Development of Foolproof Catheter Guide System Based on Mechatronic Design

N. A. Che Zakaria[1]*, T. Komeda[2], C. Y. Low[1] and K. A. Mahadhir[1]

[1]Centre of Excellence for Humanoid Robotics and Bio-Sensing, Universiti Teknologi MARA, Malaysia
[2]Research Organization for Advanced Engineering, Shibaura Institute of Technology, Saitama-shi, Saitama, Japan
*E-Mail: ayuni.uitm@yahoo.com

Summary: Minimally Invasive Surgery (MIS) techniques are a less invasive procedure than open surgery, usually involving laparoscopic devices, remote control manipulation instruments with indirect observation of the surgical field through endoscope or similar devices. Interventional Radiology (IVR) is one of the MIS methodologies. IVR procedures are for diagnostic purposes such as angiogram, and others are for treatment purposes. IVR procedure use small tubes called catheter or needles which will be inserted through body and guided to treatment area. Images from Digital Subtraction Angiography (DSA) device are used to guide IVR procedure. Conducting IVR procedure, the surgeons ended with the risk of exposure to X-rays from the DSA device. Therefore, to prevent the risk of exposure to X-rays, a tele-operated system to guide catheter or needles is developed based on a mechatronic design. The mechatronic design is specified in the form of a principle solution using a specification technique as in the software tool Mechatronic Modeller. Such principle solution serves as a basis for the first analysis, verification and validation on the systems level, and at the same time the initial point of specific concretization within the different domains. In particular, the proposed concept of control system can be re-used in the other guidance systems.

Keywords: Interventional Radiology, Tele-Operated, Foolproof Mechatronic Design.

1. General

This paper introduces to the fundamentally extended mechanical engineering design methodology. It focuses on formulating requirements and functions of the system to fulfil the principles of reliable systems where it is called foolproof system. The foolproof catheter guide system was designed to be impervious against surgeons misuse, error or failure. Foolproof system is one of the functions in the catheter guide system.

1.1. Interventional Radiology (IVR)

The Interventional Radiology has two type of treatment, one is the treatment through the blood circulatory system and another is through the human body cavity. In this study, we are focusing on the development of the blood circulatory system treatment. IVR procedure for blood circulatory system is using Digital Subtraction Angiography (DSA) device [1], one of the fluoroscopy techniques and it can lead to the X-rays exposure to the surgeons. Usually the surgeons wear protector made from lead (Pb) weighted 5.4 kg, covering glandula thyreoidea and genital gland only, exposing their neck and wrist. In order to prevent the X-rays exposure, few researches has been conducted to develop a tele-operated system for IVR catheter guide [2] but less was focused on the possibility of human error during operation.

1.2. Concept of Tele-operated system

Tele-operated control system is a close-loop system where the operator inserts the position information to the master tool in a control room and sends the information to the slave tool in the operation theatre. The slave tool will move according to the information and give feedback of tactile information from the sensor at the slave tool back to the master tool [3]. The detected force is used to activate passive actuator in the master tool. The concept is illustrated in Figure 1.

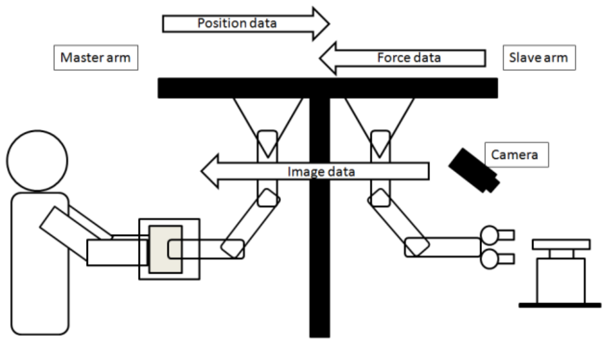

Figure 1. Concept of tele-operated system.

2. Foolproof Mechatronic Design

Recently the demand to enhance reliability of safety-critical systems such as airplanes [4] and all *X-by-wire technologies* are increasing. The reliability factor as fault detection and fault analysis has attracted in-depths research in fault-tolerance [5] or we call it foolproof in this paper. The symbiosis of the diverse domains of mechatronic enables novel functionality that was infeasible before in any of the individual domains [6]. Based on the development of conceptual mechatronic design, these foolproof systems is able to be applied in the tele-operated systems. In this paper, foolproof mechatronic design will be discussed based on an example developed for a tele-operated catheter guide system for Interventional Radiology.

Figure 2 shows the diagram of the hierarchical decomposition of system’s functionality. The term function refers to the output of the system in order to perform a task. Thus each function has its own independent sub-function. One of the independent functions other than guiding the catheter and avoiding collision with blood vessel is to enable foolproof. In enabling foolproof function, system must be able to detect abnormality and cut-off the command inserted through master tool.

