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Disposable Miniature Check Valve Design Suitable for Scalable Manufacturing

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Abstract

We present a passive, miniature check valve which can be manufactured using standard techniques ideal for low-cost, disposable systems used in medical devices and other applications. The body of the valve consists of a hollow cylindrical core, closed at one end, with a side port and a cylindrical elastomeric sleeve placed over the core body, covering the side port. The pressure required for initial opening of the valve, referred to as cracking pressure, can be adjusted, and depends predominantly on the valve core outer diameter, the sleeve inner diameter, the sleeve wall thickness, and the sleeve material's modulus of elasticity. These parameters can be controlled to tight tolerances, while the tolerances on other features can be relaxed, which simplifies valve manufacturing and assembly. Valve embodiments produced from different materials, and with varying critical dimensions, exhibited distinct and reproducible cracking pressures in the range of 2 to 20 PSI. The cracking pressure did not vary significantly as a function of flow rate. No back flow leakage was encountered up to 30 PSI, the pressure limit of the sensor used in this experiment. Most of the valves tested had small internal volumes of 3–4 μL . The internal volume can be further reduced by selecting a core of smaller inner diameter. In contrast to lithography-based microvalves that generally must be manufactured *in-situ* within the fluidic device, the herein presented valve can be manufactured independently of, and can be readily integrated into fluidic systems manufactured via a wide selection of fabrication methods.

Keywords

passive valve; microfluidics; mesofluidics; low-cost

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1. Introduction

Valves are an essential component for the control and manipulation of fluids. Many passive and active valve designs exist, each with their own advantages and limitations [1–5]. We are developing disposable cartridges for point-of-care nucleic acid testing [6,7], which require passive check valves with small internal volume, selectable non-zero cracking pressure, and the ability to be mass manufactured at low cost. Valves used in medical diagnostics and devices also have to be compatible with certain biomaterials, such as enzymes and other reagents used in clinical diagnostic applications [4,8,9]. This combination of attributes is not readily met by commercially available stand-alone passive valves, such as ball-and-spring, duckbill, and umbrella valves. For example, the Lee Company (Westbrook, CT) produces a ball-and-spring valve that meets all the physical requirements but is cost prohibitive. The remaining valve options all had recommended installation configurations that created an internal unrecoverable volume too large for a typical diagnostic assay, among other challenges. The small passive valves presented in this paper effectively address all of the above mentioned requirements.

Specialized valves made using microfabrication techniques [5,10–15], such as photolithography, can be very small and often have negligible internal volumes. However, these techniques require the valve to be, at least in part, fabricated in the same way and at the same time as the system with which it is integrated. This limits the design options greatly. Furthermore, linking macro and micro volumes in microfabricated designs is a significant challenge, one that is essential for diagnostic systems that require large initial sample input volumes and much smaller volumes during final analysis. The valve design presented herein can be made using commercially available sub-components, is low cost and easy to assemble. The valve is manufactured independently from the system into which it is inserted, and in practice is seated into a cylindrical channel or tube with a diameter matching its core, typically less than 2mm in size. The valve's internal volume is larger than that of lithography-based valves, but is comparable to or lower than that of commercially available stand-alone solutions with competitive manufacturing costs.

2. Experimental

2.1 Design and Operating Concept

The body of the valve consists of a hollow cylindrical core, capped at one end, with a side port (Fig. 1). An elastic cylindrical sleeve is stretched over the core covering the side port (Fig. 1b). When sufficient positive pressure is applied to the interior of the core, the sleeve expands and allows flow through the side port between the exterior of the core and interior of the sleeve. The radially oriented pressure out the side port, in conjunction with the friction between the sleeve and core, prevents the sleeve from slipping off. Once the pressure is reduced, the sleeve returns to its resting diameter on the core, closing the port and preventing backflow. The valve is easily integrated into a system by fitting the open end of the core into the fluid path. It can be used in an open configuration, letting fluid flow out into a reservoir, or it can be encapsulated to create an in-line check valve (Fig. 1c). Similarly functioning valve designs have been proposed [16–18]. However, the non-cylindrical

geometries proposed in these patents are likely to increase their manufacturing challenges, which is, perhaps, the reason these valves are not commercially available.

