Pressure-sensitive sleeve gastrectomy tube

Materials and Methods

The first concept employed in prototyping the sleeve gastrectomy tube involved the use of carbon impregnated foil between copper wires in sensors. These wires were connected to a circuit enabling the reading of resistance between the two wires. As pressure was applied to the sensors, the foil was compressed, and resistance decreased. Thus, decreased resistance could be read as increased pressure. Six independent sensors were attached to a 40 Fr tube.

In the second-generation design, it was decided that the use of balloons that could be inflated after the tube was passed into the stomach would improve versatility, simplify the circuit, and allow for the use of commercially-produced air/water pressure sensors with standard pneumatic fittings. This proof-of-concept prototype was comprised of two balloons over the distal 15 cm of the device, two 3/16" inner diameter (ID) PVC (polyvinyl chloride) tubes each opening into one of the balloons, an on/off valve near the proximal end of each tube, and polyurethane glue.

It was determined that for the third-generation prototype, longer balloons were necessary to accommodate the variation in stomach length among patients. The length of the proximal balloon was doubled, and the volume of the distal balloon was increased to allow for greater expansion into the pyloric antrum. It was also decided that the use of two smaller polyurethane tubes (3/32" ID) running through a single larger PVC tube (5/16" ID) would allow for a cleaner design and the incorporation of suction through the large tube.

Balloon development

The tube designing process began in the CAD (computer-aided design) software program Fusion360, where molds for the balloons were designed. The second-generation distal balloon mold begins with a 12-mm diameter at its proximal end, and expands outward in a shape amenable to filling the space of the pyloric antrum; its total length is 4.5 cm. The proximal balloon mold in the same prototype had a 12-mm diameter down its entire 10 cm length, with both ends rounded.

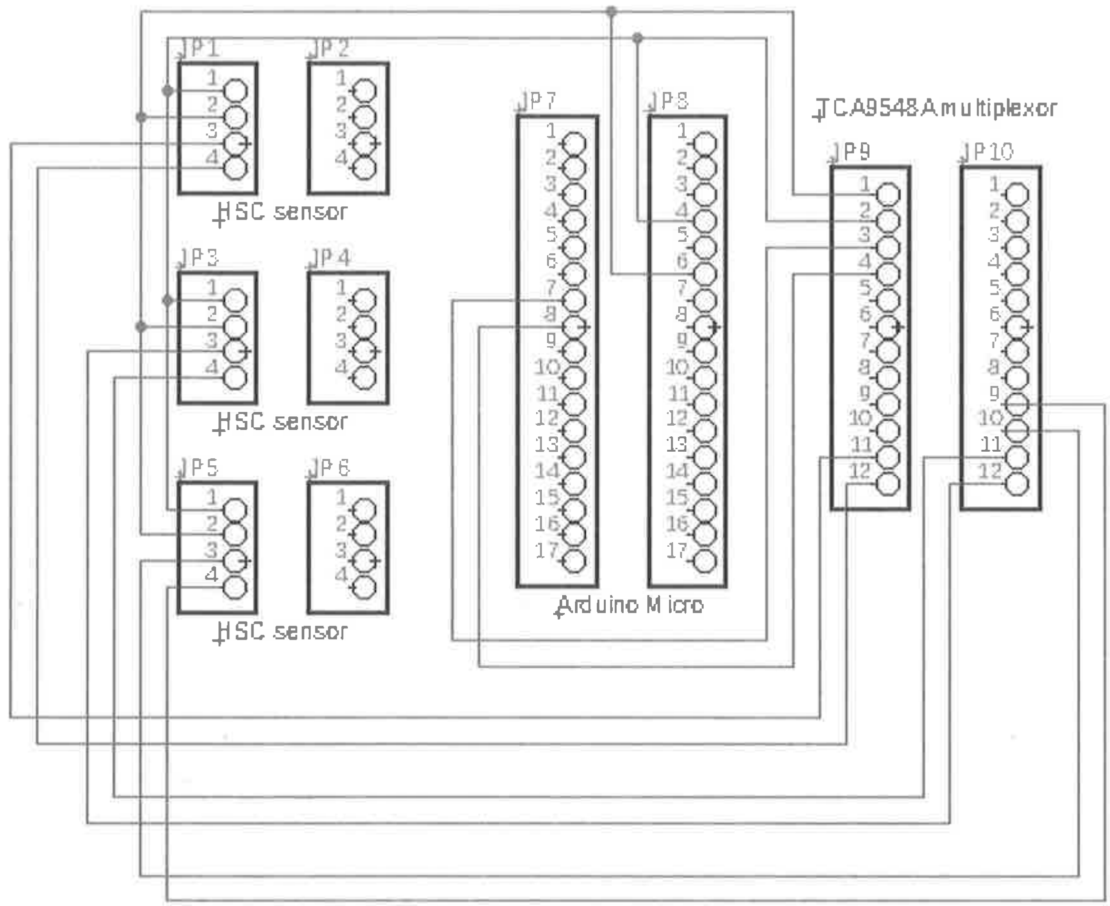
The third-generation balloon mold development followed the same process as that outlined above, but with some changes in dimensions. The proximal balloon mold is 17 cm in length and has a base diameter of 12 mm which enlarges to 16 mm at the proximal end to reduce the likelihood of tightening excessively near the gastroesophageal junction (GEJ). The distal balloon mold begins with a 16-mm diameter at its proximal end, and expands outward in a shape amenable to filling the space of the pyloric antrum; as in the second-generation mold, its total length was again 7.5 cm. The third-generation mold was more angular than the previous model to incorporate a greater volume-filling capacity.

