Montefiore
THE UNIVERSITY HOSPITAL

EINSTEIN
Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY

Robots to 2020:
Robotic Resection for Rectal Surgery

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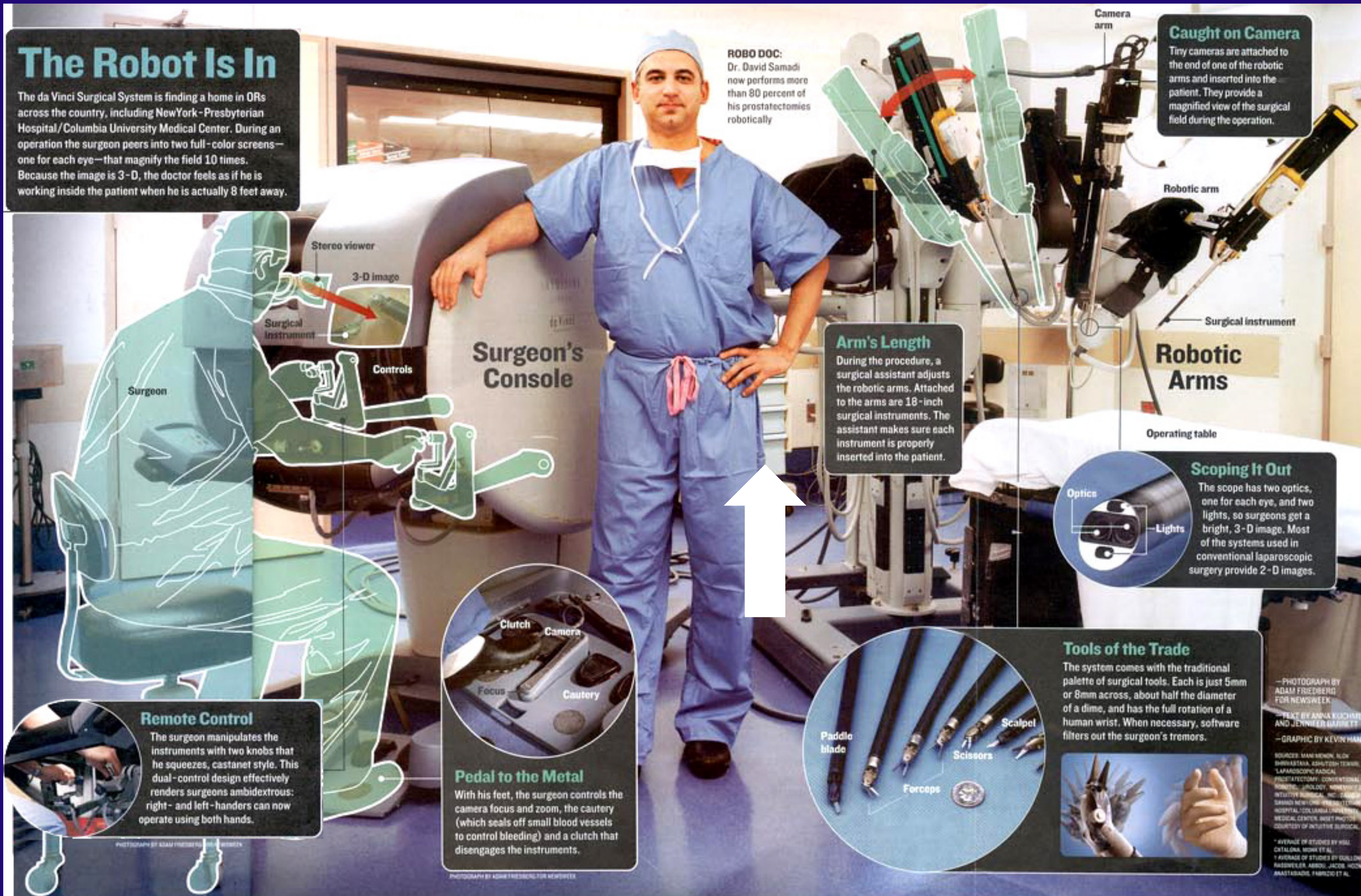


The Robot Is In

The da Vinci Surgical System is finding a home in ORs across the country, including NewYork-Presbyterian Hospital/Columbia University Medical Center. During an operation the surgeon peers into two full-color screens—one for each eye—that magnify the field 10 times. Because the image is 3-D, the doctor feels as if he is working inside the patient when he is actually 8 feet away.

ROBO DOC: Dr. David Samadi now performs more than 80 percent of his prostatectomies robotically

Caught on Camera

Tiny cameras are attached to the end of one of the robotic arms and inserted into the patient. They provide a magnified view of the surgical field during the operation.

Arm's Length

During the procedure, a surgical assistant adjusts the robotic arms. Attached to the arms are 18-inch surgical instruments. The assistant makes sure each instrument is properly inserted into the patient.

Scoping It Out

The scope has two optics, one for each eye, and two lights, so surgeons get a bright, 3-D image. Most of the systems used in conventional laparoscopic surgery provide 2-D images.

Remote Control

The surgeon manipulates the instruments with two knobs that he squeezes, castanet style. This dual-control design effectively renders surgeons ambidextrous: right- and left-handers can now operate using both hands.

Pedal to the Metal

With his feet, the surgeon controls the camera focus and zoom, the cautery (which seals off small blood vessels to control bleeding) and a clutch that disengages the instruments.

Tools of the Trade

The system comes with the traditional palette of surgical tools. Each is just 5mm or 8mm across, about half the diameter of a dime, and has the full rotation of a human wrist. When necessary, software filters out the surgeon's tremors.

—PHOTOGRAPH BY ADAM FRIEDBERG FOR NEWSWEEK
—TEXT BY ANNA KUCHMENT AND JENNIFER BARRETT
—GRAPHIC BY KEVIN HAND

Newsweek Dec 4, 2005

Mr. Firas Younis, UK

Robotic surgery

Robotic surgery

The new system “da Vinci SI HD”

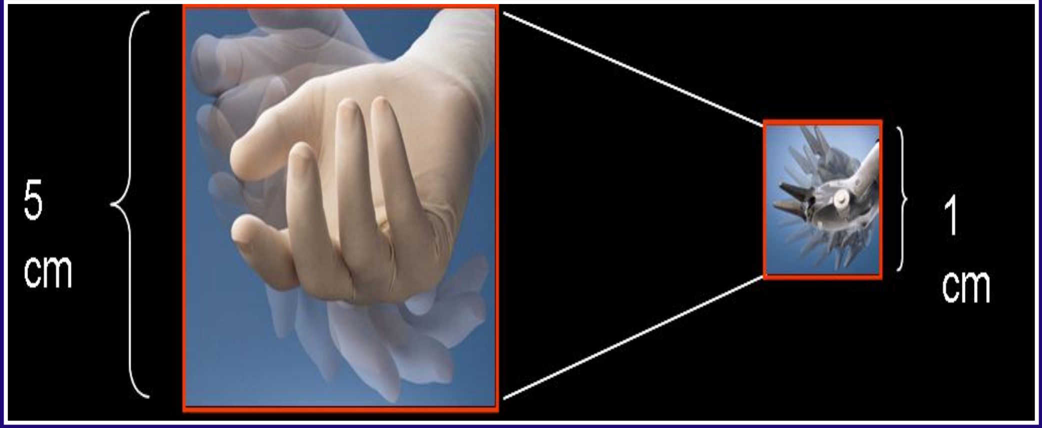
OVERCOMES LAPAROSCOPIC PITFALLS

- 3D / HD vision
- Fine dissection
- Deep, small operating fields
- High precision suturing
- Easier setup
- Tutoring

Robotic surgery

ENDO-WRIST ™ SYSTEM

- 6 degrees of freedom
- Tremor elimination
- Motion scaling



A Fool with a Tool is still a Fool

~ Grady Booch

Robotic Rectal Surgery – Hope or Hype?

