1 May 2014

Telesurgery with haptic sensation: The future of surgery

Michael Stark

The New European Surgical Academy (NESA)

Disclosure

Michael Stark is the scientific advisor for the EU/SOFAR European Telesurgical Project

“… we believe that any introduction of a new indication for the use of robotic surgery should add value to the existing methods.”

Adapted from: Tinelli A, Malvasi A, Gustapane S, Buscarini M, Gill IS, Stark M, et al. Robotic assisted surgery in gynecology: current insights and future perspectives. Recent Pat Biotechnol 2011;5:12–24.

THE DAILY ORACLE

Questions remain on value of robot prostate surgery
By Genevra Pittman
NEW YORK | Thu Sep 6, 2012 4:45pm EDT

(Reuters Health) - Men who get robot surgery for prostate cancer have fewer short-term complications than men whose procedure is done the old-fashioned way - but the newer treatment is pricier, according to a new analysis of close to 30,000 patients.

CONLIN MEZRANO
INJURY LAWYERS
COMMUNITY NEWS/BLOG

15 Mar 2013: Robotic Surgery not recommended by largest group of Ob/Gyns
By ConlinMezrano

“There is no good data proving that robotic hysterectomy is even as good as, let alone better than, existing and far less costly minimally invasive alternatives.”

Dr. James Breeden, president of the American College of Obstetricians and Gynecologists said.

Robotic Surgery is all the Rage, But Price is High

Each system ranges in price from $1 million to $2.5 million, and the use of robotic surgery increases the cost of procedures anywhere from $3,200 to $8,000.

Medscape Today NEWS

Medscape Medical News

FDA Investigates Robotic Surgery System After Adverse Event Spike

Robert Lowes

Apr 30, 2013

… In other cases, the surgical robot seemed to have a life of its own, at times inexplicably cauterizing a fallopian tube, damaging heart tissue, or refusing to let go of a patient's tissue with its grasper.

The New York Times

THE CONSUMER | FEBRUARY 25, 2013, 5:01 PM | 117 Comments

Questions About Robotic Hysterectomy

By RONI CARYN RABIN

The cost of robotic surgeries was significantly higher, with a median cost to the hospital of $8,868, compared with $6,679 for laparoscopic hysterectomy.

Comparison of robotic-assisted hysterectomy to other minimally invasive approaches.

Robotic assisted total laparoscopic hysterectomy has comparable surgical outcomes, and possibly decreased blood loss, shorter length of stay, and fewer minor complications than other methods of minimally invasive hysterectomy.

Orady M, Hrynewych A, Nawfal AK, et al. JSLS. 2012;16(4):542-8.

19th century

First reported successful laparotomy

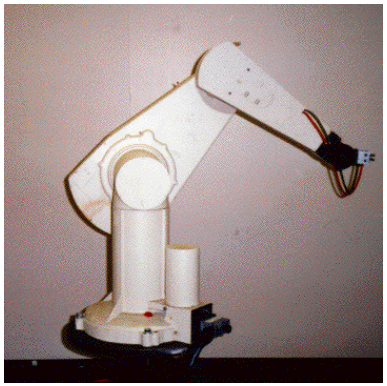
Ephraim McDowell 1771 - 1830

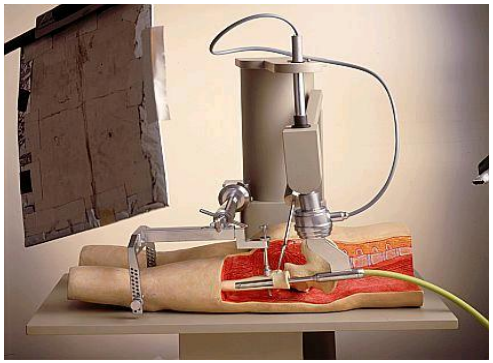
20th century: The era of endoscopy

Georg Kelling
1866-1945

Kurt Semm
1927-2003

The 21st century – The era of Telesurgery:





Main claimed advantages of existing telesurgical systems:

1. 3D stereo-vision
2. Dexterity and accuracy
3. Filtration of tremor
4. Improved ergonomy

Main disadvantages of existing telesurgical systems and why improvement is needed:

1. Lack of haptic feedback
2. Efficiency proven for limited indications
3. No access through the pouch of Douglas
4. Difficult access to patient in case of emergency
5. High investment, maintenance and operation costs

21st century: The era of telesurgery

The patient’s expectations:

- Accurate diagnosis
- Justified indications
- Safety (checklist, laboratories, available intensive care, etc.)

