SURGICAL ROBOTICS

Montpellier, France

Pôle Universitaire Européen de Montpellier et du Languedoc-Roussillon

Laboratoire d'Informatique de Robotique et de Microélectronique de Montpellier LIRMM

Frontiers of Endoluminal Robotics Surgery (Part 1)

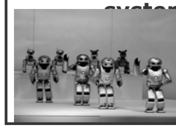
Cesare Stefanini

Scuola Superiore Sant'Anna
Pisa, Italy

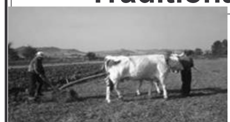
a lab of inventors and entrepreneurs

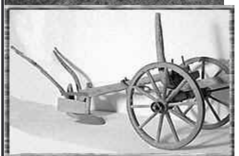
Definitions of Robotics

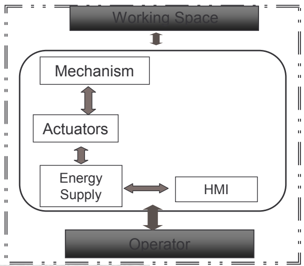
- A robot is a re-programmable, multi-functional, manipulator designed to move material, parts, or specialized devices though variable programmed motions for the performance of a task
  Robotics Industry Association (~ 1980)
- Robotics is the intelligent connection of perception to action
  Michael Brady (~1985)
- A robot is a machine able to extract information from its environment and use knowledge about its world to move safely in a meaningful and purposeful manner
  Maja Mataric (~ 1990)
- The science and technology of the design of **mechatronic systems** capable of generating and controlling motion and force
  Paolo Dario (~ 2000)

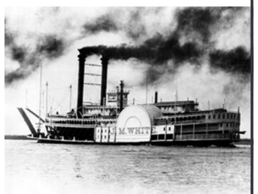


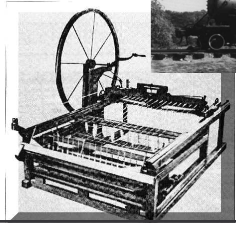
The Evolution of the Robotics Platform: from Traditional ("Pre-mechatronic") machines…



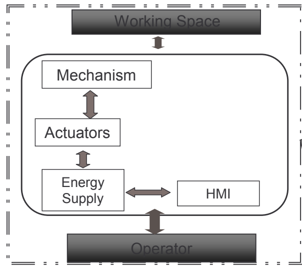


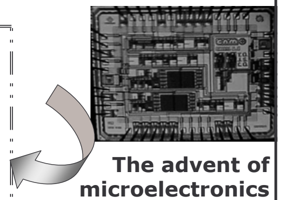




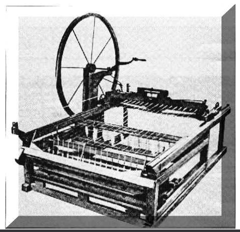


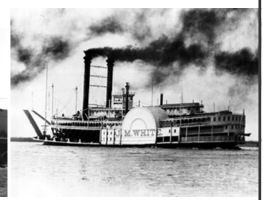
…..to Mechatronics



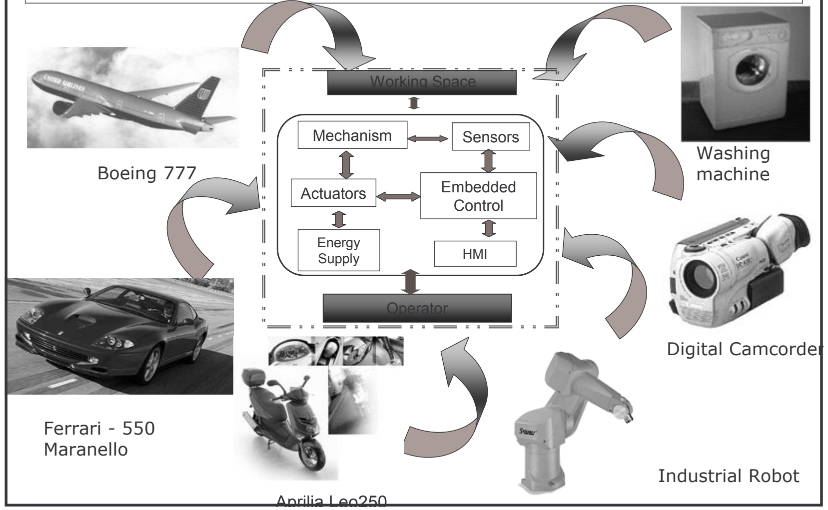


The advent of microelectronics

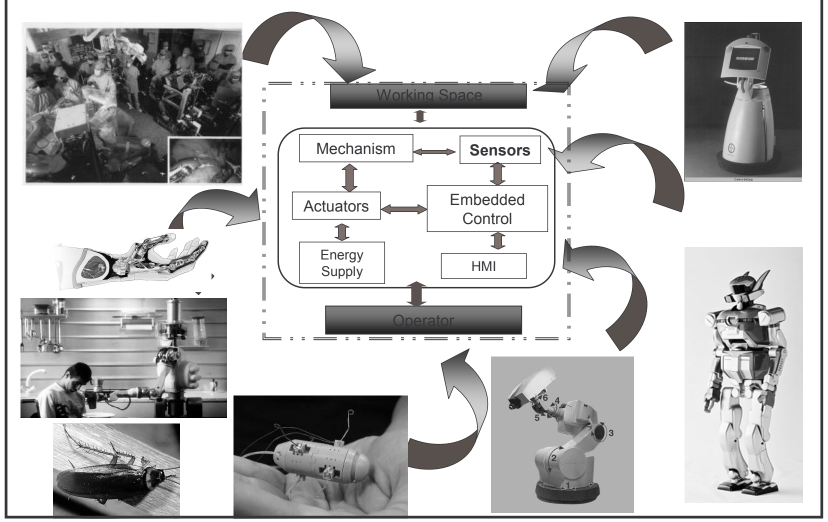




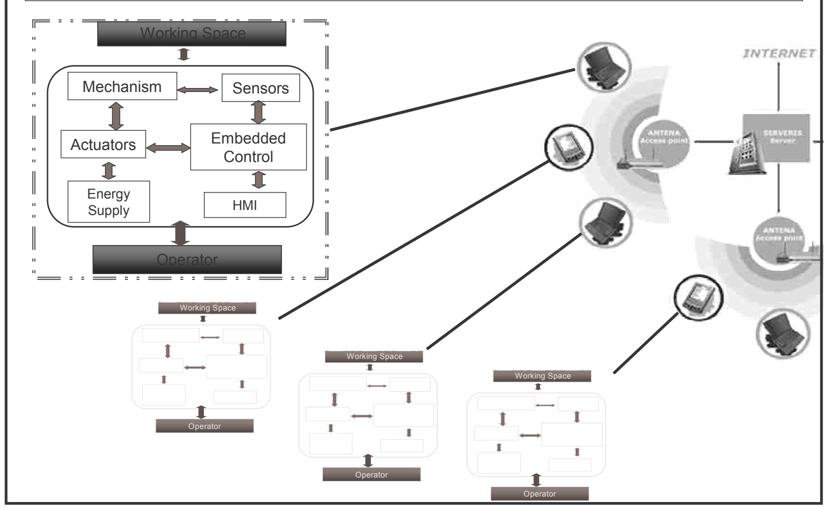
Mechatronics: the Ubiquitous Paradigm of Current Machine Design



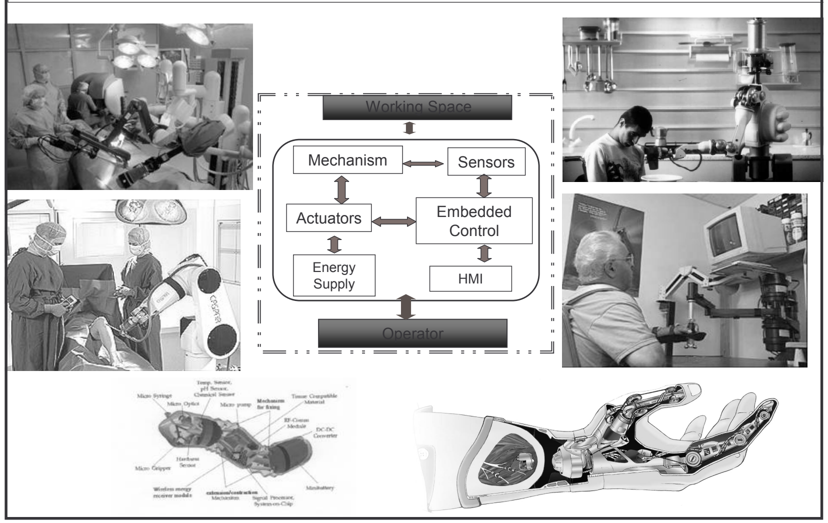
Mechatronics: the Modern Paradigm of Machine Design