The New York Times

THE CONSUMER | SEPTEMBER 9, 2013, 5:15 PM | 87 Comments

New Concerns on Robotic Surgeries

By RONI CARYN RABIN

abc NEWS

Robo-Surgeries Attract FDA Scrutiny

Apr. 12, 2013

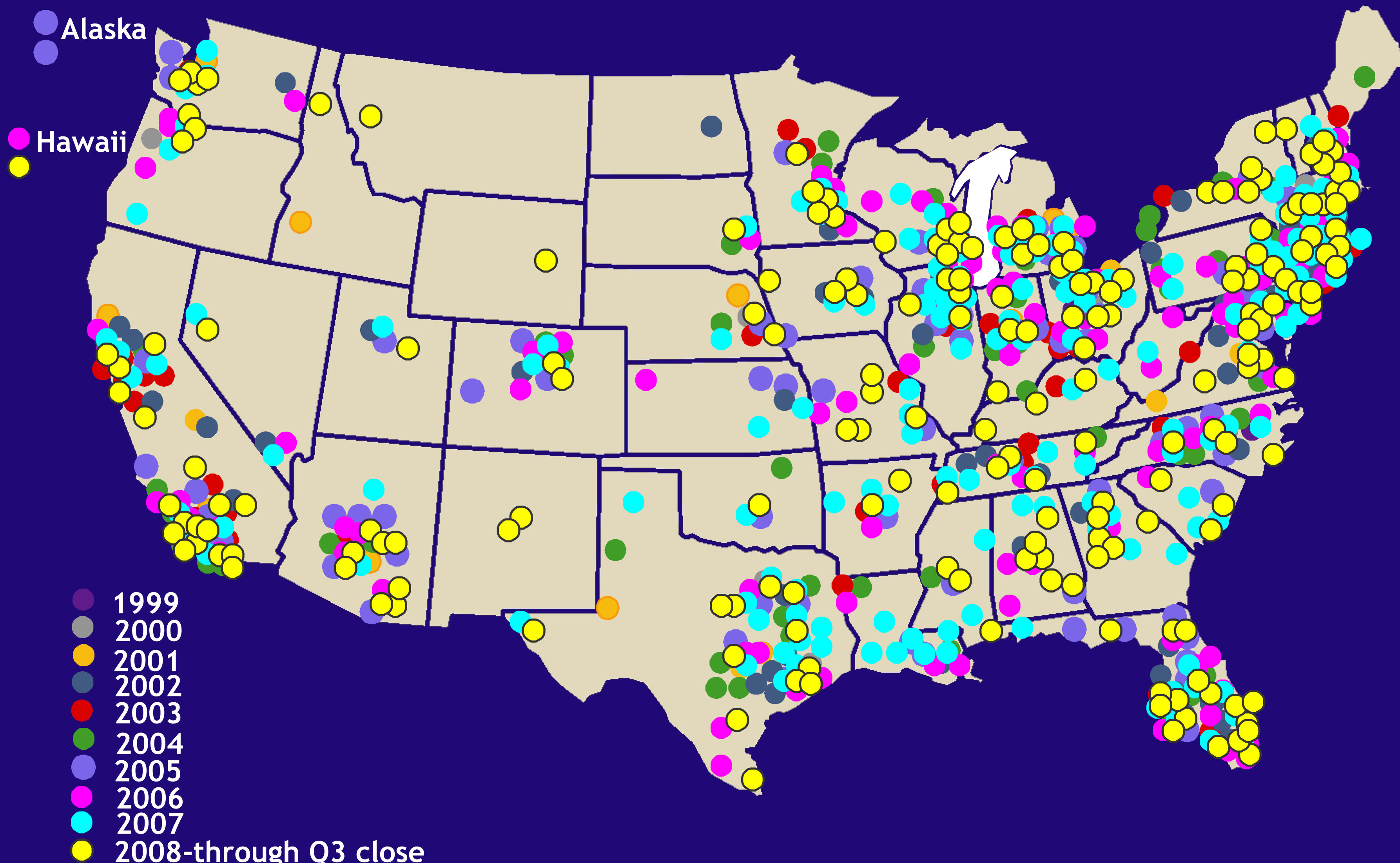
CNN

Would you have surgery at hands of a robot?

By **Nick Glass** and **Matthew Knight**, CNN
updated 5:18 AM EDT, Mon August 5, 2013 |

