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# Maximization of Hydraulic Flow through Small Flexible Polymer Tubes by the Optimization of Tubing Stiffness and Wall Thickness

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# ABSTRACT

## Maximization of Hydraulic Flow Through Small Flexible Polymer Tubes by the Optimization of Tubing Stiffness and Wall Thickness



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As illness becomes increasingly more common in the United States and across the globe, the need for better and faster medical treatment is greater than ever. The purpose of this work is to evaluate advanced polymers and polymer composites that will provide for increased fluid flow while maintaining outer dimensional, stiffness, and burst resistance characteristics when compared to a currently used material.

A polymer configuration consisting of a proprietary formulation that has a durometer approximately 10% higher than the current material with an outer wall thickness of approximately .020” passed a series of tests involving tensile strength, stiffness, flexural fatigue resistance, vacuum lumen collapse resistance and hydraulic burst resistance.

This material configuration passed the requirements for applicable test standards and had a tensile strength 13.4% less than the control group, was 52.7% stiffer, did not sustain any noticeable wear or defects during the flexural fatigue test, had a tensile strength 14.8% less that the control group during a post flex fatigue tensile test, did not burst when 150 psi was applied to it for 5 seconds, and is estimated to have a 43% higher flow rate capacity than the current material.



Keywords: carbon nanotubes, central venous catheter, flow, glass beads, stiffness, tensile

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# 1. INTRODUCTION

## 1.1. Background and Motivation

As illness becomes increasingly more common in the United States and across the globe, the need for better and faster medical treatment is greater than ever. Some treatments for these illnesses require frequent access to the patient's central vasculature. Chemotherapy, insulin delivery, dialysis, saline hydration, neonatal treatment, intravenous infusions and drug delivery applications are among those treatments.

When a patient starts long term treatment a surgeon inserts a central venous catheter (hereafter referred to as CVC). These are a subgroup of central venous access devices placed into a major vein. Long term CVCs are fitted with a cuff that allows the skin to grow into it so that the incision site doesn't stay an open wound. This catheter will stay in the patient for a minimum of three weeks and up to years (Ash, 2001). This solution also allows patients to undergo treatment without having to go under the knife every time they need a medical treatment.

Treatments do not have a specific duration or frequency but are determined on a case by case basis. However, it is not uncommon for some patients to have treatments lasting three to four hours and up to three times per week such as is a common practice for patients receiving dialysis (Hampton, 2012). Over the course of a year that could add up to 624 hours, the equivalent of 26 full days. Therein lies an opportunity for improvement. If the same level of treatment could be finished in less time, patient discomfort and inconvenience caused by central venous treatments could be reduced significantly.

## 1.2. Evolution of Central Venous Catheters

CVCs have been made out of many different materials over the years and have continued to evolve as new technologies and ideas appear. Materials that have been used in dialysis catheters have included: polyethylene, Teflon, silicone, polyurethane, and polycarbonate-based thermoplastic polyurethanes (Ash, 2001). Polyethylene is no longer used because it is intrinsically too rigid and kinks too easily. Teflon is no longer used because it cannot be molded after extrusion and is difficult to glue to any material. Silicone is not used because it is too soft and needs to have fairly thick walls in order to have the strength required for the insertion process and to keep the lumens from collapsing. Most CVCs made today are composed of polyurethane. Although polyurethane is significantly weakened by alcohol which is a main ingredient in many antiseptic cleaners. Polycarbonate-based polyurethanes have all the advantages of urethane without the severe reaction to alcohol.

## 1.3. Methodology

Adding fillers is one inexpensive potential method for obtaining different physical properties than originally offered by the base polymer. Another method is to change the base polymer to a different durometer. This research experimented with proprietary polymers and polymer composites using glass beads and carbon nanotubes as fillers in order to increase the inner diameter of the lumens of dual lumen CVCs through thinning of the walls of the tube. Research was designed and statistically analyzed as a design of experiments.

### 1.3.1. Glass Beads

Glass beads are fairly common polymer fillers since they are inexpensive, non-toxic, and non-bioactive. Kwok and his team measured how the difference in bead diameter impacts tensile modulus. They found when comparing bead diameters that as the % wt volume increased from 0-25% the polypropylene used in their study with glass bead diameters of 3.0, 5.7, and 8.9 μm generally increased the tensile modulus. Meanwhile, the polypropylene increased in tensile modulus with increasing % wt of 2.7 μm glass beads up to 7% wt volume then decreased below the tensile modulus of the polypropylene without any glass bead filler (Kwok, 2003).

### 1.3.2. Carbon Nanotubes

Carbon nanotubes (CNTs) are tiny tubes comprised of carbon molecules arranged in a cylindrical structure with diameters as small as .33nm (Peng, 2000) and a length-to-diameter ratio as large as 132,000,000:1. Carbon nanotubes are grouped into families: Single Walled Carbon Nanotubes, (SWCNTs) and Multi-Walled Carbon Nanotubes (MWCNTs). Environmental conditions during CNT creation determine which type of carbon nanotubes grows (Ajayan, 2000). As indicated by its name, SWCNTs are comprised of a single layer of carbon molecules. MWCNTs are made up of at least two layers of carbon molecule tubes set in a "tube within a tube" configuration. Although carbon nanotubes are a fairly new innovation and are still scrutinized by the Food and Drug Administration (FDA), the FDA has not come out with a statement indicating that CNTs are not allowed in medical devices.

## 1.4. Research Problem

Administering central venous medical treatments is a business with slim margins. One of the goals of medical centers is to provide the quickest service possible to their patients. A challenge with providing very fast treatments where fluid is being exchanged with the patient is that higher flow rates result in higher hydraulic resistance. In order to be able to pump faster and keep hydraulic resistance low the tubes through which the blood flows need to be enlarged. This can be done in two different ways. The first is to proportionally increase the size of the inner and outer diameters of the tube. However, doing this increases the French size of the CVC. The second option is to thin out the catheter wall by increasing the inner diameter of the tube while maintaining the outer diameter at its current dimensions. This comes with its own set of challenges as the new dimensions of the catheter must possess the characteristics to pass federal and international regulations and standards.

Hypothesis:

Advanced polymer materials will allow for the creation of a dual lumen central venous catheter that will provide increased fluid flow while maintaining outer diameter, stiffness, and burst resistance characteristics when compared to a control group.

### 1.5. Catheter Characteristics to Take into Consideration

According to the applicable standards, such as ISO 10555-1 which dictates testing for sterile, single-use intravascular catheters, central venous catheters need to be able to withstand more than 15 Newtons (3.372 lbf.) of tensile force before breaking, and approximately 150 psi of hydraulic pressure without bursting. Many of the applicable standards also outline methods for corrosion resistance and air leakage into the hub. These tests will not be part of this research.

## 1.6. Research Delimitations

Since this research only involves flexible tubing, only polymers will be considered as a possible tube medium. Catheter geometry will not be considered as a variable, however, lumen inner diameter will be considered as variable. Outer tube diameter will remain constant.

