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

Cathal Merz, Gareth O'Donnell

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**—**Buckling, coil reinforced thin-walled tubes, fracture, test method.

I. Introduction

CRTW tubes composed of an inner layer, wound reinforcement layer and outer layer are commonplace in the modern world with popular applications being in oil and gas, electrical industries and medical device industries. The CRTW tube considered in this paper has a structure consisting of a low-friction polymer inner layer, a wound nitinol ribbon reinforcement layer, an outer layer made up of multiple sections of polymer to give variable stiffness along its length and lastly a hydrophilic outer coating. The configuration of the CRTW tube considered in this research is shown in Fig. 1.

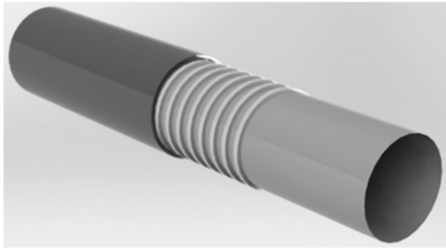

Fig. 1 Representation of the layers within the CRTW tube considered in this research

Because of the complexities associated with simulation, early device designs are currently tested using destructive test methods followed by scanning electron microscope (SEM) imaging and/or energy dispersive X-ray spectroscopy inspection. Final designs are evaluated in a similar way during final design testing. When a design passes final design testing, its capability has been proven meaning that each individual product does not have to be tested when brought into production. An important design consideration for CRTW tube performance is its ability to resist the occurrence of failure modes one and two described below:

1) Buckle only.
2) Buckle followed by outer layer fracture.

Resistance to these failure modes is determined using *manually* performed qualitative test methods. Part of the reason why designs are evaluated in this way is that there are no standardized test methods for determining mechanical properties of CRTW tube devices other than tensile strength [1]. Requirements for tensile strength of each cross section and junction with diameter greater than 0.55 mm are described in ISO1055.

Good resistance to buckling of the device is important for its performance because of the way it is loaded during use. As a CRTW tube device is advanced through tortuous blood vessels in a patient, compressive axial loads may increase gradually or suddenly which can result in failure mode one but less frequently failure mode two.

Analysis was carried out using the manual test methods to investigate which design and process factors influenced the rate of occurrence of failure mode two. Fig. 2 displays the results of this analysis for variation of a particular process setting. The results show that the occurrence of failure mode two increases with the level of this process setting that the test specimens are subject to.

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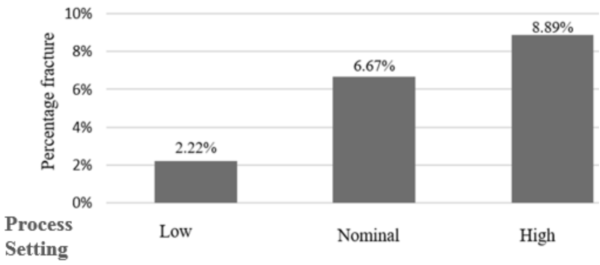

Fig. 2 Relationship between processing factors and percentage fracture determined using manual testing

In addition to fault tree analysis, fractographic examination was carried out using a SEM on specimens which had failed by failure mode two. Visual analysis of one specimen revealed two crack initiation sites, both of which were located on the interface between the outer layer and reinforcement layer [2]. Cracking in another specimen was observed to have initiated at a single site on the outside diameter of the outer layer which occurred when the strength of the material was exceeded.

In all samples, cracking progressed clockwise and/or counter clockwise until catastrophic failure occurred. No evidence was found to suggest that cracking initiated due to material defects, prior mechanical damage or molecular degradation [2]. Molecular degradation of a CRTW tube device could occur from exposure to ultraviolet rays, so it is therefore of value to rule this out as a contributing factor to failure [3].

