Medical Device Applications of Conformable Sensor Technology

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Conformable Sensor Technology has been applied to medical device applications to measure forces applied to a medical device as well as measurement of forces applied to tissue by a medical device. Conformable sensors can be attached to or incorporated within a medical device, such as a balloon, mesh, catheter, prosthetic, or instrumentation. The sensors can be used as a stand alone device to measure compression or elongation of tissue or measurement of touch sensitivity.

Neuropathy measurement is one example of an area of application, where a patient's touch sensitivity can be measured with ranges as low as milli-Newtons. The ability to digitally measure and record touch sensitivity will allow practitioners and patients to more easily monitor progression of neurological changes due to diabetes or chemotherapy. Figure 1 is an example of such a device in development. The tip of the pencil contains a thin membrane conformable sensor. The tip that is touched may be a thin balloon structure or a soft polymer protrusion. The patient touches the device until they feel it, then removes the device. Figure 2 shows the ability of the sensor to measure very light, fingertip, touches below 0.010 Newtons, an indication of good nerve sensitivity. The graph shows the response of the sensor, change in current, for four touches by a Shimpo force gauge. It can be seen that the sensor detects the initial touch well before contact is removed, which allows the practitioner to determine the difference between the onset of the touch until the patient feels the surface of the tip. The output of the device may be graphical as well as logged into a CSV formatted Excel spreadsheet for record retention.

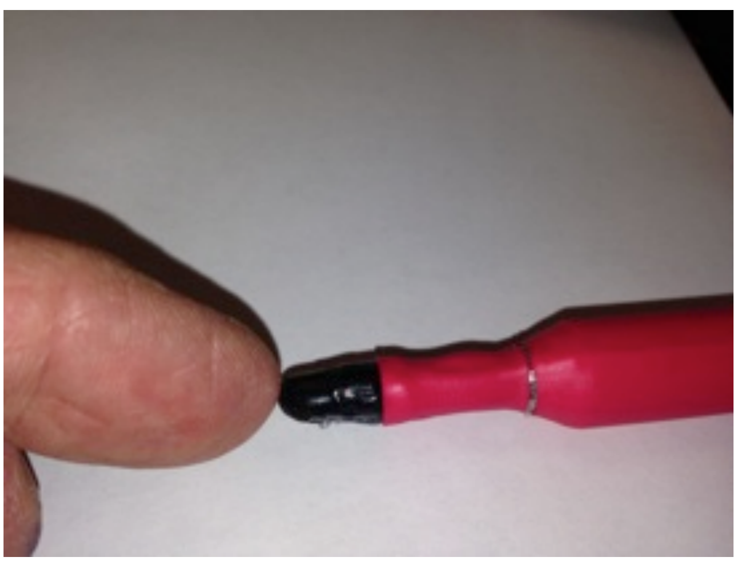

Fig 1. Conformable Sensor for measurement of neuropathy.

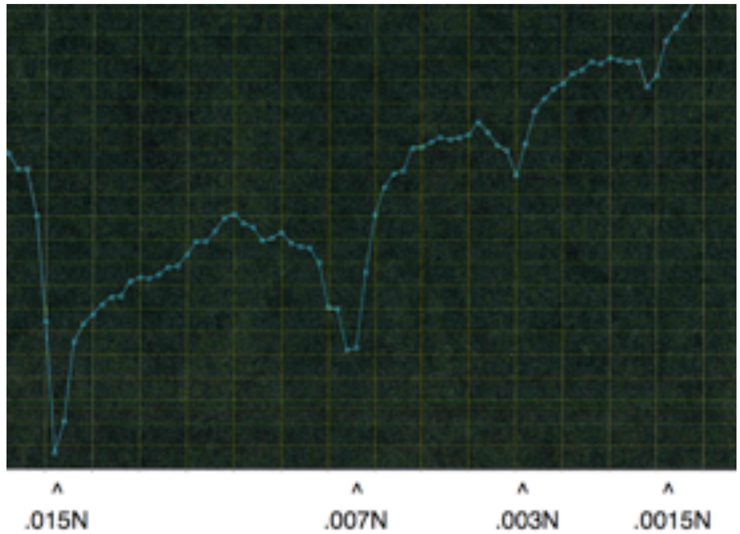

Fig 2. Graphical display of neuropathy sensor to calibrated touch.