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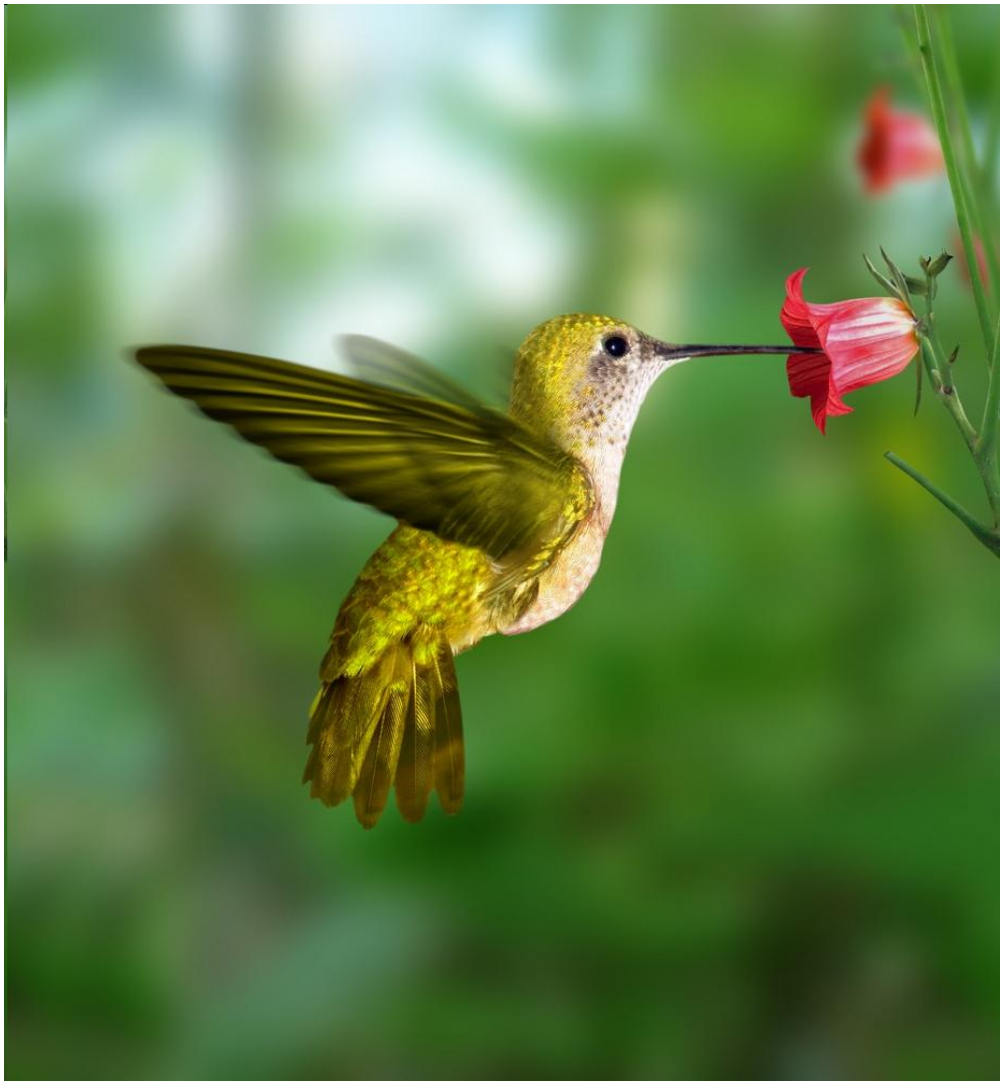
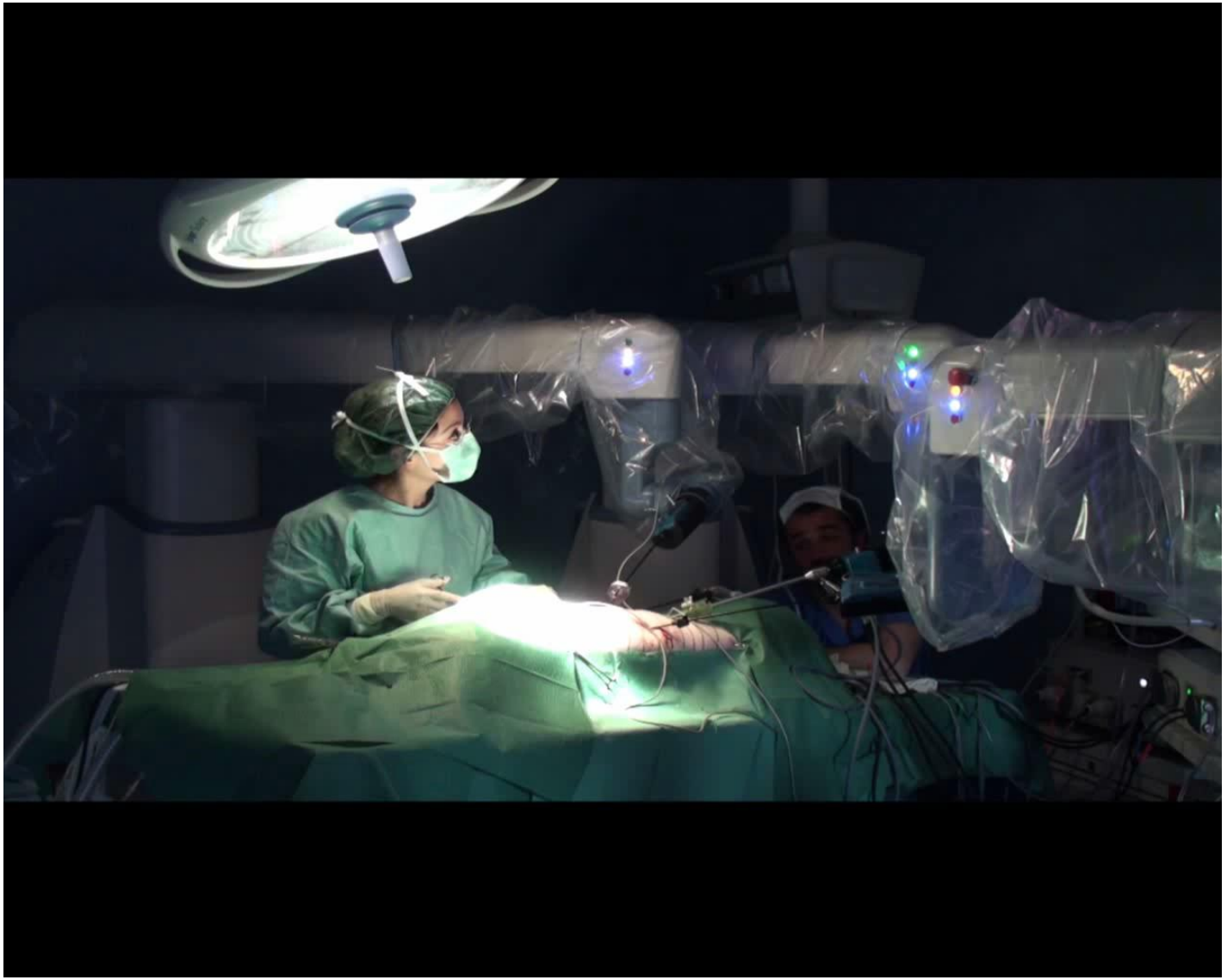
Optimal surgical tools