The mold designs were then converted to STL (stereolithography) files and sent to a Stratasys Dimension STS 1200 printer to be printed in ABS (acrylonitrile butadiene styrene). The printed molds were then glued onto insulated copper wire which formed a spiral base for the molds. The molds were next dipped multiple times in heated paraffin wax to completely coat the molds; the wax was then left to harden. The next step involved coating the molds with liquid latex: in the second-generation balloons, the first and third layers were brushed on, and the second layer was dipped—in the third-generation balloons, all three layers were brushed onto the molds to increase elasticity. The latex was left to dry completely between layer applications. After drying of the third layer of latex, the balloons were powdered with corn starch. The ends of the balloons were cut to a clean, even line, and the balloons were then rolled off the molds. A small hole was cut in the distal end of the proximal balloon. The ends of the two tubes were offset by 10 cm in the second-generation prototype, and by 20 cm in the third-generation to facilitate confluence with their respective balloons. These tubes were fastened together using polyurethane glue. The proximal balloon was passed first over the tubing until the proximal end rested 1 cm proximal to the tube opening. The distal balloon was then passed over the distal 2 cm of the tube. The balloons were then secured to the tubing in an air-tight manner with polyurethane glue. The balloons would expand upon inflation to an approximate base diameter of 40 Fr, with wider sections built into the design to prevent stricture creation and excessive tension around sphincters and junctions.

Circuit

The first circuit consisted of a simple auto-ranging ohmmeter. Each force sensitive resistor was connected in series with one of several resistors of known values. The voltage drop between the force sensitive resistor and known resistor was then measured and used to calculate the value of the unknown resistance. This value was then used to determine the relative pressure that was being applied to the resistor.

