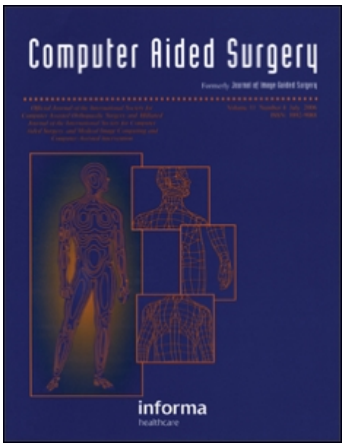

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Medical Robotics Workshop - MRWS

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SPECIAL REPORT

Medical Robotics Workshop – MRWS

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Introduction

A one-day workshop on Medical Robotics was held on June 25, 2003, at Imperial College, London, England, as part of the Computer Aided Radiology and Surgery (CARS) meeting. The goal of the workshop was to examine issues related to the development of medical robotics and the problems that are delaying the more widespread adoption of this technology. The workshop participants were an interdisciplinary mix of over 40 people from the medical fields of neurosurgery, interventional radiology, and orthopedics, among others, and the technical fields of engineering, computer science, imaging science, and physics. Industrial representatives were also included. The workshop consisted of morning plenary sessions with twelve speakers, followed by three breakout groups meeting in the afternoon. The breakout groups then summarized their conclusions in a final plenary session. A list of participants and their affiliations is given in Table I.

While medical robotics has received a great deal of press, the reality is that the clinical use of robots is still extremely limited and commercial systems are available for only a few surgical procedures. The existing medical robotics companies are all relatively small, and several have either gone out of business or been bought out in the past decade. However, one should realize that medical robotics is still a relatively young field, as the first recorded use of a medical robot was by Kwoh in 1985 for stereotactic neurosurgery [1]. Unlike other robotics fields, such as factory robotics, in which all the welds on automobile bodies are done by robots, medical robotics is still in its infancy, as the requirements for robotics in clinical applications and the development of prototype systems is still evolving.

A natural question to ask therefore might be "Is the lack of market penetration by medical robotics due to a lack of perceived need in clinical applications, shortcomings in the technology, or a little of both?" Robotics technology has been in development for over 50 years, if one considers the start of robotics to be the material-handling teleoperators developed in the 1950s for the nuclear industry. However, most people working in the medical robotics field have realized that medical robots are not the same as factory robots, and that specialized medical robots need to be developed to meet stringent safety and application requirements. Factory robots are not designed to work together with people, but medical robots must work with people in the

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Table I. Workshop participants.

Name	Affiliation
Turgut Acay	Northern Digital, Inc., Radoffzell, Germany
Eisuke Aoki	The University of Tokyo, Japan
Martin Boettcher	KUKA Robotic Group, Augsburg, Germany
Georg Brunner	Northern Digital, Inc., Radoffzell, Germany
Kiyo Chinzei	AIST, Tsukuba, Japan
Kevin Cleary	Georgetown University, Washington, DC, USA
Brian Davies	Imperial College, London, UK
Kathleen Denis	KU Leuven, Belgium
Etienne Dombre	LIRMM, Montpelier, France
Georg Eggers	University of Heidelberg, Germany
Philipp Federspil	University of Saarland, Homburg, Germany
Gabor Fichtinger	Johns Hopkins University, Baltimore, MD, USA
Patrick Finlay	Armstrong Healthcare, High Wycombe, UK
Bernd Gutmann	Innomedic, Herxheim, Germany
Claudia Haag	University of Heidelberg, Germany
Stefan Hassfeld	University of Heidelberg, Germany
Hiroshi Iseki	Tokyo Women's Medical University, Japan
Leo Joskowicz	Hebrew University of Jerusalem, Israel
Werner Korb	University of Heidelberg, Germany
Florian Kral	University of Innsbruck, Austria
Gernot Kronreif	ARC Seibersdorf, Austria
David Larkin	Intuitive Surgical, Sunnyvale, CA, USA
Tim Lueth	Charité, Berlin, Germany
Kiyoshi Matsumiya	The University of Tokyo, Japan
Seong K. Mun	Georgetown University, Washington DC, USA
Yoshihiro Muragaki	Tokyo Women's Medical University, Japan
Kiyoshi Naemura	Tokyo University of Technology, Japan
Joerg Raczkowsky	University of Karlsruhe, Germany
Andrea Ranftl	KU Leuven, Belgium
Sandra Rasche	Johnson & Johnson, Hamburg, Germany
Thomas Remmele	Innomedic, Herxheim, Germany
Fernando Rodriguez	Imperial College, London, UK
Ichiro Sakuma	The University of Tokyo, Japan
Joern Schmidt	AP-Technologies, LeBrassus, Switzerland
Sam Song	Imperial College, London, UK
Greg Stoeckis	AP-Technologies, LeBrassus, Switzerland
Nobuhiko Sugano	Osaka University School of Medicine, Japan
Jonathan Tang	Georgetown University, Washington, DC, USA
Jocelyne Troccaz	TIMC, Université Joseph Fourier, Grenoble, France
Vance Watson	Georgetown University, Washington DC, USA
Takefumi Yasunaga	Kyushu University, Japan
Dave Youmans	Johnson & Johnson, Cincinnati, OH, USA
Alex Zivanovic	Imperial College, London, UK

demanding clinical environment. The cost of building dedicated systems for this environment can be extremely high.

