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Novel approaches to particle tolerant valves for use in drug delivery systems

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Abstract

Wherever microvalves find application, they face a major problem of particle tolerance. Various approaches to overcome the influence of particles on the behavior of microvalves are known, be it special designs of sealing rims or filtering techniques. In the case of drug delivery systems, accumulation of particles directly affects their reliability, especially when considering long-term applications.

Based on our multiple experience in developing microvalves, we report a new approach of integrating a flow restrictor and a control valve in a single device by covering a rigid microchannel with an elastomer membrane. Controlling the pressure onto an elastic membrane, the cross-section of a capillary and thus the flow through a capillary in an experimental setup was reproducibly controlled. This novel concept for a variable flow controller, typically controlling nominal flowrates between 0.1 and 100 ml per day, is aimed to be operated as multistable, particle tolerant system. The capillary device without actuation unit in the presented proof of principle measures 6 mm × 6 mm × 2.5 mm.

Keywords: Particles; Microvalve; Microdosage; Drug delivery

1. Introduction

Drug delivery systems locally deliver minute amounts of drugs. Established implantable systems most often consist of a constant pressure reservoir, a fluidic capillary as fluidic resistance and a connected catheter to deliver the drug to the place where it has to be administered. The basic idea behind this method is that applying a controlled pressure across a defined fluidic resistance results in a defined flow rate.

These systems are not flexible because when implanted, the flow rate of the drug is fixed. The only possibility to adjust the dosage rate of the delivered drug to the present needs of the patient is to change the concentration, i.e., the dilution of the drug in the reservoir.

To allow the treatment of a wider range of diseases, these systems need to become more flexible and more accurate.

In former publications [1,2], we reported on the development of microvalves that can be located in series with a chosen capillary flow resistance. Such valves allow the responsible physician to actively adjust drug flow rates to the patient's condition telemetrically after implantation at high precision (Fig. 1). Future therapies will require the control of flow rates down to 1.5 μl/day (0.7–3.5 nl/min), which is in the range of the intended leakage rates of current valves. Therefore these valves will not be applicable.

Due to the omnipresent problem of trapping particles, leakage rates significantly vary. In experiments with membrane microvalves, as shown in Fig. 1, the use of upstream filters of 0.2 μm pore size did not reduce the problem since particles tend to accumulate at regions where changes in the fluidic cross-section occur. Such regions might be the interconnections of different layers or components,

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or geometrical steps resulting from individual fabrication processes.

We present a completely new approach to meet the latest requirements of drug flow control. Providing a fluidic capillary resistance with an integrated valve function. The system increases the level of integration while simultaneously decreasing the system complexity.

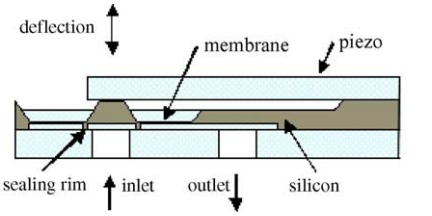
Systems that change the shape of capillaries to control flowrates have already been reported. Cousseau et al. change the length of a capillary in order to balance the influence of variations in pressure difference on the flow through the capillary [4]. Unger et al. locally change cross-sections of a flexible capillary in a binary manner to enable opening and shut down of a flow through fluidic channels [5,6]. Valve approaches to control flow rates that are reported in literature (Nguyen et al. give an overview [7]) require a permanent energy consumption to maintain an individual flow rate. In the approach presented in this paper, the main advantages are to be seen in the targeted optimization of the energy consumption by actuating the capillary valve at multiple stable states using a novel commercial actuator by Elliptec Resonant Actuator AG. In this case, energy will only be required to change the desired fluidic resistance, but not to maintain an adjusted flow rate.

Furthermore the influence of trapped particles on the flow rates differs fundamentally as compared to the one observed with conventional membrane-valves. Trapped particles will not increase the leakage rate, but reduce it. This basic system behavior makes such valves predestined for medical applications with high safety demands.

