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ORIGINAL ARTICLE

Housing design and testing of a surgical robot developed for orthopaedic surgery

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Summary *Background/Objective:* Surgical technology has advanced rapidly with the introduction of robot technology. Apart from mechanical and electronic elements, housing design is an essential component that must be thoughtfully considered, bearing in mind the general requirements for medical devices used in operating theatres. The aim of this study was to design a modern and safe housing for a surgical robotic system for orthopaedic applications in Hong Kong that would meet the general requirements for obtaining local regulatory body approval.

Methods: Based on the general requirements for Class II Medical Devices, industrial product designers worked in close collaboration with a robot research team formed by engineers and orthopaedic surgeons to design a modern and safe housing for the HybriDot® Surgical Robotic System that performs computer-assisted surgery.

Results: The design received local regulatory body approval for its application in operating theatres and was approved for orthopaedic surgery in Hong Kong after fulfilling the general requirements for safety, accuracy, movability and operability.

Conclusion: This project demonstrated a good model of multidisciplinary R&D of surgical robotics led by orthopaedic surgeons, in collaboration with mechanical and electronic engineers and industrial designers.

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Introduction

Medical robotics has been successfully developed and applied in orthopaedic surgery and other surgical fields [1—6]. Such surgery-assisting technology is appreciated by surgeons as it provides accurate geometrical positioning and exact predefined exerting forces that grant more precise surgical therapy to patients. daVinci® is a leading brand in surgical robotics; its success can be attributed to its tele-manipulator architecture that is applicable to many minimally invasive surgeries, achieving satisfactory outcomes [7,8]. In orthopaedic surgery, there is demand for a surgical tool that can be manipulated accurately and stably to the expected position/orientation on a target, e.g., to target on bone during bone resection. To fulfill the demand for surgical accuracy, Robodoc® [9,10], an image-guided robot, was developed for total hip replacement surgery and total knee arthroplasty, where its safety-checking subsystem provides adequate safety features to protect both patients and surgical team.

To develop and advance such technology, an orthopaedic surgical team developed a prototype of a manual surgical robot 8 years ago in Hong Kong (Figure 1) [11]. However, the manual procedure that produced a certain number of outliers was also dependent on surgeons' experience, and the design feature itself was far from optimum in meeting the general requirements for surgery performed in an operating theatre. With recent developments in computer navigation, computer navigation systems could be adopted to obtain more accurate operation outcome and reduce the number of outliers where the anatomical feature points on a joint are measured as reference for generating a computer model for surgical planning and simulation before implementation with the assistance of surgical robotics [12—14]. Under computer navigation guidance, surgeons are now able to place cutting blocks in the right position and orientation. In both manual and computer navigation cases, the cutting boundaries of the joint are decided on by measuring the patient's anatomic features instead of using preoperative computed tomography images. However, without a modern and safe housing, such robotics, including the commercially available daVinci® and Robodoc® surgical robotic systems, could not be approved by regulatory bodies for routine clinical applications as Class II Medical Devices [7—10].

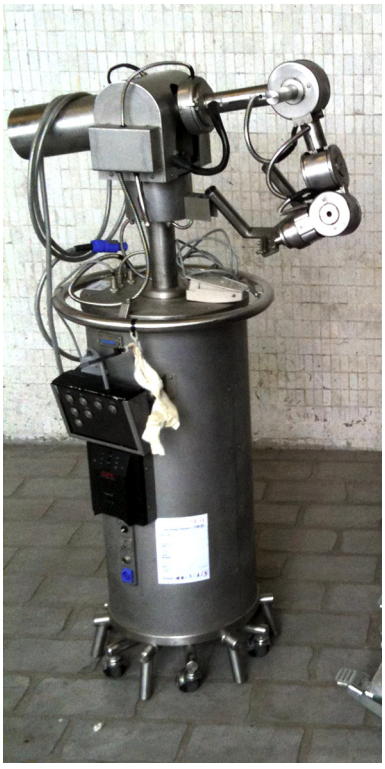

Figure 1 Prototype of the manual surgical robotics developed by the orthopaedic surgical team.

Fulfilling requirements for Class II Medical Devices, the surgical robotic housing design and manufacturing process should meet the demands of orthopaedic surgical applications in the operating room, i.e., a computer-controlled surgical system that registers the patient's anatomy to a preoperative surgical plan to guide the robotic arm during orthopaedic surgery. The housing should be compact and meet the general requirements for safety, mobility and operability, at the same time ensuring that the robot that is working in the operating room fulfills the mechanical, electrical, and sterilization requirements [15—17]. In addition, the design should allow the active—passive robot arm to operate properly at the same time; a well-considered ergonomic design would improve the interaction among the surgeons, nurses and patient [18].

The aim of this study was to design a modern and safe housing for the HybriDot® Surgical Robotic System—the first surgical robot with computer navigation function for orthopaedic applications in Hong Kong—that would meet the general requirements for obtaining local regulatory body approval from the Hong Kong Standards and Testing Centre (HKSTC) [19—22]. To achieve this objective, industrial product designers closely collaborated with the robot research team formed by engineers and orthopaedic surgeons [23—25]. The designers were responsible for the external appearance design of the surgical robot through frequent communications with the engineers and orthopaedic surgeons.

Methods

This study comprised two parts. Part I focused on external appearance design, i.e., designing the housing for the surgical robot. Part II focused on general functional tests in terms of reproducibility of the surgical robot and temperature alteration, which were essential for obtaining Hong Kong Certification Centre approval from the HKSTC [19—22].

Part I: Design principle and its realization

Requirements in three categories need to be considered in the design of the external appearance of a medical device: professional requirements, business aspects and design aspects (Figure 2). Professional requirement considerations include regulatory requirements for safety, mobility, and operability based on the IEC-60601-1 Standard issued by the