

ZBIGNIEW NAWRAT *, **, PAWEŁ KOSTKA ***

ROBIN HEART SURGERY ROBOTIC SYSTEM. CHALLENGES IN MECHANICAL CONSTRUCTION, CONTROL SYSTEM AND STUFF TRAINING BEFORE FIRST CLINICAL APPLICATION

The last decades, when robots have appeared in the operating room, showed the possibility of surgery enhancement by improving precision, repeatability, stability and dexterity. However, taking into consideration still existing limitations of robotics in surgery, and treating the robots as medical devices with the highest degree of safety level requirements, one must take a number of complex actions when preparing the experimental clinical application of a new modern robot Robin Heart.

Presented paper describes the current state of procedures carried out in the Robin Heart project of surgery robots prepared for clinical application. Based on experiences with the devices existing on the market and, first of all, thanks to knowledge and expertise gained by our team during last 12 years, intensive work are currently done in order to introduce both mechanical and electronic modifications as well as to improve the safety system. As far as human resources are concerned, a professional team able to carry out the robot-supported surgery is prepared based on the created system of technical and functional trainings on simulation stands, which also includes the developed operation planning procedures. The first telemanipulator designed for clinical practice is the Robin Heart Vision – endoscopic system manipulator.

1. Introduction

Robotic surgery is now a rapidly developing field of contemporary medicine and biomedical engineering. Hundreds of thousands of robot-supported operations are carried out every year, primarily in the field of urology, all over the world. This market is monopolized by the American company Intuitive Surgical. Over two thousands of da Vinci robots are used for research,

* *Foundation for Development of Cardiac Surgery, Zabrze, Poland; E-mail: nawrat@frk.pl*

** *Silesian Medical University, Katowice, Poland*

*** *Silesian University of Technology, Biomedical Eng. Fac., Zabrze, Poland; E-mail: pkostka@polsl.pl*

training and clinical practice. However, the problem of seeking for practical and economically verified areas of surgery robot usage and optimization of its construction is still open. At the current stage of development, they have not sufficient sensing and they are not easy and expensive in exploitation. On the other hand, undeniable advantages of the da Vinci system, such as ergonomic, really intuitive steering, wide set of operating tools and excellent 3D view from operational field allow one to use it as a perfect choice in some minimal-invasive surgery procedures.

The world leader - American surgical robots have been produced by two, currently merged, companies: Computer Motion®(Computer Motion Inc. of Goleta, Calif., CM), and Intuitive Surgical®IS. Since the introduction of its first *da Vinci* System, the Intuitive Surgical has expanded its installed base to more than 2,600 academic and community hospital sites (over 1900 in the USA, over 400 in Europe), while sustaining growth in excess of 25% annually. The *da Vinci* System is a robotic surgical platform designed to enable complex procedures of all types, which can be performed through 1-2 cm incisions or operating “ports.” Up today, approximately 1.5 million procedures including general, urologic, gynaecologic, thoracoscopic, and thoracoscopically-assisted cardiotomy procedures have been performed using the *da Vinci* Surgical System.

Since 1998, over 4000 peer-reviewed publications have appeared in various clinical journals on *da Vinci* Surgery. Approximately 46% of these publications belong to urologic surgery. In 2012, over 4500 surgeries (mostly hysterectomy and prostatectomy) have been performed using da Vinci [1]

Since January 2000, the AESOP robot (AESOP 3000, Computer Motion, Inc. Goleta, CA) has been used in the cardiac clinic in Katowice (headed by A. Bochenek) [2]. Within two years, over 250 operations (such as mammary artery harvests and EACAB Endoscopic Atraumatic Coronary Bypass Artery) were performed. In 2002, a complete surgery robot, the Zeus, has been leased out for the Katowice Cardiac Surgery Clinic for 3 months, and carried out 10 heart operations.

Since December 2010, a da Vinci robot operates in the Provincial Specialist Hospital in Wrocław. So far, with the assistance of the robot, one carried out 150 operations, including gynaecological, urological and vascular surgery procedures.

Among the competitors of the da Vinci robot, there is a Polish Robin Heart, which is being prepared for the first trials in clinical practice after in vitro and animal in vivo tests, which have already been done.

2. Robin Heart

The family of Robin Heart tele-manipulators was founded in the Foundation for Development of Cardiac Surgery of Prof. Zbigniew Religa (FRK) in Zabrze, in collaboration with specialists from several academic centres (Lodz and Warsaw Technical University) and companies (FAMED Zywiec PL, EMSI Swietochlowice PL). The project started in 2000. It was assumed that the robot would have a segment-like structure allowing different configurations set up for various types of soft tissue surgery. In particular, it should have an independent arm of the endoscopic video track with a wide range of application. The project has evolved together with the increase of experience gathered by the construction team.

