Abstract MP65-09

# ANALYSIS OF UTI RESOLUTION AND SEDIMENT FORMATION ON INTRAVESICAL BALLOON FOR THE TREATMENT OF SUI FROM TWO MULTICENTER RANDOMIZED CONTROLLED STUDIES

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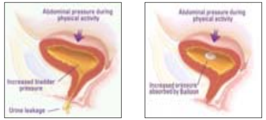
## INTRODUCTION

- **A novel free floating, non-occlusive, compliant intravesical balloon** filled with compressible gas has been evaluated in US and European multi-center randomized controlled clinical trials for the treatment of SUI. The balloon aims to reduce transient spikes in intravesical pressure that are common to all forms of SUI, regardless of their etiology.
- **Abdominal pressure spikes are strongly related to leakage** associated with SUI. When an incontinent patient laughs, coughs, or sneezes, for example, this Valsalva-like activity causes an increase in abdominal pressure. This abdominal pressure in turn, presses down on the urinary bladder causing a corresponding increase in intravesical pressure. If the intravesical pressure exceeds the urethral pressure, then leakage occurs
- **Fluids are effectively non-compressible, but gases are compressible**. The behavior of a compressible gas can be described by Boyle's Law: P1V1 = P2 V2. Using this derivative of the Ideal Gas Law as a reference, consider that in response to a pressure transient, P1→P2→P1, an air-filled balloon will momentarily contract to a new smaller volume, V2. This contraction has a time constant that is proportional to the volume of gas within the balloon, thus slowing the rate of increase of pressure.




Without balloon — With Vesair balloon

- **Applying Pressure Attenuation Technology to the Bladder**. With the addition of an air-filled balloon to the bladder, the intravesical pressure increase is dampened or attenuated.

## BACKGROUND

- **Encrustation is a concern with any foreign body** in the bladder as the foreign body acts as a nidus for stone propagation. This may impact device efficiency, precipitate urinary tract infections, or result in stone fragments dislodging from the device.
- **Two previous prospective, randomized, single blind, multicenter studies** assessed the safety and efficacy of this intravesical therapy on two different patient populations. [3, 4] Balloons from theses clinical studies were analyzed after removal from the patient to evaluate the formation of calcium oxalate and its impact to the efficacy of the device or the potential for stone formation.
- In Study 1, the protocol indicated that the balloons were intended for removal and replacement every 90 days. In Study 2, the protocol indicated that the balloons were intended to remain indwelling for up to one year.

## MATERIALS AND METHODOLOGY

- **This study evaluated a total of 642 balloons** removed from patients from two separate clinical studies.

*The Vesair ® Balloon*

- **The balloon is thin and has a low mass**. It is constructed of polyurethane film - a material with a long history of biocompatibility, including use in the urinary tract. A one-way valve seals the balloon after filling with air.
- **The buoyancy of the balloon makes it inherently non-occlusive**. Since it is free-floating and not anchored in any way, it will naturally float at the top of the bladder.
- **Insertion Device**. The balloon is inserted deflated, inside the tip of a lubricated catheter-like 18F inserter. It is inflated once it is inside the bladder and released.

1A – Study 1

1B – Study 2

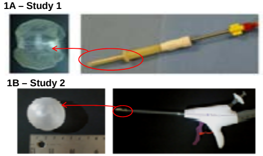
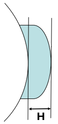


Figure 1: Balloon and delivery system

- **The balloons were removed transurethrally under direct visualization** using a custom optical grasper and placed in a specimen collection mailer and sent to a central location for analysis. All balloons were retained after analysis. The balloons were analysed by visual inspection for sediment using a 10-point scale ranging from 0 (0 to 0.1mm), 1 (0.1mm – 1.49mm), 2 (1.5mm to 2.49mm) up 10 (>9.5mm). For each device, the thickest deposit was measured at its thickest point.