da Vinci ® Surgical System

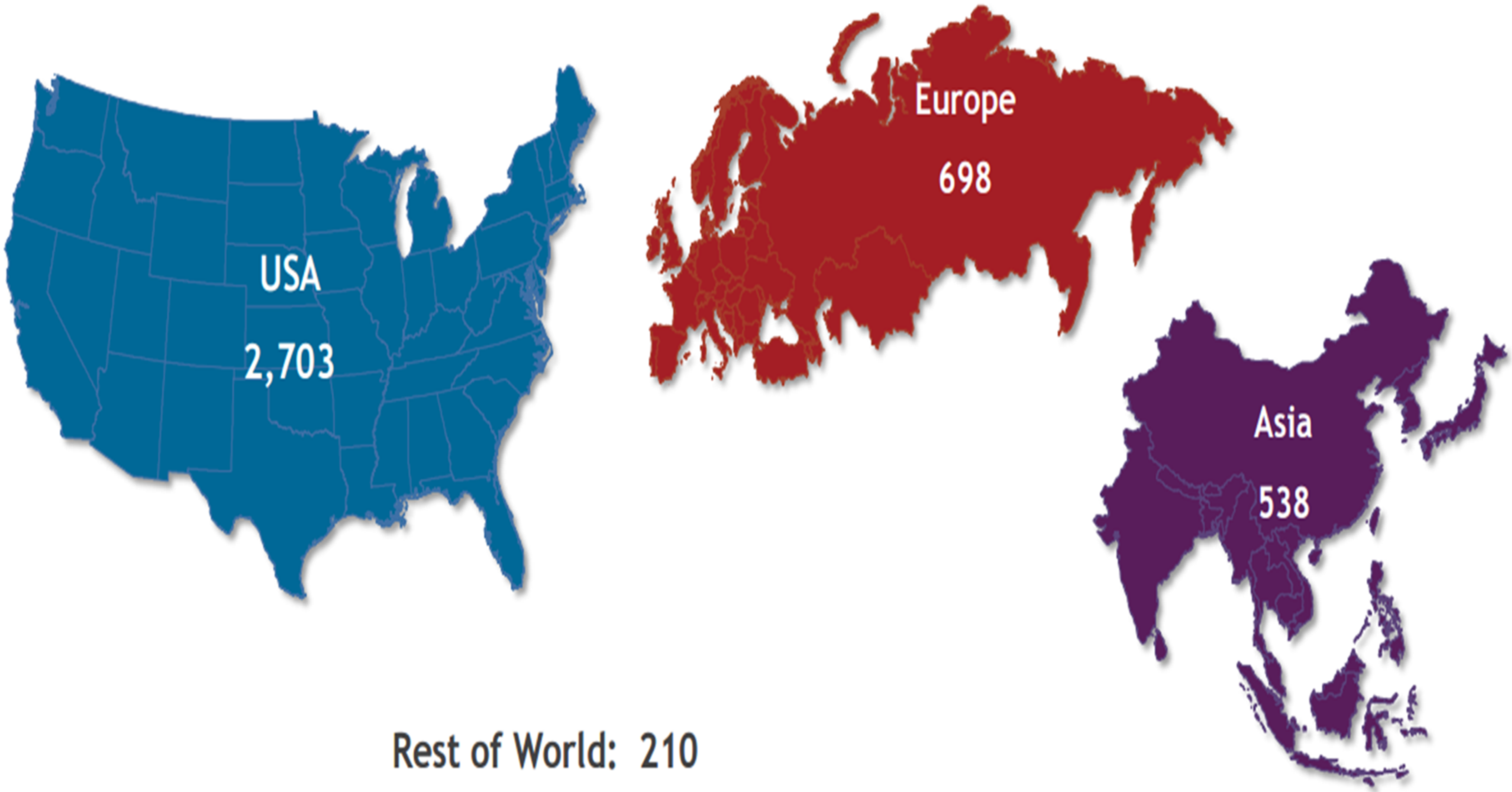
U.S. Installations 1999 – 2008



da Vinci System Installed Base

INTUITIVE SURGICAL®

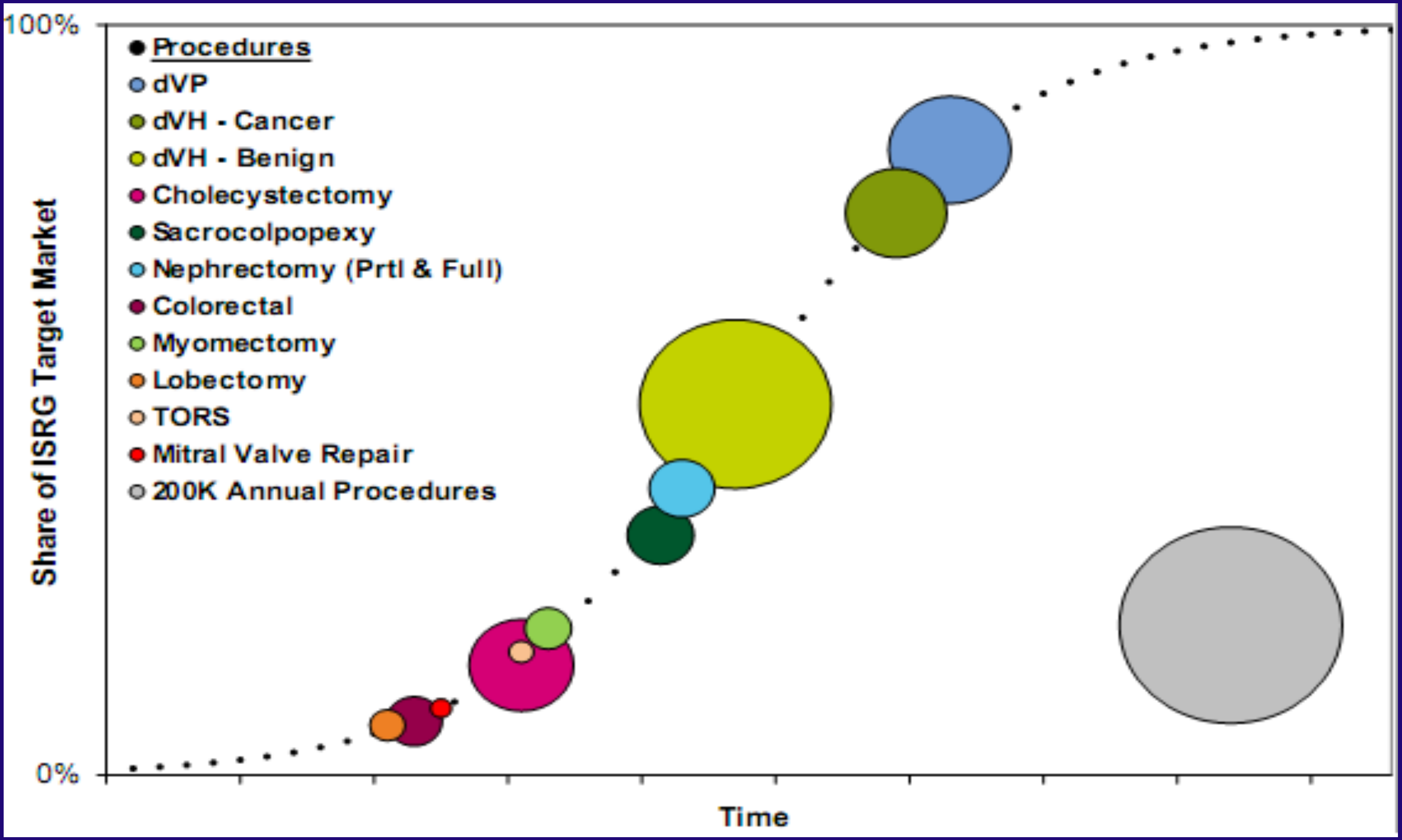
4,149 Worldwide as of June 30, 2017



Rest of World: 210

Source: Company reports

da Vinci ® Surgical Procedures
2013



http://investor.intuitivesurgical.com/

Financial Impact

Title	High	Low	Median	Cumulative Return	Annualized Return	Start Date	End Date
Intuitive Surg (ISRG) % Gr	82.95%	-3.78%	33.60%	81.72%	81.72%	11-16-2016	11-15-2017
Medical Instruments Market (ZSI103M) % Gr	21.58%	-3.76%	13.70%	20.07%	20.07%	11-16-2016	11-15-2017

Does the Robot Help with Rectal Surgery?

Challenges In Rectal Surgery

- **Angle of the Sacrum**
  - Narrow pelvis
  - Bulky mesorectum
  - Large tumor
  - Inadequate reach
  - Low rectal division
  - Obese patients
- **Upper abdominal dissection**
  - Splenic flexure mobilization
  - High ligation of the inferior mesenteric artery/vein

EARLY DATA

Robotic Colorectal Surgery
Early Case Series

Reference	Patients (n)
Weber 2002	2
Hashizume 2002	3
Vibert 2003	3
Giulianotti 2003	16
Brauman 2005	5
Ruurda 2005	23
Sebarjang 2006	7
De Noto 2006	11
Hellan 2007	39
Spinoglio 2008	50
Baek 2010	64

Robotic Colorectal Surgery Comparative Studies

Reference	Groups	Patients (n)
Delaney 2003	Lap/Robotic	6/6
Anvari 2004	Lap/Robotic	10/10
D'Annibale 2004	Lap/Robotic	53/53
Woeste 2005	Lap/Robotic	34/6
Pigazzi 2006	Lap/Robotic	6/6
Rawlings 2007	Lap/Robotic	30/27
Patriti 2009	Lap/Robotic	37/29
Baek 2011	Lap/Robotic	41/41
Kwak 2011	Lap/Robotic	59/59
Patel 2011	Lap/ Hand/Robotic	30/30/30
Bertani 2011	Open/ Robotic	34/52