To demonstrate the system behavior we compare a typical silicon membrane valve, as previously developed at our facility, with the novel approach of the variable capillary flow resistance.

1.1. Description of the bulk micromachined silicon membrane valve

As shown in Fig. 1, a piezo bender actuator is mounted on top of a silicon chip with a defined pre-stress to seal the valve against a constantly present inlet pressure. To open the valve, the piezo has to be deflected upwards to release the membrane. The pressure difference between inlet and outlet then deflects the membrane upwards and allows a flow across the valve.



Type of valve	Membrane normally closed, piezo actuated
Material	Silicon, glass
Size of membrane	4 x 4 mm^2
Thickness of membrane	27 μm
Height of sealing rim	100 μm
Height of fluid channel	30 μm

Fig. 1. Silicon membrane valve [1].

The component most critical to particles in the case of membrane valves is the sealing rim under the membrane. Here, particles tend to be trapped and accumulated. In case of the silicon membrane valve that is presented here, the membrane measures 4 mm by 4 mm in size and 27 μm in thickness. A square sealing rim of 1 mm by 1mm and 100 μm width is pressed onto the valve seat by the piezo bender actuator in order to close the fluid channel between inlet and outlet (Fig. 1). The target flow through the open valve of 3.6 ml/day, at 2.5 bar differential pressure between the inlet and the outlet of the system, is obtained at a membrane deflection of approximately 1.1 μm. The specified acceptable leakage rate measures 0.025 ml/day. During temporary occlusions at or behind the outlet port (i.e., occlusion of a catheter which presents the system outlet of the complete medical dosage system), the deflection of the valve membrane can rise up to 30 μm due to the provided inlet pressure of 2.5 bar.

Valves of this kind ideally possess only two switching states: open or closed. To achieve individual analog adjustable flow rates, the presented valve is pulse-width modulated. When driving valves in this manner, energy is permanently consumed.

1.2. Description of the new variable capillary flow resistance

In the novel approach a micromachined silicon capillary is covered by an elastic material (Fig. 2) [8]. By forcing the elastic cover into the channel across its complete length, the effective channel cross-section decreases in turn increasing

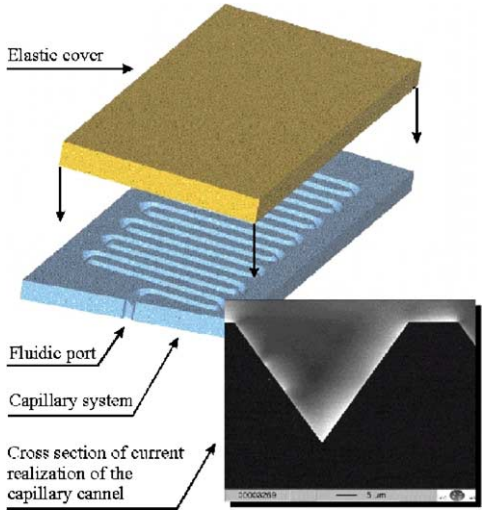


Fig. 2. Capillary valve: schematic sketch. An elastic cover is pressed into capillary channels to increase their flow resistance.

the flow resistance of the capillary. Thus the flow rate through the capillary is manipulated.

In the current realization, channels, anisotropically etched in ⟨1 0 0⟩-silicon, are covered with the elastomer Da/Pro 8602-C-40. The chosen triangular cross-section exhibits a favorable correlation between deformation of the elastic membrane into the capillaries and the resulting flow rate. In order to optimize the shape of the cross-section and to minimize the stress in the deformed material, computational models are applied. To achieve the desired flow rate, corresponding to the compared system with the silicon membrane valve (Fig. 1), the capillary for the variable capillary flow resistance has to measure 70 mm in length, 41.5 μm in upper width and 29 μm in capillary depth (Fig. 2). The resulting outer dimensions of the evaluated chip are 6 mm × 6 mm × 2.5 mm, excluding the actuation unit. In the present work, the capillary is actuated in a laboratory setup by pneumatic means. The development of an appropriate self-locking actuation unit is matter of current activities and will be presented in the future.

