Effect of surface roughness and process parameters on mechanical properties of fabricated medical catheters

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Abstract

Breakage or separation of any catheter leads to a catastrophic adverse effect on a patient’s life. Polyurethane material degradation and molecular instability during in vivo pose a major risk and cause deterioration of the medical functionality on achieving the required mechanical properties of the medical catheters. Experimental data on hand available are so far been from merchandised catheters, whereas the problem of the absence of manufacturing process technicalities exists. In this experimental study, medical catheters were fabricated in varying process conditions, for getting different surface characteristics. 12 Fr (4.00 mm) catheters were fabricated from medical grade Polyurethane (PU). The dimensional specifications were kept within the acceptable tolerance of product print. The surface roughness of catheters was evaluated using an Atomic Force Microscopy (AFM). Surface morphology was investigated through the use of a Scanning Electron microscope (SEM). A tensile testing machine with a special set up was utilized for the assessment of the mechanical properties of fabricated catheters. Tensile tests were conducted on the fabricated catheters for investigating the impact of surface roughness and chemical aging on elastic modulus (E), stress (σ) and strain (ε) at the break on the catheters. Native catheters, directly obtained from extrusion as well as chemically aged catheters were subjected to a tensile test for the exploration of the role of extrusion melt temperature and catheter surface roughness. Test results show that the catheters with a rougher surface having a strength reduction of 19% compared to smoother surface catheters. Moreover, chemical aging made a reduction in the catheter strength up to 80% of its initial strength. Statistical analysis was applied to the experimental data for the investigation of the effects of process temperature and the surface roughness of the medical catheter on its mechanical properties. The results led to the conclusion that the process melt temperature and surface roughness having a significant impact on the tensile strength of the medical catheters.

1. Introduction

Medical catheters are progressively expected to meet diverse and stringent quality requirements to ensure their efficacy in scenarios which can be life-threatening. Similar to many other invasive and implantable medical devices, medical catheters are made of relatively soft materials such as silicone, polyurethane and polyvinyl chloride (PVC) [1, 2]. They are designed and manufactured to perform an invasive or implant procedure with a smooth insertion and retrieval during and after the completion of catheterization. Catheters should have good flexibility and appropriate mechanical strength to withstand the insertion into the complicated, randomly shaped human body systems [3, 4]. It will definitely be a great help to healthcare professionals if the mechanical properties of manufactured catheters are flawless and readily known.

Polyurethane is one of the versatile and largest consumed polymers in the field of medical device manufacturing due to its superior tuneable mechanical, high flexural endurance and fatigue resistance properties. PU has also excellent biocompatible and biodegradable qualities, which are decisive for any medical
device [5, 6]. Thermoplastic elastomers (TPEs) are also one of the key polymers, which continue to gain importance in the field of the medical industry. However, due to the concern of plasticizers and chemical leaching, TPEs are currently noticed high-level usage on the exterior of medical devices [7]. As polyurethane is made of isocyanate and polyols, the polymer can be formulated to a broad range of polyurethanes with a variety of physical and mechanical properties. Since the medical catheters used to stay in the human body, the raw material used for the fabrication should have good biocompatible properties. Biocompatibility is essential due to the likelihood of the development of any adverse effects when the catheter makes interactions with body tissues, which may lead to life-threatening consequences [8]. The strength requirement on the thermoplastic polyurethane is a matter of concern since decades ago. Research works carried out with different reaction techniques demonstrated enhanced mechanical properties [9]. Techniques of strength enhancement on the bio-based polyurethane were experimented and proved by various researchers. Flax and kenaf bast fibers were exploited to reinforce with polyurethanes for the benefit of obtaining better mechanical properties [10–12].

In spite of the strength enhancement on bio-based thermoplastic composites, the usage of them on implantable medical devices is limited. Despite the superiority seen in the polyurethane raw material, the polymer extrusion process, which extrudes the medical catheter through the application of thermal energy, is a matter of concern for polymer degradation.

