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Statement
of the
European Society for Ceramic Implantology ESCI
“The clinical application of two-piece zirconia implants”

by Scientific Advisory Board and Board of Directors ESCI

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Background of zirconia oral implants

The development of high-performance ceramics – like zirconia – has provided new, metal-free treatment options for both patients and practitioners. Due to its superior biomechanical and biocompatible properties, zirconium dioxide (zirconia, ZrO_2) has prevailed over other oxide ceramics and has been used in dentistry for about 25 years. In comparison with other oxide ceramics (e. g. alumina), zirconia shows superior biomechanical properties such as high fracture toughness and bending strength[1] that give zirconia implants the ability to withstand oral occlusal forces.[2, 3] Thus, zirconia as implant material has successfully been established on the market as a reliable alternative to titanium in implant dentistry.[4]

Ceramic implants made of zirconia are not only the focus of current scientific research, also the desire of patients for metal-free, respectively full ceramic dental rehabilitations, is becoming increasingly important: ceramic implants are attractive to patients! A current interview including more than 270 patients in 2 countries has reported that 80% of the patients would prefer ceramic over metal implants.[5]

In order to establish zirconia as a reliable alternative to titanium as oral implant material, stable zirconia implants with micro-rough surfaces showing a safe and predictable capacity for osseous integration have been developed. At the beginning of 2004, the first one-piece zirconia oral implants were established on the market. Initially, creating micro-rough surface topographies on zirconia implants without compromising the biomechanical stability (such as fracture toughness and fatigue strength) was a challenging procedure from a technical point of view. Consequently, reduced survival rates[6, 7] and numerous zirconia implant fractures were reported for this “first generation” zirco-

nia implants.[8-10] Since then, the industry has continuously improved manufacture processes to produce micro-roughened zirconia implants with reliable fracture toughness and fatigue strength that show a predictable osseointegration[11] and high clinical survival rates at the level of conventionally used titanium implants mid-term.[6, 12-15]

Experimental studies have shown that the latest generation of zirconia implants with micro-rough surfaces show an identical hard tissue integration compared with titanium implants.[11, 16-20] However, the different zirconia implant systems that are available on the market show varying surface topographies and not every company offers evidence-based data or provides information regarding the implant surface and the osseointegration performance of the appropriate product. Consequently, clinicians must scrutinize if the used zirconia implant system offers scientific data regarding the osseointegration capacity.

In the last 2 decades, not only surface micro-texture but also implant macro design has been adapted. Whereas the first zirconia implant systems were limited to a one-piece design, also two-piece zirconia implants are available in the meantime. This developmental process has also been strongly influenced by the predilection of clinicians for two-piece implant designs and confirms a clear trend for "two-piece" implant designs not only for titanium but also for zirconia implants. Nowadays, one- and two-piece zirconia implants with different designs and diameters that allow the treatment of partially and completely edentulous patients have become available on the market.

Clinical data

Due to the large number of adaptations and further developments regarding zirconia implant designs and manufacture processes in a relatively short period of time, it has become quite difficult for clinicians to assess the available clinical data in relation to the zirconia implants under investigation and to evaluate the clinical relevance of the investigated implant type and the reported results.

Various clinical studies investigating different types of zirconia implants were published in the last couple of years. However, it must be considered that some recently pub-

lished clinical studies investigated zirconia implant systems that have been further developed in the meantime and that are not any longer available on the market. A meta-analysis has reported that physical properties and ongoing market availability significantly influenced the reported zirconia implant survival rates.[6] In a systematic review, the authors evaluated clinical studies investigating zirconia implants that were published between 2004 and 2017. The reported 1-year mean survival rates for commercially available zirconia implants (98.3%) were significantly higher compared with zirconia implants that are not any longer commercially available on the market (91.2%). In addition, a mean 2-year survival rate for commercially available zirconia implants of 97.2% was evaluated whereas the zirconia implant design – one-piece compared with two-piece designs – did not significantly influence the reported survival rates. In this context, it has been shown that zirconia implant survival rates have significantly increased between 2004 and 2017 and that the fracture incidence of zirconia oral implants was significantly reduced from 3.4% to 0.2%.[6] Even though meta-analyses estimating overall survival rates are currently limited to 1- and 2-years data, single studies reported longer clinical follow up periods. Regarding commercially available zirconia implants, clinical data up to and after 5 years of functional loading reporting survival rates of 95% are now available.[12, 14, 15, 21, 22]

The data of the previously reported meta-analysis were the basis for the clinical recommendations that were created for the 6th ITI Consensus Conference.[6] In this systematic review, more clinical studies investigating zirconia implants with a one-piece design were included than studies evaluating two-piece zirconia implant designs. Consequently, the main statement of the consensus conference on the clinical application of zirconia implants referred to one-piece implant designs.[7] However, the data of the meta-analysis has reported that the implant design did not significantly influence the reported survival rates. Based on the currently available clinical data, it seems that the studies investigating two-piece zirconia implants report similar survival rates compared with one-piece zirconia implants.

