Segmentation, Lamination and Post Processing of Amorphous Thermoplastic Urethane

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Abstract

Medical Device Labs, Inc. proprietary *segmenting* and *lamination technology* processes have been developed for their (**SME**thane™)[1] TPU (Thermoplastic Urethane) and (**p**AguaMedicina™)[1] super porous structural hydrogel. These materials are based on well-known formulae in combination with qualified processes that have been used to produce FDA approved Devices, such as the TigerTail [2] Ureteral Catheter.

Introduction

Process

Segmenting and *lamination* process technologies result in varied proportions of modulus exhibited at specific axial and or circumferential designations. This is possible due to specific thermal process parameters and tooling with respect to materials used.

Materials

Products can exhibit superior physical characteristics due to their synergy of optimized processes for specific materials, which results in an even distribution of molecular architecture. This is especially obvious when comparing stress / strain characteristics of an as extruded or injection molded TPU to one that has been processed in accordance with optimized time and temperature parameters. Additionally, an amorphous composition of hard and soft segment TPU's will exhibit significant predictable end product performance compared to TPE's consisting of crystalline matrices, see Figures 2.0 that unfortunately, a broad time and temperature matrix can not establish.

Technology

Products can exhibit infinite variability's of stiffness, torque, durometer, radiopacity, and volumetric change where they are required. The process responsible for these results is focused specific time and temperature parameters corresponding to thermoplastic properties of specific polymers used.

Discussion

Generally speaking, polymer properties are a result of the monomers (hard and soft segments) and the extent of cross-linking. Additionally, thermoplastic processing which includes what otherwise would be considered the "normalizing" of polymer compositions contributes to and enhances polymer performance, see Figure 2.0. When addressing this, the absence of or inadequate specification for stress relieving may result in undesirable molecular orientation, but optimized processes parameters can maximize the final result.

In one example, a core of thin wall, high durometer tube supports multiple segments axially, see Figure 1.0A. This makes up chemical, physical, and mechanical characteristics of the various components providing varying specification at specific axial and or circumferential locations.

Another example, a catheter distal tip can be a soft flexible segment, minimizing trauma, while a rigid center core maintains torque-ability and push-ability. The catheter may also or alternatively include coaxial layers laminated together such as radiopaque segments incorporated into the assembly to aid in implantation and positioning. Furthermore, given the potential for biological interaction a coaxial layer that isolates radiopaque segments from direct physiological contact is desirable.

To reliably accomplish these lamination and segmentations, this paper suggests that although many methods exist, the best method for joining and achieving optimized molecular orientation is thermal processing either individual components or an entire assembly.

This is accomplished by supporting the profile over a mandrel with no residual clearance. In fact inducing a slight load is recommended. As shown, see Figure 1.0.B, one segment may be clamped to prevent movement, while axial pressure is applied to the other end. Then the welding cycle is coordinated at appropriate time and temperature for polymer segments to orient into the best possible configuration.

Experimental Procedure

Objective

The scope addressed typically beneficial aspects of catheter design. These are:

Push-ability [3] refers to response of a tube when a longitudinal force acts along its axis. For small deflections, a spring model is used where the longitudinal stiffness is determined by:

(Equation 1.0) $K_{long} = E*A / L$;

where (K_{long}) is the longitudinal spring constant, (E) is the modulus of elasticity, (A) is cross sectional area and (L) is the length of the shaft under deflection.

Torque-ability [3] describes the behavior of a tube when a moment torques about its longitudinal axis. For small deflections this too may approximate a spring system in which torsional stiffness is determined by:

(Equation 2.0) $K_{torq} = G*J / L$;

where (K_{torq}) is the torsional spring constant, G = shear modulus, J = Polar Moment of inertia, and L = length.

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

(Equation 3.0):

(E = stress / axial strain)

Method

Tensile testing (Young's Modulus) of a segmented and or laminated finished fully processed assembly is compared to the individual components, as-supplied which serve as the control samples that otherwise would incorporate residual stresses with out proper post processing.

Conclusion

Qualification of processes can be used to achieve optimum parameters for TPE and TPU products. TPE's can be orientated in an optimum configuration, but crystalline networks may not achieve the architecture of amorphous TPU's.

A process qualification that considers a matrix of maximum and minimum parameters, results in optimum enhanced product characteristics. When comparing memory retention of TPE's such as

Nylon 6/6 to amorphous TPU, results indicated primarily due to normalization processes, reliable recovery time and ID of TPU devices processed by specific parameters results in a more consistent product; see Graph 4.0.