Polyurethane catheters are generally hollow, flexible, and in the tube form. They are usually inserted into the natural body passages and orifices or body openings created. There will be a push-pull action, which exerts tension and compression force on the catheters. Any failure that happens during the push-pull action of catheterization may lead to mortality and morbidity to hospitalized patients [13]. In this regard, the mechanical properties, especially the ultimate tensile strength of the medical catheter, become an essential criterion for the effective execution of catheterization procedures [14].

The success of any catheterization procedure depends on the minimal interaction effects with the human biological system and none of the subsequent complications. Surface roughness and its morphology of biomaterials determine the magnitude of the interactions that occur between the catheter surface and body tissues [15]. Catheter surfaces also play a key role in biofilm formation and subsequent health complications. The preliminary function of the cell attachment pertains to the aiding surface of the catheters [16]. Generally, the bulk properties of the polymer determine the mechanical behavior of the catheter, whereas the bioactivity of the resin is one of the rationales for the surface properties.

Polyurethane does not have a homogeneous crystal structure and it exists in an amorphous state. The range of the melt temperature of polyurethane makes the catheter extrusion process a tedious one for obtaining optimum surface characteristics. Achieving the desired catheter surface is a challenging task as the thermoplastic PU may stand in between the unmelt condition and the degradation condition. It is also difficult to choose and set up an optimum process melt temperature, as there are limited choices available [17]. The author’s previous experimental studies have demonstrated that implementing optimum and appropriate process melt temperature to the catheter extrusion process is a primary task to achieve desirable catheter surfaces.

Chemical aging is a matter of concern in the field of medical devices as the device loses its intended design strength due to changes in the chemical and physical structure. Aging of a polymeric catheter is an undesirable function that modifies the physical and chemical characteristics of the medical catheter [18]. Catheter material strength can be deteriorated through elevated process temperatures during the catheter extrusion process. Chemical changes are possible during the in vivo catheterization procedures, where catheters are exposed to chemicals such as alcohol. There are shreds of evidence of the degradation of the polyurethane catheters during in-vivo situations [19]. Ethanol is in use on catheters as lock solutions for minimizing catheter-related infections during the catheterization procedures. Chemicals are in exposure to catheters for disinfection and sterilization of medical catheters [20, 21]. Biodegradation is also a matter of concern relating to medical catheters and it has addressed by many researchers and solutions offered. The strategies provided by many of the research works involved the addition of polymer additives and alteration of polyurethane material physiochemical properties [22, 23]. It is uncommon to hear that a medical catheter has broken during the catheterization or its removal, despite few in the cases of epidural catheters [24].

Strength and study of mechanical properties on medical catheters available in the markets basically lack various technical details, which may have a significant impact on the outcome. Those market available catheters used to have the absence of manufacturing details and used to vary on their surface characteristics. Experimentation and comparing the results of catheters with varying materials properties and surface details might result in discrepancies. Another important parameter is the identical geometry of the tested catheter, which invariably affects the tensile strength of the tested catheters. To overcome the above deficiencies, it is decided to fabricate the catheters with varying process conditions and select the test specimens of sub-groups with geometrical identity without neglecting process information and dimensional details. The primary objective of this research work is to experiment and report the impact of process parameter variations on the catheter’s strength mechanism. In addition, steps have been taken to evaluate the effect of surface roughness.
characteristics of the medical catheter on their ultimate tensile strength. This work also focuses to explore the role of chemical aging on the strength parameters of the medical catheters. Meanwhile, this work also aims to aid the healthcare professionals, to provide the experimental knowledge on mechanical property details, which may assists in their decision making during critical situations such as of trapped or difficult to remove conditions.