In order to answer these expectations and to overcome the disadvantages, an initiative for an improved telesurgical system with haptic sensation has been launched:



A system based on a novel concept, simplicity and efficiency



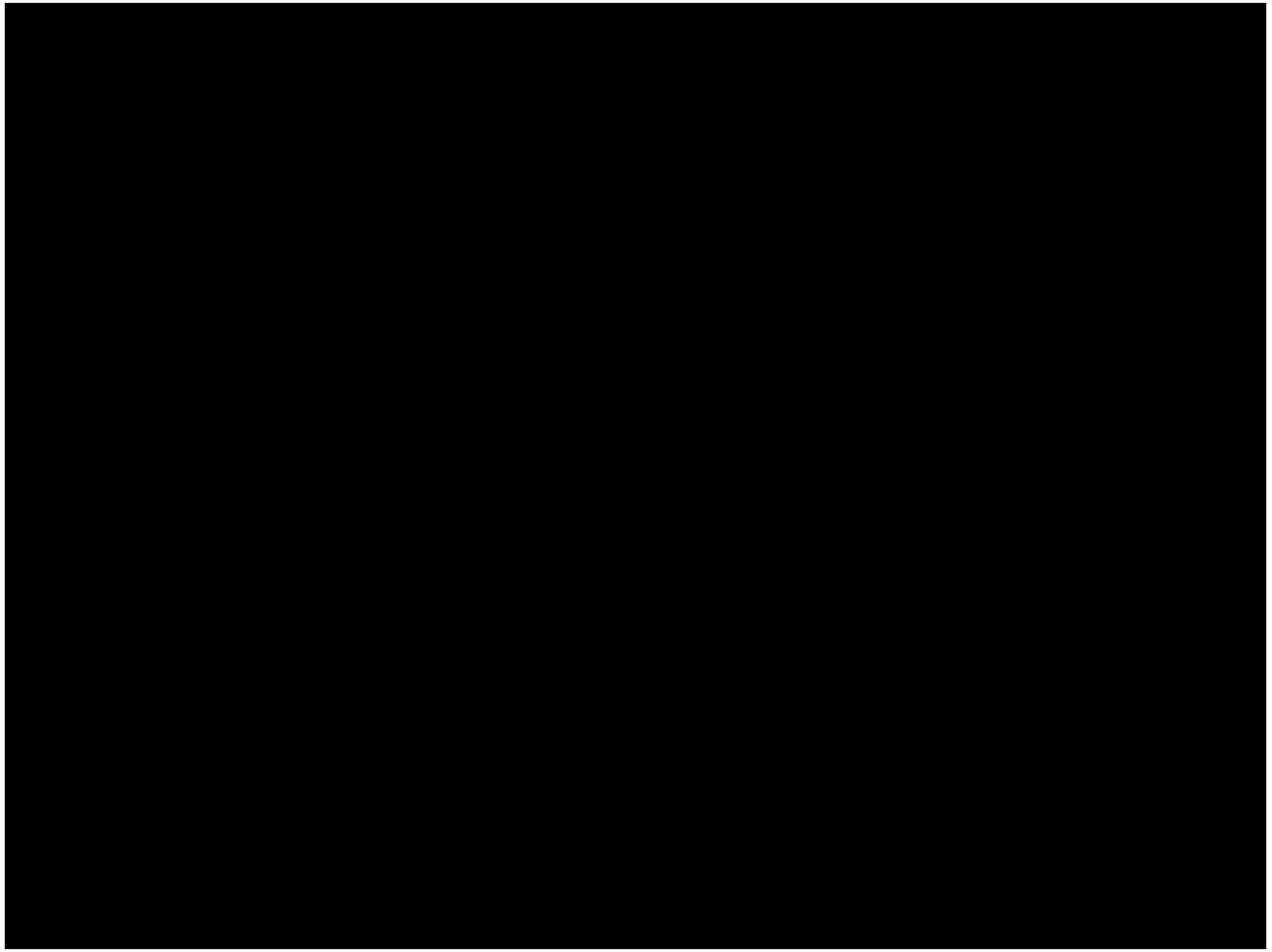
Advantages of the new system

1. Haptic sensation, 3D stereo vision, ergonomic and easy-to-use console
2. Access to the patient is always secured due to the independent arms
3. Optimal for any endoscopic procedure and access from every needed angle

Advantages of the new system (cont.)

