

# Development of a throttle for an implantable infusion pump using porous ceramics

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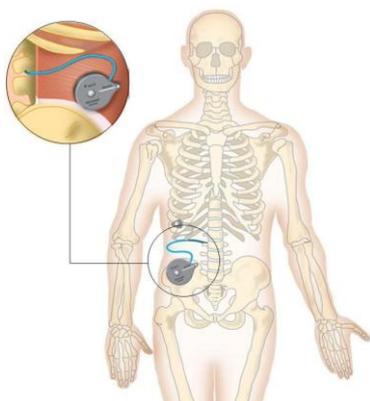
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## Abstract

Current therapy methods for the treatment of spinal pain and spasticity use gas driven, implantable pumps. This easy design offers long term durability without the need for an external energy source. Though the simple design offers benefits to the patient, its limitation to constant flow output of medicine can inhibit the patient from receiving optimal treatment as pain is variable. In consideration of treating varying levels of pain, the aim of the project is to develop a throttle within the pump that is adjustable allowing a range of medicinal dispensing

## 1 Introduction

Patients experiencing pain often suffer for extended periods of time, requiring years of therapy. Though oral and injected medication can provide relief, these methods often require numerous doctors' visits, resulting in high costs to the patient and a large time commitment on a regular basis. An implanted pump allows for more efficient treatment, as it only requires refilling 1 to 3 times a month. During surgery, the pump is implanted in the abdominal area, guiding a catheter into the spinal cord (Figure 1). Medicine stimulates the nerve, preventing the transmission of pain signals to the brain [1].



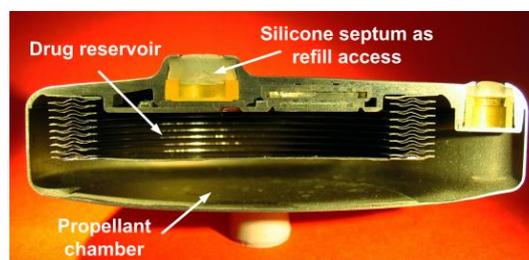
**Figure 1.** Implanted infusion pump in the abdominal area. The drug is stimulating the nerves in the spinal cord [2].

The operating mode is based on the condition of a gas and liquid mixture aggregation. The infusion pump contains two chambers that are separated by a retractable membrane (Figure 2). The bottom chamber is filled with an n-Butan-gas-liquid mixture that pushes on the membrane with a constant pressure. This sends the drug in the top chamber to the outlet over a throttle and a catheter. The constant pressure causes constant flow, while currently a micro capillary chip serves as a flow restrictor. The goal of this project is to use porous ceramics as a replacement for the mi-

cro chip in order to have adjustable flow. The desired flow range is between 70 nl/min to 4000 nl/min [3].

## 2 Materials

Porous ceramics are usually used as a separation method (filters), process technique (catalysers), and sound and heat insulators. This project uses two different materials,  $\text{Al}_2\text{O}_3$  and  $\text{ZrO}_2$ , to create two types of flow resistant throttles in the pump.



**Figure 2.** Cross view of an infusion pump. N-Butan gas-liquid mixture in the bottom chamber is pressing onto the drug reservoir, which is sending the drug to the outlet [3].

### 2.1 Throttle concept $\text{Al}_2\text{O}_3$ tube

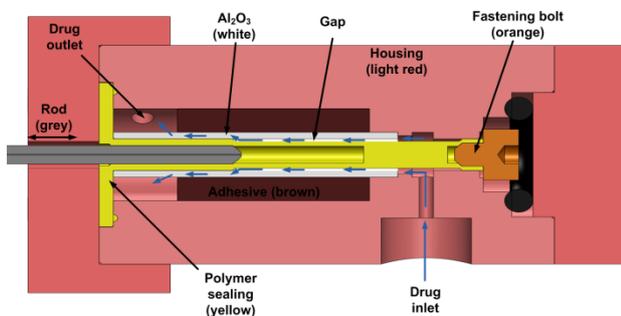
The  $\text{Al}_2\text{O}_3$  ceramic is manufactured by Fraunhofer Institute for Ceramic Technologies and Systems, Dresden, into a tube with a diameter of approximately 4 mm, a thickness of 0.5 mm, and length of 20 mm. As shown in Table 1, this ceramic was produced with a variety of pore sizes, and some with infiltration to increase flow resistivity. The variety of pore sizes and infiltrations allow a selection of different flow ranges. Compared to other ceramics, Tube #2 has a fine pored layer on the inner surface with 200 nm-pore size and a thickness of 30  $\mu\text{m}$ .

