FOCUS:
Bone and soft tissue management
starting on page 35

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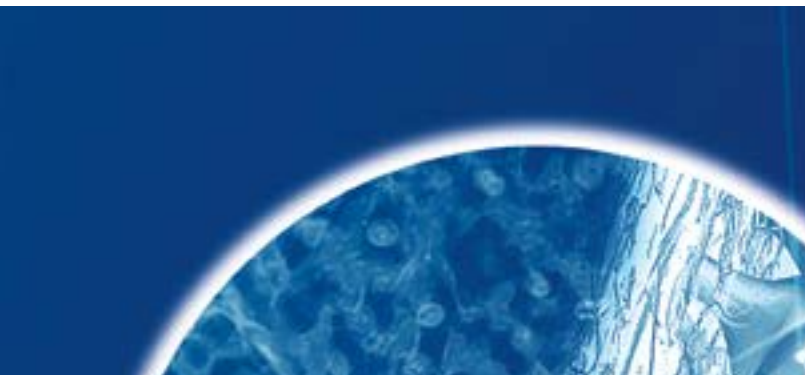
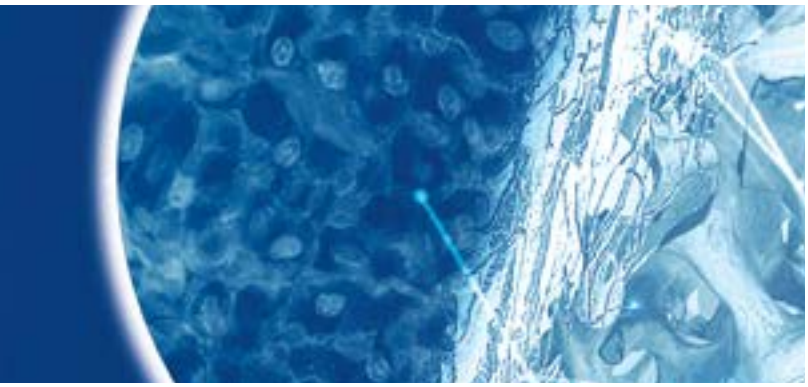
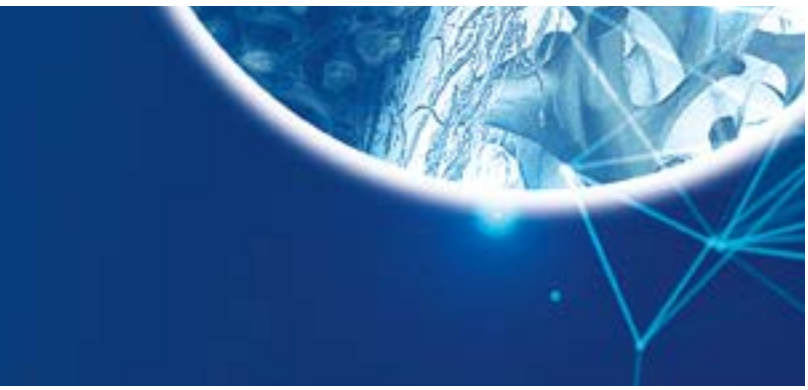




TOPIC

Bone and soft tissue management



»EDI News: New European Medical Device Regulation · Practical Guide 2021: Update "Ceramics in Implantology" »European Law: Partial access to professions and automatic recognition of professional qualifications »Topic: Dr Markus Tröltzsch in an interview about ridge preservation »Case Studies: Re-evaluating sinus lifting as first choice »Clinical Science: A randomized controlled evaluation on different implant surfaces

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What you should know about MDR!

Postponed is not canceled, so says a clever German proverb. One year ago, the EU Commission suspended the end of the transition period for the EU Medical Device Regulation (MDR) for one year due to the COVID-19 pandemic. The transition period expired though on 26 May 2021, and thus the MDR applies throughout Europe. The comprehensive reform of the entire European medical device law obviously affects also dental practices and dental laboratories. As a regulation of European law, it is directly applicable and thus replaces the Medical Device Directive MDD.

The trigger for the new European medical device regulations was the breast implant scandal a few years ago. The objective is to better monitor and document medical devices from manufacturing to use and also the risk assessment. The MDR thus focuses primarily on market surveillance and implements a number of new tasks, increases the requirements for the quality management system and for the preparation of clinical evaluations, and at the same time increases the scope of products for which clinical studies will be required in the future.

BDIZ EDI has already reported in 2019 about the MDR and its impact on dental practices. In an online seminar of the BDIZ EDI, legal counsellor Professor Thomas Ratajczak answered the participants' questions. As dentists, we are affected by the new regulations in two ways:

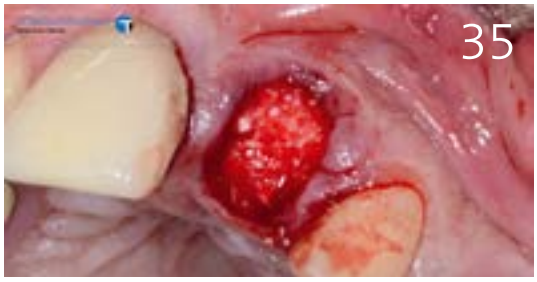
1. Indirectly in the area of purchasing serially manufactured medical devices and components. Stricter certification regulations apply here for the industry via so-called notified bodies. These are subject to approval procedures. There have been and still are considerable implementation difficulties, which were ultimately probably the real reason for the postponement of the MDR last year.
2. Dental practices are directly affected, especially in the area of processes and documentation requirements. It primarily affects the area of customized products in the dental practice laboratory. None of the processes – especially the establishment of a risk management system – is fundamentally new, but rather has been a requirement for many years.

As of May 2024, the distribution of products certified according to the old legislation will finally come to an end. However, this transitional regulation does not apply to manufacturers of customized products, such as dentists with their own practice laboratory. Since 26 May 2021, dentists who operate their own laboratories must fulfill exactly the same requirements for clinical evaluations as manufacturers of serially or industrially produced medical devices.

However, the clinical evaluation is not the end of the story. As Professor Ulrich M. Gassner, founding director of the Research Center for Medical Device Law (FMPR) at the University of Augsburg, explained to us in an interview in the EDI Journal 2019, the term "post-market surveillance" (PMS) requires that, for example, the implantologist continues even after implantation to monitor whether the safety and medical benefit of the implant is given. It must also be proven that there is permanent and ongoing recourse to a person responsible for regulatory compliance.

My suggestion is: Use our support and familiarize at an early stage with the requirements that the MDR entails for the dental practice.

Christian Berger
President



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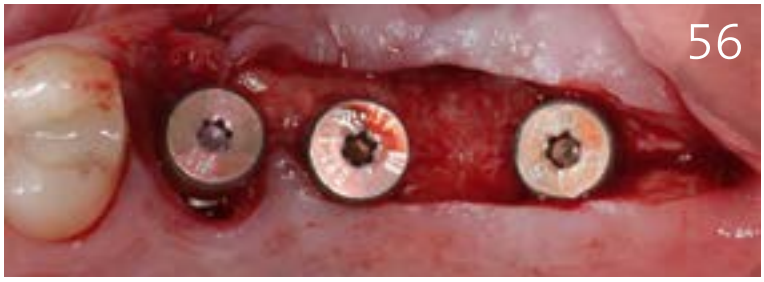

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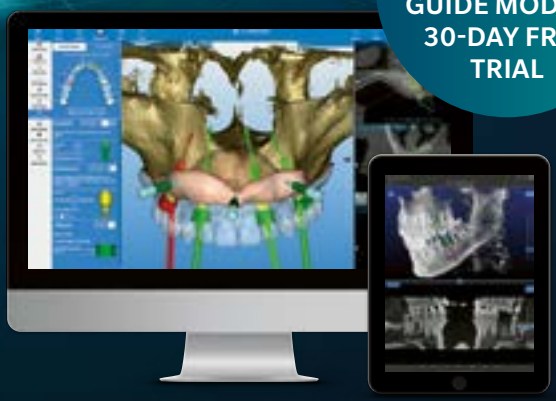

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Association of Dental Implantology UK (ADI UK)

ADI UK, founded in 1987, is a registered charity committed to improving the standards of implant dentistry by providing continuing education and ensuring scientific research. It is a membership-focused organization dedicated to providing the dental profession with continuing education, and the public with a greater understanding of the benefits of dental implant treatment. Membership of the ADI is open to the whole dental team and industry, and offers a wealth of benefits, education and support for anyone wishing to start out or develop further in the field of dental implantology.

Ogolnopolskie Stowarzyszenie Implantologii Stomatologicznej (OSIS EDI)

OSIS EDI, founded in 1992, is a university-based organization of Polish scientific implantological associations that joined forces to form OSIS. The mission of OSIS EDI is to increase implant patients' comfort and quality of life by promoting the state of the art and high standards of treatment among dental professionals. OSIS EDI offers a postgraduate education in dental implantology leading to receiving a Certificate of Skills (Certyfikat Umiejętności OSIS), which over 130 dental implantologists have already been awarded.

Sociedad Espanola de Implantes (SEI)

SEI is the oldest society for oral implantology in Europe. The pioneer work started in 1959 with great expectations. The concept of the founding fathers had been a bold one at the time, although a preliminary form of implantology had existed both in Spain and Italy for some time. Today, what was started by those visionaries has become a centrepiece of dentistry in Spain. SEI is the society of reference for all those who practice implantology in Spain and has been throughout the 50 years, during which the practice has been promoted and defended whereas many other societies had jumped on the bandwagon. In 2009 SEI celebrated its 50th anniversary and the board is still emphasizing the importance of cooperating with other recognized and renowned professional societies and associations throughout Europe.

Sociedade Portuguesa de Cirurgia Oral (SPCO)

The SPCO's first international activity was the foundation – together with their counterparts in France, Italy, Spain and Germany – of the European Federation of Oral Surgery (EFOOS) in 1999. The Sociedade Portuguesa de Cirurgia Oral's primary objective is the promotion of medical knowledge in the field of oral surgery and the training of its members.

Udruženje Stomatologa Implantologa Srbije-EDI (USSI EDI)

USSI EDI was founded in 2010 with the desire to enhance dentists' knowledge of dental implants, as well as to provide the highest quality of continuing education in dentistry. The most important aims of the organization are to make postgraduate studies meeting the standards of the European Union available to dentists from Serbia and the region; to raise the level of education in the field of oral implantology; to develop forensic practice in implantology; and to cooperate with countries in the region striving to achieve similar goals.

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European Medical Device Regulation (MDR)

What are the changes for the dental practices?

The European Medical Device Regulation (MDR) has come into effect on 25 May 2017 and has replaced on 26 May 2021 the previously applicable Medical Devices Act (MPG) and its European predecessor, the Medical Device Directive (MDD). In this overview article, the editorial team highlights what will change for dental practices. The BDIZ EDI has been providing information about the MDR since 2019.

The MDR regulates the production and processing of medical devices. It is intended to ensure the safety, suitability and performance of medical devices and their supplies, as well as the health and necessary protection of patients, users and third parties. Compared to the MDD, the regulation provides for increased requirements for the marketing and surveillance of medical devices in the European Union.

Significant changes in dental practice will be:

- the development of a risk management system (Art. 10 Para. 2, Annex I No. 3).
- the extension of the storage obligations for documentation to at least 10 years and for implantable products to 15 years (Art. 10 Para. 5 MDR, Annex XIII No. 4)
- the designation of a responsible person (Safety Officer Art. 15)
- the batch traceability (Art. 25)
- the concrete recording of all substances remaining in the medical device, systematic recording of all batches and allocation to patient work
- the adjustments to the declarations of conformity (Art. 52 Para. 8, Annex XIII No. 1)
- the clinical evaluation and post-marketing clinical follow-up of medical devices (Art. 83, Annex XIV Part A and B)
- the incident recording and reporting system, post-marketing surveillance (Art. 83, Art 87 MDR)

Medical devices in the dental practice

Many different medical devices are used in dental practices and are subject to different requirements depending on their classification.

According to Art. 2 No. 1 MDR, "medical devices" are instruments, apparatuses, devices, software, an implant, reagents, materials or other articles which are intended for use in or on humans and which achieve their effect primarily by physical means (not by pharmacologically or immunologically active means).

"Accessory to a medical device" means, according to Art. 2 No. 2 MDR, an object which, although not a medical device per se, is intended by the manufacturer to be used together with one or more specific medical devices and specifically enables its/their use in accordance with its/their intended purpose(s) or is intended to specifically and directly support the medical function of the medical device(s) with regard to its/their intended purpose(s).

"Implantable medical device" means, in accordance with Article 2(5) of the MDR, a medical device, even if intended to be fully or partially resorbed, that is intended to be used "through a clinical intervention" to

- be introduced entirely into the human body, or
- replace an epithelial surface or the surface of the eye and remain there after the procedure.

