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and Worldwide**

Shah G, Haas G

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# Use of daVinci Robot® in U.S. and Worldwide

G. Shah, G. Haas

Die Roboterchirurgie hat die minimalinvasive Chirurgie in den letzten 6 Jahren stark beeinflusst. Die Anzahl der Institutionen, die einschlägige Programme lancierten und die chirurgischen Anwendungsbereiche, die sich der Robotertechnik bedienen, haben exponentiell zugenommen. Privatspitäler und akademische Zentren – Centers in den USA und in Europa – überall werden je eigene Wege und Verfahren beschritten. Materialien und Methoden: Die Daten, die von Intuitive Surgical, dem US-amerikanischen Urologenverband und vom Accreditation Council for Graduate Medical Education bereitgestellt und an jüngsten nationalen Konferenzen über Roboterchirurgie präsentiert wurden, wurden assimiliert und auf praktische Muster und Standards analysiert. Ergebnisse: Die rasche Verbreitung robotergestützter chirurgischer Eingriffe ist auf die vereinten Anstrengungen von Gesundheitseinrichtungen und Patientengruppen zur Förderung dieser Technik sowie auf die innovativen Werbemethoden von Intuitive® Surgical zurückzuführen. Die bessere Visualisierung vitaler Strukturen, die einfachere und präzisere Gewebsmanipulation und die Verbesserung einiger kurzfristiger Parameter sind die Hauptpunkte der Unterstützungskampagne. Am Anfang der Initiative zum Start eines europäischen Roboterprogramms standen Versuche, die speziellen chirurgischen Verfahren zu modernisieren. In den Vereinigten Staaten spielen für die Entscheidung einer Institution, in das DaVinci Robot®-System zu investieren, Marktkräfte eine bedeutende Rolle, die auf tatsächliche bzw. empfundene Unterschiede zwischen den Konsequenzen bei vorhandenem bzw. nichtvorhandenem Roboterprogramm zurückzuführen sind. In Asien ist die Kaufentscheidung vom Wunsch bestimmt, mit den Führenden „mitzuhalten“. Schlussfolgerungen: Die Roboterchirurgie wird bleiben. Die aktuelle Technologie, wie wir sie kennen, ist im Hinblick auf die Anwendungspotenziale in der Zukunft erst die Spitze des Eisbergs.

Robotic Surgery has made a huge impact on minimally invasive surgery over the last 6 years. The number of institutions initiating robotic programs and the type of surgeries utilizing robotic assistance has grown exponentially. Unique patterns are emerging from private hospitals vs academic centers and from the United States vs European Centers. Materials and Methods: Data provided by Intuitive Surgical, the American Board of Urology, and the Accreditation Council for Graduate Medical Education and presented at recent national conferences on robotic surgery has been assimilated and analyzed for practice patterns and standards. Results: The rapid expansion of robot assisted surgical interventions is a result of a unified effort to promote the concept by health care providers, patient groups and innovative advertising methods by Intuitive® Surgical. Improved visualization of vital structures, easier and more precise tissue manipulation and improvement in several short-term parameters are the major points of promotion. The initial impetus to start a robotic program in Europe came from efforts to innovate the particular surgical approaches. In the United States, market forces of actual as well as perceived consequences of having or not having robotic programs play an important part in institutional decisions to invest in the daVinci Robot® system. In Asia, it has been motivated by the desire to “keep up” with the leaders. Conclusions: Robotic surgery is here to stay. The current technology as we know it is but the tip of the iceberg for what the potential applications will be in the future. *J Urol Urogynäkol 2006; 13 (4): 24–28.*

The past century has seen extraordinary changes in surgical practice. The development of endoscopy has challenged the surgeon to use 2-dimensional (2D) visual image and minimal tactile sensation to perform surgical procedures. Laparoscopy forced the surgeon to learn surgical skills in reduced depth perception and use the surgical instruments counterintuitively. Use of a robot has provided a 3D image of surgical field and haptic feedback for the surgeon [1].

## History of Surgical Robot / Milestones in use of Robot in surgery

The word “Robot” is derived from the Czech word ‘robota’, which means worker. A surgical robot is a computer-controlled manipulator with artificial sensing that can be programmed to carry out a range of surgical tasks.

Kwoh et al (1988) described use of a light duty industrial robot for stereotactic brain surgery. Davies et al (1991) used a modified industrial robot arm to perform transurethral resection of prostate. Wickham, in association with Imperial College, London, initially developed a five degrees of freedom (DOF) robot for percutaneous nephrolithotomy (PCNL). The PCNL robot currently named Access Robot (PACKY-RCM) was developed in 1996, and has been superseded by the Tracker (Urobotics) in 2002. The PACKY-RCM has six DOF and is used with fluoroscopy or CT guidance to improve the accuracy of needle placement.