Ubiquitous Mechatronics and Robotics: the Next Paradigm of Machine Design

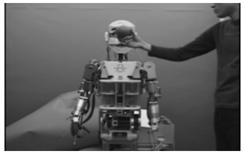


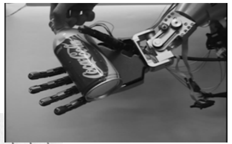
Mechatronics: the Paradigm of Bio-Robotics Design

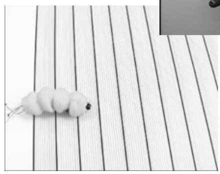


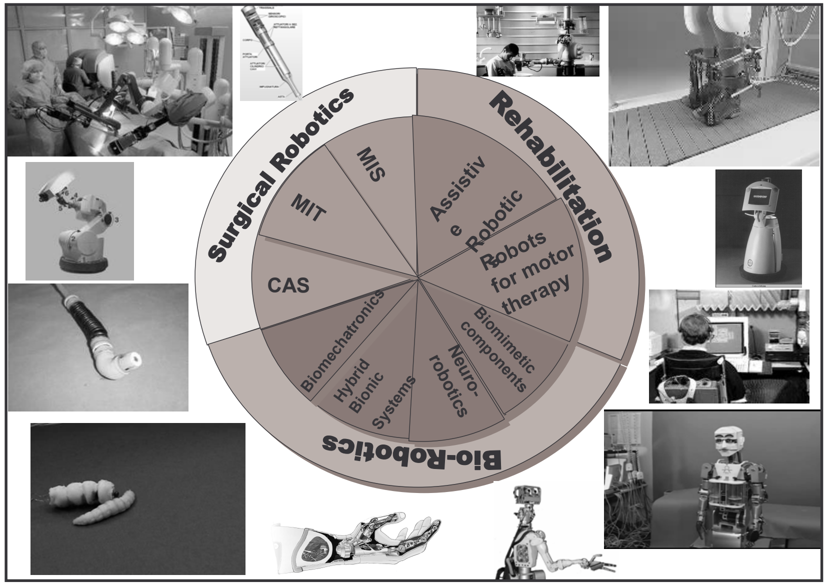
The objectives of bio-mechatronics/robotics

- To develop design theories and fabrication technologies for biomimetic and bio-inspired mechatronic systems
- To design and fabricate robotic systems that will interact with humans for restoring or enhancing human functionalities and abilities
- To develop bio-inspired physical platforms to experimentally test models of living systems and their working principles









Bio(medical) Robotics

A New Discipline Combining Leading-Edge Technology with Service to Humans

- Challenge for research
- Solutions to important societal needs
- Potential for generating a new industry

Biomedical Robotics

Robotics for Diagnosis and Surgery
- Micro-robotic systems for minimally-invasive endoscopic diagnosis and cell surgery
- Robots and mechatronic tools which improve the quality of surgery, in terms of accuracy, reduced invasiveness, predictability of results

Rehabilitation Robotics

Robots and mechatronic tools for clinical therapy in neuro-motor rehabilitation

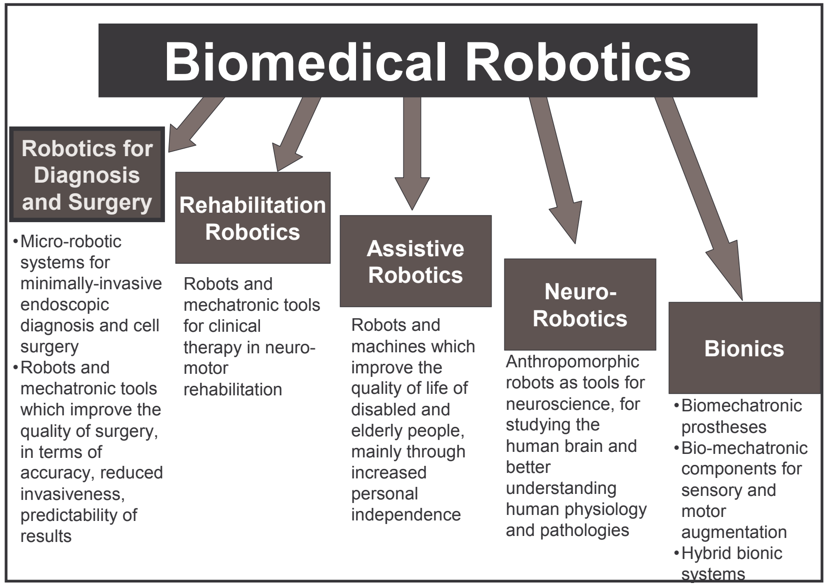
Assistive Robotics

Robots and machines which improve the quality of life of disabled and elderly people, mainly through increased personal independence

Neuro-Robotics

Anthropomorphic robots as tools for neuroscience, for studying the human brain and better understanding human physiology and pathologies