When comparing tensile strength and elongation, torque-ability and push-ability, TPU's exhibited the same superior results, see Graph 1.0, 2.0 & 3.0. These results are even more profound due to the ability to seamlessly join layers and segments achieving varied characteristics at specific locations.

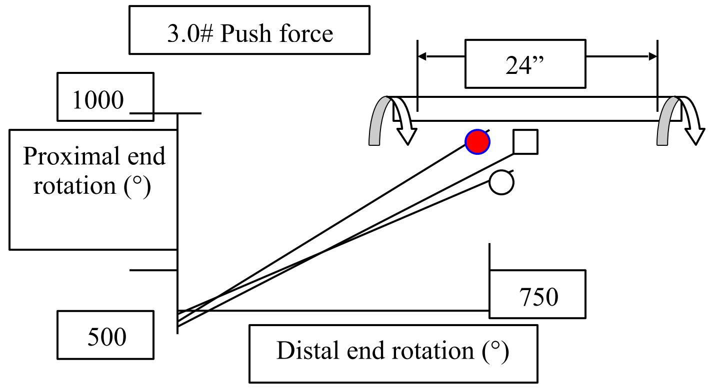
In conclusion, amorphous thermoplastic urethanes can be processed to exceed individual component characteristics; that in an end product exhibit superior physical characteristics, either cumulatively or individually. This is due to process management of thermal energy that results in an evenly distributed, superior molecular orientation of polymer hard and soft segments, not exhibited by generic rules of thumb for post processing.

References

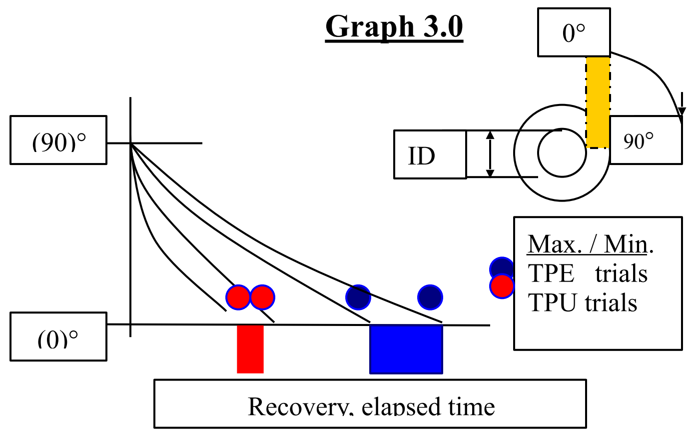
1. SMEthane and pAguaMedicina are pending trademark registration of Medical Device Labs, Inc.

2. TigerTail is a registered trademark of C.R Bard Inc.

3. Roth, Ron; January 01, 2001; Medical Device & Diagnostic Industry Magazine, Design Considerations in Small-Diameter Medical Tubing; Effective design specification methods and early manufacturing involvement can optimize product manufacturability.



