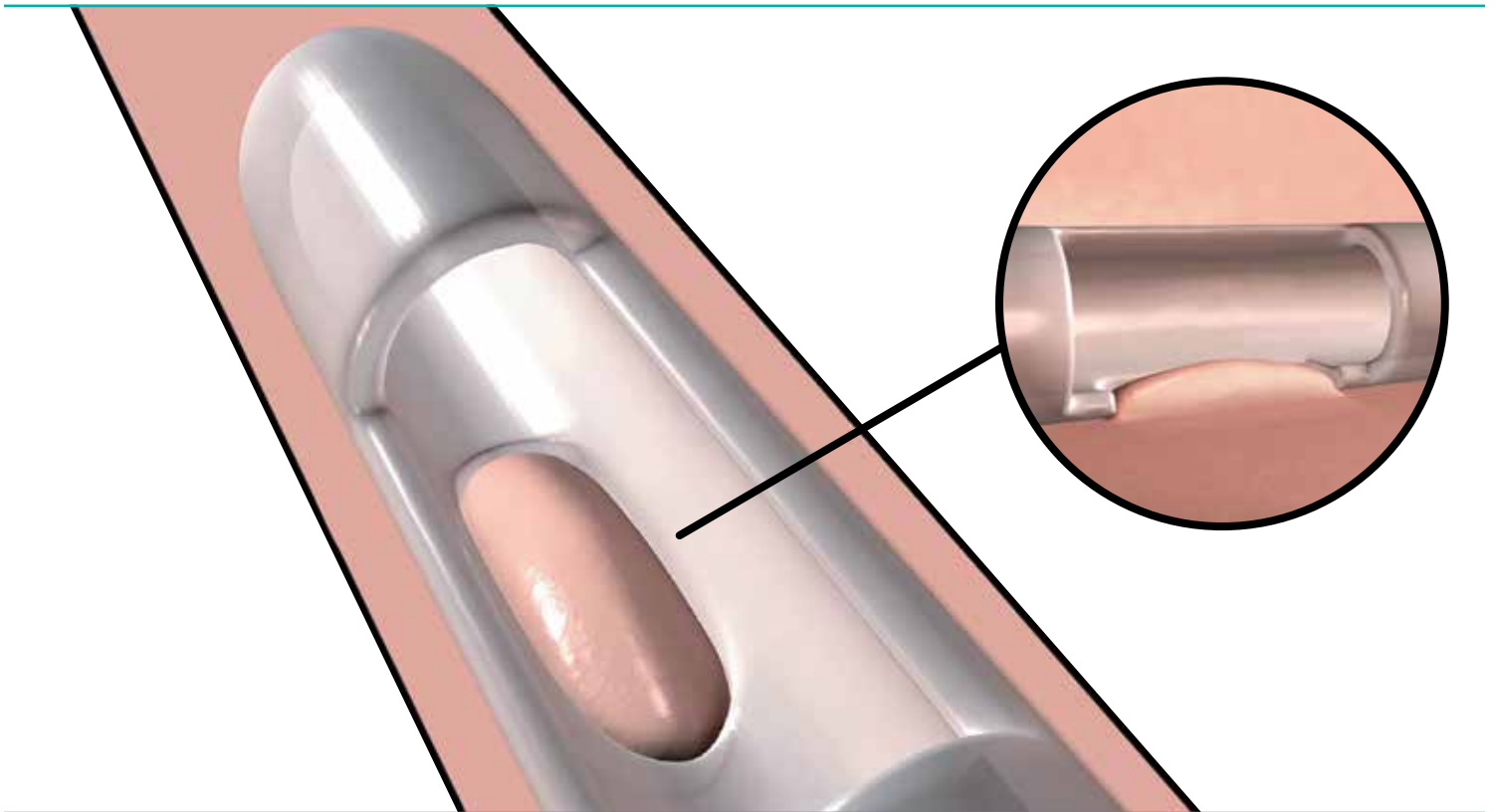


***In vitro* Testing of Porcine Urethral Tissue Deformation by Intermittent Catheter Eyelets for Size 18Fr Male**



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Studies were undertaken using an *in vitro* porcine urethra test and 3D scanner to establish whether there may be observable differences in eyelet tissue deformation between different manufactured catheters.