Assuming stationary and fully developed laminar flow, the fluidic resistance R of the channel can be described according to Eq. (1) (derived from [9]):

$$R = c\frac{\eta L(h^* + b^*)^2}{h^{*3}\, b^{*3}} = \frac{\Delta p}{q} \tag{1}$$

Here, η is the dynamic viscosity, L the channel length, b^* a characteristic width, h^* a characteristic height, c a constant which is only dependent on the cross-sectional shape of the channel, Δp the differential pressure across the device and q the resulting flowrate.

When pressing the elastic material into the capillary structure, according to Eq. 1, low deflections, e.g., small changes in the channel height, are sufficient to achieve high changes in fluidic resistance R (Fig. 3).

To avoid material creep of the polymer, it has to be assured, that no sliding and cracking of molecule chains occurs. Therefore, it's geometry and clamping is currently being optimized in order to achieve maximum changes in fluidic resistance while minimizing the internal stress in the elastic material.

2. Theoretical evaluation of the influence of particles

In the following we investigate the theoretical influence of particles on the fluidic characteristics of the conventional membrane valves and the new approach of the variable capillary flow resistance to demonstrate the system advantage of the capillary approach.

2.1. Bulk micromachined silicon membrane valve

The flow q through the membrane valve is determined by the flow resistance across the whole device. This total flow resistance R_{sum} is the sum of the flow resistances of individual sections of the valve. This is the flow resistance of the inlet port R_{in}, the outlet port R_{out}, the sealing region R_{seal}, the fluidic channel across the valve device $R_{channel}$ and the flow resistances of the individual geometrical interconnections between these regions $R_{connect}$ as given by Eq. (2):

$$R_{sum} = R_{in} + R_{out} + R_{seal} + R_{channel} + R_{connect} = \frac{\Delta p}{q} \tag{2}$$

The resulting flow q through the membrane valve when applying a pressure drop Δp of 2.5 bar across the valve is presented in Fig. 4.

For gap heights below 0.6 μm, the corresponding flow resistance R_{seal} is the main flow limiting parameter. When further increasing the gap height, the flow increases until it is limited by the sum of the remaining flow resistances to the specified flow.

In membrane valve approaches, particles can present an obstruction, blocking the direct contact between the sealing rim and the valve seat. The resulting gap between sealing rim and seat is the cause that the valve cannot get back in its original closed state, thus causing leakage. As a detail, Figs. 4 and 5 present the expected leakage flow.

As shown, particles and accumulation of particles have a great impact on the fluidic closing behavior of this type of valve. Already for particles measuring <0.09 μm in diameter, they prevent proper closing of the membrane and cause the valve to exceed the specified level of acceptable leakage.

The specified acceptable tolerance of flow rate for the membrane valve is 0.7% of the nominal flow of the above

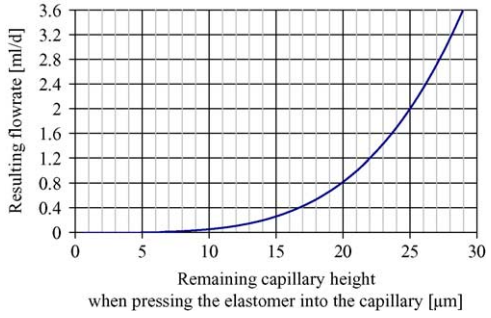


Fig. 3. Theoretical flow rate when decreasing the cross-section of the fluidic capillary by reducing its capillary height.

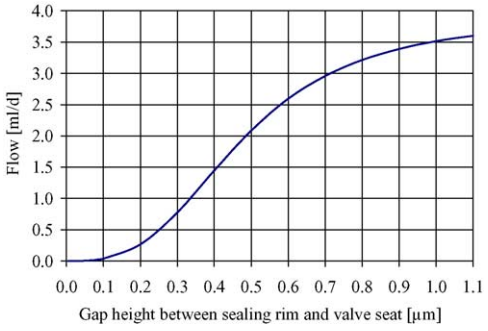


Fig. 4. Silicon membrane valve: theoretical expected flow rate vs. membrane deflection, i.e., gap height between sealing rim and valve seat.