The ROBODOC® robotic system was first used in cementless total hip arthroplasty. The Automated Endoscopic System for Optimal Positioning (AESOP®) was the first commercially available robotic system used in laparoscopy in mid 1990s. It was developed by the United States Military, using seed funding, and later on went into commercial production by Computer Motion® Inc. It was the first surgical robot approved by the Food and Drug Administration (FDA). The military took an active part in the development of multi-armed surgical robots. The initial version to the 3-armed daVinci® system (Intuitive® Surgical System, Sunnyvale, CA) was first developed by researchers at the US National Aeronautics and Space Administration. The Pentagon also participated in its development. It was intended to allow surgeons in a Mobile Advanced Surgical Hospital to operate on wounded soldiers in the battlefield.

In 1998, the daVinci® system was approved for general surgical procedures (e.g. cholecystectomy) by the FDA. Later in 2004, it was approved for cardiac and urology surgery. The Zeus system (Computer Motion® Inc., Santa Barbara, CA) came into the market in 1998. It was acquired by Intuitive® Surgical Inc. and currently supports parts and service, but no new sales are made.

The modern robotic surgical system fits into 3 categories – active, semi-active and master-slave systems. The active system has artificial intelligence, allowing the robot to perform tasks autonomously under the supervision of the surgeon. Semi-active systems have an autonomic and a surgeon driven component. The master-slave system allows the surgeon to directly operate the robot from a local or remote command center. The surgeon’s movements are translated into robotic motion. The daVinci® robot falls into this category.

From the Department of Urology, SUNY Upstate Medical University, Syracuse, NY, USA

Correspondence to: Gabriel Haas, MD, Professor and Chairman, Department of Urology, SUNY Upstate Medical University, Syracuse, NY 13203, USA, E-mail: haasg@upstate.edu

## Prostate Cancer

Prostate cancer has gained increasing importance in the area of men’s health in the United States. According to

American Cancer Society projections, there were 235,000 new cases of prostate cancer in 2005. There are 281,000 new cases projected for 2010 and 318,000 new cases for 2015.

There are many factors influencing the treatment options in prostate cancer. They are: age of the patient, patient's perception and value of the procedure (clinical efficiency/invasiveness of treatment option).

### **Milestones in Prostate Cancer Surgery**

In 1904, Hugh Hampton Young described the first radical perineal prostatectomy for carcinoma of the prostate [4]. Millins (1947) popularized retropubic open prostatectomy [5]. The technique of radical retropubic prostatectomy (RRP) was associated with significant morbidity, including excessive blood loss, sexual dysfunction and urinary incontinence. In the late 1970s and early 1980s, better understanding of the dorsal venous complex, neurovascular bundles and striated urethral sphincter helped urologists improve the outcome after RRP. Patrick Walsh (1980s) described anatomic nerve-sparing radical retropubic prostatectomy for localized prostate cancer. His technique decreased blood loss, incidence of incontinence and sexual dysfunction. His anatomic principles remain the cornerstone of modern-day nerve sparing RRP [6, 7].

The use of the laparoscope improved visualization and magnification. Due to pneumoperitoneum, there was less bleeding during the procedure. Schuessler and colleagues (1992) reported the first successful laparoscopic radical prostatectomy (LRP) [8]. Although, cancer curability with LRP was comparable to the RRP, initially it did not show any advantage over RRP with regard to the cancer control, continence or potency. It was not adopted in urology practice, with few case reports in the literature until 2000. With refinement in instrumentation (e.g. laparoscopic needle drivers) and intracorporeal suture techniques, Vallancien & Guilloneau and Abbou reported modification in LRP technique. Their stepwise approach standardized the procedure, enabling LRP to be reproducible. The operative time was 4–5 hours. Positive margin rate was 15 to 28 %. The continence rate was 72 % and potency rate was 45 % of men who were potent before surgery [9, 10]. These results renewed the interest in minimally invasive prostatic surgery. The steep learning curve was the stumbling block to teach the procedure and disseminate to urologists worldwide.

Abbou et al (2001) reported their initial experience with robotic-assisted prostatectomy (RAP) [11]. As with RAP, it has to meet the standard set by the RRP to be considered an acceptable standard of care. The outcome measures – oncologic (e.g. positive surgical margins, biochemical recurrence, cancer-specific survival) and functional (e.g. continence, sexual function) – are compared with both the procedures (e.g. RAP vs. RRP).

