360

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ANALYSIS OF SEDIMENT FORMATION ON LONG TERM INDWELLING FREE-FLOATING INTRAVESICAL BALLOONS FOR THE TREATMENT OF SUI FROM TWO MULTICENTER RANDOMIZED CONTROLLED CLINICAL STUDIES.

Hypothesis / aims of study

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.

Encrustation is a concern with any intravesical device, as the chemical constituents of the urine combine with the device to produce a matrix for the growth of stones. This formation may impact the efficacy of the device or result in stones dislodging from the device and becoming obstructive.

The two previous prospective, randomized, single blind, multicenter studies assessed the safety and efficacy of this intravesical therapy on two different patient populations.[1, 2] Balloons from these 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.

Study design, materials and methods

This study evaluated a total of 632 balloons removed from patients from two separate clinical studies. The balloons were removed 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.

539 balloons were from 159 patients in Study 1, which used a seamed pressure-attenuation balloon with a valve welded into the seam (Figure 1A) that was filled with 15cc of air. In Study 1, the protocol indicated that the balloons were intended for removal and replacement every 90 days.

93 balloons were from 79 patients in Study 2, which used a seamless Vesair® pressure-attenuation balloon with a valve welded to a small fill port (Figure 1C) that was filled with 30 cc of air. In Study 2, the protocol indicated that the balloons were intended to remain indwelling for up to one year.

Results

482 (89.4%) 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. The median indwell time was 89 days, with a range of 0 to 313 days.

89 (96%) of the balloons in Study 2 had no measurable sediment formation (Score = 0.) The remaining four balloons had a score of 1. The mean indwell time was 159 days, with a range of 4 to 413 days. A representative sample of removed balloons is shown in Figures 1B and 1D.

Sediment formation that was measurable on the devices did not affect the device functionality and did not result in any obstructive issues.

Interpretation of results

Sediment formation was much less than expected, and the design changes implemented in Study 2 further reduced sediment formation.

Concluding message

Compared to other intravesical devices, the balloon evaluated in this study was free floating, compressible, and buoyant so that it floats at the dome of the bladder, not at the base of the bladder where sediment resides. Further study is required to better understand which of these factors resulted in the reduction of sediment formation.

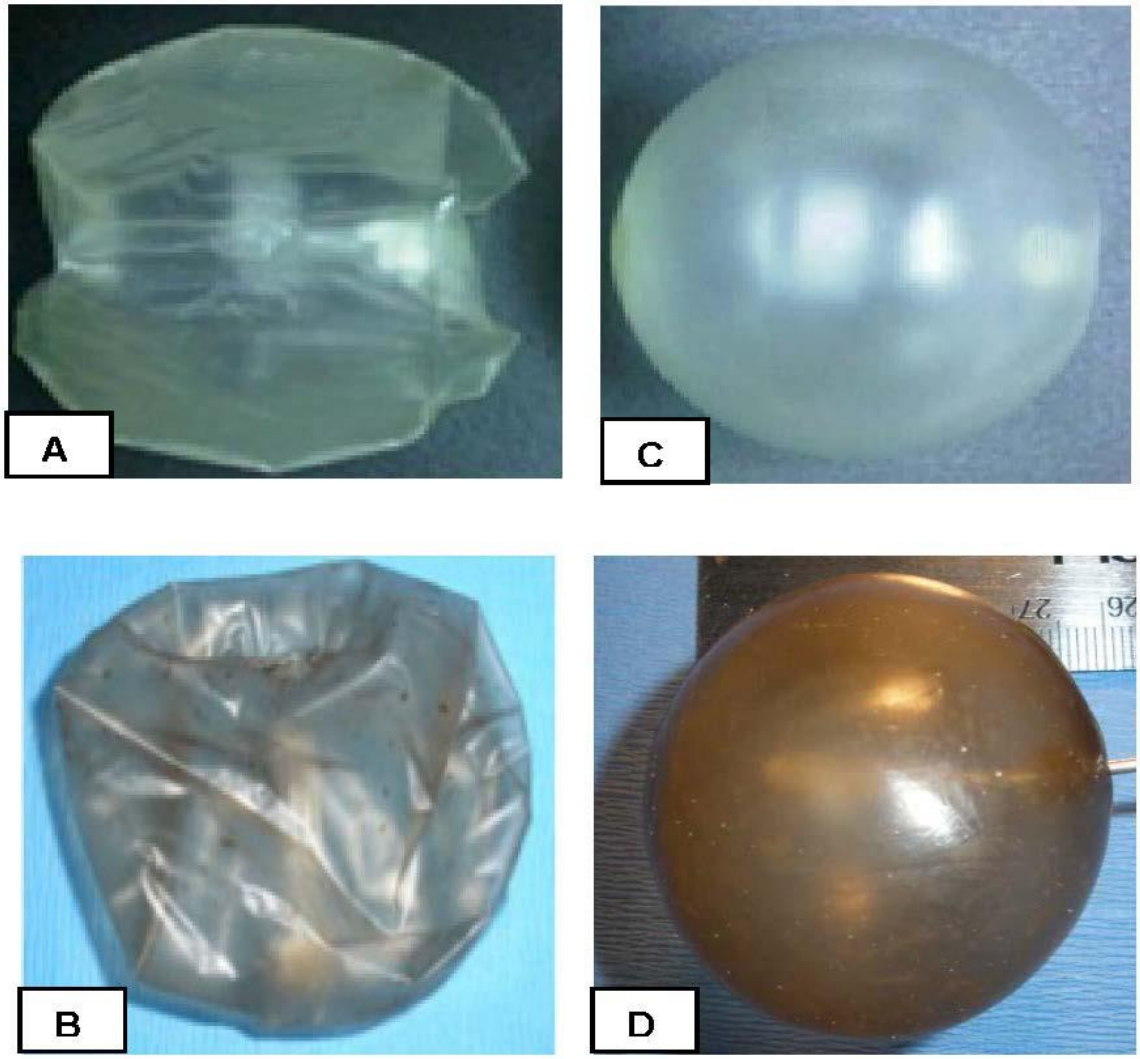

Figure 1:
A. Study 1 Balloon
B. Study 1 Balloon removed after 10 months indwelling
C. Study 2 Balloon
D. Study 2 Balloon removed after 1 year indwelling

References

1. Rovner et al, A Randomized, Controlled Clinical Trial of a Novel Intravesical Pressure Attenuation Device for the Treatment of Stress Urinary Incontinence. J Urol. 2013; 190 : 2243-50
2. Wyndaele, J.-J. et al. A randomised, controlled clinical trial of an intravesical pressure-attenuated balloon system for the treatment of stress urinary incontinence in females. Neurourol. Urodyn. doi:10.1002/nau.22798

Disclosures

Funding: Funded by Solace Therapeutics, Inc. **Clinical Trial:** Yes **Registration Number:** Clinicaltrials.gov Registration Numbers NCT00492596 and NCT01676662 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** IRBs for each US site including Western IRB, Baylor University, MUSC
Ethics committes from University of Antwerp, Maastricht Univerity Medical Centre **Helsinki:** Yes **Informed Consent:** Yes