The extent to which each of the process and design parameters effect device performance are unknown due to the manual test methods used producing binary attributive data. Additionally, there are inherent issues with subjectivity and operator error as rate of displacement, force applied and alignment are subject to the person carrying out the test. The aim of current research is to address this problem by developing a measurement system capable of quantifying the effect of varying process and design changes on CRTW tubes. Research carried out and detailed in this paper investigates the suitability of buckle and three-point bend (TPB) tests for this purpose. The outcome of using these test configurations is the recommendation that a four-point bend test be used to fulfill the aim of the current research.

II. CRTW Tube Device Use

One application of CRTW tubes is in endovascular surgery which is a minimally invasive surgical technique used to treat problems affecting blood vessels all over the body. It is the job of an interventional radiologist physician to use a combination or assembly of reinforced tubes and guide wires to navigate to the site in need of intervention and deliver treatment with the aid of various imaging modalities. Devices may be inserted into the patient via the femoral artery in the leg or brachial and radial arteries in the wrist [4]. Due to the nature in which some devices are advanced through the human body, longitudinal stiffness is maximized to prevent buckling and cross-sectional stiffness is minimized to allow navigation of the device tip around tortuous vessels [5]. Longitudinal and cross-sectional stiffness ranges from highest at the proximal end to lowest at the distal end which corresponds to the level of tortuosity these parts of the CRTW device encounter during use. The higher levels of stiffness in the proximal segment of the device lend itself to occurrence of failure modes one and two.

III. CRTW Tube Device Performance

CRTW tube device performance is often described using terms such as torqueability, trackability and pushability. Torqueability is a measure of the devices torsional stiffness and often expressed as the ratio between rotation of the proximal end to rotation of the distal end [6]. A ratio of 1:1 is highly desirable as this indicates that a turn of the proximal end by the physician will turn the distal end inside the patient by the same amount. A device like this reduces the amount of experience a physician needs to tactfully operate it. Additionally, a device of high torsional stiffness is safer to use as a device with low torsional stiffness may store energy along its length before rapidly releasing it, causing its distal end to rotate quickly and dangerously.

Device trackability refers to the characteristics of a device that enable its passage through tortuous vessels [7]. It is a combination of a device's flexibility, column strength and ability to reduce the frictional forces exerted on the device by its surrounding environment. Good trackability is imperative for successful navigation around difficult anatomy such as the ophthalmic artery [8].

The pushability of the device refers to the level of force applied by the physician to advance the device through the blood vessels to the site in need of treatment [9].

IV. Buckling of Thin Walled Tubes

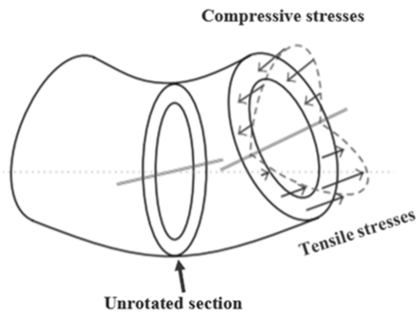

Fig. 3 An infinitesimally small section of an initially straight tube under global bending. Stress components which cause ovalization of the cross section are shown [12]

Buckling of thin walled cylinders is significantly more difficult to analyze than axial compression and bending of idealized structures which is the work of Leonard Euler, Jacob Bernoulli and many others [10]. The theory of hollow sections under bending is complex, with their analytical treatment having a history going back over a century. Brazier illustrates a point at which a bending moment applied to a tube passes through a maximum value and after which resistance to bending reduces, and failure of the structure occurs [11].

When an initially straight tube is bent uniformly, the longitudinal tension and compression which resist the applied bending moment have in-plane stress components which tends to ovalize the cross-section [12]. This effect is illustrated in Fig. 3 which represents an infinitesimally small portion of a deformed tube. The tube was originally straight but under pure bending gives rise to the compressive and tensile stresses which act at an angle to the unrotated section. As a result of these stresses, the tube cross section is deformed into an oval shape. The cross section where buckle occurs in the CRTW device would be subject to similar stresses.