2.1. Robin Heart Project - Milestones

In the first phase of the Polish Robin Heart Project, three robot models: Robin Heart 0, 1 & Robin Heart 2 (Fig.1) were created, differing from one another by the concept of control system and mounting [3,4]. Between 2007 and 2008, the Robin Heart Vision [5], a robot for tracking video endoscopic channel, was constructed and tested. In 2010, after only one year of work, a new model, the *Robin Heart mc²* appeared in the laboratory and in the Animal Experimental Medicine Centre for in vitro and in vivo tests. The robot fulfils the role of three operators: the first & second surgeon as well as the assistant holding the vision channel [6]. In the same year, after completing a 2-year project, novel mechatronic tools, the Robin Heart Uni System were created. These innovative tools allowed to put into practise the idea of using the same surgery tools both on the robotic arm, tele-controlled by the operator, and in given cases in the other way: similar to traditional laparoscopic tools - manually but driven by means of a special handle with micro-motors mechanisms.

At the same time, effective systems of Man-Machine interface including ergonomic Surgeon (Master) environment with comfortable operating position of the Surgeon, high quality vision system and intuitive contact with Master tool of tele-manipulator (including force feedback, which is still optional, in research phase) are being developed.

The Heart Robin prepared for clinical surgery has a chance to introduce a lot of innovations, desired by the surgeon, to the techniques of minimally-invasive surgery. The planned implementation of a family of Polish robotic surgical tools and the Robin Heart family depends on the success of the research plan, education, and of course on starting the production. The strategic investor is currently searched for optimization of the robot production technology.

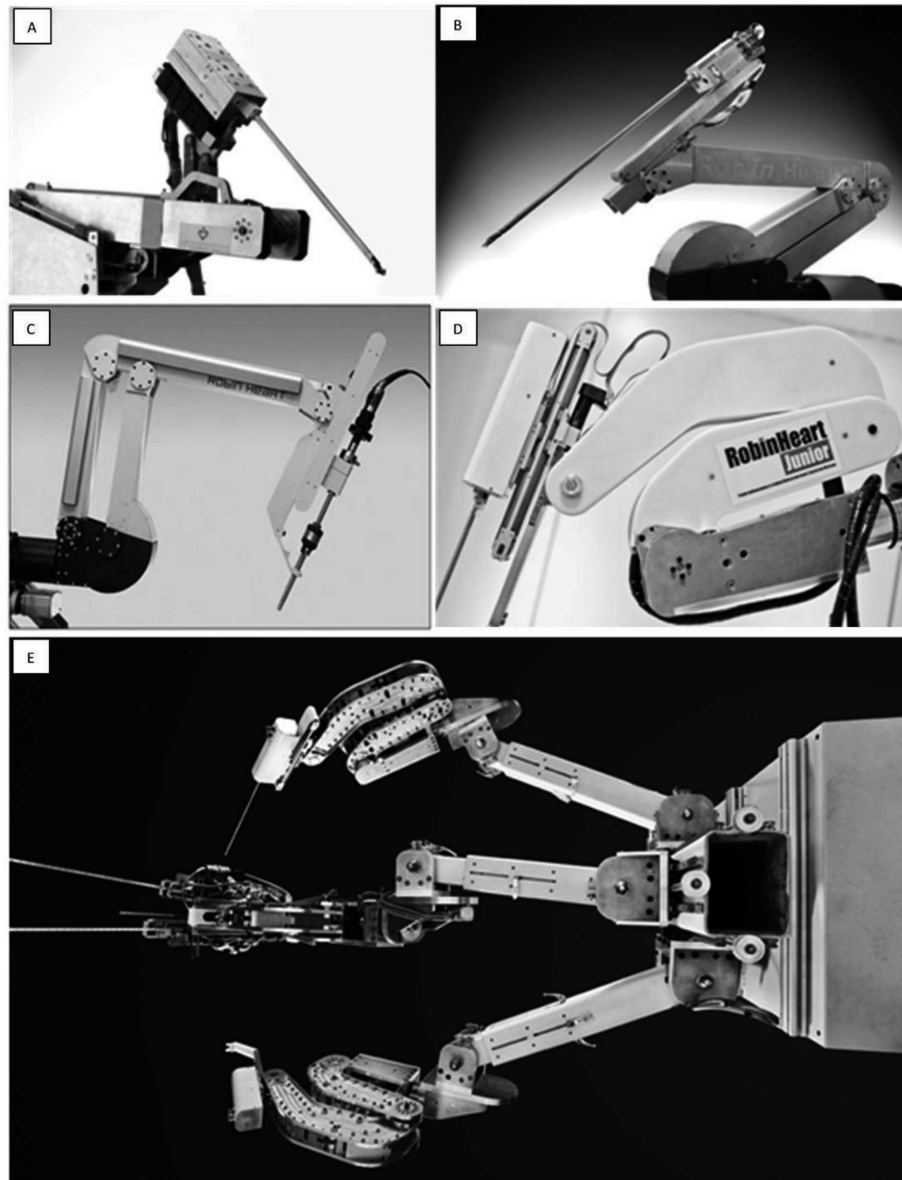
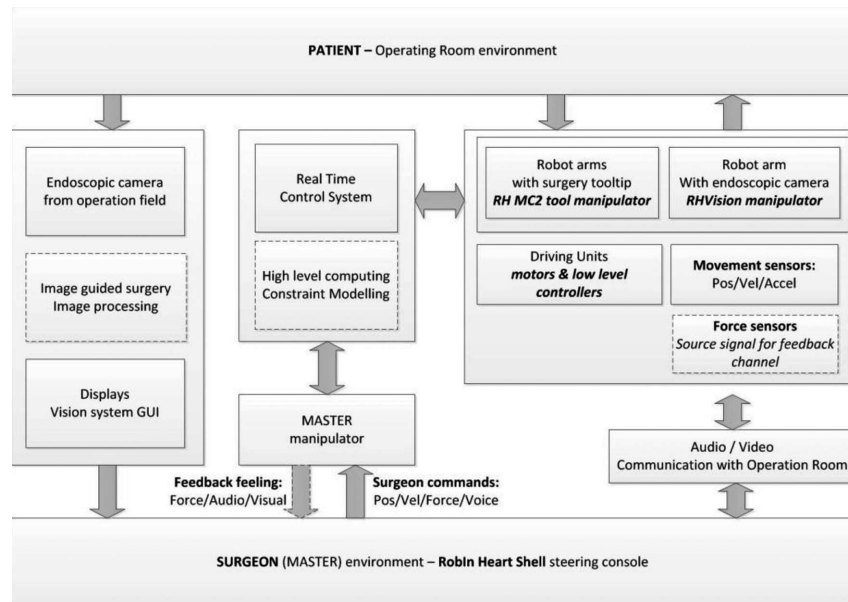


