Abdominal pressure transients are strongly related to leakage. If the intravesical pressure momentarily exceeds the urethral closure pressure, leakage occurs. If the intravesical pressure increases, abdominal pressure increases. This is due to the abdominal pressure pushing down on the urinary bladder, causing a corresponding increase in intravesical pressure. When an incontinent patient laughs, coughs, or experiences exertion, the bladder contracts to a new smaller volume, V2. This contraction results in a decrease in intravesical pressure.

**Background**

- **Air-based pressure attenuation is common:** In many non-medical applications, air is used as a means to control pressure transients.

- **Fluids are effectively non-compressible, but gases are compressible:** The behavior of a gas can be described by Boyle's Law: $P_1V_1 = P_2V_2$. 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 air within the balloon, thus slowing the rate of increase of pressure.

- **Abdominal pressure transients are strongly related to leakage:** Leakage is associated with stress urinary incontinence. When an incontinent patient laughs, coughs, or sneezes, the abdominal muscles tighten, causing 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 closure pressure, leakage occurs.

- **Experiment designed to simulate physiological transient pressure events:** The Vesair balloon is inserted into the bladder. Micturition produces physiological pressure changes in the urinary bladder, and released. The Vesair balloon is inserted, inflated, and then deflated, simulating pressure events. The balloon is inserted into the bladder, inflated, and then deflated. The vesicle balloon, however, with balloon inflated, is deflated, simulating pressure events.

- **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. This limits the rate of pressure increase in the bladder, and for short events, limits the maximum pressure that will occur in the bladder associated with pressure events. Micturition is driven by sustained pressure, it should not be affected by the presence of the balloon.

**Materials and Methodology**

- **The Vesair® Balloon:** The Vesair balloon is thin and has a low mass. It is constructed of medical grade 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, inflated, and then deflated, simulating pressure events. The balloon is inflated once it is inside the bladder, and released.

**Results**

- The results of the in-vivo measurements using a 20 msec pulse in the acrylic chamber are shown in Figure 1. For a balloon volume of 30 ml, the amplitude of a transient pressure pulse was reduced by 81% from 140 cmH2O to 27 cmH2O.

- The results of the in-vivo measurements using a 40 msec pulse in the acrylic chamber are shown in Figure 2. For a balloon volume of 30 ml, the amplitude of a transient pressure pulse was reduced by 65% from 140 cmH2O to 49 cmH2O.

**Discussion**

The in-vivo simulation provides a demonstration of how the physics of an air-based pressure attenuator system works. It verifies that the magnitude of the attenuation is of a sufficient level that it should provide a clinically relevant result when applied in-vivo.