

Improvements to the Design of a Compact Robot for Minimally Invasive Surgery

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Surgical manipulation has been successfully demonstrated using a robotic spherical serial mechanism (called CoBRASurge) having a remote center of rotation driven through a compact bevel-gear system. This cost-effective prototype confirmed surgical robots do not have to be large and expensive machines to operate effectively. After testing and assessing the device, several key design changes were proposed for a second CoBRASurge robot, which would significantly increase the overall effectiveness of the device. These design changes were found after considering

the following desirable characteristics: reliability, compactness, precision, protection from contamination, and flexibility in initial setup. These redesign characteristics led to improvements including an increase in gear transmission accuracy by decreasing gear module, implementation of a motor housing to protect against outside contamination, a new rack and pinion driving assembly for a more robust tool translation, decreased volume and weight for ease of use and overall effectiveness, and a new mounting system for a quicker and easier initial setup process. It is believed that these features will further allow the operating surgeon to more effectively complete tasks in less time, and with increased ease as compared with current laparoscopic surgery techniques, while also making multirobot cooperating interventions more feasible.

Development of an ISO 13485 AND FDA QSR Compliant Quality System for an Academic R&D Group: From Concept to Certification

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The British Columbia Institute of Technology's (BCIT) Health Technology Research Group (HTRG) is a team of multidisciplinary researchers that provides medical device development and evaluation services to clients from medical device companies, health care organizations, and academia. Researchers include biomedical engineers, biomechanics and anthropology scientists, plastics, mechanical, electrical, robotics/automation technologists, trades researchers, and industrial designers. In 2000 the HTRG embarked on the development of a quality system that complied with the design and risk management requirements of the U.S. Food and Drug Administration (FDA) Design Controls, Health Canada's Canadian Medical Device Conformity Assessment System (CMDCAS), and the ISO 13485 Medical devices—Quality management systems—Requirements for regulatory purposes (ISO 13485). An initial system was developed and launched in 2002. In 2005 we further developed the system to be fully compliant with all requirements of ISO 13485 and obtained certifica-

tion of the system in 2007. The BCIT HTRG is currently the only ISO 13485 certified academic medical device research group in Canada. The benefits of the quality system for industry clients, students, and the academic research team are discussed as well as the challenges faced in implementing a quality system in an academic research setting. The HTRG has worked with a number of multinational and international companies and would not have been able to attract these clients without operating under a certified system. Our research team is able to shorten the development time from concept to commercialization as prototypes that are developed under a certified quality system can be evaluated in surgical settings. The research staff has been able to access new research funding in part due to the quality system. The major benefit to BCIT's biomedical and other engineering students is hands-on experience with a working quality system prior to graduation. The challenges associated with introduction and acceptance of a quality system in an academic setting are also discussed along with strategies to increase acceptance of the system. Challenges include overcoming resistance from researchers that perceive quality systems as a constraint on their creativity and as a new administrative burden, managing the costs associated with developing and maintaining a certified quality system, and interfacing with outside departments in an academic environment. Strategies for overcoming these challenges include involving all researchers in the initial development of a system and creating an efficient electronic system that is easily accessed.