowed surgeons to continually push the envelope on the complexity of cases tackled with this modality. Nonetheless, laparoscopy has a few inherent limitations that have been difficult to overcome. One well-known limitation is the steep learning curve (LC) associated with intracorporeal suturing, which happens, at least in part, due to the limited number of degrees of freedom (DOF) inherent to the straight laparoscopic instruments.[1] This limitation was tackled early on in the development and evolution of robotic surgical platforms.[2–4]

Robotic-assisted surgery has seen an exponential adoption within general surgery for the past 5 years.[5] The benefits of the platform have garnered support from the abdominal wall and hernia specialists who continue to tackle increasingly complex abdominal wall problems. The DaVinci (Intuitive, CA) platform in particular has many advantages that go far

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beyond articulation and ergonomics. It has high-definition three dimensional (3D)-view with image stabilization, tremor filtration, movement scaling, image inversion, and enhanced teaching capabilities among others.

In contrast, robotic systems do require specialized and trained staff, specialized instruments, it requires significant docking and setup time that increased operative length, it has a big footprint, and can be quite costly. For these reasons, the Robotic Inguinal vs Transabdominal Laparoscopic Inguinal Hernia Repair: The RIVAL Randomized Clinical trial, which looked at primary noncomplicated inguinal hernia repairs, showed that the robotic-assisted approach had longer operative time and higher cost when compared with laparoscopic approach.[6] The higher cost was directly associated with the required training of the staff and surgeons, instrument use, and operative length.

Aiming to fill the gap between straight-stick laparoscopic equipment and robotic platform, different advanced laparoscopic devices have been developed.[1,2,7–13] These new advanced laparoscopic instruments have the same philosophy of combining the increased number of DOF of a robotic system with the known advantages of laparoscopic surgery. These instruments are specifically designed to improve the range and ease of movement, improve ergonomics, and provide for better triangulation during challenging laparoscopic tasks, such as intracorporeal suturing.[9]

The Human Xtensions HandX™ device is a handheld electromechanical laparoscopic instrument with an articulating head that allows for simple mechanical enhancements with a wrist-like range of motion.[10,14] The device requires minimal training for surgeons and can be readily deployed by staff in the operating room (OR) with minimal setup. The device is light-weight and is amenable for one-handed use. Its software allows the surgeon to perform movements in multiple directions within the surgical field.

It has built-in wireless technology to collect data regarding its use and required maintenance.[10,14] We sought to evaluate the performance of the handheld electromechanical laparoscopic device during two key steps, mesh fixation and peritoneal flap closure, of transabdominal preperitoneal (TAPP) inguinal hernia repairs. In addition, we wanted to compare results of the needle driver to the more established robotic platform as a form of reference. We also aimed to perform a direct cost analysis between these two devices for inguinal hernia repair.

Methods

Study design

A single surgeon performed 27 consecutive cases of TAPP inguinal hernia repairs using the electromechanical needleholder to fixate the mesh to the abdominal wall and for closure of the peritoneal flap. All cases were video recorded and compared with a recent consecutive series of traditional robotic TAPP inguinal hernia repairs performed by the same right-hand dominant surgeon. All cases were primary inguinal hernia repairs with no previous pelvic operations or radiation in the area. In each case, the mesh was fixed to the abdominal wall using 2-0 Vicryl (ETHICON™) suture, one at Cooper's ligament and two to the anterior abdominal wall in the superior edge of the mesh. The peritoneal flap was closed with a horizontal mattress technique using a single barbed suture (3-0 V-Loc™; Medtronic).

Data collection

The video recordings of all procedures were reviewed by an independent evaluator. The two tasks, mesh fixation and peritoneal closure, were reviewed independently by a single reviewer. For the mesh fixation task, we collected the total time to mesh fixation and time per stitch. For the peritoneal closure task, we collected time per stitch, total number of stitches, and total time for peritoneal closure. All times were recorded in seconds.

The cases were separated into right- and left-sided repairs. In bilateral inguinal hernia repairs, each side was considered as an independent case. The primary endpoint of this study was the total time to fixate the mesh and total time to close the peritoneal flap. Secondary endpoints were total number of stitches using either tool, total number of sutures for peritoneal closure, and time per stitch for either task. Number of stitches for peritoneal flap closure refers to each complete suture pass of the needle through both sides of the peritoneum for the running style suture closure.

We also evaluated the LC of the surgeon using the HandX device. We divided the needle driver cohort into three discreet groups (G1, G2, and G3) organized in chronological order to assess improvement over time.

