MEDICAL DESIGN BRIEFS

NON-CONTACT, LIGHT-BASED MEASUREMENTS FOR MEDICAL BALLOONS AND CATHETERS

One of the most prevalent measurement devices in a medical balloon or catheter manufacturing facility is the micrometer gauge. It is simple and inexpensive. But, this measurement technique is subject to a high degree of operator variability. Another limitation is that it measures total thickness only, and not the actual individual wall thickness. Furthermore, a micrometer compresses the measured part, and must, by design, come into contact with the material. The micrometer does not provide engineers with the precise and detailed information they need to develop and improve production processes. What other issues are there?

The production process for medical devices that use catheters and balloons is a manually intensive task, which has gotten more difficult as newer products have been developed. Manufacturing extruded tubing used for balloons is also quite difficult. The wall thickness and concentricity of tubing is critical to the final dimensions of the balloon. A balloon that has thinner walls on one side will expand unevenly resulting in potential complications during surgical procedures.

Figure 1- Optical signal obtained for the top wall of a medical balloon. The distance between the signal peaks is equal to the optical thickness of the wall.

As the medical device moves further down the production line, the cost of failure increases. Eliminating a balloon that costs pennies, after it is formed, is very inexpensive compared to discarding it further down the process where the balloon is incorporated into a medical device. Is there a better option than micrometers and manual methods?

White Light Interferometry Technology

This article examines a new white light interferometry technology that eliminates the subjective nature of micrometers. We will review thickness data, obtained in a series of interferometric measurements for a 2.25 x 8 mm balloon. This data will demonstrate an easy method for fast and accurate wall measurements using an all-fiber low-coherence time-domain interferometer.

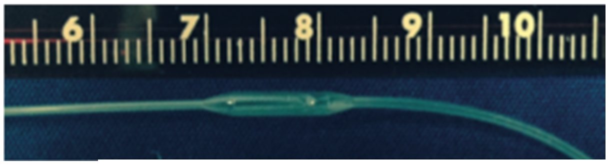

Figure 2-Shown is a measured balloon

In its simplest form, light from a low-coherence light source is directed at the sample. For each new layer (interface) where it encounters a change in refractive index (RI), a small amount of light is reflected back into the system where sophisticated and proprietary software produces highly accurate measurement results. The system is capable of measuring up to 20 different layers. The maximum thickness of the layer

is greater than one inch, and the minimum layer thickness that the interferometer can measure is approximately 12 microns (0.0005").
The interferometer incorporates a patented process to create the measurement signal, by using piezo-electric tubes wrapped in bare fiber-optic cable. The interference, or the time domain signal pattern, is created by rapidly expanding and contracting the piezo discs, thus, stretching the optical fiber. This simplified design is robust and free from free-space setup and alignment issues.

Figure 1 shows an example of the interferometric signal, acquired for a single balloon wall during a single scan of the interferometer. The peaks indicate the locations of the surfaces of the balloon wall, with the first peak corresponding to the top “outside” surface of the balloon wall, and the second peak corresponding to the bottom “inner” surface of the balloon wall with the incident light coming from the top. The distance between the two peaks is equal to the optical thickness of the wall. The physical thickness of the wall can be obtained by dividing the optical thickness by the material’s refractive index (the RI can also be measured using this method, in a special configuration, where a mirror is placed on the opposite side of the sample from the optical probe).

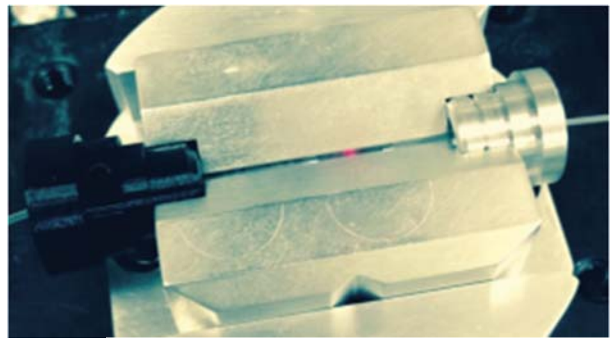

Figure 3 - Here the balloon is in a fixture.

The system software runs on the engineer’s laptop, and the measurement results are displayed and can be saved to a file, or streamed out to other third-party applications. Simplified fixturing allows for easy use by operators, and provides consistent measurement results with accuracy and repeatability of 0.1 micron.

Testing

Balloon wall testing demonstrates the high utility of this method for measuring medical devices. Figure 2 shows the 2.25 x 8 mm tested balloon. The balloon was held in a fixture, as shown in Figure 3. This device could be designed to accommodate any size balloon, inflated or not. It is merely a channel, it is the relative size of the balloon that allows the balloon to be easily rotated while still maintaining the balloon’s relative position to the probe. Other devices could be designed that are simpler and geared to specific applications.

	Test number								
Samples	1	2	3	4	5	6	7	AVG	STD
5Hz	23.94	24.25	24.61	24.33	24.86	24.59	24.25	24.40	0.3020

Table 1 Average wall thickness test of medical balloons (in microns).

A series of repeatability tests were taken on the system. The same balloon, and the same approximate location was used for all tests. The probe is used to focus the measurement light beam to a 40 microns spot on the balloon. For each test the balloon was manually rotated 360 degrees while data was gathered. A simple algorithm then sorted the data removing the obvious outliers and calculating the average thickness for a complete rotation around the balloon..

Precision Measurement Solutions

Figure 4 shows the thickness change over the 360-degree rotation of the balloon during one of the tests. Same thickness non-uniformity appears during other tests as well. As shown in Table 1, the variation in average wall thickness is less than 1 micron for all the measurements, with a standard deviation of 0.3. This is extremely consistent given the nature of balloons with walls this thin. Additionally, there is a definite thickness change in plastic materials when measuring around the circumference of a balloon.

This testing shows that with the appropriate fixturing, white light interferometry technology is ideal for non-contact, non-destructive testing of medical devices and presents what could be considered a superior method to the traditional micrometer methods used today.

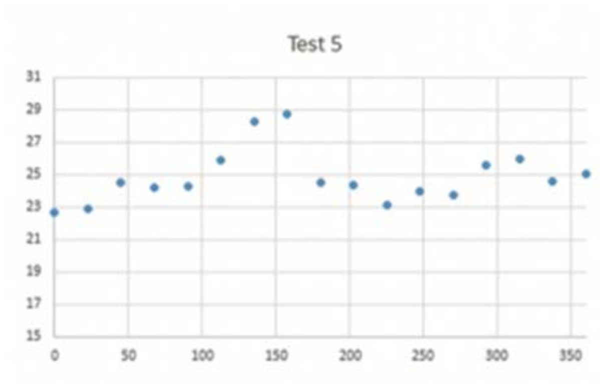

Figure 4 - Balloon wall thickness over 360-degree rotation