

Science and intended use of robotic surgeries

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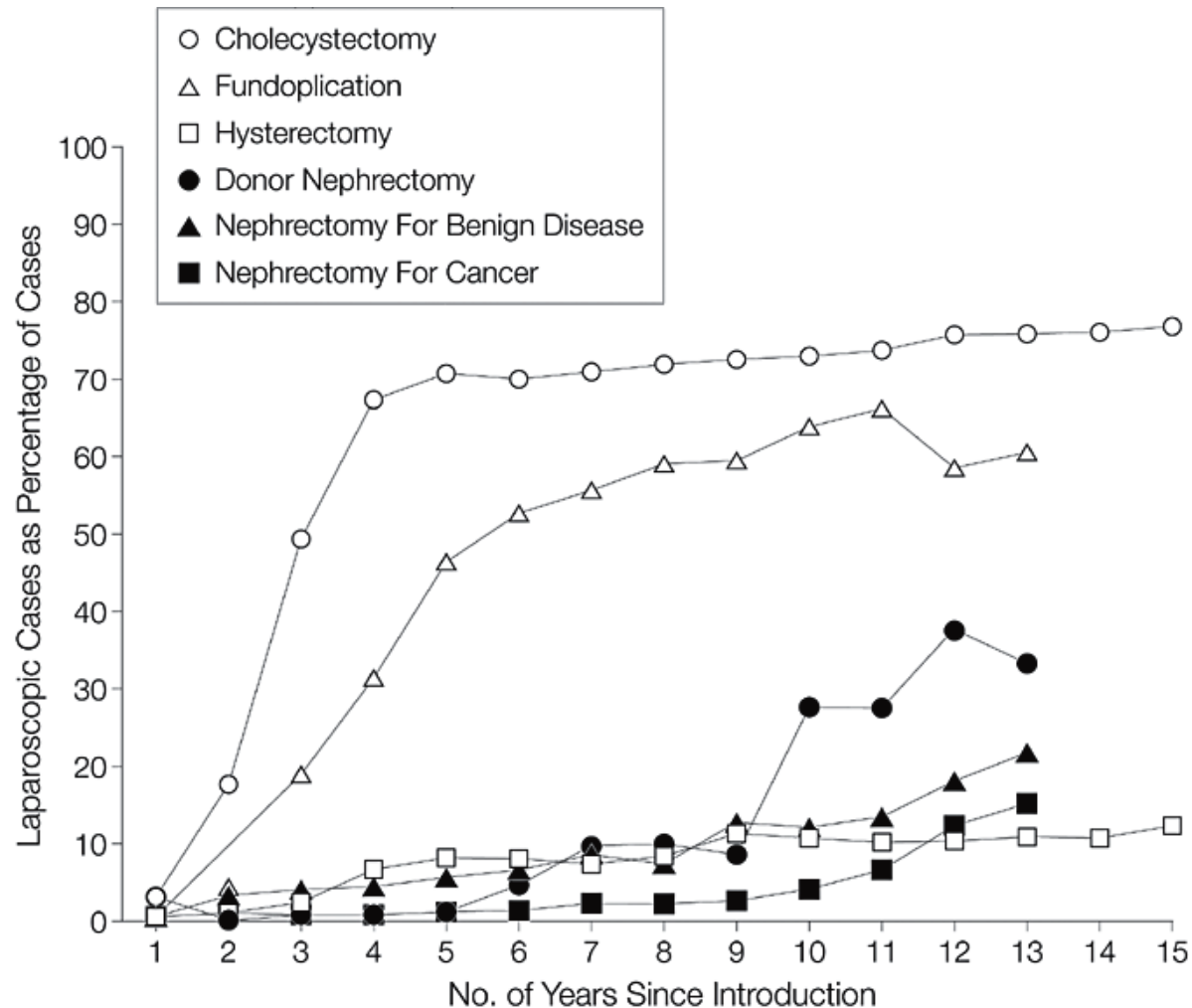
University of Michigan



Disclosures

- National Cancer Institute (1R01CA174768-01A1)
- Blue Cross Blue Shield of Michigan
 - Michigan Urological Surgery Improvement Collaborative
 - Michigan Value Collaborative

Adoption of laparoscopy



Miller et al, JAMA 2006

The challenge

How can we enhance accessibility to minimally-invasive cancer surgery (for both surgeons and patients)?

Is advanced technology the solution?

DaVinci System for Robotic-Assisted Laparoscopic Surgery

- Better visualization (3-D HD, 10X magnification)
- Wristed instrumentation (7 degrees of freedom)
- More precise movements
- Dampening of tremor
- Improved ergonomics