Bionics
- Biomechatronic prostheses
- Bio-mechatronic components for sensory and motor augmentation
- Hybrid bionic systems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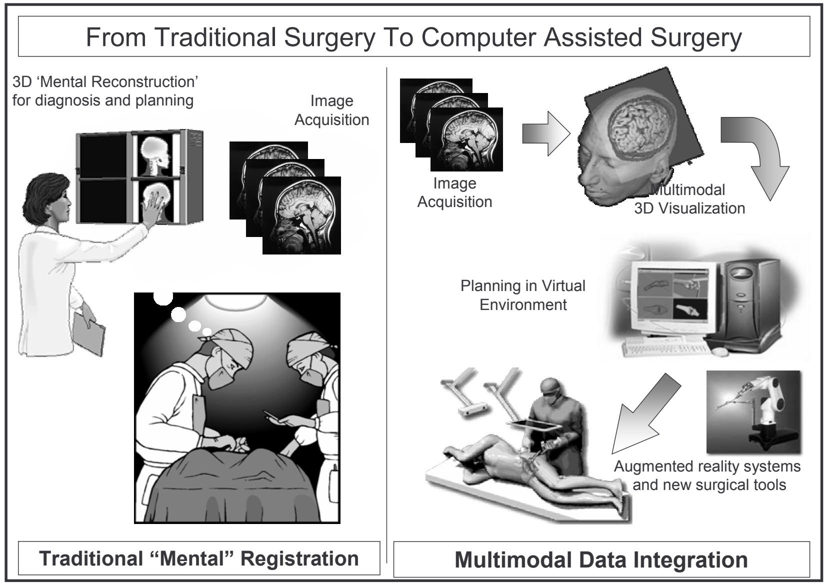
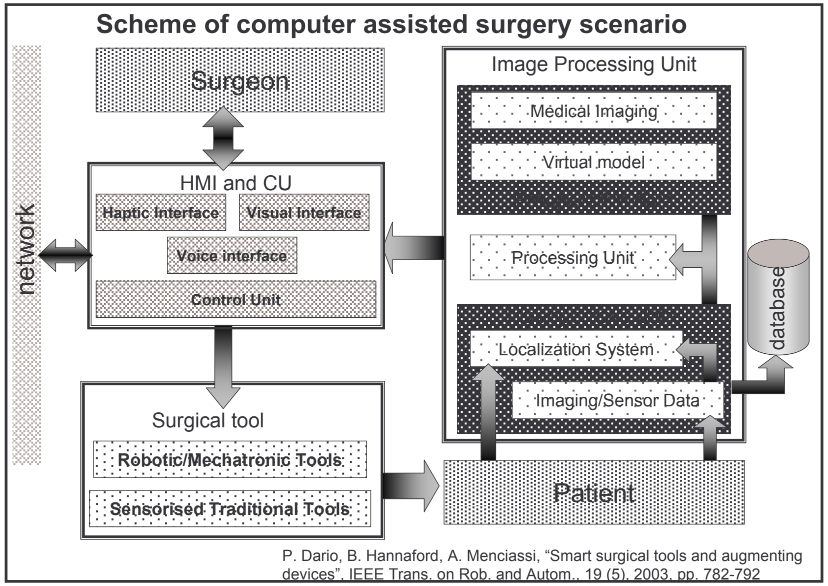
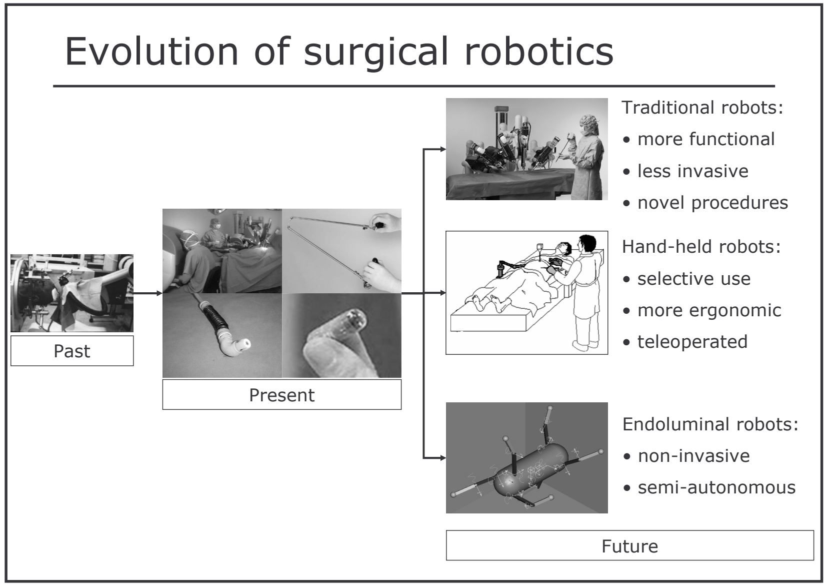
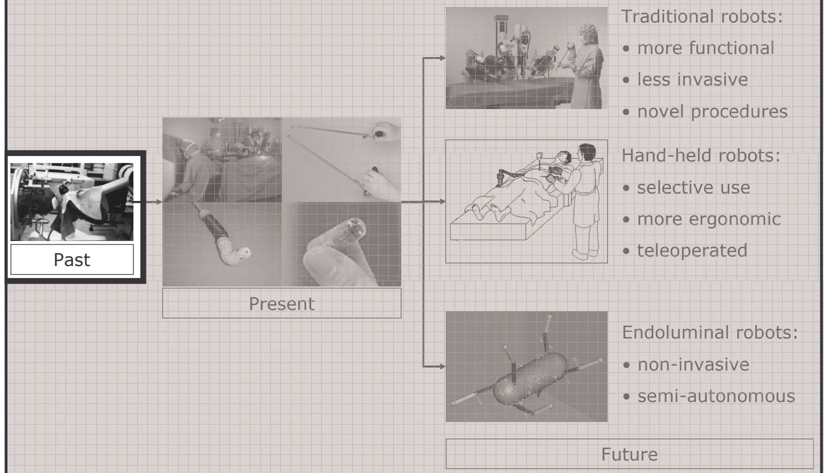

From Traditional Surgery To Computer Assisted Surgery
3D 'Mental Reconstruction' for diagnosis and planning
Image Acquisition
Image Acquisition
Multimodal 3D Visualization
Planning in Virtual Environment
Augmented reality systems and new surgical tools
Traditional "Mental" Registration
Multimodal Data Integration


Scheme of computer assisted surgery scenario
Surgeon
network
HMI and CU
Haptic Interface
Visual Interface
Voice interface
Control Unit
Surgical tool
Robotic/Mechatronic Tools
Sensorised Traditional Tools
Image Processing Unit
Medical Imaging
Virtual model
Processing Unit
Localization System
Imaging/Sensor Data
database
Patient
P. Dario, B. Hannaford, A. Menciassi, "Smart surgical tools and augmenting devices", IEEE Trans. on Rob. and Autom., 19 (5), 2003, pp. 782-792


Evolution of surgical robotics
Past
Present
Future
Traditional robots:
• more functional
• less invasive
• novel procedures
Hand-held robots:
• selective use
• more ergonomic
• teleoperated
Endoluminal robots:
• non-invasive
• semi-autonomous

Evolution of surgical robotics



History of Robotic Surgery

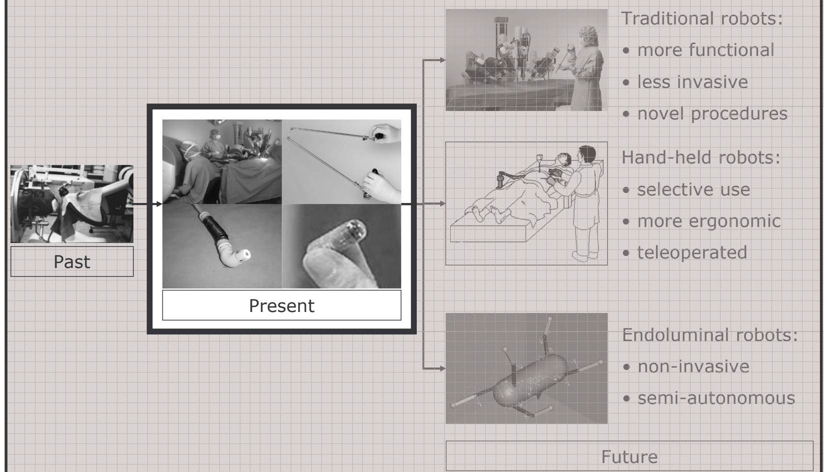
- 1985: Kwoh, Young et al.
  1st robot (Puma 560) in neurosurgery
- 1989: Benabid, Lavallée et al.
  1st patient in neurosurgery (Neuromate)
- 1991: Davies et al.
  1st patient for TURP (Puma 560)

Source: J. Troccaz, 2003

Evolution of surgical robotics

Past

Evolution of surgical robotics



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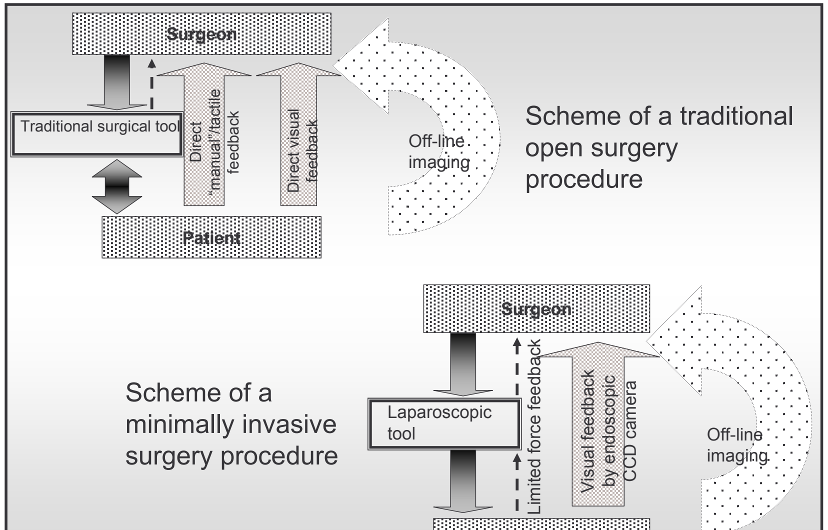
- 1991: Davies et al.
  1st patient for TURP (Puma 560)
- 1992: Integrated surgical systems
  1st hip surgery with **ROBODOC**
- 1994: Computer Motion Inc.
  1st FDA clearance: AESOP laparoscope holder
- 1998: Intuitive Surgical, Inc.
  1st st totally endoscopy CABG using the daVinci
- 2001: Computer Motion Inc. Lindberg operation:
  New-York/Strasbourg tele-operation using ZEUS.

