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DRUGAS: implantable telemetric system for measuring the portal venous pressure: assembly aspects

Abstract: Developing an implantable, telemetric pressure measuring system for venous applications makes a high degree of miniaturization necessary. Thus the influence on the measurement environment is minimized and the risk of thrombosis at small flow blood velocities is decreased. But these systems are limited in terms of accuracy and resolution. The asked system requirements could only be reached by optimising the assembly and encapsulation techniques. To achieve the high degree of miniaturization numerical simulations were performed on the shape and size of the implant and led to the development of a specific metal housing consisting of two main components. A small measuring chamber will be placed into the portal vein and is rigidly fixed to a flat circular part that contains the pressure sensor chip and a transponder board and will be located outside on top of the vein. The main focus of the assembly process was based on a stress-free design and mounting of the components.

Keywords: pressure sensor, telemetric system, medical implant, assembly process, stress-free design.

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1 Introduction

For development of a medical implant the field of application has to be defined first. The implantable system presented here will be used to measure the portal venous pressure.

The portal vein delivers the blood from the abdominal viscus (like stomach, intestine, spleen) to the liver. Its main function is the transport of nutrients and toxicants to the liver, where these substances are metabolized. Under normal conditions the portal vein has a length of 40-50 mm and a diameter of 8-15 mm, the flow velocity amounts 130-230 mm/s and the portal venous pressure is between 3-6 mmHg. [1]

More than 600.000 people in the USA (0.27 % of the population) suffer from liver cirrhosis [2]. If a liver disease is existent (because of portal hypertension, thrombosis of the portal vein, cirrhosis of the liver etc.) the pressure inside the portal vein rises to 12-20 mmHg which can lead to gastrointestinal bleedings up to death. The motivation for developing an implant for measuring this portal venous pressure is an early detection of a pressure increase, an earlier help by a doctor and at least saving lives.

2 Implant design

An implantable telemetric pressure system, as seen in **Figure 1**, normally consists of a pressure sensor which is integrated in a complex metal housing (1), connected to a telemetric unit (2) and can be read out with a readout unit (3) for wireless communication with a monitoring station.

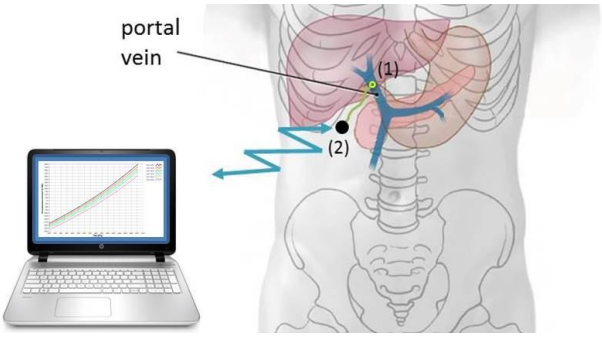

Figure 1: DRUGAS System consisting of (1) metal housing with sensor system, (2) telemetric unit and (3) readout unit

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Focussing on the sensor system including the metal housing in consideration of the geometrical requirements of the intended application area, simulations on the size and shape of the implant can be done. This leads to a first design from which the separate components can be deduced.

2.1 Simulation

By numerical simulation of blood flow in the portal vein the maximum system diameter was determined which can unhesitating be placed in the vein without influence the portal vein settings too much. Therefore a vein with a diameter of 8 mm and a sensor, placed in the middle of the vein, with different diameters were assumed. The results can be seen in **Figure 2**. The stenosis shows the quotient of the area of the sensor to the one of the vein.

As seen in the graph there is no influence of the sensor for a stenosis up to approximately 50 % which means a system with a diameter of 4 mm placed inside the portal vein does not raise its pressure. Due to that this value is set as the maximum for system diameter.

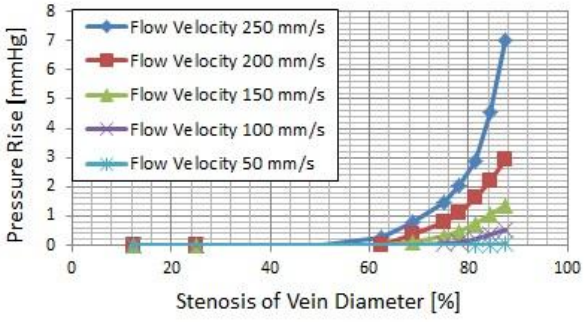

Figure 2: Simulation of pressure rise for different stenosis ratios and flow velocities in a portal vein

2.2 Design

Because a pressure sensor system consists of many different components with a non-reducible size the system does not fit completely into the portal vein. Thus an alternative design has to be planned which transfers the pressure from inside the vein to an outside placed sensor. In this case a specific metal housing consisting of two main components were developed (see **Figure 3**).

