Meadox Medicals, Inc.

103 BAUER DRIVE
OAKLAND, NJ 07436
201-337-6126
800-526-0356
TELEX 82680

November 8, 1984

Keith Kent, DMD
206 Churchill Lane
Milton, MA 02186

Dear Keith:

Enclosed you will find the results of our evaluation of your silicone coating. I have included the x-ray photoelectron spectroscopy results and the tin extraction data. Copies of all the SEM's of the coated surfaces are also included, as well as a photocopy of SEM's of the surfaces before coating. You can see that your coating leaves no visible residue on the surface.

Please let me know if I can be of further assistance with regard to this matter.

Sincerely,

Lisa A. Hill

Lisa A. Hill
Research Engineer

LAH/meg
cc: G. Cipolletti
Enclosures

REPORT ON THE CHARACTERIZATION AND BIOLOGIC INTERACTIONS OF A POLYURETHANE/SILICONE MATERIAL

for MEADOX MEDICALS, INC.

UNIVERSITY OF WASHINGTON BIOMATERIALS RESEARCH GROUP

INTRODUCTION

The materials studied were a polyurethane material overcoated with silicone and Silastic (Dow Corning) as a control material. Meadox Medicals, Incorporated provided the polyurethane, which was labeled as M10-P2. Samples were coded 277-1 to 277-39.

SUMMARY AND CONCLUSIONS

The summary of the key data from this report is provided in the accompanying Table. Details of the methodologies and also of the results obtained may be found in the separate sections accompanying this report. The most significant comments and conclusions which can be made from the data are as follows:

1) The polyurethane sample was significantly more thromboembolic *in vitro* than the Silastic control.

2) The surface composition of the material provided by Meadox Medicals was obtained by ESCA analysis. The polyurethane contains significant amounts of silicone in the surface region; in addition, the M10-P2 had a measurable signal of tin (Sn). Furthermore, it did not show a significant nitrogen signal, indicative of the fact that the hard segment is probably beneath the surface of this material, as far as the ESCA analysis is concerned. Thus, the polyurethane material contains significant amounts of only carbon, oxygen and silicon in its surface and it was significantly thromboembolic. On the other hand, the Silastic control material, which also contains significant amounts of only carbon, oxygen and silicon in its surface signal, was the least thromboembolic of all the materials tested. It is clear that the character of the silicone compounds in the surface region of the polyurethane is either different than polydimethyl siloxane and/or may not be evenly distributed on the surface in a way that would provide a surface similar to Silastic. In addition, topographical features may be playing a part here but no SEM's have been taken on these surfaces.

The M10-P2 had a yc of ca. 40 dynes/cm., as expected for a polyurethane material. A control Silastic material was also evaluated and found to be 37 dynes/cm., unusually high for a silicone rubber, (ca. 22 dynes/cm. was expected) perhaps indicative of some additional polar groups in the surface such as oxidized hydrocarbon groups, since the ESCA signal shows only carbon, oxygen, and silicon. In any case, if this material were to have a yc ca. 40, then the correlation of rates of embolization with c suggests that materials with c above 38-40 would be highly thromboembolic (Figure 1). We have just completed a study of series of widely varying materials and these data also support a similar conclusion (Figure 2).

4) The fibrinogen adsorption to M10-P2 is extremely low at short times, in fact exhibiting values which are amongst the lowest ever observed in our laboratory in this type of experiment. In general, plasma fibrinogen adsorption to the M10-P2 is significantly lower than to Silastic at most times. It appears that the low fibrinogen uptake by M10-P2 from pure fibrinogen solutions in the isotherm experiments is also expressed as low fibrinogen uptake in the plasma adsorption kinetics. Nevertheless, the Freundlich adsorption isotherm factors a & b are both higher for the polyurethane material (Figure 3,4). Factor b is a measure of the intensity of fibrinogen surface interactions. In general, it would appear that the polyurethane material, as fabricated, exhibits high thromboembolic tendencies.

5) Based on the overall results obtained, a <u>preliminary</u> conclusion is that materials with low surface energies exhibit reduced thromboembolic tendencies (Figures 1-3). Surface roughness and graft porosity have not been studied in this investigation, and they could also play a significant role in blood intereactions.