There is some reason for optimism, however. The recent surge of interest in robotics for minimally invasive surgery, as exemplified by the da Vinci system, is promising for future developments in the field. The December 2003 volume of *Surgical Clinics of North America* contained a number of articles regarding these developments and other applications of robotics in surgery. As pointed out by Prof. Jacques Marescaux [2], the feasibility of these systems has been demonstrated, and this is just a starting point for the information-driven surgical systems of the future. It should also be noted that other workshops on medical robotics have concluded that robots are an essential part of the operating room of the future, although their exact form and embodiment has yet to be determined.

Thus, the main conclusion of the workshop participants was that we are still in the early stages of the field, and robots designed specifically for medical applications are required to make progress. The technology is still immature in some ways, and not enough compelling clinical applications that are possible with current technology have been found. The participants also believed that commercialization is an important ingredient for the continued development of the field. The issue of safety in medical robotics was stressed, and it was suggested that it might be appropriate to have an international forum on this topic. The participants agreed to meet again in Berlin at the CARS 2005 meeting.

This report will next introduce the three breakout groups, followed by a summary of each breakout group's discussion and findings. The report ends with a brief overall summary and conclusions.

Breakout groups: division and instructions

The workshop was divided into three breakout groups as follows:

Group 1: Evaluation and Validation. This group addressed the issues involved in evaluating and validating medical robotics systems. For example, how can prototype systems be evaluated and validated both technically and clinically? Should there be standards for evaluation/validation? Should evaluation/validation be performed by an external group, or can it be done in-house?

Group 2: Integration and Workflow. This group addressed the issues of integration and workflow. For example, how can prototype systems be integrated into the clinical workflow without disrupting patient throughput? Should the goal always be to

minimize changes in existing workflows, or are new paradigms required?

Group 3: Commercialization and Regulation. This group addressed the issues of commercialization and regulation. For example, what are the barriers to commercializing these prototype systems? How does the regulatory environment affect the development of these systems and subsequent commercialization? Is commercialization an essential step for continued development of the field?

In addition to their specific topics, each breakout group was asked to address the following common themes:

- What is the current situation in medical robotics relative to the breakout group topic?
- What are the major factors limiting the clinical acceptance of robotics?
- What are the technical issues holding the field back?
- What are the research issues?

Breakout Group 1: evaluation and validation

This breakout group contained 17 participants representing a wide spectrum of expertise and interest. There were industrial engineers (6), practicing clinicians (3), and academic engineers (8). There were two main topics of discussion:

The first topic concerned the scope and extent of validation and evaluation. The key question was whether system designers should separate the engineering components (especially robot-related issues) and the medical/clinical aspects of the system and test them sequentially. The engineers believed that system components could be separated and that their basic functionality could be characterized to some extent invariant of the clinical application in which they are deployed. The clinical practitioners disagreed and spoke strongly against this approach, warning that there is a constant threat of losing the relevant clinical problems from such a focus. The clinical experts also suggested that engineers should not conduct system performance tests without having clinicians involved, because engineers tend to model clinical factors in an oversimplified manner, thus jeopardizing the value of any validation tests. In summary, two cultures and ways of thinking collided in these discussions: Clinicians maintained that the complexity of a clinical system is inevitable and must be handled as such, while engineers maintained their belief in the power of compartmentalization, modeling, and generalization.

The second main topic of discussion was whether outside groups should be involved in objective validation and evaluation of surgical robot systems. The participating academic engineers argued that employing external testers and evaluators is only possible if some parts of the system can be modeled and characterized in terms of general engineering models. This argument led the discussion back to the previous topic. It was also pointed out that having outside testers would make no sense unless test/evaluation protocols were already in place. It was further recognized that industry and academic research have different needs and, whereas external testing may be valuable to industry, it may not produce much benefit for academic research groups, especially considering the expenses that may be incurred. External evaluators would also most likely need replicas of the system they are to test, which is often not feasible in the academic environment, especially for image-guided robot systems that rely on expensive imaging hardware and similarly expensive infrastructural elements. It was also stressed that robot-assisted surgical systems are so novel that there are no two applications that could be fully tested by the same methodology without having full and detailed knowledge of the clinical application; an expertise typically demonstrated only by the developers. While most participants agreed that engaging external testing and validating groups might be premature for the field, it was also noted that, in some countries, external testing might be required even for a small clinical trial. For example, to conduct a trial in the UK involving, say, 30 patients, the Medical Devices Agency responsible for implementing the European Community Medical Devices Directive requires an independent certification of performance. This includes items such as electronic emissions and immunity.