Source: J. Troccaz, 2003

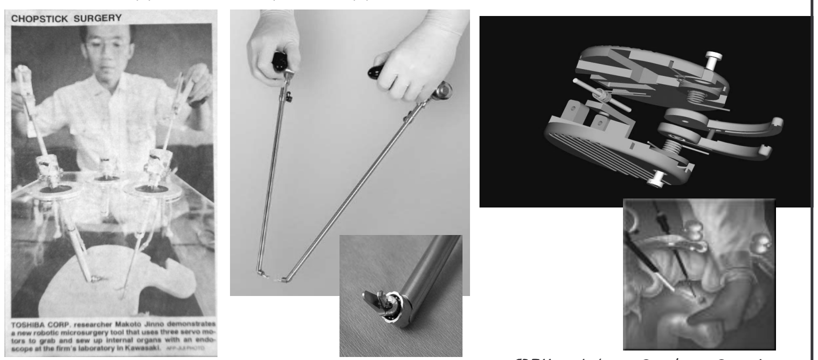


P. Dario, B. Hannaford, A. Menciassi, "Smart surgical tools and augmenting devices", IEEE Trans. on Rob. and Autom., 19(5), 2003, pp. 782-792

Enhanced traditional surgery

Polo Sant'Anna Valdera

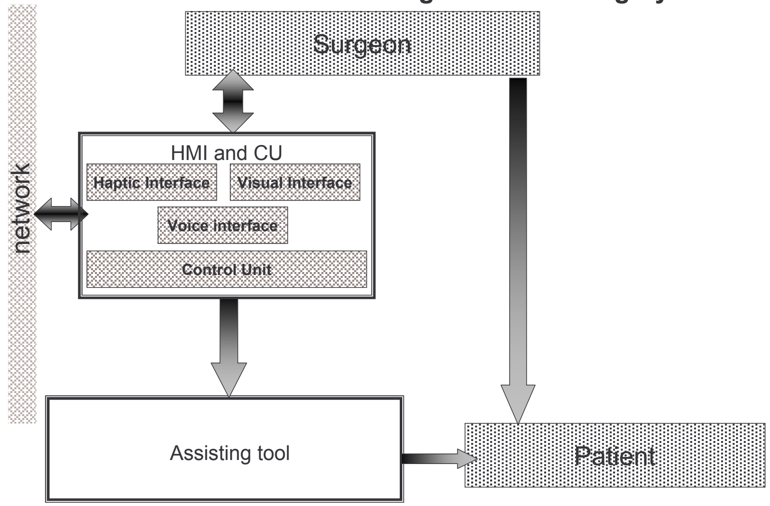
- Dexterity is provided to the tip of a traditional instrument
- No mechatronic approach, only microengineering technology.
- Fields of application: Laparoscopy



Toshiba Corp., Japan. Tuebingen Scientific GmbH., Germany

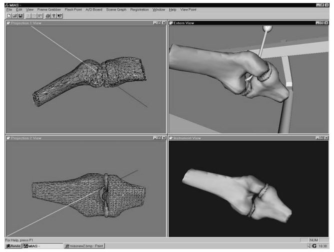
CRIM Lab, Scuola Superiore Sant'Anna, Pisa

Scheme of assisting device for surgery



Assisting devices for navigation

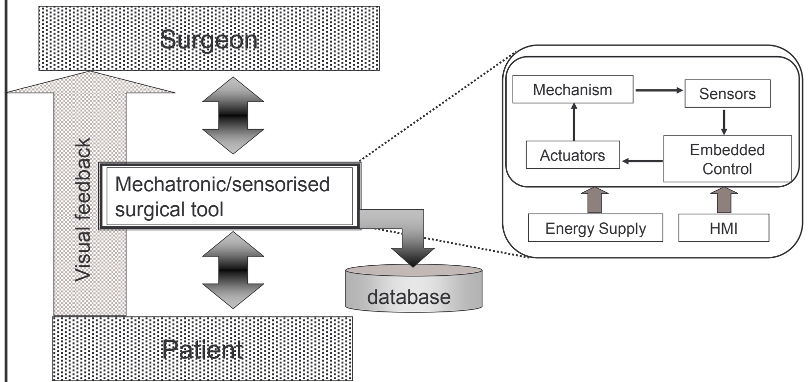
- Auxiliary devices
- Man-machine interface with voice control
- Visual feedback
- Applications: Arthroscopy, Laparoscopy



Navigation software for arthroscopy (Scuola Sant'Anna, Pisa).

Aesop, camera-holding robot for laparoscopy, voice controlled (Computer Motion Inc., USA)

Scheme of hand-held tools for surgery



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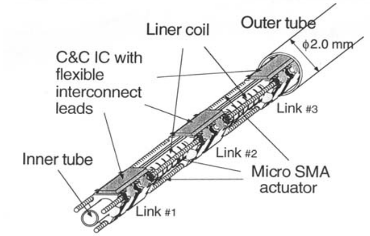
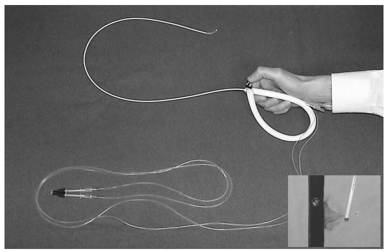
Active endoscopes

- Miniaturized extremities able to reach very small environments
- Tools dealing with structures impossible to reach in any other way.
- Minimally invasive
- Applications: Endoscopy, Cardiac surgery, Neurology



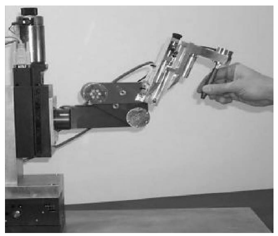
Active catheter with on board communication. O.D. 2 mm. (M. Esashi, Tohoku University, Japan).



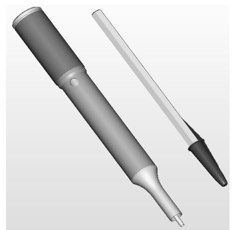
Active catheter for neuroendoscopy with steering capability and fluid circulation (Scuola Sant'Anna, Pisa).

Hand-held tools for surgery

- Active instruments cooperating with the user, portable and intuitive
- Tremor Compensation, Force reduction
- Fields of application: Eye Surgery, Microsurgery



Co-operant instrument for microsurgical procedures (R. Taylor, Johns Hopkins University, Baltimore, MD, USA).



Active hand-held instrument for tremor compensation (CRIM Lab).

Tremor Compensation

Consumer Electronics

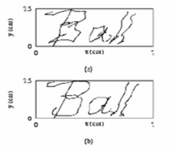
Digital Camcorder

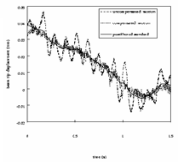
(Panasonic et al.)

Microsurgical device

Intelligent hand-held instrument for ophthalmologic microsurgery

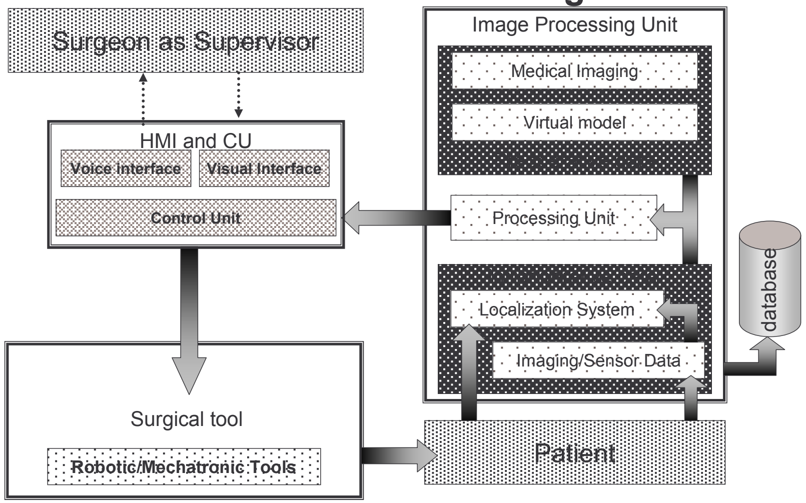
(MRCAS - Carnegie Mellon Univ. Robotics Institute - Pittsburgh, PA)





Compensation Strategy:
The instrument detects its own motion, distinguishes between desired and undesired motion using active filtering, and actively compensates for undesired motion by an equal but opposite deflection of its own tip.

