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INDUSTRIAL ROBOTIC SOLUTIONS FOR INTERVENTIONAL MEDICINE

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ABSTRACT

Robotics is believed to have the same impact on healthcare in the next few decades as it had on manufacturing in the past 30 years. The field of computer-integrated surgery is rapidly developing, providing innovative and minimally invasive solutions to heal complex injuries and diseases. Well over 200,000 successful operations have been accomplished so far primarily in neurosurgery, orthopedics, ENT surgery, pediatrics and interventional radiology. In the near future, newly developed robotic systems may conquer even the most challenging fields to support better patient care and medical outcome. Surgical robots inherited many features and concepts from industrial manipulators, while greatly evolving them. The aim of the paper is to present medical robot systems based on industrial solutions, describe their basic characteristics and deployment. Parallelisms and differences are also highlighted between devices in manufacturing and interventional medicine.

INTRODUCTION

Industrial robotics have already conquered the field of assembly, automobile industry, appliance, undersea exploration, space missions and hazardous material handling. In the past two decades, a radically new field, Computer Integrated Surgery (CIS) has also been gaining significance. Most commonly, mechatronic devices have been used for prostatectomy, neurosurgery, nephrectomy, cholecystectomy, orthopedics and radio-surgery. Robot-aided procedures offer remarkable advantages both for the patient and the surgeon, making microsurgery and Minimally Invasive Surgery (MIS) a reality, and even complete teleoperation accessible [1]. CIS can increase the stability and robustness of the system, navigate accurately based on medical images and help positioning the surgical tool to the target point (image guided surgery) [2]. Furthermore, there is the option to introduce advanced digital signal processing and control or to record the spatial points-of-interest and motions. This can be useful for surgical simulation and risk-free training. Finally, robotized equipment can greatly add to the ergonomics of the procedure, especially in the case of laparoscopic MIS.

Due to the extensive research and application background behind industrial robotics, initial surgical robot setups heavily relied on those systems, and even today, some of the most successful products effectively integrate industrial solutions.

ADVANTAGE OF ROBOTS

The industry quickly realized the potential in automation, and heavily invested in developing universal solutions for manufacturing and assembly. The primary reason

to apply robots was the accuracy, strength and speed that improved the quality of repetitive tasks, and eventually lowered production costs.

Medical applications are partially built on the same principles, to exploit the accuracy and reliability of the robots; however, tasks are typically unique, involving the semi-autonomous manipulation of deformable objects in an organic, limited environment. Beyond, the power of the manipulators enables to move medical devices in a revolutionary way. Safety is paramount in every application, and robotic hardware and software solutions allow for extensive safety implementations. Figure 1 compares relevant features of a robot versus a human operator.

| Feature | Human | | Robot | |
|--------------------|--|---|--|---|
| Coordination | Limited hand-eye coordination | - | Great precision | + |
| Dexterity | High within sensory range | + | Limited by the actual sensors, range can exceed human perception | + |
| Information | High capacity on high level - | + | Limited by AI on high level – | - |
| integration | Easy to overload on low level | - | High capacity on low level | + |
| Adaptivity | High | + | Depends on design, but limited | - |
| Stable performance | Degrades fast by time | - | Degrades slowly | + |
| Scalability | Biologically limited | - | Depends on design, can be high | + |
| Sterilization | Acceptable | + | Acceptable | + |
| Accuracy | Biologically limited | - | Designed to exceed human scales | + |
| Space occupation | Generally given (human body) | + | Currently bigger than a human | - |
| Exposure | Susceptible to radiation and infection | - | Unsusceptible to environmental hazards | + |
| Specialty | Generic (upon training) | + | Specialized | - |

Figure 1. Comparison of human and robot performance in medical applications [3]

SURGICAL ROBOTICS

There are many forms of surgical robots serving different purposes in the operating room (OR). Passive robots only act as a tool holder, once directed to the desired position. Semi-active robots perform the operation under direct human control (e.g. in compliant mode). Active devices are under computer control, and automatically perform certain interventions (e.g. bone machining). Understandably, the more repetitive and standardizable a task is, the easier it may be to apply the classic industrial concepts. Systems that are able to perform fully automated procedures—such as CT-based biopsy or cutting—are called autonomous, or supervisory controlled. If the robot is entirely remote-controlled, and the surgeon is in charge of every single motion of the robot, we may call it a teleoperated system. The latter can be realized by a master-slave manipulator system or with compliant (co-operative) control.

INDUSTRIAL ROBOT BASED INTERVENTIONAL MEDICINE

In the earliest research projects, industrial robots were directly introduced to the OR [4]. It was first proven in 1985 that robotic tools can extend human capabilities, as a brain biopsy procedure (manipulating biopsy cannulae with a Unimate PUMA 220 robot) was successfully performed [2]. In 1991, the first transurethral electro-resection of the prostate was performed with a PUMA 560 at Imperial College, London, UK.