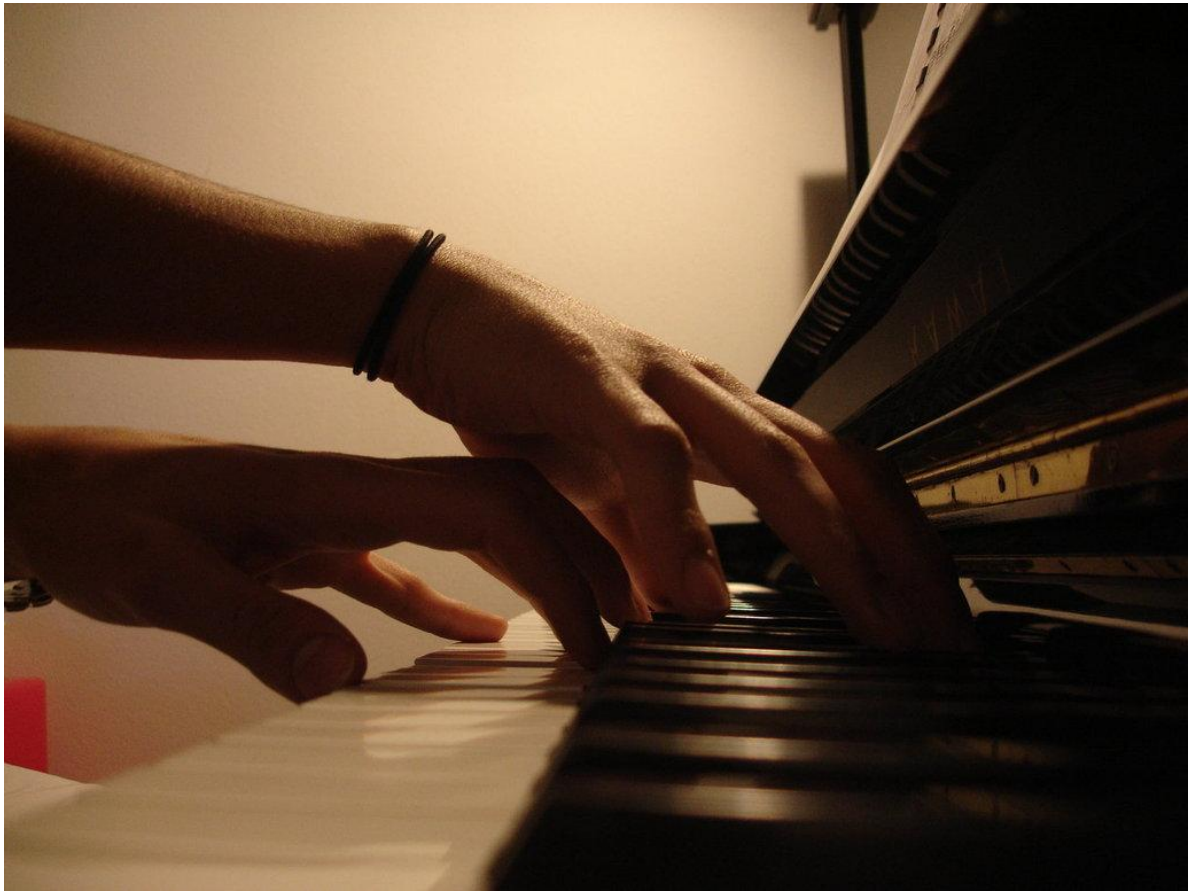
4. Fast docking
5. Cost-effectiveness: multi-disciplinarity and low costs due to the possible instruments reusability

Advantages of the new system (cont.)



Assistant-friendly

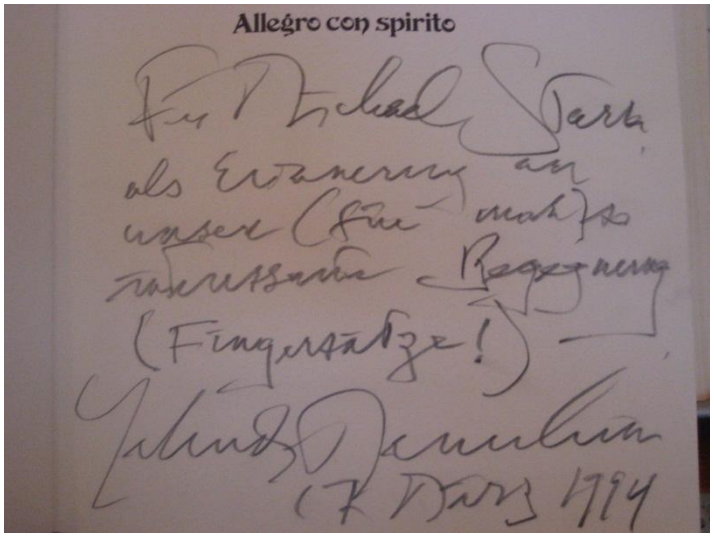
The importance of haptic sensation



The importance of haptic sensation (cont.)

The importance of haptic sensation (cont.)

The importance of haptic sensation (cont.)