Menon's group [12] from Detroit described Vattikuti Institute Prostatectomy- (VIP-) robot assisted prostatectomy. In their non-randomized comparison of 200 VIP with 100 RRP, they reported similar operative time. None of the patients in VIP group needed blood transfusion, compared to 67 % after RRP. The hospital stay was 1.2 days for VIP group, 1.3 for laparoscopic and 3.5 days for RRP. The respective catheter duration was 7, 8 and 15 days. The positive margin rate was 23 % for RRP compared to 9 % for VIP. In open cases, step-section microscopic exami-

nation of the prostate specimen was done. In VIP group, periurethral soft tissue biopsies were evaluated on frozen sections, which may have served to 'reduce' the apical positive margin rate. Menon's group has shown that once learned, the outcomes of robotic surgery improve [12]. For the established open surgeon, the training for RAP or VIP may be somewhat shorter than pure laparoscopy. In more than 300 VIP cases, the operative time was 120–160 min. with a mean blood loss of 150 ml. None of the patients needed a blood transfusion [13]. These results compare favorably with an operating time of 232 min., blood loss of 370 ml and transfusion rate of 5 % after LRP [14]. At 6 months, 96 % of patients after VIP were continent and 60 % of initially potent men had unassisted intercourse [14]. In comparison, 93 % continence and 86 % potency rates after RRP, using patient-reported quality of life survey [15]. These reports have added new hope to expand RAP as an acceptable standard of care for localized prostate cancer, considering oncologic and functional end points.

### **Factors Influencing spread of Robotic Surgery**

#### **Surgeon Factors**

Recently, great strides have been made to use laparoscopic skill among all surgical subspecialties, including urology. There is a steep learning curve for advanced laparoscopic procedures – e.g. radical prostatectomy, cystectomy, adrenalectomy etc. These procedures involve extensive reconstruction which is technically difficult to master laparoscopically without extensive experience. The robot allows the relatively less experienced laparoscopist to offer minimally invasive surgery to their patients with improved technical performance.

The robot (e.g. daVinci®) with motorized camera arms contains two lenses, providing a steady tireless, non-fogging, 3-dimensional magnified image. The operating surgeon controls the camera. The camera images are absolutely stable at all times. Robotic instruments provide 7 degrees of freedom, closely mimicking the actual movements of the human hand and wrist. It allows for finer maneuvers in tight spaces and improves surgical precision. The 3D image and easily manipulated articulating instruments have shortened the learning curve for the laparoscopically naïve surgeon. The use of filters for hand/arm tremors and addition of motion scaling have helped the surgeon significantly [3].

Pelvic open surgery for RRP requires the surgeon and assistants to adopt anatomically difficult positions causing strain on cervical and lumbar spines.

In urology, the main use of a robot for prostate surgery is due to a small deep working space, precise dissection of apex of the prostate, preservation of neurovascular bundle and urethrovessical junction reconstruction. The surgeon sits at the console which prevents any strain on the spine. The forehead is supported while leaning over a viewing box. It gives the surgeon the feeling of sitting over the patient and looking into the body. The robotic instruments are a direct extension of the surgeon's hands. The operating surgeon is less fatigued compared to open surgery. The comfort level is further increased with elimination of gown, gloves and mask.

#### **Patient Factors**

Robotic surgery has benefits for reduction in length of stay, absence of large incision, less narcotic usage compared to

open surgery, improved cosmesis and early return to normal activity. It also appears that robotic surgery has captured the public's imagination. Individual patients believe that a surgeon equipped with a million dollar robot may be able to do a better job for them.

### **Role of Intuitive® Surgical**

Intuitive® Surgical encourages competition between local hospitals. They show statistics and how hospitals can generate increase in patient load by increasing referrals. This also spreads panic over losing the patient. They sponsor regional, national or international conferences to generate interest in robotic surgery.

#### **Worldwide Installations**

At present, there are more than 300 robotic systems installed worldwide. Around 240 systems are installed in US. All the major cancer centers and major teaching hospitals have robots. The remaining 60 systems are installed in Europe, Asia and Australia. The initial impetus to start robotic programs in Europe came from efforts to innovate the particular surgical approaches. In the United States, market forces of actual as well as perceived consequences of having or not having robotic programs played an important part in institutional decisions to invest in the daVinci Robot® system. Many recently initiated programs in the United States and Asia have been motivated by the desire to "keep up" with the leaders. Over 75 % of robotic systems are installed in community based hospitals. Owning a robot because your neighbour has one is an expensive proposition. Marketing expertise should not be the driving force for this technology [2].