Fig. 1. Progress in project development – The Robin Heart family robots.: Robin Heart 0 (A), Robin Heart 1(B), Robin Heart Vision (C), Robin Heart Junior (D), Robin Heart mc²(E)

2.2. Structure of Robin Heart System

Master – Slave bilateral control is a goal of the current RH system development (Fig.2). Apart from real time control unit, working with sampling



Robin Heart full bilateral control system structure.

- under research and development

Fig. 2. Structure of Robin Heart full bilateral system with cooperation with operating room environment and staff

frequency in the range of 200 ... 1000 [Hz] (Fig.3), several signal loops are included in the robotic surgery theatre:

- HD resolution vision system as a main part of visual feedback provided to the Operator, which makes it possible to work in 2D or 3D mode, created in last two years using 3D monitor with passive glasses or real two channel optical system as an output – user interface.
- Surgeon database and advisory system with off & on-line patient diagnostic data and results of flow simulation prepared individually for him.
- External audio-video channels, supporting communication between the surgeon and the operating room staff
- Low-level control loops:
 - sensors of Master manipulator reading movement command of Surgeon/Operator
 - regulators of driving units in the Slave part of the control system based on brushless motor with rotary and linear encoders in the position feedback loop
 - safety system loops: redundant sensors in the control system, motor state monitoring, software and hardware limits

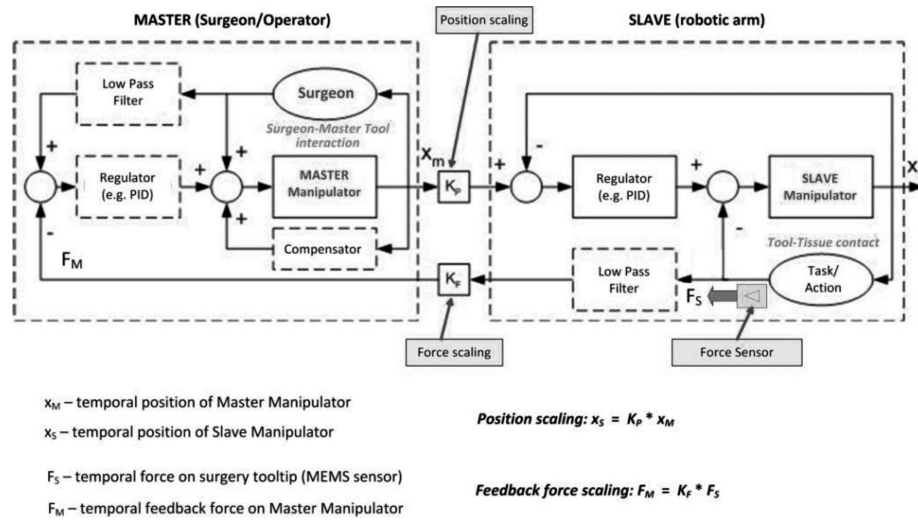


Fig. 3. Bilateral control system structure of Robin Heart Robot

3. Studies and Experiments

The implementation of robotic surgical tools into clinics is a process consisting of several difficult, demanding steps:

- Laboratory experiments on computer workstations (virtual operating room also with real Master tools)
- Laboratory tests, both functional and technical
- Laboratory experiments and training on models containing natural tissue, organs
- Experiments on living animals

3.1. Robin Heart tool mc² system

Our robots were tested during several laboratory in vitro tests, as well as in three experiments on living animals (gall bladder, heart valve repair surgery and elements of coronary artery bypass surgery [7]) at the Centre for Experimental Medicine of Medical University of Silesia in Katowice-Ligota (Fig. 4). During these crucial tests, in real surgery conditions, the initial concept of Robin Heart MC2 modular structure was positively verified. One also introduced an innovative concept, according to which, in the case of need during operation, a mechatronic tool can be removed from the robotic arm and attached to a special holder, allowing further surgery with manual control. Thanks to the experience gained in these tests, a list of corrections, necessary for the preparation of more robust clinical models, was prepared and introduced into the real prototype [6].

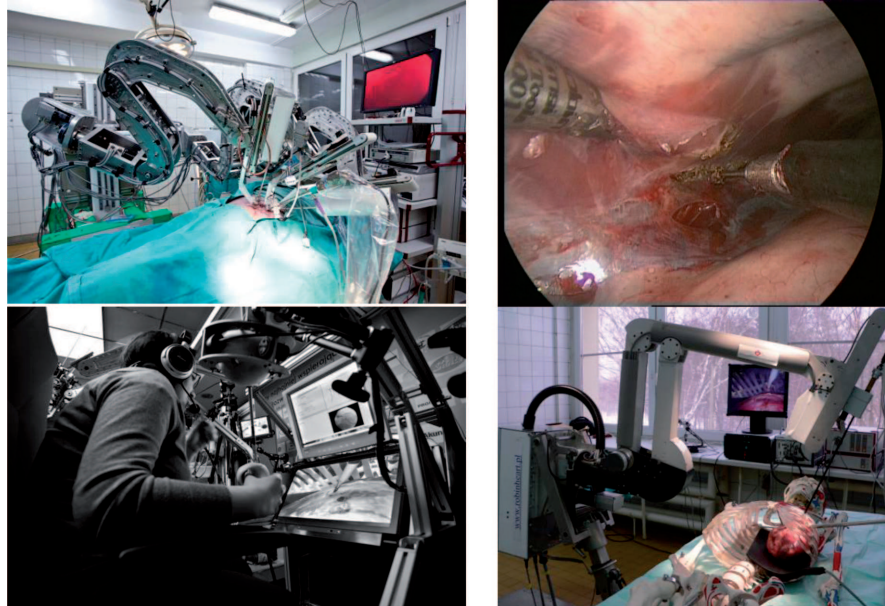


Fig. 4. Functional tests: animal experiment performed by means of Robin Heart mc² system (upper) and first, modelling, long distance tele-operation between FCSD (Zabrze) and Center for Experimental Medicine of Medical University of Silesia in Katowice-Ligota

3.2. Robin Heart Vision – single arm for camera channel

The telemanipulator, created in 2007 and based on experiences gained from the Robin Heart 1, is designed to endoscope positioning during surgery. It is ready to mount commercial vision systems made by a different manufacturer. This most advanced member of the RH family, featuring a surgeon friendly man-machine interface enabling hand or foot arm steering, gained full approval from the medical team. It has passed all laboratory tests and successfully performed experimental surgery on animals (Fig. 4). The robot vision track is mounted to the frame of the operating table and replaces one human assistant during the surgery.

Mechanical construction of RH Vision robot

The basic assumption, resulting from the field of application, is the requirement of constant point position of the entrance port on patient's skin during robot-supported MIS. It was the reason for taking into consideration the spherical type robot already from the beginning of the project, and for developing such a type of robot structure (Fig. 5).

For driving unit selection and control system development, one created a telemanipulator kinematic structure with forward and inverse kinematics.