Based on the functions listed, the developed system must follow the behaviour activities and states for each function. Figure 3 illustrates how the velocity of catheter was analyzed and the next task is identified. Information inserted was judged and the system determines its states of behaviour to maintain preciseness and safety. The state transitions show their adaptation to the activities.

Once the system judged error from surgeons, the activity ends up with halt or hard manipulation. Errors or mistakes were divided into two conditions as shows in Figure 4, E_1 and E_3. In E_1, if the contact force of the catheter and blood vessel is more than 0.12 N, the system judge that the catheter has collide with blood vessel. While E_3 is judging the velocity of the movements based on position input and will change into halt transition detecting that the surgeon has made a mistake.

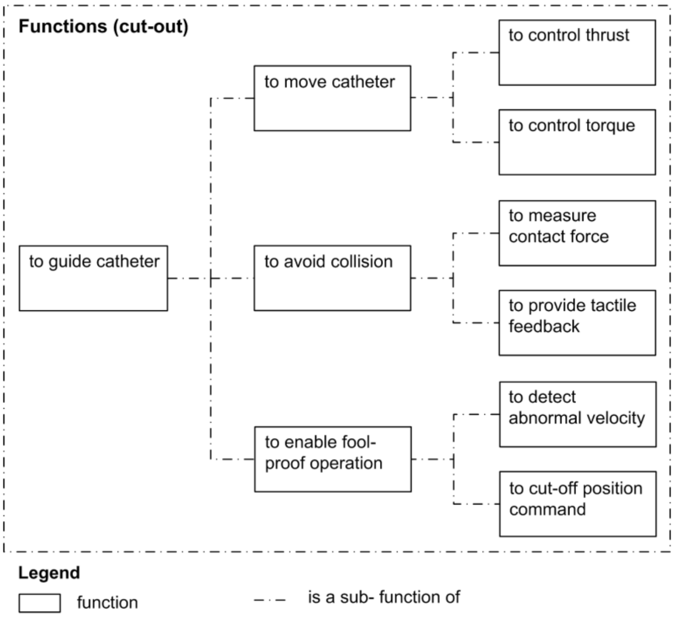

Figure 2. Functions Hierarchy of a Foolproof Catheter Guide System

3. Prototype tele-operated catheter guide system

The concept of the development of master tool was based on the requirements:

1. Posses non-intervention 2 Degree Of Freedom (Thrust and rotation)
2. Providing force sensor for the 2 Degree Of Freedom (Precision 0.1 [N])

Figure 5 shows the appearance of master tool. Thrust movement part is build from sliding screw and bearing and detected by an encoder while for the rotation part, a disk is install and connected to an encoder. Both the thrust and rotation mechanism are connected to a disk containing electrorheological (ER) fluid. When force is detected at the slave tool, the viscosity of ER fluid is increasing making its hard to manipulate the master tool.

Requirements for slave tool are:

1. Non-intervention 2 Degree Of Freedom
a. (Thrust and rotation)
2. Able to compliant catheter sizes 3-11 Fr
3. Parts attached to catheter are sterilizeable
4. Install with force sensor
5. Foolproof system
6. Lightweight and compact

Roller mechanism is applied for infinite thrust mechanism as show in Figure 6. Thrust mechanism was a combination of roller mechanism, hypoid gear, hollow stepping motor and slip ring. The rotation mechanism is using DC motor, timing belt and pulley and a cross roller bearing. 4 strain gauges is use as the force sensor.

The relations between surgeon, master tool, slave tool and other system elements are described in Figure 7: active structure of catheter guide system.

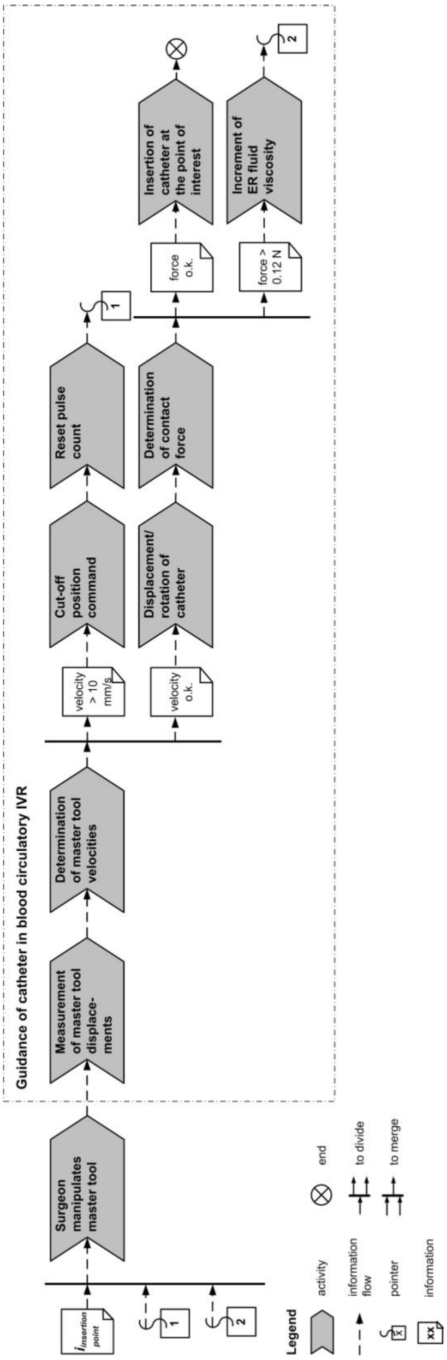

Figure 3. Behavior activities of Catheter Guide System.