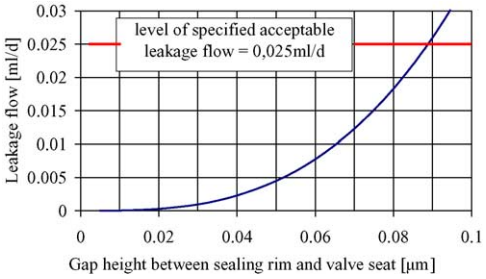


Fig. 5. Silicon membrane valve: theoretical expected leakage rate versus gap height due to trapped particles under the membrane.

mentioned application of 3.6 ml/day. This would correspond to a trapped particle under the sealing rim of only 0.09 μm in diameter. Especially in case of medical application this failure mode is problematic since the dispensed drug flow rate is expected to increase over time as particles accumulate.

2.2. New approach of variable capillary flow resistance

For the new variable capillary flow resistance, the tolerance in flow rate of 0.7% of the nominal flow (comparing the specifications of the silicon membrane valve) is expected for accumulation of particles measuring up to 16 μm in height (Fig. 6). According to visual observations of particles in the channels, the length of accumulations of particles was assumed to measure 100 times their height. Due to these local strictures, the total resistance of the capillary can be interpreted as a serial connection of different resistances. For short strictures, the influence of the sections with increased resistance on the total resistance is limited. The change of flow resulting from these accumulations is insignificant until the particles nearly block the channel to its complete height of 29 μm. This advantageous effect results from the typical local blockage of the channel covering only a low percentage of its entire length, thereby causing only a low percentage increase in flow resistance.

Filtering of particles of this size is easily possible. Even if particles occur in the system, they are expected to be transported through the device due to the high pressure gradient and the laminar flow regime in the channel. Furthermore the effect of particles on the flow behavior is basically different:

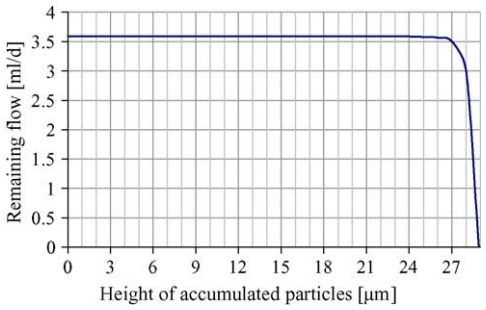


Fig. 6. Theoretical influence of trapped particles onto the flow through the capillary valve, assuming a fully opened valve.

potential particles do not increase but decrease the flow. This fail-safe principle makes the system favorable for medical applications where excess dosage may be lethal.

In the current proof of principle, the turns of the capillaries are related to the manufacturing process and exhibit 90° turns. In ongoing works, the capillaries are projected to be realized in polymers with round shaped turns to avoid disturbances in the laminar flow regime.

3. Measurements

In order to validate the theoretical expectations, both types of valves were evaluated experimentally. In this report, we compare the effect of particles on the flow behavior of the two different valve approaches.

3.1. Bulk micromachined silicon membrane valve

Fluidic measurements with deionised and 0.2 μm filtered water were performed with 20 membrane valves of the type illustrated in Fig. 1.

In a measurement setup, a pressure gradient of 2.5 bar between the inlet port and the outlet port of the valve was applied. The resulting flow due to the deflection of the membrane in the open state was measured. For 2 days, the applied pressure gradient was increased and decreased subsequently. With proceeding time, particles are trapped around the sealing rim of the membrane causing increased leakage rate in the nominally closed state (Fig. 7a and b). It can clearly be seen that there is a strong sensitivity to trapped particles,

