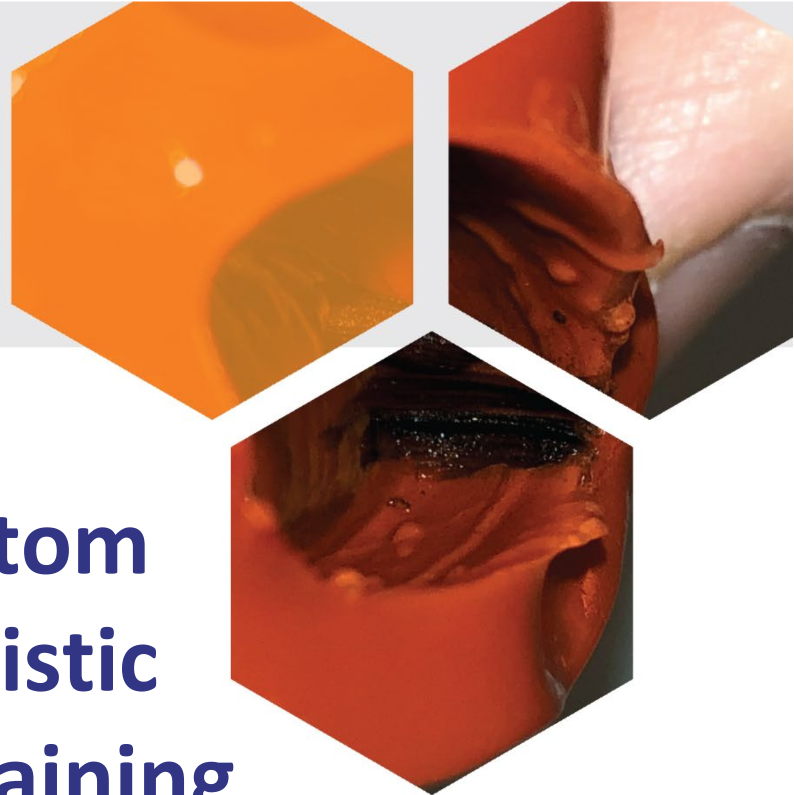

Developing a Custom Hydrogel for Realistic Electrosurgical Training

By Joseph White, Ph.D.

Summary

There is a growing demand in medical device development for reliable test materials that can be used to replace native tissue or better simulate the human organ applicable to the final use. This demand is driven partially through a desire to use consistent and stable materials for testing and development (real tissue has only a very short shelf life!) and through a wish to reduce the use of actual tissue, in light of the ethical concerns surrounding that use. Commercially-available synthetic tissue materials may look realistic but lack many of the nuanced responses that natural tissues possess. Here, one of our clients was in search of more representative synthetic tissue phantoms as surgical training materials. Specifically, the ability to cut and char during electrosurgical intervention was conventionally only obtainable using natural tissues. In this case study, we describe the development of our "e-tissue" hydrogel formulation design to char under bipolar and monopolar electrosurgical intervention in a manner consistent with that observed in real-life use.

Discussion

As ethical concerns over animal and cadaveric testing gain more influence over medical device development, the need for realistic complex anatomical models is growing. Advances in 3D bioprinting and hydrogel development increasingly allow complex geometries and shapes to be generated as synthetic surrogates for tissues and organs. However, many hydrogel systems still lack some of the niche behavior required to accurately mimic tissue in ways that are relevant for a specific application. For example, we have considered tissue models that account for the expansion of arteries, microwave penetration, and for conductivity and diffusion, as well as less quantitative metrics such as surgeon "feel" or "cuttability". These latter surgical methods are often the most important for training but can be the most qualitative and more in the realm of "psycho-rheology" [1] than mechanical testing.

When high energy intervention devices (e.g., electrocautery, radiofrequency ablation, laser cutting) are used to cut away natural tissue, the tissue chars and may produce smoke. The importance of capturing these types of niche behavior in a tissue phantom is crucial for adequate surgical training and product design. Usually, hydrogels or commercially available synthetic tissue phantoms under high energy interventions do not char and typically melt. The look, feel and behavior is therefore vastly different from the real-life situation rendering the quality of the training experience doubtful. If precise excision of tissue is required, then how the tissue responds under the tool mechanically, as well as how it cuts, is a key part of the user experience.

Figure 1: Radiofrequency ablation in knee surgery.