Test Method

Each test was carried out by conducting the following steps:

1. The catheter eyelet was pressed onto a section of porcine urethral tissue.
2. A force representative of internal urethral sphincter pressure was applied.*^{3,4}
3. A 3D scan of the tissue surface was taken.**

Four catheter brands of size 18Fr male were evaluated. Each catheter was tested four times.

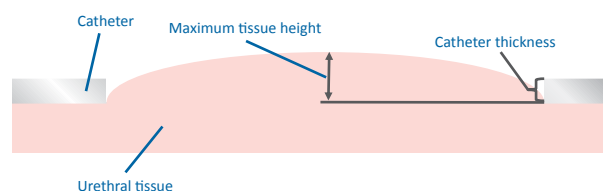
In Vitro Animal Model



Measurement

Using the 3D scan of the tissue surface, measurement of the deformation of the tissue into the eyelet was calculated by using the maximum distance of the urethral tissue from where the outer surface of the catheter would have been if there was no eyelet – see ‘maximum tissue height’ indicated in the ‘Internal Catheter View’ illustration.

Internal Catheter View



Randomization: A total of 16 tests were conducted which consisted of testing the four catheter brands by two operators performing two repetitions. All tests were randomised with a limit that all four tests on any one urethra have to be consecutive to minimise possible drying out of the urethra when exposed to air.

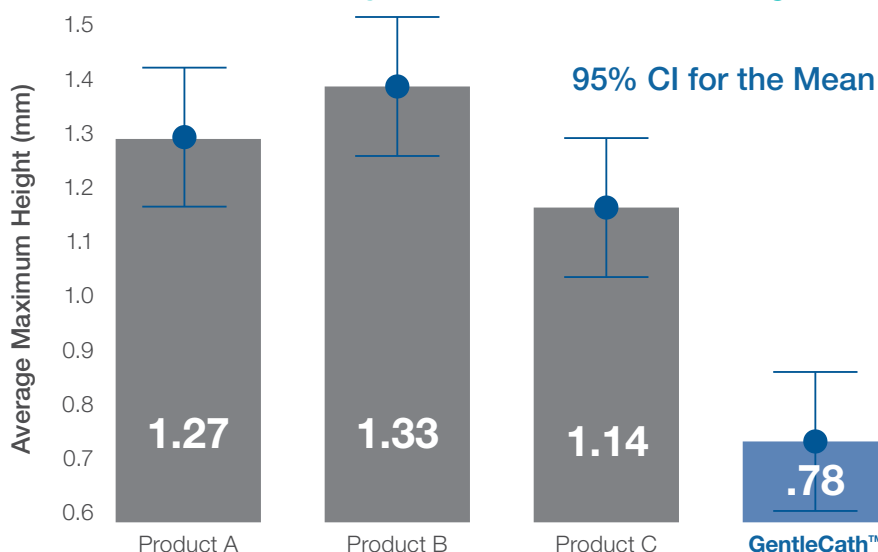
Results

It was observed that the 95% confidence interval of maximum tissue height for GentleCath™ did not overlap the 95% confidence intervals for the other brands tested. In this test there is a statistically significant difference between the maximum heights of tissue deformation among the size 18Fr catheter eyelets when tested on porcine urethral tissue ($\alpha = 0.05$).

Conclusion

In this *in vitro* test comparing the height of porcine urethral tissue deformation following insertion of an 18Fr male catheter, the height of urethral tissue in the ConvaTec GentleCath™ eyelet was lower than that observed with the other brands tested.

18FR Male Eyelet Tissue Deformation Height



* 60cm H₂O ** Calibrated scanner has a resolution of 6µm

References: 1. Dellimore KH, Helyer AR, Franklin SE (2013). A scoping review of important urinary catheter induced complications. *Journal of materials science. Materials in Medicine*, 24(8):1825–1835. 2. Walker M, Lambrethsen J, Winther T (2014). *In vitro* testing of Tissue Deformation by Catheter Eyelets. Data on file. 3. Weber AM (2001) Leak point pressure measurement and stress urinary incontinence. *Current womens' health reports*, 1(1): 45–52. 4. Marti F, Leippold T, John H, Blunski N, Müller B (2006) Optimization of the artificial urinary sphincter: modelling and experimental validation. *Physics in Medicine and Biology* 51: 1361-1375

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