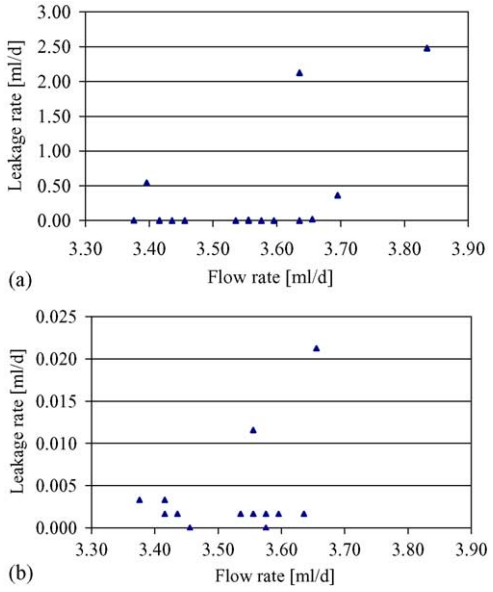


Fig. 7. (a) In a 2 days experiment, particles accumulated around the sealing rim of membrane valves (compare Fig. 1). Leakage rate in the closed state of 20 membrane valves is plotted versus their flow rate in the open state. (b) Detail of (a) leakage rate vs. flow rate of 16 of 20 membrane valves within the specified acceptable leakage rate of 0.025 ml/day.

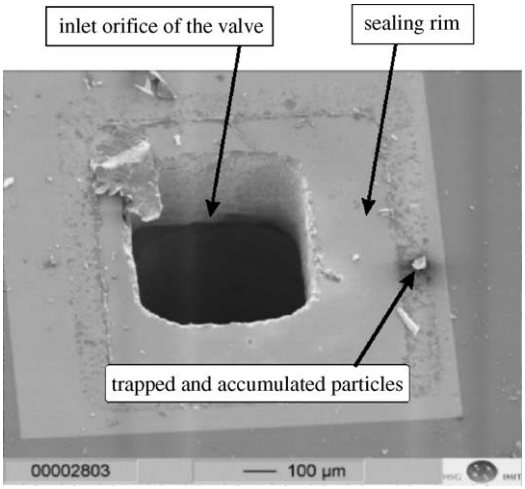


Fig. 8. Silicon membrane-valve: trapped particles on the sealing surface. Note the scale, only particles of 0.09 μm were tolerable.

causing increased leakage rate, a well-known problem for micromembrane-valves [1,7]. Here, 4 out of 20 membrane valves showed leakage rates that increased above the specified acceptable level of 0.025 ml/day.

Fig. 8 shows the inlet orifice of a tested silicon membrane valve after removing the membrane. The former location of the sealing rim as well as trapped and accumulated particles are clearly visible.

As mentioned before, leakage rates of several 10 μl per day do not allow the targeted therapies. Implementing a soft/hard sealing which is more tolerant to particles than the hard/hard sealing addresses this problem. With a soft sealing, trapped particles can be enclosed and do not result in a gap between the membrane and the sealing surface in the size of the particles. This was already proven by realizing an elastomer valve [1,3]. However, the leakage rates of these valves could also not be reduced sufficiently.

3.2. New approach of a variable capillary flow resistance

As pressure is applied on the elastomer cover, e.g., by pneumatic means, as done in the shown experiments, it is pressed into the channel and reduces its cross-section. In the experimental setup, a sealing between the elastomer cover and the silicon channel-structure as well as a sealing of the fluidical interconnections of the valve to its environment was achieved by an initial load onto the setup. In future work this will be achieved using bonding techniques.

A constant fluidic pressure across the setup induces a flow through the individual capillaries that can be controlled by the applied pneumatic pressure on the elastomer as described above. For these measurements, neither deionised nor filtered water was used to show that the device is insensitive to particles in the fluid. Future measurements will be performed using testing liquids containing particles of defined sizes.

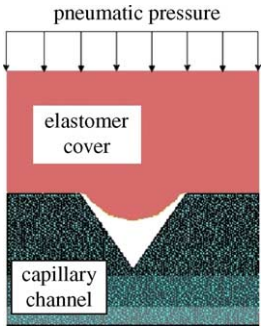


Fig. 9. Illustration of the principle of operation of the current realization of the variable flow resistance in the measurement setup.