## 1.7. Definition of Terms

*Burst resistance* - the ability of the tube to maintain structural integrity under hydraulic pressure.

*Flow* - the movement of fluid through a tube.

*Flexural fatigue resistance* - the ability of the tube to maintain structural integrity after being kinked multiple times.

*French scale* – an indication of catheter diameter, a higher French size indicates a larger diameter.

*Luer* - a connector for making leak-free connections between medical and laboratory equipment

*Lumen* - the space inside a tubular structure

## 1.8. Assumptions Made

4,500 repetitions are representative of the number of times the tube may be kinked during its useful lifetime.

# 2. LITERATURE REVIEW

## 2.1. Medical Treatments

Central venous catheters are used when repeated access to a patient's cardiovascular system is needed (Mankus, 1998). If treatment is going to last more than three weeks long term CVCs are used due to the increased infection risk of using short term catheters over time (Tal, 2008). Some of the ways that long term central venous catheters differ from short term catheters are long term catheters are usually softer than their short term counterparts and long term catheters have a cuff that the skin can grow into, closing the body off to harmful bacteria. CVCs can be utilized as temporary treatment so that a dialysis fistula can be prepared or when a fistula is not an option for the patient (Wahl, 1999). For patients whom a fistula is no longer an option, central venous catheters are devices that allows them to live an "as normal as possible" life as they can. Multi-lumen CVCs can also be used as a means to infuse multiple drugs simultaneously and independently at different rates (Lakhal, 2006).

Although the frequency and duration of medical treatments are decided on a case by case basis, it is not uncommon for treatments such as dialysis to last three to four hours per treatment, three times per week (Hampton, 2012). If you include travel and check in, this process could easily turn into a 5 hour process. This research seeks to identify a new polymer that will allow for thinner walled central venous catheters so that treatment duration can be reduced without reducing the quality of the treatment. Decreasing treatment time benefits not only the patient but also the medical treatment centers. In the United Kingdom, the number of dialysis patients 65 years of age and older grew by 29% from 2005 to 2008, with similar rates in the United States from 1993 to 1995 (Brown, 2011). And the number of patients needing dialysis treatments continues to grow. A study led by Johns Hopkins Bloomberg School of Public Health researchers indicated that the overall prevalence of chronic kidney disease increased between 1988-1994 and 1999-2004, from 10% to 13% inside the United States (Coresh, 2007). As a whole in the US, chronic kidney disease grew from 209,000 people to 472,000 in 2002 (Coresh, 2007). As of 2008, 25% of dialysis patients in the US used catheters for their dialysis treatments (Tal, 2008). In the United States, rates of ER-positive breast cancers were projected to increase 5.3% between 2011 and 2016 (Anderson, 2011) and oral cancer accounts for roughly two percent of all cancers diagnosed annually in the United States with approximately 35,000 people diagnosed with oral cancer each year (Bethesda, 2010). As central venous catheters are used during treatment in these and other instances, a need for improved catheter flow rates exists.

There are a number of concerns associated with intravenous catheters and many different ideas and technologies have been used to alleviate these concerns. Although not included as an objective in this research, infection, fibrin sheath, thrombosis, hemolysis, and blood recirculation are a few of these concerns. Patients shouldn’t have an infection when having a CVC placed and must have negative blood cultures for at least 48 hours before placement surgery because clots may form inside the catheter sheath (Wahl, 1999). One method of helping to prevent infection is by impregnating the catheter with antimicrobial/antiseptic solutions (O’Grady, 2011). Fibrin sheath occurs when tissue grows around the catheter that is inside the vein. This reduces blood flow and can provide a breeding ground for harmful bacteria. If not properly maintained, thrombosis may occur inside of the catheter. Thrombosis is the formation of a blood clot inside of a blood vessel (Mankus, 1998). This is especially dangerous because if the clot becomes dislodged it can float to smaller blood vessels blocking blood flow. Hemolysis can occur when blood is improperly manipulated or processed. A group of nurses noted that there is a direct correlation between the inner diameter of catheters and hemolysis. These nurses found that as the inner diameter of catheters grew, hemolysis occurrences declined (Kennedy, 1996). Other catheter considerations include thickness, strength, flexibility, rigidity, molding capabilities, and chemical compatibility.

Catheter wall thickness is important because the inner diameter of the catheter should be as big as possible while keeping the outer diameter as small as possible. This naturally leads to thin walls. Having a large inner diameter opening may also reduce the risk of thrombosis and fibrin sheath (Ash, 2007). Having a strong catheter that can withstand the stresses of insertion and daily use is also important. The catheter must be strong enough to avoid cracks and breaks, while at the same time being flexible enough not to pose the risk of puncturing a vein (Ash, 2001). Catheters must also be resistant to kinking. Softer materials tend to kink less than more rigid materials but they also require thicker walls. Technologies such as Nickel-Titanium wires and microtubes have been used in medical device tubing to reduce this kinking problem (Pelton, 1994). During insertion, many clinicians use ultrasound guidance as it is recognized as the gold standard for CVC insertion (Moureau, 2013). In addition to helping to prevent catheter kinking ultrasound guidance also aids in correct catheter placement (Gibson, 2013).

Central venous catheters have changed and evolved over the years, catheter geometry design includes split sheath, concentric circles, double D, and side by side circles. Each design has unique properties; however the double D design has been shown to have the least amount of hydraulic resistance, and thus best flow, for a given French size when compared against the side by side circle and concentric circle designs (Ash, 2007).

CVC materials have changed over the years as well. Materials that have been used in CVCs include: polyethylene, Teflon, silicone, PVC, polyurethane, and polyurethane/polycarbonate copolymers. Polyethylene is naturally rigid to a degree and so there was concern that it may puncture blood vessel walls. Teflon stopped being readily used because it cannot be molded after extrusion and it is difficult to flue to any material, including Teflon. Silicone is naturally very soft and flexible which means it resists kinking well. However, as a result of its low durometer it requires fairly thick walls. Silicone is able to be used with alcohol, but can be degraded by some povidone-iodine solutions and peroxide (Hamilton, 2008). PVC is less popular as a CVC because of its strong correlation with thrombus creation (Polderman, 2002). Polyurethane is the most dominate material for central venous catheters. Polyurethane can have a high or low durometer and can be molded after extrusion. The primary drawback of polyurethane is that it has a weakness to alcohol. Polyurethane/polycarbonate copolymers have all of the advantages of polyurethane and are resistant to iodine, peroxide, and alcohol (Mankus, 1998).

## 2.2. Carbon Nanotubes

Carbon nanotubes (CNT) are commonly found in aerospace materials and sporting equipment, but less commonly seen in medical applications. This is in part because of the high level of scrutiny that CNTs receive from the FDA, and slow willingness of the industry to implement new material advances. Polymer fillers, including CNTs, can be bonded to the matrix material in three ways: they can be micro-mechanically interlocked, chemically bonded, or use weak Van der Waals bonding (Bal, 2007). Micro-mechanical interlocking is difficult to achieve with nanotubes simply due to their smooth nature, however due to minor imperfections in the tube micro-mechanical interlocking is achievable. Depending on the matrix material chemical bonding is a possibility as well. In the absence of chemical bonding, weak Van der Waals bonding is the origin of the interactions between CNT and the matrix material.