The lower part is a small measuring chamber and will be placed into the portal vein. The pressure inside the vein is coupled into the implant via a pressure-sensitive membrane. Through a thin connecting tube, the pressure is relayed to the metal housing, which is located outside the vein. This flat

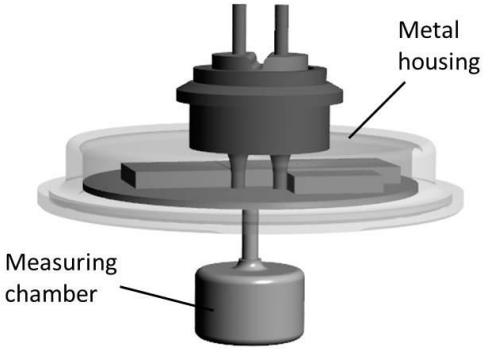

Figure 3: First design of the metal housing with integrated sensor system

circular metal housing contains the pressure sensor chip and a transponder board. A feedthrough for connecting the board to the telemetric unit is also provided.

Previous systems with this degree of miniaturization have been developed solely for arterial pressure ranges. Such systems are limited in terms of accuracy and resolution by two factors: the resolution of the sensor chip and influences due to packaging. The sensor chip used in this work shows the required accuracy of about 1 mmHg in laboratory while the final system requirements can only be reached by optimising the assembly and encapsulation techniques. The previously used assembly and encapsulation techniques for application in arteries cannot meet this requirement and hence they can‘t be used any more. Therefore the main focus of this work was on optimization of the housing and the mechanical decoupling of the sensor chip.

3 Assembly process

Concentrating on the upper part, the necessary components for the function of the system can be determined (see Figure 4). For measuring the pressure a CMOS based capacitive pressure and temperature sensor, similar to the on presented in [3], is used. A thin and flexible polyimide foil with integrated conductive lines, especially made for this

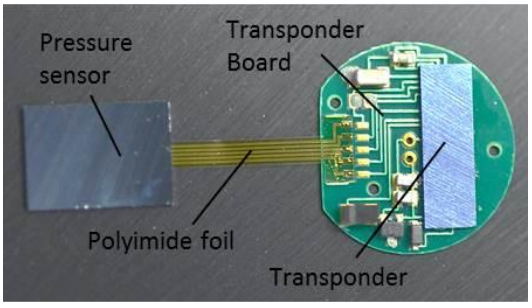

Figure 4: Connected components of the pressure sensor system

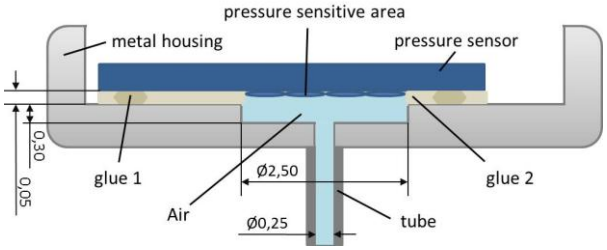

Figure 5: Schematic cross section of the gluing process

implant, electrically connects the pressure sensor with the transponder board. The PI foil is flip chip bonded onto the pressure sensor and glued on the board. With this foil a mechanically decoupling and stress-free connection can be reached. For assistance of the signal processing four capacitors and three diodes were additionally soldered in surface-mount technology to the board. Certainly the transponder chip is also flip chip bonded to the PCB while the necessary telemetric coil unit is placed outside the metal housing. This allows shorter AC signals and results in a better communication to the implant due to less damping.

Regarding the integration of the components into the metal housing leads to two steps: on the one hand side the transponder board has to be soldered to the feedthrough, on the other side the pressure sensor has to be mounted stress-free but gas-tight into the metal housing. Therefore a multi-stage gluing process is used (see **Figure 5**). At first a flexible silicon based adhesive (glue 1) is used to reduce the stress on the capacitive pressure sensor [4]. Afterwards a hard underfilling adhesive (glue 2) seals the encapsulation gas-tight.