Cost analysis

We performed a basic direct cost analysis between the robotic TAPP repair, and the TAPP repair using the new needle driver. Importantly, we did not include the capital cost associated with acquisition of the robotic platform nor the articulated needle driver. Suture material and mesh were not included in the cost analysis as they were the same in both techniques.

Cost for articulated electromechanical laparoscopic needle driver was obtained from our institution, as a calculation of cost per operation considering the cost of the disposable part, the needle driver tip, and the drapes. Cost for DaVinci instruments was also obtained from our institution, as a calculation of cost per operation taking into consideration the cost of instruments, such as force bipolar, monopolar cautery scissor, monopolar curved scissors tip cover, needle driver, robotic arm and columns drapes, and cannula seals.

Statistical analysis

Continuous variables whose distribution approximated normality were reported as mean and standard deviation and compared using unpaired t-tests. P values $<.05$ were considered statistically significant. Data were analyzed using the SPSS v.28 Chicago: SPSS, Inc. This study was approved by the Institutional Review Board number (IRB no. 2020-11210) and all Health Insurance Portability and Accountability Act compliant mechanisms were followed.

Results

We analyzed the steps of mesh fixation and peritoneal closure in 27 cases using the new handheld electromechanical laparoscopic needle driver and 27 cases using the DaVinci robotic surgical system. The procedures were performed by the same surgeon with significant experience (>300 cases) on the DaVinci platform.

Learning curve

To evaluate the LC with the new articulated needle driver, we created three groups (G1, G2, and G3) with 9 cases each in chronological order. Comparing the groups, G2 and G3 had statistically faster times for mesh fixation and peritoneal closure and both had higher number of stitches than G1. However, there was no difference between G2 and G3. Thus, G1 likely represents the LC for our surgeon performing these specific tasks with the electromechanical needle driver. As such, these last two groups were combined and called after LC. The first chronological group, G1, was labeled LC.

Comparison between LC ($n=9$) and after-LC ($n=18$) is shown in Table 1. There was a significantly faster time per stitch and faster total time for mesh fixation in the after-LC group compared with the LC group. The after-LC group also had also had a faster peritoneal time per stitch and an overall higher number of stitches thrown when compared with the LC group (Table 1).

Mesh fixation task

Mean mesh fixation time was 258.1 seconds (±100.4) using the robotic system and 391.5 seconds (±95.9) using the HandX device after-LC ($P<.001$). The mean time per stitch using the robot was 86 seconds (±33.4) and 129.7 seconds (±31.6) for the electromechanical needle driver (Table 2).

Peritoneal closure task

The average time of peritoneal closure was 418.6 (±192.1) seconds for DaVinci and 634.5 (±159.5) seconds for the after-LC group ($P<.001$). The mean number of stitches was higher for DaVinci versus the HandX after-LC group, 24.2 (6.8) versus 18.1 (3.3) (<0.001), respectively. The average time per stitch was longer using the electromechanical needle driver [34.6 seconds (±10.5) when compared with the robotic system [17.2 seconds (±5.3)], $P<.001$].

When comparing right- and left-side peritoneal closures, there was no significant difference between sides when using the robot platform (Table 3). In the after-LC group, there was no difference in the number of stitches between right and left repairs. However, mean total closure time and mean time per stitch were significantly shorter in right-sided repairs ($P<.001$). Comparing the robotic and HandX platforms by side of hernia, there was a significant difference in all measured parameters in favor of the robotic platform during the peritoneal closure, except total time to closure of the right side (Table 4).

Table 1. Learning Curve Comparing the First 9 Cases with HandX Device with the Subsequent Cases

	HandX LC (n=9)	*HandX after-LC (n=18)*	P
Mesh fixation time[a]			
Mesh fixation time	511 (195.7)	391 (95.9)	**.041**
Time per stitch	176.3 (61.1)	129.7 (31.7)	**.014**
Peritoneal closure[a]			
Time of closure	756.5 (207.7)	634.5 (159.5)	.103
Number of stitches	12.7 (2.8)	18.1 (3.3)	**<.001**
Time per stitch	58.3 (17.1)	34.6 (10.5)	**.003**

Bold values are statistically significant.
[a]Time in seconds, mean (SD).
LC, learning curve; SD, standard deviation.