Initial FDA Clearance in 2000 for
general laparoscopic procedures



Robotics vs pure laparoscopy



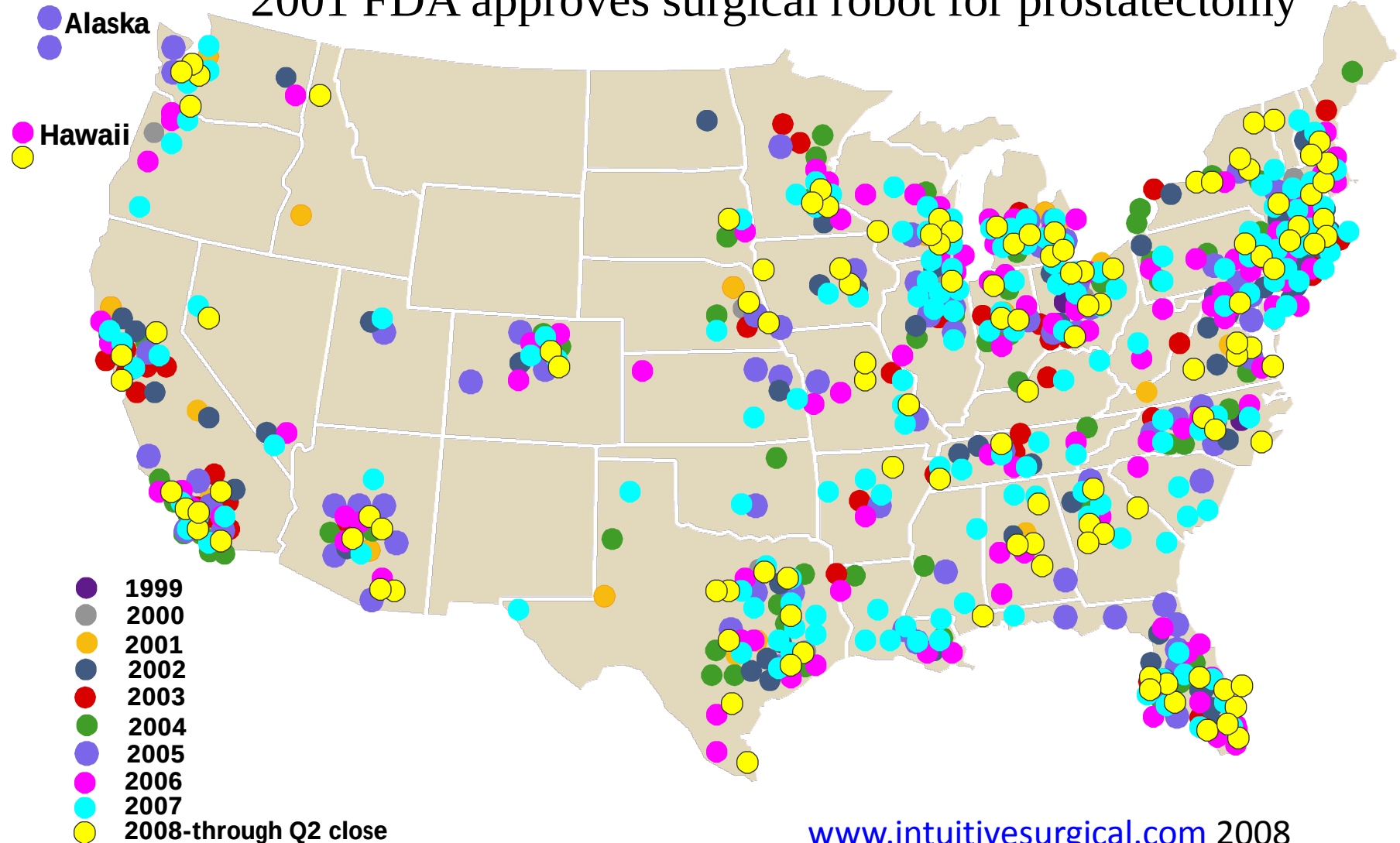
Robotics vs pure laparoscopy



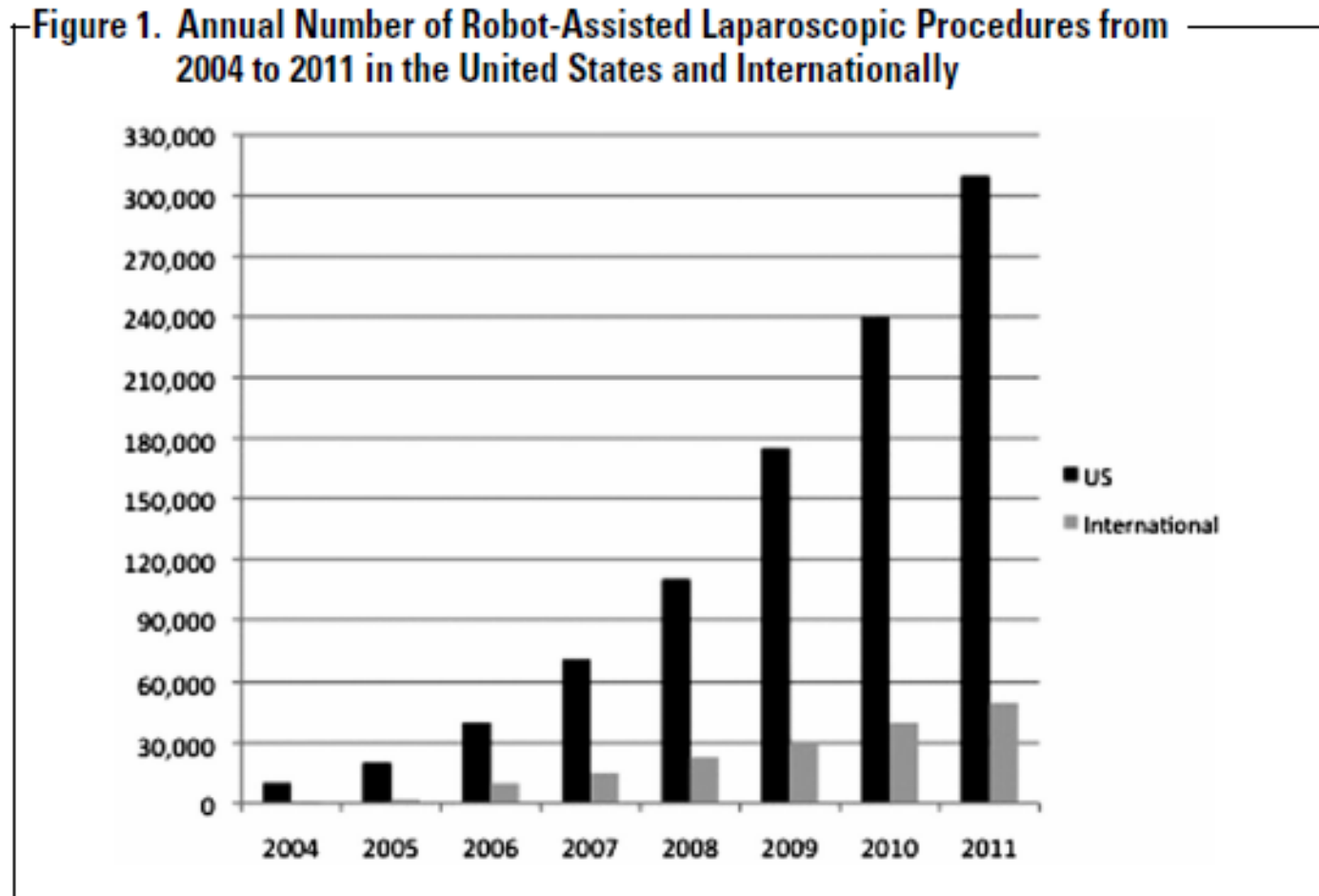
Rapid dissemination of the surgical robot