Because of the capillary effect the second adhesive does not flow into the tube or plugged it. The small gap between the pressure sensor and the metal housing, in common with the abrupt change of cross section under the pressure sensitive area of the pressure sensor, behave like a capillary break [5]. The hole gluing system acts like a mass-spring system. After these steps all components are integrated into the metal housing (see Figure 6).

4 Experiments and discussion

The moulding process is the main challenge of assembling a pressure sensor system for venous application. Thus a lot of different adhesives were tested concerning their shear strength to identify their flexibilities. This is important for the mechanical stress transfer to the pressure sensor during a gluing process. Furthermore the hard adhesives were tested for gas tightness. This was done with a bubble test to prove

Figure 6: View inside the metal housing of the pressure sensor system with integrated components.

that the entrapped air inside the measuring chamber cannot spill out. A gas leakage in a pressure chamber does not lead to pressure changes in fact of volume changes. That means that the sensor system could not measure any pressure changes and would be useless. Beside this could optically be detected that no bubbles were formed in the adhesives.

It turned out that the best flexible adhesive for this application is the Med2-4013 from Nusil and as the best hard adhesive for underfilling the Epotek 301 was found. With these adhesives first sensor systems were assembled.

To get first measuring curves of the sensor system the assembled components of Figure 4 were tested before mounting them into the metal housing. The results are shown in the upper graph of **Figure 7**. The maximal deviation of a control measurement is around 0.85 mmHg which is better

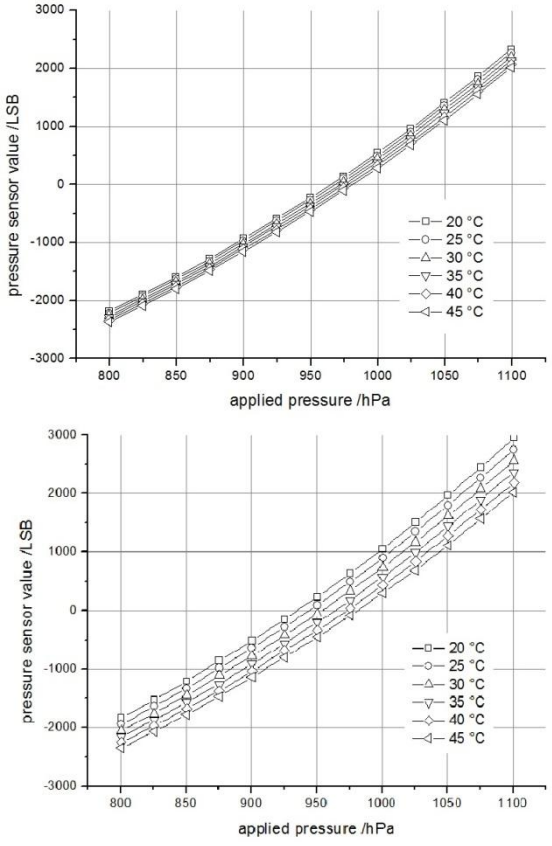

Figure 7: Measuring results of a pressure sensor system without being integrated (top) and integrated (bottom) in a metal housing

Figure 8: Final design of a welded pressure sensor system for venous application

than requested. After the mounting process of the pressure sensor in the metal housing a second measurement was done. The results can read off in the lower diagram of Figure 7.

Comparing both measurements reveals that the gluing process has only little influences on the performance of the sensor system. Indeed hysteresis of 1.5 – 2.3 mmHg can be shown and the long-term stability is not studied yet. Furthermore all previous measurements were done with open housings. Measurements with hermetically closed housings have to follow.

5 Conclusion

A simulation of the sensor system leads to a final design of two main parts: a metal housing with a diameter of 12.8 mm and a height of 4 mm and a measuring chamber which is rigidly fixed with to the metal housing and has a volume of 12.2 mm³. **Figure 8** shows the final pressure sensor system.

So a new implantable telemetric pressure sensor system for measuring the portal venous pressure and its assembly aspects has been presented. The assembly process promises to be stable and is expected to transfer as little as possible stress to the pressure sensor.

Author's Statement

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