DESIGN OF AN IMPLANTABLE MICROPUMP

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ABSTRACT
The implantable programmable micropump is an interesting solution to treat chronic diseases such as diabetes with regular micro-injections of medicine. However, current applications of micropumps are limited by their rather expensive cost. The challenge is therefore to develop a low cost alternative by reducing the number of parts and by simplifying the assembly. As the pump and its tank will be placed under the skin in order to increase comfort, such a system should be small and reliable. In this paper, we present the micropump we developed within the framework of the 4M-µ pump interuniversity project (*Methods and Means for the Miniaturization of Machines*).

INTRODUCTION
The explosion of new technologies and particularly recent innovations in the micro-mechanical and medical areas open up new paths and opportunities to relieve patients' illnesses. Recent studies have shown that there is a steadily growing market for Microsystems, and in particular for drug delivery systems. According to [5] the drug delivery market is estimated at US $20 billion and is segmented into four categories: oral (53%), inhalation (27%), transdermal (10%) and implanted (8%). The implanted market is growing rapidly. Recently Richard Park [6] reported that the FDA had granted marketing clearance to the first device for diabetics that integrated an insulin Medtronic pump and a Becton dose calculator. These systems constitute a new step in diabetes management which automatically measures the blood sugar concentration then transmits the insulin dosing to the pump. Implanted micro pumps can also be used for the control of refractory cancer pain [7]. An implanted pump permits to reduce the dose and thus to minimize toxicity and "opium" side-effects. However a study performed by ALCIMED [8] clearly showed the lack of medical implanted programmable pump devices that can be used for specific cancer pain treatment. The only programmable pump available on the market is the SynchroMed® from Medtronic based on US patent 6485464 and following. Other uncertainties upon the use of micro-pumps are lack in medical knowledge in pump implantation and maintenance implanted pump.
In the design of the new implanted pump presented in this paper, we try to focus on the cost and in particular on the assembly cost by reducing the number of parts.

PUMP SPECIFICATIONS
The implanted pump should have a streamlined, flat, small and lightweight shape. A flat ellipsoid for example, affords minimal constraints and maximal comfort to the patient. Adaptable medication flow with flow rates around 0.3 ml per hour and injection unit around 0.2µl covers the demands of the patient and the medical profession. A three-day to three month period between two refilling processes affords sufficient mobility to the patient while

three years is the minimum battery life time. Sterilizable biomaterials compatible with body temperature (between 37°C and 42°C), EN-10993 class VI norm [10] and medication are chosen. A negative pressure reservoir and watertightness of the active pump guarantee the safety of the device.

CONCEPTUAL DESIGN

In a micro-system, many functions need to be fundamentally reconsidered. Scale laws make some physical principles useless for microsystems, while other principles, although without interest in macrosystems, may be extremely useful for miniaturized systems. Pump functions have thus to be carefully analysed during the conceptual design. This analysis is reported in [2]. For example, the hinge function requires particular attention:

- classical bearings such as ball bearings, sliding bearings and other pivots may be difficult to realize at the micro scale. As it is very difficult to manufacture small parts with good tolerances, the guiding precision may be insufficient for a particular application.
- Assembly of small components may become very difficult, there is therefore a need for a device composed of a minimal number of components
- In micromachines, friction may become very important compared to other forces and torques.
- In some applications, e.g. in medical devices, cleanliness exigencies practically prohibit the use of greasy lubricants.

Consequently, we chose a notch hinge described and analysed in [1].

DESIGN

The micropump schematic view is illustrated on Figure 1. The rotating piston is actuated by an electromagnet. A circular notch hinge is used as piston bearing and guiding system. Two globe valves (one inside the piston and one inside the casing) are used to control fluid displacement during piston rotation. It is important to mention that the piston and electromagnet core are made of magnetic stainless steel whereas the casing is made of titanium alloy (EN-TiAl6V4).