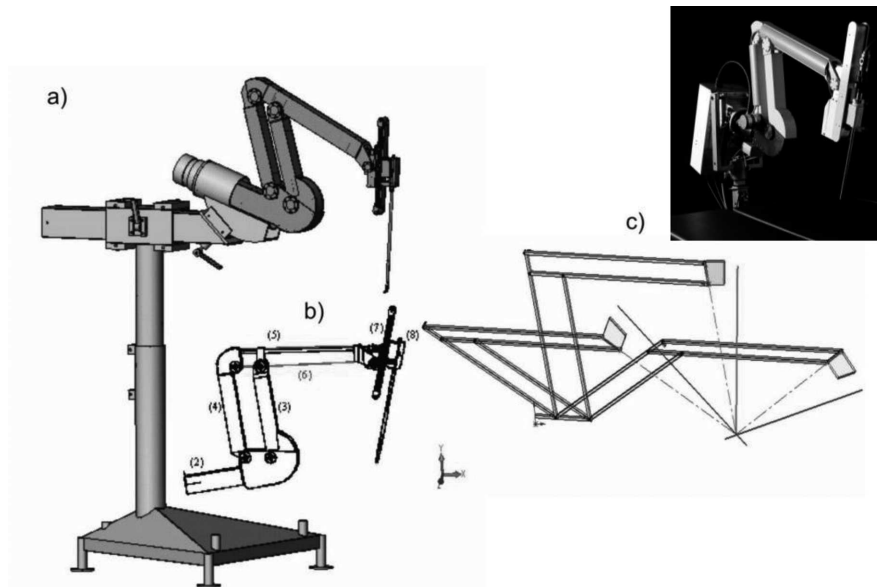


Fig. 5. General view of Robin Heart Vision with constant point visualization in extreme position of DOF2

The structure, and the computed coefficients, are presented in Fig. 6 and Fig. 7 [8,9].

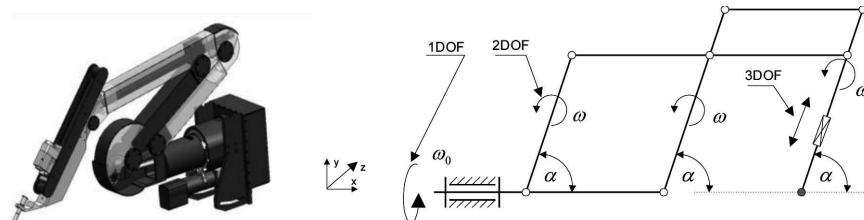


Fig. 6. Construction and kinematics of Robin Heart Vision

The Maxon motor combinations consisted of brushless DC motors, planetary gearhead, hall sensors and the rotary encoders that were used for precise positioning as driving units for every degree of freedom in RH Vision tele-manipulator.

Chosen tests for RH system verification

Apart from functional tests, performed both *in vitro* and *in vivo* in an animal lab, a set of technical test was carried out to determine the characteristics of the developed product (Table 1, Fig. 8).

Accuracy and hysteresis tests of RH Vision arm

Based on the above-presented measurements, one computed limit values of basic parameters:

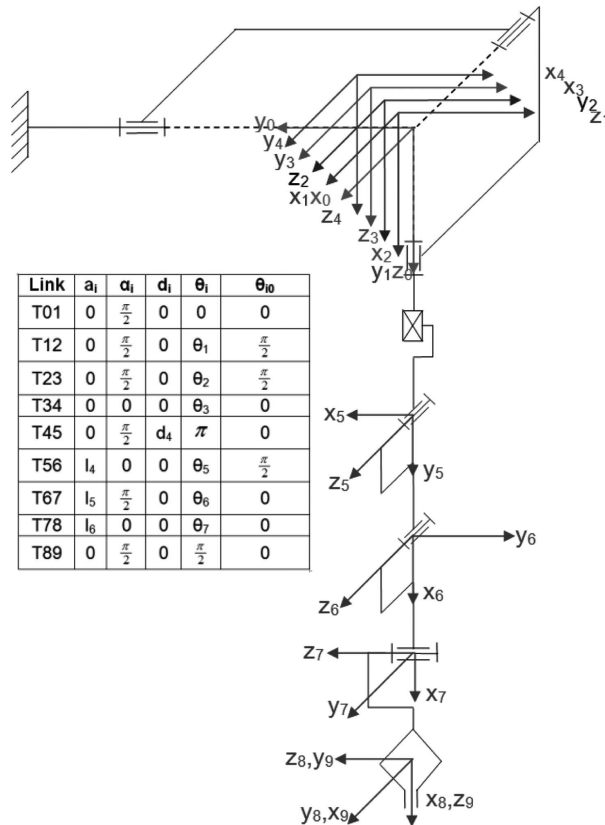


Fig. 7. Kinematic structure of RH Vision surgery telemanipulator

Table 1.