An implantable product is also any product intended to be partially inserted into the human body by clinical intervention and to remain there for at least 30 days after the intervention.

Medical device classification

As in the past, medical devices are classified into classes I, IIa, IIb and III, considering their intended purpose and the associated risks. If the device in question is intended to be used in combination with another device, the classification rules are applied separately to each device. Classification is carried out in accordance with Annex VIII of the MDR.

Class IIa, IIb and III medical devices must bear – in addition to the CE marking – the number of the noti-

fied body that has carried out a conformity assessment procedure for the medical device in question. Class I medical devices are only required to bear the CE marking.

"CE conformity marking" or "CE marking" means a marking by which a manufacturer indicates that a device complies with the applicable requirements set forth in the MDR or in other Union legislation concerning the affixing of the relevant marking.

Except for custom-made or investigational devices, all medical devices bear a CE mark of conformity, Annex V of the MDR.

For the dental practice, the first important distinction is between mass-produced medical devices and custom-made devices.

Medical devices manufactured as standard

Most medical devices used in dental practices are mass-produced by third parties. The manufacturers of these medical devices classify them.

Customized dental products

According to Art. 2 No. 3 MDR, a "custom-made device" means a device that is specially made in accordance with a written prescription issued by a person authorized by his or her professional qualifications under national law to issue prescriptions, who is responsible for determining the exact design and characteristics of the device – which is intended for a single patient only – to meet exclusively the patient's individual condition and needs. The method of manufacture is not relevant. Restorations made using CAD/CAM are also a custom-made product.

Customized products are for example:
- fixed dentures
- removable dentures
- splints.

However, mass-produced products that must be adapted to meet the specific requirements of a professional user and products that are mass-produced by industrial processes in accordance with the written regulations of a person authorized to do so are not considered custom-made products.

Not customized products are, for example:
- ready-made teeth
- industrially produced attachment elements
- implant components.

Customized products are usually class I or class IIa medical devices. Only abutments are currently classified by some manufacturers as implantable medical devices, surgically invasive, in class IIb.

Risk management system

Annex I (No.3) MDR requires manufacturers to implement a risk management system. For dental practices that manufacture custom products, this means that an appropriate risk management system must be introduced and continuously documented.

A risk management system consists of:
- a risk management plan (risk management documents, the result of the initial risk analysis)
- a risk analyses (product groups, product life phases, risk minimization)
- a monitoring plan and safety report (product monitoring)

Note: It is true that denture repairs and extensions are not new productions. Nevertheless, documentation and traceability must be ensured regarding the materials that were newly introduced as part of the repair and extension.

Responsible person

Manufacturers – including dental practices where custom products are manufactured – must have at least one person in their organization with the necessary expertise in the field of medical devices who is responsible for ensuring compliance with the regulatory requirements.
The tasks of the person responsible for regulatory compliance clearly exceed the tasks of the previous safety officer for medical devices. Especially the system of recording and reporting of incidents and post-marketing surveillance is to be emphasized.

This responsibility can be assigned to the practice owner or to the dental technician in the practice's own laboratory. Micro and small enterprises, i.e. those that employ fewer than 50 people and whose annual turnover or annual balance sheet does not exceed €10 million, are not required to have a person responsible for regulatory compliance; however, they must have continuous and permanent access to such a person. This means that external service providers can fully assume the function of responsible persons for small and micro-enterprises.

Traceability

According to Art. 25 MDR, all economic operators of a medical device (manufacturer, authorized representative, importer, distributor) must ensure identification within the supply chains. For dental practices, this means working with distributors and importers as well as manufacturers or their authorized representatives to achieve an appropriate level of product traceability. Within the period of 10 years (15 years

for implantable devices) it must be possible to declare to the competent authority:

- From whom was which product obtained?
- To whom was which product supplied?

This requires not only a concrete recording of all materials which remain in the medical product, but also a system of batch traceability with allocation to the respective patient restoration.

Declaration of conformity

The previous documentation of the declaration of conformity for customized products must be adapted to the new requirements of the MDR. Thus – in addition to the name and address of the manufacturer – all manufacturing sites must be indicated. In addition, the retention period for the documentation has been increased from 5 to 10 years. For implantable medical products, a retention period of 15 years applies. Content requirements are also available online.

Monitoring the marketing placing of medical devices

Manufacturers – including dental practices that produce customized products – must plan, set up, document, apply, maintain and update a post-market surveillance system for each medical device.

For this purpose, according to Art. 84 and Art. 86 MDR, a

- post-marketing surveillance plan and a
- regularly updated report on safety are required.

According to Annex XIV, Parts A and B of the MDR, a clinical evaluation and a post-market clinical follow-up of the medical devices must also be carried out. The clinical evaluation should be planned, continuously performed and documented for each medical device. The post-market clinical follow-up should be a continuous update of the clinical evaluation. The methods and procedures for proactive collection and evaluation of clinical data should be described.

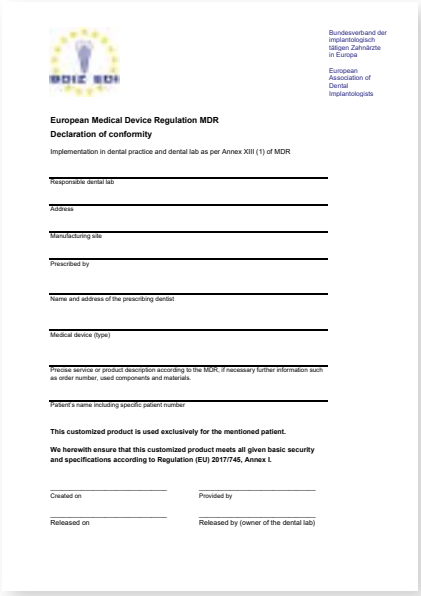
Incidents must be monitored and reported

The MDR requires a system of recording and reporting of incidents, post-market surveillance. The system for recording and reporting incidents, post-market surveillance specifies how

- incidents are recorded and evaluated,
- serious incidents are reported,
- if necessary, recalls are carried out or information on measures is provided.

The reporting deadline for serious incidents (corresponding to the previous reportable incident) has been reduced from 30 days to 15 days in accordance with Art. 87 (2) MDR.

In case of a serious risk to public health, a notification is required after 2 days at the latest after the manufacturer has become aware of it. In case of death or serious deterioration of health, notification is required after 10 days at the latest. *AWU*



Bundesverband der implantologisch tätigen Zahnärzte in Europa

European Association of Dental Implantologists

European Medical Device Regulation MDR
Declaration of conformity

Implementation in dental practice and dental lab as per Annex XIII (1) of MDR

Responsible dental lab

Address

Manufacturing site

Prescribed by

Name and address of the prescribing dentist

Medical device (type)

Precise service or product description according to the MDR, if necessary further information such as order number, used components and materials.

Patient's name including specific patient number

This customized product is used exclusively for the mentioned patient.

We herewith ensure that this customized product meets all given basic security and specifications according to Regulation (EU) 2017/745, Annex I.

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MDR forms online

As described in the article, the BDIZ EDI makes the necessary forms available on the www.bdizedi.org/en/website. The PDFs are interactive, meaning they can also be filled out electronically. For more Information, please contact us: office-munich@bdizedi.org

To download the form obove, please scan the QR code or visit: https://bdizedi.org/en/mdr-transitional-period-runs-out-on-may-26th/

Not ready yet

In late March 2020, the European Commission announced that the entry into force of the EU Medical Device Regulation (MDR) would be postponed by one year. Although BDIZ EDI welcomed this decision, it does not go far enough for the association. Even before the Corona pandemic, BDIZ EDI had demanded a delay of two years. Now it should have been at least three years to ensure the MDR's viability. Unfortunately, the MDR has now been in force since 26 May 2021.

Even before the corona pandemic, the BDIZ EDI had demanded that the implementation should be postponed by two years due to – among other things – a lack of Notified Bodies and a non-functional central EUDAMED database. None of the objectives of the MDR can be achieved by the original effective date. There had been some movement in this matter; for example, at the end of October 2019, EUDAMED was postponed by two years, to 26 May 2022.

BDIZ EDI President *Christian Berger* said: "We welcome the fact that the EU Commission is moving. However, a postponement by one year will by no means be enough to guarantee the functionality of the MDR." Due to the economic standstill now caused and still to be caused by the COVID-19 pandemic, the BDIZ EDI President called for an extension of the transitional regulations by three years.

MDR – a roadblock to innovation

The MDR was originally supposed to apply throughout the European Union from 26 May 2020. Market observers and especially the entire dental sector see the MDR as a roadblock to innovation – with serious repercussions for the practice of medicine and dentistry and ultimately for patients as the stream of new and innovative products dries up. Our fear is that especially small and medium-sized manufacturers of medical devices will fail to clear the regulatory hurdles of the MDR as the certification process becomes more expensive and more complicated.

According to a survey conducted among dental companies by the law firm Ratajczak & Partner in Sindelfingen, Germany, on behalf of the BDIZ EDI, over 80 per cent of respondents feel sure that the MDR will lead to an increase in costs for existing as well as new products. It is feared that there will be a cost increase of 22 per cent on average. Almost 50 per cent of respondents forecast supply bottlenecks for existing products, bottlenecks that are related to the implementation of the MDR and therefore also have an impact on the supply of medical devices to dental practices. *AWU*

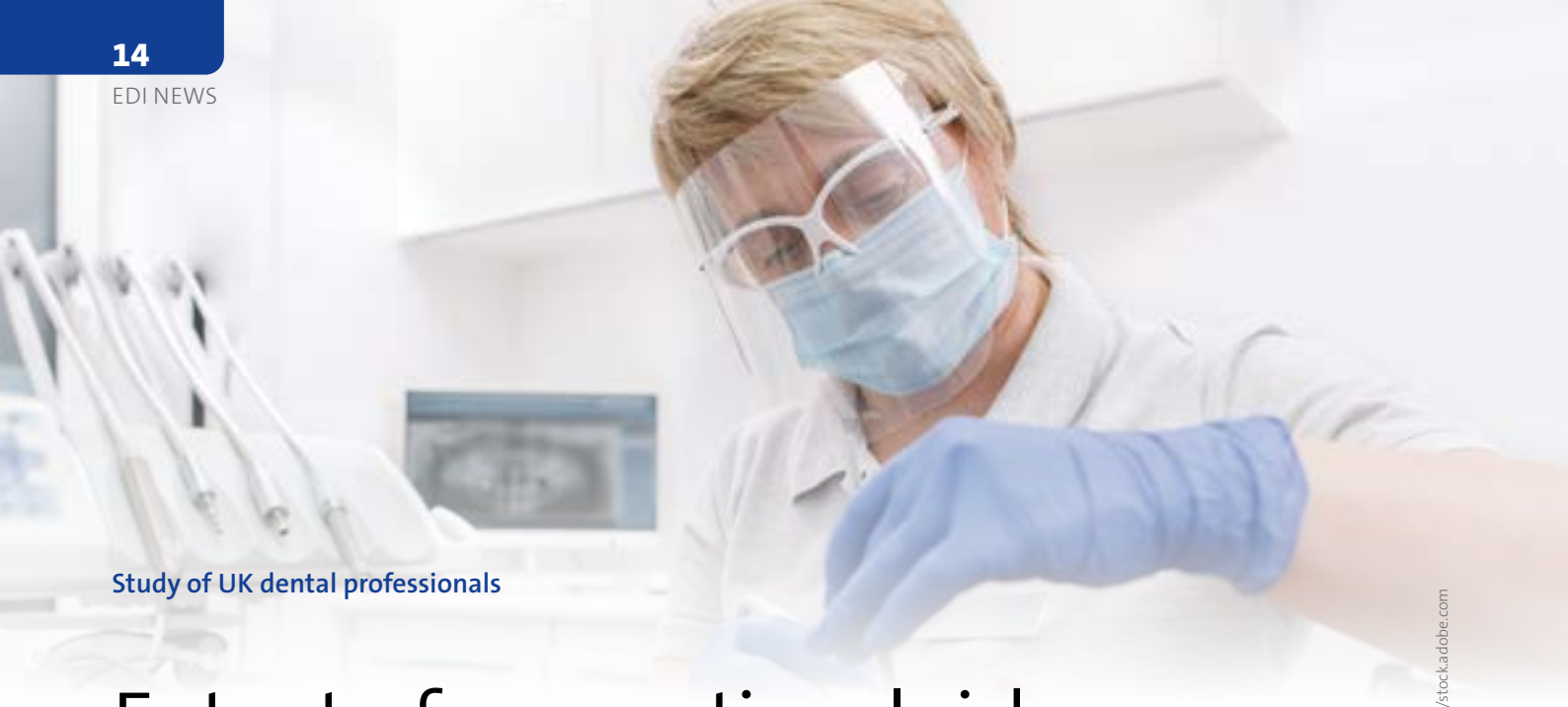


Photo: Ihor/stock.adobe.com

Study of UK dental professionals

Extent of occupational risk of SARS-CoV-2 infection

A University of Birmingham-led study of over a thousand dental professionals has shown their increased occupational risk of SARS-CoV-2 infection during the first wave of the pandemic in the UK.