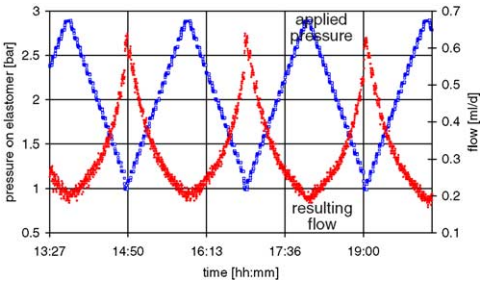


Fig. 10. In a long-term test, the flow rate was manipulated repeatedly by applying a triangular pressure signal on the elastomer.

To characterize the dynamic behavior, in particular to detect potential plastic deformation, an increasing and decreasing pneumatic pressure signal was applied onto the elastomer (see Fig. 9). The pressure drop across the device was measured with a Motorola MPX5500 differential pressure sensor, the resulting flow through the device with a flow sensor, developed by HSG-IMIT [10,11]. The cross-section, i.e., the fluidic resistance of the capillary, was changed, resulting in the flow also depicted in Figs. 10 and 11. The shown measurement was carried out over a period of more than one week showing no similarities to the flow irreproducibility found for the membrane valve as shown in Fig. 7. In this case, a constant pressure gradient across the capillary was used at 2.5 bar (36.26 PSI).

As visible, the flow signal follows the pressure signal: increasing the applied pneumatic pressure on the elastomer cover of the capillaries results in a decrease of the flow

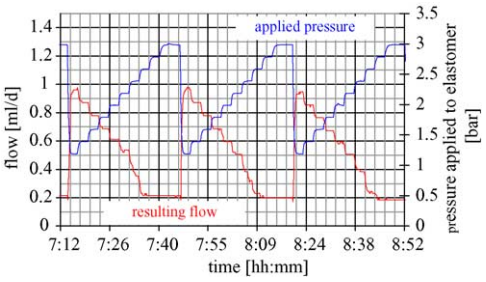


Fig. 11. In a long-term test, the flow rate was manipulated repeatedly by changing the pressure on the elastomer stepwise.

through the device. At higher pneumatic pressures, the slope of the change in resulting flow decreases as the elastomer experiences an increased level of deformation that finally settles in the channel (see Fig. 12). The higher the pressure on the elastomer the more difficult it is to cause deformation into the channels. This behavior is assumed to be overlapped by the strongly time-dependent elasticity of elastomers: deformation takes time. These time-dependent effects are matter of current evaluations.

When pressing the elastic cover into the capillaries repetitively by progressive stages of applied pneumatic pressure, the fluidic resistance across the capillaries is increased stepwise. Fig. 11 shows that defined stable states of constant flow rates can be reproducible realized.

Depending on the length of the capillary and its initial geometry, the flow range can be adjusted to the individual application. Fig. 12 demonstrates the realization of a variable fluidic resistance controlling flow rates of 0.83 ml/day down to 0.45 ml/day. Capillaries of varying geometries are to be investigated to realize the control of flow rates down to a complete shut off of the flow.

In order to investigate a long-term behavior of the novel elastomer valve an experiment was conducted repeatedly increasing and decreasing the applied pneumatic pressure on the elastomer for several hours and continuously measuring the flow. A time-dependent behavior of the deformed elastomer was found as shown in Figs. 13 and 15.