Table 2. Comparing HandX (After-Learning Curve) Device for Transabdominal Preperitoneal Hernia Repair Versus Robotic-Assisted (DaVinci System) Technique (Suture Fixation of the Mesh and Suture Closure of the Peritoneum)

	HandX after-LC	*DaVinci*	P
Mesh fixation[a]			
Mesh fixation	391.5 (95.9)	258.1 (100.4)	<.001
Mesh time per stitch	129.7 (31.6)	86 (33.4)	<.001
Peritoneal closure[a]			
Time of closure	634.5 (159.5)	418.6 (192.1)	<.001
Number of stitches	18.1 (3.3)	24.2 (6.8)	<.001
Time per stitch	34.6 (10.5)	17.2 (5.3)	<.001

[a]Time in seconds; mean (SD).
LC, learning curve; SD, standard deviation.

Cost analysis

In our cost analysis, we compared the direct cost per surgery for the handheld electromechanical needle driver device and the DaVinci instruments and materials used per case. Mesh type was the same for both techniques, varying between size and weight of the same brand. The cost of the HandX was 310 USD per case, whereas the DaVinci cost was 973 USD (Table 5).

Discussion

The paradigm of surgical care was upended by the introduction and subsequent evolution of laparoscopic

Table 3. Comparison of Right and Left Peritoneal Closure Using DaVinci (After Learning Curve) and HandX

Peritoneal closure[a]	*Right*	*Left*	P
DaVinci	$n=16$	$n=11$	
Number of stitches	23.8 (7.9)	23.3 (4.9)	.596
Time per stitch	17.8 (6.1)	16.2 (3.9)	.454
Total closure time	444.2 (229.7)	381.3 (119.6)	.414
HandX (after-LC)	$n=9$	$n=9$	
Number of stitches	18.1 (3.4)	18.2 (3.3)	.946
Time per stitch	27 (3.2)	42.2 (9.8)	**<.001**
Total closure time	520.1 (84.3)	748.8 (132.4)	**<.001**

Bold values are statistically significant.
[a]Time in seconds, mean (SD).
LC, learning curve; SD, standard deviation.

Table 4. Peritoneal Closure Using the HandX Device Versus DaVinci System for Anatomical Right or Left Hernia Repair

Peritoneal closure[a]	*HandX (after-LC)*	*DaVinci*	P
Right side	*n* = 9	*n* = 16	
Time of closure	520.1 (84.3)	444.2 (229.7)	**.353**
Number of stitches	18.1 (3.4)	24.8 (7.9)	<.001
Time per stitch	27 (3.2)	17.8 (6.1)	.026
Left side	*n* = 9	*n* = 11	
Time of closure	748.8 (132.4)	381.3 (119.6)	<.001
Number of stitches	18.2 (3.3)	23.3 (4.9)	.016
Time per stitch	42.2 (9.8)	16.2 (3.9)	<.001

[a]Time in seconds, mean (SD).
LC, learning curve; SD, standard deviation.

surgery. Yet, despite continued innovation and incremental improvements of the technology over the years, laparoscopy has not seen the widespread adoption it once promised. In recent years, robotic platforms have evolved to overcome some of the shortcomings of laparoscopy and have positioned themselves as the natural evolution of minimally invasive surgery.

However, robotic surgery is plagued by issues of cost, a significant footprint, highly specialized training for surgeons and staff, and surgical outcomes that are not yet very well established. As such, few companies are working to develop instruments with some of the benefits of robotic platforms and bringing them to laparoscopy. In this study, we show that the use of the articulating HandX laparoscopic instrument is a viable, safe, and cost-effective alternative to a robotic platform for certain complex tasks during inguinal hernia repair.

In our study, the fully articulating electromechanical laparoscopic needle driver was evaluated in completing two key tasks during TAPP inguinal hernia repairs: mesh fixation and peritoneal flap closure where suture skills are required. Previously, we demonstrated that after as little as 10 cases, the use of the new articulated needle driver was comparable with standard laparoscopy using tackers to complete mesh fixation and closure of peritoneal flaps during TAPP repairs. We

Table 5. Cost Analysis of Major Devices with Either HandX-Assisted Technique or DaVinci-Assisted Technique

	Instrument expense
HandX-assisted laparoscopic technique	
Disposable needle holder	285.00
Drape	25.00
Total cost per operation (USD)	310.00
DaVinci robotic technique	
Force bipolar	235.00
Monopolar cautery scissor	320.00
Tip cover	20.00
Needle driver	170.00
Drapes	174.00
Cannula seals	54.00
Total cost per operation (USD)	973.00

showed that deployment of the articulating electromechanical device was more cost-effective when compared with the routine use of tackers.[10]

In this study, we evaluated the new articulated electromechanical device for mesh fixation and peritoneal closure using the DaVinci robotic system as a point of reference. Ultimately, even after passing the LC of the articulated needle driver, the completion of these two specific tasks were faster on the robotic platform.