Scheme of autonomous surgical robots



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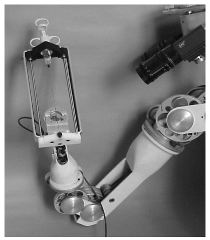
Autonomous surgical tools

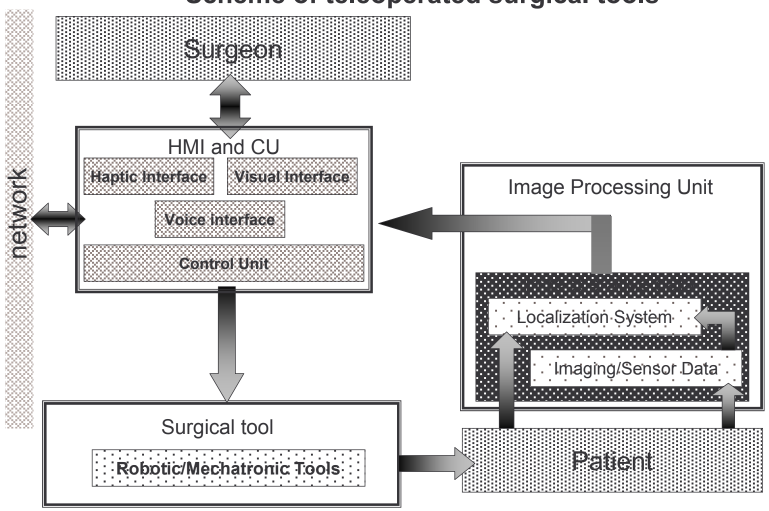
- <u>The Robot is used as a highly accurate CNC machine</u>
- Pre-operative planning and simulation through virtual modeling
- Registration with the anatomy
- Fields of application: Orthopedics, Neurosurgery, biopsy

CASPAR robotic arm (URS Ortho GmbH & Co. KG, Rastatt, Germany).



Robotic arm for Computer assisted Biopsy (CRIM Lab).

Scheme of teleoperated surgical tools



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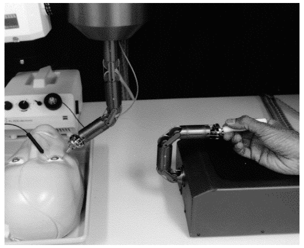
Teleoperated surgical tools

- Robot used as a "slave" system, under visual feedback
- Motion scaling and tremor compensation
- Fields of application: Laparoscopic and thoracic MIS, Eye Surgery

The DaVinci" system (Intuitive Surgical, Inc., Mountain View, CA, USA).

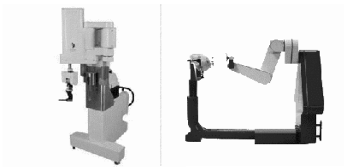


The "RAMS" system (Jet Propulsion Laboratory, Pasadena, CA, USA).

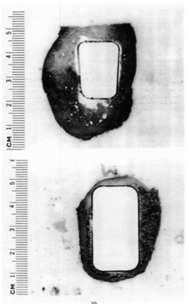
Surgical and Diagnostic Robots: applications

Type of Interaction	Type of Access: Traditional Access	Type of Access: Minimally Invasive Access	Type of Access: Endocavitary/ endoluminal access
Autonomous systems	ROBODOC CASPAR	Stereotaxis Inc	Endoscopic Microcapsules
Interactive systems	Eye scalpel RinC	AESOP MIAS	Active Catheters
Teleoperated systems	Mammotome PAKY	da Vinci ZEUS	Neuro-endoscopy
Passive systems	PinPoint	HALS (non robotic)	Given Imaging (non robotic)

ROBODOC Surgical System
computer-controlled surgical robot for creating an exact implant cavity in the patient femur during Total Hip Arthroplasty (THA).

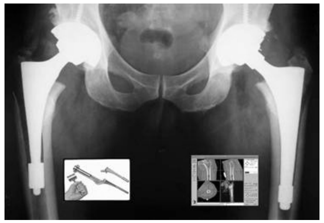


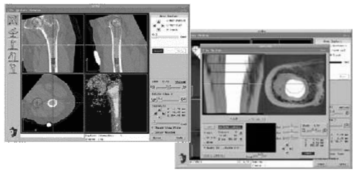
Bone implant comparison



Manual broach method
20% contact surface
1-4 mm gap size

ROBODOC method
96% contact surface
0.05 mm gap size

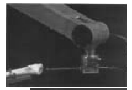


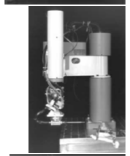


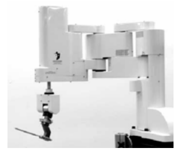
ORTHODOC
Pre-surgical planning station

http://www.robodoc.com

ROBODOC Generations







- Prototype: Feasibility study (1986)
- Alpha: Canine System (1990)
- Beta: Human clinical prototype
  - Version 1: 10 patient study (1992)
  - Version 2: Multi-center trial (1993)
- Commercial Product
  - C System: First version (1996)
  - D System: Custom electronics (1999)

Source: http://www.cs.jhu.edu/~cis/cista/145/Lectures/KazanzidesRobodocLecture.pdf

Numerous studies demonstrated that the ROBODOC system was safe and effective

- **ROBODOC was used for Primary total hip replacement, Revision hip replacement and Total knee replacement**
- **(1996 – Operating room teams at three U.S. hospitals): in 300 clinical trials the robot precisely prepares the femoral canal for the cementless prosthesis**
- **(1997 – Berufsgenossenschaftliche Unfallklinik, Frankfurt): in 465 patients, the high precision in reaming, leading to a superb bone implant contact, absolute stability and primary healing between implant and bone. A second system of Robodoc was installed**
- **(1998) The combined experience of the United States Food and Drug Administration multicenter trial and the German postmarket use of ROBODOC on over than one thousand patients lead to this expression: "The ROBODOC system is thought to be safe and effective in producing radiographically superior implant fit and positioning while eliminating femoral fractures"**

From Technical Wonder to Malpractice Liability

In 1997, a patient, after receiving an artificial hip, said: "It fits real well, but I can't walk any more"

• (2000 – Klinik und Poliklinik fur Orthopadie, Martin-Luther-Universitat Halle-Wittenberg): in 87 procedures analysed, only in few cases the potential of the system can be used beneficially. After one year some complications were noticed in 41 patients: thrombotic embolism (2) (one lethal), fracture of the greater trochanter using the straight stem (3), aseptic drainage due to hematoma (2). Further 12 patients noticed a postoperative pain at the distal marking pin location (condylus femoris medialis) for an average of 3 months.

• (2001 – Department of Orthopaedic Surgery, University of Innsbruck, Austria): some studies demonstrated that ROBODOC's high-speed cutter produces an aerosol cloud of irrigation fluid, blood, and tissue debris, which is an infection risk for the surgical team. In 11 of 20 specimens examined, the 2-pin-based ROBODOC hip arthroplasty procedures had injured some nerves, that can cause pain in patients. A study, designed to measure temperatures in the cutting area, showed a mean temperature of 94 degrees C in proximal areas and a mean temperature of 172 degrees C in the area of the distal cement plug.

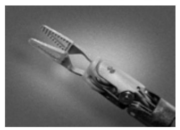
- (2002 – Stiftung Orthopadische Universitatsklinik, Heidelberg, Germany): a study on 48 type of synthetic femora placed with hand-broaching and robotic systems was done. Results said that some stems were more stable in hand-broached femora.
- (2004 – Department of Orthopaedic Surgery, Osaka University Medical School, Japan): it was demonstrated that the ROBODOC femoral milling system may reduce the risk of clinically significant pulmonary embolism during cementless THA and that the clinical femoral canal preparation results in a high degree of accuracy.
- (2005 – Medizinischer Dienst der Spitzenverbande der Krankenkassen): a study based on 57 publications and three HTA-reports concluded that patients must be informed about risks, complications, benefits and especially alternatives to a robot-assisted operation. The prospective procedure of management of assumed malpractice concerning Robodoc can not be standardised, but each case must be evaluated individually. Consequently, implementation of a structured malpractice management system for health insurance and medical advisory services should be useful. Additionally, health service should implement an "early warning system" for innovative procedures.