Chosen technical parameters of RH Vision System [8]

Movement range	DOF1 [deg]	DOF2 [deg]	DOF3 [mm]
assumed	150	120	150
achieved	187	117,5	effective: 165 total: 400

- Positioning repeatability: not worse than 0.03 [mm].
- Positioning accuracy: not worse than 0.1 [mm].

3.3. Long-distance telemanipulation experiment

The Zabrze team with the support of the EMITEL also made the first teleoperation experiment in Poland in 2010. The surgeon behind the console in the FRK in Zabrze operated remotely the robot Robin Heart (pig heart in a model of human chest) placed in the CMD of Silesia-Ligota [6]. Surgeon-operator steered the tool tip by means of Master arms fixed to the console of

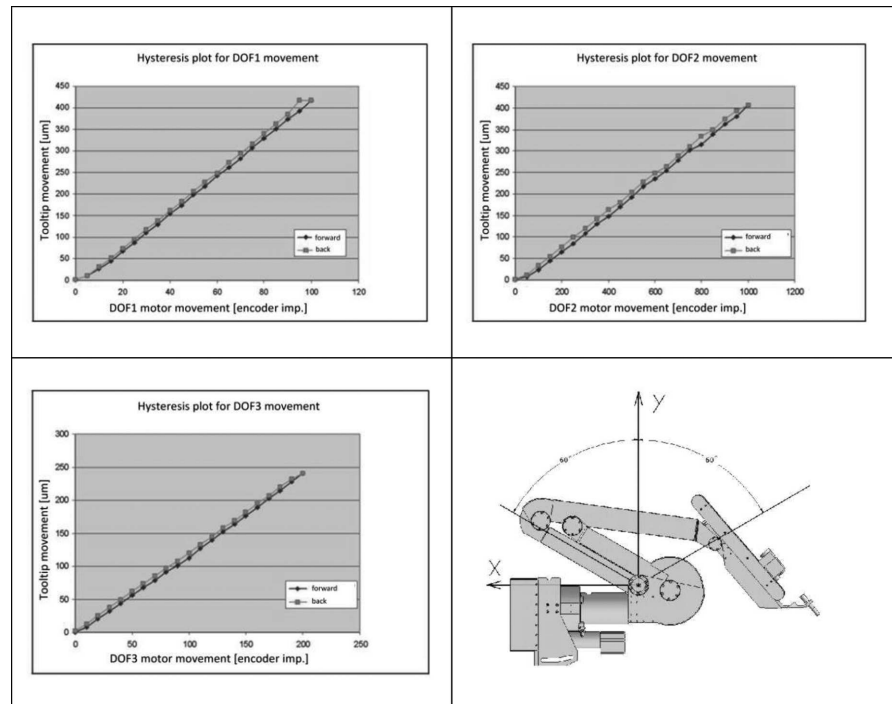


Fig. 8. Hysteresis test results for robot movement in DOF 1,2 and 3

Robin Heart Shell. The main goal of this experiment was to develop and test a distributed control system, and to measure some delay-related parameters important for making effective surgery:

- Delay of manipulation transmission: $D_{MT} = 2$ [ms]
- Delay of image transmission: $D_{IT} = 280$ [ms]

The measured value of D_{IT} was close to the limit ensured correct eye-hand coordination, making it possible to perform eg. cholecystectomy. However, this delay was too large to allow for operating on the heart (Fig. 4).

4. Training System for Staff Skills Improvement and Operation Pre-Planning

The training system, aimed at experimental clinical studies, developed in the FRK during last several years consists of:

- testing stands and program of surgery planning: Virtual Operating Room (Fig. 9)
- laparoscopic surgery training phantoms (Fig. 10)
- endoscopic surgery training by means of virtual reality technology
- physical stands for Robin Heart tests
- virtual reality environment for Robin Heart Robots manipulation training

- advisory system and database presented from the Robin Heart Shell steering console to the Surgeon during operation.



Fig. 9. An example of set of virtual models of both robots, anatomical parts and surgery room environment for operation pre-planning