The importance of haptic fingertip sensation (cont.)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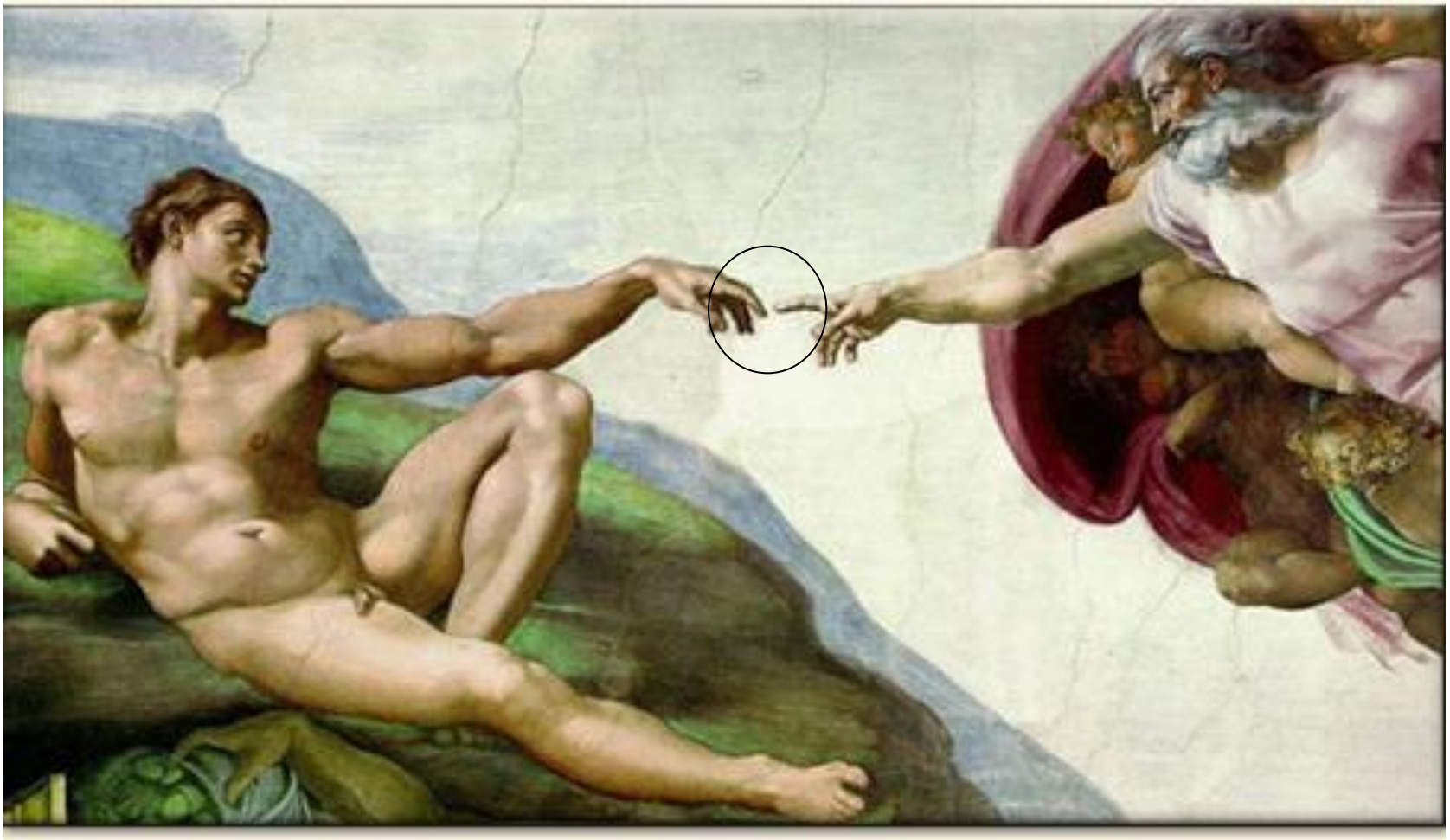
The renaissance of abdominal surgery:
Back to the Fingertips!



Main features of the Telelap Alf-x:

- Extremely short response time < **30 msec**
- High sensitivity: **35 g**
- Motion scale: **1:1**
- Force feedback scale: **1:1**

Main features of the Telelap Alf-x:

Remote controlling & haptic sensation

The advantages of tactile sensing

- Tissues are palpable: useful to find hidden lesions, estimate their density and consistency.

- Control of the force exerted while stitching and tying knots, preventing tearing of the sutures, damage to tissues and unnecessary bleedings.

Safety Through Force Control

- No over-extension of the entry site. The point of trocar entry is recognized as the axis to all instruments' movements.

- Limiting or stopping motion when exceeding programmed force thresholds

Eye-tracking system

1. Zoom function by approaching/retracting the head
2. Any point the surgeon looks at moves to the center of the screen
3. 3D stereo vision – similar to the vision of open surgery

Eye-tracking system (cont.)

Eye-tracking system

Ease of use

- No need to change endoscopic habits
- Short adaptive time
- The system is used as a training tool

Universality

- Large range of standard reusable instruments
- Articulated tip instruments
- Any surgical instrument can be adapted to the system

Correspondence

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Journal of Gynecologic Oncology
jgo

Telesurgery is promising but still need proof through prospective comparative studies

To the editor: With great interest we read the article "Total laparoscopic hysterectomy versus da Vinci robotic hysterectomy: is using the robot beneficial?" by Soto et al. [1], which was published in your journal. The introduction of any new surgical system is expected to provide added value for existing ones, and we absolutely accept the conclusion of this excellent article that with experience a totally endoscopic hysterectomy still is superior to robotic surgery. Despite extensive work, telesurgery is probably still in its infancy. In our opinion, the main reason for the long operative time is the lack of haptic sensation and the reliance on visual force feedback.

There have been claims that the results of visual force feedback and haptic feedback are comparable [2]. In a novel European telesurgical system, the Telelap Alf-x, the lack of tactile feedback has been overcome, and the surgeon can accurately feel the tensility of the knots she/he ties, which makes the telesurgical endoscopic procedure as similar as possible to open surgery. In experimental surgeries that were performed to find out whether haptic sensation will influence the operation time, the average time for cholecystectomy using the Telelap Alf-x was 31.75 minutes as compared to 91 minutes using a conventional telesurgical system [3]. Haptic sensation probably contributed to the self-confidence of the surgeon, who was not dependent on visual force feedback only.

The Telelap Alf-x system is composed of 1 or 2 consoles and 3 or 4 long arms which enable abdominal or transdouglas access and to move freely around the patient during the surgery. The console supplies open 3D sight and is equipped with an eye-tracking system which moves any point that is looked at to the centre of the screen and instruments are activated by looking at the respective icon. The system stops movement when the surgeon's eyes are not fixed at the screen. All instruments are quickly attached to the arms by magnets and detect the pivot point on the fascia automatically to avoid extension of the incision. The instruments are reusable, and 1:1 haptic feedback is transmitted from the tip of the instrument to the surgeon's fingers when pushing or pulling, enabling to feel tissue consistency and the tension when knotting sutures.

