Fig. 1

Fig. 2

Harnessing the advantages of ceramics

High aesthetics, strength, great biocompatibility—zirconia is a material that offers a wide variety of benefits for implant patients. However, zirconia also has its limitation and it would be foolish to overlook them. By developing an entirely new production material, the implant manufacturing company Argon Medical has addressed these limitations. At IDS 2019, Richard Donaca, head of the Germany-based family business, spoke with *ceramic implants* about their new ceramic implant system.

Mr Donaca, at the IDS 2019 you presented a new ceramic implant. What is unique about it?
The material we have developed for our new ceramic implant system is compounded according to a patented formula. The special feature is that it has a synthetic content and, thus, also a certain elasticity is given. This is very important to us because elasticity allows us to achieve a higher tensile strength. In general principle ceramic is extremely stable—even more stable than titanium. However, there has always been the following problem: when loading forces beyond a certain maximum limit act on the ceramic, the material tends to break rather than relocate or trap the loads. We have taken on this problem in the development of our new system. The new material allows us the elasticity that is needed in our field, whereas this material also works extremely accurate and is also used in measurement springs. The material is already certified as a class III product. Its origin is from the medical sector and has not yet been harnessed in the dental field. Of our new ceramic implant product range, there will initially be a one-piece version with different diameters. However, the implants will be available soon as a two-piece version. In my opinion, we are at the forefront of this technology as we start with a diameter of 3.3 mm and then go up to 4.3 mm and 5.3 mm.

How does the implant–abutment connection of your new system look like?
In order to achieve the desired tightness, we have chosen a one-degree cone, which ensures the connection between implant and abutment. On the bottom of the abutment is the so-called “nose”, which connects the implant with the abutment by spreading the flanges of the nose with a firm click. In addition, there is a screw-in stabilising pin, which ensures that the implant components are connected to each other. The one-piece system will be released around April or May. The two-part system will be ready for the market a bit later, probably in the summer, because we are currently analysing three materials for the abutments. Manufacturing the abutment out of the same material as described earlier would be one option. In addition, it is possible to make it from polyether ketone ke-

Fig. 1: Richard Donaca (CEO of Argon Medical, left) and Jürgen Isbaner (board member of the OEMUS MEDIA AG). **Fig. 2:** The Argon Medical booth at this year's IDS, where the company presented their new ceramic implant system.

tone (PEKK) or a fiber-reinforced plastic. At the moment, I am still using a test technique to find out which material is most suitable—because of course, the implant structure should also have a certain elasticity. However, I have already noticed that PEKK is not exactly successful in this context. However, the fiber reinforced plastic is very promising and an abutment of the same material as the implant body will probably work fine as well.

> "Our new material has a synthetic content and, thus, a certain elasticity."

What are the big current challenges for Argon Medical?

One big challenge is to harness all the benefits of our newly developed material. So it could be used in very small dimensions and for example you can manufacture membrane fixation pins. We are currently working on ensuring complete freedom from metal, as more and more customers and patients are demanding it. Another challenge is the increasingly difficult approval of new medical devices. There is not only the DIN EN ISO 14801 standard, like the dynamic fatigue test for dental implants, under the stipulation of which we have to produce our implant abutments. For example, we have recently applied for approval of new titanium bases in the US. In the past, it was always common practice to test only the connection of the abutment. However, the Food and Drug Administration (FDA) now states, "A titanium base is part of a complete system and a complete system must be tested as one unit." So now we have the duty to mechanically rebuild everything from scratch. This means that both the implant and the abutment have to be redone, a certified zirconium and a certified adhesive must be used—and all this must then be tested together as one unit.

How do you prepare for the new European Medical Devices Regulation coming into force?

We are currently in the middle of our preparations for the forthcoming European Medical Devices Regulation (MDR). In April, we have our first FDA hearing, and I suspect that the FDA will also be geared towards the upcoming MDR. Of course this topic is a special challenge, as it simply demands very defined processes. So far it raises the impression that not even the authorities are prepared for it yet. However, our certification body, BSI, as the largest certification body in the world, is very concerned about this topic. I have the impression that in this context, the chaff will be separated from the wheat—so to say—because the large corporations are also involved in the competent committees—and so they then steer the topic of MDR. The certification bodies and the smaller companies get a lot of pressure from the top. The corporations do of course have the necessary manpower and capital to cushion it all up to some extent. In addition, they do often have entire departments that deal exclusively with MDR. In the future, we will probably also have to bring a few people on board, who are only specialised in this topic.

Does that mean for you as a consequence that you have to adjust prices upwards?

I don't think we will do that. Rather, we will try to cover any additional costs related to MDR by growth and increasing volumes. Our new ceramic implant is expected to cost 199 Euro and for the abutment we are calculating so far with 69 or 79 Euro. We're still barely half the price of most manufacturers, and we are convinced that it is the best way to stay with this philosophy.

Thank you for the interview.

contact

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