

Application Note

Measurement Solutions for Industry

In this issue:

The Measurement of Cannulae and Injection Needles using Focus Variation

Introduction

Both Cannulae and Injection needles effectiveness are tested using the measurement of penetration force and track force in a well-established and standardized technique. These results indicate if the product is suitable for patient use or not by measuring the force needed for insertion.

If a device fails this test then there is a need to understand the reason why it has failed and to optimise the manufacturing process so that failures are reduced.

The performance of these devices is dictated by

- a) The sharpness of the tip
- b) The cutting edge radius
- c) Burrs on the inner and outer surfaces
- c) The surface finish of the needle

All of these have their respective manufacturing specifications. And the question arises what can be done to find the cause of the problem if the needles fail the test.

With all measurements being fully traceable to international standards, known levels of uncertainty and highly repeatable the technique has become a “go to” technique for many users.

Optical 3D Metrology.

Using Optical 3D metrology allows the manufacturer to accurately measure these key features. Unlike conventional contact metrology optical metrology is non-contact and provides a full 3D view of the item under test and it is on this 3D model that measurements are performed.

The instrument used for these measurements is the Bruker Alicona InfiniteFocusSL (figure 1) system fitted with a rotation device. The rotation device allows the needle to be rotated through 360° to provide a full colour high resolution data set. This data can be compared against CAD.



Figure 1 InfiniteFocusSL

Full 3D Model

These 2 images, figure 2 and 3 show a full 3D view of the tip of the needle in high resolution. This will display any surface defects, cutting edge defects and burrs.



Figure 2

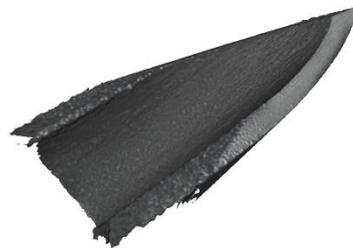


Figure 3

Cutting Edge Radius

The cutting edge itself has a major influence on the performance of the needle and. Using the optical measurement process the edge can be easily displayed and measured (figure 4 and 5). Figure 5 shows the measurement of the edge using 500 profile lines placed across the edge. This is showing an edge radius of 4.35µm

