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CONVECTION-ENHANCED THERMO-THERAPY CATHETER SYSTEM: MICRONEEDLE COMPRESSION STRENGTH TESTING WITH VARIOUS DUROMETERS

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ABSTRACT

The Convection-Enhanced Thermo-Therapy Catheter System (CETCS) was developed by our group at The University of Texas at Austin for the treatment of glioblastoma. This arborizing catheter is remotely operated and provides the ability to position and infuse in regions of the tumor and tumor margins to increase the dispersal volume coverage capability. The next step in developing this device is the further characterization of the materials being used in this design.

Device characterization included evaluating the behavior of the microneedles under compression while they were in contact with several types of durometers (50A, 80A, 90A, and 95A). This test method was used to determine if the microneedles would experience breakage at the tip or along the microneedle.

After the compression-durometer testing, it was determined the tips of the microneedles were more likely to puncture the durometer prior to experiencing any breakage. The device's microneedles are not expected to come into contact with materials that have a higher durometer rating of 50A and will be acceptable in the current CETCS design meant for the treatment of glioblastomas.

Keywords: Convection-enhanced, microneedles, durometer

1. INTRODUCTION

The Convection-Enhanced Thermo-Therapy Catheter System is a device designed by the Rylander lab at The University of Texas at Austin. It is an arborizing catheter that consists of six microneedles extending out of the main cannula. The intention of this device is meant for the treatment of glioblastomas. A major design characteristic of this device is to have the microneedles withstand the normal loads expressed by the brain tissue and tumor tissue throughout a treatment session.

During the development of our device, we have consulted with a designer of a predicate device that loaded their device compressively in order to determine the structural integrity when in contact with a material that was comparable to a 50A durometer. In order to prove compliance with a predicate device, the CETCS's microneedles were evaluated under compression loading of the microneedles onto various types of durometers (50A, 80A, 90A, and 95A).

Understanding how effective the choice of materials is at dealing with the treatment of glioblastomas and working in the clinically relevant environment will determine if we need to explore a material change. In addition, this will prove that our device is as efficient as the predicate device.

2. MATERIALS AND METHODS

2.1 Microneedle Preparation

The microneedles (n=4) were cut from 150 µm ID/360 µm OD fused silica capillary tubing (TSP250350, Polymicro Technologies, Phoenix, AZ), at about 8 cm. Then they were polished and secured between two small acrylic plates (about 1 cm x 3 cm), using a medical-grade epoxy (EA M-21 HP, LOCTITE-Henkel). The microneedles were placed so that a region of the microneedle was exposed (~5.5 cm) to allow for the flushing of the microneedles prior to testing to remove any remaining debris after the manufacturing of the microneedles. The region coming in contact with the durometer had ~1.5 cm of the microneedle, see Figure 2 for a visual of the assembled microneedle. After the epoxy had cured pictures, pre-compressive loading, were taken using a CNC video measuring system, iNEXIV VMA-2520 (Nikon, Melville, NY). An example image is seen in Figure 1.

FIGURE 1: MICRONEEDLE PRIOR TO ANY COMPRESSIVE LOAD.

2.1 Compressive Loading onto Various Durometers

Compressive loading was achieved by using an Instron. Figure 2 shows how the microneedle sample was secured and in contact with the 50A durometer. The compressive loading of the microneedles was done at a rate of 1 N/min until the microneedle reached 1 N. Success if this experiment meant the microneedles did not break upon completion of the testing. Once the testing of each durometer was completed, the microneedles were analyzed taking another picture of the tip. At the end of all the testing, a final picture of the microneedle tip was taken to check for damage.

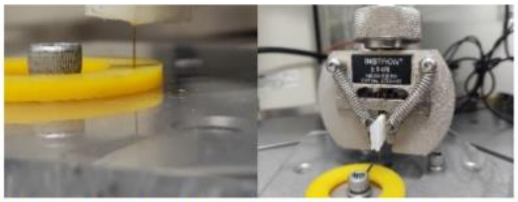

FIGURE 2: THE MICRONEEDLE IS CLAMPED AND SECURED TO THE INSTRON AND THE NEEDLE TIP IS IN CONTACT WITH THE DUROMETER

3. RESULTS AND DISCUSSION

Figure 3 is three images of microneedle number 4 before and after compressive loading. Photos A and B are side views of the microneedles and photo C is the tip of the microneedle post testing. There are no major cracks along the edges of the microneedles nor are there jagged edges on the tip of the microneedles. It is noteworthy that the tip of the microneedle seems to be discolored. This could be parts of the durometers remaining in the microneedles post-testing. In addition, for photo C there does not seem to be a major fracture in the microneedle tip.