The observational cohort study, published on 3 June 2021, in the Journal of Dental Research, involved 1,507 Midland dental care practitioners. Blood samples were taken from the cohort at the start of the study in June 2020 to measure their levels of antibodies against SARS-CoV-2, the virus that causes COVID-19.

The team found 16.3 % of study participants – which included dentists, dental nurses and dental hygienists – had SARS-CoV-2 antibodies, compared to just 6 % of the general population at the time. Meanwhile, the percentage of dental practice receptionists, who have no direct patient contact, with SARS-CoV-2 antibodies was comparable to the general population, supporting the hypothesis that occupational risk arose from close exposure to patients.

A matter of ethnicity?

The study also found that ethnicity was also a significant risk factor for infection, with 35 % of coloured participants and 18.8 % of Asian participants having SARS-CoV-2 antibodies, compared to 14.3 % of white participants.

Blood samples were taken from participants three months later, in September 2020, when dental practices in England had re-opened with enhanced PPE and infection control measures in place, and once again in January 2021, six months after the start of the study, during the second wave of the pandemic when healthcare workers were being vaccinated.

The results showed that of those who had previous COVID-19 infection, over 70 % continued to have SARS-CoV-2 antibodies both at three months and six months later, and they were at a 75 % reduced risk of re-infection with the virus.

The study also demonstrated the immunological impact of COVID-19 vaccination, with 97.7 % of those without previous infection developing an antibody response at least 12 days after their first Pfizer vaccine. In those with evidence of previous infection, the antibody response was more rapid and higher in magnitude after a single dose of the Pfizer vaccine.

Furthermore, none of the cohort with a level of SARS-CoV-2 antibodies greater than 147.6 IU/ml in their blood tested positive for COVID-19 throughout the six-month period from the first to the final blood tests.

First author Dr Adrian Shields, of the University of Birmingham's Institute of Immunology and Immunotherapy, said: "Understanding what an antibody test result means to an individual with respect to their risk of infection is essential to controlling the pandemic. "Our study has taken the first steps in defining the level of antibody in a persons' blood necessary to protect them from infection for six months. Furthermore, by comparing the antibody levels we have found in dentists to those contained in widely available reference material produced by the World Health Organization, we hope the protective level

we found can be easily confirmed and compared by other laboratories."

Corresponding author Professor Thomas Dietrich, of the University of Birmingham's School of Dentistry, adds: "Critically, only 5.3 % of the cohort developed an antibody response that exceeded this threshold of 147.6 IU/ml following the first wave of the UK pandemic. This suggests that natural infection alone is unlikely to generate meaningful, durable herd immunity."

Co-corresponding author Iain Chapple, Professor of Periodontology at the University of Birmingham and Consultant in Restorative Dentistry at Birmingham Community Healthcare Trust, adds: "Dental professionals are thought to be at high risk of exposure to SARS-CoV-2 because they routinely operate within patients' aerodigestive tract and regularly carry out aerosol-generating procedures that result in the production of airborne particles.

"Through our research, we have clearly shown that dental professionals were at increased occupational risk of exposure to SARS-CoV-2 prior to the new PHE guidance on PPE. The occupational health measures that have been put in place in general dental practice as a consequence of COVID-19 appear to remove that increased risk, however, this will need to be thoroughly investigated to see if they have successfully interrupted transmission of SARS-CoV-2 and other respiratory viruses."

Co-corresponding author Professor Alex Richter, also of the University of Birmingham, said: "This is the first time the occupational risk of exposure to a potentially fatal respiratory virus has been studied in a large dental cohort.

"It is important that we now progress our research to ensure we have an understanding of how people are protected from re-infection with COVID-19 following natural infection and vaccination.

"The nature and duration of immunity in these cohorts will be critical to understand as the COVID-19 pandemic progresses, particularly with respect to the efficacy of vaccination strategies – single-dose, multiple-doses, vaccine combinations – and in relation to novel viral variants of concern."

Source: University of Birmingham

Athens, Greece, from 2 to 3 July 2021

BDIZ EDI and Masterminds

One of the few face-to-face symposia this year will be the Masterminds4 in Athens, Greece to be held from 2 to 3 July 2021. BDIZ EDI is the cooperation partner of the Hellenic Society of Medicine and Dental Technology.

For 2021, the scientific team of the Hellenic Society of Medicine and Dental Digital Technology, along with "Omnipress News", are organizing the Dental two-day congress "Masterminds4", on Friday the 2nd and Saturday the 3rd of July, with two distinguished invited speakers and persons who have offered a lot in the field of dentistry.

More specifically, Professor Massimo Simion from Italy is one of the pioneers of the guided bone regeneration procedure in the area of implant dentistry. Through his thirty-year experience, he will convey his experiences in this area, as well as the secrets of success in cases of extended deficit of the alveolar crest, in both the maxilla and the mandible, and he is going to present the management of various complications that may arise in handling such cases, which is a challenge for clinicians.

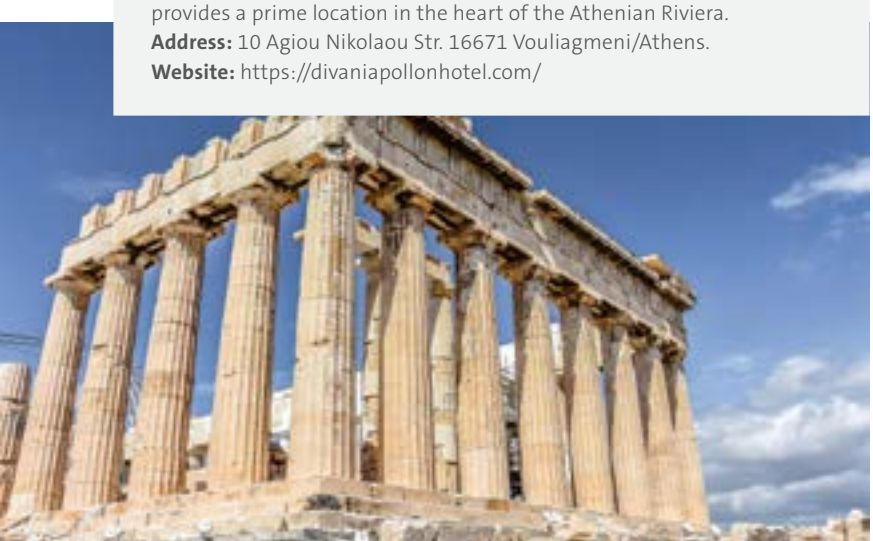
The congress will also feature Dr Iñaki Gamborena from Spain whose lectures will focus on the key factors affecting the success of treatment in the aesthetic zone, both in patients with a purely dental arch and in implant restorations. His presentations will include the surgical and the prosthetic management of these cases, and he will also elaborate on the management of complex cases with past failures.

Both the responsible society and organizer hope that the combination of these two very experienced clinicians will give participants the opportunity to attend lectures on diverse and most interesting topics and will allow to discuss daily clinical concerns.

The congress language will be English with simultaneous translation into the local language. The symposium organized by Omnipress and its CEO Yannis Roussis features an attractive programme tailor-made for clinical practicability.

Venue

As one of Athens' most iconic hotels, Divani Apollon Palace & Thalasso provides a prime location in the heart of the Athenian Riviera.
Address: 10 Agiou Nikolaou Str. 16671 Vouliagmeni/Athens.
Website: https://divaniapollonhotel.com/



More information and registration

Via the below QR code, you can directly access the programme and registration form of "The Masterminds". https://omnipress.gr/en/shop/congresses/the-masterminds-vol-iv-2/

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European Consensus Conference (EuCC) updates 2007 consensus paper

Practical Guide 2021: Update “Ceramics in Implantology”

The European Consensus Conference (EuCC) under the auspices of the BDIZ EDI discussed online at the end of February the possible uses of ceramics in implantology and implant prosthetics : in addition to abutments and superstructures, one-piece and two-piece ceramic implants were also scrutinized. The coordinated Practical Guide 2021 will be available shortly, , updating the paper from 2007: Update Ceramics in Implant Dentistry.

The participants from universities and practice initially discussed online on the basis of a working paper from the University of Cologne and taking into account the practical guide from 2007. The points worthy of discussion were voted on in the following weeks by moderator Professor Jörg Neugebauer, BDIZ EDI board member. The consensus paper covers abutments, superstructures and one-piece and two-piece ceramic implants.

From the immunological and biological point of view, the EuCC states that commercially available implants inserted according to the manufacturer’s instructions (Instructions for use) achieve good osseointegration and soft tissue biocompatibility as well as good clinical success.

For the one-piece ceramic implants, the EuCC dispels previous concerns. For example, the risk of implant fractures is low with the implants currently available on the market. Any overloading in the early healing phase can be prevented by splints or by a temporary restoration without functional loading.

Regarding the two-piece ceramic implants, the EuCC states that different designs of abutment connections are available, some of them with metal cores. However, the concept of metal-free implant constructions is being abandoned. The EuCC notes that abutment fixation requires a specific protocol according to the manufacturer’s instructions. The EuCC notes, “Scientific evidence for two-piece implants is scarce.”

According to EuCC, ceramic abutments score higher in esthetics than metal abutments, especially in patients with thin tissue phenotypes. The reduced biofilm adhesion compared to titanium is also highlighted. However, abutments connected to titanium implants should also be made of titanium, according to EuCC.

Zirconia superstructures are meanwhile common. The EuCC requires a special design and trained practitioners for frameworks with ceramic veneers as implant superstructures in order to avoid chipping. From the EuCC’s point of view, there is little medium- or long-term evidence for the use of monolithic zirconia.

The conclusion of the EuCC: “Ceramic solutions are available for all aspects of implant treatment. The implant dentist/physician and the restorative dentist must be appropriately trained to ensure the best possible therapy for each patient.”

AWU

The printed version of the Practical Guide 2021 will be available for BDIZ EDI members

The members of the BDIZ EDI will continue to receive the Practical Guide via circular letter this year. Due to the pandemic, the 16th Expert Symposium will take place during the 30th Expert Symposium on Regenerative Dentistry in Fuerteventura. Date: 28 October to 4 November 2021. You will find further information on the program in this magazine.

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30th Anniversary: The Expert Symposium for Regenerative Dentistry

Review and preview on oral implantology

"30 years of implantology – safe innovations and proven concepts" is the major topic of the 30th International Expert Symposium on Regenerative Procedures in Dentistry. Professor Joachim Zöller, University of Cologne, Germany, is hosting the anniversary event in Fuerteventura. The date: 28 October to 4 November 2021.

For the past 30 years, the host and scientific director of the expert symposium: Professor Joachim Zöller

"We are all very excited about the 30th anniversary symposium from 28 October to 4 November at the Robinson Club Esquinzo Playa in Fuerteventura," says Vice President of BDIZ EDI and initiator of the expert symposia in Fuerteventura, Professor Joachim Zöller. "Since this particular symposium regrettably had to be postponed by one year due to the pandemic, we are more than confident that it will take place this year – together with the 30th anniversary of the Robinson Club Esquinzo Playa."

The organizers are confident that after the summer the vaccination should be largely completed and the rapid tests will be further improved – and then probably can be made everywhere. In addition to the extensive hygiene measures that the club is implementing, the organizers will possibly also move the symposium from the Pyramid to the large Theatro so that the spacing rules and the infection control can also be complied with during the scientific lectures.

Traditionally, the "white BBQ evening" will again be held outdoors, accordingly, the risk of infection is low in this case. " Altogether, we can look forward to a special anniversary event. We can expect an excellent scientific program with many speakers and a remarkable supporting program," said Professor Zöller. The speakers have prepared their presentations according to the special requirements of the anniversary symposium, so that the participants can certainly expect a retrospective, but also an overview of the future of oral implantology.

Lots of workshops in Fuerteventura

As always, the expert symposium will feature numerous workshops enabling the interactive knowledge transfer. The contents can be better deepened in small working groups. In addition to the high-tech and specific procedures for implant therapy, the program once again offers the opportunity to think outside the box. Topics of general medicine, including emergency training, round off the program.

For further information on the congress trip and to register, visit www.experten-symposium.de

Travel organization and registration

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Lectures, workshops and hands-on in a relaxed atmosphere

16th Experts Symposium: Fuerteventura instead of Cologne

For the first time in the history of the Expert Symposium, the one-day event will not take place in Cologne during the carnival season as usual, but on Fuerteventura. The date is: 28 October to 4 November 2021. The change is due to the COVID-19 pandemic.