CNT have remarkable strength properties in the axial direction but are relatively weak in the transverse. To help compensate for this in this study the carbon nanotubes weren't forced into a unidirectional pattern, and thus helped strengthen the matrix material in all directions.

### 2.3. Glass Beads

Glass beads have been used as fillers in polymers for a long time. They are fairly inexpensive and have properties that make them more desirable than other cheaper fillers such as clay, ground limestone or minerals.

In a comparison of the effect of bead diameters of 2.7, 3.0, 5.7, and 8.9 μm it was observed that as the % weight (wt) volume increased from 0- 25% the polypropylene used in their study with glass bead diameters of 3.0, 5.7, and 8.9 μm generally increased the tensile modulus. Meanwhile, the polypropylene with glass bead a diameter of 2.7 μm increased up to about 7% wt volume then decreased below the tensile modulus of the polypropylene without any glass bead filler (Kwok, 2003).

## 3. METHODOLOGY

The scope of this research was to use an existing dual lumen fluid delivery polyurethane catheter as the control material and the standard for comparison to three proposed alternate materials. This research included three different proprietary polymers. These will be referred to as samples: A, B, and C. Each polymer was tested with three different wall thicknesses (referred to as wall thickness: 1, 2, and 3.) The first material (A) was a composite of the control polyurethane compounded with approximately 4% by weight glass beads. The glass beads are soda lime solid glass microspheres approximately 4 microns in diameter. The second material (B) was a composite of the control polyurethane compounded with approximately 1% by weight carbon nanotubes. The carbon nanotubes used in this research were a mix of single walled and multi-walled nanotubes of varying diameters and lengths. The third material (C) was the control polymer with an increased Shore A hardness. An increase in hardness is an indication of a more crystalline structure. The proposed resin formulation had an approximate hardness increase of 10%. The dimensions of the dual lumen tubing was a fixed OD and three specified wall thicknesses, .020” (1), .015” (2), .010” (3). All tubing samples were cut to 3 inch lengths unless otherwise stated and preconditioned in 37$^{o}$C deionized water for a minimum of two hours before performance testing occurs. All results were statistically analyzed.

### 3.1. Dimensional Testing

Controlled dimensions are defined in Figure 3. For this work only the lumen area was measured. Measurements were made using a coordinate measuring machine. This was measured on ten samples .2” tall taken from ten different areas of the tubing.

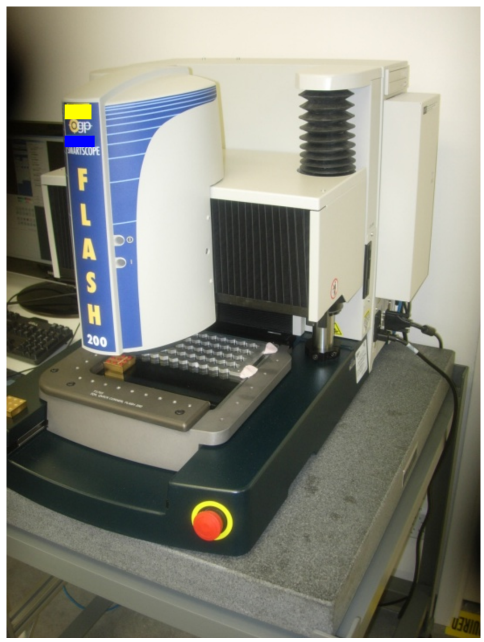


**Figure 1 - Coordinate Measuring Machine**

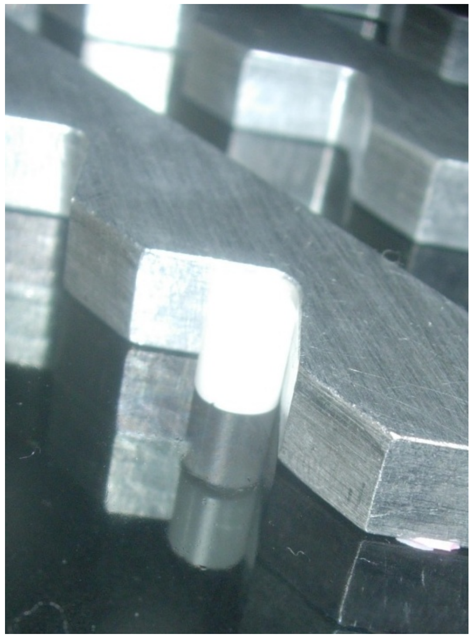

**Figure 2 - Tubing Segment Being Measured**

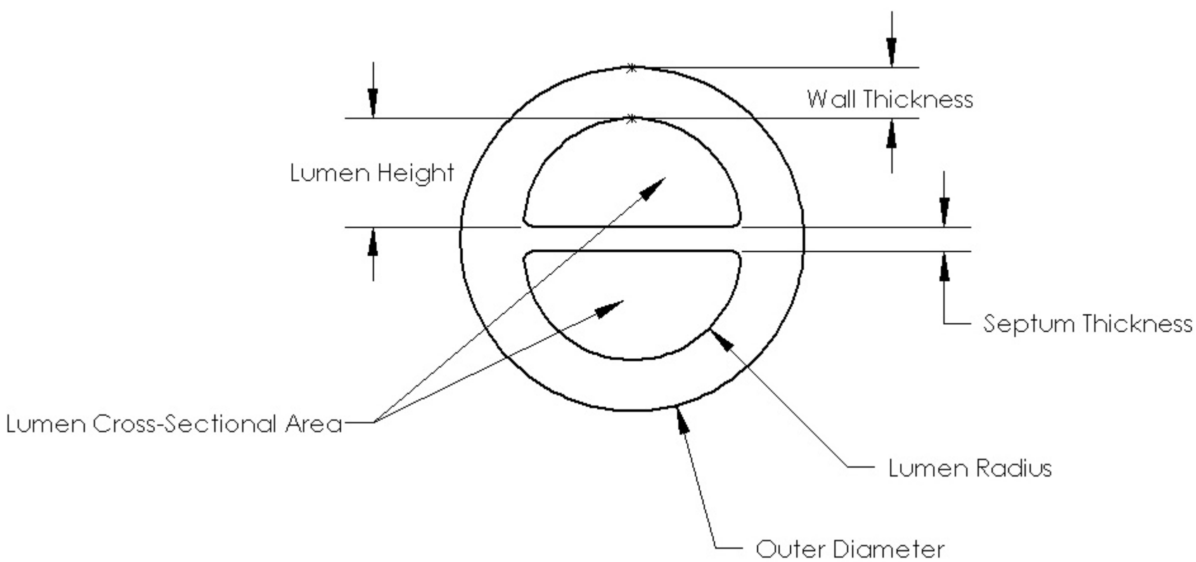


**Figure 3 - Visual Definitions of Measurements**

### 3.2. Tensile Tests

Tensile tests were conducted using an Instron 5965 and 2kN pneumatic side action grips as shown in Figure 4. Gauge lengths were set to 1 inch and the cross head speed was 20 inches/min. Maximum tensile strength was recorded through Instron's Bluehill 2 software.