In orthopedics, one of the earliest surgical robots—the ROBODOC Surgical Assistant System—was developed at IBM Yorktown Heights Research Center. A 5 degree of freedom (DOF) IBM SCARA robot (manufactured by Sankyo Seiki) was custom designed for hip replacement procedures and knee prosthetics. Integrated Surgical Systems Inc. (Sacramento, CA) sold more than 50 systems across Europe and Asia, and most recently it became the first Food and Drug Administration (FDA) approved automated bone milling robot.

One of the most successful applications is the CyberKnife (Accuray Inc.) radiation therapy robot (figure 2). The system integrates image guidance and robotic positioning. A 6 MeV LINAC (relatively light-weight linear accelerator) X-ray source is directly mounted on a KUKA 6 DOF industrial manipulator (KUKA Roboter GmbH). Its primary use is irradiation of brain and spine tumors. The CyberKnife moves the radiation beam by physically repositioning the radiation source and continuously compensates for patient motion through the analysis of and body mounted fiducials and pre-operative 4D-CT images [5].

X-ray cameras

Linac robot treatment couch

A-Si detectors



Figure 2. The CyberKnife radiation therapy setup based on a KUKA manipulator Figure 3. The RehaRob upper-limb therapeutic robot with two ABB manipulators

SIEMENS has lately introduced its Artis zeego multi-axis system family that uses industrial manipulators to arbitrarily move a C-arm around the patient, in order to acquire high quality 2D and 3D reconstruction images [6].

Not exactly surgical technology, but the RehaRob (figure 3) is an internationally recognized physiotherapeutic robot applying the same concept [7]. It was developed at the Budapest University of Technology and Economics and four other institutes for upper-limb motion therapy for the disabled. The system integrates two unmodified ABB robots (IRB 140 and IRB 1400H) and a custom designed arm holder.

The once commercially available Computer Assisted Surgical Planning and Robotics system (CASPAR from orto Maquet GmbH) used a retrofitted Staubli RX-90 robot for autonomous implantation of knee prostheses. The company got defunct after serious stability and robustness issues arose with the system. The modified version of the CASPAR is currently used in the Robot-based Navigation for Milling at the Lateral Skull Base (RONAF) project at the Universitat Bayreuth, Germany. The system's purpose is the interactive supervision of a surgical robot during cranial drilling [8].

The NeuroMate robot (Schaerer Mayfield NeuroMate Sarl) was the first neurosurgical robotic device to get CE mark in Europe, and then the FDA's approval for stereotactic neurosurgical procedures in 1997. Originally developed at the Grenoble University, France, the 5 DOF NeuroMate was based on a modified version of an industrial AID manipulator. The technology was later bought and commercialized by Integrated Surgical Systems Inc. The robot is still in use in some clinics, and it has been integrated to innovative research setups, such as the image-guided skull base drilling project at the Johns Hopkins University (figure 4) [9].

MAJOR DIFFERENCES

The above mentioned research projects and commercial systems took advantage of the automated control of the robots, replacing (partially) the human operator. However, due to the uniqueness of every procedure, these concepts cannot be applied straight in interventional medicine. The most important differences are grouped into the following categories.

Task specificity

While classical industrial robots do mostly automatic manipulation of rigid parts with well-known shape in a specially prepared environment. The task of surgical maneuvering differs case by case, it is necessary to adapt to patients' conditions. The working environment of the robot is not entirely predictable and cannot be modeled completely, as on one hand, the living organ has complex non-rigid characteristics, and there is no standard equipment in the OR [10].

Even though the task is generally well-defined and the decisional autonomy of the robot is very limited, it is required to adapt to the changing conditions through high level sensory integration and flexibility. The robot design must accommodate to several strict limitation (sterilization constraints, electrical and magnetic compatibility, any specific constraints of the target application). The later is a serious constraint e.g. in MR compatible robotics, where no ferro-magnetic materials are allowed in the device. NeuroArm (figure 5) is typical case of application-based design, as it is absolutely MRI compatible (up to 1.5 Tesla magnetic field) [11]. It is a recent teleoperated anthropomorphic robot from a University of Calgary led Canadian consortium for stereotaxis and microsurgery. Beyond motion scaling and high definition visual feedback, it is able to provide very accurate 3D information of its two 7 DOF arms.

Another major limiting factor is the available physical space. This especially applies to the space directly above that patient that has to be shared with other instruments, and cleaned in some cases for human access. Probably even more important is the size of the surgical actuator, as robotic intervention aims to be minimally invasive. Limiting the size of the tools and structures entering the human body should not be achieved by losing the dexterity and manipulability.