Two-piece zirconia implants – reliable prosthetic connections

Scientific studies have not only examined the clinical performance of two-piece zirconia implant systems, but also evaluated the reliability and stability of screw-retained implant-abutment connections. Most recently, the stability of a titanium-zirconia screw-retained connection has been directly compared with a conventional titanium-based connection in an in vitro study. The results have shown no statistically significant differences between the investigated groups. Consequently, the authors reported “The connection of the tested screw-retained zirconia crowns in two- piece zirconia implants is comparable to standard titanium implants in the specific in vitro testing” and “Based on the results of the present study, the connection between crown and the two-piece zirconia implant seems to be suitable for clinical application.“[23]

It is particularly important to evaluate studies and implant systems individually according to the material and type of connection. For example, the stability and fracture resistance of ceramic implant systems was tested in vitro in accordance with ISO standard DIN 14801 in various studies. These studies demonstrated that the tested two-part zirconia ceramic implant systems can withstand the physiological masticatory forces in the long term and the stability is considered sufficient for clinical application.[24-29]

Two-piece zirconia implants – reliable clinical applications

Regardless of the available scientific studies, the question whether one- or two-piece zirconia implants are used depends not only on the preference of the dentist/surgeon, but mainly on the individual clinical situation. There are specific indications in which the use of a two-piece zirconia implant concept offers a more reliable clinical outcome compared with a one-piece implant design. For example, completely edentulous jaws, soft bone conditions or when bone augmentations are performed simultaneously with implant placement and/or when primary implant stability is hardly to achieve, respectively when uncontrolled mechanical loading of the implant must be avoided. With a one-piece implant concept, the abutment is an inherent part of the implant that penetrates the soft tissue into the oral cavity. Thus, uncontrolled early loading cannot be

completely avoided. Furthermore, with one-piece implants the prosthetic suprastructure has to be cemented on the implant. In addition, not every clinical situation allows placing the implant in a correct prosthetic angulation and the implant has to be inserted in an angled axis. Regarding prosthetic implant axis corrections, two-piece zirconia implant concepts offer more options than one-piece concepts due to the fact, that individually designed abutments can be fabricated. Moreover, cementation of the prosthetic suprastructures can be avoided since two-piece zirconia implant concepts allow for the fabrication of reversibly screw-retained prosthetic reconstructions. Thus, prosthetic "flexibility" and "reversibility" must be emphasized in many clinical situations. Therefore, the use of two-piece zirconia implant concepts - as with titanium implants - has become indispensable in everyday clinical practice. So far, more clinical studies are available that investigate one-piece compared with two-piece implant concepts. However, based on the clinical data available so far, meta-analyses have reported that the zirconia implant concept – one-piece compared with two-piece – did not significantly influence the clinical survival rates up to 5.1 years (mean follow up: 2.4 years).[6] Single studies investigating two-piece zirconia implant designs even reported clinical data up to and after 6.7 years of functional loading.[30, 31]

Summary and Conclusion

Based on the scientific data available to date, micro-rough zirconia implant surfaces show osseointegration capacity compared to their micro-rough titanium implants counterparts.[11, 16-20] This applies also to one-piece and two-piece ceramic implants, since the material, the implant geometry and the surface design do not differ between one- and two-piece implants received from the same manufacturer. Moreover, scientific data supports that - depending of course on the design and material type - two-piece zirconia implant connections can withstand oral masticatory forces.[23-29] Consequently, based on the currently available scientific data, the two-piece zirconia implant concept can be recommended for clinical application after correct diagnostic evaluation and appropriate patient information.

Statement key points:

- The two-piece zirconia implant concept offers advantages over the one-piece concept regarding prosthetic flexibility and clinical indications.
- Two-piece zirconia implants can resist clinical masticatory forces.
- Fracture resistance and mechanical stability of two-piece zirconia implants may vary as a function of different manufacturing processes, material properties, implant geometries and prosthetic connection concepts.
- One-and two-piece zirconia implants demonstrate same level of osseointegration and biologic integrity.
- For clinical successes, each manufacturer's guidelines regarding the strict application for the specified clinical indications should be followed for the respective two-piece zirconia implant.
- The ESCI Scientific Advisory Board states, based on the conclusions above, that the two-piece zirconia implant concept is appropriate for clinical application.

This Statement by ESCI was formulated, confirmed and signed by the ESCI Scientific Advisory Board and ESCI Board of Directors (in alphabetical order):

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Zürich, Switzerland, 09th June 2021

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