Slide courtesy of Danil Makarov, MD, NYU

2001 FDA approves surgical robot for prostatectomy

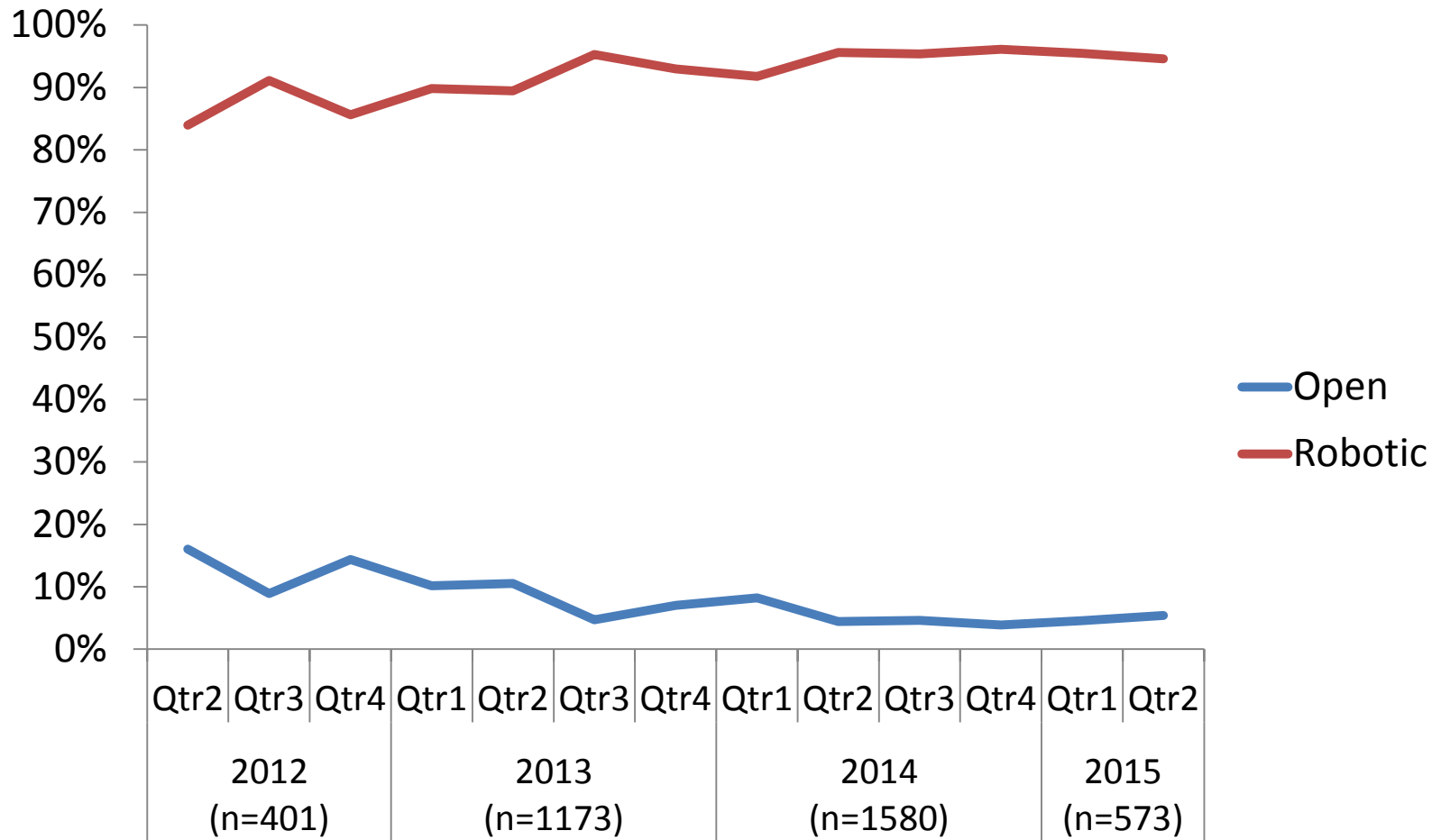


Rapid dissemination of the surgical robot



Sustained adoption of the surgical robot

**Utilization of robotic vs. open prostatectomy in MUSIC
March 2012-June 2015**

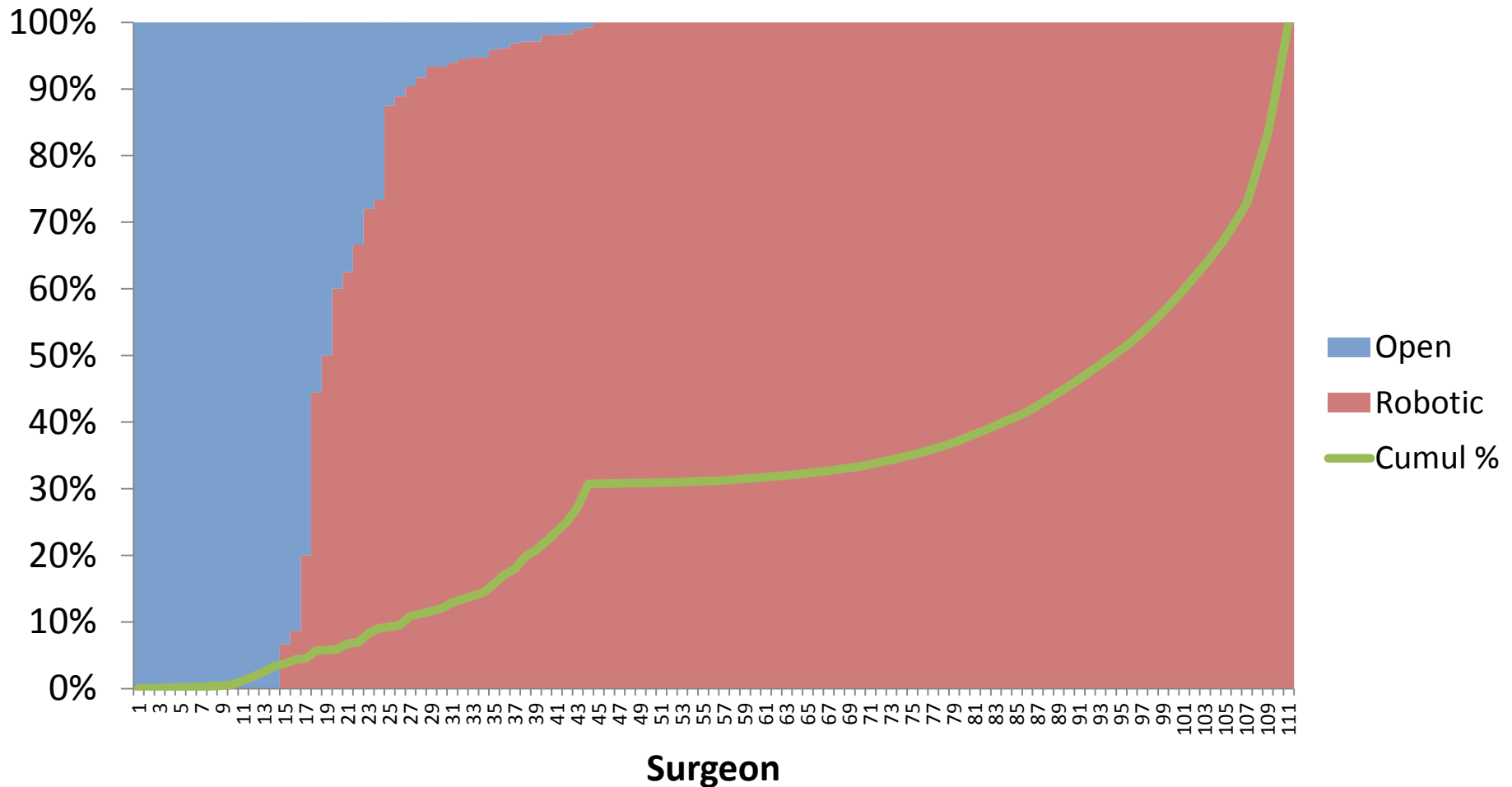


Sustained adoption of the surgical robot

Use robotic vs. open prostatectomy by surgeons in Michigan

March 2012 - June 2015

111 surgeons | 3,730 radical prostatectomies (93% robotic)



Expanding applications for cancer surgery

- Urological
 - *Prostate, Bladder, Kidney*
- Gynecological
 - *Uterine, Cervical, Ovarian*
- Colorectal
- Endocrine
 - *Pancreas, Thyroid*
- Thoracic
 - *Lung, Esophageal*
- Head and Neck
 - *Tonsil, Tongue Base*

Intended benefits of robotic cancer surgery

Perceived benefits of robotics vs conventional approaches

Site	Cancer control	Complications	Functional outcomes	Short-term recovery
Prostate				
GYN				
Colorectal				
Endocrine				
Lung				
Head and Neck				



