ROBOTIC-LIKE SUTURING WITHOUT A ROBOTIC SURGICAL SYSTEM

SAGES 2018 Poster, By Kent Bowden, DO, FACOS

Dr. Kent Bowden, DO presented a case at SAGES, 2018, discussing the merits of the latest in low-cost robotic technology. Below you'll find the content from that presentation and poster

01. BACKGROUND

Despite high implementation cost and steep learning curve, the adoption of robotics in general surgery has accelerated dramatically. It is now estimated that more robotic procedures are performed by General Surgeons than either Gynecologists or Urologists. Driving this adoption is robotic hernia repair and other suture intensive-procedures.

The core enabling technologies of the daVinci® Robotic System (Intuitive Surgical, Inc., Sunnyvale, CA, USA) are:

- Intuitively controlled wristed instruments
- 3 dimensional (3D) laparoscopic vision

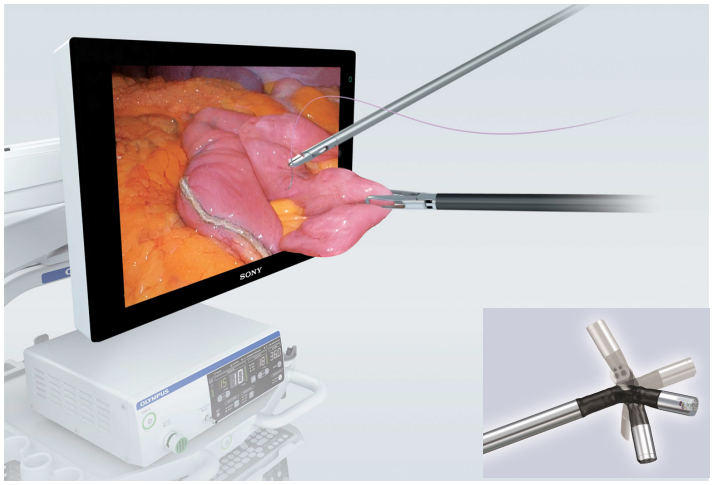
The aim of this single-center experience was to evaluate if "robotic-like" functionality may be achieved during laparoscopic surgery through the integration of two novel technologies, the FlexDex Needle Driver™ (FlexDex Inc, Brighton, MI, USA) and The ENDOEYE FLEX 3D Videolaparoscope (Olympus Corporation, Tokyo, Japan).

02. DEVICES

OLYMPUS ENDOEYE FLEX 3D:

The ENDOEYE FLEX 3D Video-laparoscope (ENDOEYE FLEX 3D) is commercially available and used in conjunction with the Olympus EVIS EXERA III imaging platform. ENDOEYE FLEX 3D is indicated for use within the thoracic and abdominal cavities including female reproductive organs. The ENDOEYE FLEX 3D enables observation and therapy in the entire peritoneal cavity by maintaining optimum and correct visual orientation with up to 100° of articulation in all directions.

The chip-on-tip, dual lens design is key to helping restore natural 3D vision and depth perception. The ENDOEYE FLEX 3D utilizes high density CCD image sensors to provide dynamic, high-definition 3D images.



FLEXDEX NEEDLE DRIVER:

The FlexDex Needle Driver (FlexDex) is a commercially available, wristed laparoscopic instrument that is intuitively controlled by the surgeon. The instrument is intended for single-use in minimally invasive surgical applications involving laparoscopic suturing procedures.

FlexDex has a 35 cm working length and is compatible with an 8 mm trocar. The instrument is purely mechanical, low cost, disposable and provides robotic functionality with laparoscopic tactile feedback.

03. METHODS

From March to December 2017, using the FlexDex Needle Driver, a General Surgeon in a rural setting completed a case series of 55 laparoscopic inguinal and ventral hernia procedures. These hernia procedures were selected based on their rapid adoption in robotics. Standard laparoscopic 2D vision was used in the first 20 procedures with the following 35 completed using the Olympus ENDOEYE FLEX 3D.

Cases included:

- 19 Ventral Hernia
- 23 Unilateral TAPP
- 13 Bilateral TAPP

55 procedures were then compared to a similar case matched series of 101 robotic procedures from surgeons at a larger hospital within the same health system.