Robotic rectal resection

Reported series

Author	Year	Refer.	Pts.	Op. time *(min)*	Conversion	Morbidity	Mortality
D'Annibale*	2004	Dis Colon Rectum	53	240	9.4%	15%	0
Hellan	2007	Ann Surg Oncol	39	285	2.6%	12.1%	0
Baik	2008	Surg Endosc	9	220.8	0	0	0
Spinoglio*	2008	Dis Colon Rectum	50	338.8	4%	14%	0
Choi	2009	Surg Endosc	13	260.8	0	23%	0
Luca*	2009	Ann Surg Oncol	55	290	0	12.7%	0

** Including colonic resections*

Challenges In Rectal Cancer

- OUTCOMES!
- Lymph Node Yield
- Margins
- Total Mesorectal Excision (TME)

Robotic vs. Laparoscopic TME

Early Comparative Study

- 53 Robotic vs. 53 Laparoscopic
- Case matched

- **No advantages:**

Specimen length
Lymph nodes retrieved
Surgery time
Conversion rate
Length of stay
Return of bowel function
Complication rate

D'Annibale, Dis Colon Rectum 2004

Open vs. Robotic TME
Prospective Data

- 34 Open vs. 52 Robotic (by surgeon preference)
- 15-month period

- Overall morbidity rates: **No advantages**
- Number of lymph nodes: **No advantages**

Bertani et al. Int J Colorectal Dis 2011

Robotic vs. Laparoscopic TME
Comparative Study

- 29 Robotic vs. 37 Laparoscopic
- No advantages:
  - Blood loss
  - Complication rate
  - Lymph nodes retrieved
  - Distal margin
  - Recurrence rate (12 month follow-up)
- ↑ Operative time:
  - 165 min Lap vs. 210 min Robotic ($p < 0.05$)

Patriti, JSLS 2009

Robotic vs. Laparoscopic TME

Case-matched

	Robot = 41 n (%)	Lap = 41 n (%)	*p*
Median distal margin (cm)	3.6 (0.4-10)	3.8 (0.4-11)	0.66
Positive circumferential margin	1 (2.4)	2 (4.9)	0.99
Mean number of lymph nodes	13.1 (3-33)	16.2 (5-39)	0.07
Mean operative time (min)	296 (50-520)	315 (74-584)	0.35
Conversion	3 (7.3)	9 (22)	0.11
Mean time liquid diet (days)	2.3 (1-13)	2.4 (1-9)	0.73
Mean LOS (days)	6.5 (2-33)	6.6 (3-20)	0.87
Complications	5 (12.2%)	2 (4.9%)	0.20
Anastomotic Leak	3	1	
Abscess	2	1	
Mortality	0	0	

NO ADVANTAGE

Baek et al. Surg Endosc 2011

Robotic vs. Laparoscopic TME

Prospective

	Robotic (59)	Lap (59)	*p*
Median operation time (min)	270 (241–325)	228 (177–254)	<.0001
Median no. of retrieved LNs	20 (12–27)	21 (14–28)	0.70
Positive circumferential margin (%)	1 (1.7)	0 (0.0)	0.99
Median distal resection margin (cm)	2.2 (1.5–3.0)	2.0 (1.2–3.5)	0.86
Postoperative morbidity	14	10	0.35
Anastomotic leak	8 (13.6)	6 (10.2)	0.61
Surgical site infection	1 (1.7)	0 (0.0)	0.99
Anastomotic bleeding	4 (6.8)	0 (0.0)	0.12
Respiratory	1 (1.7)	0 (0.0)	0.99
Others	0 (0.0)	4 (6.8)	0.12

DISADVANTAGE

Kwak JM et al. Dis Colon Rectum 2011

Laparoscopic vs. Open vs. Robotic TME: Prospective

	Open (88)	Lap (123)	Rob (52)	*p*
Mean operating time (min)	233.8 (59.2)	158.1 (49.2)	232.6 (52.4)	<0.001
Flatus passage (days)	4.4 (3.0)	3.0 (1.1)	3.2 (1.8)[a]	<0.001
Morbidity (%)	18 (20.5)	15 (12.2)	10 (19.2)	0.229
Hospital stay (days)	12.8 (7.1)	9.8 (3.8)	10.4 (4.7)[a]	<0.001
Proximal margin (cm)	12.4 (6.6)	16.9 (8.4)	16.5 (6.0)	<0.001
Distal margin (cm)	2.3 (1.5)	3.2 (2.1)	2.8 (1.9)	0.002
Circumferential margin (mm)	8.5 (5.7)	8.2 (5.8)	7.9 (4.5)	0.89
Retrieved LN (n)	18.5 (10.9)	15.9 (10.1)	19.4 (10.2)	0.06

DISADVANTAGE

Park JS et al.Surg Endosc 2011

Robotic vs. Laparoscopic vs. Hand-assisted Colon and Rectal Resections - Case-Matched

	Lap (n=30)	Hand (n=30)	Rob (n=30)	*p*
Intraoperative Parameters				
Operative time (min)	181.6±52.5	158.3±51.0	237±56.8	<*.02*
Blood Loss (mL)	129.4±108.3	149.1±122.0	100.8±48.5	NS
Pathology outcomes (malignant cases only)				
Lymph nodes	20.9+13.0	16.3+6.9	17.3+5.4	NS
Postoperative Outcomes				
Complications	3 (10%)	4 (13.3%)	4 (13.3%)	NS

DISADVANTAGE

Patel et al. DCR 2011

Laparoscopic vs. Robotic TME
Randomized Control Trial (Pilot)

	Robotic (n=18)	Lap (n=18)	*p*
Operative time (min)	217	204	0.48
Ileus (days)	1.8	2.4	0.07
Hospital stay (days)	6.9	8.7	0.001
Lymph nodes	20.0	17.4	0.44
Proximal margin (cm)	10.9	10.3	0.55
Distal margin (cm)	4.0	3.7	0.47
Macroscopic completeness	17	13	0.368

Baik et al. Surg Endosc 2008

Laparoscopic vs. Robotic TME
Meta-Analysis of Short Term Outcomes

- Systematic review, meta-analysis of 8 trials
- 344 robotic vs 510 laparoscopic rectal cancer procedures
- Decreased conversion to open in the robotic group (p=0.0007)
- No difference in OR time, hospital stay, morbidities

Trastulli et al. Colorectal Dis 2012

How Much $$

Laparoscopic vs Robotic Colorectal Surgery Costs

- Premier Perspective Database study
  - Large hospital-based US database
  - 17,265 laparoscopic vs 744 robotic colorectal resections
  - Study period: 2009 and 2011
  - Colonic and rectal cases included
    - Similar findings for both groups

Keller et al. Surg Endosc 2013

Laparoscopic vs Robotic Colorectal Surgery Costs

Outcome variables	LAP (N = 17265)	RALR (N = 744)	Difference	p value
	Mean	Mean		
Hospitalization cost	$16,350	$21,622	–$5,272	<0.001
Room and board	$5,470	$6,095	–$624	0.0183
Central supply	$3,073	$5,155	–$2,082	<0.001
Surgery	$3,645	$4,875	–$1,230	<0.001
Anesthesia	$559	$520	$39	0.0959
Pharmacy	$1,372	$1,791	–$419	<0.001
Laboratory	$400	$560	–$160	<0.001
Other	$1,939	$2,772	–$833	<0.001

