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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

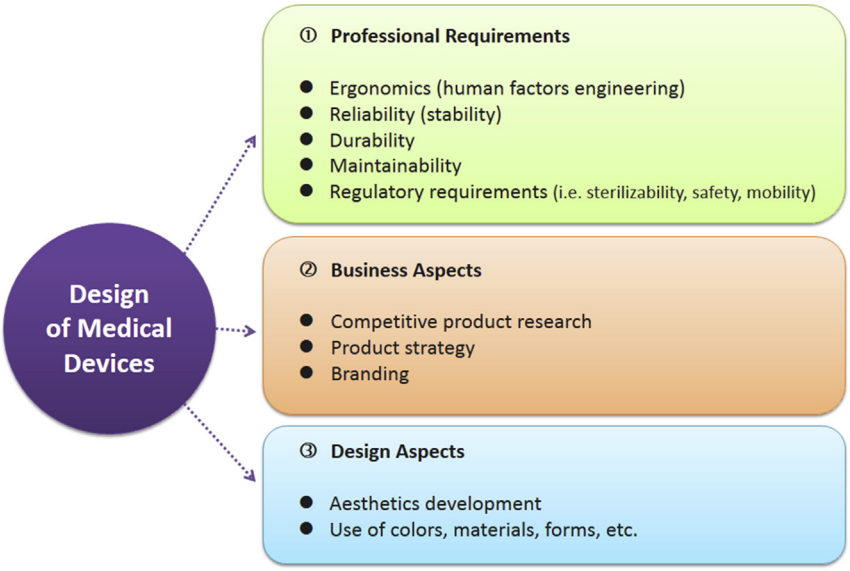


Figure 2 Requirements in external appearance product design of a medical device.

International Electrotechnical Commission (IEC) [15]. "Safety" is concerned with the mechanical and environmental requirements as well as the hygienic aspect regarding sterilization/disinfection of robotic components, while "mobility" and "operability" are essential elements of a multipurpose and active system.

General design approaches

In designing the housing of the HybriDot® Surgical Robotic System, the four distinct phases described below were followed (Figure 3 and Supplementary Figure 1).

Phase 1: Research and analysis—the task was to develop product design specifications, including structural analysis (ergonomics, safety, sizes), users' experience (shaping, details, safety, ergonomics, user experience, functionality), and functionality (mobility, operability together with design of accessories and selection of materials) of the robotics. Product design specifications included the following key elements based on the Form and Style for American Society for Testing and Materials (ASTM) Standards [26]: (1) a statement of what a not-yet-designed product is intended to do; (2) to ensure that the subsequent design and development of a product meets user needs; (3) is one of the elements of product lifecycle management; (4) acts as an initial boundary in the development of products (Figure 4).

- The surgical robot is composed of a control system, an image-guided navigation system (IGNS), and a robotic arm to be used for positioning and supporting surgical tools or instruments in conjunction with the IGNS.
- The material of choice for all external parts was acrylonitrile butadiene styrene (ABS). This material has the advantages of high impact resistance, toughness, heat and chemical resistance that operates between −20°C and 80°C. The material can also undergo sterilization with ethylene oxide gas, hydrogen peroxide gas plasma, peracetic acid immersion or ozone that is used for heat- and moisture- sensitive medical devices.