The BDIZ EDI Board has decided to organize this year's 16th Expert Symposium as a part of the Expert Symposium on Regenerative Procedures in Dentistry. As every year, the latter will take place with a dental-scientific program lasting several days at the Robinson Club in Fuerteventura.

The date and the program of the 16th Expert Symposium on the topic Update Ceramics in Implantology have not yet been fixed. This year's Practical Guide of the European Consensus Conference on Implantology (EuCC) – which is traditionally discussed before the Expert Symposium – is introduced in this issue. Members will receive the Practical Guide as usual via circular letter.

Attendees who do not want to miss the Expert Symposium can contact the travel agency for the week-long event at the address on page 20. The date and program will soon be available on the BDIZ EDI website under "Events".

Cases are also discussed with the speakers during the breaks

Relaxing after an interesting day of training

Professor Joachim Nickenig shows how it works in a hands-on workshop.

Full house during Professor Joachim Zöller's lectures.

Curriculum in dental implantology offered by BDIZ EDI and University of Cologne, Germany

A must-have not only for beginners

The BDIZ EDI regularly offers profound basic training in oral implantology in cooperation with the University of Cologne, which stands out for the great emphasis it places on hands-on exercises. A special feature is that training modules that were not acquired at BDIZ EDI can be integrated into the BDIZ EDI Curriculum Implantology if their scientific character is recognized. Advantages of the Curriculum include high quality, small groups of no more than 20 to 25 people and low fees.

The BDIZ EDI Curriculum in implantology is not only for beginners a must-have. In cooperation with the University of Cologne, Germany, the BDIZ EDI regularly organizes a profound basic course in implantology, which scores with a high proportion of practical exercises. A special feature is that continuing education modules which were not acquired with the BDIZ EDI can also be integrated into the curriculum of the BDIZ EDI if their scientific nature is recognized.

The advantages are:

- High quality
- Small learning groups (max. 20–25 people)
- Low charges

Outlook

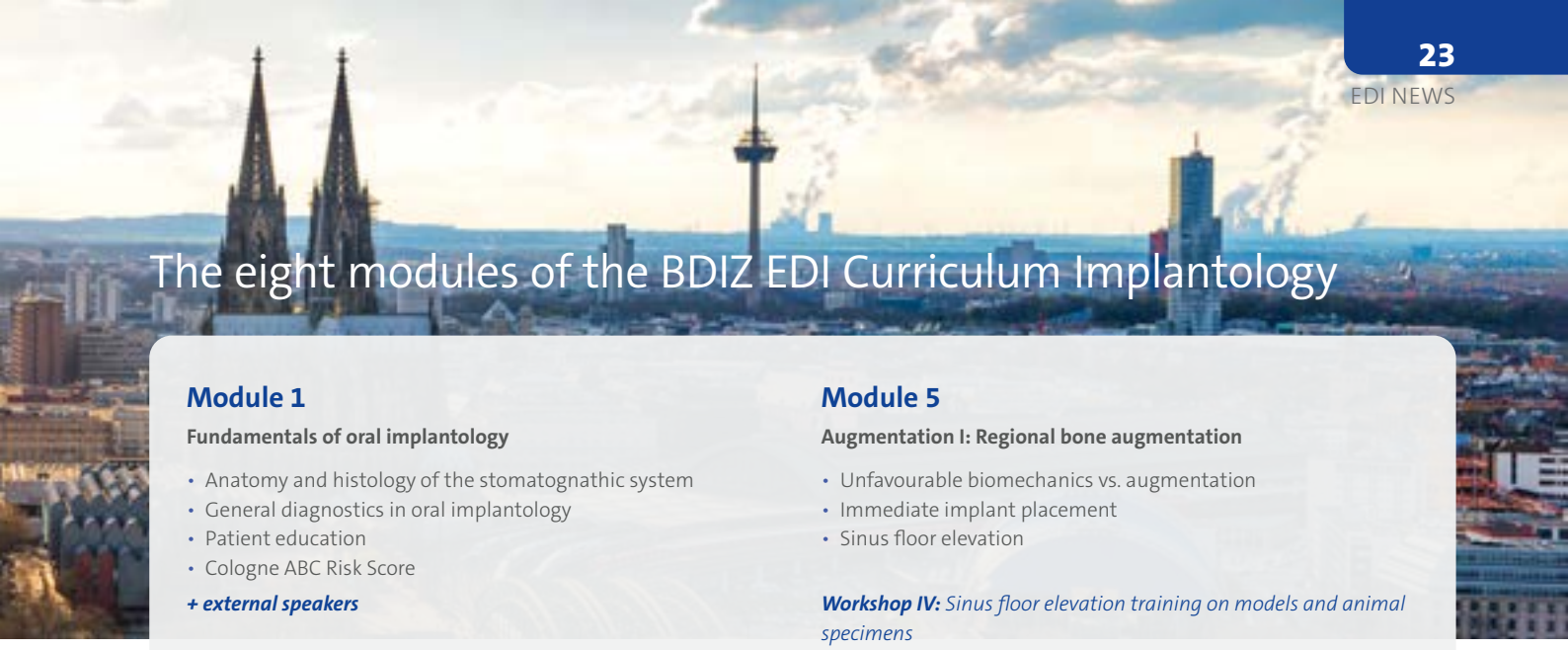
Currently, the Curriculum in implantology is only offered in this form in German language at the University of Cologne under the direction of Professor Joachim E. Zöller and Professor H.J. Nickenig. Similar curricula are now also available at some associated partner associations of the BDIZ EDI in Poland, Greece and Serbia.

This sets the association above many other concepts. Previous graduates praise the hands-on operations on human specimens and the realistic exercises that are the result. This practical instruction represents an essential teaching unit for each curriculum block. Human specimens from the anatomical institute of the University of Cologne are prepared at different stages and tissue depths, so that not only the spatial orientation but also the structures worth sparing can be studied.

The modules systematically expand on each other so that in the course of the curriculum the participant receives a complex overall package of implantology for the practice, starting with a simple standard protocol and extending to 3D-supported augmentation techniques and complex implant prosthetics.

The integration of current topics and therapy methods (3-D guided surgery, bone preparation using ultrasound, CAD/CAM technologies for bone regeneration, etc.) complete the picture of the practice-oriented curriculum.

For the final examination, two implant surgery and/or implant prosthetic cases will be presented and discussed by each participant. Finally, there will be an exam and the certificate will be handed over.



The eight modules of the BDIZ EDI Curriculum Implantology

Module 1

Fundamentals of oral implantology

- Anatomy and histology of the stomatognathic system
- General diagnostics in oral implantology
- Patient education
- Cologne ABC Risk Score

+ external speakers

Module 2

Indications, diagnosis and treatment planning

- High-risk patients and monitoring
- Description of indications
- Avoiding malpositioning
- Patients with coagulation disorders

Workshop I: *Surgical and prosthetic protocols*

+ external speakers

Module 3

Implant systems, instruments, advanced diagnosis

- Diagnostic tomography
- Fundamentals of 3D diagnostics
- Surgical templates/guide sleeves
- Choice of implants/Comparison of implant systems

Workshop II: *3D workshop with interactive planning*

Demonstration of different instrument sets

Case presentations by participants I

Module 4

Implant prosthetics I and minimally invasive surgery

- State of the art in tooth extraction
- Implant prosthetics (instruments, impressions, abutments)
- Minimally invasive procedures (flapless surgery, 3D bone splitting, sinus floor elevation)
- Emergencies in the dental practice

Workshop III: *Surgical and prosthetic protocols, instrument sets*

Modified bone splitting using Piezosurgery

Case presentations by participants II

Curriculum online
Interested?
If you are considering participating in one or more modules of the BDIZ EDI curriculum, please contact us: office-munich@bdizedi.org

Module 5

Augmentation I: Regional bone augmentation

- Unfavourable biomechanics vs. augmentation
- Immediate implant placement
- Sinus floor elevation

Workshop IV: *Sinus floor elevation training on models and animal specimens*

Exercise in customized bone regeneration

Case presentations by participants III

+ external speakers

Module 6

Implant prosthetics II and soft-tissue management

- Antibiotic therapy
- Implant re-entry and soft-tissue corrections
- Implant prosthetics II: Teeth and implants
- Implant prosthetics III: Removable restorations

Workshop V: *Hard- and soft-tissue management: Exercises on porcine jaws*

Soft-tissue techniques I and II for augmentation, implantation and exposure

Case presentations by participants IV

Written examination

Module 7

Augmentation II: Bone grafting and distraction

- Iliac-crest transplants
- Fundamentals and results of distraction osteogenesis
- Implant prosthetics in the anterior region

Practical exercises on human specimens; practical training of the acquired surgical techniques

+ external speakers

Case presentations by participants V

Module 8

Recall – Coping with complications – Future perspectives

- Recall
- Peri-implantitis therapy
- Oral implantologists in court
- Ceramic coating of implants

+ external speakers

Final exam

BDIZ EDI president interviewed by the Croatian Dental Herald

We need a powerful organization

For many years, the Croatian Dental Chamber is a collaboration partner of the European Association of Dental Implantologists (BDIZ EDI). Now, the Croatian Dental Herald pays attention to this fruitful cooperation in an interview with BDIZ EDI President Christian Berger.

BDIZ EDI President Christian Berger

Mr. Berger, could you please introduce yourself to our readers?

My motivation to enter the dental way was almost innate because my father is a dentist too and during my childhood, he took me to his office and lab on a regularly basis, where I "worked" with his dental technician. And his intention finally worked out.

Though, I first trained as a dental technician to learn how work is done in the lab and then studied dentistry in Antwerp, London (Ontario) and Heidelberg.

After becoming a specialist in oral surgery, I worked at the University's Department of Oral and Maxillofacial Surgery in Heidelberg. Finally, I decided to return to my hometown Kempten, which is located in the utmost southwest of Germany and close to the Alps and King Ludwig's Castle, to continue my father's practice.

In addition to all the honorary activities as the President of the Bavarian Dental Chamber, Board Member of the German Dental Association and the President of the European Association of Dental Implantologists, I'm still working in my office – because this is my real passion.

You have been the President of the European Association of Dental Implantologists since 2005. Could you tell us something more about the European Association of Dental Implantologists?

Be aware that this will not be a short answer!

Since 1988, the BDIZ EDI has covered all areas to advance the field of oral implantology and in particular implanting dentists in different ways: scientifically, practice-oriented, patient-oriented and above all "by practitioners for practitioners" – this has always been the guiding principle.

I have been involved from the beginning and was able to witness from the inside how oral implantology became a scientific discipline and established in dental practices. We are still working on that, now on a European basis. Since 2006, the European Consensus Conference (EuCC), under the auspices of the BDIZ EDI, has been releasing guidelines each year, which have the status of a recommendation, to support the practitioner in current issues of implant therapy.

We on the Executive Board are committed to the interests of the dental profession throughout Europe. That is why we organize – with or without cooperation partners – the European Symposium, the Expert Symposium in Cologne, the many papers we provide for the practice, e.g. the BDIZ EDI Quality Guidelines, the annual EuCC Guideline, the patient brochure on implant care and much more. The EDI Journal passes on all our work to the readers – also in postgraduate education, where we offer the entire curricula Implantology or modules from this curriculum with the University of Cologne throughout Europe.

What are the strategic plans of the European Association of Dental Implantologists?

In times like these, we need an efficient, capable, active, and powerful professional organization with a comprehensive approach to create more favourable framework conditions and influence political decisions across Europe. This is exactly what we are doing. We consistently advocate for political framework conditions for the professional environment of our members in Berlin and in Brussels. We closely follow legislative developments and contribute opinions, such as on the Medical Devices Regulation, to name the current EU regulation that also affects dental practices.

As many countries went into lockdown, we quickly organized free webinars so that clinicians could earn CE credits during the downtime and gain insight into various aspects of implant dentistry and, of course, aspects of health policy and hygiene. We already offer this to all our European partners. Our speakers cover the full range of experience in all aspects of practicing as an implantologist.

In all, we are a European non-profit organization that shares the knowledge I have been talking about with all partner associations and organizations that

are willing to cooperate with us., And, since we have been asked to cooperate with implantologists in India, this is no longer limited to Europe

Have you had the opportunity to work with the Croatian Dental Chamber? Could you tell us something more about this collaboration?

Yes, indeed, more than once. We were cooperation partners in two European symposia that we organized and held together: in Split in 2011 and in Dubrovnik in 2017. In 2019, the Croatian Dental Chamber was our partner at the International Dental Show IDS in Cologne. We shared the booth together and it was a perfect combination of the entire approach that a dental chamber offers and the part that BDIZ EDI offers for implantology. In Split we had the official ceremony for Professor Pavel Kobler who passed the exam and became the first "Expert in Implantology" from Croatia.

You are a lecturer for various national and international conferences and training programs. Do you have plans to hold a lecture in Croatia in the future?

