RF WELDING OF THERMOPLASTIC POLYURETHANE

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Abstract

The reliable and repeatable assembly of thermoplastic polyurethane components can be achieved by using RF energy to produce for example, flexible 93A distal tips on rigid 60D TigerTail[1] Ureteral Catheter shafts designed and built by Medical Device Labs[2] and distributed through C.R Bard Urology until 1998.

Industry has produced similar differential moduli in various ways. One generally accepted methodology is to heat shrink tube over the two adjoining tube OD's while having a mandrel maintain the ID, see Figure 5.0. This kind of assembly in a butt or coaxial joint is a relatively simple but labor-intensive assembly method[3].

Although this has been widely practiced, there are limitations. One key issue is controlling the heat applied, which typically subjects the polymers to damaging levels of heat that will alter their architecture. To address this draw back, an additional post process that attempts to normalize the thermoplastic is employed.

Another development[4] has resulted in an in-line extrusion processes that claims to accurately provide multiple durometers axially at a specific pitch. This process leads to a relatively expensive component cost and only provides a large scale or coarse arrangement of materials.

Alternatively a cost effective, reliable union can be accomplished with novel tooling developed by MD Labs attached to a RF generator.

Introduction

To accomplish a reliable transition between two TPU differential durometer components the primary objective is the application of optimized localized process temperatures. Generally speaking, this is accomplished when polymer properties are allowed to exhibit an even distribution of amorphous hard and soft segment in the molecular architecture in process, see Figure 3.0.

Although normalization of many TPE's will exhibit similar results, they typically are not as dramatic or predictable as TPU results, see Graph 1.0. Additionally, any thermoplastic processing which includes what otherwise would be considered "normalizing" should be integrated into one single process when ever possible.

In either case, a seamless transition between components is desirable as is the superior joint strength and conservation of individual component characteristics such as their durometers. Using a process that manages the energy required to heat and cool is the goal of this comparison.

Materials & Methods

Components consisted of round extruded aliphatic polyurethane tube 1.25 mm OD x 0.625 mm ID. Distal tips material was 93A and proximal material was 65D.

The goal is to determine the most effective process to axially join these materials. To be successful and for this analysis to have meaning, it should be established that a thorough mixing and seamless transition of segment polymer is achieved. Between segments the heating and cooling profile is very important, as is adequate time to orientate molecular architecture. When tested, it should be obvious that strength, elongation and flexibility were achieved and preserved.

RF processing utilized MD Labs proprietary tooling consisted of a multiple wrap coil that was integrated concentrically into the tooling, cooling jackets and die. The tooling was adjustable in order to locate both cooling jackets and coil exactly with respect to the location of the seam between both components.

An automated cycle clamped one segment to prevent movement, while axial pressure was applied to the other end, see Figure 2.0. Then the cycle continued with heat (RF) and cooling profile coordinated for a corresponding time.

Alternatively, “Shrink tube” processing which used the same size and durometer components as RF assemblies relied on heat from a hot air source to be applied to an exposed area after shrink tube was coaxially placed over the joint and component transition region, see Figure 4.0 and 5.0.

Young’s Modulus (Modulus of Elasticity) (E)) describes elastic properties by the ratio of stress to the strain of objects; where:

Equation 1.0

$$E = \text{stress} / \text{axial strain}$$

Using Equation 1.0 as a basis, tensile testing of segmented assemblies (non-sterile) was compared to conventional shrink tube heated assemblies. In this manner the concentration and characteristics of polymer at the transition (flexibility, quality and reliability of the interface) could be modeled and its effect on and the correlation to strength and elongation determined.

Data and Results

Results indicated a significant increase in elongation for similar tensile loads, see Graph 1.0. This increase in elongation; samples (3 thru 10) suggests the MD Labs process resulted in transitions that were twice as flexible as heat shrink processed transitions.

This observation is further underscored by RF process samples #1, & #2, which exhibited extraordinary tensile strength and elongations, but were excluded from Graph 1.0

Conclusion

The controlled and focused use of energy results in a strong very flexible union of two thermoplastic urethane components. The strength and increase in transition flexibility is due to the controlled process and the corresponding normalization and orientation of the polymers in process.