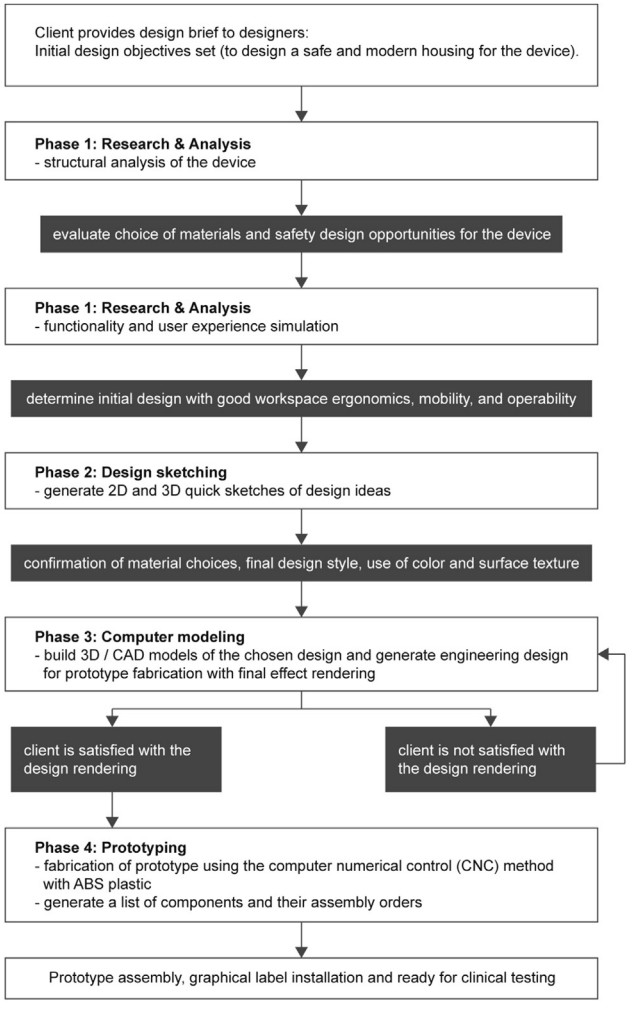


Figure 3 Decision tree of the four design phases used in the external appearance design of the HybriDot® Surgical Robotic System.

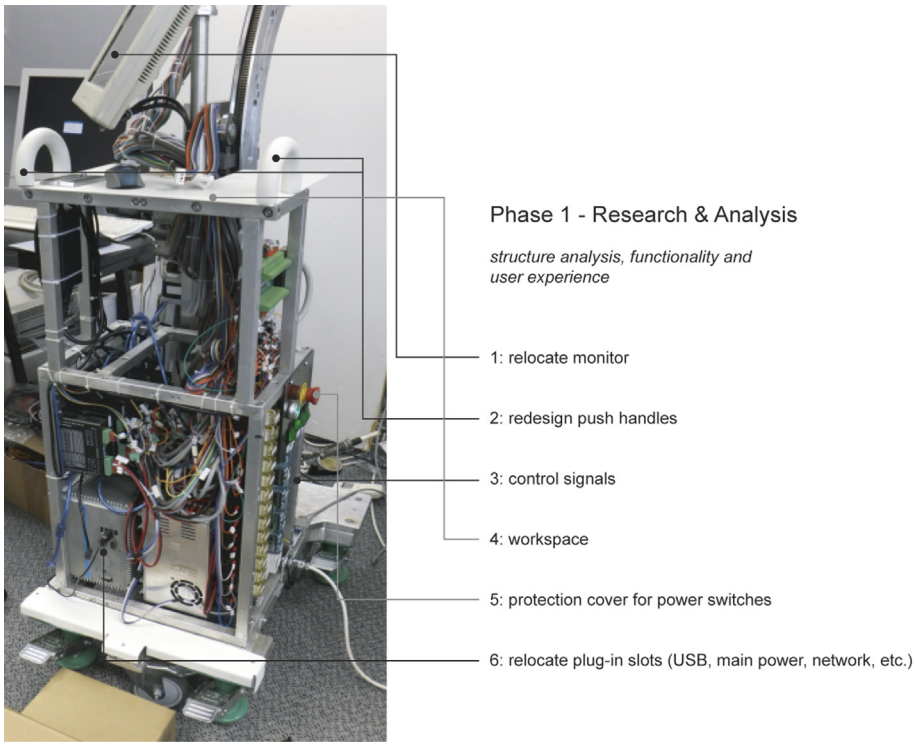


Figure 4 Phase 1—research and analysis with task to develop product design specifications, including structure analysis, functionality of the robotics, and user experience.

- The robotic arm needs to be able to hold cutting jigs or drilling guides to perform common surgical procedures. The robotic arm was formed by six parts with seven degrees of freedom. The six parts included: (1) shoulder girdle, a non-movable junction between the robotic arm and the control system; (2) shoulder, 90-degree clockwise and counterclockwise pivot movement between the shoulder girdle and shoulder; (3) arm; (4) forearm; (5) wrist; and (6) handle for manual adjustment. The type and range of motion between every two parts are summarized in Table 1.
- Mobility, workspace and operability were considered in the exterior design of the control system and IGNS. As the system would be moved manually rather than with a remote control, wheels and push handles were designed for system mobility. Ergonomic factors were the main consideration for the keyboard, IGNS monitor and control signals. Operability issues included power switches, plug-in slots and heat dissipation during the operation of the control system.