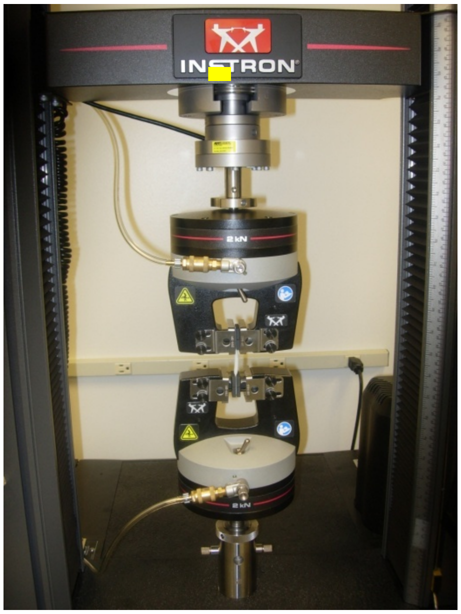


**Figure 4 - Instron Tensile Testing Machine with Tubing Segment Installed**

### 3.3. Stiffness Tests

Stiffness tests was performed using an Instron 5965 using a 3-point bend test with supports two inches apart, See Figure 5. The septum was placed parallel to the ground. Crosshead speed was 2 inches/min. Total cross head movement was .06 inches; measurements were taken automatically through Instron's Bluehill 2 software .03 inches after contact has been made by the aluminum blade. As there is no standard to test against for stiffness there is no definitive way to reject any of the test configurations. An end user evaluation would be required to determine whether or not a specific configuration is too stiff or not stiff enough.


**Figure 5 - Instron Machine with Tubing Segment Undergoing Stiffness Testing**

### 3.4. Flexural Fatigue Tolerance Tests

Using the same samples that were used in the stiffness test a flexural fatigue tolerance test was performed on a pneumatic apparatus that took the samples from 180° (Straight) to 30°. See Figure 6 and Figure 7. Samples were flexed 4,500 times, after a rest period of at least 24 hours samples were characterized based on discoloration, cracking, and other deformations. These samples were then tensile tested following the parameters specified in the tensile test section.

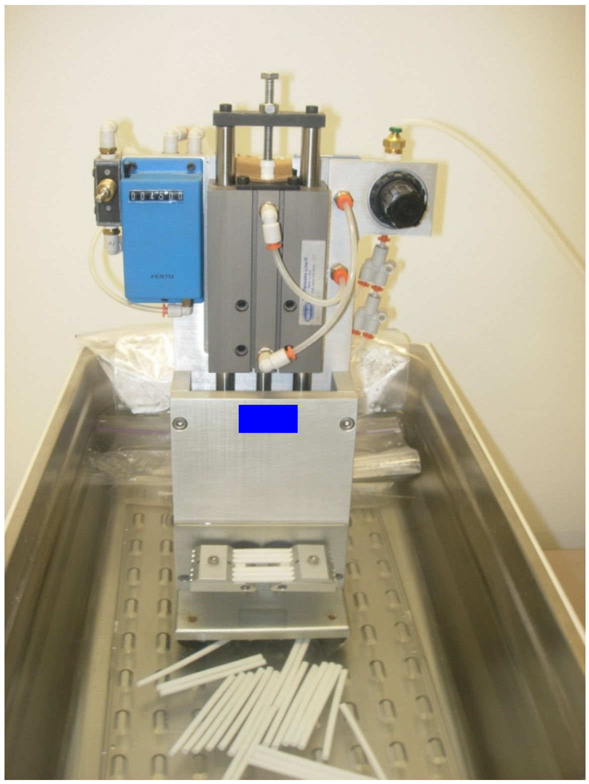

**Figure 6 - Flexural Fatigue Tester, Open Position**

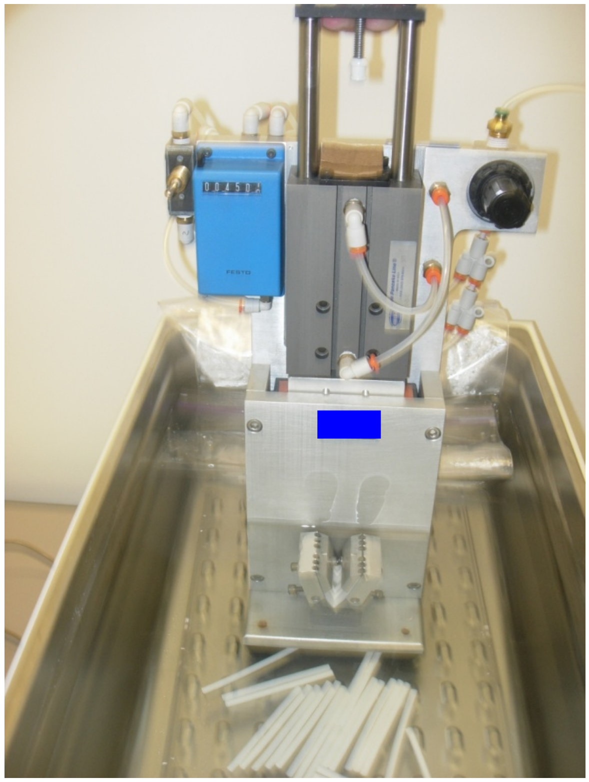

**Figure 7 - Flexural Fatigue Tester, Closed Position**

## 3.5. Lumen Collapse Resistance Tests

Lumen collapse resistance tests were performed by fitting a luer attachment on to one end of the samples via a UV bonding process, the other end was pinched closed by hemostats. The luer attachment was fitted to a device capable of measuring pressure and a syringe capable of creating a vacuum. See Figure 8. Maximum vacuum was applied to six inch tubing samples.