Assessments included:

- Learning curve of FlexDex with ENDOEYE FLEX 3D
- Improvement of general laparoscopic skills
- Surgical efficiency outcomes including:
- Total operating room (OR) time
- Procedure time (cut to close)
- Hospital Contribution Margin

04. RESULTS

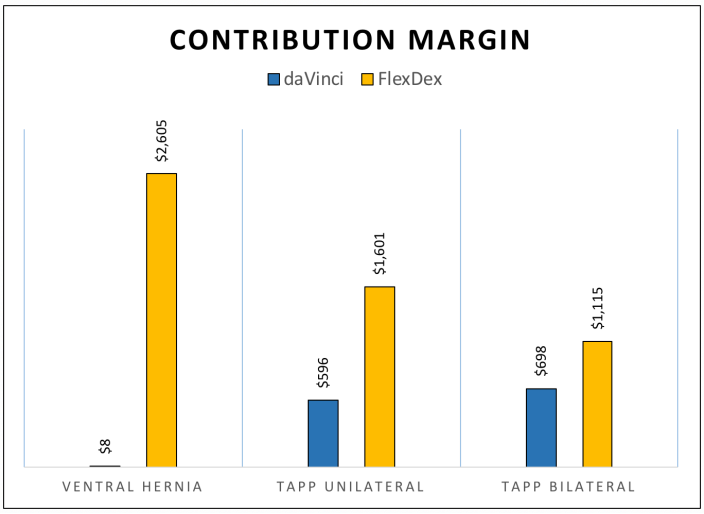
1. Learning Curve: Proficiency with FlexDex was achieved after approximately 6 hours of training in a laparoscopic box trainer prior to clinical use. After the first 20 procedures with FlexDex and the addition of 3D vision, procedure times decreased.

2. Skills Improvement: Historically, we considered laparoscopic suturing to be complicated and inefficient, and we relied on tacking devices for mesh fixation. However, with ENDOEYE FLEX 3D and FlexDex, all tacking devices have been eliminated and suturing technique improved. All surgeries were completed without any complications.

3. Surgical Efficiency: Compared to the robotic group, ENDOEYE FLEX 3D and FlexDex times were numerically superior but not statistically significant. Economic data was reported by Munson Health System and demonstrated a clear financial advantage to ENDOEYE FLEX 3D and FlexDex for all procedures.

CONTRIBUTION MARGIN

- Ventral Hernia - $2,605 vs $8 robotic
- TAPP Unilateral $1,601 vs $596 robotic
- TAPP Bilateral $1,115 vs $698.



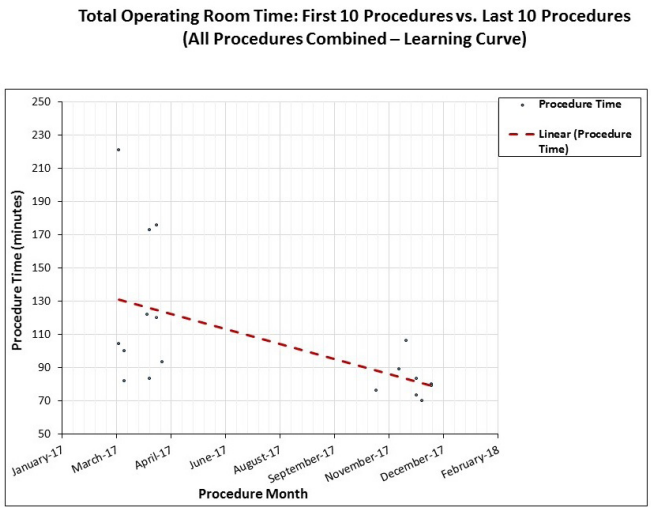
**Contribution Margin is the portion of hospital revenue remaining after variable costs, including disposable instruments (da Vinci & FlexDex), mesh and other consumable supplies.*

**The contribution margin needs to pay for Fixed Costs (service contract, capital depreciation & hospital salaries).*

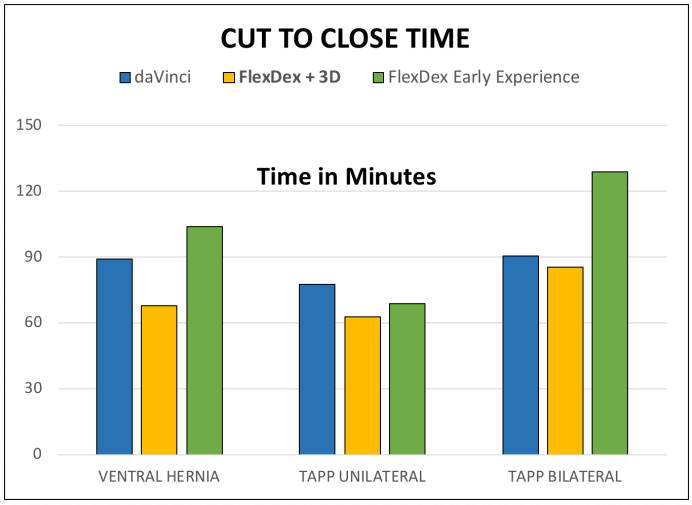
**The Capital purchase of the da Vinci robot and ENDOEYE FLEX 3D is separate from fixed costs and does not influence the contribution margin.*

It is important to note that capital costs and service contracts were excluded, so were any additional fixed costs associated with running or maintaining a da Vinci robotic program. Had these expenses been included in the economic data, the financial advantage to ENDOEYE FLEX 3D and FlexDex would be even greater.