Repeated alternating of the applied pressure shows a hysteresis of the resulting flow through the capillary (Fig. 13) and the elastomer deformation (Fig. 14), respectively. This can be explained with two effects. On the one hand, the deformation of the elastomer is time-dependent—compare Fig. 10. The recovering of the original shape of the elastomer takes longer than the preceding deformation. On the other hand, the force acting on the elastomer from inside the channel is dependent upon the contact area between elastomer and fluid. An increasing deformation of the elastomer inside the channel results in a decreasing contact area between pressurized fluid in the channel and the elastomer. Thus, the force onto the elastomer from inside the channel is dependent upon elastomer deformation. The higher the pneumatic pressure, i.e., the higher the elastomer deformation, the smaller the counter

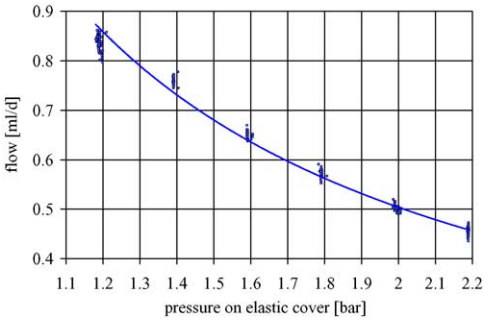


Fig. 12. Resulting flow through the capillary valve vs. the applied pressure on its elastic cover.

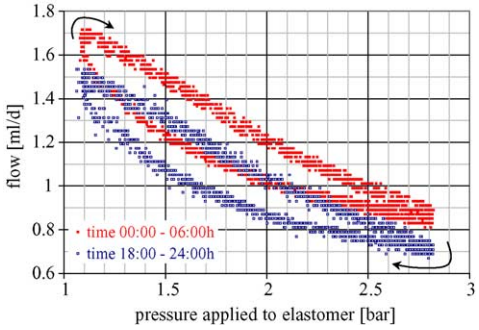


Fig. 13. Hysteresis of resulting flow through the capillary different points of time.

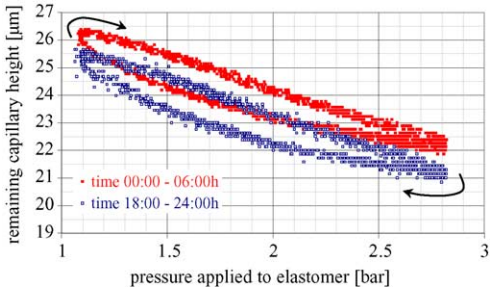


Fig. 14. Hysteresis of elastomer deformation at different points of time when applying linear pneumatic pressure ramps on the elastomer.

force from inside the channel. Both effects are reflected in the shown hysteresis.

In the given diagram, this hysteresis in elastomer deformation at two different periods in time is plotted. At the later period, the hysteresis of deformation or flow, respectively, has moved towards smaller flow rates, which is a result of greater deformations of the elastomer. Interpreting these two hysteresis plots, one can conclude, that each curve of hysteresis is in fact not completely closed due to a proceeding elastic deformation of the elastomer. Several different types of elastomer were tested. The elastomer Da/Pro 8602-C-40 showed no plastic deformation after several weeks of experiments.

Based on the measured flow q through the capillary, the realized geometrical changes of the capillary can be derived. Therefore, the appropriate deformation of the elastomer is calculated using Eq. (3) [9]. Here, h_{cap} is the remaining height of the capillary when applying pneumatic pressure onto its elastomer cover, ζ a geometrical factor, η the dynamic viscosity of the liquid, $\Delta p = p_1 - p_2$ the applied pressure drop across the whole device and 2ϕ the angle at the bottom of the capillary which is 70.6° in the case of an anisotropic etch of

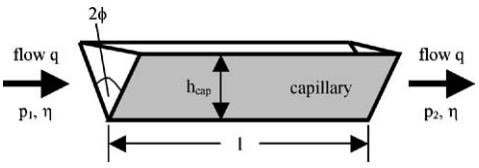


Fig. 15. Relevant parameters and their correlation.

⟨1 0 0⟩ silicon (compare Fig. 15). Analogical correlations are given in [12].

$$h_{\text{cap}} = 2\sqrt[4]{\frac{\xi\eta lq(1+1/\sin\ \phi)^2}{2\Delta p\ \tan\ \phi}} \quad (3)$$

4. Discussion

For silicon membrane valves, trapped particle result in a leakage gap depending on the size of the causative particle. This is improvable using various alternatives, such as multiple sealing lips or flexible materials [3], but cannot be prevented completely.