The second version of the circuit was completely redesigned to read values from industrial pressure sensors. To ensure high-accuracy pressure sensing while maintaining a relatively low cost, three 0-1 PSI Honeywell HSC Compensated/Amplified pressure sensors were used. These three sensors were interfaced with an Arduino Micro using the I2C (Inter-integrated circuit) serial bus. This interchange was facilitated by a TCA9548A multiplexor to allow for multiple serial devices with the same digital address to be used with a single microcontroller (See Fig 1-2). Real-time pressure readings are sent from the board to a main computing device (e.g. laptop or tablet) where they are displayed.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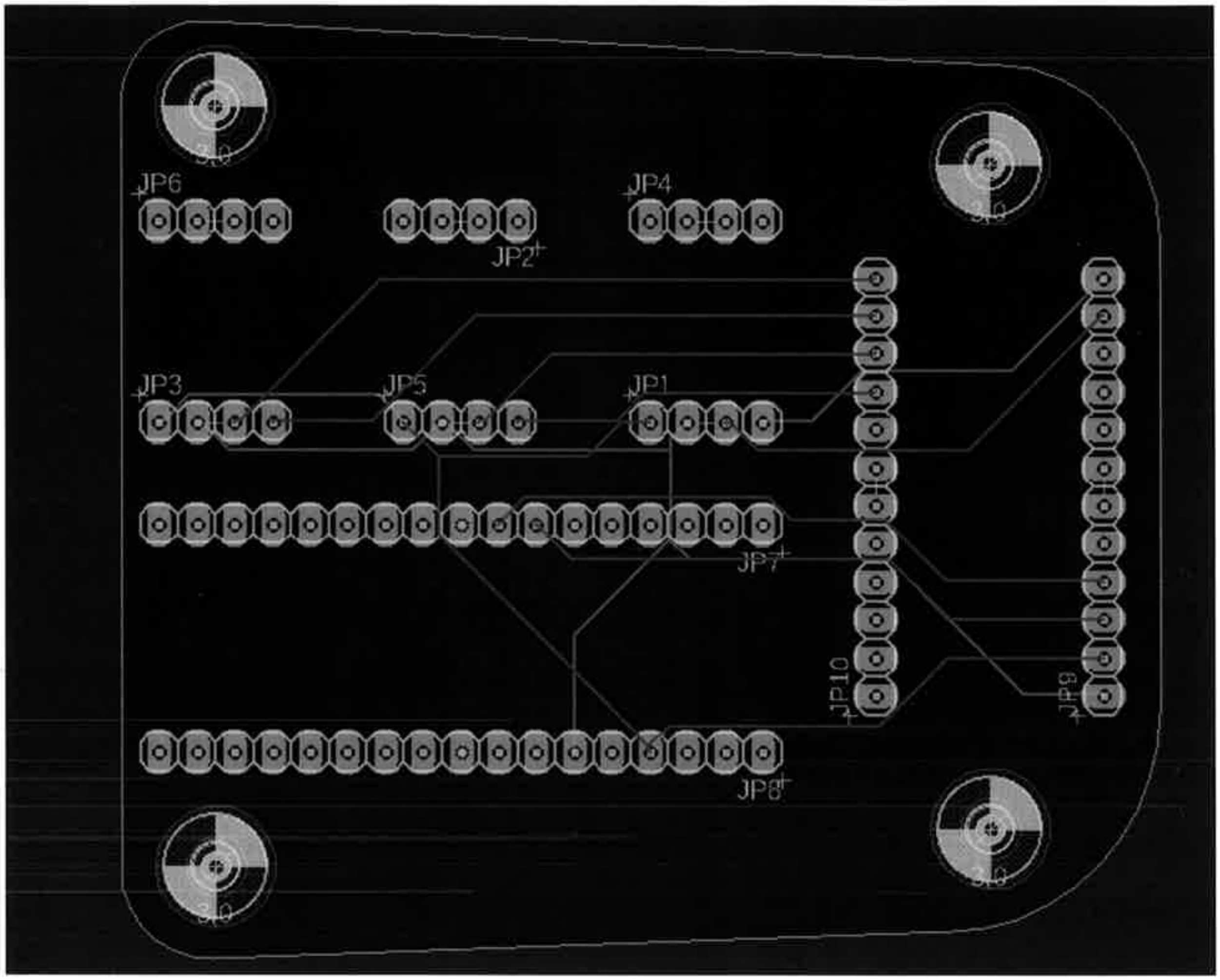
TCA9548A multiplexor



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