System configuration starts with receiving visual information from DSA device, and the master tool is manipulated. Slave tool will move catheter based on inserted position command and have direct contact with blood vessel. Detected force command is converted into analog input to increase voltage of ER fluid which is the element of tactile feedback.

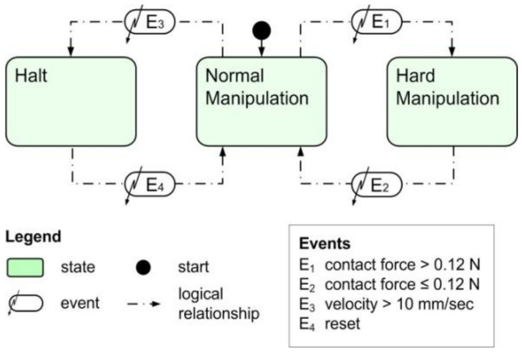

Figure 4. State of Foolproof Catheter Guide System.

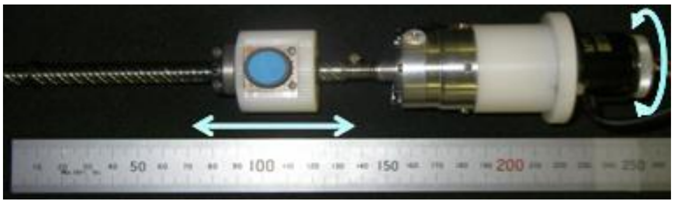

Figure 5. Master tool appearance.

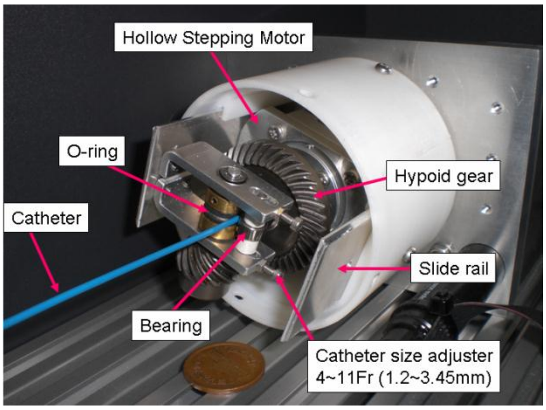

Figure 6. Slave tool appearance.

4. Conclusion

This paper focuses on the principle solution describing the mechatronic design of a foolproof catheter guide system. It is the first application example using such specification technique in the field of medical engineering. Instead of using the principle solution for new product development, this paper use the principle solution (system functions, behaviour activities, behaviour states, etc) as a guideline to improve the existing prototypes of the catheter guide system aiming to enhance the reliability, stability and performance of the tele-operation. In particular, the proposed concept of control system can be re-used in the other guidance systems.

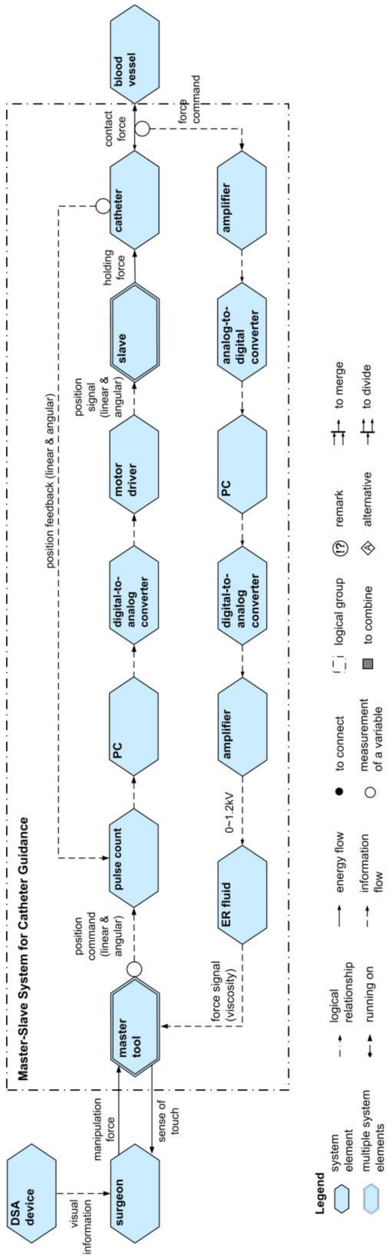

Figure 7. Catheter Guide System active structure.

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