Phase 2: Design sketching—the task was to generate design concepts (Figure 5). We did product research on medical robot exterior designs ranging from humanoid to mechanical aesthetic. Most surgical robots have a mechanical aesthetic with an abstract geometric exterior design. We preferred a hybrid design combining simple geometric forms with humanoid features. Sketches were generated based on the hybrid aesthetic concept.

Phase 3: Computer modelling—the task was to generate 3D models for machining. This process included design modification (design details, modifications, and evaluation of technical issues), engineering design (assembly methods of components and machinability), and precise engineering models for generating the final model ready to produce and render.

Phase 4: Prototyping—the task was to realize the design and build a prototype for clinical tests and trials. This involved preparing a list of components, graphics, labels, and finishing for assembly (Supplementary Figure 2).

Fabrication and assembly

Fabrication was based on our design (see above). The device was assembled by our team members in the Prince of Wales Hospital, Hong Kong, based on the design concept and steps stated above.

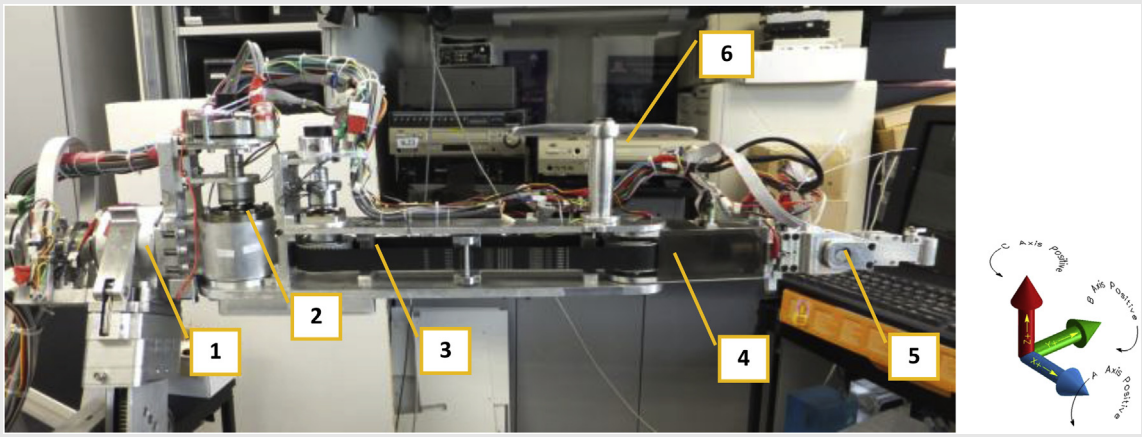
Part II: General functional and clinical tests

For Class II Medical Devices for use in operating theatres, we conducted the following tests: (1) temperature; (2) repeatability; (3) surgical workspace trial; and (4) clinical trial (passive position control of the robot arm by the surgeon under navigation guidance). In the operating theatre under navigation guidance, we performed repeatability (precision) and accuracy testing for the position of the robotic arm and evaluated the temperature changes in the locking system of the mechanical compartment and housing over time after the device was switched on. The design was capable for the seven degrees of freedom of the robot.

Clinical testing

For product registration of Class II Medical Robotics, apart from product design with a focus on housing design for the

Table 1 Summary of six parts of the robotic arm.



Part no.	Part name	Function	Type of joint	Range of motion (°)
1	Shoulder girdle (junction)	Determines the overall angle of the arm	Motor powered along the B axis	235
2	Shoulder (pivot)	Has the largest range and sets the height of the arm	Motor powered along the C axis	180
3	Arm	Adjusts the final position in a smaller range	Motor powered along the C axis	160
4	Forearm	Adjusts the final position in a smaller range	Gear-belt powered by the arm motor	160
5	Wrist	Adjusts the final operation angle precisely	Motor powered along the B axis	270
6	Handle	Unlock to manually control the robotic arm movement	Fixed	—

surgical robotics, essential machine testing is required by the regulatory body [19—22,26].

Results

The current study focused on the housing design of a modern surgical robot—the HybriDot® Surgical Robotic System, and essential testing before routine clinical application. As surgical robotics is categorized under Class II Medical Devices, the housing design and manufacturing process were completed to satisfy the demands of its orthopaedic surgical applications in the operating theatre.