- **All costs higher, no clinic advantages of robot**

Keller et al. Surg Endosc 2013

Cost (US)
Laparoscopic vs. Robotic

Delaney *et al.* 2003

- ↑ Total hospital costs
- $2946 Laparoscopic vs. $3722 Robotic

Rawlings *et al.* 2007

- ↑ Total operating room costs
- ↑ OR personnel costs
- ↑ OR supply costs
- ↑ OR time costs

Cost
European (€) Robotic Colectomy

	Open	Laparoscopic	Robotic
Diagnostic costs	547	547	547
Histology processing	145	145	145
Drugs and O.R. materials	483	483	483
Disposable materials	1,694	2,066	3,166
Robot depreciation charge	0	0	914
Hospital stay	3,625	2,750	3,000
O.R. indirect costs	795	1,128	1,011
Personnel costs	599	849	761
Total	7,888	7,968	10,027

DISADVANTAGES

Bertani et al.Int J Colorectal Dis 2011

Cost
European (€) Robotic TME

	Open	Robotic
Diagnostic costs	547	547
Histology processing	145	145
Drugs and O.R. materials	483	483
Disposable materials	2,511	3,140
Robot depreciation charge	0	914
Hospital stay	4,500	3,500
O.R. indirect costs	954	1,417
Personnel costs	718	1,067
Total	9,858	11,214

DISADVANTAGES

Bertani et al. Int J Colorectal Dis 2011

Easy To Learn?

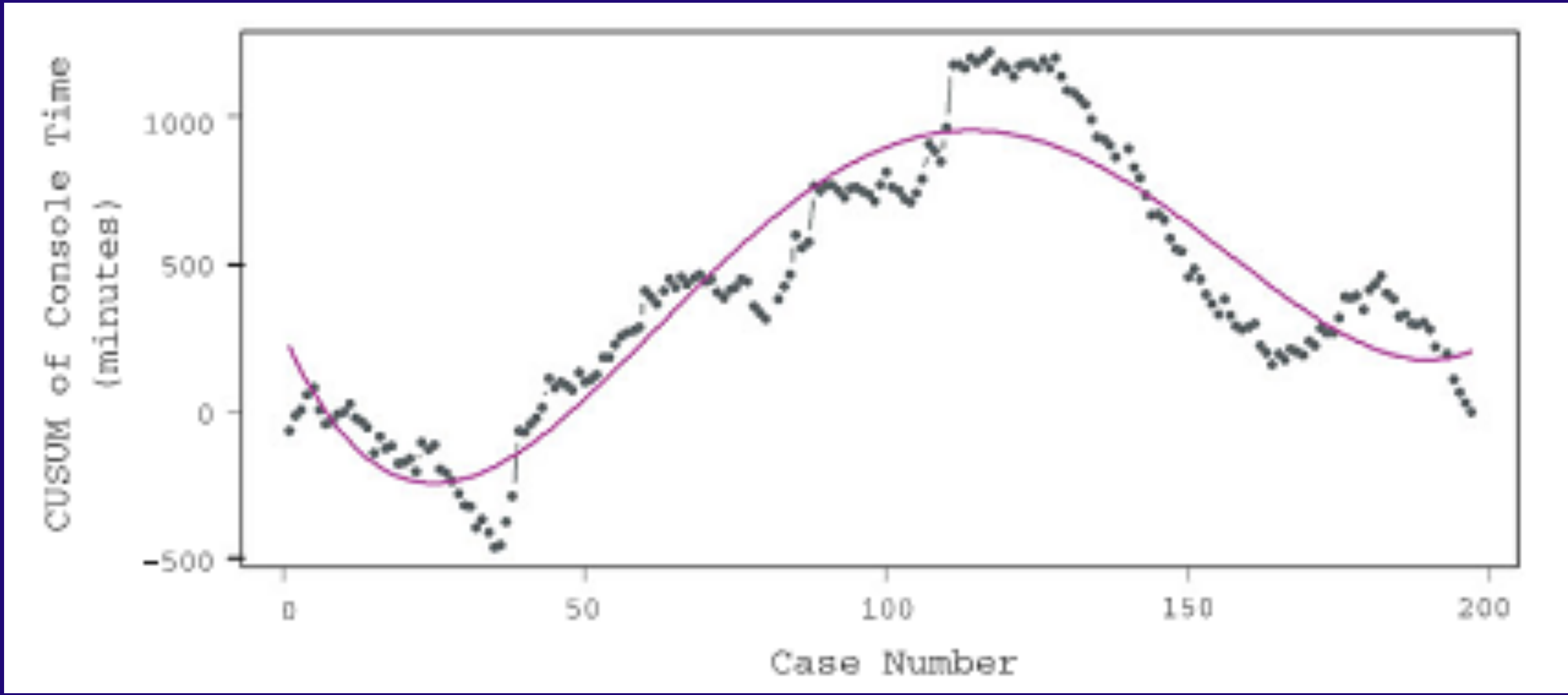
Learning Curve of Robotic Rectal Surgery

- Multiphasic learning curve
  - Initial learning phase – 35 patients
  - Second phase, more challenging cases – 93 patients
  - Concluding phase – 69 patients

- Docking time learning curve – 35 patients

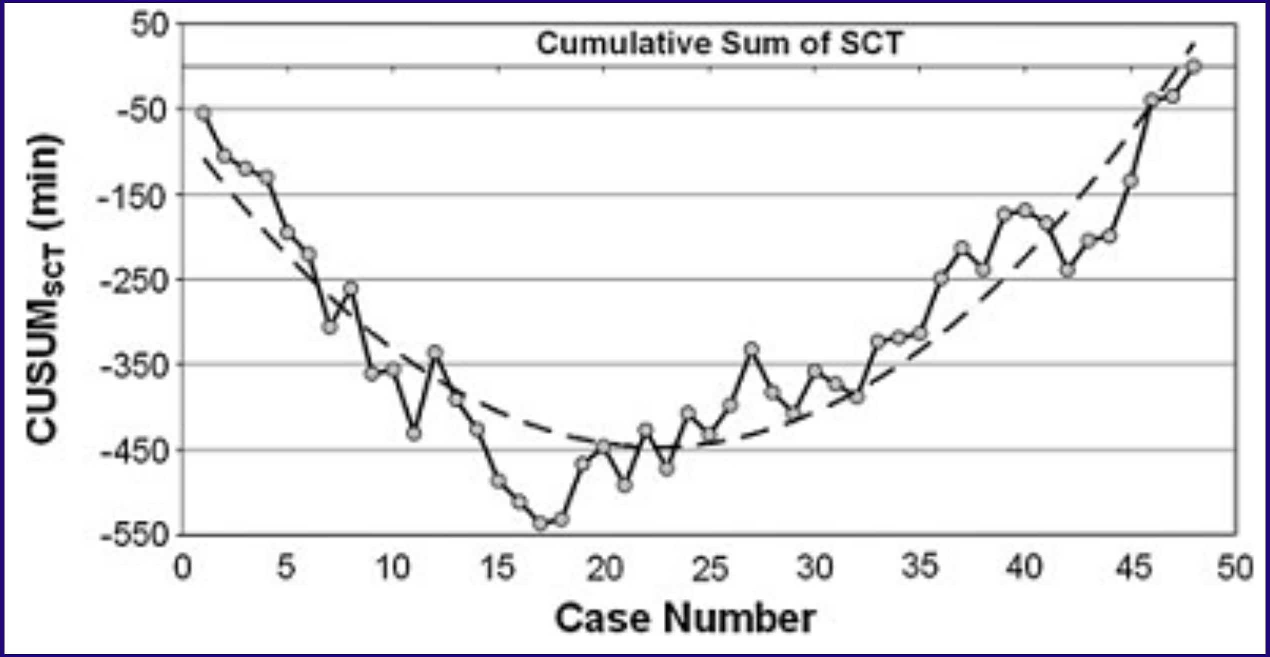
Sng et al. Surg Endosc 2013

Learning Curve of Robotic Rectal Surgery



Sng et al. Surg Endosc 2013

Learning Curve for Left-Sided and Pelvic Robotic Colorectal Surgery



- “Mastery phase” of learning reported after only 25 cases
  - CUSUM analysis of console time