The  $\text{Al}_2\text{O}_3$  ceramic tube is bonded into housing by Loctite Sealant 5248, which has a viscosity of 65 000 mPa s.

**Table 1.** List of Al<sub>2</sub>O<sub>3</sub> tubes with information about the pore size and infiltration

#	Pore diameter tube	Particle size infiltration	Porous layer on inner surface
1	0.80 μm	3 nm	-
2	0.80 μm	3 nm	200nm
3	0.41 μm	3 nm	-
4	0.21 μm	3 nm	-
5	0.11 μm	3 nm	-
6	0.80 μm	-	-
7	0.41 μm	-	-
8	0.21 μm	-	-
9	0.11 μm	-	-

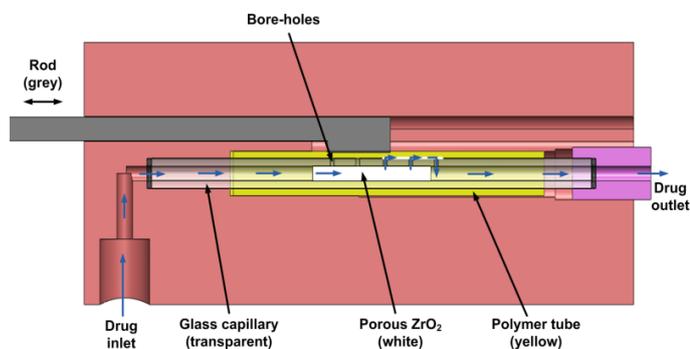
Normal fluid flow travels through the gap shown in Figure 3. By pushing an elastic polymer-sealing rod into the tube, the gap is closed and the fluid flow goes through the pores of the ceramic with a higher resistivity.

**Figure 3.** Construction of a throttle with Al<sub>2</sub>O<sub>3</sub> ceramic

## 2.2 Throttle concept ZrO<sub>2</sub> cylinder

In contrast to the Al<sub>2</sub>O<sub>3</sub> ceramic, the ZrO<sub>2</sub> ceramic is housed in a glass capillary, by heat shrinking. The ceramic has a diameter of 1.1 mm and the glass an outer diameter of 2.3 mm. The average pore diameter is 0.2 μm. This ceramic offers the advantage of a simpler design with the glass housing.

In this design, the ceramic cylinder was drilled with an excimer-laser (Figure 4). These 4 bore holes, with a diameter of 0.35 mm, allow flow variation by means of option flow outlets for the medicine.

**Figure 4.** Construction of a throttle with ZrO<sub>2</sub> ceramic

An elastic polymer tube is covering the glass. A rod is used to adjust the flow by pressing the polymer tube on the bore-holes and closing them step-by-step. The flow depends on the number of open bore-holes.

## 3 Methods

### 3.1 Permeabilities

To determine the flow properties of each material and type of ceramic, it is necessary to determine permeability values. The permeability is described in the Darcy's law [4]

$$\kappa = \frac{u \cdot \eta \cdot \Delta x}{\Delta p}$$

where  $u$  is the flow velocity,  $\eta$  the dynamic viscosity,  $\Delta x$  the path length through the material, and  $\Delta p$  is the pressure difference.

### 3.2 Demanded force for the rod

For the patient to adjust the flow of the pump by remote, the pump requires an energy source. To minimize this energy input, the friction between the rod and the ceramic must also be minimized. To reduce friction of the rod between the rod and the ceramic, three lubricants were used during force measurements: C-graphite powder, silicone fluid lubricant (MED400, Nusil) and long-term grease. In the tests, a combination of all these lubricants offers the best solution.