Completion of design, fabrication and assembly

The housing design and manufacturing of the HybriDot® Surgical Robotic System met the general requirements for safety, movability and operability of the IEC-60601-1 standard with specifications on general safety and essential performance and was certified accordingly (Supplementary Figures 3 and 4). "Safety" pertains to the mechanical and environmental requirements as well as hygienic aspects regarding sterilization/disinfection of the robotic components. The system has good movability and operability that are essential for such multipurpose and active system. The device has good mobility in interactive needs between surgeon(s), staff, and the patient. The active medical device was also designed with influence of human factors, clinical constraints and specifications for the medical purpose.

Precision and repeatability

Repeatability of the positioning and orientation of the surgical robotics: Our device achieved a position accuracy of a mean error of 0.73 mm and an orientation accuracy of a mean error of 1.98° (Table 2 and Figure 6).

Monitoring temperature changes at the joints of the surgical robotics: The temperature changes of the joints in locked static state over 6 minutes were minimal and within the safety requirements of IEC-60601-1 (Figure 7).

Clinical test

After completion of the precision and repeatability tests, we successfully performed a series of first-in-man clinical tests in human patients. A number of cases were successfully treated using the HybriDot® Surgical Robotic System at the Prince of Wales Hospital, Hong Kong, including percutaneous screw fixation for pelvi-acetabular fracture and distal locking of inserted intramedullary nails (Supplementary Figures 5 and 6).

Discussion

There is increasing medical need for minimally-invasive bone-cutting operations, and this is the foundation for

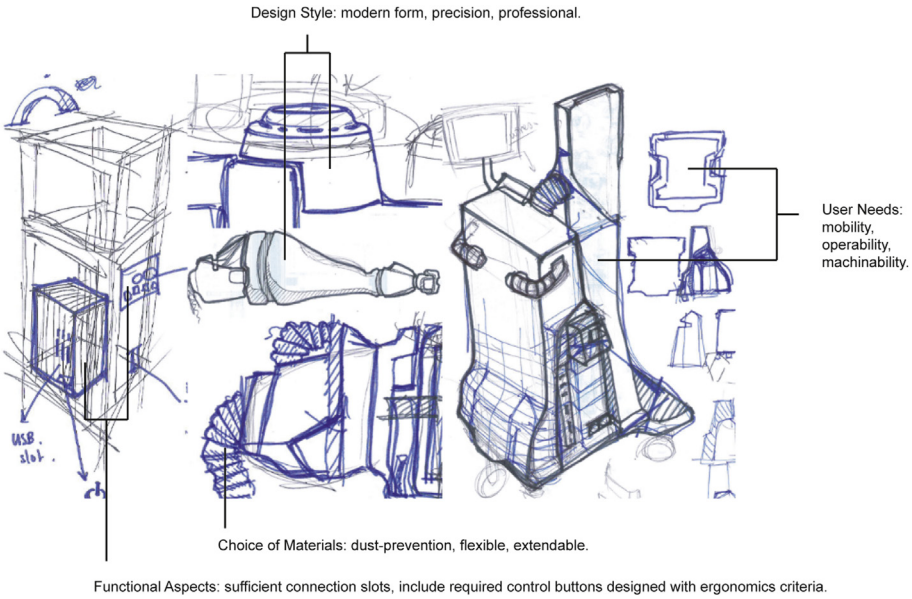


Figure 5 Sketch for Phase 2 design: (i) design style and functional aspects (key elements: shaping, details, safety, ergonomics, user experience, functionality); (ii) user needs (key elements: mobility, operability, machinability); (iii) selection of materials and use of colour and texture (key elements: safety and regulations).

Table 2 Repeatability test of position and orientation.

	Mean error (e_{avg})	Root mean square error (e_{rms})	Standard deviation (e_{std})	Maximum deviation (e_{max})
Position (mm)	0.726	0.811	0.361	1.497
Orientation (°)	1.978	2.186	0.932	3.978

Position accuracy, mean error = 0.726 mm; orientation accuracy, mean error = 1.978°; acceptable for surgical use.

surgical robot development in orthopaedics. Based on our prototype [11,13], we developed the orthopaedic surgical robotic system HybriDot®, which is a successful model for orthopaedic translational research and development in medical equipment towards advanced clinical applications. This work was a clinician-led collaborative project with a graduate from Central Saint Martin's College of Arts & Design in London and staff from N.D. Industrial Design in Shenzhen, China, with the objective of designing a modern, safe housing for the HybriDot® with computer navigation function for orthopaedic applications in Hong Kong, which met the general requirements for obtaining local regulatory body approval, i.e., Hong Kong Certification Centre approval from the HKSTC [19—22].