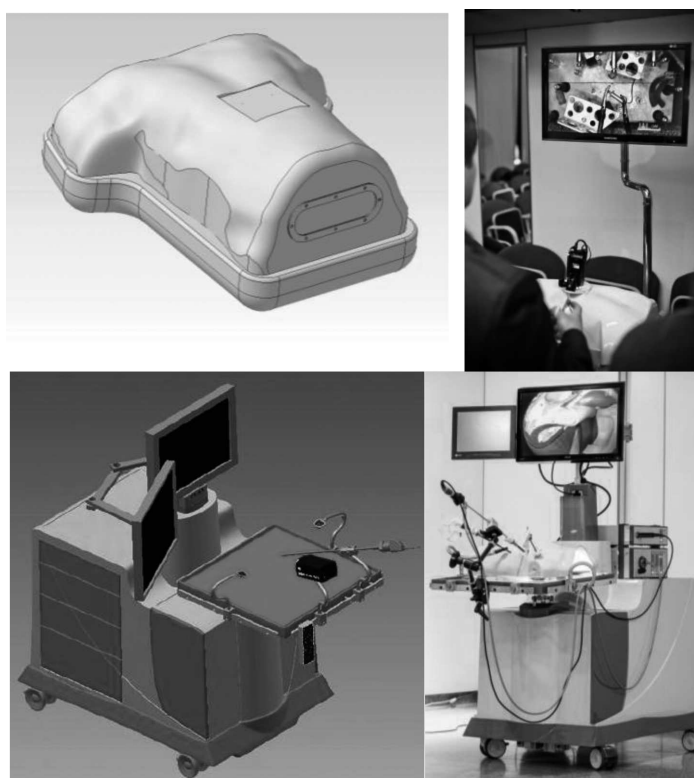


Fig. 10. Physical testing stands: nBody (upper), nBox (lower). CAD model and test on final product developed in FRK during Biomedtech Silesia Surgery workshop, FRK Zabrze, in December 2012

The next stage of development of surgery staff skills were the exercises on physical training stands, which were developed in our Institute to represent the conditions of a real operating room during *in vitro* experiments on

artificial or real tissue. Two different functional stands were created in the last 3 years: a simpler, cost effective model: *nBody* (Fig. 10a) and a more complex one, the *nBox* model, which also contains a hydraulic system for more advanced surgery simulation (Fig. 10b).

An important element of the system developed in the FRK is a training program organized during annual surgical workshops. There were over 1500 participants (mainly medicine students and doctors), participating in this events during last 10 years. They learned about the secrets of surgery, from classical, through laparoscopic to robotic. About 40 unique testing stands were created and used.

Education systems play an important role in the preparation of the target group of potential users of the developed devices. They are also important for verification of developed products and may determine their potential market success.



Fig. 11. Elements of training program (upper site from left): virtual operating room (surgery planning), surgery workshops performed on real stands, surgery tasks on real animal tissues, and final animal experiments on live pigs



Fig. 12. Original training stand of laparoscopic and robotic surgery

5. Technical Arrangement of Clinical Experiment

Current improvements in the Robin Heart are aimed at improvement of several factors that are crucial at this stage of development:

- construction of mechatronic surgery tool
- Master, man-machine manipulator optimization
- safety system development
- robot placement/mounting to operating table

Modifications associated with the implementation of the first clinical trials are introduced in the robot Robin Heart Vision. An example of such a modification can be the change in the mounting of the sterilizable endoscopic channel, where a more comfortable front removing type was applied (Fig. 13).

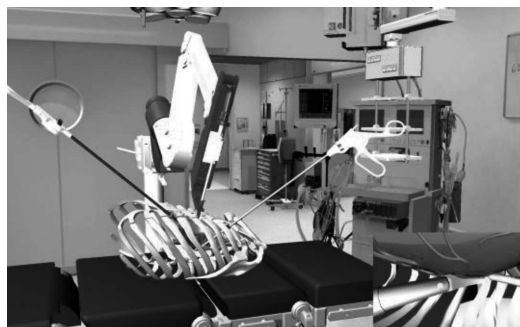


Fig. 13. Model operations on the heart of a robot Robin Heart Vision – Virtual operating room. Modifications can be observed in mounting of robot's camera

Another adaptation procedure concerned fixing of RH Vision arm to the newest carbon based surgery table, placed in one of the most modern operating theatres in Polish cardiac surgery clinic – Silesian Center for Heart

Diseases in Zabrze. As a final result of optimization procedure it was decided to make a special attachment for this experimental robot to be ready to carry out the hybrid surgery procedures [10,11].

Currently, the robot Robin Heart Vision is ready for certified safety studies required for clinical trials of experimental procedure. The research will be carried out after obtaining positive results of all studies and approval by the Ethics Committee.

A list of critical cases was prepared to describe a set of danger situations and the required system/user reactions. As an example, the courses of velocity, position and current recorded during simulated arm collisions are presented in Fig. 14.