V. Existing Test Methods

Testing is an essential part of engineering design and manufacture. Measurement of the mechanical properties of the CRTW tube device sections are imperative for an effectively designed product, however no standardized test method for achieving this exists [1]. Also, due to the competitive nature of the medical device market, test methods are typically not disclosed by manufacturers to the public.

A buckle test method for catheters and applicable to CRTW tube devices and in the public domain is described by A. Bailly et al. and shown in Fig. 4 [13]. Either end of a long test specimen are brought together and pulled at constant speed through a slot until buckle occurs. The parameter measured is the height of the specimen remaining above the slot when buckle occurs.

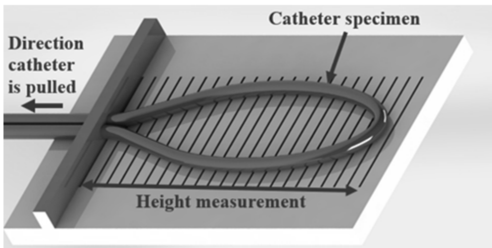

Fig. 4 Buckle test method described by Bailey et al. [13]

Some relevant test methods for determining the mechanical properties of flexible tubes are presented in ISO-10619-1, Rubber and Plastics Hoses and Tubing - Measurement of Flexibility and Stiffness This standard presents a method similar to the manual test method mentioned in section I. Introduction [14].

ISO 178, Plastics - Determination of flexural properties describes in detail the procedures for determining the flexural properties of a preferred test specimen by three-point bend testing. Test specimens of rectangular cross section are defined in terms of their own relevant material standard and dimensions of length, breadth and height. The span of the two lower supports and test speeds are also defined [15].

ISO 527 "Plastics - Determination of tensile properties" contains detailed instructions on how to determine the tensile properties of specimens including for anisotropic specimens with detail comparable to ISO 178 [16].

VI. Methodologies Employed for Test Method Development

The rationale behind initial test method selection was linear in nature. Test methods suitable for measuring the mechanical properties of the proximal segment of the CRTW tube device were selected, developed and their suitability as a design and process change effect measurement tool assessed by attempting to measure the same relationship between the process setting and rate of occurrence of failure mode two shown in Fig. 2. The test method development plan entailed repeating these steps until a test method that is practical, repeatable, reliable and sensitive enough to quantify the effect of design and process changes is developed. It was decided that use of a materials test frame would be advantageous as the user is granted control over the criteria for initiating the test, variables during the test, criteria for ending the test and the outputs from the test. A test carried out on a test frame would be an improvement on the manual test methods with respect to repeatability, reliability and the types of results obtained i.e. from binary qualitative to quantitative. The experiment outputs were chosen to be force and displacement. Maximum force, yield point and break point can be read from resulting data and calculation of stiffness measurements is possible. The method of experiment planning used was the one-factor-at-a-time method with the process setting being chosen as the first factor to change as had been the case with the manual test methods.

One-way ANOVA with five percent level of significance is used to determine whether a statistically significant difference exists between samples. For experiments where there are more than two samples, one-way ANOVA is used to determine if a difference exists between samples followed by Tukey post-hoc tests to determine between which samples the difference exists [17]. The primary advantage of using this statistical model compared to multiple T-Tests is that the family error rate remains constant [18].

The test samples are described as High, Nominal and Low. The Nominal sample is so named as the experiment variable is not changed from the manufacturing setting allowing the sample to act as a control. The experiment variable is set at a high value for the High sample and at a low value for the Low sample. The experiment variable is varied by the same magnitude from the Nominal sample for both the High and Low samples. The test specimens comprise of a segment of the CRTW tube device cut to length. The length of the test specimens is informed by Saint-Venant's Principle such that the end conditions do not affect the stress conditions at the longitudinal centre of the test specimen, where failure occurs.

VII. Buckle Test Method

Compression tests are one of the most fundamental forms of materials testing. The buckle test described in this paper refers to a compression test in which the test specimen is tested until buckling occurs. The extensive use of compression tests in materials testing, their simplistic nature and the wealth of knowledge that exists on this test configuration support the choice of this configuration. Additionally, the loading conditions introduced by this configuration are like those seen during the manually performed test methods and during use of the device.