Though several fixing mechanisms and mechanical setups are available for the gripping of catheters during the tensile testing, it is inevitable to eradicate the possible damage or rupture of the catheter during the tests. The slippage of catheters also causes inaccurate results during the testing. The silicone inner-shank eliminates these flaws during the tensile test of the catheter. In addition to this, the current work emphasizes the importance of technical information pertaining to catheter fabrication and geometrical consistency, which are directly having a significant impact on the mechanical properties. The study on the chemical aging and the results presented here will lead to the cautious usage of chemicals and alcohols in the catheters.

2. Materials and methods

Medical grade thermoplastic polyurethane (TPU) with the trade name of Pellethane 2363 having, shore hardness of 80 A from Lubrizol Advanced Materials, Inc., Ohio, USA, was used for the fabrication of catheters. Pellethane is an aromatic polyether TPU and having the melt flow index (MFI) of 10 g/ 10 min, as per the technical data issued. Ethanol of 96%, used for chemical aging, was sourced from M/s Fischer Chemicals, India.

2.1. Catheter extrusion process

A medical extrusion machine at M/s Forefront Medical Technology was used for the extrusion of polyurethane catheters of size 14 Fr. (4.00 mm). The precision extrusion machine has an accurate temperature measurement system, where the temperature measuring thermocouples were embedded into the insulation medium of ceramic. The extrusion machine screw has a diameter of 45 mm and the L/D ratio of 25.

The catheter extrusion process depends entirely on three principal parameters, viz., frictional forces generated during the processing of the polymer, thermal energy and rheological properties of resin. Barrel temperature, die temperature and the speed of the screw are highly essential inputs in the single screw extrusion process. However, process melt temperature is the critical and key parameter, which is directly responsible for homogeneous polymer melt and extrudate quality [25]. In the experimental fabrication, nine sets of catheters were extruded in between the melt temperature of 173 to 197 °C and labeled as PU_N1 to PU_N9, to differentiate it from chemically aged catheters.

Dehumidified polyurethane pellets were transferred to the extrusion machine hopper for the fabrication of sample catheter specimens. Optimized process parameters setting along with predetermined temperature values were loaded into the extrusion machine. For each process settings, the extrusion machine was allowed to run for
stable process conditions and samples were collected. Online dimensional measurements were performed on the extruded catheter tubes to ensure the outer and inner diameters were within allowable specifications as shown in figure 2.

In this experimental evaluation, catheters were fabricated at the melt temperature in between 173 °C to 197 °C. Despite the polymer data-sheet recommends 204 °C as the maximum melt temperature, 200 °C was set as the maximum die temperature since the molten polyurethane beyond 200 °C show a higher fluidity and difficulty in the control of the product shape.

2.2. Chemical aging process
Ethanol of 96% was used in the preparation of chemically aged catheter samples. Catheter specimens were immersed in a closed clean beaker completely filled with ethanol. The entire set up was incubated at 37 °C for a duration of 14 days. The specimens were taken out prior to tensile testing and dried in the air.

2.3. Surface roughness (Ra) evaluation
Despite several methodologies and terminologies developed for expressing the surface roughness parameter, Ra—the arithmetical mean roughness value is the prominent parameter used for the surface roughness evaluation and indication. Roughness parameter Ra usually have some variations during the measurement and a mean of minimum three measurements usually provide the actual magnitude of the roughness feature [26]. Atomic Force Microscope (AFM) of NTMDT Integra Prima was used for surface scanning and assessment of the mean surface roughness parameter. The AFM tip is made to scan a minimum of three locations on the sample catheter surface and the mean results were recorded. In order to visualize the topography of the catheter external surface, images were taken with the help of the Scanning Electron Microscope (SEM) made of Hitachi-Japan.