Despite the promising data resulting from our preliminary studies, we insist that telesurgery should have defined indications and should not be used unless prospective comparative studies have proven its superiority over conventional endoscopy.

CONFLICT OF INTEREST

M. Stark is a scientific director of the EU-SOFAR telesurgical project. E. R. Morales is a director of robotic department of SOFAR. S. Gidaro is a surgical consultant of robotic department of SOFAR.

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1. Soto E, Lo Y, Friedman K, Soto C, Nezhat F, Chuang L, et al. Total laparoscopic hysterectomy versus da Vinci robotic hysterectomy: is using the robot beneficial? J Gynecol Oncol 2011;22:253-9.
2. Reiley CE, Akinbiyi T, Burschka D, Chang DC, Okamura AM, Yuh DD. Effects of visual force feedback on robot-assisted surgical task performance. J Thorac Cardiovasc Surg 2008;135:196-202.
3. Jayaraman S, Davies W, Schlachta CM. Getting started with robotics in general surgery with cholecystectomy: the Canadian experience. Can J Surg 2009; 52:374-8.

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Optimised meta-analysis should be based on standardised methods

"Only standardized and optimized surgical methods will allow valuable meta-analysis and enable a comparison of surgical outcome in different institutions and by different surgeons."

Stark M. BJOG. 2011;118(6):765-6.

Surgical logbook

ELSEVIER

THE JOURNAL OF
MINIMALLY INVASIVE
GYNECOLOGY

Special Article

The Importance of Analyzing and Standardizing Surgical Methods

Michael Stark, MD*, S. Gerli, MD, and G. C. Di Renzo, MD, PhD

From the New European Surgical Academy (NESA) and the HELIOS Hospital Group, Berlin, Germany (Dr. Stark), and the Department of Obstetrics and Gynecology, University Hospital Monteluce, Perugia, Italy (Drs. Gerli and Di Renzo).

ABSTRACT The outcome of operations performed in different institutions or by different surgeons can hardly be compared if the operative methods are not standardized. Six different vaginal hysterectomy methods were studied. The steps common in all of them were defined. These steps were analyzed for optimal performance and sequence during the operation. The resultant modified method was subjected to a prospective randomized study, which showed that the operation time and the need for pain drugs were reduced. This method was introduced to several departments in different countries. The optimization and standardization of surgical methods are expected not just to improve the postoperative outcome, but also to enable a comparison between different departments and surgeons. Journal of Minimally Invasive Gynecology (2009) 16, 122–125

Keywords: Vaginal hysterectomy; Surgery; Hysterectomy; Vaginal surgery; Vaginal prolapse; Surgical technique; Surgical method

Surgical logbook

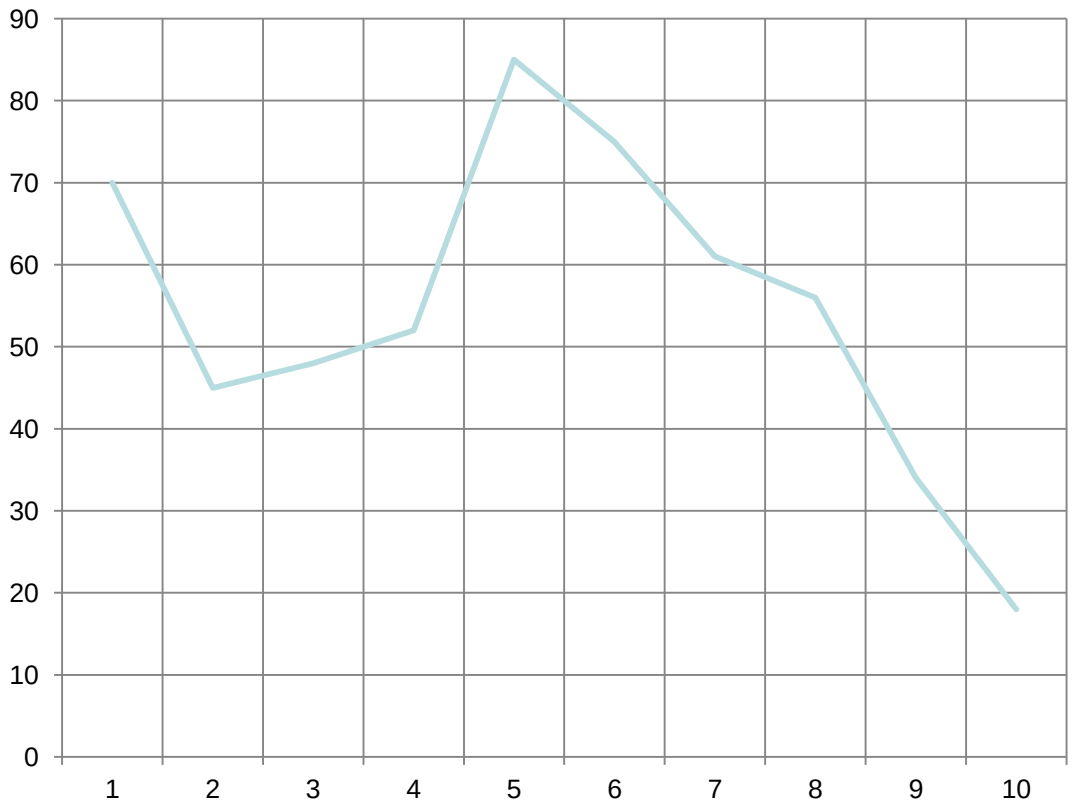
Therefore, the system is introduced together with a suggested optimal surgical logbook designed by opinion leaders in general surgery, gynaecology, urology, etc.