Bokhari et al. Surg Endosc 2011

Learning Curve for Robotic Rectal Surgery is Unclear

- Experienced laparoscopic single surgeon experience with robotic TME
  - First 40 cases compared to next 40 cases
  - No learning curve demonstrated (OR time)
    - Interpretation – technique is quickly adopted OR learning curve longer than 80 cases?

Akmal et al. Surg Endosc 2012

Robotic Surgery – Short Term Outcomes are Affected by Provider/Hospital Volumes

- National inpatient database review over 18 month period

- 1428 robotic colorectal cases

- Volume of surgery defined as low, medium, or high:
  - Hospital - <10, 11-20, >20 cases
  - Surgeon - <5, 6-15, >15

Keller, Hashemi, Lu, Delaney. JACS 2013

Robotic Surgery Outcomes – Volume of Surgery

- Majority of robotic colorectal surgery performed in low volume practices:
  - 71% of cases at low volume hospitals
  - 84% of cases by low volume surgeons

- **Low volume associated with higher patient costs (vs high volume)**
  - **$23,667 vs $17,515 ($p<0.0001$)**

Keller et al. JACS 2013

Robotic Surgery Outcomes – Volume of Surgery

- Low volume associated with more complications:
  - Overall complications ($p<0.0009$)
  - Hemorrhage ($p=0.0005$)
  - Ileus ($p=0.0031$)

- Longer length of stay in low volume hospitals ($p=0.0053$)

Keller et al. JACS 2013

Robotic Surgery Outcomes – Conclusion of Study

"While surgeons and hospitals continue to selectively explore robotics, this should be limited to high volume and interested surgeons and hospitals to offer high quality outcomes to patients."

Keller et al. JACS 2013

Summary of Evidence
Robotic Colonic Surgery

- Systematic Review:
  - 15 robotic colonic surgery articles compared to Cochrane review and 4 RCT of laparoscopic colonic surgery trials
  - Robotic surgery:
    - Higher overall costs
    - Longer operative time
    - Equivalent complications and conversion rates
    - Selection bias in included patients

Fung & Aly, DCR 2013

Summary of Evidence
Robotic Rectal Surgery

- <u>Systematic Review:</u>
  - 18 studies - robotic vs laparoscopic rectal surgery (11 case series, 7 comparative)
  - Robotic surgery:
    - Higher overall costs
    - Longer operative time
    - Lower conversion rates (significant in some studies)
    - Trends toward better leak rates and nerve preservation in some studies

Scarpinata & Aly, DCR 2013

Summary of Evidence

Robotic Colorectal Surgery

- **Most POTENTIAL benefit for rectal surgery**
- **Safe and feasible with equivalent complications in experienced hands**
- **POTENTIAL shorter learning curve (vs laparoscopic learning curve)**
- **Increased operative time**
- **Increased costs**

Aly, Int J Colorectal Dis 2013

Future Research
ROLARR Trial

Int J Colorectal Dis (2012) 27:233–241
DOI 10.1007/s00384-011-1313-6

An international, multicentre, prospective, randomised, controlled, unblinded, parallel-group trial of robotic-assisted versus standard laparoscopic surgery for the curative treatment of rectal cancer

Fiona J. Collinson · David G. Jayne · Alessio Pigazzi · Charles Tsang · Jennifer M. Barrie · Richard Edlin · Christopher Garbett · Pierre Guillou · Ivana Holloway · Helen Howard · Helen Marshall · Christopher McCabe · Sue Pavitt · Phil Quirke · Carly S. Rivers · Julia M. B. Brown

- 20 centers, 8 countries
- 400 patients randomized to robotic or laparoscopic surgery
- 5 year study period
- Recruitment began in January 2011
- Estimated Date of Completion: June 2018

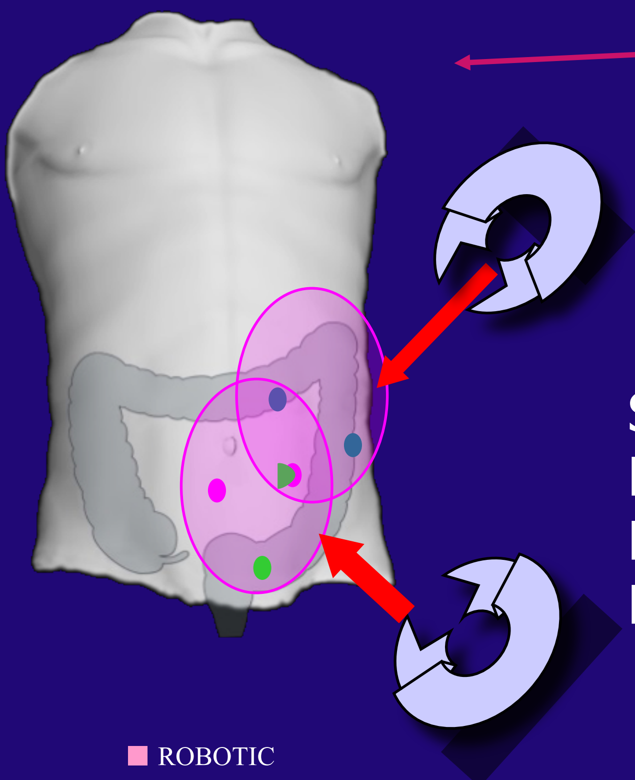
- Initial results of ROLARR trial were presented at the ASCRS June 2015.
- Analysis of data up to 30 d post operatively
  - Primary endpoint: conversion to open surgery, CRM positivity and safety data up to 30 d post operatively.
- No statistically significant differences between:
  - laparoscopy and robot-assisted surgery
  - with respect to a number of variables.
- Observed conversion rate lower following robotic surgery
  - But not statistically significant evidence of superiority compared to laparoscopic surgery.