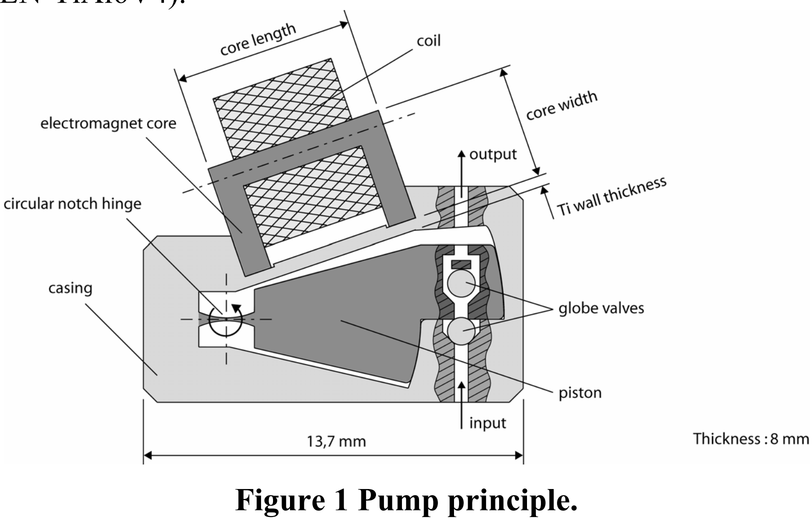


Figure 1 Pump principle.

The micro-pump working principle is illustrated on Figure 2. At the rest position (Figure 2.a.), the piston pushes the input valve ball onto its seat thereby ensuring input valve tightness. This piston thrust is due to the elastic return force of the circular notch. The electromagnet is then powered on to trigger piston rotation (Figure 2.b.). The piston valve ball is pressed onto its seat and a depression occurs in admission chamber. This depression causes the input valve ball to leave its seat and fluid to fill the admission chamber through the input channel. At the other side of the piston, fluid is constrained to leave the ejection chamber through the output channel. This pumping phase ends when the piston reaches its extreme position (Figure 2.c.). The electromagnet is then powered off and, thanks to the elastic return force of the circular notch hinge, the piston returns to its rest position (Figure 2.d.). The overpressure which occurs in the admission chamber causes the input valve ball to be pressed onto its seat. Fluid is transferred from the admission chamber to the ejection chamber through the piston valve. The piston valve ball is no longer maintained on its seat and fluid is free to flow through the piston valve. This pumping phase continues until the piston reaches its rest position (Figure 2.a.). The full pumping cycle is then ready to start over again.

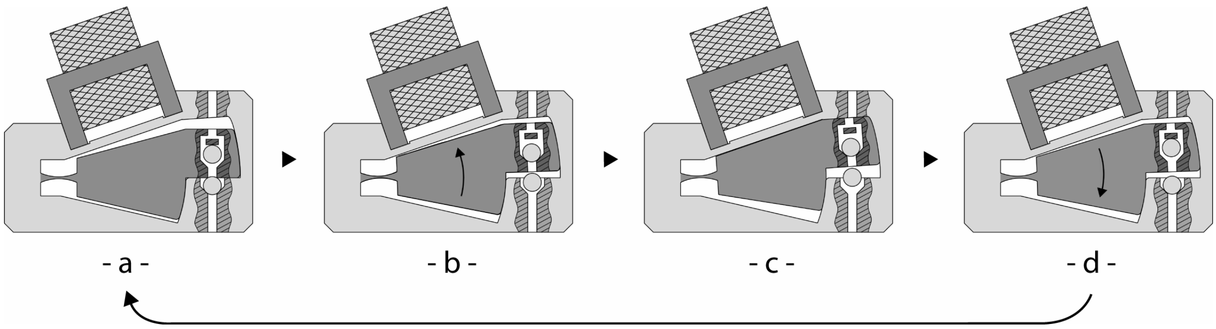


Figure 2. Pump principle

CONSTITUTIVE PARTS

Circular notch hinge

Titanium alloy (TiAl6V4) hinges with thicknesses between 66 and 175 µm were manufactured using Wire Electro-Discharge Machining (WEDM) [9]. The part to be manufactured is placed in a dielectric solution and a voltage difference between the conductive part and the wire produces an electrical arc forming smelts and vaporizing the material locally.

