A Hardware-in-the-Loop Simulator Concept for the Minimally Invasive Surgery

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Introduction

Hardware-in-the-Loop (HIL) simulation is an established technique for tests and validation of a controller device [1]. In the field of medicine, different types of simulators have been used successfully in the development phase of medical control strategies and devices. This is necessary since the real patient cannot be involved in the design phase. However, the patient or a part of the patient as well as a medical device are parts of the control loop.

To replace the patient up to final clinical trials, a HIL-Simulator should be developed. The HIL-Simulator should behave like the relevant part of the patient to realize an interaction with the medical device in experiments. It emulates the physiological behavior of the interesting part of the human body. With a HIL-Simulator, tests and evaluations can be performed repeatedly and safely.

In this paper the concept of a HIL-Simulator for different interventions in *M*inimally *I*nvasive *S*urgery (MIS) is introduced.

Medical devices in MIS

Minimally invasive surgery is characterized by small incisions. Therefore, it results in benefits of reduced complication and fast recovery of the patients [2]. To improve visibility and accessibility in the operation area during MIS, gas or liquid is used for flushing the operational area via trocars. During flushing, bleedings and inflows to the tissue need to be avoided. Gas is used for flushing larger operation regions like the abdominal area or the uterus. The corresponding medical device is called insufflator. In contrast, for an arthroscopy operation located in the knee or the shoulder, liquid should be used instead of gas. In this case, a double roller pump is used as a medical device.

Fig. 1 illustrates these typical two cases of medical devices in MIS.

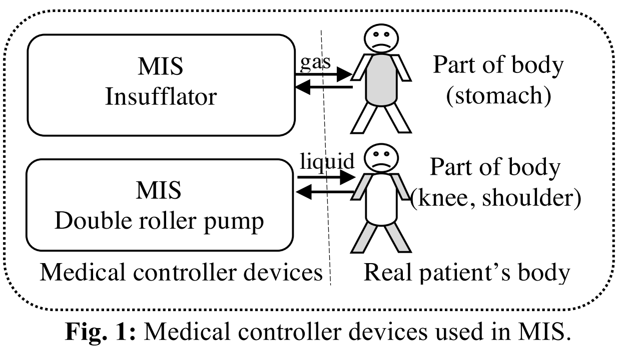

Fig. 1: Medical controller devices used in MIS.

The configuration of the medical device for a knee arthroscopy is shown in Fig. 2. The double roller pump is used for regulating the inflow and outflow of liquid to the knee.

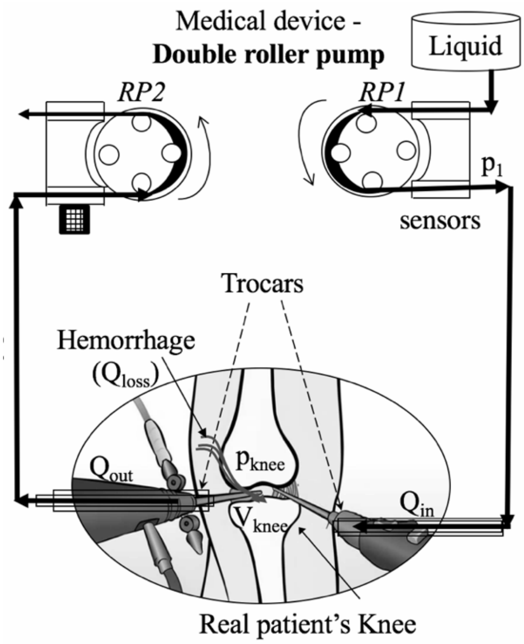

Fig. 2: An overview of the knee arthroscopy.

A surgeon can set the outflow rate of liquid Q_{out} by roller pump RP2 during MIS to regulate visibility in the operational area. This action results in a change of the volume inside the knee V_{knee}. Thus, the inflow of liquid to the knee Q_{in} should be controlled independently to compensate this disturbance via roller pump RP1. The speed of the roller pump RP1 need to be adjusted automatically depending on the pressure in the patient's knee p_{knee} to ensure accessibility to the operational area.

The relationship between the pressure in the knee p_{knee} and volume of the liquid V_{knee}, inflow Q_{in} and outflow Q_{out} from the knee are shown in equations (1) and (2).

$$p_{knee} = f(V_{knee}) \quad (1)$$

$$\dot{V}_{knee} = Q_{in} - Q_{out} - Q_{loss} \quad (2)$$

Q_{loss} is called the consumable component of the flow created from the hemorrhage or the flow back at the local area of MIS.