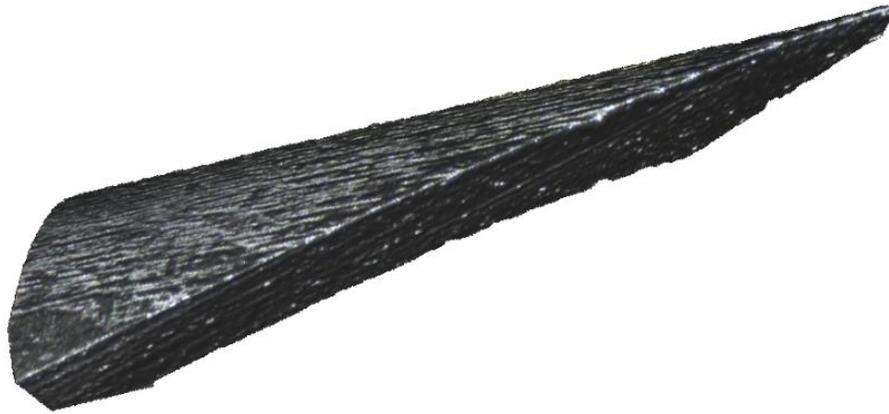


Figure 4

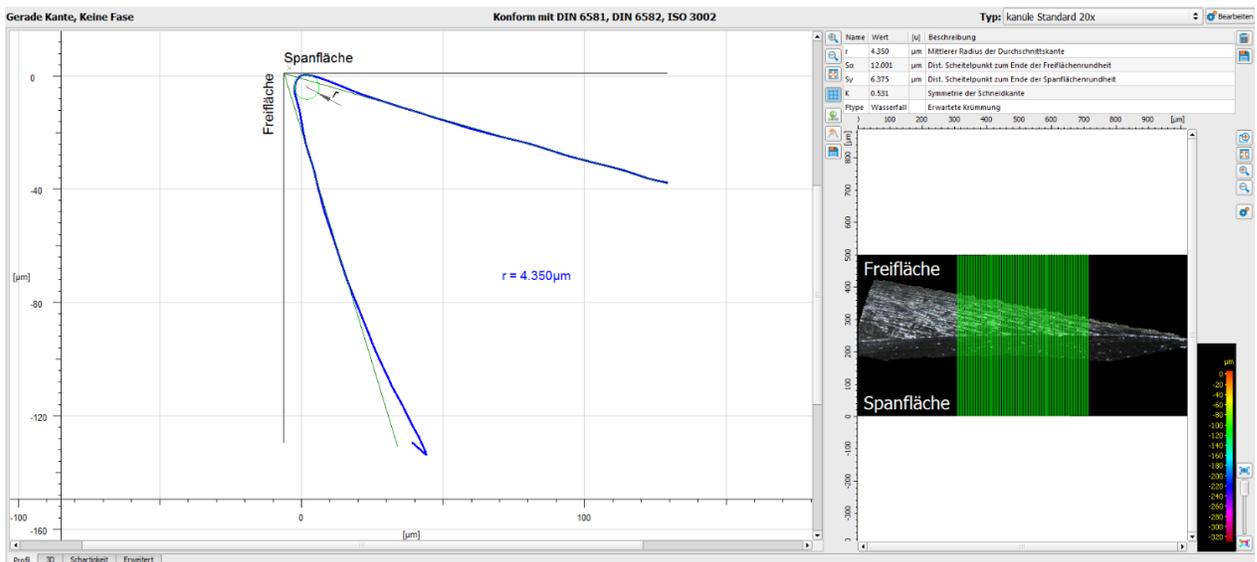


Figure 5

Surface Finish

Using a 3D model of the cutting edge it is now possible to place a measurement line directly along the cutting edge. To measure the roughness and chipping along the edge, in this case the measurement is showing as $0.977 \mu\text{m Ra}$. It is also possible, using the same method, to measure the roughness on the outside and inside the needle point in any direction as displayed in figure 7. It is also possible to measure the roughness on the cutting edge as shown in figure 6.