Since Dr Hrvoje Pezo and Professor Kobler, the presidents of the Croatian Dental Association, regularly come to Cologne and actively participate in the European Consensus Conference, I would not say no if I received an invitation.

You are also an appointed certified expert witness in implantology, oral surgery, periodontology and prosthodontics of the Bavarian Dental Chamber. How long have you been in the dental profession?

I started my own practice in 1989 and since then I have worked for the Bavarian Dental Chamber as an assessor, as chairman for public relations, as chairman for continuing education and thus also responsible for the Bavarian Dentists' Day, for 12 years as vice president and now for 8 years as president – in other words, quite a long and steady honorary career in the chamber. I still enjoy this work, but also the work in the BDIZ EDI.

In addition to the function you perform, you also own a dental practice. How do you balance your work and personal life?

Good question! Sometimes, I don't know! Seriously, it's all down to good organization - and professional staff that I work with. I really enjoy the time I spend working in the practice and I love having my "base" with family in Kempten. After meetings and congresses I am always very happy to come back to my hometown and my family.

Do you have any hobbies? How do you spend your free time?

Professor Pavel Kobler has been awarded as the first specialist in implantology (EDA) in Croatia. BDIZ EDI President Christian Berger (left), President of the Croatian Dental Association Dr Hvroje Pezo (right).

Don`t ask, there is not enough free time. My sports are skiing and rowing. Because of my time in London and Antwerp I am very interested in languages. I love history and cultures with Roman background because I speak Latin. Culture is one of the reasons why I like to travel and read books.

The COVID-19 pandemic has changed a lot, it has also changed the dental profession. How do you see the future of our profession?

If we've learned anything in that time, it's that dentistry has quickly understood how to manage the risks of COVID-19 infections. Dentists have always been accustomed to treating the very places where most infections begin: the mouth, nose, and throat. While the situation in the oral cavity is not as easy to manage, this recognition also highlights the fact that dentists routinely work in a potentially infectious environment. Dentists' awareness of the importance of protective measures has always been high. We have proven that we are able to handle the situation to protect the patient and to protect ourselves and our teams. It is very important that our chambers and associations successfully bring these aspects to the public!

On the other hand, dental practices will face reduced throughput and an increase in protective equipment on average. The good news is that we have all learned that oral care is the most important thing for oral health and beyond.

And finally, do you have a message for our readers, how to remain optimistic in these difficult times?

Dentistry is a medical specialty and, as an academic subject, continues to play an important role in maintaining people's oral health. Dentists work very individually and with high levels of individual competence.

Once again, thank you very much for the interview. I hope that in the future we will have an opportunity to have you over as a guest lecturer here in Croatia.

The interview was conducted by Maja Mlinarević, dipl. Novinar, Croatian Dental Herald.

Editor and publisher of BDIZ EDI konkret and EDI Journal

The cooperation continues

After the previous publisher teamwork media GmbH declared insolvency, BDIZ EDI is pleased that the publication of the two professional journals BDIZ EDI konkret and the English-language EDI Journal could be ensured at short notice. The publisher BDIZ EDI and Mediengruppe Oberfranken (MGO) have agreed at the end of March 2021 on the further cooperation.

"This new start is part of our aim to further improve our service for you as a partner in the industry. In the future, we will offer combined print and online solutions. Thus, we would like to know what your expectations are regarding the German and/or the English specialist journal", states a letter that BDIZ EDI and the new teamwork media GmbH & Co. KG/ MGO addressed to the industry partners.

This realignment is also associated with a new name. In the future, the dental industry partner of the EDI Journal und the BDIZ EDI konkret will be supported by Silke Matschiner-Oltmanns as a media consulter at teamwork media. She has many years of experience in the publishing field, having held various positions in different specialized publishing houses.

Dr Alina Ion will contribute her dental expertise. As in the past, she will be responsible for the area of continuing education and for the structuring of the magazines. She remains the editorial contact for the dental industry for both professional magazines. As the managing editor, she will select the specialist articles in close consultation with Professor Neugebauer, who is the head of the scientific advisory board and a member of the board of BDIZ EDI.

The further head of our professional magazines remains the editor-in-chief Anita Wuttke.

Her tasks include the content conception of the magazines: the health and association policy input as well as the innovative focuses of BDIZ EDI konkret and EDI Journal. In the future, she will also deal much more intensively with the concerns of the industry partners – be it anniversaries, new products and innovations.

"Both journals have an undisputedly significant position in the market. Our readership in Germany and Europe is diverse: members, subscribers, universities, associations, societies, dental bodies, dental chambers, associated partners of BDIZ EDI from Europe and beyond, insurance companies, legal experts, clearing centers, dental laboratories, European parliamentarians, EU Commission, the European umbrella organization Council of European Dentists (CED), the Federation Dentaire Internationale (FDI) as the world's largest dental association, the German Federal Ministry of Health, the German Federal Ministry of Justice, the German Federal Ministry of Finance, lobbyists in Brussels and Berlin and last but not least, you as our partner in the market", is the wording of the letter signed by BDIZ EDI President Christian Berger on behalf of the publisher and teamwork media/ MGO Managing Director Bernd Müller for the publisher's side.

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European Semester Spring Package

To help Member States strengthen economy

The European Commission has presented the European Semester Spring Package begin of June, which focuses on providing fiscal guidance to Member States as they continue the process of gradually reopening their economies. This guidance aims to help Member States strengthen their economic recoveries, making the best possible use of the Recovery and Resilience Facility (RRF), the key instrument at the heart of Next Generation EU. The European Semester has been adapted this year, given the links to Member States' recovery and resilience plans, laying out the investments and reforms that the RRF will finance. The activation of the general escape clause of the Stability and Growth Pact in March 2020 allowed Member States to react swiftly and adopt emergency measures to mitigate the economic and social impact of the pandemic.

Source: European Commission

COVID: Englands traffic light list for travel

Portugal on UK's red list

Portugal has questioned the UK's decision to remove it from the travel green list end of May. The move to the amber list means UK tourists should not visit the country and returnees must isolate for 10 days. UK's Transport Secretary Grant Shapps cited rising cases and a COVID mutation found in Portugal, saying ministers did not want to take risks before the planned final easing of England's restrictions. But Portugal said it could not understand the "logic" of the move. A post from the Twitter account of Portugal's foreign affairs minister said: "Portugal continues to carry out its prudent and gradual deconfinement plan, with clear rules for the safety of those who live here and those who visit us." In the first review of England's traffic light list for international travel, no new destinations were added to the green list, where travellers must be tested but do not have to quarantine on their return. Seven countries – Afghanistan, Bahrain, Costa Rica, Egypt, Sri Lanka, Sudan, and Trinidad and Tobago – are being added to the red list. Holidaymakers should not travel to amber or red list countries, according to government guidance.
Scotland, Wales and Northern Ireland have confirmed they will adopt the same changes, which came into effect on 8 June. The green list will reviewed again on 28 June.The travel industry has criticised the change, saying it will threaten jobs and consumer confidence – with the boss of Heathrow Airport warning the sector faces "another lost summer".

Source: BBC

Photo: kalhh/pixabay

Still searching for the origins of COVID-19

Unanswered questions

Joe Biden's chief medical adviser Dr Anthony Fauci has called on China to release the medical records of nine people whose illnesses might provide vital clues into whether COVID-19 first emerged as the result of a lab leak. Fauci, the head of the US-National Institute of Allergy and Infectious Diseases, or NIAID, told the Financial Times that the records could help resolve the debate over the origins of a disease that has killed more than 3.5m people worldwide. The records in question concern three researchers at the

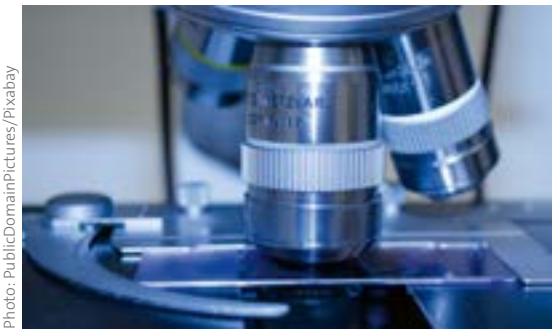


Photo: PublicDomainPictures/Pixabay

Wuhan Institute of Virology who reportedly became sick in November 2019, and six miners who fell ill after entering a bat cave in 2012. Scientists from the Wuhan Institute of Virology subsequently visited the cave to take samples from the bats. Three of the miners died. Shi Zhengli, the institute's leading expert on coronaviruses, has previously denied there were any infections at the lab – a claim Fauci did not dispute, but said should be investigated further. "I would like to see the medical records of the three people who are reported to have got sick in 2019," Fauci said. "Did they really get sick, and if so, what did they get sick with? "The same with the miners who got ill years ago ... What do the medical records of those people say? Was there [a] virus in those people? What was it? It is entirely conceivable that the origins of Sars-Cov-2 was in that cave and either started spreading naturally or went through the lab." The state department declined to comment on whether the Biden administration had asked China for the medical records. China's foreign ministry declined to say whether it would consider releasing the medical records of the nine individuals at a press briefing end of May. But Wang Wenbin, a spokesman, repeated a statement made by the institute in March that none of its staff had ever been infected with COVID-19.

Source: Financial Times

Update from the 74th World Health Assembly

Approval of the WHO Oral Health Resolution

Since May 28th 2021, oral health is on the political agenda of all World Health Organization member states since they have approved the Oral Health Resolution brought forward under the leadership of Sri Lanka. The Academy of Dentistry International, ADI, quotes this as a remarkable achievement and a great opportunity for governments together with oral health professionals and their teams to take on social & human responsibility for oral health and for universal health coverage. This means a shift from the traditional curative approach towards a preventive approach that includes promotion of oral health within families, schools and workplaces, and integrates timely, comprehensive and inclusive care into the primary health-care system. The resolution, which was approved by a WHO committee, acknowledges the tremendous global burden of oral diseases and the importance of oral health in overall health and well-being. If adopted by the entire organization, the WHO would urge member states to take action to address risk factors for poor oral health, shift to a prevention-first treatment model, and strengthen the provision of oral healthcare services as part of universal healthcare coverage. ADI offers a multiple decade experience to better integrate oral health into global health policies! Therefore, the organization welcomes and applauds WHO on the truly farsighted resolution of the 74th Health Assembly with the ongoing participation.

Source: ADI

European Commission in June

Proposal for digital identity for all Europeans

The European Commission proposed a framework for a European digital identity which will be available to all EU citizens, residents and businesses in the EU. Citizens should be able to prove their identity and share electronic documents from their European Digital Identity wallets with the click of a button on their phone. They will be able to access online services with their national digital identification, which will be recognised throughout Europe. In the press statement they say that very large platforms will be required to accept the use of European Digital Identity wallets upon request of the user, for example to prove their age. Use of the European Digital Identity wallet will always be at the choice of the user. Margrethe Vestager, Executive Vice-President for a Europe Fit for the Digital Age said: "The European digital identity will enable us to do in any Member State as we do at home without any extra cost and fewer hurdles. Be that renting a flat or opening a bank account outside of our home country. And do this in a way that is secure and transparent. So that we will decide how much information we wish to share about ourselves, with whom and for what purpose. This is a unique opportunity to take us all further into experiencing what it means to live in Europe, and to be European."

Source: European Commission

14th European Symposium organized by EDI Macedonia was held online

Implantology from A to Z

A highlight in the BDIZ EDI year is most certainly the European Symposium, which takes place each year with a different partner in a different European country. Due to the Corona pandemic, the event originally planned for May 2020 in Skopje had to be postponed and presented online at the end of May. It has been organized by EDI Macedonia together with the Albanian Association for Implantology in Macedonia (AIAM). The motto was: Implantology from A to Z.

Implantology from A to Z was the motto of the 14th European Symposium.

BDIZ EDI was the cooperation partner of EDI Macedonia and AIAM. Therefore, renowned German speakers were giving their lectures online. The one-day congress was a very international congress presenting different topics and methods of implantology.
The event started with the opening address by the two moderators, Dr Fisnik Kasapi from EDI Macedonia and Professor Jörg Neugebauer, Board Member of BDIZ EDI, who chaired the online congress. Dr. Vikas Gowd from Mangalore/India was the very first speaker on the topic of immediate implant placement and loading in molars – myth or reality.
Professor Hakan Özyuvaci from Turkey presented new concepts in oral implantology and BDIZ EDI president Christian Berger introduced some consensus recommendation from the European Consensus Conference (EuCC) under the auspices of BDIZ EDI to proof the long term success in dentistry. Immediate implants in the esthetic zone was the title Dr Jan Willem Vaartjes from Amsterdam/the Netherlands contributed to the congress. All the way on air from the Unites States, Dr Sammy Noumbissi was talking about zirconia ceramic implants – a viable and fast-growing alternative in dental implantology. Professor Jörg Neugebauer from Landsberg/Germany focused on efficient therapy options with short, diameter-reduced and angulated implants, which is also a guideline of the European Consensus Conference.