We were tasked with developing a hydrogel system for use as a surgical training tissue phantom for bipolar and monopolar electrosurgical sphincterotomy. The ability to cut and cauterize tissue using electrical energy requires appropriate electrical conductivity and thermal decomposition modalities in order to produce a cut behavior that matches the cutting process but also produces smoke and chars in the same manner as the native tissue. Typically, electrosurgical cutting vaporizes tissue by creating spark events close to, but not contacting, the tissue. Alternatively, cutting by desiccation occurs when the electrode comes in direct contact with tissue to concentrate the current at the tissue site, thereby heating and driving of moisture to then cut through the tissue [2].

Conventional tissue phantoms are often composed of synthetic, solid polymers. The benefits of these materials are obviously stability/shelf-life but the usual choices (silicones or polyurethanes) for tissue phantoms not only lack the right tactile feel compared to natural tissue, they also do not respond to electrical energy in the same manner either. Hydrogels on the other hand provide a similar tactile feel to natural tissue (unsurprisingly given the hydrogel-like nature of tissue), but many common hydrogel chemistries are either non-responsive to electrical energy or melt under high temperatures.

Taking inspiration from the Maillard reaction (i.e., browning of food under heat), we developed our "e-tissue" hydrogel system to produce char and smoke similar to natural tissue (represented by a chicken heart, known to be good surrogates for representative tissue cutting), as well as cut during electrosurgical intervention. This formulation combines knowledge of suitable chemistries and structures to achieve the mechanical feel, as well as the inclusion of other species to achieve the required arcing (cutting) and burning behavior. An example of the possibilities of this process is shown in Figure 2.