2.4. Tensile testing setup and method
Criterion Electromechanical universal Test System of MTS System Corp., with a force capacity of 5 KN was utilized to perform the tensile test on fabricated catheter specimens. As catheters are hallowed polymeric flexible tubes, it is difficult to hold them on the conventional fixtures of the tensile testing machine without a possible rupture. A cylindrical shank was made with Elastosil E 43, made of M/s Wacker Silicones. This flexible silicone shank was inserted into both ends of the catheter specimens to be loaded on the tensile testing machine. Catheter specimens with the silicone shanks were gripped on the special fixture as shown in figure 3.

Test procedures followed were based on ISO 10555–3 and the gauge lengths of the catheter specimens were kept as 20 mm for all the cases and were strained at the rate of 400 mm per minute. The geometrical parameters of the catheters were measured and it was ensured all the specimens tested were within the dimensional
2.5. Statistical analysis
One-Way ANOVA is a parametric procedure and was chosen to perform the statistical analysis in the study of the statistical significance of the input factor which is melt temperature on the output of tensile strength of the fabricated catheters. Nine different catheters were fabricated from nine different processing conditions which are considered as nine levels in the ANOVA analysis. Each level has three replicates and a total of 27 tensile data were available for statistical analysis. Minitab software was employed for the investigation of the effect of the process melt temperature on the ultimate tensile strength of the catheters. Hypothesis (H0) was assumed as the non-existence of any significant impact of process melt temperature and surface roughness on the ultimate tensile strength. An alternative hypothesis (H1) assumed the existence of a significant impact of barrel temperature or melt temperature and surface roughness on the mechanical properties.

3. Results and discussion
Catheters made of polymeric materials like Polyurethane are susceptible to both thermal and chemical degradation during manufacture and catheterization usage. A major portion of the thermal degradation is directly from the process melt temperature during the catheter extrusion process and subsequently from the environment. As invasive or implanted catheters exposed to diverse chemically active agents and body fluids, biodegradation along with chemical reactions is inevitable.

3.1. Surface roughness and its effect on tensile strength
Fabricated catheters samples were scanned through AFM for the measurement of surface variations in terms of \( R_a \) values. The comparison of AFM surface scan on rougher and smoother catheter surfaces is shown in figure 4. The catheter surface fabricated at a lower melting temperature has micron-level surface features of peaks and valleys. On the other hand, the catheter with the smoother surface has nano-level rugosity and the magnitude of the peaks and valleys are insignificant. The average roughness values of the measured catheters are recorded in figure 5. As reported in an earlier work by the author [27], the surface roughness is a dependent parameter of process melt temperature. The SEM images obtained from the extraluminal surface of the fabricated catheters are shown in figure 7. The SEM images clearly indicate the varying surface morphology of catheter surfaces.

The values of ultimate tensile strengths of the fabricated native catheters are shown in table 1. Catheters produced with low melting temperatures provide lower strength compared to those with a higher melt temperature. Figure 6 illustrates the relationship between the catheter surface roughness and the ultimate tensile strength. Catheters produced with low melting temperatures have surfaces with un-melt polyurethane. This unmelt, non-homogeneous molten polymer generates a specific surface pattern as shown in figure 7.

The stress-strain behavior of native polyurethane catheters observed during the tension test experiment is shown in figure 10(a). The percentage of elongation on the native catheters has a variation of 82% while...
comparing the same between the catheters of higher and lower surface roughness. A catheter having a smoother surface has a maximum strain with larger elongation. The large strain behavior demonstrates the softening of PU catheters produced with a homogeneous mix of hard and soft segments. The quantum of the existence of hard
segments is critically significant for the mechanical properties of PU. The hard segments enhance the chemical crosslinks and imparting a higher range of strain behavior.

3.2. Role of process melt temperature
Polyurethane is a plasticizer-free, segmented polymer that comprises alternating isocyanate and polyols, which are responsible for the hard and soft segments. Polyurethane basically has a range of melt temperatures for the extrusion process due to the presence of hard and soft segments that have different glass transition temperatures \[28\]. The hard segments of PU are held together by hydrogen bonds, which form physical cross-links and it shall be noted that these physical cross-links are prone to thermal energies of melt temperatures.