No perceived benefits



Mixed perceptions



Perceived benefits

State of the clinical science

- Few Randomized Controlled Trials (RCT)
 - Radical cystectomy (removal of the urinary bladder)
 - Excision of rectal cancer
 - Radical prostatectomy (removal of the prostate)
- Many observational studies
 - Single institutional case series
 - Data often lack clinical granularity and key outcomes

Radical cystectomy for bladder cancer

- Single institution RCT from Memorial Sloan-Kettering
- N = 118 patients (58 open, 60 robotic)
- Clinical stage Ta-3, N0-3, M0
- Primary outcome: Major complications within 90 days of surgery
- Lower blood loss but longer OR time with robotics
- No difference in length of stay or rates of complications

Mesorectal excision for rectal cancer

- Robotic vs Laparoscopic Resection for Rectal Cancer (ROLARR)
- Rectal cancer amenable to curative surgery
- Primary outcome: Rate of conversion to open surgery
- Other outcomes : Cancer control (radial margin positivity), complications, 30 day mortality, 3 year disease-free and overall survival, sexual function

Clinical trials.gov

Pigazzi, Annual Meeting American Society of Colon and Rectal Surgeons, 2015

Ongoing Trials

- RAZOR: Multi-institutional RCT for radical cystectomy in the US (open vs robotic)

Smith et al, BJU Int, 2014

- Multi-institutional RCT for radical prostatectomy in Australia (open vs robotic)

Gardiner et al, BMC Cancer, 2012

The remaining evidence

Benefits of robotic vs open surgery include:

- Facilitates laparoscopic surgery
- Smaller incisions
- Shorter hospital stay
- Easier short-term recovery

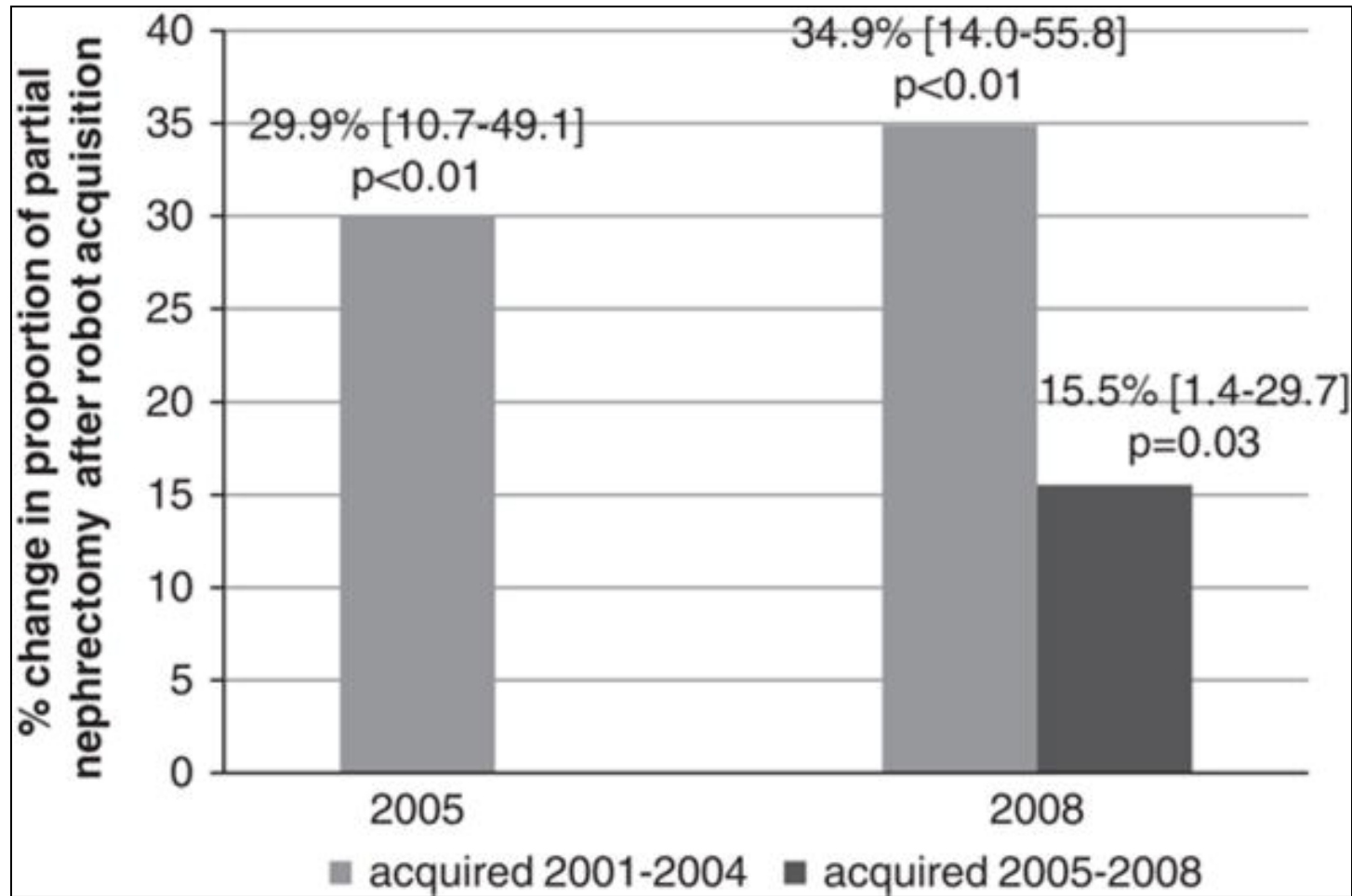
Mixed results for robotic vs open surgery:

- Complications

No clear benefits for robotic surgery for:

- Cancer control
- Functional outcomes such as urinary control and erectile function

Robotics facilitates laparoscopic surgery



Easier short term recovery with robotics

	Robotic (n=3474)	Open (n=256)
Median length of stay (days)	1	2
% cases with LOS 1 day	76%	23%
% cases with LOS $\leq$ 2 days	93%	63%
Median blood loss (cc)	100	500

Data from the Michigan Urological Surgery Improvement Collaborative, 3/2012 – 6/2015

Unintended consequences of robotic cancer surgery

Consumer-directed advertising

HEALTH

Salesmen in the Surgical Suite

By RONI CARYN RABIN MARCH 25, 2013



Ann Johansson for The New York Times

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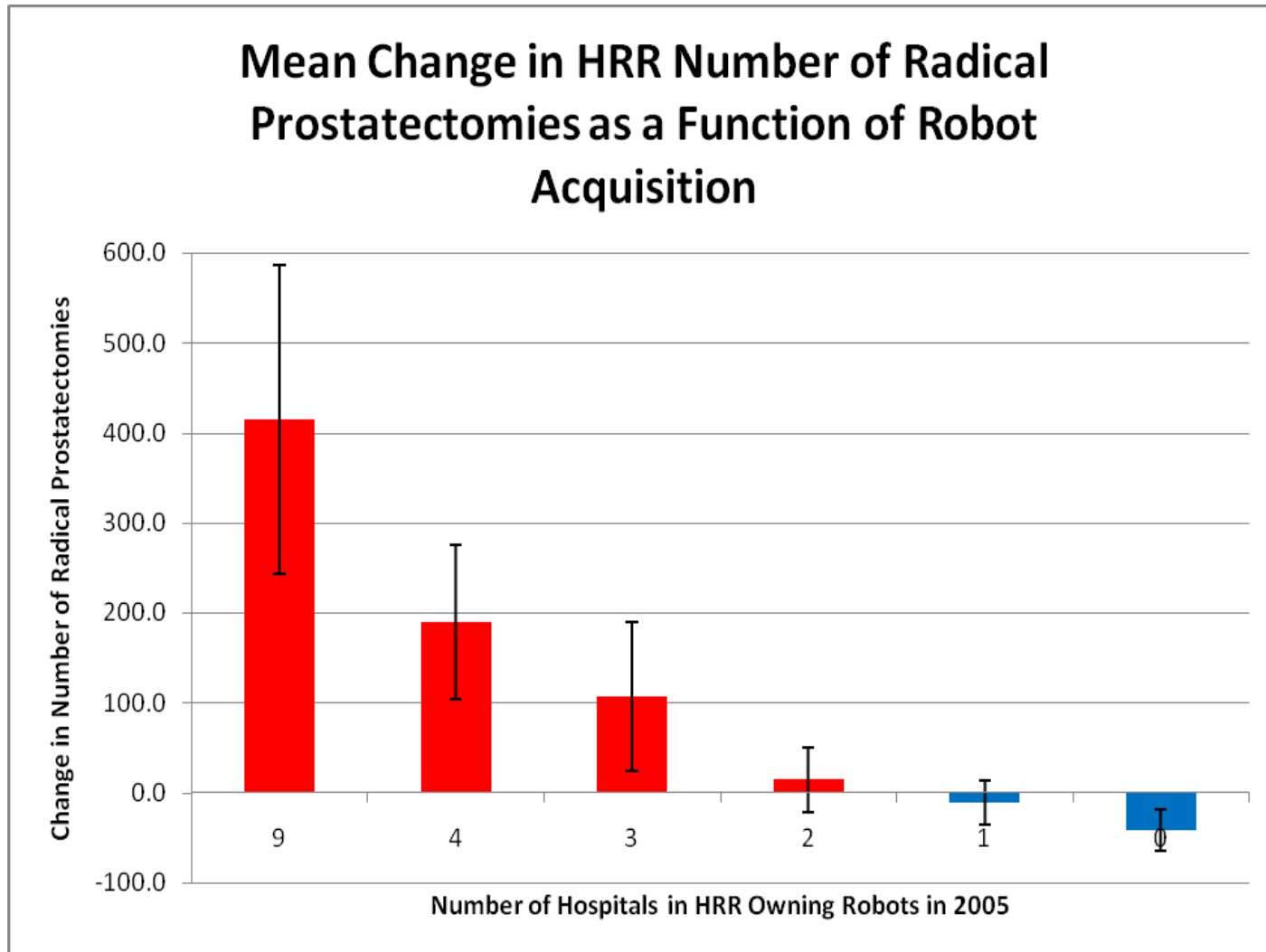
Tweet

When Fred E. Taylor arrived at Harrison Medical Center in Silverdale, Wash., for a routine [prostatectomy](#), he expected the best medical care new technology had to offer: robotic surgery, billed as safer, less painful and easier on the body than traditional surgery.

