Case Study of Mobilize Lubricious Compounds

Compounding Solutions hired an independent 3rd party medical device contract manufacturer specializing in catheter manufacturing and testing to conduct a case study to review the effects of Pebax 6333 SAO1 MED & Pebax 2533 SAO1 MED loaded with Mobilize, a lubricious additive, against natural Pebax resins.

SCOPE

Both Pebax 6333 and Pebax 2533 were compounded using a 27mm twin screw co-rotating extruder at Compounding Solutions. These resins were extruded into 20" long sections of tubing with outer and inner diameters of 0.081" and 0.069", respectively. The tubing was then tested for the following:

- Dimensional Stability
- Insertion Force
- Flow Rate
- Shaft Leak Test
- Tensile Strength

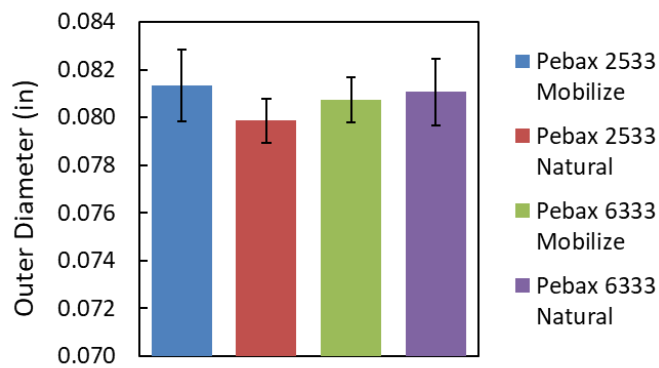
SUMMARY

- The natural Pebax and Mobilize compounds were extruded and laminated using the same processing parameters. No changes in processing were necessary.
- No significant effects on tensile strength, shaft leak test, flow rate or dimensional stability were observed amongst the Mobilize compounds.
- The Mobilize compounds reduced the insertion force by 30% compared to natural Pebax.
- Incorporating Mobilize into a typical catheter build can reduce the cost of the device by as much as 50%.

RESULTS

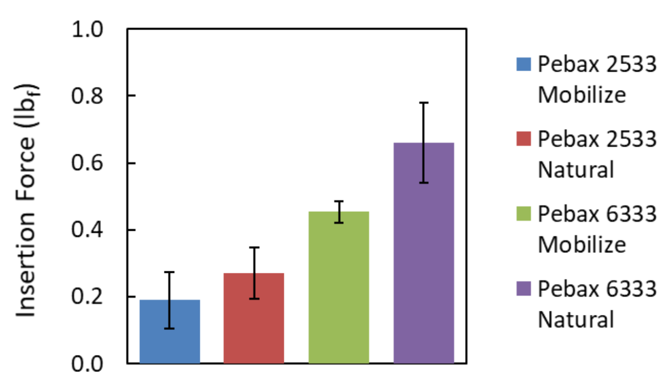
Dimensional Stability: The outer diameter was measured at five points along each 20" section of tubing using a laser micrometer. The average outer diameter of 15 tubes of each material is shown in Figure 1. There is no significant difference between the various materials.

Figure 1. Extruded tubing dimensional stability.



Insertion Force: The tubes were inserted through a track which simulated a fistula fixture. This contained a bend radius of 1" and used a standard 7-French introducer. All samples were conditioned in 37°C deionized water. The average force required to insert 15 tubing shafts of each material is shown in Figure 2. A 30% reduction of required insertion force was found using the Mobilize additive in both the hard and soft grades of Pebax.

Figure 2. Required tube insertion force.