The completed preclinical results: Total Nephrectomy – Learning curve

Table 1. Operation Times and Blood Loss in Experimental Nephrectomies

No.	Operation time (minutes)	Blood loss (ml)	SIDE
1	70	< 20	L
2	45	< 20	R
3	48	< 20	L
4	52	< 20	R
5	85	< 20	R
6	75	< 20	R
7	61	< 20	R
8	56	< 20	R
9	34	< 20	L
10	18	< 20	R

The completed preclinical results: Total Nephrectomy – Learning curve



The completed preclinical results: Cholecystectomy

Number of procedures	Number of arms used Described system	Average operation time (min) Described system	Median operation time (min) Conventional telesurgical system
4	**3**	**31.75 (30-35)**	**91**

Stark M, Gidaro S. Ruiz Morales E. The future of gynaecological surgery - telesugery with haptic sensation. Gineco.ro, 2011, 7(26): 210-3.

The completed preclinical results: Partial nephrectomy

Number of procedures	Number of arms used Described system	Average operation time (min) Described system	Median operation time (min) Conventional telesurgical system
2	**3**	**115 (110-120)**	**140**

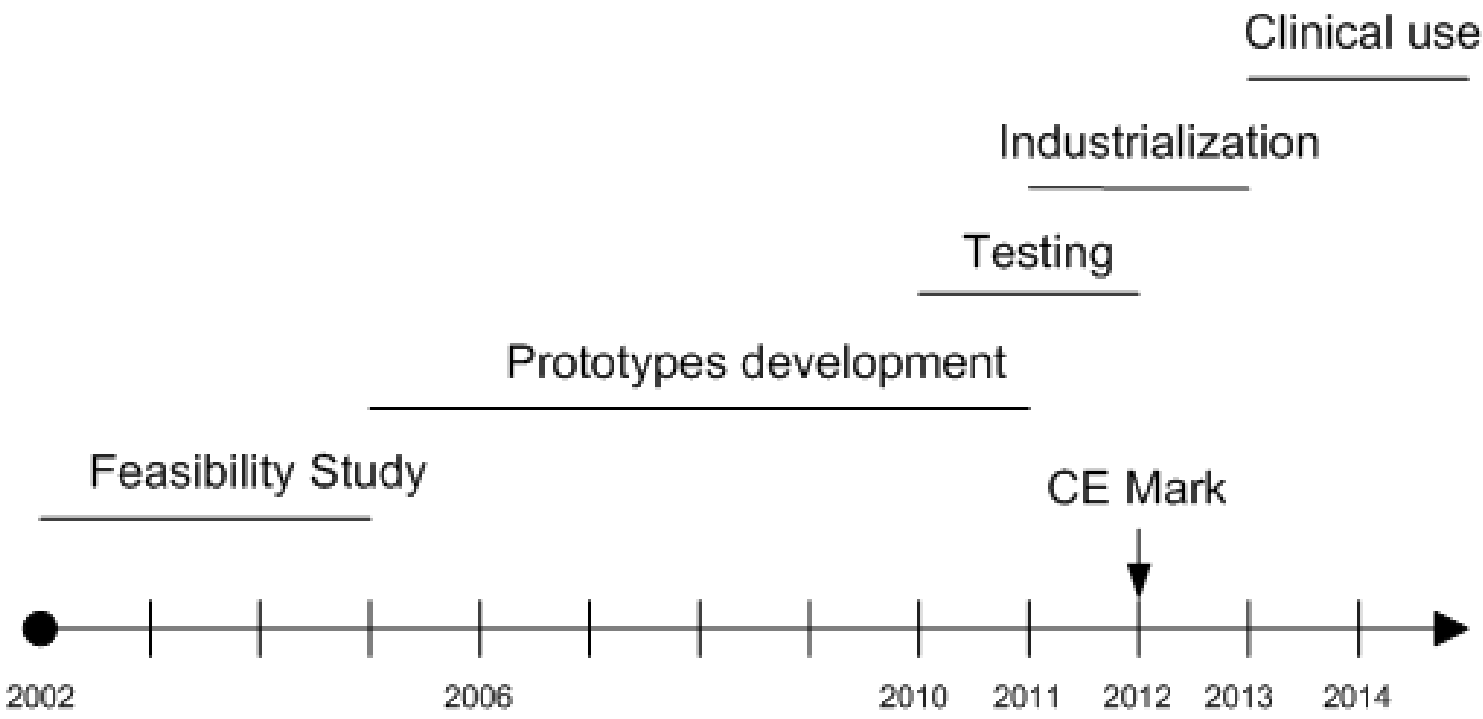
Stark M, Gidaro S. Ruiz Morales E. The future of gynaecological surgery - telesugery with haptic sensation. Gineco.ro, 2011, 7(26): 210-3.

The completed preclinical results: Total Nephrectomy

Number of procedures	Number of arms used Described system	Average operation time (min) Described system	Average estimated blood loss (ml) Described system	Average operation time (min) Endoscopy
4	**3**	**53.75 (45-70)**	**< 20**	**75.7**

Stark M, Gidaro S. Ruiz Morales E. The future of gynaecological surgery - telesugery with haptic sensation. Gineco.ro, 2011, 7(26): 210-3.