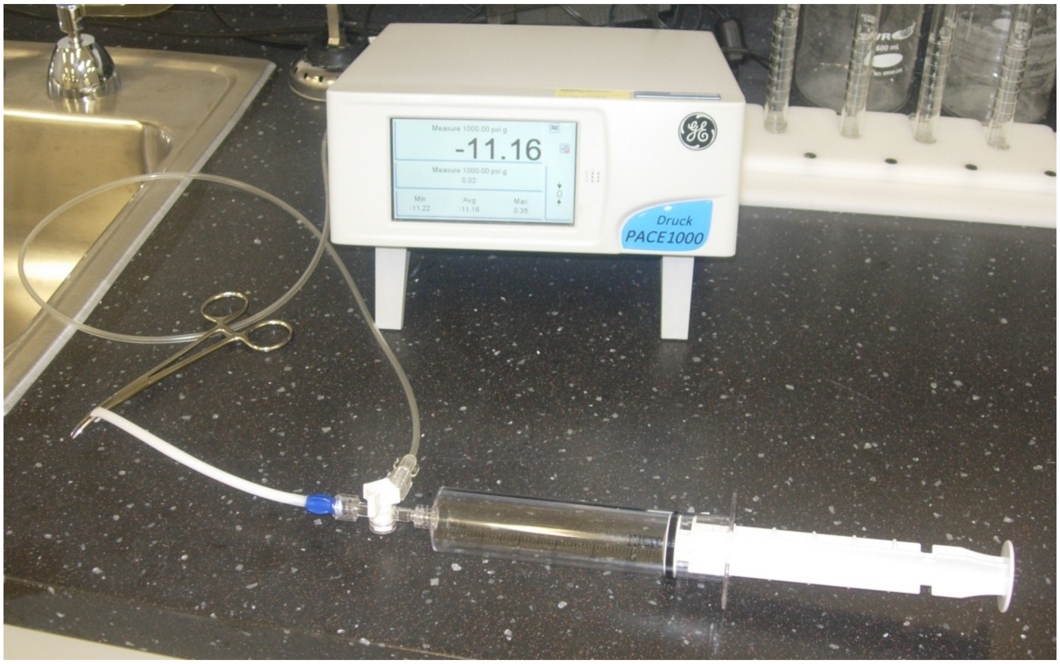


**Figure 8 - Vacuum Test Setup**

### 3.6. Hydraulic Burst Resistance Tests

Hydraulic burst resistance tests were performed using the same tubing samples as the lumen collapse tests. Samples were folded and clamped with hemostats so the test length was approximately 3 inches. Test samples were then attached by the luer fitting that was applied for the lumen collapse test to a hydraulic testing machine. Samples were pressurized to 150 psi and held at that pressure for 5 seconds as shown in Figure 9. Ramp rate was 50 ml/min. Results were recorded manually as pass/fail.

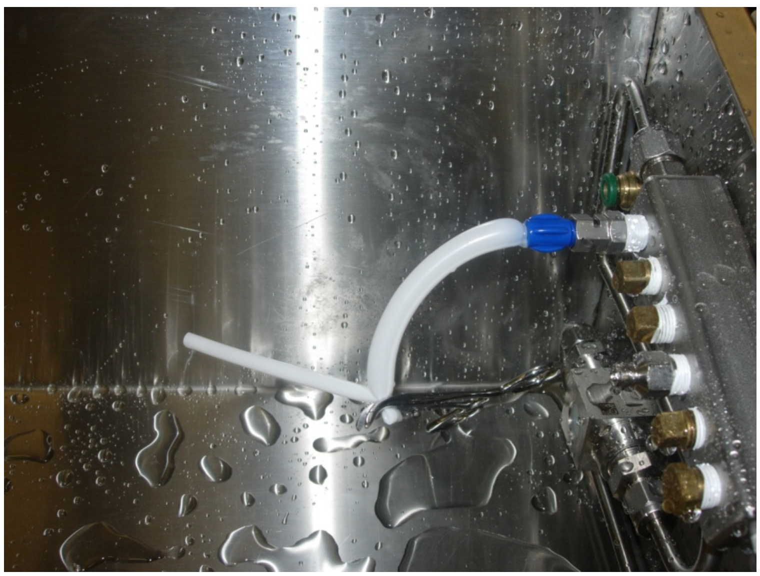

**Figure 9 - Tubing Segment Undergoing Hydraulic Burst Resistance Testing**

## 4. RESULTS AND ANALYSIS

This section reports the results of the mechanical performance tests and a discussion and comparison of the data in regards to the material choice and tubing design. Most results from this section are presented as a percentage of the control group with 100% being identical to the control.

### 4.1. Dimensional Measurements

The dimensional measurement that is of most interest in this document is the lumen cross-sectional area, these dimensions are reported in Table 1 which shows the results of the measured cross sectional area for the test samples, in relation to the control samples.

**Table 1 - Dimensional Measurement Characterization, Lumen Cross-Sectional Area**

| Configuration | A1 | A2 | A3 | B1 | B2 | B3 | C1 | C2 | C3 | Control Group |
|---|---|---|---|---|---|---|---|---|---|---|
| Mean ($cm^2$) | 0.1104 | 0.1268 | 0.1359 | 0.1179 | 0.1290 | 0.1374 | 0.1137 | 0.1275 | 0.1315 | 0.0795 |
| Std. Dev. | 0.0059 | 0.0066 | 0.0052 | 0.0053 | 0.0082 | 0.0105 | 0.0042 | 0.0031 | 0.0055 | 0.0045 |

## 4.2. Tensile Testing

Samples were tensile tested per the method described in section 3.2. The data was then analyzed using an F-Test, which allows for a different number of samples in each group, for each of the test samples in comparison to the control group.

The 'A' group polymer compound results were as follows. For the A1 group, the F-Test inference p-Value was 0.000; for the A2 group, the F-Test inference p-Value was 0.000; and for the A3 group, the F-Test inference p-Value was 0.000. For an alpha value of 0.05 for significance, this demonstrates the A1, A2, and A3 configurations are statistically significantly different from the control configuration. These configurations had a lower tensile strength than the control material due to reduced wall thickness, and decreased polymer chain entanglement, which allowed for the chains to slip and move thus decreasing strength. Although the configurations used with the group 'A' material exhibited a decrease in mechanical properties performance when compared to the control group, they still met the minimum requirements for the applicable standard tests and thus material 'A' in any of the tested configurations could be considered a viable alternative for the control material.

The group 'B' polymer compound samples were individually compared statistically using an F-Test in relation to the control material. The B1 group, F-Test inference p-Value was 0.000; for the B2 group, the F-Test inference p-Value was 0.000; and for the B3 group, the F-Test inference p-Value was 0.000. For an alpha value of 0.05 for significance, this demonstrates the B1, B2, and B3 resin compounds are statistically significantly different from the control material. These resin compounds had a lower tensile strength versus the control material for reasons similar to the samples from group 'A'. Although the configurations used with the group 'B' material exhibited a decrease in mechanical properties performance when compared to the control group, they still met the minimum requirements for the applicable standard tests and thus material 'B' in any of the tested configurations could be considered a viable alternative for the control material.

The F-Test results for the group 'C' polymer compound in relation to the control material were: The C1 group F-Test inference p-Value was 0.000; for the C2 group, the F-Test inference p-Value was 0.000; and for the C3 group, the F-Test inference p-Value was 0.000. For an alpha value of 0.05 for significance, this demonstrates the C1, C2, and C3 resin compounds are statistically significantly different from the control material. These resin compounds had a lower tensile strength versus the control material due to decreased wall thickness. Although the configurations used with the group 'C' material exhibited a decrease in mechanical properties performance when compared to the control group, they still met the minimum requirements for the applicable standard tests and thus material 'C' in any of the tested configurations could be considered a viable alternative for the control material.

A one-way ANOVA analysis of A1, B1, and C1 indicated that they were not equivalent shown by a p-Value of 0.000. A2, B2, and C2 indicated that they were not equivalent shown by a p-Value of 0.000. A3, B3, and C3 indicated that they were not equivalent shown by a p-Value of 0.000. Table 2 shows the characterization as compared to the control group (% of control sample value).