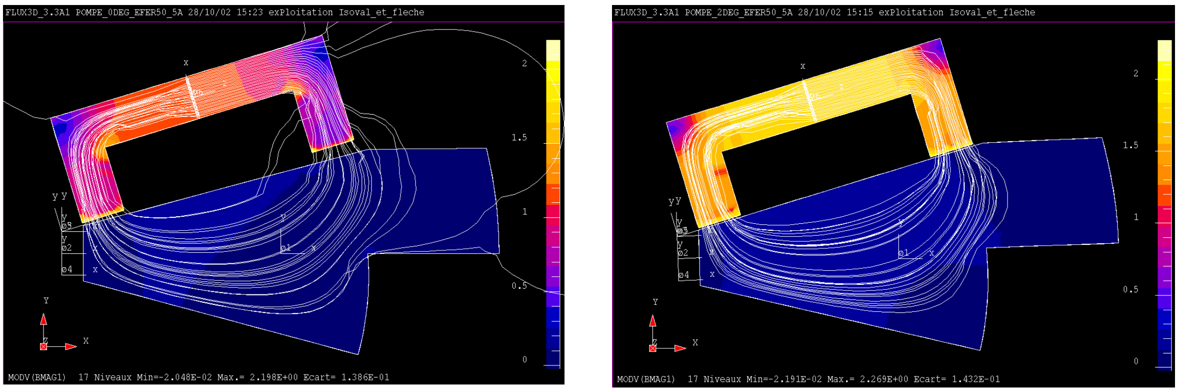
The first step was to determine the geometry of the hinge (mainly the diameter and the thickness) to achieve a good agreement between two exigencies: the hinge has to be sufficiently stiff to produce an elastic return to its original rest position, but not too stiff because it will be actuated via an electro magnet. It has also to use as little energy as possible (the battery has a fixed autonomy). The calculation procedure is described in [3] and [1]. There is also an additional constraint: the technical limitation fixed by the manufacturing process and by the machine in use [9].

Electromagnet

The piston alternating angular displacement is 2 degrees wide and the maximum working frequency is only 1 Hz which is enough to meet medical requirements regarding the flow rate. The main difficulty was to design a micro-actuator able to develop a torque of 2 mNm which is very high for such small systems. This is the torque required to deform the circular notch hinge with maximum deflection and to overcome the pressure. Magnetic actuation seemed therefore to be the most suitable for our micropump [4]. Indeed, it yields a higher force than most other-type actuation principles such as, for instance, electrostatical actuation. In addition, although piezoelectric actuation also develops high forces, magnetic actuation does not require high driving voltages which are unacceptable in implantable systems. Several types of electromagnetic micromotors were described in [4]. This study shows that the torque developed by permanent magnet micromotors is more than one order of magnitude higher than that developed by the other types of usual magnetic micromotors. However, contrary to variable reluctance or induction micromotors, their miniaturization remains limited for technical reasons explained in [4]. Indeed the permanent magnet micromotors examined are nearly all above the 100 mm^3 range.

In spite of the high force developed by permanent magnet motors, the electromagnet was finally preferred to the latter for the following reasons : its very simple structure makes it convenient to miniaturize and the produced force can be easily calculated with some accuracy. In addition, the force developed by the electromagnet can be very high using a small airgap between moving and non-moving parts. In this micropump, the airgap can be limited to very small values as it is related to the piston angular displacement which is only two degrees wide. Finally, the brushless permanent magnet micromotor is more suitable for applications requiring continuous rotation which is not the case here.

Finite element simulations were performed in order to optimise the force developed by the electromagnet and its size. These were done using the finite element software Flux3D® from Cedrat Corporation. The system model (with flux lines and magnetic induction) is illustrated on Figure 3 (non-magnetic elements are not represented as they have no influence on the magnetic flux).