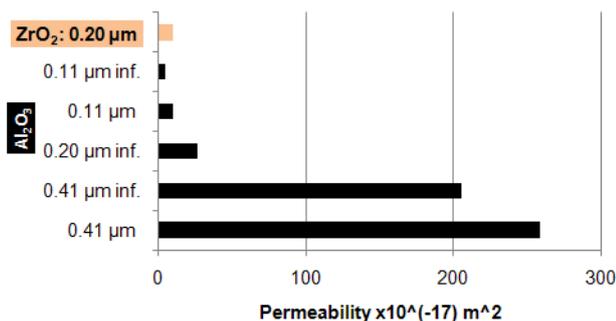
### 3.3 Flow Simulation with GeoDict

The permeability results from the experiments were used with the simulation software "GeoDict" to predict the flow. "GeoDict" is a special software for porous media and composite material. With this software different throttle structures can be generated and physical laws like the Darcy's equations can be used. In this project the flow through ceramics with different pore-size, the flow with different rod position, the influence of the gap width, facing surface and the geometry of the inlet and outlet can be determined for the Al<sub>2</sub>O<sub>3</sub> tube. Flow with different bore size and bore-hole and rod positions and the influence of the gap and geometry of the inlet and outlet for the ZrO<sub>2</sub> ceramic can be predicted.

## 4 Results

### 4.1 Permeability results

In Figure 5, the graph shows the permeability for each Al<sub>2</sub>O<sub>3</sub> tube and ZrO<sub>2</sub> cylinder. The permeability of the infiltrated tube with 0.11 μm pore size is 3% of the value for the (none-infiltrated) tube with 0.41 μm. The infiltration of the Al<sub>2</sub>O<sub>3</sub> tubes with 3 nm particles has a significant impact on the flow (between 25% and 50%). The ZrO<sub>2</sub> cylinder has 36% of the permeability value for the Al<sub>2</sub>O<sub>3</sub> with the same pore diameter (0.20 μm, infiltrated).

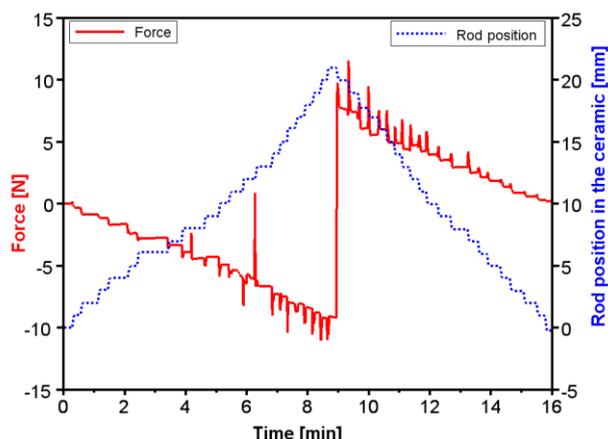


**Figure 5** Permeabilities of Al<sub>2</sub>O<sub>3</sub> tubes and ZrO<sub>2</sub> cylinder. The values vary between 5.54e-17 m<sup>2</sup> and 2.58e-15 m<sup>2</sup>.

### 4.1 Force results

During the test, the rod was inserted into the cylinder in 1 mm intervals, pausing for several seconds in between each push to allow the polymer tube to relax.

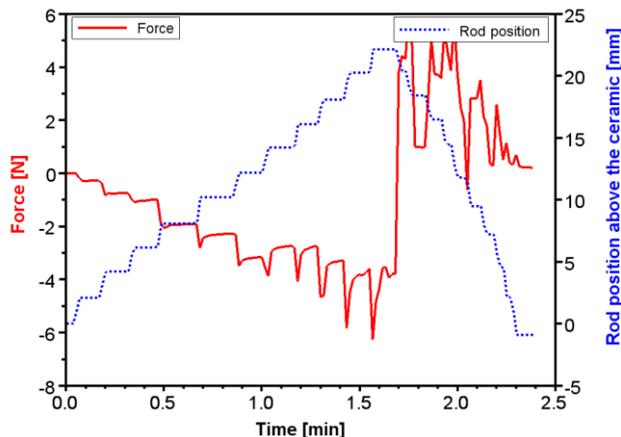
In the throttle variant with Al<sub>2</sub>O<sub>3</sub>, the maximal needed force is around 10 N at a rod position of 20 mm in the ceramic (Figure 6).