Rectal robotic surgery

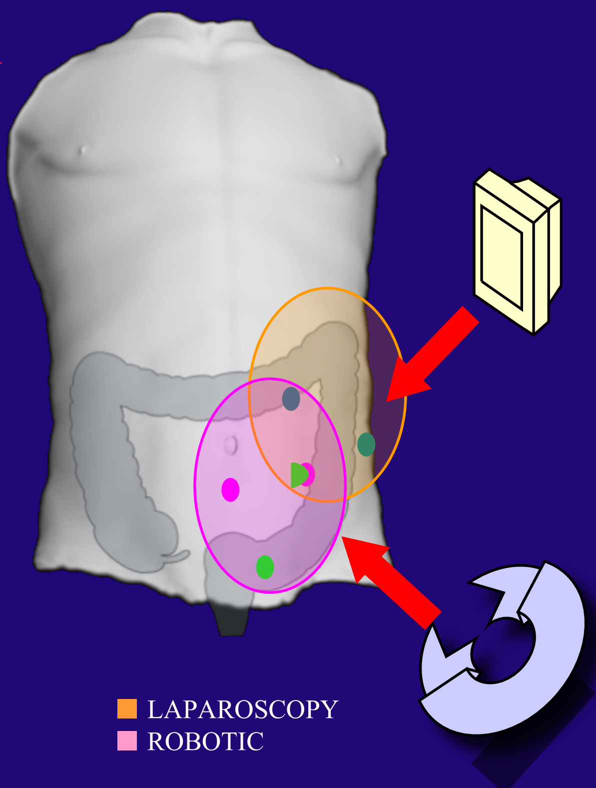
Technical aspects

SURGICAL STRATEGY

Full robotic technique



Hybrid (lap/rob) technique



Surgical steps
Patient positioning
Robotic cart
Ports

da Vinci Xi Surgical System

Future of Robotic Surgery

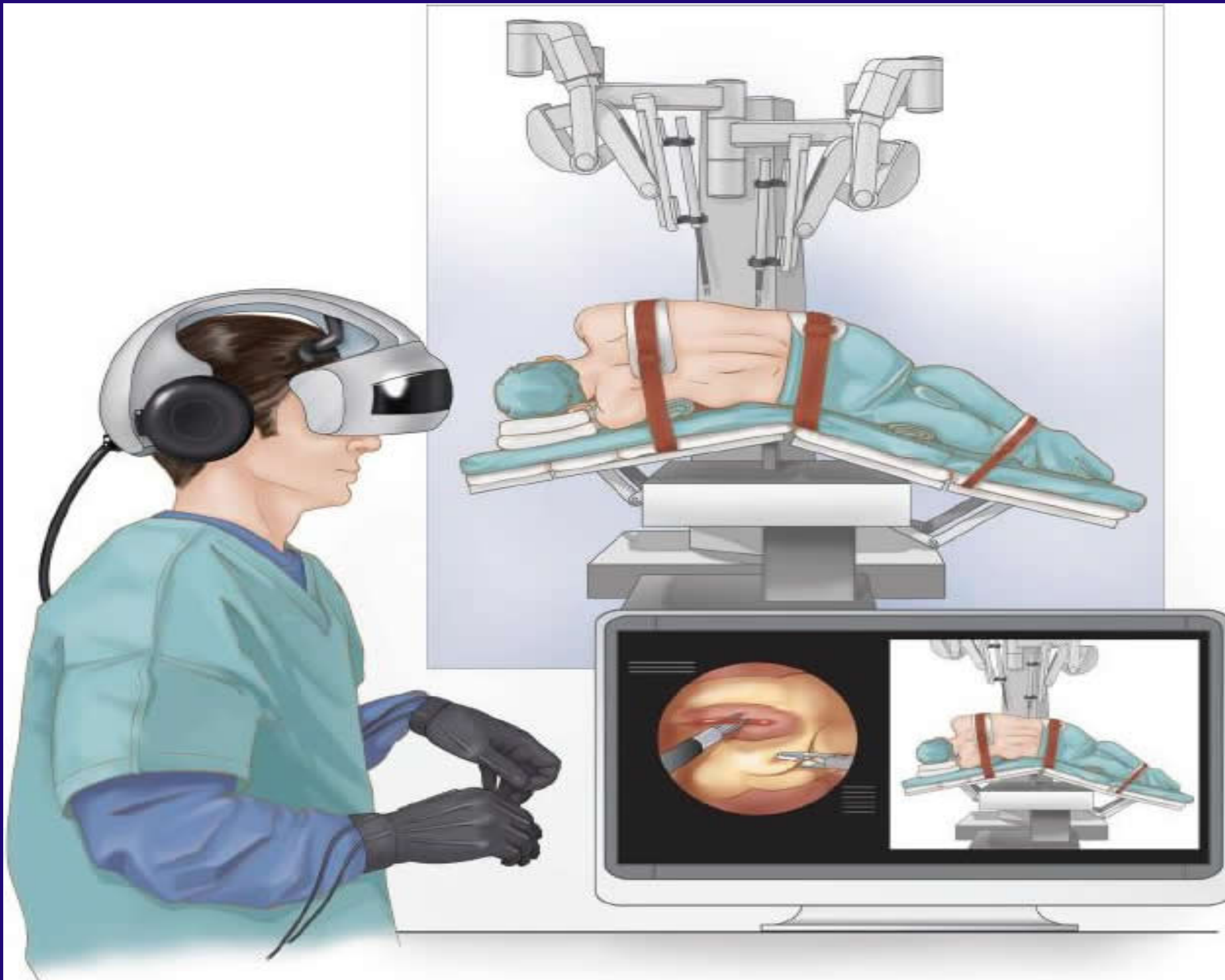

da Vinci


TITAN MEDICAL.
Open 3D High Definition Visualization
Natural Multi-articulated Handle Control Interface
Camera Insertion Tube with Self-Cleaning Lens
Multi-articulated Instruments with Replaceable Tips
Single-Arm Mobile Patient Cart
L
R
SPORT™
SURGICAL SYSTEM

Future of Robotic Surgery
New Prototypes

- AVRA Surgical Robotics (USA)
- *Google and Johnson & Johnson – Verb Surgical*
- IBIS Robot (Japan)
  - Pneumatic arms
- DLR Miro Robot (Germany)
- Human Extensions (Israel)
  - Hand-held robotic arm extension
- Raven Surgical Robot (USA)

Raven Prototype



Robotic Colorectal Surgery

Proven Benefits

Surgeon ➢ Possibly ergonomic

Hospital ➢ Yes - market share

Shareholder ➢ Yes - definite financial

Patient ➢ No

BUT WAIT!
What About Those Nerves!

Male urinary and sexual function after robotic pelvic autonomic nerve-preserving surgery for rectal cancer

- **Prospective study included 137 of the 336 male patients who underwent surgery for rectal cancer.**

- **Urinary and male sexual function was studied by means of a questionnaire based on the International Prostatic Symptom Score and International Index of Erectile Function.**

Wang et al. Int Journ of Medical Robotics, 2016 -China

	Laparoscopic surgery (n = 66)			Robotic surgery (n = 71)		
	Pre-op	Postop	p	Pre-op	Postop	p
•* p < 0.05 for postoperative vs pre-operative values. •# p < 0.05 for robotic vs laparoscopic operation.						
Total IPSS	4.12 ± 5.48	9.66 ± 5.74*	0.031	4.04 ± 5.26	6.79 ± 5.69#	0.061
Incomplete emptying	0.33 ± 0.67	0.97 ± 1.16	0.118	0.37 ± 0.79	0.81 ± 0.96	0.428
Frequency	0.54 ± 0.87	1.31 ± 1.71*	0.043	0.67 ± 0.96	1.01 ± 1.24	0.381
Intermittenc y	0.47 ± 0.91	1.14 ± 1.06	0.082	0.43 ± 0.84	0.73 ± 0.98#	0.152
Urgency	0.48 ± 0.67	0.91 ± 1.22	0.351	0.31 ± 0.73	0.84 ± 1.05	0.417
Weak stream	0.81 ± 1.21	1.86 ± 1.73	0.284	0.76 ± 1.24	1.04 ± 1.26#	0.158
Straining	0.66 ± 0.96	1.17 ± 1.14	0.117	0.61 ± 1.05	0.97 ± 1.17	0.331
Nocturia	0.97 ± 1.14	2.23 ± 2.05*	0.035	0.94 ± 1.27	1.44 ± 2.11	0.489