The operation, on Sept. 9, 2008, was supposed to take five hours. But it

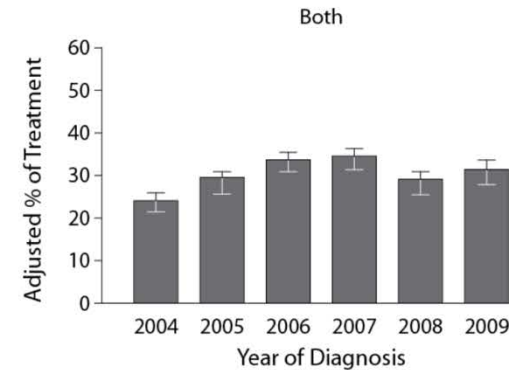
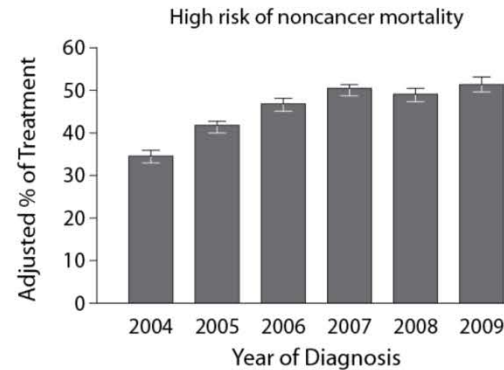
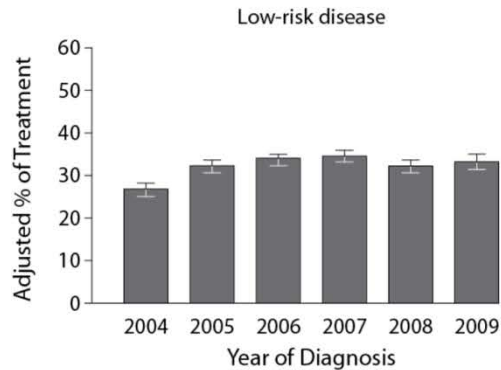
For a physician referral call Physician Select at 1-877-242-4200.

Potential for overtreatment

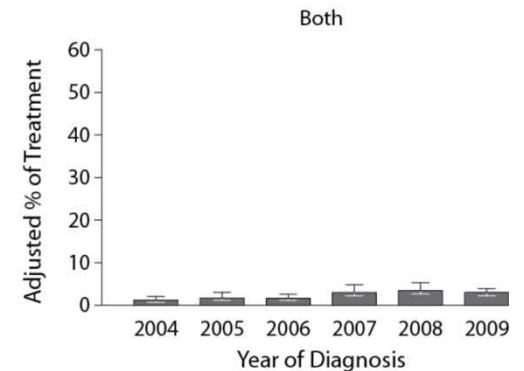
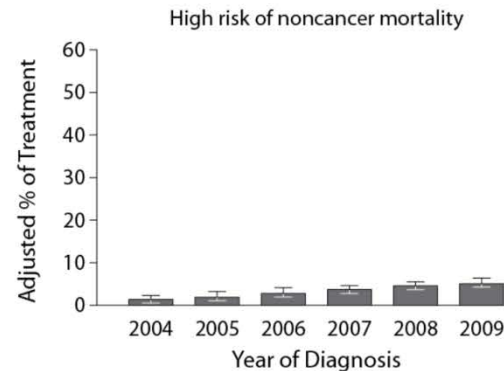
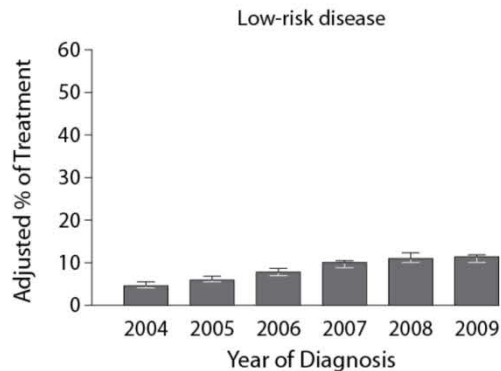


Potential for overtreatment

A IMRT



B Robotic prostatectomy



Higher costs

- > \$1 million purchase price for robotic unit
- Annual service contract (>\$150,000)
- Disposable instruments (\$1500-\$2000 / case)
- Change in the volume of patients treated

Higher costs

Procedure	Standard Surgical Approach	Mean Cost per procedure in 2007	Estimated change in cost
Radical prostatectomy	Open	\$11,352	\$400-4,800*
Radical cystectomy	Open	\$32,388	\$1,600*
Low anterior resection	Open	\$16,688	\$1,600
Esophagectomy	Open	\$39,622	\$2,700*
Lung lobectomy	Open	\$23,021	\$3,900
Nephrectomy	Laparoscopic	\$14,943	\$10,600
Hysterectomy	Laparoscopic	\$8,951	\$2,500
<u>Overall estimate</u>			<u>\$3,200*</u>

* Includes amortized cost of the robot itself

Adapted from Barbash and Glied, NEJM, 2010

Unexpected adverse outcomes

- Secondary treatments
- Adverse functional outcomes
- Patient safety events
- Deaths

Unexpected adverse outcomes

	Relative likelihood of outcome with robotic vs open prostatectomy
30 day genitourinary complications	1.93 (1.26 – 2.97)
90 day genitourinary complications	1.69 (1.13 – 2.53)

Gandaglia et al, JCO, 2014
Barry et al, JCO, 2012

Unexpected adverse outcomes

Underreporting of Robotic Surgery Complications

Michol A. Cooper, Andrew Ibrahim, Heather Lyu, Martin A. Makary

Cooper et al, J Healthcare Quality, 2013



THE CONSUMER

New Concerns on Robotic Surgeries

By RONI CARYN RABIN SEPTEMBER 9, 2013 5:15 PM 110 Comments



A technologist with the da Vinci surgical system, which has been criticized in a series of reports. Mike Spencer/Wilmington Star-News, via Associated Press