The pressure required for initial opening of the valve, commonly referred to as cracking pressure, of the herein described valves can be tuned to a desired value by adjusting easily controllable valve dimensions. Being able to select the cracking pressure allows for fine-tuned fluidic control and is of particular importance when applied within a system of multiple chambers separated by check valves. In such a system, valves can be selected with increasing cracking pressures to direct flow sequentially through the chambers. One example thereof is the cartridge for isothermal amplification coupled with lateral flow detection described in [6,7].

We developed a mathematical model for an idealized case, using elasticity theory of thick-walled cylinders (Supplementary Material), which predicts that the cracking pressure of the valve is dependent solely on the modulus of the sleeve material, the outer diameter of the core, and the inner diameter and wall thickness of the sleeve. Although this model is based on an idealized case, we expect that we can create valves with different and tunable cracking pressures by varying the above mentioned core and/or sleeve geometries.

In reality other factors likely contribute to the valve performance, such as small adhesive forces and/or friction between the core outer surface and the inner surface of the sleeve, and axial deformation of the sleeve. Such additional forces likely contribute to the two distinct observable pressures associated with the opening of the valve. First, there is an initial pressure spike indicating the true cracking pressure, where the pressure inside the valve core is large enough to stretch the sleeve open. After this initial pressure spike, there is a lower pressure associated with maintaining the valve in the open position. We refer to this pressure as the sustained open pressure.

Fluid typically exits the valve in one direction through the notch between the outer surface of the core and the inner surface of the sleeve. This fluid exerts a force on the sleeve along the axis of the core, which has two main components. First, the sleeve section lifted off the core by the fluid experiences viscous drag in the direction of the flow. Secondly, the rest of the sleeve that remains in direct contact with the core experiences an inertial force, in the direction opposite to the flow. As the flow rate increases, the inertial force likely will dominate. However, as long as this inertial force is smaller than the frictional force between sleeve and core, the sleeve remains in position. We found this to be the case at all flow rates tested herein, and we anticipate that significantly higher flow rates will not be required in the envisioned applications.

2.2 Valve Fabrication

According to our model, the valve cracking pressure depends predominantly on the diameters of the core and sleeve, which are made from rigid and elastic tubing readily available with precise diameters at low costs. The tolerances on other features, such as the geometry of the side port, length of the sleeve, or position of the sleeve, depend mainly on additional considerations such as valve seating and method of insertion into the final device. For example, the precise design and dimensions of the notch do not affect valve

performance as long as the notch is fully covered by the sleeve with sufficient margins on both sides of the notch, and does not change the structural integrity of the core. Rough cuts of the notch with varying shapes and dimensions were shown to not affect the cracking pressure. The tolerances for these other parameters are larger than the needed tolerances for core OD, sleeve ID, and sleeve wall thickness, which simplifies valve manufacturing and assembly, since these other features of the valve are substantially more expensive to manufacture to the same precision.

Two different embodiments of the valve were assembled and tested (Fig. 2). The first valve consisted of a core that was fabricated from stainless steel hypodermic tubing (Small Parts, Inc), sliced into short sections using a cutting wheel on a rotary tool. We then cut a notch on the side into each core tubing segment to create the side port, and sealed one end of each segment with UV curing glue (KOA 300, Kemxert Co.) or with melted polycarbonate. The valve sleeve was made from silicone tubing (VWR International, LLC), which was pushed over the core, covering the side port. Air was injected into the valve to inflate the sleeve tubing above the cracking pressure. This relieved any axial deformation that may have occurred while placing the sleeve on the core. Excess silicone was cut away with scissors. We fabricated two sets of test valves using this method, with different dimensions for the core and sleeve (Table 1).

The second valve embodiment consisted of a core fabricated from PEEK tubing (Zeus Inc.), sliced into short segments using a razor blade. We then cut a notch into the side, and sealed one end of the core by melting the PEEK material. The valve sleeve was made by casting silicone (R 1328, Silpak Inc.) into short cylinders with varying inner diameters and wall thicknesses. These sleeves were then pushed over the PEEK core, covering the side port. As for the previous design, air was injected into the valve to relieve any axial deformation of the sleeve. We fabricated several sets of test valves with constant core dimensions and sleeve wall thickness, but with varying sleeve inner diameters (Table 1, Fig. 2).