**Table 2 - Tensile Testing Characterization**

| Configuration | A1 | A2 | A3 | B1 | B2 | B3 | C1 | C2 | C3 |
|---|---|---|---|---|---|---|---|---|---|
| Mean | 62.0% | 55.8% | 44.6% | 70.3% | 65.6% | 50.0% | 86.6% | 66.2% | 63.6% |
| Std. Dev. | 1.718 | 2.804 | 1.136 | 1.610 | 0.820 | 1.827 | 1.592 | 1.693 | 1.831 |

### 4.3. Stiffness Testing

As there were an equal number of stiffness samples between each of the test groups and the control group a T-Test was performed for each of the treatment combinations.

For the A1 group, the T-Test inference p-Value was 0.000; for the A2 group, the T-Test inference p-Value was 0.000; and for the A3 group, the T-Test inference p-Value was 0.000. For an alpha value of 0.05 for significance, this demonstrates the A1, A2, and A3 configurations are statistically significantly different from the control configuration. These configurations require less force to deflect the tube than the control configuration due to decreased wall thickness, and decreased polymer chain entanglement, which allowed for the chains to slip and move thus increasing plasticity. Although the configurations used with the group ‘A’ material exhibited a decrease in stiffness, there is no known standard test or requirement to determine acceptability. Thus material ‘A’ in any of the tested configurations could be considered a viable alternative for the control material.

For the B1 group in relation to the control material, the T-Test inference p-Value was 0.000; for the B2 group, the T-Test inference p-Value was 0.000; and for the B3 group, the T-Test inference p-Value was 0.000. For an alpha value of 0.05 for significance, this demonstrates the B1, B2, and B3 configurations are statistically significantly different from the control configuration. These configurations require less force to deflect the tube than the control configuration for the same reasons that were given for group ‘A’. Also as with group ‘A’ due to the lack of a known standard test or requirement to determine acceptability, material ‘B’ in any of the tested configurations could be considered a viable alternative for the control material.

The T-Test for the group ‘C’ polymer compounds individually in relation to the control material. For the C1 group, the T-Test inference p-Value was 0.000; for the C2 group, the T-Test inference p-Value was 0.000; and for the C3 group, the T-Test inference p-Value was 0.000. For an alpha value of 0.05 for significance, this demonstrates the C1, C2, and C3 configurations are statistically significantly different from the control configuration. The C1 and C2 configurations required more force to deflect the tube than the control configuration due to the polymer properties, while the C3 configuration required less force to deflect the tube than the control configuration due to decreased wall thickness. Although the configurations used with the group 'C' material exhibited a change in stiffness again there is no known standard test or requirement to determine acceptability. As such material 'C' in any of the tested configurations could be considered a viable alternative for the control material.

A one-way ANOVA analysis of A1, B1, and C1 indicated that they were not equivalent shown by a p-Value of 0.000. A2, B2, and C2 indicated that they were not equivalent shown by a p-Value of 0.000. A3, B3, and C3 indicated that they were not equivalent shown by a p-Value of 0.000. Below is a characterization table as compared to the control group (% of control group value).

**Table 3 - Stiffness Testing Characterization**

| Configuration | A1 | A2 | A3 | B1 | B2 | B3 | C1 | C2 | C3 |
|---|---|---|---|---|---|---|---|---|---|
| Mean | 52.8% | 47.0% | 29.7% | 57.5% | 44.8% | 31.8% | 152.7% | 113.1% | 87.0% |
| Std. Dev. | 0.222 | 0.388 | 0.087 | 0.250 | 0.135 | 0.158 | 1.076 | 1.193 | 0.769 |

### 4.4. Flex Fatigue Resistance

All configurations were able to endure 4,500 flex repetitions without sustaining any noticeable wear or defects. This is likely because the material properties of the test groups are similar enough to the control group thus no noticeable difference can be detected at 4,500 flex repetitions. This indicates that all samples would pass this criterion for selection as an alternative for the control sample in this test.

### 4.5. Post Flex Fatigue Tensile

A different number of samples were analyzed thus an F-Test was performed for each of the treatment combinations. For the A1 group, the F-Test inference p-Value was 0.000; for the A2 group, the F-Test inference p-Value was 0.000; and for the A3 group, the F-Test inference p-Value was 0.000. For an alpha value of 0.05 for significance, this demonstrates the A1, A2, and A3 configurations are statistically significantly different from the control configuration. These configurations had a lower tensile strength versus the control material due to the flexural fatigue preconditioning which may have had a larger impact on these test samples due to the filler material, reduced wall thickness, and decreased polymer chain entanglement which allowed for the chains to slip and move thus decreasing strength but increasing plasticity. Although the configurations used with the group 'A' material exhibited a decrease in mechanical properties performance when compared to the control group, they still meet the minimum requirements for the applicable standard tests. Thus, material 'A' in any of the tested configurations could be considered a viable alternative for the control material.

For the B1 group, the F-Test inference p-Value was 0.000; for the B2 group, the F-Test inference p-Value was 0.000; and for the B3 group, the F-Test inference p-Value was 0.000. For an alpha value of 0.05 for significance, this demonstrates the B1, B2, and B3 resin compounds are statistically significantly different from the control material. These resin compounds had a lower tensile strength versus the control material for reasons similar to group 'A'. Although the configurations used with the group 'B' material exhibited a decrease in mechanical properties performance when compared to the control group, they still meet the minimum requirements for the applicable standard tests. Material ‘B’ in any of the tested configurations could be considered a viable alternative for the control material.

Group ‘C’ was also compared to the control material using an F-Test. For the C1 group, the F-Test inference p-Value was 0.000; for the C2 group, the F-Test inference p-Value was 0.000; and for the C3 group, the F-Test inference p-Value was 0.000. For an alpha value of 0.05 for significance, this demonstrates the C1, C2, and C3 resin compounds are statistically significantly different from the control material. These resin compounds had a lower tensile strength versus the control material due to decreased wall thickness. As with ‘A’ and ‘B,’ although the configurations used with the group ‘C’ material exhibited a decrease in mechanical properties performance when compared to the control group, they still meet the minimum requirements for the applicable standard tests. As such material ‘C’ in any of the tested configurations could be considered a viable alternative for the control material.

A one-way ANOVA analysis of A1, B1, and C1 indicated that they were not equivalent shown by a p-Value of 0.000. A2, B2, and C2 indicated that they were not equivalent shown by a p-Value of 0.000. A3, B3, and C3 indicated that they were not equivalent shown by a p-Value of 0.000.

A one-way ANOVA analysis of A1, B1, and C1 indicated that they had a statistically significantly different variance with a p-Value of 0.000. A2, B2, and C2 indicated that they had a statistically significantly different variance with a p-Value of 0.000. A3, B3, and C3 indicated that they had a statistically significantly different variance with a p-Value of 0.000. Below is a characterization table as compared to the control group (% of control group value).