The current study focused on the housing design for a modern surgical robotics system and essential testing for Class II Medical Devices before clinical application. As surgical robotics, the housing design and general and essential testing of the entire function of the machine were completed to the satisfaction of the requirements for orthopaedic surgical application in the operating theatre, i.e., the housing design, general safety and essential performance, including mobility and operability, met the IEC 16061-1 international standard [15,19—22]. The housing ensures that the robot working in the operating theatre fulfills the mechanical, electrical, and sterilization requirements. Based on the experience from our trial run, the design allowed the active—passive robot arm to actuate seven motors properly at the same time and interact well with the surgeons, nurses and patients. Our device achieved a position accuracy of less than 1 mm, orientation accuracy of less than 2° and temperature change of less than 3 °C. These are well within the safety ranges defined by IEC-60601-1 [15,19—22].

The surgical robot HybriDot® has both automatic and manual functions for application, e.g., for drilling and tapping before the insertion of screws into a bone [11,13]. To reduce the subjective factor in parameters such as time, linear velocity, angular velocity, resistance force, penetration depth, and temperature, automated bone drilling is recommended and can entirely solve the problems that usually arise during manual drilling. In the current study, use of the robotic arm resulted in satisfactory precision and stable temperature during operation. An experimental setup was designed to identify bone drilling parameters such as the resistance force arising from variable bone density, appropriate mechanical drilling torque, linear speed of the drill, and electromechanical characteristics of the motors, drives, and corresponding controllers. Automatic drilling guarantees greater safety for the patient. Moreover, the robot presented is user-friendly because it is simple to set robot tasks and process data are collected in real time.

The current housing design enabled satisfactory contact of the surgical robotic arm with the human body. Its specific