The ultimate tensile strength of the catheter fabricated at melt temperature yielded 37.03 MPa, which is 19% lower strength compared to the catheters produced on the upper value of the melt temperature range. Catheters extruded with low melt temperatures were seen having a surface of repetitious waviness and ridge type pattern. The skin rupture of the extrudate is the rationale that explains the production of lower tensile strength for the catheters of low melting temperatures.

When adequate thermal energy is not supplied to polyurethane, it results in a non-homogeneous molten polymer. This un-melt polymer creates a crystalline solid structure on the catheter tube when the extrudate exits from the extrusion die. Furthermore, recrystallization is initiated when this extrudate is cooled under the downstream cooling section, generates a heterogeneous surface morphology and a rougher surface. Catheters fabricated at low melt temperatures exhibit rough surfaces of more varying peaks and valleys. It is already noticed that the low melt temperature is the rationale for the high surface roughness of the catheters. Rough surfaces had been generated due to the inadequate thermal energy, which produced less viscous polymer melt.
The absence of a homogeneous mix of polyurethane segments leads to low crosslinking densities and subsequently produce less strength. Thermal decomposition of polyurethane is a complex and heterogeneous activity, that happens due to multiple physical and chemical activities. Thermogravimetric (TGA) studies used to deliver the various decomposition steps of the process [29]. Thermal degradation of the medical catheters is expected to happen when the polymer is exposed to elevated temperatures during the extrusion process. However, in the fabrication of catheters, it is unlikely to exceed the maximum temperature specified by the material-technical datasheet. This is due to the excess fluidity of the molten polymer and the adversity of process control for the achievement of the desired shape and dimensional. Earlier studies have demonstrated that the urethanes start to breakdown very slowly between 150° to 200 °C and decomposition will happen at temperatures between 200° to 250 °C [30]. Generally, polyurethanes delivers two characteristics peaks during the process of material degradation on a TGA analysis. Figure 9 shows the weight loss and decomposition peak details of PU catheters sample subjected to TGA analysis. The primary degradation stage happened at a temperature of 320 °C and secondary degradation at 440 °C. The results closely correlate with the studies of earlier researcher’s works about the thermal stability of polyurethane polymer [31]. The breakage and decomposition of the urethane bonds of hard segments are responsible for the primary degradation and the secondary decomposition is due to the fragmentation happen in the soft segments of polyols. The reason for the observation of reduced tensile strength of the catheters fabricated at lower melt temperatures is due to the weak bonding that occurred during the extrusion process. However, at melt temperature within the primary decomposition and at the range of melting temperature of PU produced higher strength because of homogeneous melt that produces strong bonding.

3.3. Tensile strength of chemically aged PU catheters

The stress-strain curves for chemically aged catheters are shown in figure 10(b). Chemical aging has a direct impact on the catheter’s strength and the test results show reduced ultimate tensile strength values for all the nine sets of catheters. The combined stress-strain curves are depicted in figure 8. Ethanol fluid locks are used in the long term catheters for minimizing the risks of catheter-associated infections. The use of ethanol in catheters leads to structural changes and elution of molecules from catheter polymers [32]. The early physical observation on ethanol aged catheters is swelling and dimensionally oversized on an average by 10 to 15% on the outer diameters.

It is noticed that the tension test result of chemically aged catheters has a decrease in tensile strength compared to its native catheters. A reduction of tensile strength was observed ranging from 42 to 48%, due to the rough catheter surface compared to a finer one. Tensile strength reduction of 80% noticed when compared to finer native catheters. The principal factors affecting the tensile strength are hydrolysis and oxidization. The hard segments which are held together by hydrogen bonds get weakened by the hydrolysis and the action of polymer separation. Earlier research works, on CVC polyurethane catheters by Mokha et al [33] provided the conclusion that the ethanol negatively affects the tensile properties and elasticity. However, this study does not consider the roles of catheter manufacture and dimensional impacts. The results obtained from this experimental work...
contradict the research work of Francesca et al [34], which reports the absence of any significant impact due to chemical aging of commercially available polyurethane central venous catheters. Contrary to this, the reported work of Busch et al [18], presents a tensile strength reduction of 82% on chemically aged polyurethane catheters, which correlates to current experimental findings.