In our study, after the completion of 9 cases, there was no difference in time doing the tasks with the articulated needle driver, which we attributed to be the surgeon's LC with the instrument. Several studies addressed the acquisition of proficiency by a cohort of surgeons in different surgical platforms.[15–17] Sodergren et al. evaluated the rate of learning and proficiency using single incision laparoscopic surgery with straight or articulating instruments.[15]

The McGill Inanimate Systems for Training and Evaluation of Laparoscopic Skills program developed with the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Fundamentals of Laparoscopic Surgery (FLS) Committee showed a correlation between performance scores in the simulations and in-training surgical skills evaluations performed by attending surgeons at the end of clinical rotations.[17] Muysoms et al. showed a decrease in retromuscular dissection time of robotic transabdominal retromuscular umbilical prosthetic hernia repair, which was the most significant of all steps during the console time.[16]

We did not expect the electromechanical needle driver to outperform the more established robotic platform, especially in the hands of a surgeon who has performed >150 robotic inguinal hernia repairs. Mesh fixation and peritoneal flap closure on average took 2.2 and 3.6 minutes longer using the articulated needle driver, which may invalidate the use of the device to some surgeons. However, there are many other factors not captured in this comparison that are worth considering. For one, the robotic platform requires extensive training for OR staff, which may require higher compensation compared with those well versed in laparoscopy.

The articulated needle driver requires minimal setup and a few minutes of training for the surgical tech. Docking time takes an average of 8 minutes (480 seconds) in our institution, which can significantly impact operative times, and is another issue related to the robotics platform. With its large footprint, docking the robot can significantly impact operative times. Comparatively, the HandX device can be readily set up and deployed by the scrub tech without adding time to the operation itself. Finally, the issue of operative cost cannot be overlooked when comparing a potential alternative to the robotic platform.

There is no doubt that the robotic platform does have some advantages in complex inguinal hernia repairs. In fact, even in our study the simple fact that left-sided flap closures were significantly easier on the robot compared with the HandX device highlights its unique advantages for more complex or dexterous tasks. Nonetheless, operative cost remains a contentious topic in robotic surgery and skeptic of robotic platforms rightfully point out that the use of the robot may not provide additional benefit in all cases and be quite costly. As the RIVAL trial concluded, this may be particularly true for uncomplicated unilateral primary hernias.[6] However, surgeons who may want the benefits of a fully articulating instrument without the added cost of the robotic platform may opt for a laparoscopic device such as the new articulated needle driver even for uncomplicated unilateral repairs.

To perform our basic cost analysis, we removed the capital cost of the HandX device and of the DaVinci platform as the companies have different strategies according to each institution. Also, we chose to compare the direct cost per operation, not per instrument. To perform the surgical steps with the laparoscopic articulated needle driver, the surgeon usually requires reusable instruments such as scissors, hook cautery, and graspers in addition to the needle driver. Given that these instruments are reusable, long-lasting, and with no predetermined lifespan, it would be difficult to estimate a cost per operation related to their use. On the contrary, when using the robotic platform, each additional instrument that is used has an associated cost per operation that related to a predetermined lifespan.

Therefore, a cost comparison based on the platform used per operation was more feasible and widely applicable than simply comparing the cost of the two needle drivers, of which the robotic is cheaper.

The cost per case using the DaVinci platform was substantially higher than using the handheld electromechanical device, but it does not deliver all other technical advantages of the robotic platform such as 3D vision, tremor filtering, and scaling. The fully articulating needle driver may be a good alternative especially in places where cost is the biggest issue for not using the robot in primary uncomplicated unilateral hernias. Furthermore, the articulating electromechanical needle driver may be a good alternative in gaining suturing capabilities at a fraction of the cost of the DaVinci.

Limitations of the study

This is a retrospective study with a small sample that is evaluating the LC of 1 surgeon, already proficient in robotic surgery. In this study, we had a small sample size that was underpowered to detect small differences. In addition, we are comparing an early experience using the HandX laparoscopic device to performing the same set of tasks on the DaVinci Surgical robot, a system on which our surgeon has a significant amount of experience.

As far as the platforms themselves, the DaVinci system has numerous advantages that are far superior to the standard laparoscopic technique. These include but are not limited to complex visualization, articulation, and overall better ergonomics. This cannot be modified when using the articulated needle driver. Furthermore, our study did not look at ergonomic of each platform, which may be an important consideration between the two platforms.