- Surgeon learning curve demonstrates better efficiency over time with ENDOEYE FLEX 3D and FlexDex.



- Across all cases evaluated (Ventral Hernia, TAPP Unilateral Hernia, and TAPP Bilateral Inguinal Hernia) we demonstrated improved cut to close times with the implementation of ENDOEYE FLEX 3D and FlexDex as compared to da Vinci.



- Inguinal Hernia (Bilateral and Unilateral) with ENDOEYE FLEX 3D and FlexDex showed a steep curve demonstrating improvement and overall improved OR times and cut to close times as compared to da Vinci.
- Ventral Hernia with ENDOEYE FLEX 3D and FlexDex showed improvement over time and relative to da Vinci it showed similar total OR times and cut to close times.

*For detailed graphs and cost analysis data comparing implemetation of FlexDex vs daVinci system, visit flexdex.com/norobot.

DISCLOSURES

Kent Bowden DO, FACOS is a shareholder in FlexDex and is a paid consultant for Olympus.

05. CONCLUSIONS

In conclusion, this retrospective review using concurrent case controls demonstrate that ENDOEYE FLEX 3D and FlexDex can provide excellent alternative to the da Vinci system in suture intensive procedures. This can be accomplished at lower startup and lower maintenance costs both initially and year over year.

We demonstrate equivocal or better OR times both in utilization and in cut to close times in certain cases. We demonstrated a significant difference in Contribution Margin as compared to the da Vinci system. The combined technologies demonstrate time and financial savings compared to the da Vinci system in this single system assessment.

Further studies done as a multicenter study to asses times and contribution margins will add to this initial promising data. Additional work could look at FlexDex efficiency and accuracy in the 2D environment as compared to the 3D environment.

Overall, the ENDOEYE FLEX 3D and FlexDex eliminated the reliance on tacking devices and enabled “robotic-like” suturing for both mesh fixation and fascial closure.

Limitations: This data represents one surgeon utilizing ENDOEYE FLEX 3D and FlexDex and is compared to a few surgeons on the da Vinci systems. More studies looking at true costs of the da Vinci robotic system compared to other modalities should be conducted and will help to bring validity to the assertion that ENDOEYE FLEX 3D and FlexDex can help to protect small hospitals from the high costs of implementing and maintaining a robot in centers without a robot. This may also validate the concept of diverting cases off of the da Vinci that may not be appropriate for it and thereby address the backlog of cases that develops in robot equipped centers.

06. RELATED LINKS

KENT BOWDEN'S YOUTUBE CHANNEL

https://www.youtube.com/channel/UCYqJ2JMukAPqPLCMZj4hO4A

FLEXDEX SURGICAL

https://flexdex.com

OLYMPUS ENDOEYE FLEX 3D

http://medical.olympusamerica.com/products/laparoscopes/endoeye-flex-3d

MUNSON HEALTHCARE CADILLAC

http://www.munsonhealthcare.org/cadillac-surgery

FLEXDEX DEVICE ON SOCIAL MEDIA

https://www.facebook.com/groups/1750933158543553/

07. AUTHOR INFORMATION

Kent Bowden DO, FACOS

BIO: Dr. Bowden is a Graduate of Michigan State University College of Osteopathic Medicine in 2005. He completed his Residency at Ingham Regional Medical Center in Lansing Michigan in 2010, and aftwerward entered into private practice and has been in Cadillac MI since. Munson Cadillac is a small community hospital serving a rural population of 80,000 patients. Dr. Bowden's practice is mixed surgical and endoscopic as a community general surgeon. His objective as a surgeon is to provide cost effective and cutting edge procedures in the community to attract patients and keep them local allowing them to trust and enjoy the personalized care they can receive in a community setting.

927 Carmel ST, Cadillac, MI 49601 | 231-876-3876 | drbowdendo@yahoo.

WORK EXPERIENCE

Munson Healthcare Cadillac

General Surgery 2010- Current

Broad Spectrum Community Based General Surgery

Emphasis on diseases of the Abdomen, Digestive Tract, Breast, Advanced Laparoscopy and Endoscopy

EDUCATION

American College of Osteopathic Surgeons

Fellow of the American College of Osteopathic Surgeons 2017

Satisfaction of Criteria to qualify as a Fellow of the College

Ingham Regional Medical Center

General Surgery Residency 2010

Broad Spectrum Community Based General Surgery Training

Chief Resident 2009-2010

Michigan State University- College of Osteopathic Medicine

Doctor of Osteopathic Medicine and Surgery 2005

Michigan State University- College of Natural Science

B.A. Human Biology 2001

Deans List, Graduation with Honors

AWARDS

Recipient of Paul C Linnell Scholarship 2002 – 2005

MEMBERSHIPS

American College of Osteopathic Surgeons 2006- Current

Michigan Osteopathic Association 2001- Current

Wexford County Physicians Health Organization 2010- Current