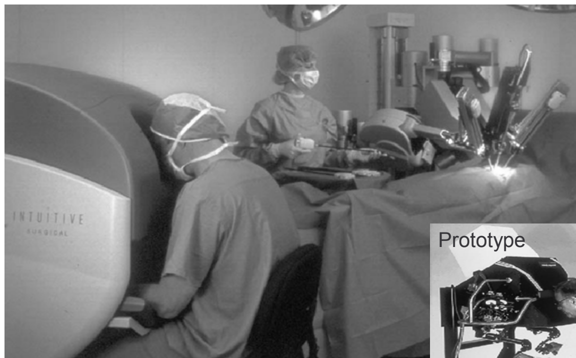
Robodoc has been used for 14,000 to 15,000 surgeries around the world (up to Dec 31, 2004). German surgeons started using it in 1995.

The number of German centers still using Robodoc has dwindled from 70 to merely a dozen, casting doubt over the future of this once-promising technique.

INTUITIVE SURGICAL
da Vinci™ Surgical System

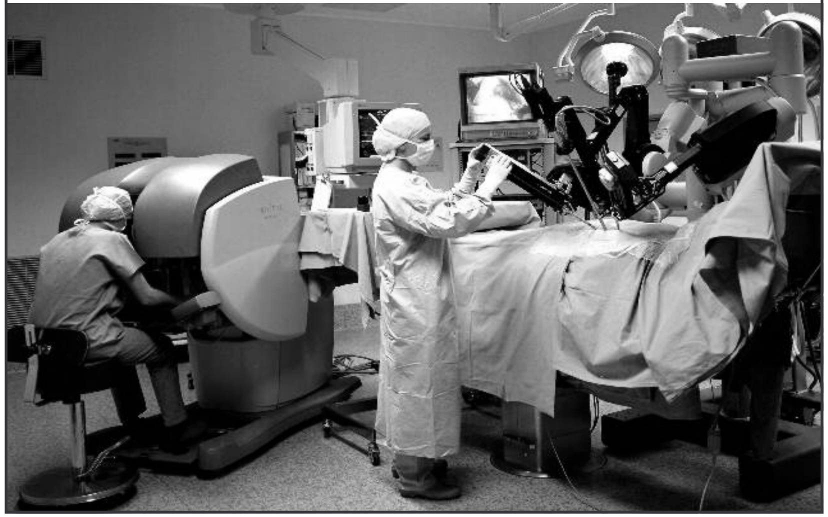
- Master-slave manipulator equipped with 2 articulated joints at the tip of the surgical instruments allowing 7 degrees of freedom
- Mimics the movements of surgeon's wrist and fingers in the abdominal or thoracic cavity



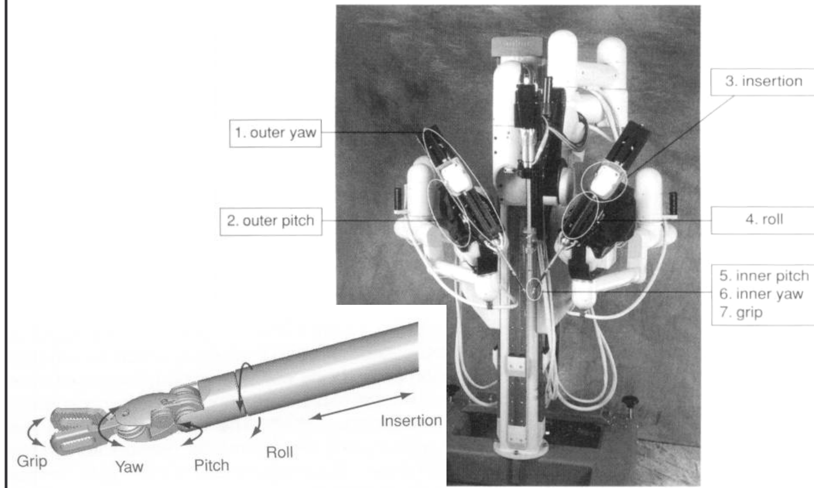


Prototype

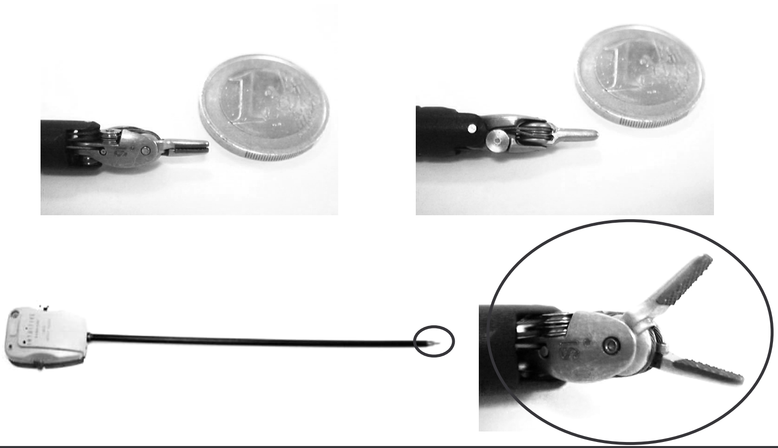
The “Da Vinci” system



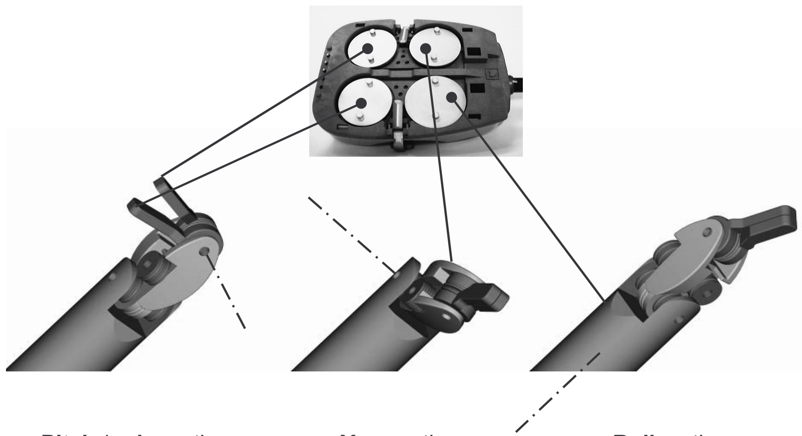
The “Da Vinci” system – slave DOFs



Robotic wrist for endoscopic surgery: the Intuitive “Endowrist”



Four Endowrist Degrees of Freedom



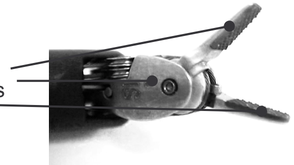
Pitch / **grip** motion **Yaw** motion **Roll** motion

Some details on endowrist

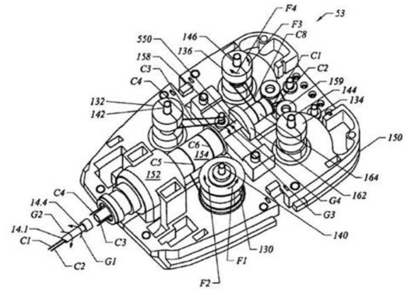
- Transmission:
  - ➢ miniature, 0.35 mm diameter cable
  - ➢ very flexible, bundles of about 100 stainless steel wires
  - ➢ pulling force: more than 30 N.