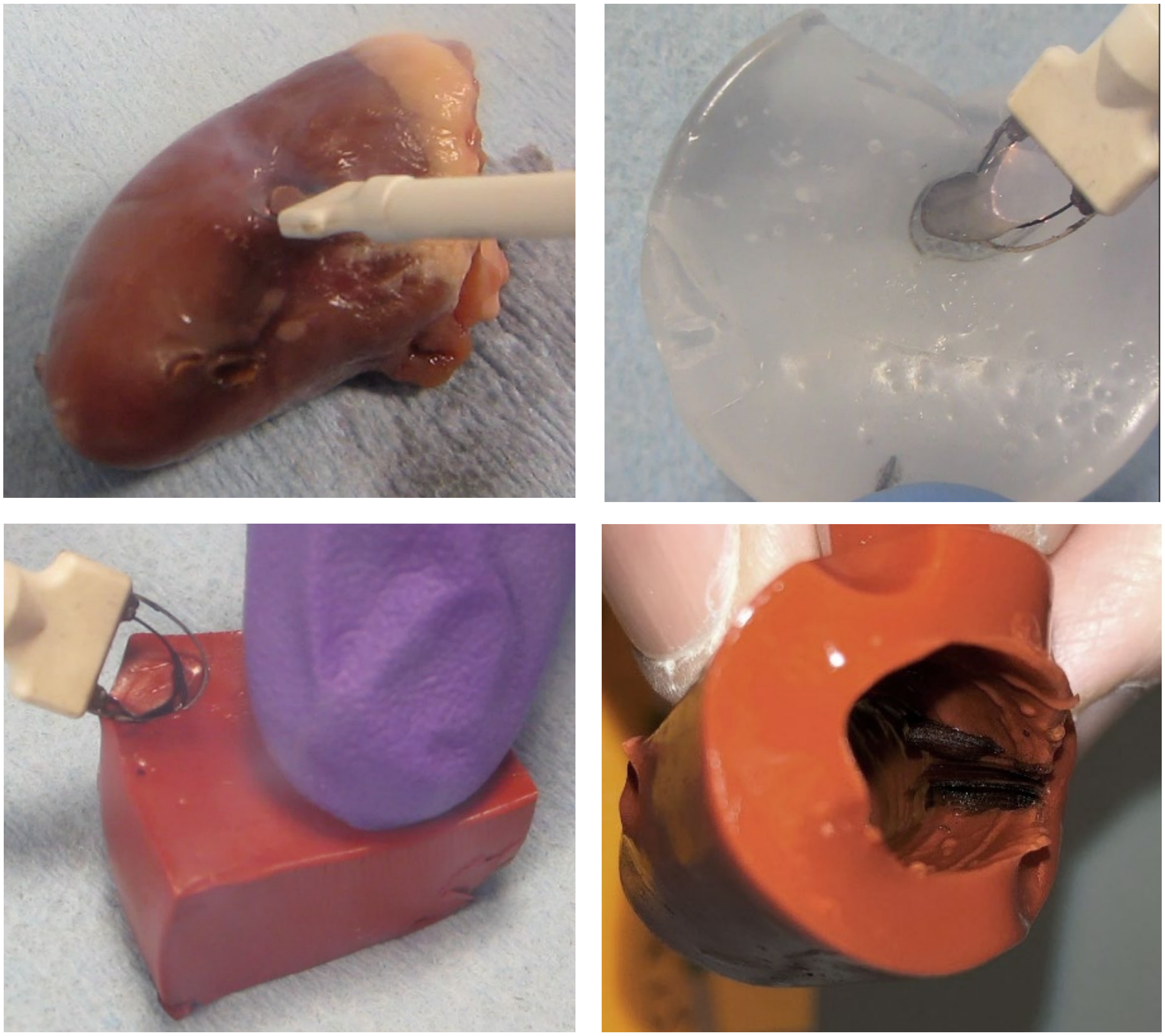

Figure 2: Upper left: Chicken heart under bipolar electrocautery produces char and smoke during cutting. Upper right: Translucent e-tissue option under bipolar electrocautery produces char and smoke during cutting. Lower left: Red e-tissue option under bipolar electrocautery produces char and smoke during cutting. Bottom right: Red e-tissue cast as papilla produced char and smoke under monopolar electrocautery during similar sphincterotomy training.

Conclusions

CPG leverages its extensive hydrogel expertise to assist medical device developers and synthetic tissue model designers in creating custom tissue model formulations development and lab-scale manufacturing. Our rich expertise in testing, and particularly the adaptation of standardized tests for unusual needs, gives us a unique experience in test design and development. Coupling that experience with a deep understanding of materials science and hydrogel chemistry allows us to assist in the construction and validation of novel, application specific, test materials and configurations for use as test-beds, surgical training tools or marketing demonstrators, as shown in Figure 3.

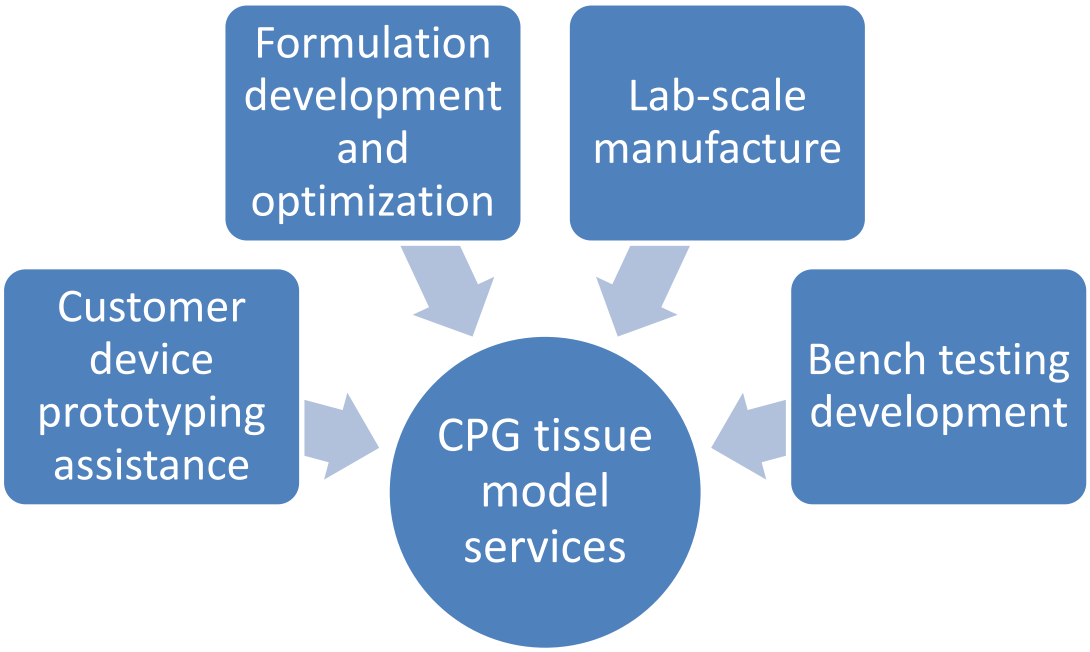

Figure 3: Outline of custom tissue model services at CPG

References/Notes

[1] "Connecting mechanical testing techniques to user perception" Cambridge Polymer Group. 2015.
[2] "Principles of Electrosurgery" Covidien. 2008.

About Joseph White, Ph.D.

Joseph White, Ph.D. is a Cambridge Polymer Group Research Scientist II, specializing in biomaterials, including hydrogels for medical applications. He has co-authored numerous publications, including studies on oxygen transport enhancement and the development of composite hydrogels with improved mechanical properties. Joe has presented his work at major scientific conferences and contributed to several SBIR projects focused on innovative biomedical solutions. He holds a patent for a thermo-reversible amphiphilic gel device, reflecting his commitment to advancing biomaterial technologies.

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