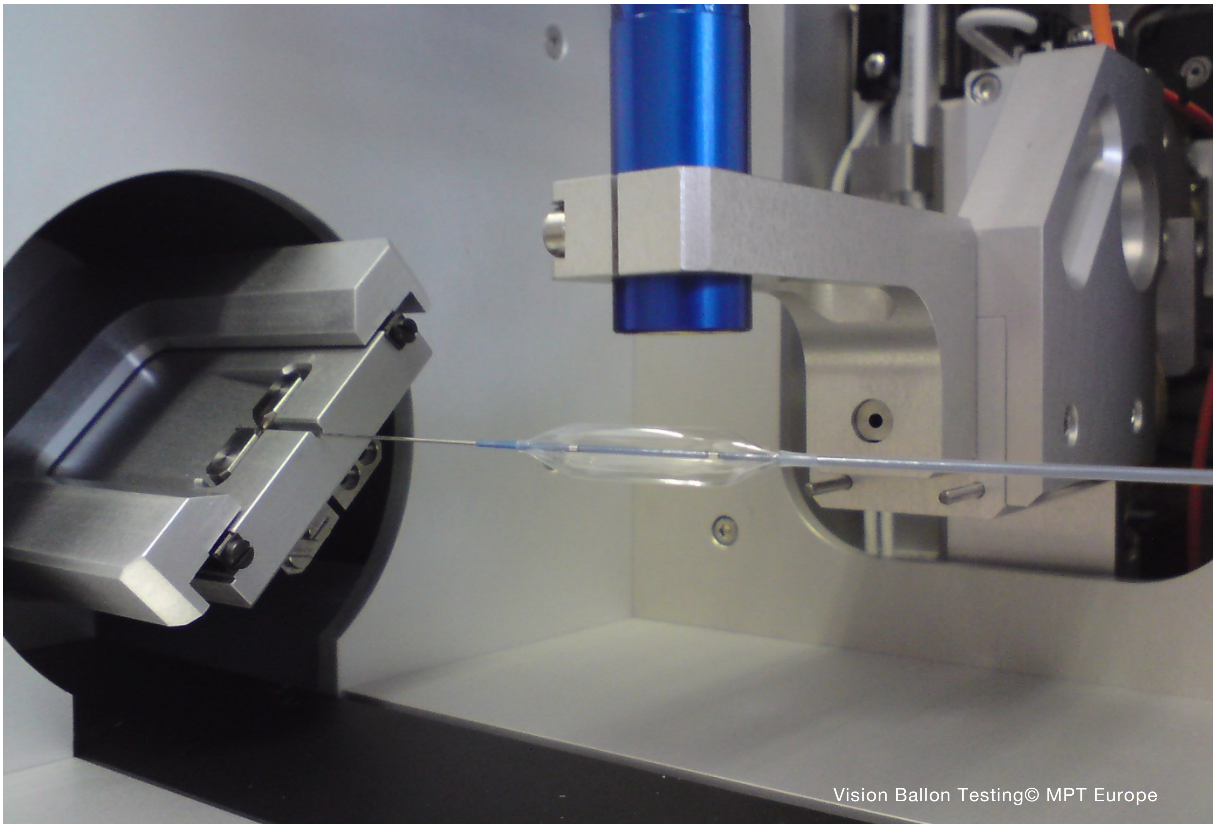
THICKNESS MEASUREMENTS ON BALLOON CATHETERS

NONCONTACT MEASUREMENT OF MEDICAL PLASTICS


Vision Ballon Testing© MPT Europe

It is almost impossible for the wall thickness of balloons and thin-walled tubes (from which balloon catheters are manufactured) to be measured from the inside. The wall thicknesses can merely be estimated mechanically. But a simple solution exists in the form of optical noncontact measuring techniques which offer thickness measurements as a starting point, because these techniques offer so much more.

Balloons for angioplasty are usually produced from continuous thin-walled tubes. They are used to widen narrowed or obstructed arteries and veins. The inflated balloon forces expansion of the narrowing within the vessel, opening it up with resulting improved blood flow. The balloon is then deflated and withdrawn. The starting materials are mostly polyurethanes, Nylons or PET with wall thicknesses of 0.015 mm to 0.06 mm (for balloons), comparable to the thickness of human hair. The physical properties of these materials mean that they are globally used for numerous applications (not only in the medical sector). Of particular importance in the medical fields are properties such as resistance to sterilization, gliding properties, mechanical flexibility, processability as well as mechanical and chemical resistance.

Historically, parameters such as angles, lengths and diameters were measured with optical measurement systems because they are accessible. Wall thicknesses were determined by compressing the two tube walls together, measuring with a micrometer gauge and halving the result. The accuracy of this procedure is compromised by varying textures and definitely by the soft and yielding material and its low thickness. In addition the subjective nature of the measurement and its influence on results cannot be neglected. Measurement techniques are being extended beyond their capabilities with new, higher quality catheter balloons because of more frequent checking, the need to test at higher mechanical loading plus the analysis being performed under clean-room conditions due to hygiene regulations. Additionally, with the increased use of higher quantities, manufacturing operations require the parallel use of multiple blow-moulding units, further stressing the need for a robust testing technology.