| H (mm) | Score |
|---|---|
| 0 - 0.1 | 0 |
| 0.1-1.49 | 1 |
| 1.5-2.49 | 2 |
| 2.5 - 3.49 | 3 |
| 3.5 - 4.49 | 4 |
| 4.5 - 5.49 | 5 |
| 5.5 - 6.49 | 6 |
| 6.5 - 7.49 | 7 |
| 7.5 - 8.49 | 8 |
| 8.5 - 9.49 | 9 |
| > 9.5 | 10 |

Figure 2: Scoring of Sediment on Balloon

- 537 balloons were from 159 patients in Study 1, which used a seamed pressure-attenuation balloon with a valve welded into the seam (Figure 3A) that was filled with 15cc of air.
- 105 balloons were from 75 patients in Study 2, which used a seamless Vesair pressure-attenuation balloon with a valve welded to a small fill port (Figure 3B) that was filled with 30cc of air.

## RESULTS

*Study 1*

482 (89.8%) of the balloons in Study 1 had no measurable sediment formation (Score =0). 33 had a score of 1, 15 had a score of 2, four had a score of 3 and three had a score of 4. All sediment for balloons with a score greater than 1 was located at the valve/seam interface.

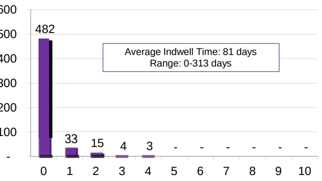



Figure 3: Deposit Score Per Balloon, 10 Point Scale
537 balloons from 159 patients

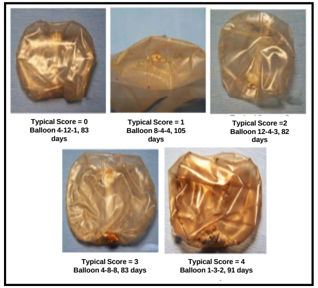



Figure 4: Sediment scoring samples – Study 1

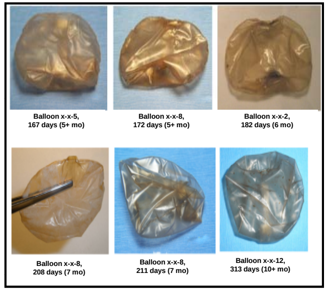



Figure 5: Representative samples – Study 1

*Study 2*

101 (96%) of the balloons in Study 2 had no measurable sediment formation (Score = 0.) The remaining four balloons had a score of 1. None of these 4 balloons were associated with a UTI and all 4 met efficacy endpoints.

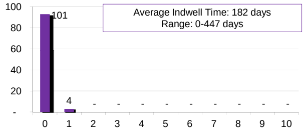



Figure 6: Deposit Score Per Balloon, 10 Point Scale
105 balloons from 75 patients

## RESULTS (CONT'D)

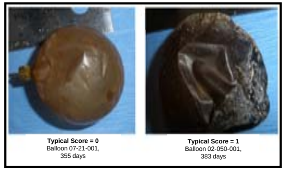



Figure 7 Sediment formation on balloon – Study 2


Figure 8 Representative samples – Study 2

Ten patients were diagnosed with a single UTI during Study 2. Eight resolved their UTI symptoms with the balloon in place. Two patients had the balloon removed prior to resolution. All 10 balloons had a sediment score of 0 when eventually removed.

*Overall, in both studies:*

- Any sediment formation that was measurable on the devices did not affect the device functionality and did not result in any obstructive issues.
- Representative samples of sediment from balloons were determined to be calcium oxalate by SEM Analysis.

## DISCUSSION

- The Vesair Balloon is unlike other urological devices that remain in the urinary tract for extended periods of time.
- Previous analysis demonstrated that the balloon is highly buoyant and floats at the top of the bladder, not at the based of the bladder where sediment resides. The balloon moves continually as the patient moves, and contracts and expands with changes in intravesical pressure.
- The balloon design changes implemented in Study 2 further reduced sediment formation.

## CONCLUSION

- Sediment formation was much less than expected
- There was no correlation between sediment formation and UTI.
- Resolution of UTI with the balloon indwelling was achieved.
- Further study is required to better understand and further reduce sediment formation.

*References*
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