Resistance of Indwelling 100% Silicone Foley Catheter Balloons to Osmosis

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ABSTRACT

Three independent in-vitro bench studies were designed to determine if 100% silicone Foley catheter balloons are more susceptible than latex Foley catheter balloons to premature deflation due to osmosis while in-vivo. Osmosis is defined as the passage of water from a region of high water concentration through a semi-permeable membrane to a region of low water concentration.

- The first study was a 10-day immersion study designed to determine if there is any difference in osmosis when Dover™ 100% silicone Foley catheter balloons are filled with water and immersed in different body temperature water bath fluids (water vs. pseudo-urine). This study involved filling each 5cc balloon with 10cc of sterile water and then measuring each catheter’s weight at time intervals up to 10 days in each water bath fluid. (Figure 1)

- The second study was a 6-day water immersion study directly comparing Dover 100% silicone Foley catheter and latex Foley catheter balloons, which were filled with water and then immersed in body temperature water. This study involved monitoring balloon diameters at time intervals up to 6 days. (Figure 2)

- The third study was a 3-month water immersion study of Dover 100% silicone Foley catheter balloons. This was done in order to investigate long-term deflation resistance in a simulated bladder environment due to osmosis. In this study, after day 22, each catheter was checked regularly for both balloon deflation and valve operation. All of the catheter balloons were deflated and re-inflated with an empty syringe twice a week after day 22. (Figure 3)

These three studies were performed at Kendall Healthcare Products Company with Dover 100% silicone and latex Foley catheters.

- Study #1 Results: There was no difference in osmosis recorded for Dover 100% silicone balloon catheters immersed in body temperature water versus those immersed in artificial urine.

- Study #2 Results: There were no balloon deflations recorded due to osmosis for either the Dover 100% silicone or the latex Foley catheter balloons after six days.

- Study #3 Results: No balloon deflations were recorded for the Dover 100% silicone balloons after they were immersed in body temperature water for three-months.

BACKGROUND

100% silicone Foley balloon catheters, filled with sterile water, have been used in the market for the past 30 years.

“The bladder is a balloon-like organ that changes shape according to the amount of urine it contains. It looks like a deflated balloon when it is empty and then becomes somewhat pearshaped when the amount of urine inside increases.”

Bladder Anatomy

Urine trickles down the ureters from the kidneys to the bladder. The bladder has elastic, flexible walls, which allow it to expand as it fills and then contract to expel urine when you urinate.
STUDY MATERIALS AND METHODS

In-Vitro Study # 1 :

Dover 100% silicone Foley catheters were filled with 10cc of sterile water and immersed in both body temperature water and pseudo-urine baths. This in-vitro bench-top study was conducted in order to explore potential osmosis differences between these two different water bath fluids (n=7 each).

Figure 1 below represents test Group #1 over 10 days.

RESULTS STUDY # 1

- Water vs. Pseudo-Urine Water Bath Comparison:
  No osmosis differences were observed between Dover 100% silicone Foley catheter balloons immersed in water vs. pseudo-urine.

In-Vitro Study # 2 :

A direct balloon diameter comparison was performed between Dover 100% silicone Foley catheter balloons and latex Foley catheter balloons, which were filled with 10cc of sterile water and immersed in a body temperature water bath for six days. This in-vitro bench-top study was conducted to explore potential osmosis differences between these two balloon materials (n=32 each).

Figure 2 below represents test Group #2 over 6 days.

RESULTS STUDY # 2

- Silicone vs. Latex Comparison:
  No differences were observed between Dover 100% silicone Foley catheter balloons and latex Foley catheter balloons.

- Balloon Deflation Due To Osmosis:
  Neither balloon material deflated due to osmosis when filled with water and immersed in body temperature water for 6 days.
ASTM Standard F 623-99 for Foley catheters requires that balloons be able to be deflated with a syringe within 15 minutes after being immersed for 7 days in body temperature water.

Figure 3 below illustrates balloon water volume loss over time.

In-Vitro Study # 3:
8F 3cc, 16F 5cc, & 24F 30cc — 2 way Dover 100% silicone Foley catheters were filled with water and then fully immersed in body temperature water to simulate the normal bladder environment for a duration of three months (n=30 each). Current indication for use of urinary Foley catheters is 30 days or less.

RESULTS STUDY # 3
• Balloon Deflation Due to Osmosis: No full or partial deflation were recorded. The test represented a total of 90 balloons tested having been subjected to body temperature water immersion for 3 months.

• Catheter Valve Failure: There were no incidents of catheter valve failure throughout the 3-month test period.

• Balloon Deflation Time: All catheters emptied in less than 2 minutes after 3 months, exceeding the 15-minute specification per ASTM Standard F 623-99.

CONCLUSIONS:
Based upon the experimental conditions outlined within these three independent studies:

1. Immersion bench testing in a body temperature water bath environment offers the best approach to understanding this in-vivo application.

2. There is no difference in osmosis between 100% silicone Foley catheter balloons soaked for 10 days in body temperature water versus those soaked in body temperature pseudo-urine.

3. Dover 100% silicone Foley catheter balloons are comparable to latex Foley catheter balloons with respect to osmosis.

4. Dover 100% silicone Foley catheter balloons exhibited no deflation when subjected to long-term immersion

Sources