Telelap Alf-x - History
CE mark and clinical use

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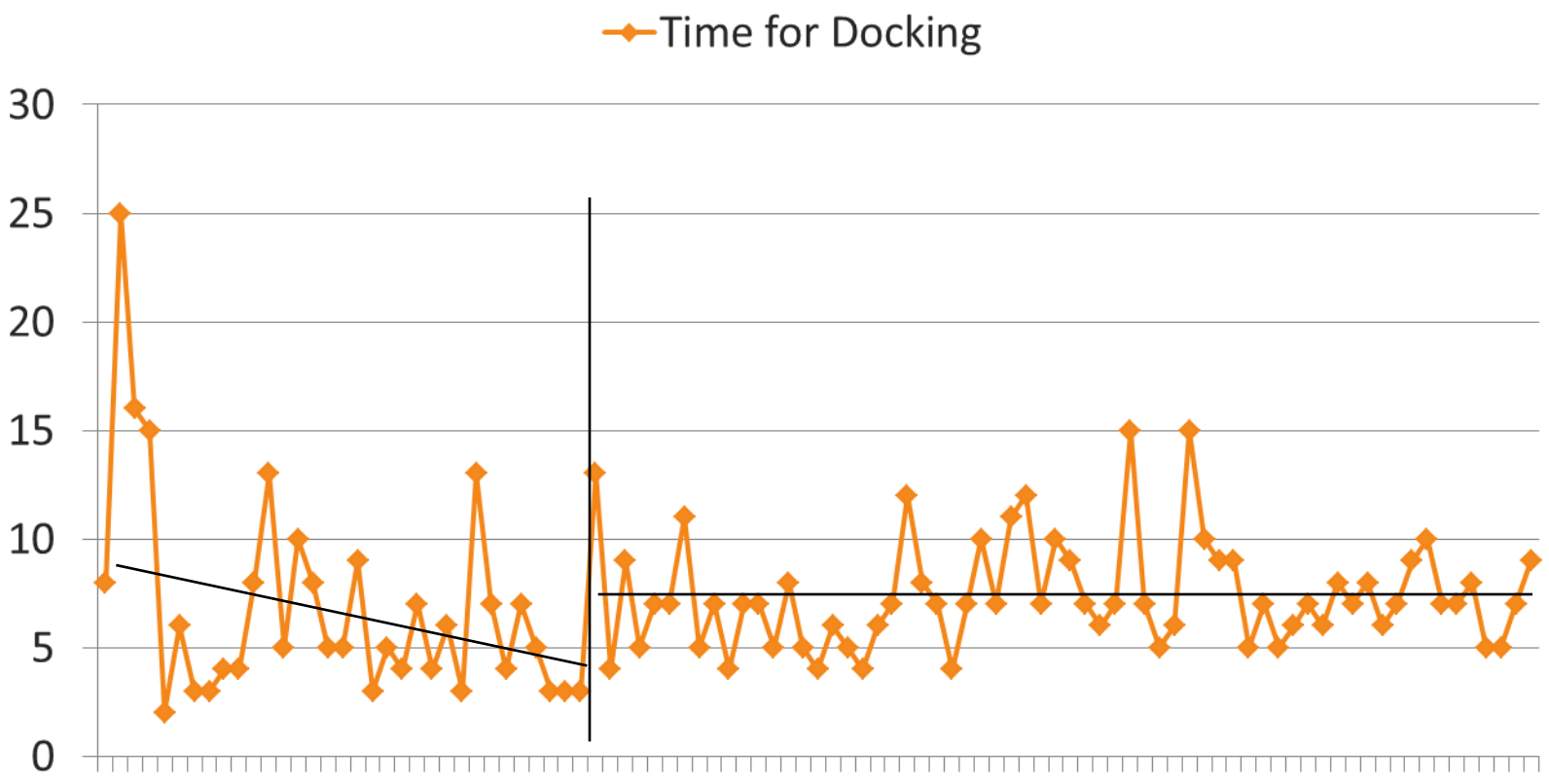
Telelap Alf-x - Docking
Quick time for docking: first 97 cases

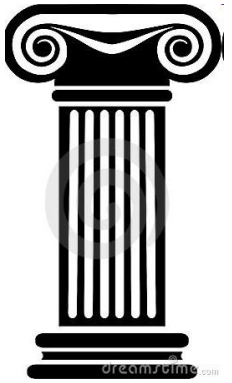


Telelap Alf-x – Clinical study
28-02-2014

97 procedures in gynecology

Surgical procedure	Amount
• Ovarian Cyst (enucleation/ovariectomy)	46
• Prophylactic bilateral salpings-oophorectomy	10
• Ectopic pregnancy salpingotomy	0
• Ectopic pregnancy salpingectomy	0
• Infertility and sterility (endometriosis treatment, chromosalpingography)	0
• Myomectomy (single)	3
• Myomectomy (multiple)	0
• Total hysterectomy with bil adnexectomy	37
• Total hysterectomy without adnexectomy	11
• Radical Hysterectomy	1
• Eradication of Pelvic endometriosis	1
• Salpingectomy for Tubal inflammatory pathologies	0
• Lymphadenectomy pelvic	10
• Lymphadenectomy aortic	0

The Telelap Alf-X simulates open surgery while operating endoscopically. Therefore, it is expected to bring about a renaissance of abdominal surgery.



Registry

All surgeries that are performed are monitored by a central (voluntary) registry in Berlin for the exchange of information, avoidance of complications, statistics and publications.

European certification

In January 2012, the Telelap Alf-x was approved for clinical use in Europe. The first clinical usage started at the Gemelli University Hospital, Rome in November 2013.

The first 100 gynecological operations performed using the Telelap Alf-X

Despite lack of experience, the overall mean docking time of the Telelap Alf-x was 6.2 min in the first 20 cases, as compared to 6.4 min in an existing system[1].

[1]Iranmanesh P et al. Docking of the da Vinci Si Surgical System® with single-site technology. Int J Med Robot. 2013;9(1):12-6.

The first 100 gynecological operations performed using the Telelap Alf-X

The performed operations:
adnexal masses, hysterectomies

Overall average surgical procedure time in the first 20 operations:
75 minutes

These numbers are improving constantly.

The advantages of modularity

Thank you for listening.