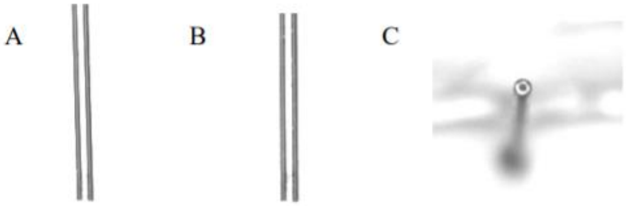

FIGURE 3: SIDE IMAGES BEFORE (A) AND AFTER (B) COMPRESSIVE LOADING OF THE MICRONEEDLES AND A PHOTO OF THE TIP OF THE MICRONEEDLE POST TESTING

Figure 4 represents the reaction of the microneedles being compressed onto the 50A durometer material. Before the test could finish, the microneedle punctured the durometer, and the needle tip was no longer under the compressive load on the durometer surface. This can be seen in the graph as the sharp drop in the experienced load on the microneedles. N3 was the only group to reach the 1 N limit. Also, images were acquired after the test and there was no apparent change to the needle tip or the long sides of the microneedles.

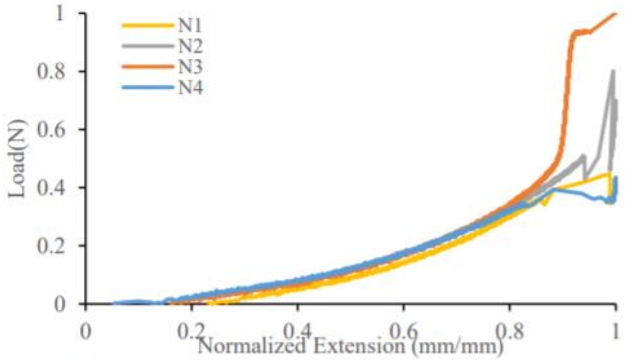

FIGURE 4: SIDE IMAGES BEFORE (A) AND AFTER (B) COMPRESSIVE LOADING OF THE MICRONEEDLES AND A PHOTO OF THE TIP OF THE MICRONEEDLE POST TESTING

Figure 5 illustrates how the microneedles behaved under a 0.2 N/min rate of loading with the 95A durometer. All the needles responded similarly. The plateau region of the graph, denoted by the orange box, is when the needle began to bend, a dissimilar response to when the durometer was being punctured. In addition, only one of the microneedles was able to get to the 1N limit. The others experienced a max load of, N1 = 0.70 N, N2 = 0.91 N, and N3 = 0.76 N, prior to bending. Even though the needles experienced bending on the last durometer, 95 A, there were no major signs of damage to the microneedles, as seen in Figure 3.

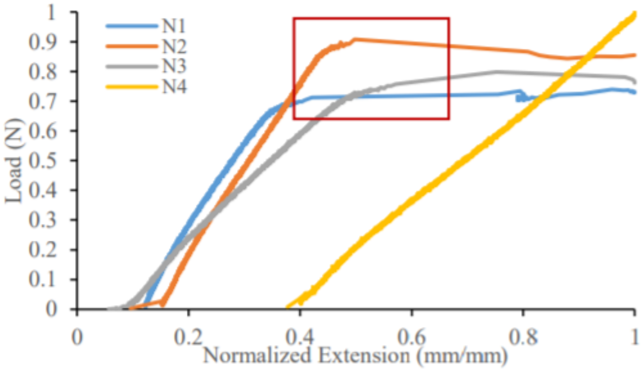

FIGURE 5: LOAD EXPERIENCED BY THE MICRONEEDLES AT A RATE 0.2 N/MIN WITH THE 95A DUROMETER

4. CONCLUSION

For this experiment, we evaluated the structural integrity of the microneedles. More specifically, how they would respond to compressive loading onto various material types (50A, 80A, 90A, and 95A). The biggest challenge was finding a rate that would work and not end the test prematurely. At the end of this testing, we found the microneedles were more likely to bend or puncture the materials than to break or be damaged by this load. However, there were breaks in some of the preliminary trials, due to over-bending of the microneedles, another test that can be run on the assembled microneedles.

Further testing of the microneedles needs to be conducted, for example, we also want to analyze how an axial tension load on the assembled microneedles would respond, and even determine the effects of having a lateral load on the microneedles.

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