Touch sensitivity may also be measured against tissue samples as in a grasping device for surgical applications. In this scenario, the conformable sensor material may be applied to the surface of the grasping device to measure the force applied to the tissue. Figure 3 shows the surface of a grasping device with a sensor molded to the surface of the device for the purpose of direct contact measurements to tissue during compression. Figure 4 is a graph of various compressive forces applied by the grasping device of Figure 3, on a very soft synthetic tissue sample. The resultant sensor output, in Ohms resistance change, demonstrates the capability of the sensor to measure the force applied during the grasping action, as well as the resultant relaxation of the soft synthetic, rubber, tissue sample.

Fig 3. Grasping device with molded sensor technology surface

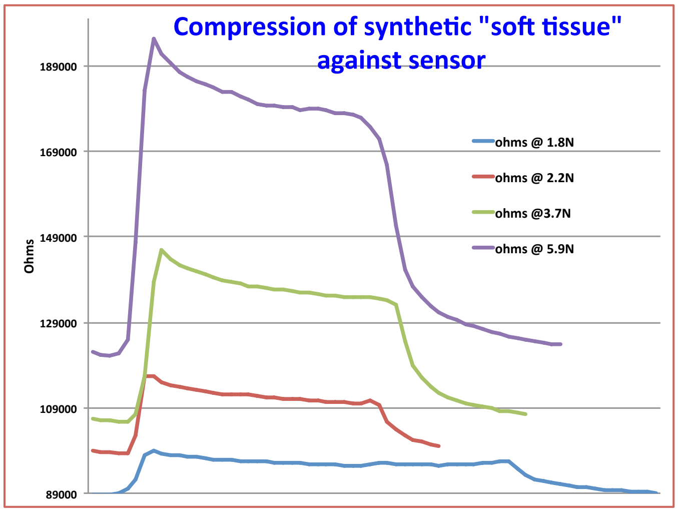

Fig 4. Output, in Ohms, of sensor in figure 3, when compressed against soft synthetic tissue, 1-6 Newtons.

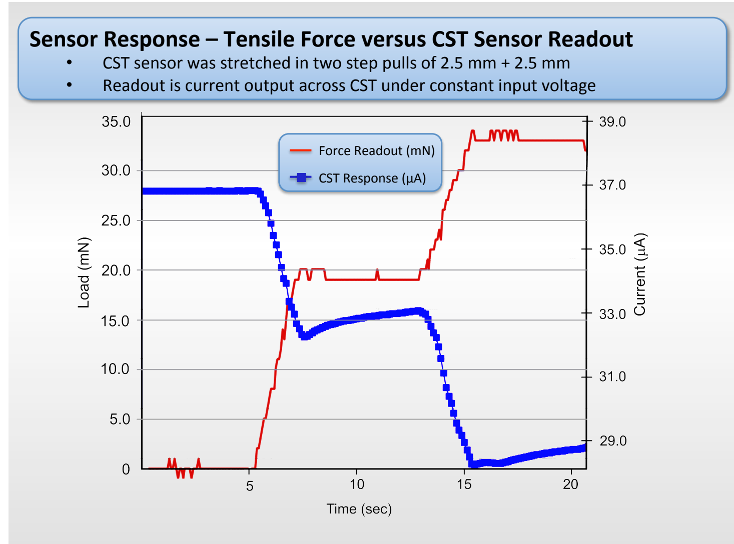

Fig 6. Sensor response for mesh device sensor in figure 5 (blue), mounted on a mesh, pulled 2.5 mm by a force gauge.