In the afternoon, Professor Qenan Ferati from Tetovo/Macedonia and Dr Safet Zuferi, Gostivar/Macedonia chaired the second half of the congress. Professor Thomas Ratajczak, legal advisor of BDIZ EDI introduced the new European Regulation on Medical Devices and to what extent dentistry is affected. Professor Andrzej Wojtowicz from Warsaw/Poland lectured about predictability and safety of machined surface on hybrid implants and zygoma rescue procedures. Professor Qenan Ferati gave insights on how to manage challenges during maxillary sinus elevation. Protocols of prosthetic rehabilitation in all-on-8 in Albania was Professor Koco Gjilo's lecture who is coming from Tirana. Dr Iskra Kocheva, Macedonia, focused on a very hot topic: management and control of COVID-19 risks in dental settings and Implantology. The last two lectures were given by two Macedonian speakers: Dr Nedim Kasami with short implants in everyday practice – advantages and disadvantages and Professor Enis Redzep who introduced a guide through complications in implantology – diagnostics and management of clinical cases.

This online congress organized and technically supported by a team of six members of EDI Macedonia and AIAM showed that no matter in what time zone you are, you could bring together the world of implant dentistry very easily. More than 100 participants were online.

AWU

Lecture of Professor Neugebauer

Lecture of Professor Noumbissi

Academy of Dentistry International (ADI)

New president

Jacob G. Park, D.D.S., a member of the ADA Council on Scientific Affairs and chair of the Standards Subcommittee for the council, was elected as president of the Academy of Dentistry International in February during its board of regents meeting.

Dr Park is also chair of both CAD/CAM subcommittees in the ADA Standards Committee on Dental Products and the U.S. Technical Advisory Group to the International Organization for Standardization Technical Committee on Dentistry.

Dr Park is a professor of dentistry/clinical at both the School of Dentistry and Medical School of the University of Texas Health Science Center at San Antonio. He holds fellowships with the International Congress of Oral Implantologists, American College of Dentists and International College of Dentists.

"My goal as president of the ADI is to lead the academy in the right direction to heal unthinkable trauma from COVID-19 and create a positive environment which will help our members move back to 'normal,'" Dr Park sayed during inauguration. "I feel that being the president of this prestigious organization is such a lifetime honor and I will do my best to serve the academy with the highest level of efforts."

The ADI represents more than 3,000 fellows in more than 85 countries. Dr Park succeeds Dr Gerhard K. Seeberger, D.D.S., a native of Germany now living in Italy and being President of the Federation Dentaire Internationale (FDI).

Jacob G. Park, D.D.S.

Healthcare association of the year

BDIZ EDI's associated partner the Ogolnopolskie Stowarzyszenie Implantologii Stomatologicznej (OSIS EDI) has been awarded with the "British Corporate LiveWire Prestige Award" in Poland and is therefore the health care association of the year 2020/2021 in Poland.

The president of OSIS EDI, Professor Andrzej Wojtowicz proudly announced this award for OSIS EDI recently. The award is for providing excellent information and support in the dentristy industry – in particular the legal area. "Dental implants are clearly a big decision for individuals so it is important patients get the correct advice. We appreciate you also provide the platform the professions in the dentistry to further themselves with extra information and courses", says the jury of Corporate LiveWire Prestige Awards, London/UK. For 16 years they award on an international basis. In 2017 the group introduced regional awards to recognise smaller, independent businesses that are extremely successful on a local or national level. They plan releasing the annual 2021 Poland Business Publication and will be promoting all of those recognised.

OSIS EDI will also be featured in a magazine coming out in the country. The Poland Prestige Guide will be available to over 500,000 global subscribers. It will also reach over 30,000 readers located across the country in print and digital formats. Copies will be made available to both businesses and residents in the region.

The Corporate LiveWire platform provides business professionals and individuals in the corporate sector with information on the latest news and developments from around the globe.

Source: OSIS EDI, Poland

Partial access to professions and automatic recognition of professional qualifications

Gaps in knowledge must be compensated

In its decision from 25.02.2021 (Case C-940/19), the European Court of Justice (ECJ) dealt with the interpretation of the amended Directive 2005/36/EC (Art. 4f para. 6). The subject of the decision was the question of whether the Member States are prevented by the new version of the Directive from allowing partial access to professions if automatic recognition of professional qualifications is already regulated for these professions under the Directive.

The facts of the case

In the original case, several French associations of medical professions, including the professional association of French dentists (Les Chirurgiens-Dentistes de France), objected to decrees issued by the French Ministries of Social Affairs and Health. The decrees regulated the implementation of Decree No. 2017-1520, which in turn served to implement the Code de la santé public (Public Health Code). At issue was, whether the content of the regulations to be implemented in the Code de la santé public is compatible with European law. The regulation provided for so-called partial access to all regulated health professions. Thus, the regulation also affected professions that are subject to automatic recognition under Directive 2005/36/EC.

For the professions defined in the directive (e.g. physician, dentist, pharmacist, nurse, midwife), this means that the qualifications obtained in the country of origin, such as basic medical training or specialist medical training, are automatically recognized in other European countries. A separate equivalence test is then no longer necessary. The reason for that is that uniform standards for professional qualifications have been created in the EU. Automatic recognition is only possible if the professional training was completed in an EU country and the requirements of the directive are also met. If the vocational training is completed in a third country, e.g. in the USA, a so-called equivalence test will take place. Within the framework of the equivalence test, the training and the professional profile in the country of origin are compared with the professional profile and the training in the host country. If the training or job descriptions differ significantly, the differences identified must be eliminated through training and/or examination before recognition of the professional qualification is possible.

The possibility of a partial access to the profession means that a partial authorization to practice can be granted despite the determination of the lack of equivalence.

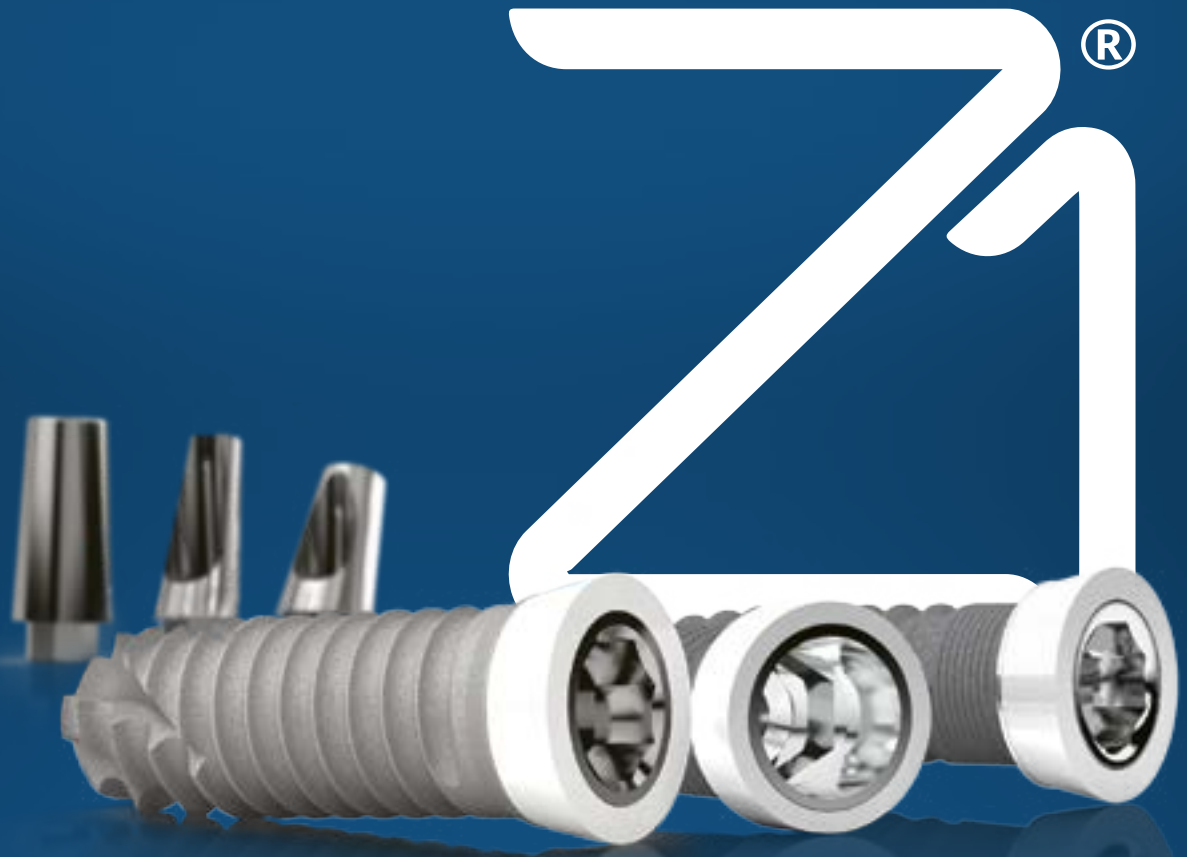
The interest groups claimed that the decrees were unlawful because they were based on a statutory provision in the Code de la santé public, which provides for the possibility of partial access also to health professions. In the view of the professional associations, this was incompatible with the new version of Directive 2005/36/EC in Art. 4f (6). The regulation states:

"This article does not apply to professionals who are subject to the automatic recognition of their professional qualifications under Title III Chapters II, III and IIIa." Um die Frage nach der Vereinbarkeit mit der europäischen Richtlinie zu klären, setze das Gericht das Verfahren aus und legte dem EuGH die folgende Frage zur Vorabentscheidung vor:

Does Article 4f(6) of Directive 2005/36, as amended, prevent a Member State from introducing the possibility of partial access to one of the professions to which the mechanism for the automatic recognition of professional qualifications provided for in Chapter III of Title III of the directive applies?

The ECJ's decision

The ECJ has concluded that Art. 4f(6) of Directive 2005/36/EC must be interpreted as not precluding legislation under which there is the possibility of partial access to one of the professions covered by the automatic recognition of professional qualifications. ››



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In its reasoning, the ECJ pointed out that the Directive does provide for a system of automatic recognition of evidence of formal qualifications for the professions of doctor, nurse, dentist, veterinary surgeon, midwife and pharmacist in the course of coordination. However, Art. 4f(6) of the amended Directive does not refer to the profession as such, but to professionals to whom the automatic recognition applies. This follows from the wording of the provision, since it concerns individuals (paras. 20-23).

According to the ECJ, this interpretation is also in conformity with the context and the objective of the Directive. It is clear from both, the legislative history and the system that the EU legislator intended to distinguish between the terms "profession" and "members of the profession" (para. 25). Thus, in the context of the amendment by Directive 2013/55/EU, it was discussed whether the professions subject to automatic recognition should be excluded from partial access. However, this proposal did not prevail. Instead, the bodies involved in the legislative process agreed to include the term "professionals" in the new regulation (marg. no. 26 f.).

According to the ECJ, the statements in the recitals of the directive, which provide for the possibility of refusing partial access for overriding reasons in the public interest – especially in the case of health professions – also support this view. Only if the possibility of partial access exists could it also be denied (para. 29).

Partial access is also in line with the general objective of the Directive to remove obstacles to the free movement of persons and services between Member States. It can also be deduced from Directive 2013/55/EU, which introduced the amendments, that the new provisions were intended to go beyond the previous directive, which only provided for an activity in the same profession. However, the possibility of partial access is also intended to cover cases in which the activities previously performed are part of a profession that covers a broader range of activities in the host member state than in the country of origin. If the differences in the fields of activity were too great, the professional would have to complete a full training program to make up for his gaps (para. 30).

According to the ECJ, the rejection of partial access in health care professions would lead to obstacles to mobility. The harmonization of the professions would not be affected by this. This is because the activity is carried out under the name of the Member State of origin, translated if necessary, and on condition that the professional indicates the scope of his professional activity to the recipients of the services (para. 33). Professionals of the professions already exempted in the Directive are not affected by partial access because they are already subject to automatic recognition.

Summary

The ECJ has thus established that there is also the possibility of partial access to the profession in the case of professions that are subject to automatic recognition. Therefore, if only part of the respective health profession in the country of origin is the subject of training in the host country and automatic recognition is therefore not possible, the possibility of partial access to the profession should always be examined and, if necessary, a corresponding application should be submitted.

However, whether partial access to the profession is possible in the respective host country depends on the national regulations. However, the ECJ's decision also clarifies once again that the member states have the option of refusing partial access for overriding reasons of general interest.