Graph 3.0

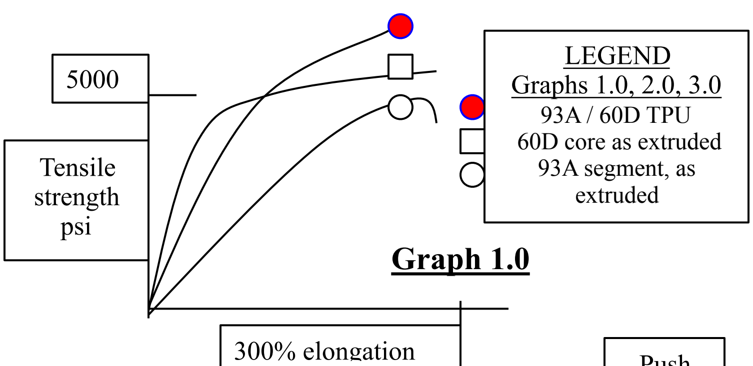


Graph 4.0

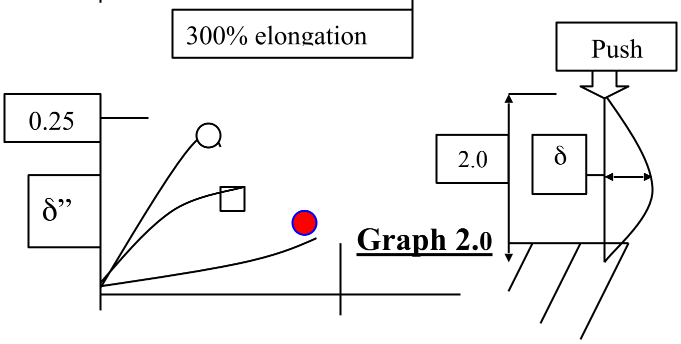
Figures

Figure 1.0A

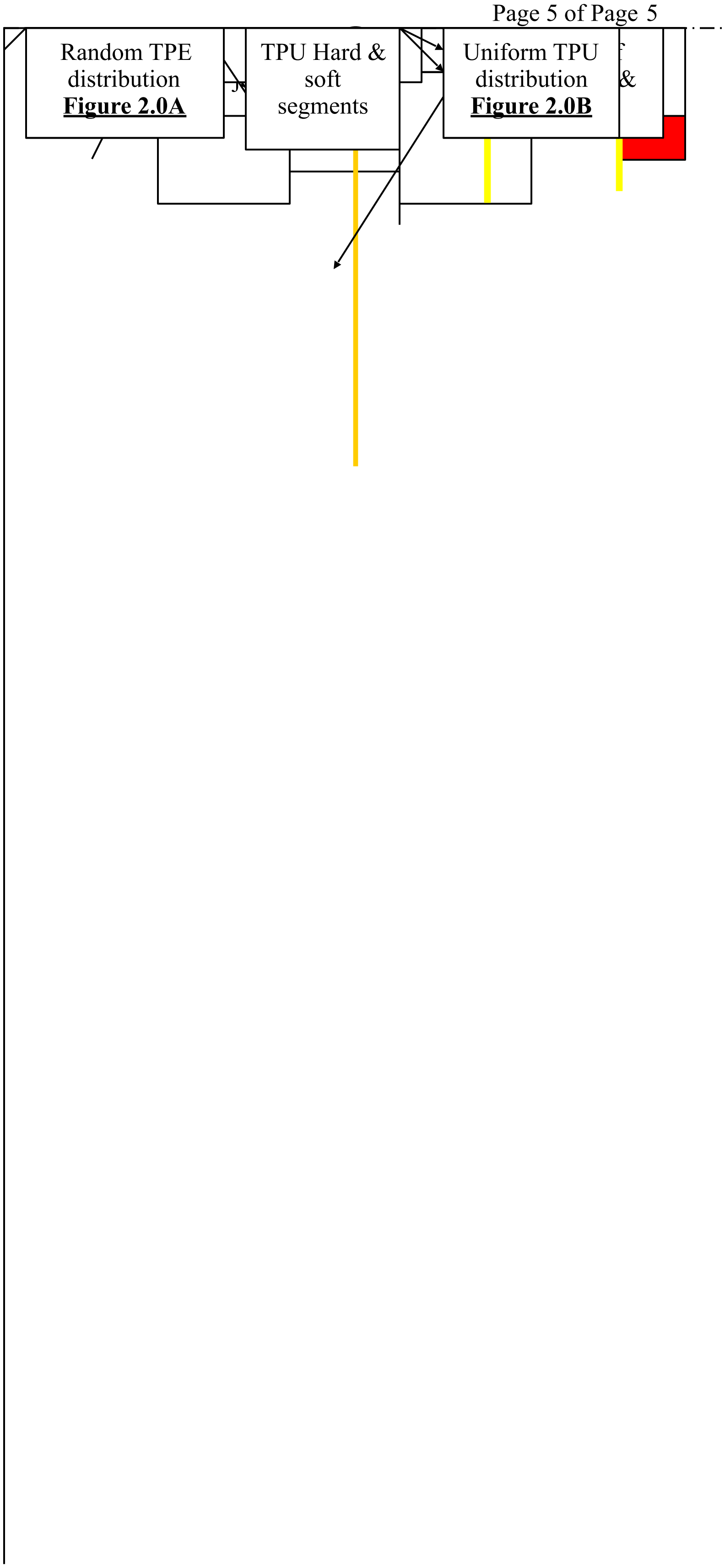
Data



Graph 1.0



Graph 2.0


Random TPE distribution
Figure 2.0A
TPU Hard & soft segments
Uniform TPU distribution
Figure 2.0B