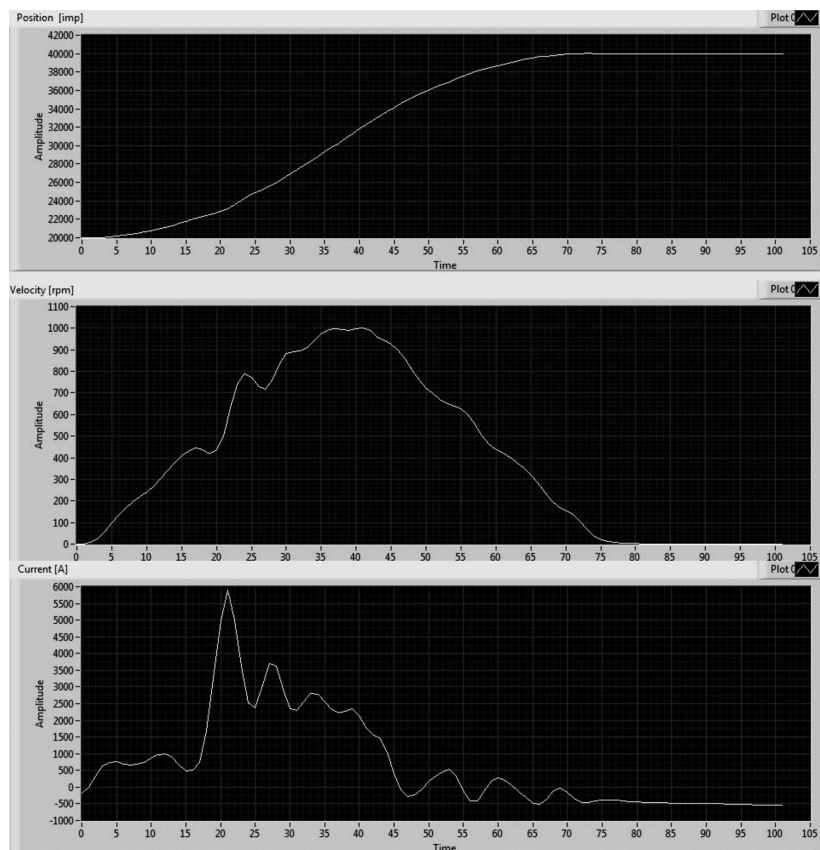


Fig. 14. Recorded velocity, position and current courses during simulated arm collision

One can see the moment of collision (a disturbance in velocity is visible), after which the arm returns safely to normal work (smooth trajectory of position).

The systems of surgical robot Robin Heart mc2 are currently being modified, including wiring, driving units and certain parts of the mechanical system (gears) which are replaced. This will improve its surgical possibilities, and the introduced modifications will bring relevant features of durability, performance and safety during subsequent tests. The tests of the control system will be carried out during long-distance teleoperations that are planned to be performed in one-year time. It is not planned to use this robot for clinical experiment, but it will be used to test the new technology and design concepts that will be used in the upcoming clinical model.

6. Summary

Polish surgery robots are original technical solutions, whose value is confirmed by the obtained patents and comparative analysis carried out by researchers in this field [6]. Experimental studies carried out on animals and successfully prepared teleoperation proved effectiveness and correctness of the developed mechatronic systems. The Polish robot will introduce a number of useful innovations into this kind of devices. Surgical robots give an opportunity to introduce new standards and treatment procedures to deal with difficult patient cases, for which current methods are neither secure nor efficient.

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Telemanipulator chirurgiczny Robin Heart. Opis konstrukcji mechanicznej, systemu sterowania i programu szkoleń dla personelu przed pierwszą aplikacją kliniczną

Streszczenie

Pojawienie się w ostatnich dekadach na salach operacyjnych klinik zautomatyzowanych telemanipulatorów wprowadziło nowy standard w chirurgii małoinwazyjnej dzięki poprawie precyzji działania, powtarzalności ruchów i procedur, zwiększenia komfortu pracy chirurga-zdalnego operatora – bardzo istotnego przy często długotrwałych zabiegach. Aby osiągnąć ten etap wdrożenia klinicznego, biorąc pod uwagę z jednej strony wciąż istniejące ograniczenia tego typu zabiegów oraz konieczność spełnienia bardzo rygorystycznych wymagań certyfikacji samego produktu medycznego o najwyższym w tym przypadku stopniu inwazyjności konieczne jest nie tylko opracowanie samego produktu finalnego spełniającego wymagania norm lecz również certyfikacja całego procesu technologicznego jego wytwarzania. Celem pracy jest przedstawienie przygotowań do badań klinicznych, po fazie testów laboratoryjnych i na zwierzętach samego systemu robota, stanowisk testowych oraz przygotowania kadry dla jego obsługi dla projektu polskiego telemanipulatora chirurgicznego RobinHeart. Przedstawiony został projekt mechaniczny, systemu sterowania oraz stanowisk trenerów-symulatorów i wybrane elementy modyfikacji podsystemów, powstałe na bazie 12 letnich doświadczeń zespołu i analizy rozwiązań światowych, dla najbliższego wdrożeniu robota RobinHeart Vision, przeznaczonego do zdalnej manipulacji torem wizyjnym podczas operacji małoinwazyjnych.