**Table 4 - Post Flex Fatigue Tensile**

| Configuration | A1 | A2 | A3 | B1 | B2 | B3 | C1 | C2 | C3 |
|---|---|---|---|---|---|---|---|---|---|
| Mean | 64.2% | 52.8% | 45.3% | 74.2% | 68.0% | 57.6% | 85.2% | 75.7% | 61.9% |
| Std. Dev. | 1.709 | 2.145 | 1.002 | 1.691 | 2.161 | 1.870 | 2.277 | 2.075 | 1.421 |

### 4.6. Lumen Collapse Resistance

All configurations using material from group ‘A’ collapsed when maximum achievable vacuum was placed on the test samples. These configurations had a lower lumen collapse resistance versus the control material configuration due to reduced wall thickness, and decreased polymer chain entanglement, which allowed for the chains to slip and move thus decreasing lumen strength and increasing plasticity, allowing the lumen to collapse. The results from this test indicate that none of the configurations using the material from group ‘A’ should be considered as viable alternatives for the control material configuration.

All configurations using material from group ‘B’ collapsed when maximum achievable vacuum was placed on the test samples. These configurations had a lower lumen collapse resistance versus the control material configuration for similar causes as group ‘A’. Thus, this test indicates that none of the configurations using the material from group ‘B’ should be considered as viable alternatives for the control material configuration.

The C2 and C3 configurations collapsed when maximum achievable vacuum was placed on the test samples. These configurations had a lower lumen collapse resistance versus the control material configuration due to reduced wall thickness. The C1 configuration did not collapse when maximum achievable vacuum was placed on the test samples. This configuration performed equally as well as the control group configuration due to the polymer compound properties. The results from this test indicate that the C2 and C3 configurations using the material from group 'C' should not be considered as viable alternatives for the control material configuration; however, the C1 configuration could be considered a viable alternative for the control material. As this test was a pass/fail test, a chi-square analysis was used.

**Table 5 - Lumen Collapse Resistance Characterization**

| | Sample Groups | | | | | | | | | | Totals Column |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | A1 | A2 | A3 | B1 | B2 | B3 | C1 | C2 | C3 | Control | |
| **Passed** | 0 | 0 | 0 | 0 | 0 | 0 | 10 | 0 | 0 | 10 | 20 |
| **Failed** | 10 | 10 | 10 | 10 | 10 | 10 | 0 | 10 | 10 | 0 | 80 |
| **Total** | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 100 |
| | Chi-squared calculated | | | 100.00 | | | | | | | |
| | Chi-squared critical | | | 16.92 | | | | | | | |

Since chi–square calculated is 100.00 and greater than chi–squared critical of 16.92 we have enough evidence to reject the null hypothesis that all of the samples are equivalent.

## 4.7. Hydraulic Burst Testing

None of the configurations using material from group 'A' were able to withstand 150 psi for 5 seconds. Failure modes from these configurations included breaking the outer wall of the tube, bursting through the septum, and bond failure. The first two failure modes were due to reduced wall thickness, and decreased polymer chain entanglement, which allowed for the chains to slip and move thus decreasing lumen strength. The bond failure mode was likely due to poor adhesion between the adhesive and the test sample, insufficient adhesive applied to the bonding area, or material deterioration due to UV light exposure or adhesive contact. Since the failures that did burst through the tubing wall were not able to withstand 150 psi for 5 seconds, it is unlikely that any of the bond failures would have produced a test sample that would have been able to pass this test. The results from this test indicate that none of the configurations using the material from group ‘A’ should be considered as viable alternatives for the control material configuration.

All the samples from group ‘B’ failed to withstand 150 psi for 5 seconds. All failures from group ‘B’ involved bond failure. The reasons for the bond failures were likely similar to the reasons given for group ‘A’. Since all of the failures occurred at the bond joint instead of breaking the tubing wall, it is not possible to determine at this time if any of the bond failures would have produced a test sample that would have been able to pass this test. Per the results, none of the configurations using the material from group ‘B’ should be considered as viable alternatives for the control material configuration without further investigation.

The C1 and C2 configuration groups were able to withstand 150 psi for 5 seconds. These configurations performed equally as well as the control group configuration due to their polymer compound properties. Only 2 samples from the C3 configuration were able to withstand 150 psi for 5 seconds. Failure modes from the C3 configuration included one sample that broke the outer wall of the tube and seven samples that experienced bond failure. The bond failure mode likely had similar reasons for failure as groups ‘A’ and ‘B’. It is unclear if any of the bond failures would have produced a test sample that would have been able to pass this test. The results from this test indicated that the C1 and C2 configurations could be considered as viable alternatives for the control material configuration. While the C3 configuration should not be considered as a viable alternative for the control material configuration without further investigation. As this test was a pass/fail test, a chi-squared analysis was used.

**Table 6 - Hydraulic Burst Testing Characterization**

| | Sample Groups | | | | | | | | | | Totals Column |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | A1 | A2 | A3 | B1 | B2 | B3 | C1 | C2 | C3 | Control | |
| **Passed** | 0 | 0 | 0 | 0 | 0 | 0 | 10 | 10 | 2 | 10 | 32 |
| **Failed** | 10 | 10 | 10 | 10 | 10 | 10 | 0 | 0 | 8 | 0 | 68 |
| **Total** | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 100 |
| | Chi-squared calculated | | | | 92.65 | | | | | | |
| | Chi-squared critical | | | | 16.92 | | | | | | |

Since chi–square calculated (92.65) is greater than chi–squared critical (16.92) we have enough evidence to reject the null hypothesis that all of the samples are equivalent.

## 4.8. Theoretical Change in Fluid Flow Rates

Ignoring any other changes that may occur by changing the lumen cross-sectional area the hydraulic flow rate continuity law equation can be used to calculate theoretical differences in achievable flow rates. This equation is as follows:

$$\textit{Flow rate } (Q) = V \textit{ (velocity of flow) } x \; A \textit{ (cross-sectional area of flow)} \qquad (4\text{-}1)$$

Assuming that 450 ml/min is within the normal operating range of the control group, the value of the cross-sectional area given in Table 1 can be used in the equation above to calculate the velocity of flow as approximately 5,660 cm/min. Using that velocity as a constant and inserting the other cross-sectional area values from Table 1 theoretical flow rate values are calculated and given in Table 7.

**Table 7 - Theoretical Flow Rates**

| Configuration | A1 | A2 | A3 | B1 | B2 | B3 | C1 | C2 | C3 |
|---|---|---|---|---|---|---|---|---|---|
| Theoretical Flow Rate (ml/min) | 625 | 721 | 772 | 670 | 731 | 779 | 644 | 724 | 746 |

# 5. CONCLUSIONS AND RECOMMENDATIONS

## 5.1. Conclusions

The objective of this research was to analyze and determine if an alternate new polymer or polymer composite material would be a viable replacement for currently used materials and designs that would allow for a maximized fluid flow for medical treatment catheters. Per the results above, only one configuration was determined to be an acceptable replacement for the control material. This configuration was the C1 configuration. This configuration did not have any filler material added to it, but did have a shore A hardness rating approximately 10% higher than the control group with a wall thickness of .020”

The harder configuration with a .020” wall thickness had a maximum tensile strength average of 13.4% less than the control group average. It was found that all of the test configurations yielded lower values than the control group in tensile testing; however, all configurations pass the tensile requirements set forth in the applicable standards and thus this test does not limit any of the possible configurations as an alternate to currently marketed catheters. The harder configuration with a .020” wall thickness was 52.7% stiffer than the control group as well as did not sustain any noticeable wear or defects in the flexural fatigue test. It can be noted that all of the materials and various wall thickness configurations performed equally as well in the flexural fatigue test compared to the control material of the currently marketed catheter.

