

Test Method Development for Evaluation of Process and Design Effect on Reinforced Tube

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Abstract : Coil reinforced thin-walled (CRTW) tubes are used in medicine to treat problems affecting blood vessels within the body through minimally invasive procedures. The CRTW tube considered in this research makes up part of such a device and is inserted into the patient via their femoral or brachial arteries and manually navigated to the site in need of treatment. This procedure replaces the requirement to perform open surgery but is limited by reduction of blood vessel lumen diameter and increase in tortuosity of blood vessels deep in the brain. In order to maximize the capability of these procedures, CRTW tube devices are being manufactured with decreasing wall thicknesses in order to deliver treatment deeper into the body and to allow passage of other devices through its inner diameter. This introduces significant stresses to the device materials which have resulted in an observed increase in the breaking of the proximal segment of the device into two separate pieces after it has failed by buckling. As there is currently no international standard for measuring the mechanical properties of these CRTW tube devices, it is difficult to accurately analyze this problem. The aim of the current work is to address this discrepancy in the biomedical device industry by developing a measurement system that can be used to quantify the effect of process and design changes on CRTW tube performance, aiding in the development of better performing, next generation devices. Using materials testing frames, micro-computed tomography (micro-CT) imaging, experiment planning, analysis of variance (ANOVA), T-tests and regression analysis, test methods have been developed for assessing the impact of process and design changes on the device. The major findings of this study have been an insight into the suitability of buckle and three-point bend tests for the measurement of the effect of varying processing factors on the device's performance, and guidelines for interpreting the output data from the test methods. The findings of this study are of significant interest with respect to verifying and validating key process and design changes associated with the device structure and material condition. Test method integrity evaluation is explored throughout.

Keywords : neurovascular catheter, coil reinforced tube, buckling, three-point bend, tensile

Conference Title : ICBBBS 2020 : International Conference on Biotechnology, Bioengineering and Biological Solutions

Conference Location : Barcelona, Spain

Conference Dates : February 10-11, 2020