Initial testing was carried out using a prototype fixture which held the test specimen in a pinned-pinned configuration. The sensitivity of this test set-up was checked by testing three samples each consisting of specimens made from the proximal segments of different thin-walled reinforced tube devices. Results showed a statistically significant difference between samples providing motivation to optimise the buckle test.

The optimised buckle test made use of a new fixture which minimised noise caused by the friction at the pinned ends by using ball bearings and improved the dimensions at the pinned ends of the test specimen such that they were aligned with the axis of rotation of the pin. The suitability of this test configuration as a process and design effect measurement tool was assessed by testing specimens made using high, nominal and low process setting. The results from this experiment showed that a statistically significant difference between the samples did not exist. A repeat of this experiment using higher rates of displacement indicated insufficient sensitivity of this test method and so a TPB test was next developed. The rational behind the choice of a TPB test is that it loads the test specimen in bending and the CRTW tube device is known to fail in bending during use. In addition to this, the choice of a TPB test configuration is informed by the manual test methods currently used for design evaluation as they too bend the test specimen until failure.

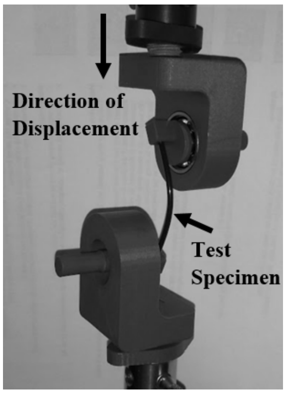

Fig. 5 Optimized buckle test configuration

The shape of the output curve from the buckle test is shown in Fig. 6. Characterization of this output curve was carried out using micro-CT. Three specimens were imaged: a control, a specimen tested to maximum force and a specimen tested to buckle. The point of zero slope on the output curve is taken as the point of maximum force and it is at this point that the polymeric elements within the CRTW tube device structure have plastically deformed. One form of plastic deformation is apparent on the outside of test specimen at this point in the form of stretch marks on the outer layer corresponding to the space between the reinforcement layer material. This plastic deformation is also apparent when the test specimens are removed from the test fixture as they do not return to their initially straight shape. After the maximum force point, the force/displacement graph continues in a downward arc before dropping suddenly. This drop illustrates the plastic deformation of the reinforcement layer as was determined using micro-CT imaging and shown in Fig. 7. Characterization of the output graph is important for design and process change effect evaluation of CRTW tubes. The maximum force and buckle points can be identified and compared to other designs using this data and related to likelihood of failure occurrence.

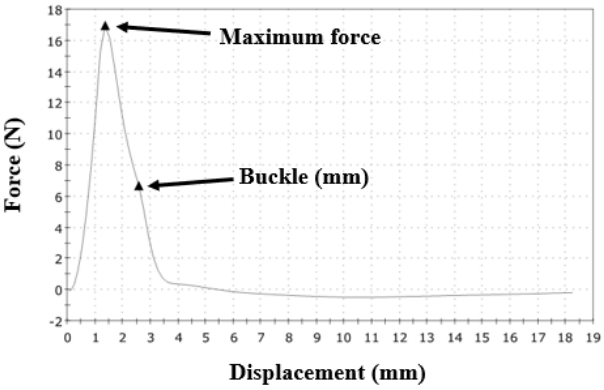

Fig. 6 Output graph from buckle test showing points of maximum force and buckle

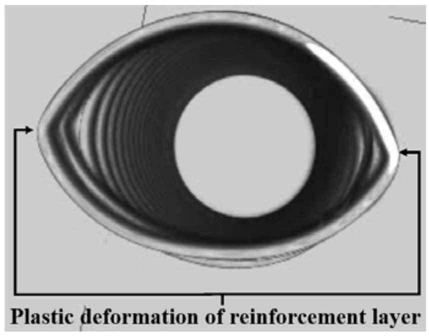

Fig. 7 Image obtained from micro-CT data showing plastic deformation of the reinforcement layer where buckle had occurred