**Figure 6.** Force (red) in dependence of the rod position inside the Al<sub>2</sub>O<sub>3</sub> tube (blue) and time

In the second method, a force of 6 N is mandatory with the same speed of the rod (Figure 7). Based on the tests, the long-term grease showed a better affect on reducing the friction, in comparison to the other lubricants.

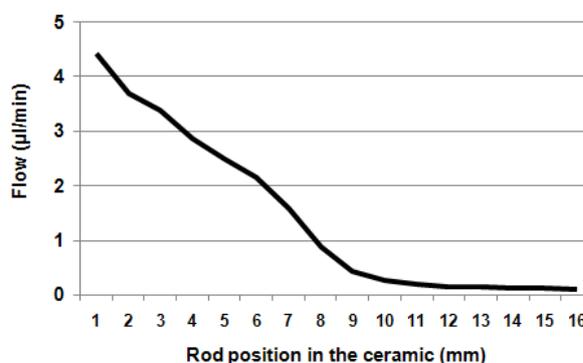
Peaks in the graph are resultant of uneven movement of the rod in the ceramic tube. A much lower maximal force was achieved by reducing the jerky movements or smaller steps from 1 mm to 0.1 mm. This will be done machine-aided with the pulsation-free, high-precise device “Nemesys” (company Cetoni GmbH, Korbußen).



**Figure 7.** Force (red) in dependence of rod position above the ZrO<sub>2</sub>-cylinder (blue) and time

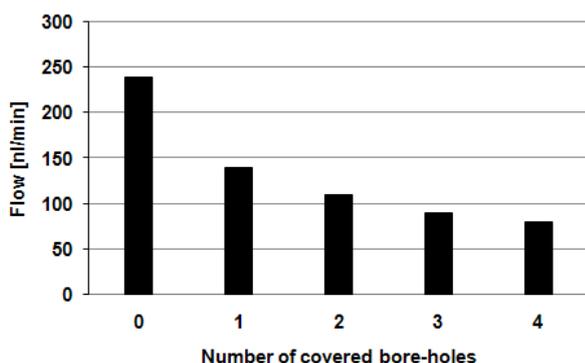
### 4.2 Flow results

Depending on the depth of the rod, Figure 8 shows that the fluid flows between 0.15 μl/min and 4 μl/min in the Al<sub>2</sub>O<sub>3</sub>-tube #2 (infiltrated with 0.8 mm pore size). This ranges falls within the desired range previously mentioned. When adhering the ceramic tube to the metal housing, a “free spot” of 2 mm is left, allowing the fluid flow to in the radial direction of the tube. Pushing the sealant rod deeper than these 2 mm increases the fluid path length, as a result showing a steeper decrease in flow in the initial insertion of the rod into the tube.



**Figure 8** Flow through the Al<sub>2</sub>O<sub>3</sub> tube #2 as a function of the rod position

During flow tests, the ZrO<sub>2</sub> cylinder achieves a stepwise flow range between 80 nl/min and 240 nl/min (Figure 9). By closing the first bore-hole, the flow decreased about 40% (from 240 nl/min to 140 nl/min). By closing the fourth bore-hole, the flow decreased approximately 10% (from 90 nl/min to 80 nl/min). This is noticeably less than the first bore hole covering. With this, changing the position of the first bore hole will adjust the fluid flow closer to the desired 4000 nl/min.



**Figure 9** Flow through the  $ZrO_2$  cylinder as a function of covered bore-holes

## 5 Conclusion

This project aimed to develop two different throttle types that allow adjustable flow in infusion pumps, to better treat pain in patients. The throttles used  $Al_2O_3$  tube or  $ZrO_2$  cylinder. Primarily, the permeability was determined for flow simulation in “GeoDict”, a special software for porous media. In this experiment, the measured flow range of the  $Al_2O_3$  tube falls in the desired range. However, the maximal flow of the  $ZrO_2$  cylinder must be increased and can be done so by moving the position of the first bore-hole closer to the entry face.

Future work for this project will involve completing flow simulations of all the  $Al_2O_3$  types, with different rod position and simulating the flow of the  $ZrO_2$  throttle with different positions of bore-holes and different diameters. After measuring the flow of through these materials in an experimental set up, the results from the experiment will be compared to measurements taken in the flow simulations.

## 5 Acknowledgement

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