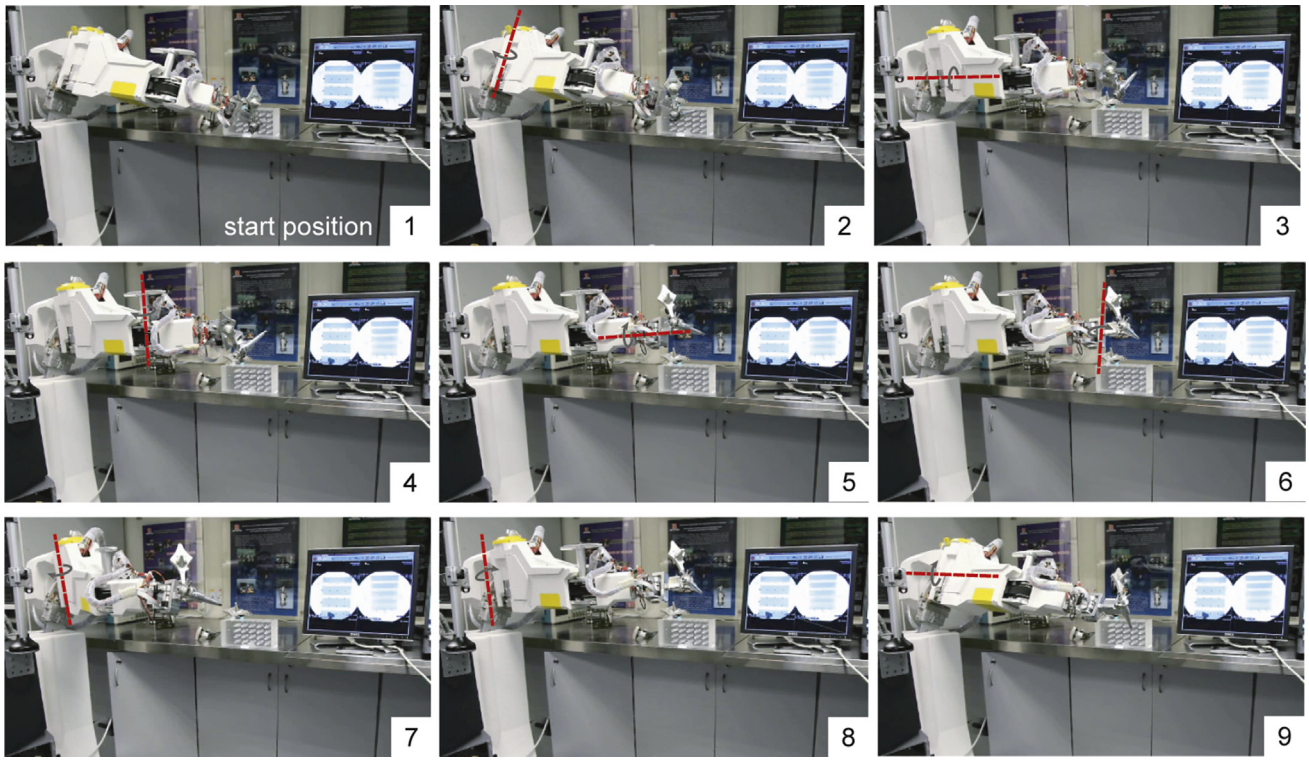


Figure 6 Repeatability tests for the first generation of surgical robotics with computer navigation function in Hong Kong designed by the multidisciplinary team led by orthopaedic surgeon Dr. K.S. Leung.

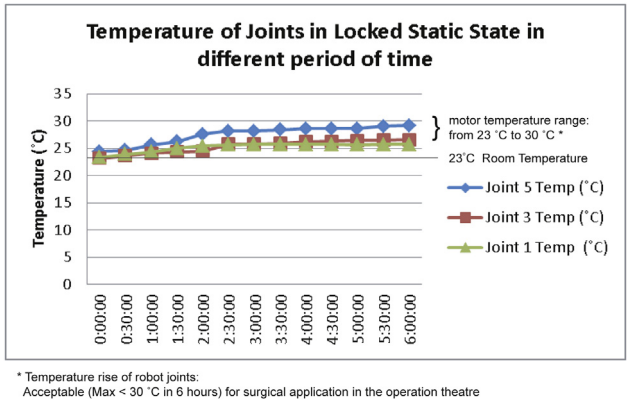


Figure 7 Changes in the temperature of joints in locked static state over time.

functionalities, optimal size, being easily movable, manually controllable and its safe impression in design maximize its surgical applications in the operating theatre. We tested the design elements for dependability (safety, reliability, availability, confidentiality, integrity, and maintainability) and found that the robot exhibited sufficiently high movability and operability for clinical cases at the Prince of Wales Hospital in Hong Kong, including percutaneous screw fixation for pelvi-acetabular fracture and distal locking of inserted intramedullary nails. The reported studies suggest that robotic assistance enabled inexperienced orthopaedic surgeons to perform more accurately [27,28].

The FDA classifies medical devices into three categories, namely Class I, Class II and Class III, based on the risks associated with the device. Class I devices are deemed to be low risk and therefore subject to the least regulatory controls, while Class III devices (such as replacement valves) are considered the highest risk devices and typically require pre-market approval ("PMA") in addition to passing general controls. Surgical robotics are Class II medical devices [16] that are subject to IEC-1606-1 tests [15]. Although at the moment, there are no strict pre-market controls to assess the safety, efficacy and quality of medical devices to safeguard public health or specific guidelines in Hong Kong to register Class II medical devices, we followed those established by the FDA to ensure the long-term sustainability [20] of our medical device and its future registration for clinical applications locally, regionally and internationally to benefit our routine clinical practice and patients, in addition to following a recently-proposed regulatory framework that may require licenses for certain medical device products under the Hong Kong Medical Device Regulations & Approval Process [20—22]. We followed all mandatory requirements and the Hong Kong Government's Medical Device Administrative Control System (MDACS), with voluntary listing of Class II and Class III (Medium Risk) Medical Devices on the safe use of medical devices, although the classification of a particular medical device depends on its actual design, intended use, and other factors [20,21].

Future efforts will be on experimental studies to evaluate HybriDot®'s intelligent control architecture for monitoring the progress and safety of orthopaedic surgeries and, eventually, for its modification and optimization towards commercialization.

In conclusion, this project demonstrated a good multidisciplinary model in the R&D of the surgical robot HybriDot® led by an orthopaedic clinical team in collaboration with mechanical and electronic engineers, as well as industrial designers, to meet the increasing demand for minimally invasive orthopaedic surgery. Based on the general requirements for Class II Medical Devices, we designed a modern and safe housing for the first generation of surgical robot with computer navigation function that was approved for orthopaedic applications in Hong Kong.

Conflicts of interest

Lai-Yin Qin and Jing Zhou Wen are affiliated with N.D. Industrial Design Ltd., Shenzhen, China. Chun-Sing Chui and Kwok-Sui Leung has no conflicts of interest to be declared.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.jot.2016.02.002.

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