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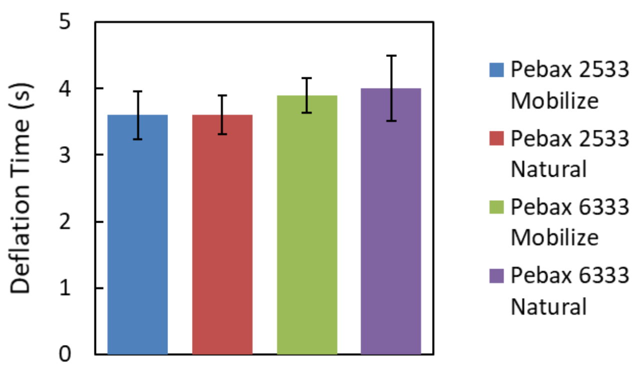
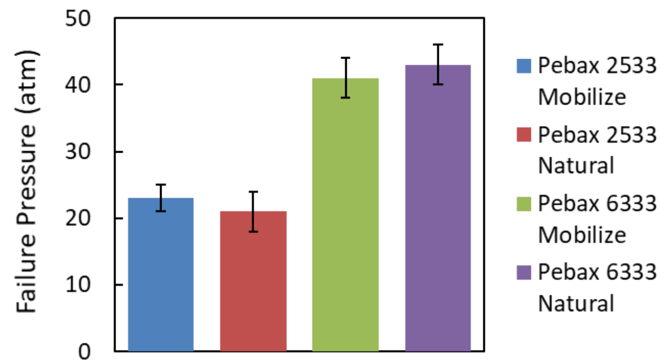
Flow Rate: This test measures the time required for a given volume of water to pass through the shaft under constant pressure. Two shafts were bonded onto a standard over-the-wire hub, leaving a clearance of 0.001213 in^2. Through this clearance, 37°C deionized water was drawn at a constant pressure. The average time required for 10mL liquid to flow is shown in Figure 3. There is no significant difference between all materials.

Figure 3. Time required for 10mL of water to pass through shaft at constant pressure.



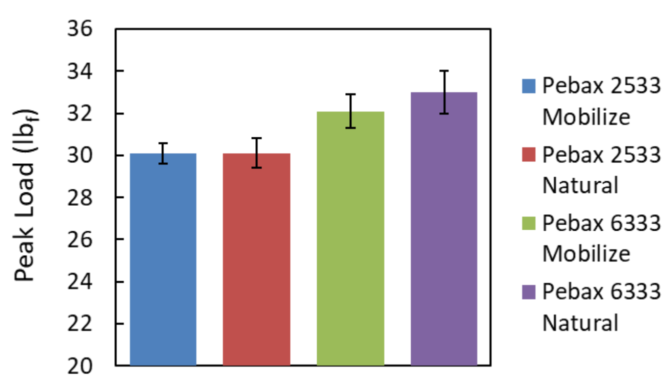
Shaft Leak Test: The tubing was tested for leaks using a HBLT leak test machine. The average failure pressure of 15 tubes is shown in Figure 4. No significant difference was observed between the loaded and natural tubing.

Figure 4. Pressure at which leak was detected on HBLT leak test machine.



Tensile Strength: Tubing samples were tested according to ISO-1055:2013. The samples were strained until failure. The average peak load of 10 tubing samples of each material is shown in Figure 5. There is no significant difference between natural and loaded tubes.

Figure 5. Peak tensile load applied to tubing.



Compounding Solutions

MOBILIZE

Case Study of Mobilize Lubricious Compounds - Dollarization

Compounding Solutions has presented the benefits of adding the Mobilize additive to increase lubricity. Moreover, adding Mobilize to your catheter tubing compound can save you money. Shown below is a simple catheter build using an etched PTFE liner, Pebax with $BaSO_4$ outer layer, FEP shrink tubing and a hydrophilic coating versus a catheter build made with Pebax, $BaSO_4$ & Mobilize outer layer.

Component	Catheter Build without Mobilize	Catheter Build with Mobilize	Notes
PTFE Liner @ 4ft length	$5 per length	$0.00	The PTFE liner can be eliminated with the benefits of reduced insertion force and ease of removal from mandrel with Mobilize.
Pebax Compound Outer Layer @ 4ft length	$2.40 per length	$2.60 per length	The cost of 50lbs of Pebax with $BaSO_4$ compound = $30/lb. The cost of 50lbs of Pebax with $BaSO_4$ & Mobilize compound = $60 /lb.
FEP Shrink Tubing @ 4ft length	$5 per length	$5 per length	Necessary cost in building of the catheter.
Hydrophillic Coating @ 4ft length	$4 per length	$0.00	The Mobilize additive reduces the coefficient of friction by 30% of both the inner and outer surface.
TOTAL	$16.40 per length	$7.60 per length	**54% COST REDUCTION**

The above dollarization does not consider the most recent discovered benefit of Mobilize, increased production speed. Customers have reported a significant reduction in die head pressure, allowing for up to 15% faster line speed/output rate, realizing reduced operating costs.

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