Footnotes

Tiger Tail is a registered trademark of C.R Bard, Inc. Urology Division

[2] Medical Device Labs, Inc; P.O. Box 793, Natick, MA. 01760

[3] Benjamin, Thierry; U.S. Patent 6,245,053; Soft Tip guiding catheter and method of fabrication

[4] TIE™ ;Total intermittent extruded tubing; Putnam Plastics, LLC, Dayville, Ct.

[5] MD Labs Process qualification data

[6] C.R. Bard 510k data (K033719)

[7] No failure at this elongation

[8] Approximate, maximum

Charts, Figures &Tables

<table>
<tr><th colspan="5"><u>Table 1.0</u>
See Graph 1.0</th></tr>
<tr><th rowspan="2">Sample No.</th><th colspan="2">MD Labs RF process[5]</th><th colspan="2">Shrink tube process[6]</th></tr>
<tr><th>Load kg</th><th>%E[7]</th><th>Load kg</th><th>%E</th></tr>
<tr><td>1</td><td>3.9</td><td rowspan="2">800</td><td rowspan="8">2.2</td><td rowspan="8">300[8]</td></tr>
<tr><td>2</td><td>2.8</td></tr>
<tr><td>3</td><td>1.77</td><td rowspan="6">600</td></tr>
<tr><td>4</td><td>1.8</td></tr>
<tr><td>5</td><td>1.72</td></tr>
<tr><td>6</td><td>1.71</td></tr>
<tr><td>7</td><td>1.77</td></tr>
<tr><td>8</td><td>1.56</td></tr>
</table>

9	1.65			
10	1.5			

Figure 2.0

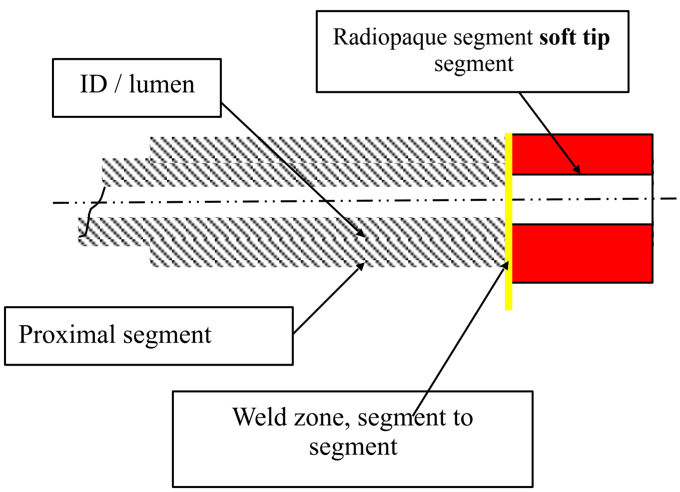


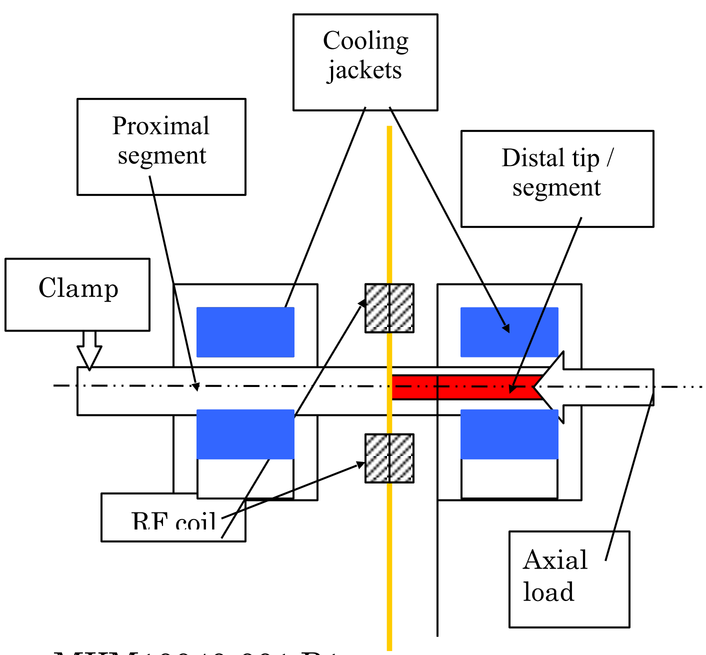
Figure 1.0

Figure 3.0: Schematically describes the distribution (orientation) of hard and soft TPU segments comprising the molecular architecture where
("x") = hard segments and
("y") = soft segments.