Conclusion

- **Robotic surgery shows distinct advantages in protecting the pelvic autonomic nerves and relieving post-operative sexual dysfunction**

Wang et al. Int Journ of Medical Robotics, 2016

Urogenital function in robotic vs laparoscopic rectal cancer surgery: a comparative study

Panteleimonitis et al. Int Jour of Colorectal Dis, 2017 (UK)

	Laparoscopic	Robotic	p value
Baseline MUF			
•Frequency	1.63	2.51	0.013
•Nocturia	2.06	2.91	0.013
•Urgency	0.59	1.63	0.003
•Initiation/straining	0.16	0.26	0.576
•Poor flow	0.69	1.26	0.090
•Incomplete bladder emptying	0.92	1.20	0.406
Change from baseline			
•Frequency	0.57 ± 0.16	−0.31 ± 0.22	0.002
•Nocturia	0.63 ± 0.17	−0.20 ± 0.19	0.002
•Urgency	0.69 ± 0.21	−0.66 ± 0.29	<0.001
•Initiation/straining	0.39 ± 0.12	0.09 ± 0.13	0.094
•Poor flow	0.73 ± 0.18	−0.14 ± 0.21	0.002
•Incomplete bladder emptying	0.16 ± 0.20	−0.63 ± 0.26	0.017

	Laparoscopic	Robotic	p value
Baseline MSF			
•Sexually active	Yes 36, no 13	Yes 13, no 22	
•Libido/arousal	0.31	0.54	0.422
•Erection	0.69	0.85	0.712
•Stiffness for penetration	0.86	1.15	0.547
•Orgasm/ejaculation	0.17	0.92	0.057
Change from baseline			
•Libido/arousal	1.56 ± 0.28	0 ± 0.30	0.001
•Erection	1.53 ± 0.29	0 ± 0.20	<0.001
•Stiffness for penetration	1.39 ± 0.29	−0.38 ± 0.21	<0.001
•Orgasm/ejaculation	1.78 ± 0.31	−0.15 ± 0.25	<0.001

- **Conclusion:**

  - **Robotic rectal cancer surgery might offer better post-operative urological and sexual outcomes compared to laparoscopic surgery in male patients and better urological outcomes in females.**

  - **Larger scale, prospective randomized control studies including urodynamic assessment of urogenital function are required to validate these results.**

Panteleimonitis et al. Int Jour of Colorectal Dis, 2017 (UK)

So NOW,
Robotic Surgery:
Hope or Hype?

Robotic Colorectal Surgery

Proven Benefits

Surgeon ➢ Possibly ergonomic

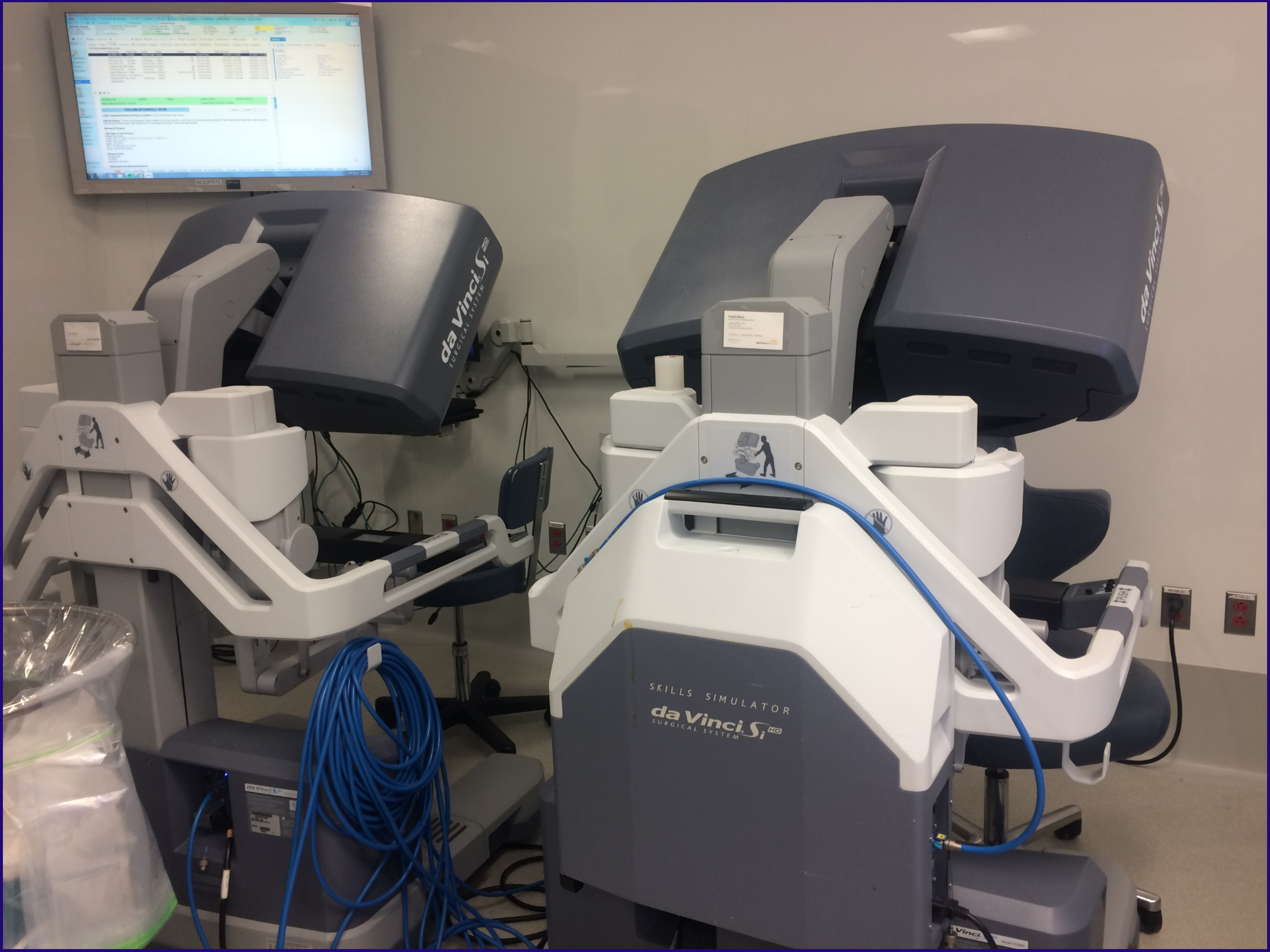
Hospital ➢ Yes - market share

Shareholder ➢ Yes - definite financial

Patient ➢ MAYBE!

Robotic surgery


stryker
1
2


SKILLS SIMULATOR
da Vinci Si HD
SURGICAL SYSTEM