Application of Conformable Sensor Technology (CST) has also been applied to medical devices such as mesh retainers for hernia and prolapsed organs. There the distance that the mesh is stretched, and the load or stress that is placed upon the mesh, can be determined. The sensor may be part of the device or may be a removable item once the device is implanted. Balloon medical devices may also incorporate micron thick conformable sensors for measurement of inflation and pressures exerted upon the balloon device. Figure 5 below shows two examples of such sensor devices; a sensor for application in mesh devices, and a balloon medical type device, which may include catheter balloon devices. As an example, Figure 6 shows the graphical resultant output, in amps, of a sensor mounted on a mesh device with the mesh pulled 5 mm in two 2.5 mm steps. The device, secured to a fixture, was pulled by a Shimpo force gauge mounted on a translation stage. As an example, Figure 7 shows the graphical resultant output, in amps, of a sensor mounted within a thin balloon wall. The balloon wall thickness was 80 microns including 20 micron thick sensor. The balloon was expanded into a soft synthetic tissue that was mounted onto a fixture affixed to a Shimpo force gauge.

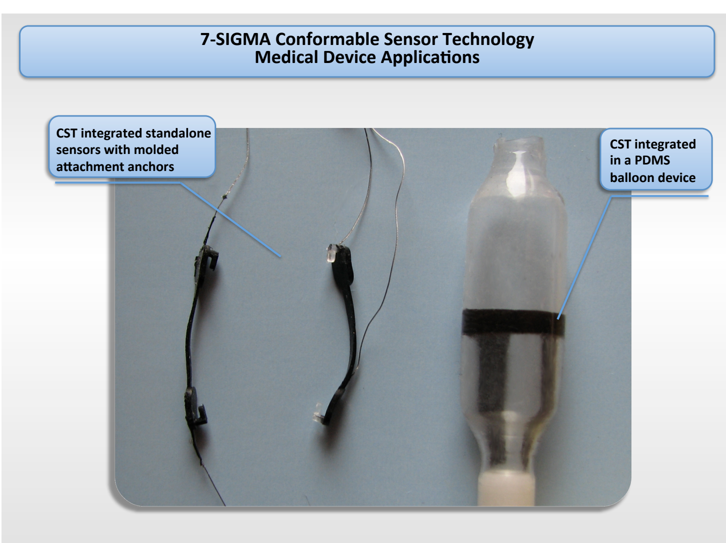

Fig 5. Examples of medical devices sensor applications. Left two for mesh devices, right for balloon devices.

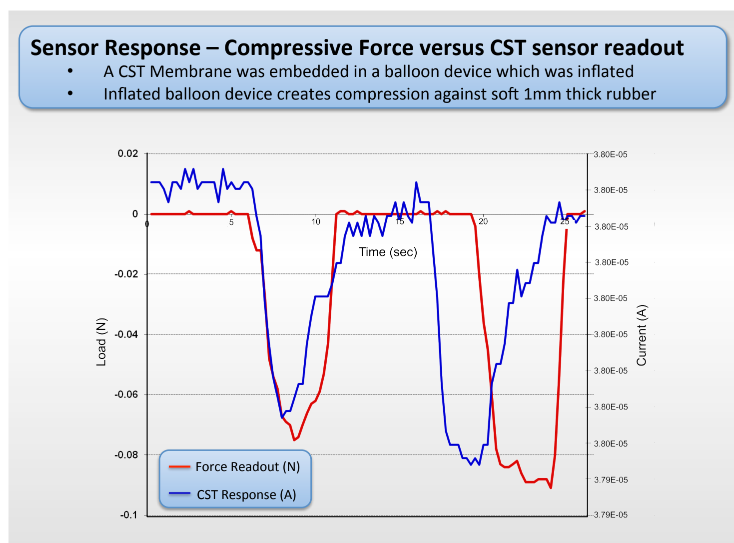

Fig 7. Sensor response, blue, to compression of a balloon device into soft synthetic tissue sample.

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