Umbrella valve design for intravenous fluid delivery system

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Introduction: Intravenous (IV) fluid delivery systems are used to deliver a wide variety of medicine to over 25 million hospitalized patients annually [1]. Commonly, as shown in Figure 1a, an IV bag is connected to an administration kit that includes a spike, drip chamber, tubing, stopcock, and catheter. A major risk associated with these systems is the possibility of compromising sterility through (1) flow back, the regurgitation of blood in the line that can lead to infection, (2) and drain out, the complete emptying of fluid in the IV bag, allowing for air bubbles to enter the patient's vein. Several solutions to this problem exist, such as electronic infusion devices [2] and back-check valves [3], but these do not satisfy the set of risks described or they can be time consuming, complex and expensive. We report the design of a simple, passive umbrella valve integrated with a spike for an IV fluid delivery system that meets these requirements with comparable flow rates to a conventional spike.

Materials and Methods: As seen in Figure 1, the spike was redesigned to incorporate an umbrella valve. The umbrella valve operating principle is that elastic deformation of an annular polymer membrane under hydrostatic pressure (e.g., from the IV solution) passively opens/closes the valve against a valve seat and regulates flow rate through flow holes (See Figure 1b). Flow conditions were modeled using the Navier-Stokes equations and finite element analysis was performed to validate these closed-form models. Fabrication of a prototype was involved 3D printing acrylonitrile butadiene styrene (ABS) plastic and purchasing a commercially available umbrella valve diaphragm (Minivalve, Inc, UM180.001SD) of 50 durometer silicone, both FDA approved materials. Performance of the assembled and sealed prototype was compared with a conventional spike. For these experiments, either the umbrella valve with integrated spike or a conventional spike alone was utilized with the standard administration kit and IV bag in order to measure flow rate and elimination of flow back and drain out.

Results and Discussion: At typical IV bag pressures (1.1 kPa) flow rates of 92% of standard spike performance were obtained. While the umbrella valve with integrated spike prototype was capable of achieving a maximum flow rate of 3.13 mL/sec, flow rate in clinical practice is far lower, rarely exceeding 0.56 mL/sec (2 L/hr), as controlled by the stopcock (See Figure 1a) so this design is capable of meeting clinical flow rate expectations. Testing of flow back prevention showed successful sealing before drain out at a shut-off pressure of 0.062 kPa (0.25 inch of saline). Comparison with modeled performance is underway.

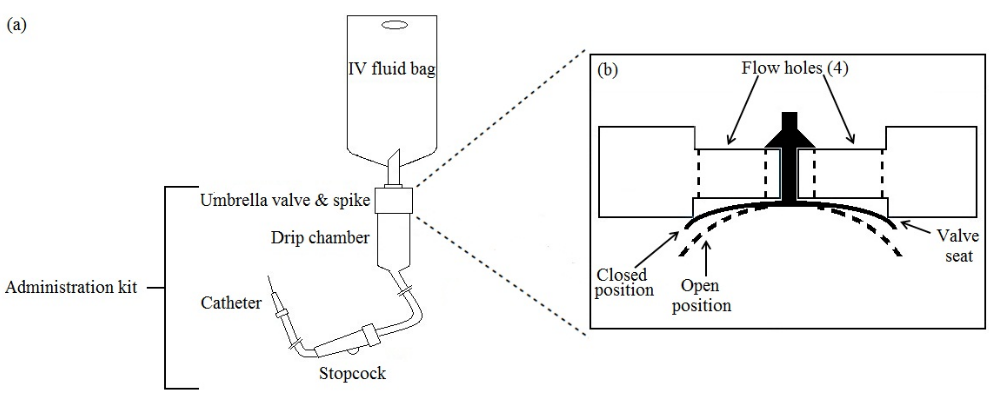

Figure 1. (a) Intravenous delivery system with umbrella valve design with integrated spike and (b) detailed view of the umbrella valve design that maintains 92% of the flow rate of a conventional spike while eliminating risks of flow back and drain out.

Conclusions: The umbrella valve design with integrated spike offers the simplicity and performance (i.e., flow rate) of the conventional spike while offering added risk mitigation for flow back and drain out.

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