There were several other issues noted by this working group. While it seems that collaboration between industry and academia is necessary to drive the field forward, it was noted that industry typically has different needs and practices from those of academic researchers. Another common problem for the field is that there are no standards for reporting accuracy and comparing the performance of systems. However, since the field is still in its infancy, it was felt that it may be too early to define standards for robotic systems, and the best we may be able to do at present is make recommendations.

Breakout Group 2: integration and workflow

This breakout group was composed of 17 persons belonging to worldwide organizations with a good balance between clinicians (neurosurgery, orthopaedics, and cranio-facial surgery), scientists

(robotics, imaging, planning), and industry personnel (medical robotics, robotics, medical instrumentation). The scope of the discussion covered two topics:

Concerning *integration*, the discussion revolved around the "ease of use" of a robot in the operating room (OR). The group discussed the difficulties in OR integration and examined research or development directions that could improve such integration. Concerning *workflow*, the need to keep robot-assisted procedures similar to manual procedures to facilitate robot integration was stressed.

All the participants agreed that robot integration in the OR is intrinsically difficult, and that different technological, psychological, and economic issues exist. Robots have to be made smaller and cheaper. The participants were also convinced that the clinician must be involved from the very beginning of the project (even for upstream research) and must participate in all stages of system development.

It was underlined that the issues are different for research projects and products. It was also noticed that there is a contradiction because systems are generally kept rather close to the workflow so as to enter the OR as quickly and easily as possible, while, at the same time, one can foresee that robots might really have added value by doing things in dramatic new ways (such as automation of some sub-procedures like suturing) or for procedures that a human surgeon cannot carry out (such as operating on a beating heart).

The group also noted that the appreciation of value depends on many factors. Even for research projects where the surgeon may be more understanding of problems, reliability is an issue. Objective evaluation is complex as the robot has three clients – the patient, the surgeon, and the hospital – each having their own criteria.

The question of development methodology came up several times during the discussion. It was considered that modeling the workflow in some manner could make the integration easier and improve system adequacy. Safety analysis was also one of the components that were considered to be important, but it was underlined that safety requirements have to be more specified, depending on the clinical application and the acceptability of hazards. The human factor has to be modeled as well as the technological components. Regulations differ from country to country and require more or less "quality assessment", even for research projects.

Finally, it was underlined that having ORs dedicated to experimental surgery in the hospitals that would enable the different stages of robot evaluation to take place in the clinical environment could perhaps facilitate the clinical integration of robots. Simulators could also contribute to this integration and modeling of the workflow, while recognizing that this would be a simplification of the real OR environment.

Breakout Group 3: commercialization and regulation

This group consisted of 14 persons, including scientific, clinical, and commercial expertise. The topic of commercialization was discussed more heavily than that of regulation.

It was debated without conclusion that commercialization is necessary to advance the field and propagate some of the advances made. Commercial efforts in medical robotics have had mixed success to date, and many robotic companies have gone out of business. There is a current trend towards slowing of venture capital for new companies. It was mentioned by finance specialists that funding will decrease even more if a profitable robot project does not materialize in the next two years. Thus, shorter-term projects are advised, as longer-term projects may fail because of loss of funding during the research and development phase.

Barriers to commercialization were also discussed. The consensus seemed to be that clinical applications must be chosen very carefully to ensure that the benefits of a robotic approach outweigh the costs. A favorable cost/benefit ratio has not been shown in many instances, and sometimes the situation has seemed to be more of a technology push than a market pull. Key questions for any project are to define the value added, or identify a process which cannot be performed without the robot, and thereby determine the money that users would pay for the robot. A rough rule of thumb for the market price of a robot was ten times the cost of manufacturing.

In addition, it was noted that a standard research platform that was available for a reasonable price would be a welcome development, but it is not clear that a large enough market exists for such a system, or that a general-purpose research platform would be sufficient for most applications.

There is a need for more controlled clinical studies with these devices to establish their efficacy and justify the technology.

The regulatory environment was discussed briefly, and it was perhaps somewhat surprising that most of the industrial participants did not consider the regulatory environment a barrier to developing the field. As a matter of fact, there have recently been a number of inquires about establishing a set of preliminary recommendations for safety in medical robotics, and this may be an appropriate task for future workshops.

Summary and conclusions

While the field of medical robotics is still in its infancy and commercial applications are still limited, it is interesting to note that most of the clinical participants in the workshop do feel that robots will play a large role in the future of medicine, and that this role is still being defined. Therefore, there is an urgent need for prototype systems to investigate new clinical applications and for engineering/clinical partnerships to develop these devices. Commercialization is seen as being essential to advance the field, despite the difficulties of commercializing these systems. Since several medical robotics vendors have gone out of business, hospitals may be wary of purchasing these systems from small companies, and it may be necessary to involve the major medical manufacturers in this process. While there is much work to be done, all of the workshop participants expressed optimism regarding the future of medical robotics, and it was agreed that forums such as this workshop are useful to continue development of the field.

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