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In early March 2009, Erin Izumi, a woman in her 30s from Tacoma, Wash., underwent robotically assisted surgery to treat endometriosis. The operation at St. Joseph Medical Center dragged on for weeks before

Moving forward

Platinum Opinion

Moving Beyond the Headlines: Improving the Technical Quality of Radical Prostatectomy

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Miller and Birkmeyer, Eur Urol, 2014

Video review for surgeons-in-training

- RCT involving 41 resident surgeons
- Video review of robotic simulator exercises
- Intervention: Peer performance feedback through a social networking page
- Findings: Residents receiving video-based feedback more comfortable with robotic surgery and more satisfied with learning experience

Video review for fully-trained surgeons

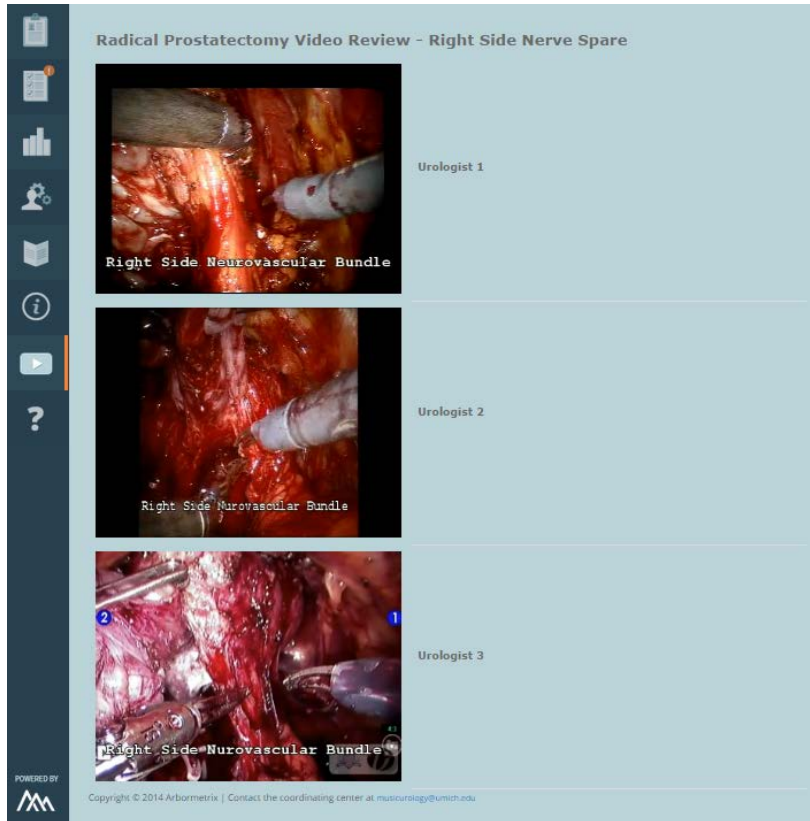
Robotic prostatectomies by 12 fully-trained surgeons in Michigan
Video reviews by peer surgeons and anonymous “crowd” workers

Video ID	# of Expert Ratings	Expert Mean* (95% CI)	Expert Rank	# of Crowd Ratings	Crowd Mean* (95% CI)	Crowd Rank
11	30	21.7 (20.2 – 23.1)	1	231	20.9 (20.4 – 21.4)	5
2	26	21.0 (19.5 – 22.5)	2	201	20.3 (19.8 – 20.9)	7
4	21	20.4 (18.7 – 22.1)	3	174	20.7 (20.2 – 21.3)	6
3	24	20.5 (18.9 – 22.1)	4	200	20.9 (20.4 – 21.4)	4
8	17	20.5 (18.6 – 22.3)	5	132	21.8 (21.2 – 22.4)	1
12	24	19.4 (17.8 – 21.0)	6	207	21.2 (20.7 – 21.7)	2
7	29	19.2 (17.8 – 20.7)	7	236	20.9 (20.4 – 21.3)	3
10	20	18.8 (17.1 – 20.5)	8	170	20.0 (19.5 – 20.6)	9
1	30	18.4 (16.9 – 19.9)	9	228	20.2 (19.7 – 20.7)	8
9	29	18.2 (16.7 – 19.7)	10	227	19.9 (19.4 – 20.4)	10
5	31	16.2 (14.7 – 17.6)	11	236	19.5 (19.0 – 20.0)	11
6	37	15.8 (14.5 – 17.2)	12	289	19.2 (18.7 – 19.6)	12

Ghani et al,
Under peer
review

*Mean values calculated from linear mixed effects model using ratings across all video segments

Video review



- Video assessment by peers or “crowd” is feasible
- Measurable differences evident between surgeons?
- Does technique/skill correlate with outcomes?
- Can coaching improve performance?

Conclusions

- Robotic cancer surgery has disseminated rapidly over the last decade
- Implementation has yielded both intended benefits and some unintended adverse consequences, including higher costs
- Comparative clinical and cost effectiveness vs laparoscopic and open surgery remains incompletely defined
- Ongoing efforts are needed to improve the application, performance, and outcomes for robotic cancer surgery

Thank you