The term f is a nonlinear function that describes the dependency of the volume V_{knee} on the pressure p_{knee}. If the volume V_{knee} increases, the pressure p_{knee} will also increase. This can result in a liquid flow back into the tissue or the blood vessel when p_{knee} is higher than the pressure of the blood p_b. Otherwise, it results in hemorrhage when p_{knee} is lower than p_b. Both of these two cases are undesirable in MIS. So the main objective for solving these problems is maintaining the pressure p_{knee} at the appropriate value of the blood pressure. This is done by the double roller pump controller device.

In the following section, the arthroscopy is used as an example for the description of a HIL-Simulator concept.

HIL-Simulator concept

For the development of a double roller pump control device, a HIL-Simulator should replace a human knee. Therefore, a simulator must reproduce the main essential properties of a knee. A general block diagram of the HIL-Simulator interacted with the medical device is illustrated in Fig. 3.

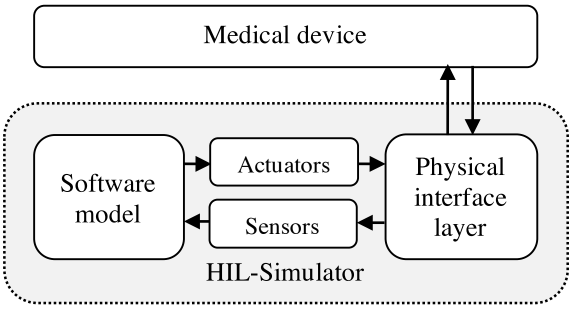

Fig. 3: Structure of the HIL-Simulator.

The HIL-Simulator consists of a software model and a physical interface layer with sensors and actuators [3]. For the application case of arthroscopy, the software model calculates physiological values for the pressure p_{knee} and volume V_{knee} of a real knee, depending on the values interaction with the connected medical device measured by suitable sensors. The physical interface layer realizes the connection between the software model and the medical device. The actuators are used to reproduce the calculated references from the software model.

A concrete realization of this HIL-Simulator is shown in Fig. 4.

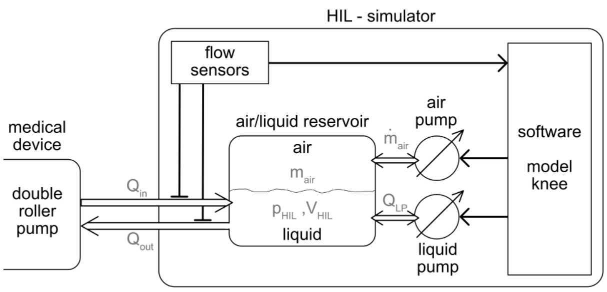

Fig. 4: Realization of a HIL-Simulator.

The air/liquid reservoir of the HIL-Simulator is the connection to the medical device to emulate the physiological states of the knee. These states are the pressure p_{HIL} and the volume of the liquid V_{HIL}, and stand for real the states p_{knee} and V_{knee}. The flow rates Q_{in} and Q_{out} represent the interaction values with the medical device and are measured by flow sensors. This information is included in the software model for calculation the reaction of the knee to the interaction with the medical device. The reservoir is connected to the software model via the actuators - an air pump and a liquid pump. These pumps are used to control the appropriated values of p_{HIL} and V_{HIL}. Two pumps are necessary to control the two states independently. The usage of pumps for air and liquid extends the usability of the HIL simulator to pneumatic and hydraulic processes for further research.

Different types of actuators were analyzed with respect to their applicability in the introduced HIL-simulator concept. Controller structures were developed and implemented in a test bench for selected types of pumps. First results show sufficient results in respect of control accuracy and dynamic properties.

The design of the HIL-Simulator should allow a high flexibility with regarding to the connected medical devices. The interface was constructed for general purpose application for hydraulic and pneumatic medical processes. Different parts of the human body can be emulated with a fixed hardware structure and a flexible software core [5].

Conclusion

An overview concept of a HIL-Simulator was introduced in this contribution. This approach was developed and implemented in the field of minimally invasive surgery. The structure of the hardware of the HIL-simulator was presented. Further research is necessary to combine first results of tests with the actuators with a future sensor platform. Software models have to be built on the basis of clinical data.

The final HIL-simulator will be usable for the analysis of the dynamic behavior of medical device in a virtual physiological environment [6]. The results will provide a solution for a safe, long-term tests for the development phase of medical devices.

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