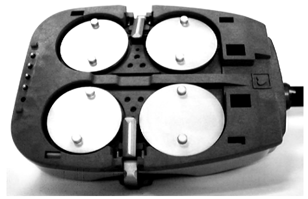
7 x 19

- Kinematics ranges:
  - ➢ roll and yaw motion: ± 90° (yaw is much more than the human hand)
  - ➢ gripper opening: 150°
- Fabrication:
  - ➢ micro casting for the main link and the jaws
  - ➢ laser etching of the working jaws surface
  - ➢ precision machining of the pulleys

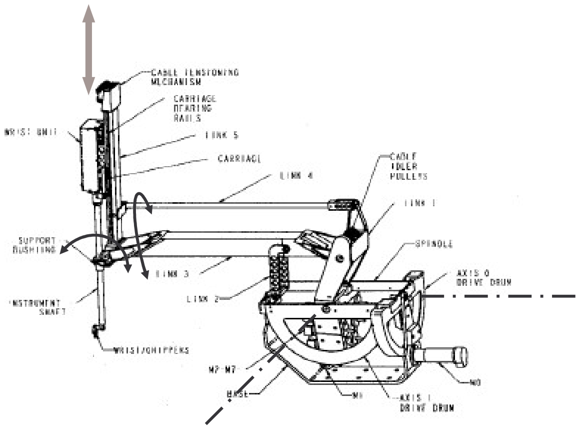


Robot / end-effector interface





Three external degrees of freedom



da Vinci: summary of about 70 abstracts of clinical studies published in 2000-2005

Teleoperation Units sold

- Up to April 2001, Computer Motion shipped 1,350 systems to customers worldwide, including 578 AESOP's, 723 HERMES, 46 ZEUS and 3 SOCRATES
- Intuitive Surgical daVinci population:
  - 34 units sold in 2001
  - 60 units sold in 2002
  - 149 units sold up to Dec. 31, 2002

Source: Computer Motion and Intuitive Surgical Press Releases

Robotic surgery Vs traditional laparoscopy

The Da Vinci system has been used for:

- prostatectomy
- cholecystectomy
- adrenalectomy
- thoracic surgery
- vascular procedures
- thymectomies
- fundoplication
- esophageal dissection
- extirpation of mediastinal masses
- lower lobectomy

Robotic surgery Vs traditional laparoscopy

- Same hospitalization time
- Similar blood loss
- Same cauterization time
- Enhancement of learning curve for Robotic surgery
- Patient-reported mean pain scores were almost identical

Use of telerobotic systems

- Number of robotic procedures performed

	Intuitive Surgical da Vinci system	Computer Motion Zeus system (estimated)
General surgery	2220	100
Thoracic/vascular surgery	1993	570
Gynaecology/urology	1145	270

Source: JP Ruurda et al., Ann R Coll Surg Engl 2002; 84 (July): 223-226

According to published information, we estimate that there were about 50-100 da Vinci systems sold at the time. This means that, on average, each da Vinci system performed about **1.5 interventions per week**.

Robotic surgery Vs traditional laparoscopy

- Same hospitalization time
- Similar blood loss
- Same cauterization time
- Enhancement of learning curve for Robotic surgery
- Patient reported mean pain scores were almost identical
- **Robotic surgery is expensive**
- **Robotic surgery has higher operative duration time**

da Vinci costs

- Initial investment and running costs amount to approximately $800,000 initially and $100,000 per year
- This increases the average cost of treatment per case by $1,500–2,000, in a scenario with 200 procedures per year, in a 10 years time frame

[J. Rassweiler & al. Min Invas Ther & Allied Technol 2001, 10(6) 261–270]

[R. Costi & al. Am Coll Surg 2003, 197(3) 500-507]

Operative times in Robotic and traditional Laparoscopic surgery

- **Prostatectomy:** *163 minutes Versus 100 minutes*
  (Department of Urology, University of California-Irvine, UCI Medical Center, Orange, CA, USA. - 2003)
- **Adrenalectomy**: *132 minutes versus 82 minutes.*
  (Ospedale San Giovanni Battista Le Molinette Università degli Studi di Torino. – 2003, CHU de Nancy-Brabois , France- 2003)
- **Fundoplication:** *97 minutes, versus 83 minutes.*
  (Ospedale San Giovanni Battista Le Molinette Università degli Studi di Torino. - 2003)
- **Cholecystectomy:** *60-171 min (52 min for the robot-assisted act itself) versus 70-90 minutes.*
  (Innsbruck University Hospital -2002)

Some procedures have to be completed with traditional laparoscopic technique

- ***Heart surgery:***
  - ***75 cases from june 1999 to january 2002, 18 procedures completed with traditional Laparoscopy.***

  (Department of Thoracic and Cardiovascular Surgery, Johann Wolfgang Goethe University, Frankfurt, Germany)
- ***Adrenalectomy:***
  - ***9 cases from January to September 2002, 4 procedures completed with traditional Laparoscopy***

  (Ospedale San Giovanni Battista Le Molinette Università degli Studi di Torino - 2003)
- ***Cholecystectomy:***
  - ***25 cases , 2 completed with traditional Laparoscopy caused by system breackdown (Innsbruck University Hospital - 2002)***
  - ***35 cases, 1 completed with traditional Laparoscopy (Universitair Medisch Centrum Utrecht - 2002)***
- ***Aortic anastomoses:***
  - ***5 cases, 1 completed with traditional technique depending to external conflicts betwe the robotic arms (Mondor Hospital Creteil France- 2002)***
- ***Prostatectomy :***
  - ***159 cases June 2003 and May 2004, 1 completed with traditional technique (Department of Urologic Surgery, Vanderbilt University Medical Center, Nashville, Tennessee)***

The good news is…

- In radical prostatectomy (LRP), proven clinical advantages:
  - significant improvement in potency outcomes
  - at 6 months, 96% patients were continent

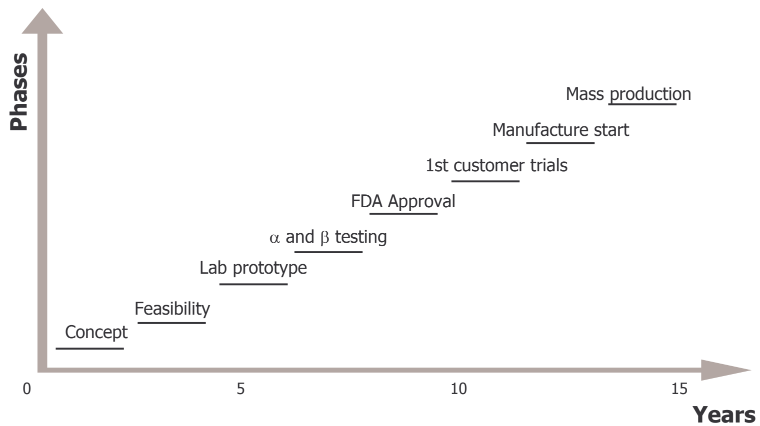
159 cases of prostatectomy from June 2003 to May 2004 (Department of Urologic Surgery, Vanderbilt University Medical Center, Nashville, Tennessee)

1,600 robotic procedures as of May 2005 (20/25 per week) (The Vattikuti Institute for Prostatectomy - Detroit)

Lessons learned

The Robotic systems for Computer Assisted Surgery that we know today were actually conceived and designed almost 20 years ago, by pioneers who explored this new field by observing surgeon's actions and reproducing them by a robot, with the goal of increasing the accuracy and ultimately the quality and predictability of intervention