VIII. Three Point Bend Test Method

The suitability of a TPB test for design and process effect evaluation was investigated with informative conclusions in relation to the finalised measurement system being drawn from four experiments (TPB test 1 to 4). The span of the lower anvils and the displacement rate of the upper anvil during the test were informed by ISO 178 [15]. The parameters chosen for statistical analysis were maximum force (N) and bending stiffness measurement (N/mm). This paper presents the stiffness results only as this data was shown to be superior to the maximum force data in terms of probability values and coefficient of determination.

The results from TPB test 1 were promising with the stiffness measurement of the low temperature sample having a statistically significant difference with respect to the nominal and high temperature samples. This provided motivation to carry out further tests as no difference between samples had been measured in the buckle test experiments indicating that there was insufficient sensitivity. Fig. 8 shows the relationship observed between the samples. It is contrary to the relationship presented in Fig. 2 which prompted further investigated as carried out through TPB test 2.

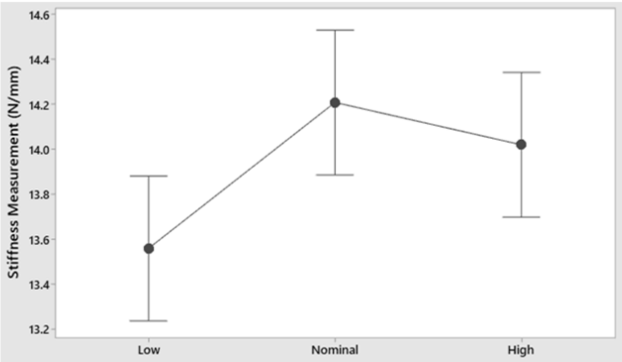

Fig. 8 Interval plot of TPB tests 1

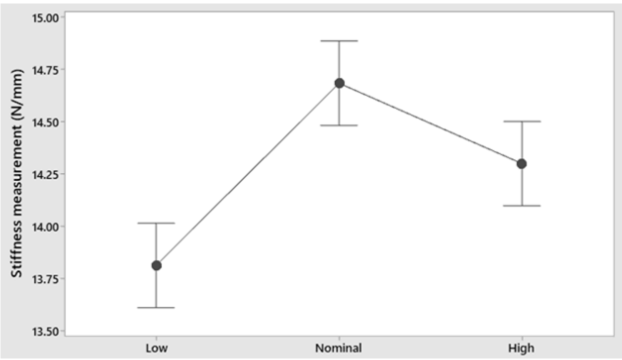

Fig. 9 Interval plot of TPB test 2

The purpose of TPB test 2 was to verify whether the relationship between low, nominal and high samples shown previously was true, an anomaly or caused by insufficient sensitivity and experimental power. Thirty specimens were tested in each sample with the results of TPB test 2 displaying the same relationship as TPB test 1 as presented in Fig. 9. Investigation into these results revealed that not all the test specimens for TPB test 2 had been manufactured using the same process machine and that this was a potential confounding variable. This discrepancy was addressed, and the nominal sample data was replaced with a new set of data obtained using specimens manufactured on the correct process machine. The relationship between high, nominal and low samples did not change but a statistically significant difference between the samples made using differing machines existed confirming that processing machine is a confounding variable.

In order to test the reliability of the three-point bend test set-up, TPB test 3 was conducted using three samples. The parameter varied between low, nominal and high samples was reinforcement layer pitch. The envisaged effect of increasing and decreasing reinforcement layer pitch on the test specimens is a respective decrease and increase of stiffness measurement of the specimen. The results of TPB test 3 shown in Fig. 10 indicate that the test method is reliable from the strong negative correlation between pitch and stiffness.