2.3 Valve Testing

Each valve tested was connected to a syringe pump (KDS-210, KD Scientific Inc.) and a fluid-filled pressure sensor (PX40, Omega Engineering, Inc) via a T-junction. The syringe pump had a rated accuracy of 1% and reproducibility of 0.1%. The pressure sensor had a rated 0.3% linearity corresponding to a maximum error of 0.09 PSI in pressure. At the outlet, the valve was open to atmosphere such that the gauge pressure measured by the sensor represented the pressure drop across the valve, which was recorded over time. The influence of orientation (horizontal vs. vertical alignment of valve) is on the order of 0.014 PSI, which is below the standard deviation of the valve cracking pressure, therefore negligible.

Fluid testing was performed using a reaction buffer typically employed in nucleic acid amplification [6], which contains buffer components and electrolytes, as well as surfactant (0.05% Triton X 100). We chose this buffer to demonstrate that the valve is functional under the intended operating conditions. We expect the same to be the case for other buffers typically used in biological applications, but the exact valve performance would need to be characterized for different buffers and applications.

3. Results and Discussion

3.1 Cracking and Sustained Open Pressures

We determined the cracking and sustained open pressures for the stainless steel and PEEK core valves (Table 2). With the syringe pump set to a fixed flow rate, the pressure upstream of the valves increased until it reached the cracking pressure. Thereafter, the pressure held steady at the sustained open pressure (Fig. 3ai and ii, respectively).

All valves tested provided distinct and reproducible cracking and sustained open pressures (Table 2, Fig. 3), with pressure values ranging from 2 to 20 PSI, depending on the valve type. This ability to tune the cracking and sustained open pressures enables ready fabrication of valves suitable for different applications. No back flow leakage was encountered prior to exceeding the measurement capabilities of the pressure sensor (30 PSI). Furthermore, the observed trends in cracking pressure agree qualitatively with the trends predicted by the model (see Supporting Information). Steel valve set 2 has significantly larger cracking and sustained open pressure values compared to steel valve set 1, as expected based on the larger difference between the core outer and sleeve inner diameters, and the larger sleeve wall thickness for set 2. For the PEEK core valves, as predicted by the model, the cracking and sustained open pressure decreased as the inner diameter of the sleeve increased (Fig. 3c). Furthermore, upon decreasing the flow rate from 500 to 200, and 100 $\mu\text{L}/\text{min}$, the cracking and sustained open pressures for representative steel and PEEK valve sets decreased slightly, by up to ~ 1 PSI (Table 2).

The cracking versus sustained open pressure was not significantly different for the steel valves (p value = 0.499), but for the PEEK valves, the cracking pressure was 2.0 ± 0.8 PSI larger than the sustained open pressure (p value = 0.00012). We hypothesize that the difference between cracking and sustained open pressure depends primarily on the materials used for the sleeve and core, which dictate the adhesion and friction between the sleeve and core. The cast silicone sleeves appear to have much stronger adhesive interactions with different surfaces, compared to the sleeves obtained from silicone tubing. If having a cracking pressure spike is undesirable for a particular application, this can be remedied by choosing different sleeve and/or core materials.

3.2 Internal Volume

The internal volume within the valve depends on the internal geometry and length of the core. The stainless steel core valves had an internal volume of 15 μL for set 1, and 3 μL for set 2. The internal volume of the PEEK core valves was 4 μL . The volume can be reduced without changing the cracking pressure or sleeve material by increasing the wall thickness of the core, thereby reducing the internal diameter and volume. However, reducing the internal diameter of the core increases the overall flow resistance. Therefore, the most suitable core ID has to be selected based on the requirements of a given application.

3.3 Compatibility with Nucleic Acid Amplification

We have incorporated the PEEK core valves described herein into a disposable cartridge that is used to execute isothermal nucleic acid amplification coupled to lateral flow detection [7].

