

New Design and Materials for Customizable Oropharyngeal Airways

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Problem and Motivation

Traditional oropharyngeal airways are used to prevent the tongue from occluding the airway during unconsciousness and allow air to flow easily into the lungs. They are produced in standardized sizes (Figure 1) and are made of materials that don't conform to a patient's individual anatomy.

If the device is too large, excessive forces are applied radially to the throat during insertion (Figure 2b), causing trauma. If the device is too small, the device will not prevent the tongue from blocking airflow (Figure 2c).



Figure 1. Standard sizes of oropharyngeal airways.



Figure 2. Effects of using incorrect sized devices.

Shape memory polymers offer two unique solutions to these problems:

- The shape memory effect (Figure 3) allows for easy insertion.
- A Tg set at body temperature allows the device to be in its viscoelastic regime, permitting easy removal.

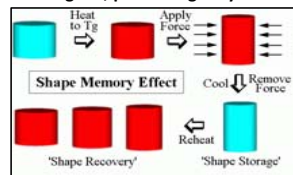


Figure 3. Shape memory effect.

Objectives

Design an innovative oropharyngeal device that is

- Non-damaging to the airway
- Quick to open the airway
- Economical to manufacture
- Non-toxic over short time periods

Methods

A poly(methyl-co-isobornyl) acrylate system and a linear urethane system are pursued as viable systems. Each system is polymerized, mixed, injection molded, and radiation cross-linked (Figure 4). The following tests were then performed:

- Dynamic Mechanical Analysis (DMA) to determine Tg and rubbery modulus
- Degradation study in saliva simulated solution (pH = 7) and gastric simulated solution (pH = 2)

Results and Discussion

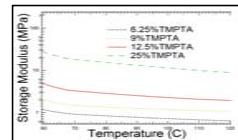


Figure 5. DMA of Acrylates

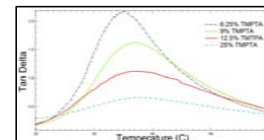


Figure 6. Tan delta curves of Acrylates.

Figure 5 displays a clear trend of increasing storage modulus with increasing crosslinker concentration at temperatures above Tg for the acrylates. This is a key material property as the storage modulus at high temperatures is proportional to the recoverable force. Figure 6 plots the tan delta of each material and shows that Tg increases with increased crosslinking. All materials have a glass transition temperature near body temperature, which is ideal for this application.

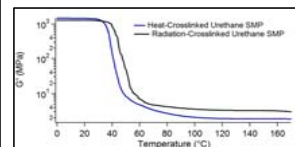


Figure 7. DMA of heat-crosslinked and radiation-crosslinked urethanes.

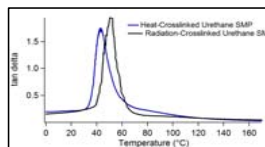


Figure 8. Tan delta curves of heat- and radiation-crosslinked urethanes.

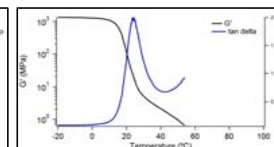


Figure 9. DMA and tan delta curves of 15% 1,8-octanediol.

Figure 7 shows that radiation crosslinking results in a 60% higher rubbery modulus than heat crosslinking for the TMHDI/2-butene-1,4-diol urethane system. Furthermore, Figure 8 shows radiation crosslinking results in a glass transition that is 15% narrower than heat crosslinking, though the Tg increases from 41 to 52°C. Figure 9 indicates that the Tg of a TMHDI/2-butene-1,4-diol/1,8-octanediol system can be lowered to 23°C. Thus, if irradiation results in the predicted 10°C Tg increase, the crosslinked material will have a Tg around 5°C below body temperature.

Table 1. Percent Mass Change of Acrylates

	High Cross-linker 1	High Cross-linker 2	High Cross-linker Average	Low Cross-linker 1	Low Cross-linker 2	Low Cross-linker Average
pH = 2	0%	0.96%	0.48%	-	0.71%	0.71%
pH = 7	0%	2.33%	1.17%	0%	0%	0%

Table 2. Percent Mass Change of Urethanes

	Sample 1	Sample 2	Sample Average
pH = 2	-0.43%	-1.11%	-0.77%
pH = 7	-1.54%	-2.13%	-1.83%

Tables 1 and 2 indicate that there is minimal mass loss of both polymer systems in the gastric simulated solution and the saliva simulated solution, which are the most extreme environments seen by the device.

Design Results

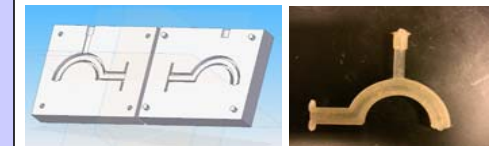


Figure 7. Mold design for device.

Figure 8. A sample acrylate prototype.

Injection molding has been utilized successfully to mold the acrylate and urethane systems. The polymer is first chipped and melted in the injection molder at 215°C. It is then injected into an aluminum mold, seen in Figure 7, at a pressure of 1 MPa.

Injection molding has caused minor cosmetic defects such as trapped air bubbles and a slight discoloration in the acrylates. Likewise, bubbles have formed in the urethanes during injection molding due to residual solvent, requiring lower molding temperatures and radiation crosslinking.

Future Work

While both the polymer systems and the mold design need some adjustment, both systems appear to be sufficient for use. However, further testing must be performed to ensure that the devices are safe.

- Strain recovery tests must be performed using ASTM standard 1573-95 for oropharyngeal airways to ensure that the device recovers sufficiently at body temperature.

- Degradation testing must occur on constrained devices in gastric and saliva simulated solution to determine if external forces will cause the material to degrade.

- Swelling tests must be performed to ensure that the device will not swell inside the throat, which would cause excessive strain on the tissue.

- FTIR spectroscopy must be performed to determine the level of solvent remaining in the material.

- Packaging and constraining devices must be developed to prevent device recovery.

References

- http://www.hughsun.com/Canula_Catheter_Tube_01.html
- W.L. McNiece, S. F. D. (2004). "The Pediatric Airway." *Seminars in Pediatric Surgery* 13(3): 152-165.
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