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Editorial

Robot, heal thyself: What ails Robotic Surgery?

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Back in the late eighties, at the dawning of minimal access surgery, robotic surgery too appeared on the horizon. The next decade was a heady time of daring innovation and upheaval of archetypes, with a *fin de millénaire* receptivity to change. It was almost as though we humans were perfecting endoscopic surgical techniques to eventually hand them over to androids that would then carry out our operative bidding with unerring precision.

Robotic surgery really took off in 2000. The only commercially available platform, and the only one licensed by the FDA, is the da Vinci Surgical System from Intuitive Surgical Inc. of Sunnyvale, California. It is in effect a computer-refined tele-manipulator with hyper-flexible end-effectors and a high definition three-dimensional imaging system accessed at an ergonomic console. The surgeon's movements are filtered, focused and stabilized, and then mirrored by the robotic arms on the patient-side cart that perform the procedure. Da Vinci maintains that this is 'robot-assisted minimal access surgery' and reiterate the 100% control of the device that is always with the surgeon. For the SF-oriented, these are less Isaac Asimov's positronic robots than Robert Heinlein's waldoes.

However, in the fifteen years since, what should have been a vibrant surgical modality is beset with controversy and uncertainty, and tainted with allegations of commercialism, misinformation and twisted ethics. There are no competitors to speak of, never a good sign, and the sole player today is plagued with bad press, FDA recalls, sinking stock value, lawsuits, and a saturated national market. With media searchlights on operative mishaps like death and damage resulting from electrical burns, instruments dropping off into patients, interrupted video feeds, sudden shutdowns and worse, one wonders: what happened?

Intuitive Inc. reports dropping sales, having shipped 45 da Vinci systems in the US in the first three months of 2014, down about 61% from the 115 sold in the same period the previous year. Revenue dropped 24% to \$465 million in the first quarter of 2014, compared with \$611 million for 2013¹. Clearly, fewer hospitals are investing in the system and the company is under pressure to boost sales.

Why then is robotic surgery losing its shine? The ECRI Institute, a nonprofit organization that has analyzed more than 4,000 studies on robotic surgery, states: "The evidence isn't strong enough to determine whether or not a robot is better than traditional minimally invasive surgery, but the evidence does indicate that it's better compared to open surgery — more evidence from higher quality studies may change this conclusion²." In a press statement, the President of the American Congress of Obstetricians and Gynecologists claimed: "...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" and advised women to "separate marketing hype from reality"³. A recent JAMA study found that the percentage of robotically performed hysterectomies has increased from under 0.5% to nearly 10% over the past three years⁴. This despite the added cost of over \$2000, longer operating times, and no proven benefit.

It was in the field of urology, notably radical prostatectomy, where robotic surgery first made significant inroads into conventional practice because it offered the only real minimal access to the prostate. Today, well over 80% of prostatectomies in the US are performed as da Vinci surgery. However, though bleeding is less, the true metrics that matter - rates of post-operative impotence and incontinence - remain substantially the same⁵. There are no RCTs showing a clear benefit; indeed, apart from a few retrospective studies showing an improvement of a day or two in length of stay, there is nothing to justify the additional per-procedure cost of upto \$5000, even disregarding fixed costs. All this, against increasing evidence that, for low-risk prostate cancer, the best policy is to 'wait and watch'.

The purported advantages of robotic surgery are filtered precision of movements, confined space maneuverability, 'wristed' instruments giving multiple manipulation axes, and efficient surgeon ergonomics. Undeniably, these are real advantages for confined-space procedures, and consequently robotic surgery remains the first choice for radical prostatectomy and some 'niche' procedures, such as in otorhinolaryngology. All this comes at a cost

that is often unjustifiable. Each da Vinci system costs close to \$2 million and comes with the mandatory annual maintenance contract of about \$150,000. With over \$2000 worth of proprietary instruments expended per procedure, the cost-benefit ratio is badly skewed.

Despite media hype, robotic surgery is not 100% safe, given that it is really a refined manipulation system for human surgeons. Horror stories of robotic surgery mishaps abound but, in all fairness, these are mostly the faults of the surgeons, rarely the tool. The safety profile of a procedure depends on how frequently it is performed. ECRI's list of ten top health hazards for 2015 and 2014 notably includes robotic surgery; they fault not the device but the hazy and inadequate certification requirements to use it.

A study of 10,624 adverse events in robotic surgery reported to the FDA notes that, from 2000 to 2013, there have been 144 robotic surgical deaths, 1,391 injuries, and 8,061 malfunctions, out of over 1.7 million procedures⁶. The number of adverse events per procedure has not fallen since 2007 and is significantly higher for complex and infrequently performed surgery. There is therefore pressure on the manufacturers to push sales and expand the indications into new fields. Advertising is targeted at the public, and seeks to position robotic surgery as cutting-edge technology that obviates the much-dreaded 'human error'. Aggressive direct-to-consumer marketing of modern medical technology leads patients to seek out hospitals offering these glamorous if unproven options. A backlash has arisen and critics decry these snake-oil marketing tactics as 'criminal', while surgical robots have been branded 'a solution in search of a problem' or, worse, 'real life Terminators'.

Small and rural hospitals in the US are installing robotic units in a bid to upgrade their image as well as to lure patients and attract young surgical talent. Patients will choose a hospital that boasts a robot (even if they neither need nor opt for robotic surgery) as they perceive it as a state-of-the-art facility. Surgeons too prefer working where they can get their hands on a robotic system.

Credentialing is literally all over the place: da Vinci provides a day of hands-on training and, under lobbying from salesmen, some hospitals are now reducing the required five mentored procedures to three. An average surgeon can be credentialed in robotic surgery over a weekend. Salespeople haunt the OR (as tech support) to handhold new surgeons and coerce conversions from an endosurgery list to a robotic-surgery list. With adventurous surgical teams, coercive salesmen, misled patients, and pressure for ROI, there is a unified, almost sacred, urge to feed the machine. This bid to drive volumes

comes at an ironic cost beyond the initial outlay and the AMC: insurance reimbursement to the hospital is the same for all minimal access surgery, traditional and robotic, despite the cost variance. If only there were less pressure on rookie surgeons to perform poorly indicated procedures on suboptimal patients...

Intuitive Surgical Inc's webpage on 'clinical evidence' naively graphs an annually increasing number of 'Robotic Publications'⁷. No, idle robots are not being seconded to writing articles, at least not yet, but the twee bar diagram is symbolic of the obfuscation around robotic surgery today. Despite the growing controversy parodied by the graph's rising trend, the only real demerit of robotic surgery is cost, given that it is at least as good as conventional minimal access surgery for most applications, and arguably better for a few. At present, industrial monopoly and the economies of scale are at cross-purposes. Only when the next generation of devices boosts benefits and/or lowers costs radically, will the dust settle and robot-assisted surgery assume its logical place as the next step in the evolution of minimal access surgery. We are not there yet.

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