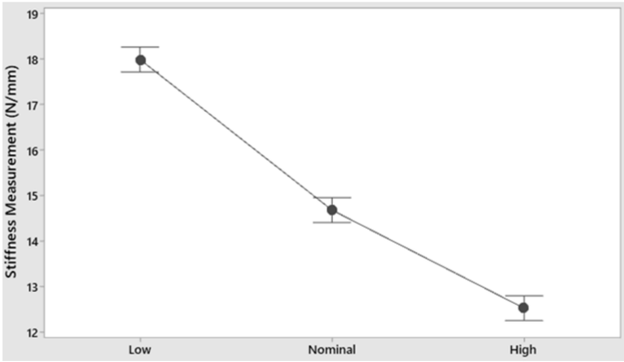

Fig. 10 Interval plot of TPB test 3

TPB test 4 was carried out as a final repeat of TPB test 1 with additional precautions taken to control confounding variables. The results of this test, shown in Fig. 11, differed unexpectedly to the results of TPB test 1 and 2 suggesting that the test method is in fact not sensitive enough to accurately measure the difference between CRTW tube specimens made at high, nominal and low process setting. The test method is observed to give reliable readings as per TPB test 3, but these results fall over a larger interval with a maximum difference in means of 5.45 N/mm in comparison to 0.65, 0.53 and 0.42 N/mm for TPB test 1, 2 and 4 respectively. Characterisation of sensitivity of the TPB test could be completed by carrying out additional experiments where pitch is used as the variable.

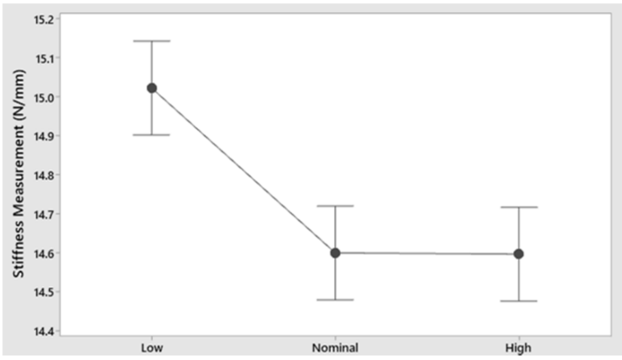

Fig. 11 Interval plot of TPB test 4

The results of TPB test 1 to 4 can therefore be used to inform the basis for a calibration procedure as part of the final measurement system design. Such a procedure will be used to identify the interval over which results can be reliably obtained. This could be achieved through decreasing the difference in pitch between high, nominal and low temperature samples in proceeding tests until the relationship between stiffness measurement and pitch is no longer appearing reliably. The interval for which the test method can be said to reliably produce data may be taken as the interval in which results show the same relationship as Fig. 10 before becoming noisy.

IX. Conclusions

The results of this work can be used to rationalise suggestions for a finalised measurement system such as the test configuration, guidelines for interpreting the results and calibration.

A. Test Configuration

Based on findings from the buckle and TPB testing, the test method implemented in the finalized measurement system should comprise of a four-point bend test. The rationale supporting this is the insufficient sensitivity observed in results from these test configurations. A four-point bend test eliminates shear at the longitudinal center of the test specimen where failure occurs and it allows the specimen to fail in pure bending which is more relevant to how the device fails during use [2]. Additionally, four-point bending is more suitable for non-homogenous test specimens as the stress concentration on the specimen is spread between the two loading anvils whereas for a three-point bend test it is concentrated under the single loading anvil, which is undesirably coincident with the region in which failure occurs [19].

B. Guidelines for Interpretation of Results

Output plots for both the buckle test and TPB test follow the shape represented in Fig. 6. Guidelines for interpreting areas of significance associated with the graph are described in section VII. Buckle Test Method. The sequence of events leading to failure of the test specimen will be the same in four point bending as in three-point bending as they are both bend tests. Hence, the output plot from the four-point bend test will follow the same trajectory and these guidelines will be applicable.

A foundation, a finalized measurement system for effect evaluation on CRTW tube device performance, has been provided. It is hoped that the findings and lessons learned presented in this paper facilitate an avenue for further innovation in the area of intravenous medicine.

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