Although all the test configuration samples yielded lower values in tension than the control group, they all passed the tensile requirements set forth in the applicable standards. During the post flexural fatigue tensile test the harder configuration with a .020” wall thickness had an average maximum tensile strength 14.8% less than the average of the control group.

Only the samples from the harder configuration with a .020” wall thickness passed the lumen collapse resistance and maximum vacuum tests. Thus, this configuration is the only possible alternative to the control group. The harder material with a .020” and .015” wall thicknesses passed the hydraulic burst test and indicated per this test they are possible alternates to the control group. The harder configuration with a .020” wall thickness did not rupture within 5 seconds of being held at 150 psi.

Based on a theoretical calculation, it is estimated that the harder configuration with a .020” wall thickness would be able to flow at approximately a 43% higher rate than the control group. With the reduction in wall thickness, another benefit to using this configuration is a cost reduction due to less material being used for each catheter.

## 5.2. Summary

Per the results from all the tests performed the harder configuration with a .020” wall thickness is the only possible candidate as an alternative polymer for the medical treatment catheter selected as the control group for this work.

## 5.3. Recommendations

Further testing is recommended as follows: Fully constructed catheters are recommended so the actual flow rates can be measured as well as manufacturability can be assessed with the decreased wall thickness. The completed catheters will further allow for improved hydraulic burst test results as it will eliminate the bond failure mode and allow for all applicable failure modes associated with fully constructed catheters. A larger sample size for burst testing is also recommended. A kink resistance test should be conducted in future testing as it may reveal other tubing properties not found in this work. Different filler ratios of the glass beads and the carbon nanotubes from those used in the proprietary composites used in this research may also yield more favorable results than those found in this work. A higher glass bead %wt ratio would potentially increase the hardness of the original polymer and allow the structure to pass all of the tests performed in this research such as by increasing the CNT ratio it may allow for a better mechanical interlocking between the nanotubes.

## REFERENCES


Ajayan, P., L. Schadler, C. Giannaris, and A. Rubio. 2000. Single-walled carbon nanotube-polymer composites: Strength and Weakness. *Advanced Materials* 12, no. 10: 750.

Anderson, W. F., H. A. Katki, and P. S. Rosenberg. 2011. Incidence of breast cancer in the united states: Current and future trends. Journal of the National Cancer Institute, 1397.

Ash, S. R. 2007. Fluid mechanics and clinical success of central venous catheters for dialysis-answers to simple but persisting problems *Seminars in Dialysis* 20, no. 3: 237.

Ash, S. R. 2001. The evolution and function of central venous catheters for dialysis. *Seminars in Dialysis* 14, no. 6: 416.

Bal, S., and S.S. Samal. 2007. Carbon nanotube reinforced polymer composites - A state of the art. *BULLETIN OF MATERIALS SCIENCE,* 379.

Brown, E.A., and L. Johansson. 2011. Dialysis options for end-stage renal disease in older people. *NEPHRON CLINICAL PRACTICE,*.

Coresh, J., P. Eggers, J. W. Kusek, A. S. Levey, J. Manzi, E. Selvin, L. A. Stevens, and F. Van Lente. 2007. Prevalence of chronic kidney disease in the United States. *Journal of American Medical Association* 298, no. 17: 2038.

Gibson, F., A. Bodenham, and R. P. Mahajan. 2013. Misplaced central venous catheters: Applied anatomy and practical management. British Journal of Anaesthesia, 333.

Hamilton, H. 2008. Central venous catheters. Ed. Andy BodenhamChiester: Wiley.

Hampton, T. More is better: Frequent or extended dialysis treatments benefit kidney failure patients. American Society of Nephrology. http://www.eurekalert.org/pub_releases/2012-02/ason-mib021712.php (accessed 04/04, 2012).

Jaques, P. F. 1998. Maintenance of long-term dialysis catheters. *Techniques in Vascular and Interventional Radiology* 1, no. 3: 148.

Kennedy, C., S. Angermuller, R. King, S. Noviello, J. Walker, J. Warden, and S. Vang. 1996. A comparison of hemolysis rates using intravenous catheters versus venipuncture tubes for obtaining blood samples. Journal of Emergency Nursing, 566.

Kwok, K. W., Z. M. Gao, C. L. Choy, and X. G. Zhu. 2003. Stiffness and toughness of Polypropylene/Glass bead composites. *Polymer Composites* 24, no. 1: 53.

Lakhal, K., M. Ferrandière, F. Lagarrigue, C. Mercier, J. Fusciardi, and M. Laffon. 2006. Influence of infusion flow rates on central venous pressure measurements through multi-lumen central venous catheters in intensive care. Intensive Care Medicine, 460.

Mankus, R. A. 1998. Comparison of blood flow rates and hydraulic resistance between the mahurkar catheter, the tesio twin catheter, and the ash split cath. *ASAlO Journal (American Society for Artificial Lnternal Organs)* 44, no. 5: M532.

Moureau, N., M. Lamperti, L. J. Kelly, R. Dawson, M. Elbarbary, A. J. H. Van Boxtel, M. Pittiruti, and R. P. Mahajan. 2013. Evidence-based consensus on the insertion of central venous access devices: Definition of minimal requirements for training. British Journal of Anaesthesia, 347.

National Cancer Institute, National Institute of Dental and Craniofacial Research, 2010. Oral cancer statistics oral cancer in the united states. Ed. National Institute of Dental and Craniofacial Research (U.S.). Vol. no. 10-6423.

O'Grady, N. P., et al. 2011. Guidelines for the prevention of intravascular catheter-related infections. AJIC: American Journal of Infection Control,.

Pelton, A. R., Duerig, T. W., , N. Rebelo, and A. Wick. 1994. Experimental and fem analysis of the bending behavior of super elastic tubing Pacific Grove, California, SMST International Committee, November.

Peng, L. M., Z. L. Zhang, Z. Q. Xue, Q. D. Wu, Z. N. Gu, and D. G. Pettifor. 2000. Stability of carbon nanotubes: How small can they be? *Physical Review Letters,* 3249.

Polderman, K., and A. Girbes. 2002. Central venous catheter use. Intensive Care Medicine, 1.

Tal, M. G., and N., Nina. 2008. Selecting optimal hemodialysis catheters: Material, design, advanced features, and preferences. *Techniques in Vascular and Interventional Radiology* 11, : 186.

Wahl, S. I., and C. Jacob. 1999. Central dialysis catheters. *Techniques in Vascular and Interventional Radiology* 2, no. 4: 221.