- a - piston position : 0° (airgap maximum)

- b - piston position : 2° (airgap minimum)

Figure 3. FE simulation

Figure 4 shows a comparison between FE simulation and a simple analytical model for the following parameters: core length: 4.5 mm, core width: 1.0 mm, core thickness: 3.5mm, titanium wall thickness: 0.05mm, current: 335 mA and coil windings number: 400. The torque developed by the electromagnet can expressed as :

$$Torque = \frac{\mu_0 A n^2 I^2}{2} \frac{da(\theta)}{a(\theta)\, d\theta}$$

where :

- μ_0 is the airgap permeability
- A is the surface of the airgap section
- n is the number of coil windings
- I is the coil current
- θ is the piston angular displacement
- $a(\theta)$ is the airgap length

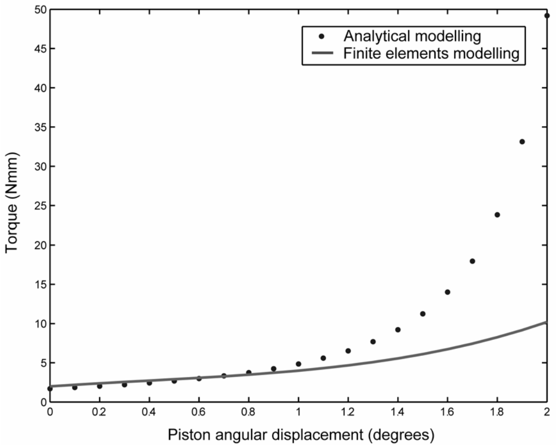


Figure 4. Comparison between FE simulation and analytical model

This shows that analytical and finite element model agree for low piston angular displacement. Differences between the two models for high θ values are due to magnetic saturation which is not taken into account in the analytical model.
It plainly appears that finite element models are necessary to accurately foresee the electromagnet behaviour.

CONCLUSIONS

Figure 5 presents the pump prototype without tank and battery. Materials should satisfy class VI certification from the 10993 European norm which cover medical devices. The choice was made to use a well known titanium alloy (EN-TiAl6V4) for all non magnetic parts and EN-X20Cr17 stainless steel for the magnetic parts. The valve balls are made from ruby so as to obtain the most perfect possible surface state, and thereby ensure an optimal watertightness. The titanium casing was milled using a classical 5 axis milling machine. The notch hinge guiding system, piston and electromagnet core were manufactured using Wire Electrical Discharge Machining (WEDM). Among all the parts, the notch hinge was the most difficult to manufacture because of the hinge dimensions and tolerances.
The main disadvantage of this pump is the peripheral leakage which still remains between the moving part and the housing. Nevertheless, the pump is compact, does not require lubrication nor release particles, provides a precise guiding and is composed of a small number of parts. Reduction of part number is very important because it simplify assembly process and increase system security.

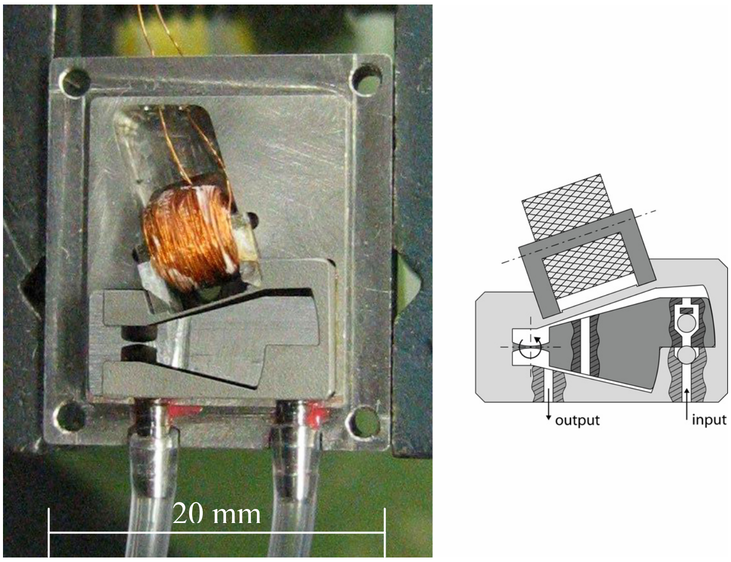


Figure 5. Prototype

ACKNOWLEDGEMENTS

This work was sponsored by the Région Wallonne in the frame of the 4M-µpump project and the Belgian Program on Interuniversity Attraction Poles initiated by the Belgian State – Prime Minister's Office – Science Policy Program (IUAP-24).

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