Development of a novel biomedical product

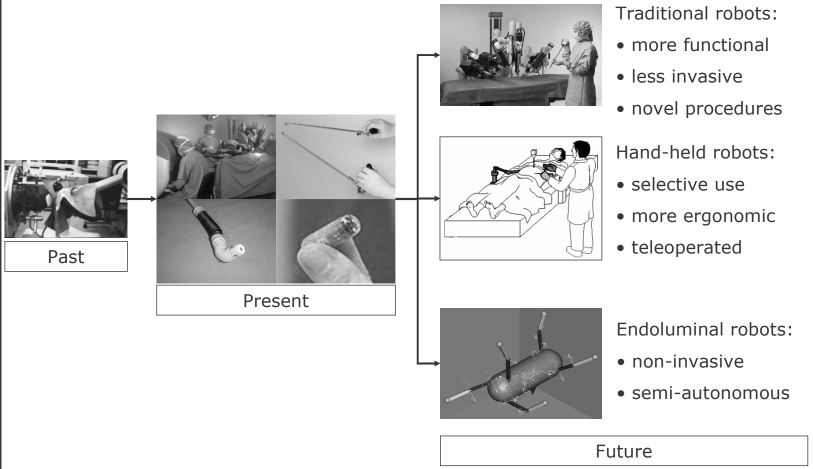


Source: A. Cuschieri, 2002

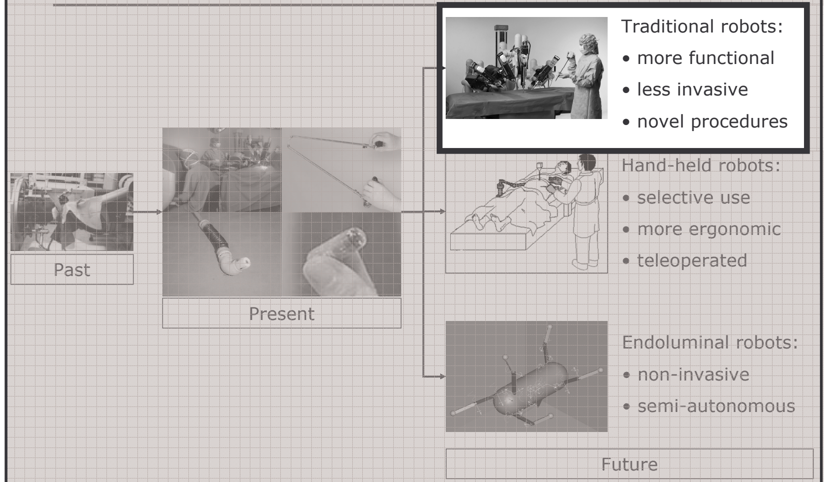
Trends in Computer Assisted Surgery

- Observing surgeon's actions and reproducing them by a robot, with the goal of increasing the accuracy and ultimately the quality and predictability of intervention
- Extending surgeon's capabilities in space (teleoperation) and size
- Augmenting surgeon's capabilities by means of hand-held instruments
- Extending surgeon's capabilities and reducing invasiveness by endoluminal surgery

Evolution of surgical robotics

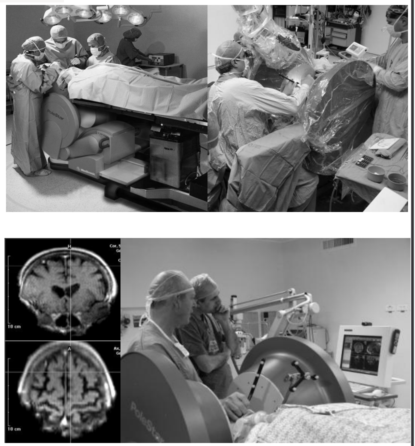


Evolution of surgical robotics



Intraoperative Imaging: PoleStar® N20 Medtronic

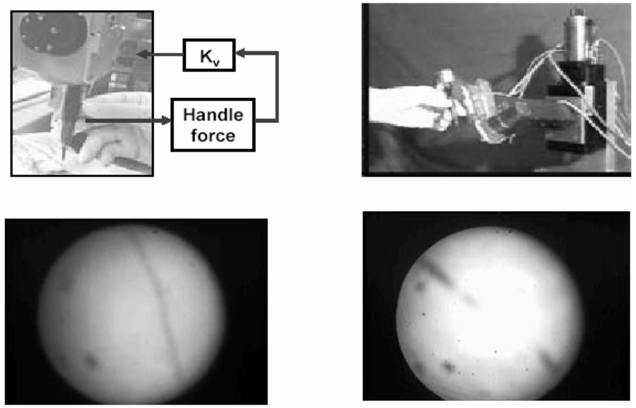
- Combining intra-operative imaging with surgical navigation in a completely registration-free system for neurosurgery
- The PoleStar® N20 provides quality MR images before, during and after surgery in the OR. These powerful images enable the surgeon to:
  - Plan the best approach and trajectory
  - Locate and excise lesions with confidence
  - Eliminate uncertainties due to changes in anatomy
  - Evaluate the margins of a lesion
  - Detect and remove residual tumor
  - Verify complete resection prior to closure



Navigation system: OrthoPilot Aesculap

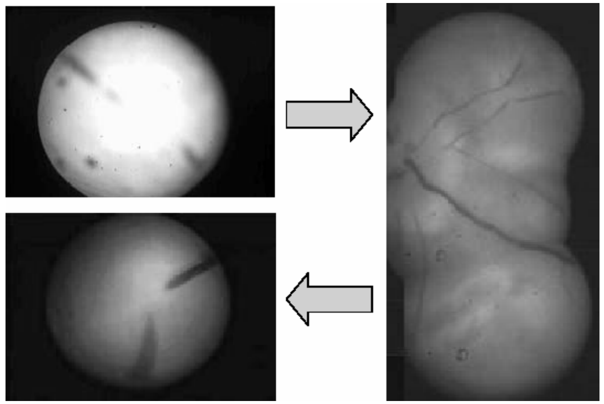
- Anatomically accurate positioning of implants, with the shortest possible extension of operating times
- Achieve the surgical objective without having to perform preoperational examinations or to take radiation-intensive and expensive CT or MRI scans
- There are surgeries in Knee Arthroplasty, Hip Arthroplasty and Anterior Cruciate Ligament Replacement.
- Localizer: Polaris NDI (Northern Digital Inc.): Hybrid Polaris Camera for active and passive techniques.

Steady Hand Guiding for Microsurgery



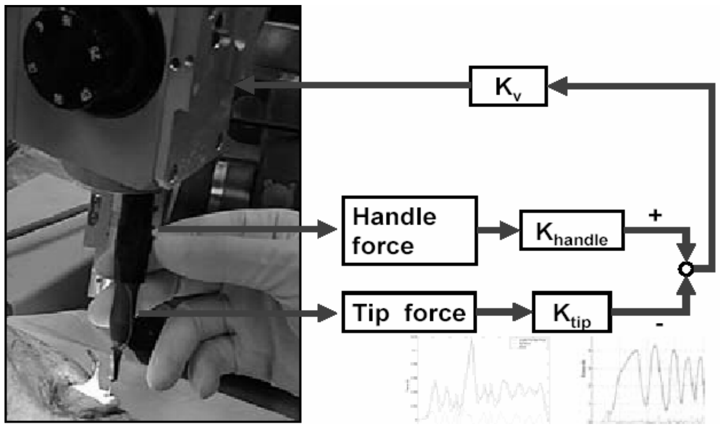
Free hand motion   Steady hand motion

Stable platform for interventions



R. Kumar, 2001

Steady Hand Force Scaling



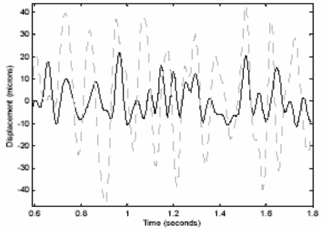
D. Rothbaum, J. Roy, L. Whitcomb, *et al.*

Micron: Active Cancellation with Freehand Device

Micron incorporates motion sensing and endpoint control

- small, hand-held design
- active tremor cancellation
- new system meets goal of < 10μm rms motion

Precise control of piezoelectric actuators is needed for effective active tremor compensation.



Active error compensation via Micron, displaying uncompensated (green) vs. compensated (blue) results.

Riviere, Ang, et al. (CMU)

Non-invasive surgery

AccuRay CyberKnife

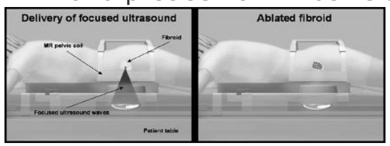
Image-Guidance System + Multi-Jointed Robotic Arm

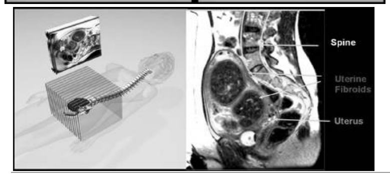
- **Planning:** CT Scanning and advanced treatment planning
- **Positioning:** The patient lies on a table with only the face mask or body mold used for immobilization
- **Verification:** The image-guidance system verifies the tumor location and compares it to previously stored data
- **Targeting:** When the tumor movement is detected, the robotic arm is repositioned within a fraction of a second
- **Repeat:** This verification process is repeated prior to delivery of each radiation beam
- **Treatment:** hundreds of finely collimateed radiation beams deliver precision radiosurgery to the tumor
- **Completion:** Following CyberKnife treatment, the patient goes home. There is zero recovery time.

www.accuray.com

InSightec ExAblate 2000

- ExAblate uses Magnetic Resonance guided Focused Ultrasound to treat tumors inside the body.
- Simultaneously, MRI is used to locate anatomy and indicate temperature changes inside the body allowing for a precise non-invasive surgical procedure.





www.insightec.com