#### **Cost consideration of daVinci® robot system**

At the present time, the four-arm system is \$ 1 to 1.3 million. The yearly service contract is around \$ 100,000. The operating room retrofit cost \$ 5–15,000. The 3D imaging projection costs \$ 35,000. The cost of training nursing staff, surgical technician and their salary/benefit package is around \$ 200,000. The cost of instruments with limited number of 'lives' per case is around \$ 400–800 [3].

Intuitive® Surgical has a monopoly on the market. It sells the robot, the instruments for the robot and its service contract. As with most forms of technology, prices come down over time. For example, it is cheaper to buy a powerful computer now than one developed 10 years ago. The number of computers sold in US outnumbered the number of television sets in the last decade. These changes are due to a decrease in cost and increased use of computers in our day to day activities. It is believed that the cost of a robot will decrease over time. In contrast, in surgical robotics, no price reduction is seen in any of the devices or instruments, in the last 10 years. Intuitive® Surgical has the monopoly over the FDA approved surgical robot system. The prices appear to increase, which is the main factor against rapid spread of robotic surgery. At present, the consumer is always confronted with the dilemma of making large investments in technology now that is certain to change in the future.

#### **Limitations of daVinci® robot system**

The present daVinci® system is heavy and cumbersome. It takes up a lot of space around the operating table and at

the surgical consol. The robot arms are fixed to the independent floor based unit which makes it difficult and dangerous to change the configuration of the operating table once the robot is docked. At present, there are a limited number of instruments available for use. The instruments have a limited number of uses before they become unusable [3].

The robot system lacks haptic feedback. Thus, the surgeon can not feel the texture of the tissue upon which he is working or the tension on the knots, while tying. So, it is common for new robotic surgeon to break suture when tying knots until he becomes familiar with the appearance of a taut suture [3].

### **The daVinci® Robot Utilization**

At present, Henry Ford hospital has two machines being used for 8–10 hours/day. Six cases are done per day. Hospitals which do 120 cases/year do better financially. At the University of California and Henry Ford Hospital, RAP is listed as an "outpatient" procedure since the average hospital stay is 23–27 hours. The patients' expectation of early discharge in US are different compared to patients' from rest of the world. Castello (2005) from Australia reported the hospital stay for RRP 5 days compared to 2 days for RAP [17].

Scales et al (2005) demonstrated the RAP is cost competitive at a medical center where hospitalization costs are higher. In low cost care settings, RAP would need to occur as an outpatient procedure to be cost competitive with RRP. When the case volume is more than 10 cases/week at specialist centers with dedicated robotic surgical teams, the amortized cost of the robot purchase and maintenance decreased below \$ 500/case. If the operative time is decreased below 165 minutes, RAP would achieve cost equivalence to RRP. In summary, local cost structure and practice patterns, i.e. volume and operative time have a determining role as to whether RAP is a competitive technology. RAP at a higher volume center may be cost competitive with RRP in the community setting [18].

Menon and Ahlering have reported the 3D image capabilities and easily manipulated articulating instruments in telerobotic systems shorten the learning curve of complex procedures (e.g. radical prostatectomy), even for laparoscopically naïve surgeons. Early results have shown that RAP results are comparable with open surgery [19, 20].

In 2 independent reports, Menon and Ahlering et al compared their personal results. The RAP operative time was similar to RRP, but there was significant reduction in blood loss, transfusion rate, hospitalization time (< 27 hours), catheterization duration and perioperative complications. They have reported similar positive margin rates (15 to 18 %), and continence rates (75 % to 80 % with no pads at 3 months). In short, experienced open uro-oncologists have achieved better results compared to open surgery with regards to recovery time and short-term outcome [19, 20]. It is still unclear if the improved visualization provided by the modern telerobotic system will translate into superior long-term outcomes.

It appears that patients and urologists are rapidly accepting the use of robots in radical prostatectomy. The number of RAP has tripled by the end of 2005.

## Training

An enormous interest has been generated to perform robotic-assisted laparoscopy during the last 2 years. A good support system is important to establish the robotic program in the hospital. The training of surgeon assistants and nursing staff is crucial. Didactic and videotape sessions are predominately informational in nature. The crucial teaching involves a non-clinical and a clinical phase. Non-clinical hands-on experience is achieved via pelvic trainers, animal laboratories or cadaver dissection and Robot Intuitive® courses. In the clinical training phase, surgical skills are acquired through observing, assisting and finally performing surgery under the direct guidance and supervision of an experienced surgeon-mentor. This mentor-trainee mini-fellowship in a protected environment allows skill and confidence building of the postgraduate urologists. It will decrease the learning curve and limit the conversion rate and complications [21].