x x y y x y	**x** y **x** y **x**
x y y x y x	y **x** y **x** y
x x y y x y	**x** y **x** y **x**

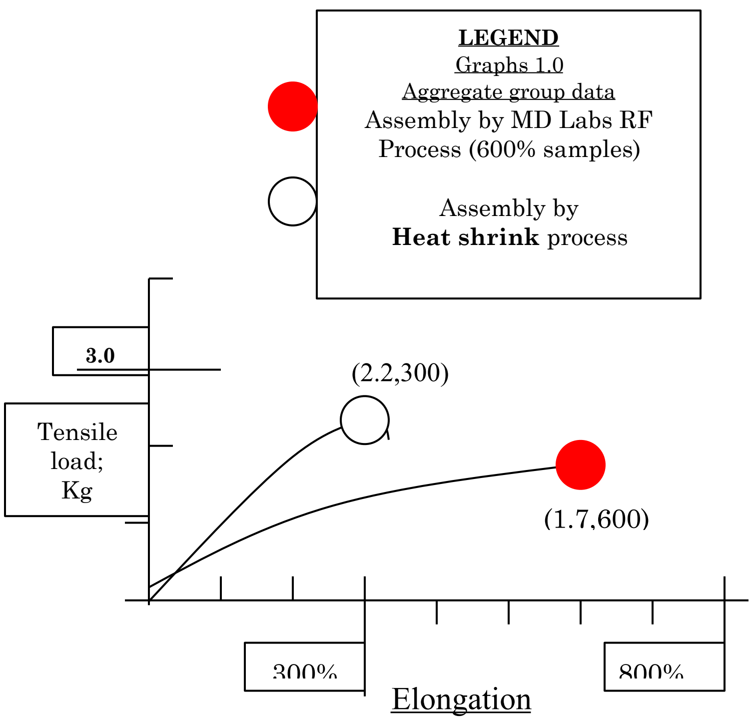
Stressed segments (left hand) array, once normalized exhibit an even distribution of segments (right hand array).

Figure 3.0



Shrink tube

Figure 4.0



Graph 1.0

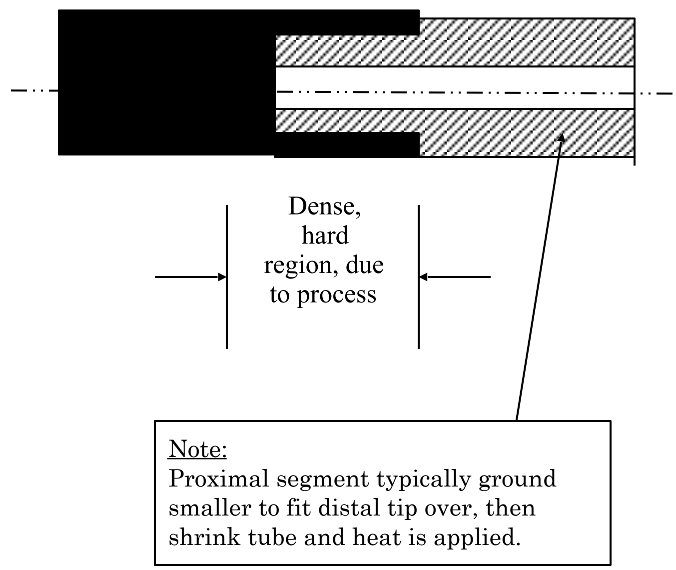


Figure 5.0

Key Words, Phrases

(RF) Radio Frequency,
Thermoplastic Polyurethane,
Molecular Orientation,
Transition