Evaluating the Level of Adhesion and Optimizing Thermal Bonding between Nitinol Wire and Thermoplastic Polymer Films.

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Statement of Purpose: The manufacture of flexible biomedical implants, like embolic protection devices and stent grafts, which consist of a metallic wire and a thermoplastic fiber / film, is currently a major challenge for the medical device industry[1]. Though thermal bonding is preferred over the use of adhesives as it leads to savings in terms of time and money, we believe surface treatments for nitinol wire and polyurethane (PU) film prior to thermal bonding may yield significantly improved results. In this study, the nitinol wire and the polyurethane film, which can be used in designing embolic protection devices were treated with helium and helium-oxygen radio frequency plasma as well as a mechanical roughening technique followed by thermal bonding so as to create an adhesion test sample. Various combinations of treated and untreated samples were assessed using a modified ASTM adhesion strength method to determine the strongest combination.

Methods: The polyether urethane film under study was supplied by American Polyfilm (Branford, CT). The film had a gauge of 5mil (i.e. thickness = 0.11 mm) and was optically clear in appearance. Silver colored, chemically etched and annealed 0.015 inch diameter nitinol wire was obtained from Fort Wayne Metals.

A single composite pull-out test specimen required 4 film components and one straight wire component. A DC5 hot press (George Knight and Co., Brockton, MA) was used to assemble the 5 components by thermal bonding. The wire component was sandwiched between the front and back layers of the PU film as shown in Figure 1. The optimum bonding conditions for assembling these composite nitinol wire / PU film specimens required 180° C for 30 seconds under standard pressure.

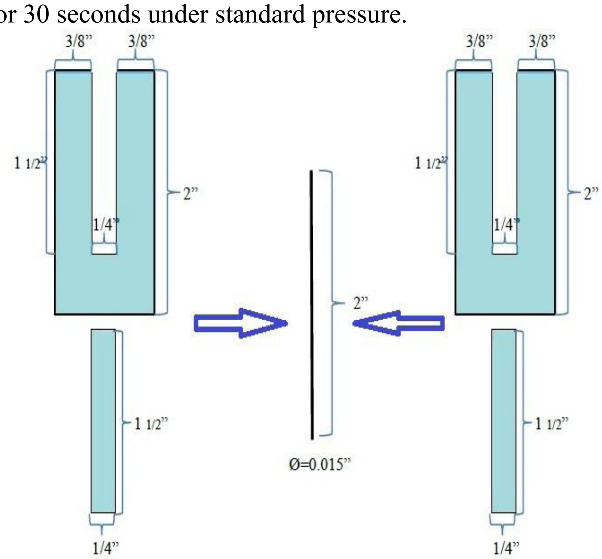

Figure 1. Dimensions of Film and Nitinol Wire Components for Pull-out Strength Test.

In order to remove any contaminants the film components were first cleaned with hexane and 2% Triton-X non-ionic detergent, followed by rinsing with distilled water. A laboratory atmospheric pressure plasma reactor (APPR) Model 300-13 from APJeT was used for exposing the samples to plasma treatment. A helium gas flow of 40 L/min was used as the feed gas to initiate and maintain the plasma. For the procedure was the same to that of helium-plasma treatment except for opening and closing the oxygen valve, so as to provide the flow of 0.2 SLPM, in addition to the helium valve at the same time. In order to mechanically roughen the nitinol wire, the nitinol wire was rubbed along the jaded surface for period of 30 seconds until the wire acquired a roughened appearance. A tabletop mechanical testing machine, Model 313 Series (Test Resources Inc., Minneapolis, MN) was used to perform the pull out test method using a 250 N load cell.

Results: The pull-out strength test results from the modified test method involving the "as-received" nitinol wire, Roughened nitinol wire, helium plasma treated wire, helium-oxygen plasma treated wire thermally bonded to PU film are given below.

Composite Sample	**Pull-out Force (N)**	
	Mean	**Standard Deviation**
Nitinol wire / PU film	**18.45**	**1.97**
Roughened Nitinol Wire/PU film	**20.76**	**4.36**
He plasma treated Nitinol wire / PU film	**16.36**	**3.79**
He-Oxy plasma treated Nitinol wire / HPU film	**14.6**	**2.28**

Conclusions: By modifying the surface chemistry and topography of the nitinol wire and the polymeric film it was possible to substantially improve on the level of adhesion.

Further studies of the surface topography as well as physical and chemical changes taking place at the surface of the nitinol wire and polyurethane film were conducted by using scanning electron microscopy (SEM), x-ray photoelectron spectroscopy (XPS) and contact angle measurements.

References:

1.Yoon H J Appl Biomater Biomech. 2010:8(1):7-13