Conclusions

The robotic system performed faster in two complex tasks during TAPP inguinal hernia repairs when compared with a software-driven handheld articulated laparoscopic instrument. Despite this, the needle driver may provide a cost-conscious alternative that is easier to deploy, requires very little ancillary staff training, and is likely as safe as the current standard of care.

Authors' Contributions

D.L.L. and X.P. were equally responsible for data curation, formal analysis, resources, conceptualization of the project, and writing the original draft. F.M. was responsible for conceptualization of the project, project administration, supervision, data curation, writing the original draft, and writing review and editing.

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References

1. Bensignor T, Morel G, Reversat D, Fuks D, Gayet B. Evaluation of the effect of a laparoscopic robotized needle holder on ergonomics and skills. Surg Endosc 2016; 30:446–454.
2. Feng J, Yang K, Zhang Z, et al. Handheld laparoscopic robotized instrument: Progress or challenge? Surg Endosc 2020;34:719–727.
3. Koh DH, Jang WS, Park JW, et al. Efficacy and safety of robotic procedures performed using the da Vinci robotic surgical system at a single institute in Korea: Experience with 10000 cases. Yonsei Med J 2018;59:975–981.
4. Matthews CA. Surgical techniques: Robot-assisted laparoscopic colposacropexy with the da Vinci(®) surgical system. J Robot Surg 2009;3:35–39.
5. Pereira X, Lima DL, Friedmann P, et al. Robotic abdominal wall repair: Adoption and early outcomes in a large academic medical center. J Robot Surg 2021:1–10 [Online ahead of print], DOI: 10.1007/s11701-021-01251-2.
6. Prabhu AS, Carbonell A, Hope W, et al. Robotic inguinal vs transabdominal laparoscopic inguinal hernia repair: The RIVAL randomized clinical trial. JAMA Surg 2020;155:380–387.
7. Feng J, Yan Z, Li M, et al. Handheld robotic needle holder training: Slower but better. Surg Endosc 2021;35:1667–1674.
8. Sieber MA, Fellmann-Fischer B, Mueller M. Performance of Kymerax© precision-drive articulating surgical system compared to conventional laparoscopic instruments in a pelvitrainer model. Surg Endosc 2017;31:4298–4308.
9. Sánchez-Margallo JA, Sánchez-Margallo FM. Initial experience using a robotic-driven laparoscopic needle holder with ergonomic handle: Assessment of surgeons' task performance and ergonomics. Int J Comput Assist Radiol Surg 2017;12:2069–2077.
10. Needham V, Camacho D, Malcher F. Initial experience using a handheld fully articulating software-driven laparoscopic needle driver in TAPP inguinal hernia repair. Surg Endosc 2021;35:3221–3231.
11. Sipahi M, Arslan E. A new needle holder design to facilitate intracorporeal knot tying. Surg Innov 2018;25:199–202.

12. Zapardiel I, Hernandez A, De Santiago J. The efficacy of robotic driven handheld instruments for the acquisition of basic laparoscopic suturing skills. Eur J Obstet Gynecol Reprod Biol 2015;186:106–109.
13. van der Vliet WJ, Spaans LN, Bonouvrie DS, Uittenbogaart M, Leclercq WKG. Safety and efficiency of an articulating needle driver in advanced laparoscopic abdominal surgery. J Laparoendosc Adv Surg Tech A 2021 [Online ahead of print], DOI: 10.1089/lap.2021.0272.
14. Xtensions H. Human Xtensions Receives FDA Clearance for Its HandX, the First in a Line of Smart Digital Handtop Solutions [Internet]. https://www.prnewswire.com/news-releases/human-xtensions-receives-fda-clearance-for-its-handx-the-first-in-a-line-of-smart-digital-handtop-solutions-677636573.html (last accessed May 4, 2021).
15. Sodergren M, McGregor C, Farne HA, et al. A randomised comparative study evaluating learning curves of novices in a basic single-incision laparoscopic surgery task. J Gastrointest Surg 2013;17:569–575.
16. Muysoms F, Van Cleven S, Pletinckx P, Ballecer C, Ramaswamy A. Robotic transabdominal retromuscular umbilical prosthetic hernia repair (TARUP): Observational study on the operative time during the learning curve. Hernia 2018;22:1101–1111.
17. Peters JH, Fried GM, Swanstrom LL, et al. Development and validation of a comprehensive program of education and assessment of the basic fundamentals of laparoscopic surgery. Surgery 2004;135:21–27.

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