### Types of Surgical Cases done, using daVinci® Robot system

- **Cardiac** – Cardiac revascularization, mitral valve repair, aortic ring ligation, PDA ligation
- **Gen. Surgery** – Roux-en-y gastric by-pass, Nissen Fundoplication, Heller myotomy, colectomy, cholecystectomy
- **Thoracic** – Thymectomy, lobectomy, esophagectomy, mediastinal tumor resection
- **Urology** – Prostatectomy, cystectomy, nephrectomy, partial nephrectomy, ureteral reimplantation, pyeloplasty
- **Gynecology** – Hysterectomy, myomectomy, sacrocolpopexy, tubal reanastomosis, ovarian transposition

- **Neurosurgery** – Stereotactic retractor guidance/positioning, needle/electrode placement, skull surgery, neuroendoscopy, microneurosurgery

## Future of Robotic Surgery

Surgical robotics has bright future. It is hoped that the telerobotic system will be equipped with integrated real-time imaging systems. Telerobotics will be used for remote telesurgery, telementoring and proctoring.

Rigorous scientific evaluation is necessary before adopting robotic assistance for any surgical procedure. Legal and licensing barriers will need to be overcome before telesurgery becomes clinically viable. Randomized trials and prospective data comparing robotic to open and laparoscopic surgery are necessary. Validated patient-satisfaction surveys are also important.

Robotics is rapidly becoming a part of the operating room of the future. As surgery continues to be less invasive in the future, the instruments of our intervention will more and more be delivered via robotic or computer-assisted interface. We hope that in the future a decrease in cost will make robotic assisted surgery more affordable to many more than a privileged few [2, 3].

## Conclusions

Robotic surgery is here to stay. The current technology as we know it is but the tip of the iceberg for what the potential applications will be in the future.

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**Dr. Gaurang Shah**

Chief Resident in Urology, Department of Urology, SUNY Medical University



**Dr. Gabriel P. Haas**

Professor and Chairman, Department of Urology, SUNY Upstate Medical University.

Dr. Haas graduated with a Bachelor of Science from University of Michigan in 1978 and received his Doctor of Medicine from Wayne State University, Detroit, Michigan in 1982. He completed his urology resident training at Henry Ford Hospital, Detroit, Michigan in 1987. He became affiliated with the Uniformed services University in 1987, when he was a Fellow and Clinical Associate at the Surgery Branch of the National Cancer Institute, Bethesda, Maryland, in the laboratories of Steven A Rosenberg. Besides his many duties and responsibilities at SUNY Upstate as a the Chairman of the Department of Urology, Dr. Haas is also the Chief Consultant in Urology with the Albert Schweitzer Hospital Decapelles, Haiti and has been a Medical Examiner at the United Arab Emirates University in Dubai.

Dr. Haas' clinical activities are focused on GU malignancies. Recently, he developed robotic surgery program in Syracuse. He also maintains an active Basic Science laboratory and continues to participate on NIH study sections. He currently serves as President of the Northeast Section of the AUA.

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## Fachinformation zu S. 29

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Qualitative und quantitative Zusammensetzung: 1 ml Injektionslösung enthält 250 mg Testosteronundecanoat, entsprechend 157,9 mg Testosteron. 1 Ampulle mit 4 ml Injektionslösung enthält 1000 mg Testosteronundecanoat. Anwendungsgebiete: Testosteronersatz bei männlichem Hypogonadismus, wenn der Testosteronmangel klinisch und labormedizinisch bestätigt wurde (siehe Abschnitt 4.4 „Warnhinweise und Vorsichtsmaßnahmen für die Anwendung“). Gegenanzeigen: Die Anwendung von Nebido ist kontraindiziert bei androgenabhängigem Karzinom der Prostata oder der männlichen Brustdrüse; früheren oder bestehenden Lebertumoren; Überempfindlichkeit gegenüber dem arzneilich wirksamen Bestandteil oder einem der sonstigen Bestandteile. Sonstige Bestandteile: Benzylbenzoat, Raffiniertes Rizinusöl. Pharmazeutischer Unternehmer: Schering Austria GmbH, Wienerbergstraße 41, 1121 Wien. Verschreibungspflicht/Apothekenpflicht: Rp, apothekenpflichtig. Pharmakotherapeutische Gruppe (ATC) : ATC-Code: G03B A03. Stand der Information: Juni 2005.

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