For fluidic systems that execute nucleic acid amplification, components that come in contact with sample or master-mix fluids should be free of the target DNA or RNA, or products of target amplification, to prevent false positive amplification. For our prototype development, we found that DNA contamination can be eliminated by subjecting cartridge components to a dry-autoclave cycle for 50 minutes at 120°C. We dry-autoclaved 8 fully-assembled PEEK core valves, and determined their valve cracking pressures before and after autoclaving (See supporting information, Table S1). Autoclaving decreased the valve cracking pressure by less than 1 PSI, within the error bars of the experiment, and did not seem to adversely affect their performance.

Furthermore, the valves come in contact with the master-mix prior to isothermal Loop Mediated Amplification (LAMP) [19]. None of the valve materials inhibited the LAMP reactions (See Fig. S1, Supplementary Material), and autoclaving did not affect the amplification results. We further demonstrated LAMP-based DNA amplification in our cartridge configuration including the valves [7], and the valves functioned in this system as expected.

4. Conclusions

We demonstrated a stand-alone, miniature check valve design with selectable and reproducible cracking and sustained open pressures. The axial flow alignment of the valve lends itself to be press-fit, or similarly inserted into a flow path. The valves can be fabricated in a simple and reproducible manner from readily manufacturable, low-cost materials. The current prototype production process involves manual cutting, sealing, and notching of the rigid core, which alternatively can be accomplished through industry-standard deep draw production methods. Likewise, we used casting to generate elastomeric sleeves of varying inner diameters, but for mass production, the sleeves can be more readily obtained in large volume by injection molding, or by cutting silicone tubing of the appropriate inner diameter and wall thickness into shorter pieces. Therefore, the production of these valves can be scaled up to large-volumes using traditional manufacturing techniques. The valves can be manufactured from non-reactive materials that are compatible with challenging applications such as automation of biological assays [7].

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Biographies

Anna Hickerson

Dr. Hickerson has a Bachelor of Science degree in Engineering and Applied Science as well as a PhD degree in Bioengineering from California Institute of Technology. Since joining KGI in 2005, Dr. Hickerson has designed and developed various instruments for nucleic acid testing. As part of the Niemz lab engineering team, she has designed and manufactured cartridges and components for isothermal nucleic acid amplification, and is currently developing the instrument control system for automated and fully integrated assay execution. She teaches a course on medical device and diagnostic product development.

Hsiang-Wei Lu

Dr. Lu has a Bachelor of Science degree in Aerospace Engineering from the University of Maryland, College Park, a Master of Science degree in Aero/Astro Engineering from Massachusetts Institute of Technology, and a PhD degree in Mechanical Engineering from the University of California, Los Angeles. Dr. Lu joined Keck Graduate Institute in 2010 as a postdoctoral fellow. As part of the Niemz lab engineering team, he designs and manufactures cartridges for isothermal nucleic acid amplification, with emphasis on miniaturized inexpensive pumping and appropriate thermal control. He also developed a small inexpensive sample collection device for infectious disease diagnosis based on volatile organic compounds, and disposable electrowetting devices for DNA extraction and amplification.

Kristina Roskos

Dr. Roskos has a Bachelor of Science degree in Electrical Engineering from the University of California, San Diego, a Master of BioScience degree and a PhD degree in Applied Life Sciences with focus in Medical Devices and Diagnostics from Keck Graduate Institute in Claremont, California. Dr. Roskos joined the engineering team in the Niemz Lab in 2008, where she provides the link between assay optimization and device development. Her PhD thesis focused on design, manufacturing and testing integrated cartridges and associated instruments to execute isothermal nucleic acid amplification coupled with lateral flow detection.

Thomas Carey

Mr. Carey recently graduated with a BS in engineering from Harvey Mudd College. He has completed two summer undergraduate research internships in the Niemz Lab at Keck Graduate Institute (2011 and 2012). He has contributed to two projects for CareFusion Corporation: developing an auto-identification device for IV pumps and designing a system to prevent deformation of PVC IV tubing due to repeated compression by a peristaltic pump. Additionally, he competed for four years on the Claremont-Mudd-Scripps NCAA DIII swim team and served as webmaster for the Harvey Mudd chapter of Engineers for a Sustainable World.

