

Simulated Tissue Deflection Comparison of the ACCU-TRACE™ Intrauterine Pressure Catheter to Products on the Market

Tyco Healthcare / Kendall - LTP Division - Research & Development

PURPOSE

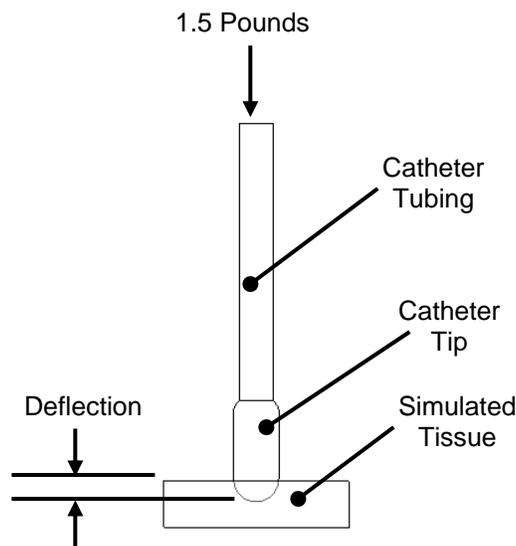
Compare the simulated tissue deflection of the ACCU-TRACE intrauterine pressure catheter to products currently on the market.

TEST METHODS

Samples of the Kendall ACCU-TRACE IUPC were randomly selected after being exposed to a worse case sterilization process. Samples of the Clinical Innovation and Utah Medical products were randomly selected from product obtained through normal hospital distribution channels that were packaged and labeled as sterile.

The simulated tissue deflection was measured using an Instron® 3365 Tensile Tester. Test samples were prepared by cutting the catheters four inches from the tip. The catheter was placed in an Instron 3365 Tensile Tester such that the catheter tube was horizontally aligned and the tip was in contact with rubber foam which was selected as a good representation of human tissue. A compressive load of 1.5 pounds was applied axially and the maximum tissue deflection was recorded. 1.5 pounds was experimentally determined during simulated insertions to be the maximum load that could be applied to the catheter during insertion. The test set-up is schematically shown in figure #1 below.

Figure #1 – Simulated Tissue Deflection Test Setup



Data analysis was performed using Minitab® Statistical Software Release 14.

TEST RESULTS

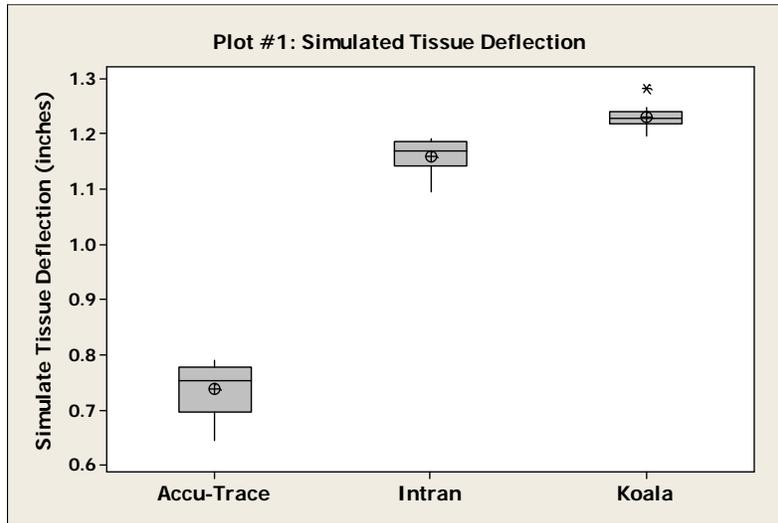
	Kendall ACCU-TRACE	Utah Medical Intran®* 650	Clinical Innovations Koala®* IUPC 5000
Sample Size	10	10	10
Reorder Number /Lot Number	56300 Lot: 502861	IUP-650 Lot: 140259	IPC-5000E Lot: 05335
Mean Simulated Tissue Deflection (inches)	0.74	1.16	1.23
Standard Deviation (inches)	0.05	0.03	0.02

Data Analysis

T-tests using a 95% confidence interval were performed on all the data comparing the different catheters. In all cases the differences between the catheters was statistically significant with p-values < 0.05.

	Utah Medical Intran® 650	Clinical Innovations Koala® 5000
p-value compared to Kendall ACCU-TRACE™	0.0	0.0

Plot #1: Boxplot of the simulated tissue deflection for each catheter with the interquartile range indicating the middle 50% of the observations and whiskers indicating the lowest and highest values in the data set (excluding outliers).



CONCLUSIONS

- The Kendall ACCU-TRACE intrauterine pressure catheter has a lower mean simulated tissue deflection than the Utah Medical and Clinical Innovations catheters and the difference is statistically significant (p-value < 0.05).
Clinical relevance: less simulated tissue deflection will result in a lower likelihood of uterine perforation and/or fetal injury, and increased patient comfort.