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Dr Markus Tröltzsch in an interview about possibilities for bone regeneration suitable for everyday use

Ridge preservation is part of the standard surgical routine

The preservation of the alveolar ridge is a basic prerequisite for any type of further restoration. However, the practitioner must consider the possible work conditions, the material type, potential diseases and the expected result. Dr Markus Tröltzsch, oral and maxillofacial surgeon (Germany), guided the attendees of the BDIZ EDI webinar in mid-March 2021 through the possibilities of bone regeneration suitable for everyday use. The editors of EDI Journal spoke with him about this topic.

Ridge preservation: What importance do you attribute to this procedure?

In my opinion, the technique is now part of the standard surgery, and there are several reasons for that. Tooth extraction is unfortunately sometimes the last option, even though tooth preservation is very important. Nevertheless, there are quite a few situations in which we must intervene. When we manipulate oral tissues, preservation - as with the tooth - is often the better option than reconstruction. And because that's the case, ridge preservation is a predictable, highly feasible, financially manageable procedure that can prevent significant limitations for patients later.

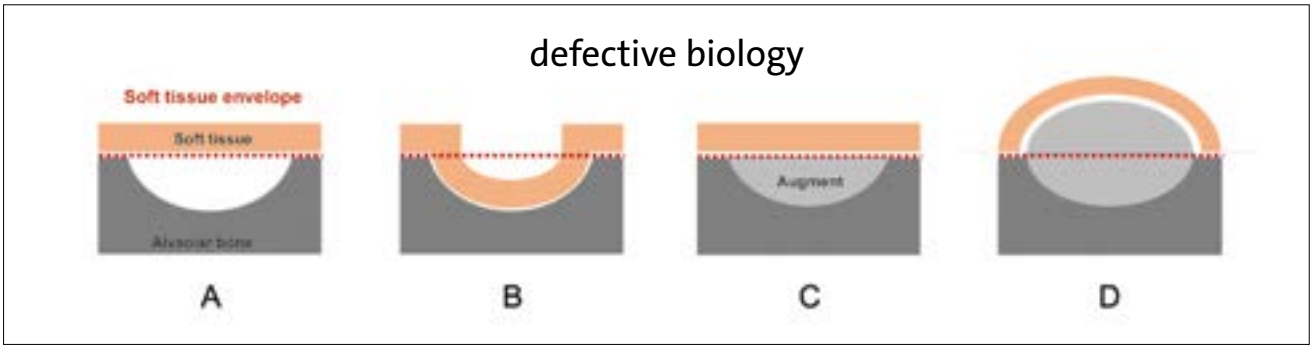
Therefore, it belongs to the tooth extraction repertoire. And from my point of view, you are doing absolutely nothing wrong if you inform the patient about this option. Otherwise, you must be prepared that the patient will come in one or two years and ask why you did not inform them after the extraction that the bone could have been preserved. But even with special indications, such as with large cysts or wisdom tooth extractions, we now use ridge preservation protocols to safely close defects or protect delicate structures such as the inferior alveolar nerve or the adjacent tooth roots.

Why are you referring to ridge preservation and not to socket preservation, which would be the more common term?

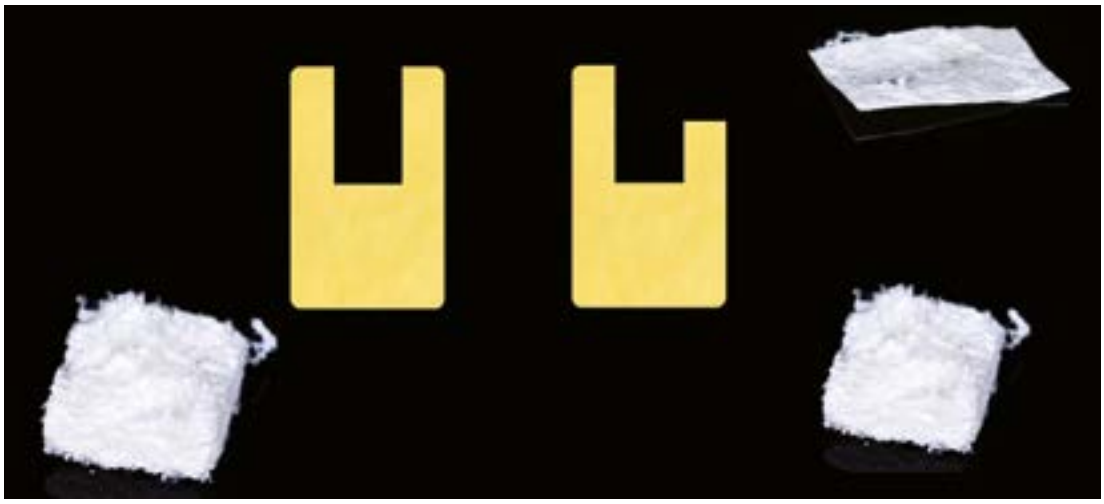
A renaming is currently underway in the dental community. In fact, it is not the extraction socket that needs to be preserved, as it is supposed to heal. It is the alveolar ridge that needs to be maintained.

What are the prerequisites for the preservation of bone structures?

The biology of the defects is very important when we approach the regeneration or preservation of the enoral structures, because we can determine the



Schematic view of the bone contour, the soft tissue envelope and of an augmentation inside and outside the soft tissue envelope. The illustration applies to horizontal, vertical and combined alveolar ridge defects. The soft tissue envelope (red line) describes the natural dimension of the bony alveolar ridge (A). If such a defect is not augmented, the soft tissue prolapses, and the bone contour is altered (B). A distinction is made between augmentations inside (C) and outside (D) the soft tissue envelope



Left: Ridge preservation in preserved bone walls without membrane
Right: Ridge preservation with partially non-preserved bone walls with membrane

regeneration potential from them. Based on the literature and on clinical experience, we can clearly say that the larger the defect, (i.e., descending from a three-, two-walled defect, etc.), the higher the regenerative effort and the more the material and the surgeon must perform. For the classic ridge defects, you can basically use any material. In the 2021 S2k guideline on bone graft substitutes[1], we were able to determine that strictly from a statistical point of view and based on the amount of literature available, the xenogeneic materials are the ones ahead, although not as an absolute.

What about barrier materials?

In the case of a three-walled extraction socket, i.e. a socket where only the tooth is missing at the top and everything else is intact, we do not need an additional barrier, because the bone represents the barrier. But if a bone wall is partially or even completely missing, we need a barrier. It is interesting that collagen-based membrane in small defects compare very well, both in terms of regeneration and complication rates.

In the 2021 S2k guideline "Implantological Indication for the Use of Bone Graft Substitutes", you have stated that risk factors can be clearly identified for augmentations despite the sparse data available. Does this also apply to ridge preservation – for example, to habits such as smoking? Is smoking a contraindication?

We have several hundred cases per year in Ansbach. I am currently working on an evaluation of 1,200 ridge preservation cases. I have not found an increased complication rate in smokers. We have a complication rate that is clearly below 1:250. We needed to remove the material in only 1:1,000 cases, i.e. almost never.

Dr Markus Tröltzsch

Dr Markus Tröltzsch
Physician and dentist
Dental specialist for oral surgery
Specialist for oral and maxillofacial surgery

Dr Markus Tröltzsch studied dentistry and medicine at the University of Erlangen, Germany, where he received his PhD in both disciplines. After working and studying at the Westmead Medical School in Sydney, Australia and at the University Hospital in Zurich, Switzerland, he joined the Department of Oral and Maxillofacial Surgery at the Ruhr University in Bochum (Professor Kunkel).
He then moved to the University Medical Center in Göttingen, Germany (Professor Schliephake), where he completed his residency in oral and maxillofacial surgery and was appointed senior physician at the University Department of Oral and Maxillofacial Surgery. He has been in private practice in Ansbach since March 2017.
Dr Markus Tröltzsch was elected in 2016 Chairman of the Academy of Practice and Science (APW) of the German Society of Oral and Maxillofacial Surgery (DGZMK), and re-elected in 2020.
His scientific focus is on augmentation (bone augmentation of the jaw bones).
He is a speaker at many national and international scientific events and regularly contributes as an author to AWMF guideline conferences.
Dr Markus Tröltzsch wrote the book "Medicine in Daily Dental Practice" together with his brother Dr Matthias Tröltzsch and a further author.

[1] S2k Guideline 2021: Implantological indication for the use of bone graft substitutes, AWMF Register Number: 083-009 (Germany)

However, we always inform patients about this and ask them to refrain from smoking a few days before the procedure and until the sutures are removed.

Is antibiosis necessary, perhaps locally?

Ridge preservation does not trigger antibiosis per se. And I have a request: Do not use local antibiotics in connection with the bone graft substitute! On the one hand, this violates every guideline, on the other hand, it can lead to the patient's "allergization" and, finally, to the development of resistance. Antibiotics are given systemically, we disinfect locally.

What is your standard protocol for a ridge preservation?

Tooth removed, biomaterial placed, closed with a loose suture! After two weeks, the situation will be relatively stable. In the case of pre-diseased patients (diabetes, bisphosphonate therapy, radiation), I always add PRF to the material and have achieved good results. However, it is not possible to recommend PRF for everyday use, and we must point out that there is a significantly increased risk for complications. If time permits, we like to wait six months before implantation.

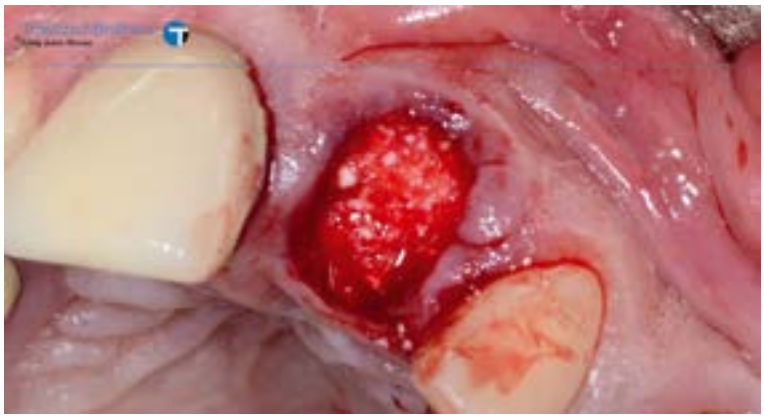
In the presented case, we show the extraction of an anterior tooth in a male, smoking, and diabetic on anticoagulants due to coronary artery disease patient. You can clearly observe the bone quality six months after the extraction.

What about the Platelet Rich Fibrin (PRF), is it possibly sufficing without additional material?

There is a 2018 EAO consensus paper on this: It is then alone enough, when all the bone walls remained, and we have reason not to use something more potent. PRF alone is better than no ridge preservation, but bone graft substitutes achieve better results than PRF alone.

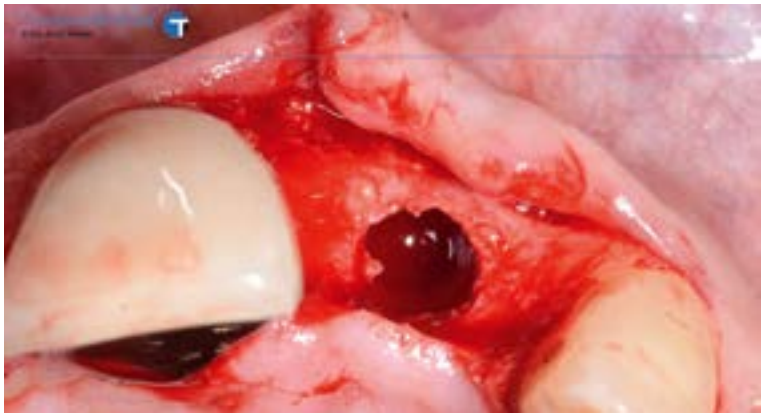
How do you proceed with the various types of defects?

The standard protocol of ridge preservation has been described above. There are extended defects where the combination of biomaterial, PRF and membrane is no longer enough. If we need to displace



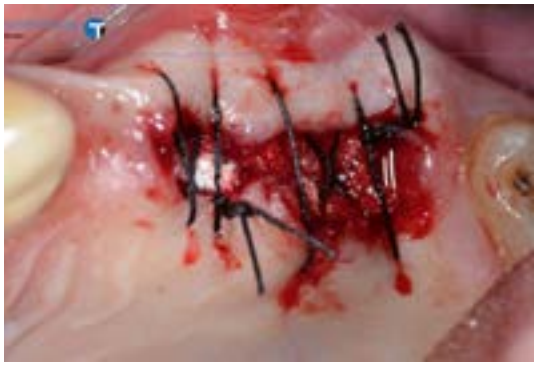
Extraction of tooth 21 and ridge preservation (material: Bio-Oss Collagen, Geistlich)

Healed alveolar ridge after four weeks



Implantation in the area of ridge preservation six months after tooth extraction with excellent bone quality

State after tooth extraction and ridge preservation in posterior region with adaptation suture



the soft tissue more than 1–2 mm, we need additional reinforcement. Meanwhile, in some cases we resort to a tried and tested approach: bovine material, PRF and umbrella screws. I personally think this is a great idea! From the scope of application, this is, so to speak, a lateral and vertical augmentation quickly "homemade" without having to plan it with the 3-D grid. The prerequisite is that this must be decided intraoperatively – and you also must manage to tighten the screw when there is little bone. For large defects – i.e. over 3 mm – the digitally planned 3-D grid or other augmentation procedures for complex lateral and vertical defects are used.