Certain areas, such as neurosurgical procedures, offer more predictable working environment. In the case of brain surgery the skull gives a rigid frame, therefore it is easier to register real word structures to preoperative scans of the patient. (This is the basis of effective image-guided surgery). Second, the compactness of the head allows less soft tissue motion during the intervention, enabling a more accurate use of preoperative planning.



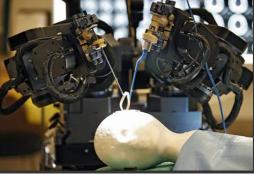


Figure 4. Robotic skull base surgery setup with a NeuroMate at the Johns Hopkins University [9] Figure 5. Custom designed MRI compatible neuroArm robot at the University of Calgary [11]

Safety is extremely important in automation, to prevent any kind of injury and damage. In industry, the major approach is to keep people and vulnerable structures away from the workspace of the robots. Naturally this is impossible in the case of medical applications. These robots directly contact the human body, and in many cases the operating surgeon is also within the close proximity. In every system, additional safety measure should be applied concerning both the hardware and the software. In surgical robotics, emergency action does not only mean halting the robot, in certain applications the immediate recovery is required in a safe pathway, further complicating the safety requirements [12].

Another great challenge is the adaptation to changing conditions. This means soft tissue characteristics, tissue manipulation, motion of body fluids and the radical changes in the OR environment (rearrangement of the setup, lighting conditions, etc). These safety concerns prevented the approval of many automated interventional systems, and lead the research community towards human-integrated control solutions, such as telesurgery and hands-on surgery [13]. The most successful surgical robot is the remote-controlled da Vinci (Intuitive Surgical Inc.). It is a complete teleoperated robot, guided entirely by a master human-machine interface on the surgeon side (figure 6), while the patient side consists of two custom built, tendondriven, 6+1 DOF slave manipulators and a camera holder arm (figure 7). The greater positioning structures are passive SCARA arms. The systems is designed for laparoscopic procedures, and therefore equipped with dual endoscope to enable stereo vision. It provides built-in tremor filtering and motion scaling. In the past 7 years, approximately 80,000 operations have been performed with more than 1000 da Vincis only in the U.S. The second generation of the robot—da Vinci S—was completed by 2003 with HD cameras, augmented ergonomic features and a fourth robotic arm for servicing tasks.





Figure 6-7. Master controller and the new patient side manipulators of the da Vinci robot from Intuitive Surgical Inc. (Photo: USA today)

The human factor

The interdisciplinary field of surgical robotics requires the close co-operation of medical doctors and engineers. The surgeons must be involved in the research from a very early stage to identify the targets and set the guidelines for the development. The surgical procedures are not as easily definable as assembly tasks, and require the integration of human and robotic skills into a common framework. The physicists often work on the human-machine interface as an integrated part of the robot workcell. The general control features of the systems should also consider that the operator is not a robot specialist [14]. Time constraints apply to the setup and

registration procedures required beforehand the operation, and should rely minimally on the human operators to allow for fast intervention in the case of emergency. *Cost-effectiveness*

Based on the above mentioned uniqueness of the field, the spread of the technology has been moderate in the past decades. While there is a clear need for accuracy and robust operation in many procedures, the associated high expenses prevent the wider use. Several projects have been an economical failure as the high development and production costs can only return with significant market penetration. In many countries the state-run healthcare system cannot provide support for the million-dollar robot investments, forming a barrier to their deployment.

Regulatory and legislative bodies are not prepared to handle the legal consequences of the extensive use of CIS technology. The serious moral and ethical questions associated with automated health-care scares not just the public, but many professionals as well. The earliest systems (such as the ROBODOC and the NeuroMate) had to fight all the prejudices and misbelieves when entered the market, and this resulted in lower selling.

The development and production costs can be reduced by increasing the number of systems built, but that would require a definite target application, where robotic surgery has most advantage, and therefore can quickly return the investment. Also, integrating industrial models can help to cut the prices, but this reduces the specificity of the robot.

CONCLUSION

Robotic surgery is entering its adulthood due to the continuous development made by research groups all over the world. From the close co-operation of engineers and physicians great medical robotic innovations were born to increase treatment delivery precision and augment human dexterity.

In the past two decades, most of the developed systems integrated industrial robots and concepts, however, new manipulators tend to be custom designed to better serve the targeted medical field's purposes. Just like industrial robotics before, surgical robotics must find its most profitable application area and reach the critical market size that can support the significant R&D spendings required. In the short term future, computer-integrated surgical technology will already reshape human healthcare.

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