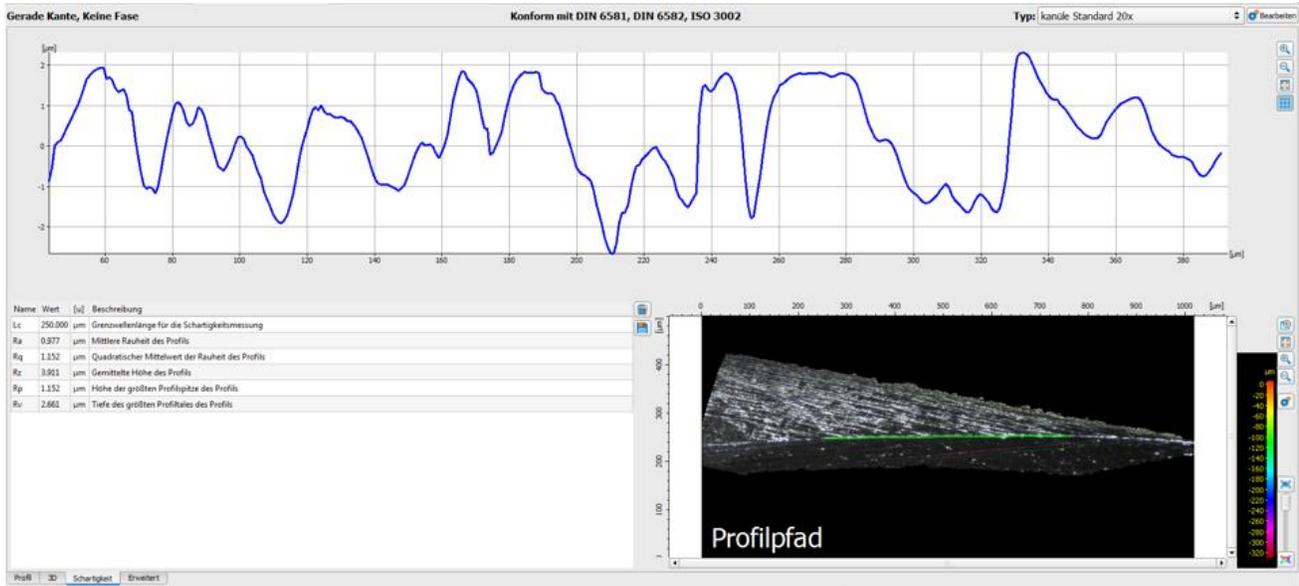


Figure 6

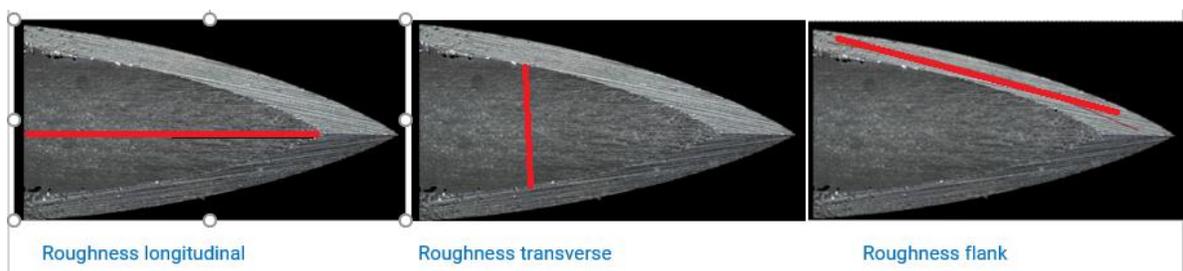


Figure 7

Geometry Measurement

Using the 3D geometry measurement tools it is also possible to measure total geometry such a sphere and cylinder as shown in figure 8. In this case showing a radius of 382.54 μm .

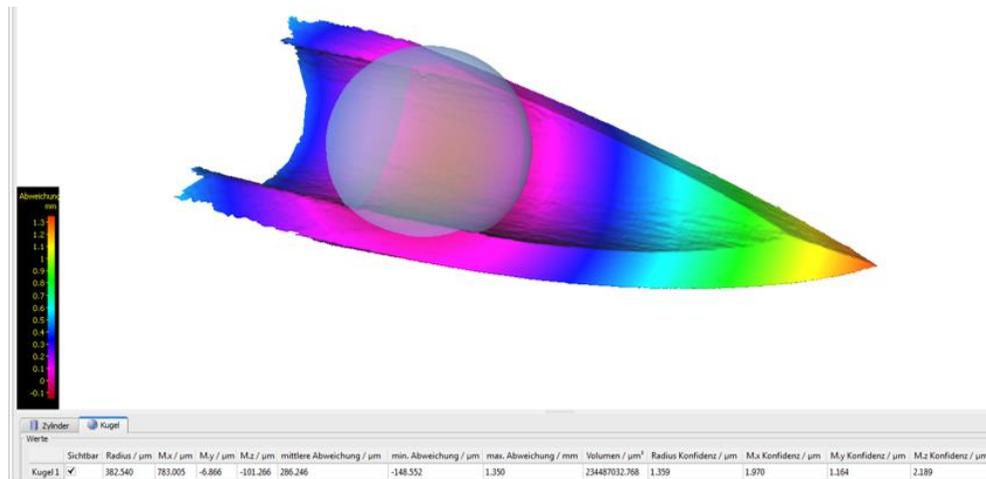


Figure 8

Also displayed in figure 8 is the ability to directly compare against CAD to show variation from design.

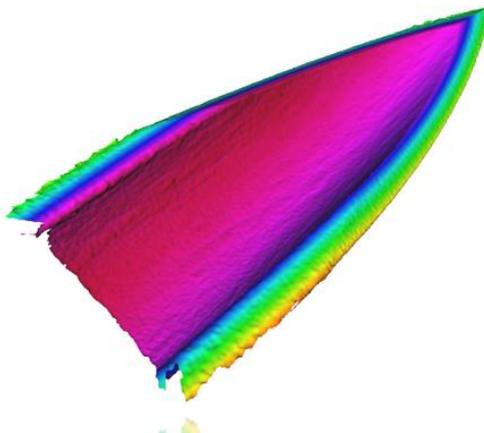


Figure 9

Conclusion.

Using Optical Metrology as a tool to assess the geometric elements of these medical devices is a clear way to ensure that the devices conform to design. It also provides a method to understand why a product fails during the penetration and track force test.