Angelika Niemz

Dr. Niemz has a Bachelor of Science degree in Chemistry from University of Konstanz, Germany, and a PhD degree in Chemistry from the University of Massachusetts. She joined Keck Graduate Institute in 2002, first as Assistant and since 2008 as Associate Professor. In 2009, she worked during a 6-month sabbatical for Roche Molecular Diagnostics in Switzerland, began serving as Director of Research at Keck Graduate Institute, and was named the Arnold and Mable Beckman Professor. Dr. Niemz teaches courses on medical diagnostics, high throughput technologies, and instrumentation development.

Fig. 1. Valve design components: (a) inner rigid core with one end capped and one side port; (b) rigid core with elastomeric sleeve covering side port; (c) encapsulated valve for in-line use.

Fig. 2. Different embodiments of the sleeve valve. (a) Stainless steel core tubing with silicone tubing sleeve. (b) PEEK core tubing with cast silicone sleeves, with varying sleeve inner diameters, as indicated in the figure.

Fig. 3.

Cracking and sustained open pressure for different valve embodiments. (a) Pressure as a function of time for a representative steel valve, indicating (i) cracking pressure and (ii) sustained open pressure; (b) Cracking and sustained open pressures for the two stainless steel valve sets; (c) Cracking and sustained open pressures for PEEK valve sets 1–5, as a function of silicone sleeve inner diameter

Table 1

Key dimensions and physical parameters for the valve sets

	Stainless Steel Valve Set 1	Stainless Steel Valve Set 2	PEEK Valves
Core Outer Diameter	$0.065 \pm 0.0005''$ (1.65 ± 0.01 mm)	$0.042 \pm 0.0005''$ (1.07 ± 0.01 mm)	$0.061 \pm 0.0003''$ (1.56 ± 0.007 mm) ^c
Core Inner Diameter	$0.047 \pm 0.0005''$ (1.19 ± 0.01 mm)	$0.027 \pm 0.0005''$ (0.69 ± 0.01 mm)	$0.03 \pm 0.002''$ (0.76 ± 0.05 mm)
Sleeve Inner Diameter ^a	$0.058''$ (1.47 mm)	$0.030''$ (0.76 mm)	$0.047 - 0.057''$ (1.19 – 1.45mm) ^d
Sleeve Wall Thickness ^a	$0.009''$ (0.229 mm)	$0.018''$ (0.46 mm)	$0.017''$ (0.43 mm)
Sleeve axial modulus of elasticity ^b	482 ± 37 PSI	229 ± 19 PSI	79.0 ± 0.1 PSI

^a Sleeve inner diameter and wall thickness when sleeve is relaxed.^b Determined experimentally by performing a tensile test (Instron ®) with 10 replicates for each sleeve material.^c Measured for actual PEEK tubing batch used in valve construction.^d Multiple valve sets were fabricated with different sleeve inner diameters, see Fig. 2.

Table 2

Cracking and sustained open pressure for different valve sets

Valve Type ^a	Flow rate [$\mu\text{L}/\text{min}$]	Cracking Pressure [PSI]	Sustained Open Pressure [PSI]
Steel set 1	500	6.00 ± 1.38	5.39 ± 0.71
Steel set 1	200	4.93 ± 1.09	4.74 ± 0.75
Steel set 2	500	19.89 ± 1.73	19.29 ± 1.77
PEEK set 1	500	7.41 ± 0.57	4.82 ± 0.30
PEEK set 2	500	6.64 ± 0.43	3.76 ± 0.22
PEEK set 3	500	6.22 ± 0.63	3.41 ± 0.20
PEEK set 4	500	5.31 ± 0.58	2.94 ± 0.19
PEEK set 5	500	5.24 ± 0.32	2.22 ± 0.80
PEEK set 6 ^b	500	7.81 ± 0.53	6.23 ± 0.50
PEEK set 6 ^b	200	7.83 ± 0.52	6.08 ± 0.71
PEEK set 6 ^b	100	7.00 ± 0.57	5.34 ± 0.83

^a Five to ten identically manufactured valves tested per data set.

^b PEEK set 6 manufactured using sleeves with inner diameter nominally identical to PEEK set 1, but manufactured using a different mold with slight differences in other parameters.