Taking advantage of softer sealing materials—as compared to the shown silicon membrane and sealing rim—an enclosure of trapped particles is enabled, yet still no systems have been presented that might meet latest requirements for some medical applications of leakage rates below 1 μl/day [1].

The novel variable capillary flow resistance approach addresses this problem as in this case particles do not tend to increase, but reduce the flow, a mode favorable in drug delivery systems. Due to the strongly time-dependent behavior of elastomers, limitations for the novel valve can be seen in applications that require fast switching times below or in the range of few seconds.

Numerical simulations are currently performed to evaluate the internal stress in the elastomer cover [13].

In the current measurement setup, the deformation of the elastomer is a result of an applied pneumatic pressure. In this case, the tension in the elastomer does not decrease with time of multiple elastomer deformation steps. This long-term deformation could be minimized by a distance-controlled actuation instead of a pressure- or load-controlled actuation as used for the shown experiments. Here, the internal tension in the elastomer is expected to decrease with time.

5. Conclusion

Low particle tolerance is a critical aspect that is overcomed with the new approach of a capillary valve as presented. Particles in the capillary system do not tend to be trapped and accumulated due to the homogeneous and laminar flow that is expected through the whole device. A further advantage towards conventional systems is that particles that are omnipresent in fluids do not increase, but decrease the leakage rates in the closed state. This safety aspect facilitates medical applications.

Currently established microvalves typically possess only one or two stable states. Depending on the applied actuation mechanism, the new variable capillary flow resistance possibly can be operated in multiple stable states.

At present, investigations are carried out to optimize the capillary itself. In order to reduce the internal stress induced in the elastic cover, the realization of differently shaped channels is projected. Another approach is to realize the capillaries themselves in elastomer materials.

In a series of complementary projects, HSG-IMIT, together with its partners, will be working on the next generation of the described systems for the years to come. The appropriate results will be presented in future publications.

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Herbert Ernst studied mechanical engineering at the Technical University Braunschweig, Germany, where he received his M.S. degree in 1997. Following his diploma thesis he worked at the Institute for Microsystem Technology (IMTEK) of the Albert-Ludwigs University in Freiburg as fellow researcher where he received his Ph.D. degree in 2001. He currently works at the Hahn-Schickard research Institute (HSG-IMIT) in Villingen, Germany, where he heads the department of microdosage-systems. His main scientific interests cover microfluidic system approaches for diagnostic and therapeutic applications.

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Hermann Sandmaier received the M.S. and Ph.D. degrees in electrical engineering from Munich Technical University in 1982 and 1988, respectively.He was working with the Fraunhofer Institute in Munich from 1982 to 1995, developing microsensors for physical and chemical quantities as well as microfluidic devices. He is currently head of the Institute for 'Mikro- and Informationstechnik', a research center of German 'Hahn-Schickard Gesellschaft', and a professor at Stuttgart University. His research interest focuses on microsensors, microfluidics, and microelectromechanical systems besides topics in technology, fabrication, and modelling.

He received the Schlumberger Award in 1989. In 1998, he has organized the MEMS Workshop in Heidelberg. He was an Editorial Board Member of Sensors and Materials, Steering Committee Member of MEMS-Workshop, Program Committee Member of Sensors and Eurosensors as well as European Technical Program chair of Transducers '01 in Munich. Currently he is an Editorial Board Member of the Journal of Micromechanics and Microengineering.

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Thorsten Goettsche studied mechanical engineering at the University of Stuttgart, Germany, where he received his diploma in 2001 on the subject piezoelectrically controlled microvalves. In 1999, he worked for 6 month at NIHON KOHDEN Co., Tokyo, Japan in the microsensor department. Since 2001, he is a member of the microfluidics department at the HSG-IMIT (Institute for Micro- and Information Technology of the Hahs-Schickard-Gesellschaft) in Villingen-Schwenningen, Germany. His main scientific focus are the assembly technology and microfluidics, especially drug delivery systems.