Why is it so essential for the quality assurance to document exact measurement results - ideally for the whole balloon volume? The reason for this is the way the balloons are produced by blow moulding. Blow moulding systems use special mould tools, which are shaped on the inside like the final balloon. During the production cycle the forming tools go through a series of heating and cooling events, whereas the tube undergoes stretching. Depending on the surface area of the balloon differing tensions within the balloon will result leading to varying thicknesses (figure 1). The stretching process is the most crucial part of the production process but the temperature profile and stretching speed used during the moulding process are also influential.

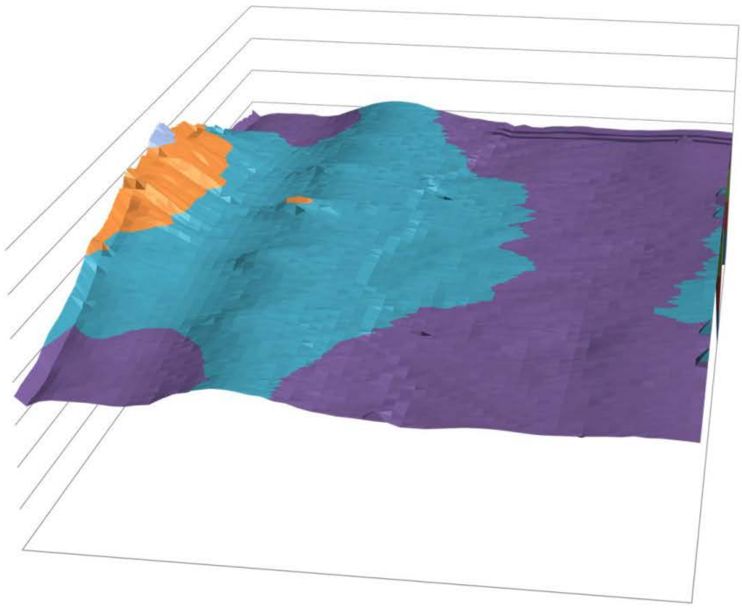


Fig 1:

Balloon for angioplasty, 360 degree scanning**.** 40.000 points were measured. Colors indicate single wall thickness from proximal to distal side. © MPT Europe, NR Leek, Netherlands

It is possible that even after a thorough visual inspection faults can remain undetected. However having knowledge about the condition of the balloon wall gives information about the quality of the product. While the balloons are being blown, the highest tensions appear where the row sleeving turns into the balloon segment. This results because the wall thickness of the hollow parts is the thickest whilst the shoulder radius is the thinnest and during this stage of production the balloon can rupture in these areas. It was proved using high-speed photographs that balloons tend to break, while under pressure near the thickest parts of the balloon. If it is not possible to generate a complete measurement of the balloon, it can suffice to only measure specific reference points. In fig. 1 areas with thicker parts are showing incomplete stretching of the balloon material.

Noncontact measuring systems e.g. by MPT Europe (NR Leek, Netherlands) can not only measure the wall thickness on any area, but also the geometry of an inflated or deflated balloon. These measurements allow the calculation of the balloons growth over time. It has been observed that the wall thickness decreases with time, while the balloon is still growing. Even silicone breast implants can be measured; such implants are significantly thicker with wall thickness of 2 mm. This can be done non-destructively, while the implant still sits in the mould. As always, the wall thickness is the most interesting part to analyze, due to the probability of it varying in thickness during the manufacturing process (Dip Coating).

Balloon dilatation is usually used to expand stents, which remain in the contracted area when the water or contrast media filled balloon (no air is used to fill the balloon) is emptied and removed from the artery. Even the thickness of drug impregnated coatings on stents can be measured.

The sensors are equipped with optical probes (figure 2), which can measure both thickness and distances and such measurement techniques are now widely distributed and being used for instruments, implants or packages, which adds up to a huge amount of medical material. The noncontact measurement principle is especially valuable as these systems are widely used for clinical and clean room applications. High measuring rates and freedom from temperature dependency aids the inline-usage, which is mandatory in highly automated mass production of medical products.

Fig 2:

Optical sensor CHRocodile SE by Precitec Optronik was designed for the noncontact measurement of topography and layer thickness. The Interferometric measuring range spans 3 µm to 180 µm. © Precitec Optronik

Additional applications

Additional applications of noncontact measuring techniques include the capability of precisely determining the fill levels of liquids, a requirement for some filling techniques for medications. The wall thicknesses of disposable plastic syringes can be determined. Small medical vials need to be sealed on the upper end. The coatings are so thin that only noncontact systems can validate whether the sealing would last or not.

Furthermore there are new line sensors available, which can process 3D-topographies up to 200 times faster than conventional point sensors. These systems could be used to measure bioresorbable stents, the current end point in a chain of development. These stents are also coated and have been designed to give a blood vessel additional stability after releasing the medication. Its body wall structure consists of biodegradable polylactic acid (PLA) which completely dissolves after a certain time. The thickness can be measured without any contact and then displayed as a high resolution 3D-topography.

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