Medical polyurethanes are copolymers, which contain both hard and soft segments within it. While applying loads, phase separation and evolve of microstructure used to happen on the segmented polyurethane. This is due to the internal deformation initiation and further propagation. The content of the hard segment influences the phase separation and plays a major role in physical and mechanical properties [35]. The calculation of the modulus of elasticity of rougher surface catheters, from the stress-strain data, produced 5.35 MPa for the rougher catheters, whereas for smooth surface catheters, the modulus value increased to 6.22 MPa.

3.4. ANOVA results
Data analysis through ANOVA revealed the relationship between input parameters and output responses of catheter fabrication. The significance of influencing input parameters on the mechanical strength is identified through F-test. This analysis was carried out for a level of significance of 5%, i.e., for a 95% level of confidence. The results predicted as [F(8,18) = 28.135.4, p = 0] and [F(8,18) = 18220.7, p = 0] for tensile strength of...
native catheters and chemically aged catheters. For the results of ANOVA, it is inferred that the process conditions have a strong influence on the mechanical strength of the medical catheters. The surface roughness of the catheter has a significant role in the reduction of the tensile strength.

4. Conclusions

In this experimental research work, polyurethane medical catheters were fabricated with nine sets of varying process conditions. The surface analysis revealed the fabricated catheter sets differing on their surface characteristics, especially on the surface roughness parameter $R_a$. In consideration of in-vivo conditions of catheterization, a set of catheters were subjected to chemical aging before the application of tensile test evaluation. The ultimate tensile strength of native and chemically aged PU catheters was evaluated and the following conclusions were drawn.

(1) Catheter surface characteristics have a significant difference based on the process melt temperature. The fabricated catheters were been having a range of measurable surface parameter $R_a$ from 13 to 576 nm.

(2) Tensile tests on native catheters reveal the direct influence on the mechanical properties from the process melt temperature and subsequently have an effect on the catheter surface characteristics. Catheters having the lowest surface roughness have the highest strength and $R_a$ is inversely proportional to the tensile strength. The ultimate tensile strength of a fine surface catheter is 19% higher than the rougher surface catheter. The strain on the tested catheter samples revealed that the catheters with smooth surfaces have a percentage of elongation of 82% more when compared to rougher catheter surface samples.

(3) Usage of alcohol on catheters is inevitable for the catheterization process due to various reasons such as disinfection, cleaning and catheter lock solution. As a disinfectant, ethanol acts as a protective agent against the immediate adherent of harmful bacterial matters. Ethanol used as an ethanol lock solution also performs as an anti-microbial agent on catheters. Tensile test results reveal the presence of strength reduction on chemically aged catheters up to 80%. Despite the ethanol solutions weakening the catheter strength due to the aging effect, the experimental strength values presumably exceed the requirement of in-vivo conditions. While analyzing the role of surface roughness on chemically aged catheters, the resulting tensile strength values resemble the same trend of native catheters. It is observed a similar pattern of the outcome on the ultimate tensile strength as a rougher catheter surface yielded a lower strength.

(4) Based on this experimental study, both native and chemically aged catheter strengths were explored with respect to the manufacturing process conditions and catheter surface characteristics. It is also evidenced that the reduction in the ultimate tensile strength of the catheters, when the surface is rough, which is caused by inadequate process melt temperature. The variations on the strengths of polyurethane catheters, shed a light to the catheter manufacturers to tighten the process window in order to enable fine surfaces to be achieved by optimum process melt temperature without any surface deviations.

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