Perhaps a note on the escalation cascade: if all bone walls are preserved, the biomaterial is enough. If one bone wall is missing and we are still within reasonable limits, we combine the biomaterial with a resorbable collagen membrane. However, if we have a defect laterally and vertically up to 2 mm, we use the umbrella screw. With larger defects, we additionally plan the augmentation with the 3-D grid.

Would you please summarize what is to be considered in ridge preservation?

Gladly. First, we need to consider anatomical structures and pay attention to the defect's configuration. The scientific background is important for the materials to be used. I refer you once again to the S2k guideline on bone graft substitutes. We must have the relevant medical history from the patient. In my opinion, ridge preservation is a possible procedure that should be explained to the patient, because it has a high level of safety and good results. Of course, the documentation is crucial, and we must pay attention to the right combination of materials. The practitioner should always check if the intended material has good data for the indication.

Dr Tröltzsch, thank you very much for your comments on ridge preservation.

The interview was conducted by Editor-in-Chief Anita Wuttke.

The talk is available as a video on the YouTube channel of the BDIZ EDI:

Efficient, reliable and stable

With a vast, world-class assortment of products and solutions for implant treatment, Dentsply Sirona offers complete solutions that create the best possible workflow and make work flow better. Clinicians will benefit for example from the Ossix products' being implemented into a wide range of these solutions and workflows.

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Updated design of one-piece ceramic implants to optimize hard and soft tissue management

Alternative to titanium implants

JÖRG NEUGEBAUER[1,3,4], STEFFEN KISTLER[1], FRANK KISTLER[1], SANDRA KIRCHMAIER[1], GÜNTER DHOM[2,3]

Implants made from ceramic have been available since the beginning of modern implantology. Due to the tooth-like color of the material and the lack of metal, a white, metal-free implant restoration is propagated. The advantage of tooth-colored implant bodies is particularly evident in thin mucosa situations, since no dark shimmering of the metal can then be seen. Nevertheless, the market penetration is still very low, since the material requires some special features in the treatment procedure in order to ensure that the success rates that can be reliably achieved with titanium implants can also be realized with ceramic implants.

Implant design factors

In the past, the use of Al_2O_3 ceramics as an implant material has not been proven due to the loss of mechanical stability with associated fractures caused by aging [27]. Therefore, implants made of zirconium dioxide have been offered for nearly 20 years. Here, too, problems with mechanical stability became apparent, especially in the early years, because the design of titanium implants was adopted almost one-to-one without paying attention to the special characteristics of ceramics. With a reduced diameter and a strong concavity, fractures were observed after only a short period of use. Most systems on the market today have taken this experience into consideration, so that fractures due to design features are no longer to be expected [3, 23]. For the long-term stability of the implants, the fabrication from hard HIP´ed/ Hot Isostatic Pressed zirconia has also proven to be effective.

Since ceramics cannot be industrially manufactured like metal and the strength is determined by minimum wall thicknesses, the implant bodies are essentially commercialized as one-piece implants. For the various two-piece implants available on the market, there are different concepts for joining the abutment parts. Since additional materials are required here, a completely metal-free implant restoration can no longer be realized due to the screw connection, or special adhesives are required, which make a connection in the moist oral environment possible only with a great deal of effort.

Therefore, one-piece implants with an integrated abutment are favored by most manufacturers. In addition to the specific design for a ceramic implant, the

1 I One-piece ceramic implants with prosthetic and impression caps (whiteSKY, bredent medical, Germany) without contamination with nickel or radioactive substances [12].

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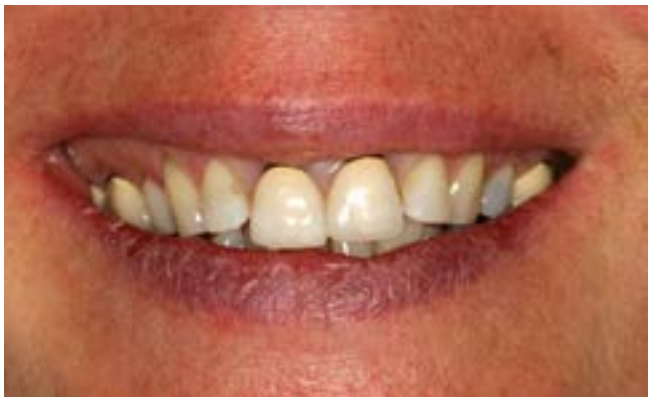
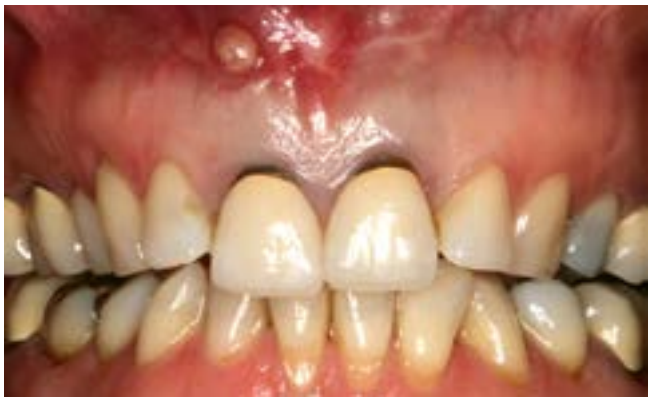
[3] Steinbeis University, Transfer Institute Management of Dental and Oral Medicine, Berlin, Germany
[4] Interdisciplinary Polyclinic for Oral Surgery and Implantology, Clinic and Polyclinic for Oral and Maxillofacial Plastic Surgery at the University of Cologne, Germany



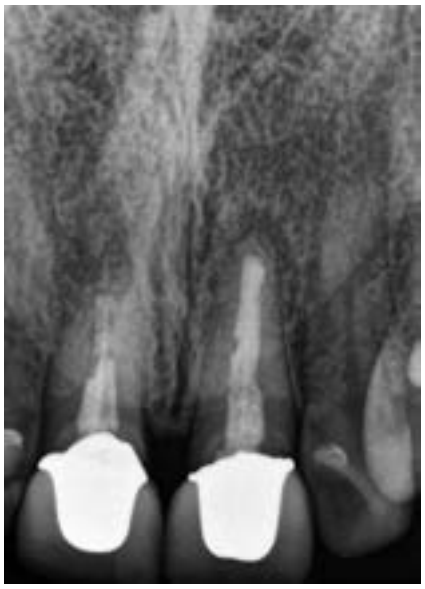
2a I Initial situation with non-defective crowns



2b I The avital teeth shimmering through the thin gingiva

chemical composition of the ceramic material is also significant. Whereas in the early years of the use of ZrO_2 in dentistry there were warnings of contamination of radionuclides in the starting material [20], recent studies show that, depending on the manufacturer, contamination can occur not only with radionuclides or radioactive elements, but also with other base metals [12]. Since ceramic implants are placed especially in patients with titanium or metal intolerance, sensitization can occur even with low doping with metals such as chromium and especially nickel, but also the radioactive elements thorium and uranium [12] (Fig. 1).

In addition to the white color of the implant body, the very good soft tissue behavior – which has already been observed with first-generation ceramic implants – is discussed as an advantage over titanium implants. A reduced biofilm accumulation compared to titanium is assumed based on experimental studies [1, 22]. This advantage, however, is controversially discussed, as also plastics show a low plaque adhesion compared to ceramics and titanium, so that the main influencing factor is assumed to be the surface topography instead of the material selection. However, since modification or damage by dental instruments is almost impossible on ceramic implants due to the high hardness, especially during recall with implant cleaning, it can be assumed that ceramic implants show a very long-term stable surface in the transgingival area.



2c I Radiographic findings of the teeth with chronic, partially painful apical periodontitis.

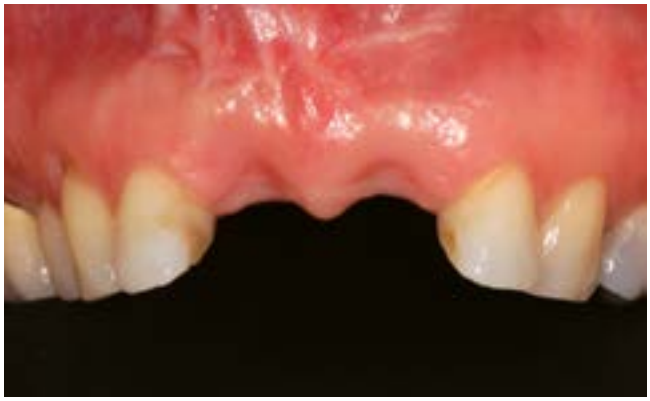
For a tight soft tissue closure, the concave design in the collar region has already proven its worth since the days of the Tübingen implant, which allows the implant-bone interface to be embedded and thus well sealed by the peri-implant soft tissue. The industrial design of the transgingival area allows a more homogeneous surface topography to be achieved than is possible with the individual dental design of the ceramic denture. Therefore, in the posterior region, the abutment component of the implant may well protrude transgingivally over the soft tissue without any hygiene restrictions.

Due to the one-piece design, it is necessary to avoid micromovements of the implant to achieve osseointegration. This can be achieved with the so-called protective splints or with an immediate restoration. For a successful immediate restoration, especially with the reduced bone quality in the maxilla, the possibility of achieving a high primary stability is a prerequisite for long-term success. In this case, self-tapping double threads which allow lateral condensation of the bone bed by means of a coordinated surgical protocol have been successful. Animal studies have now shown that the immediate loading of the implants in the immediate restoration trains the bone [9]. Physiological loading results in peri-implant remodeling with a a significantly improved bone-implant contact than is possible with technically complex optimization of the implant surface [6, 16].

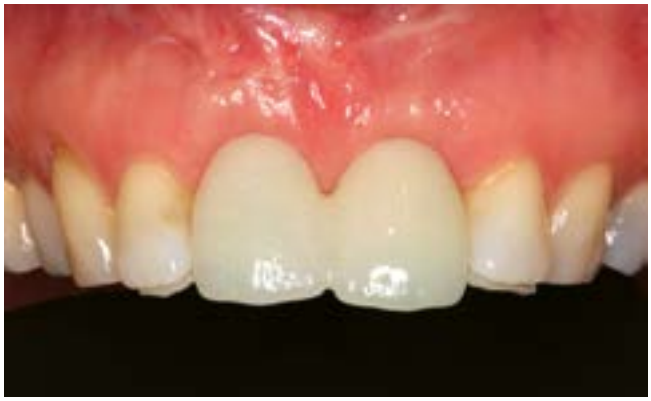
Surgical procedure

In order to place the implants in a sufficiently dimensioned bone bed, it is often necessary to use a two-stage augmentative procedure. Regional augmentation, e.g. with bone substitute material and membrane technique – which have become routine procedures for circumscribed defects in subgingivally healing implants – can only be successfully implemented to a limited extent in transgingivally healing implants. In addition to onlay plasty, bone splitting can also be used if the width of the alveolar ridge is sufficiently large. However, special attention must be paid to the possibility of achieving primary stability, which can be achieved more reproducibly with conical and cylindrical implant bodies than with purely parallel-walled or purely conical implants [18].

Therefore, implants with a combined cylindrical-conical implant core – which also feature a double-thread (whiteSKY, bre-

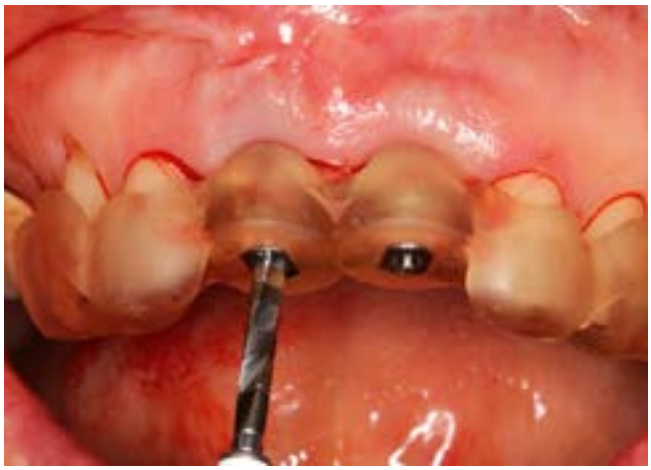


3a I Healed hard and soft tissue situation four months after extraction and revision of the inflamed tissue

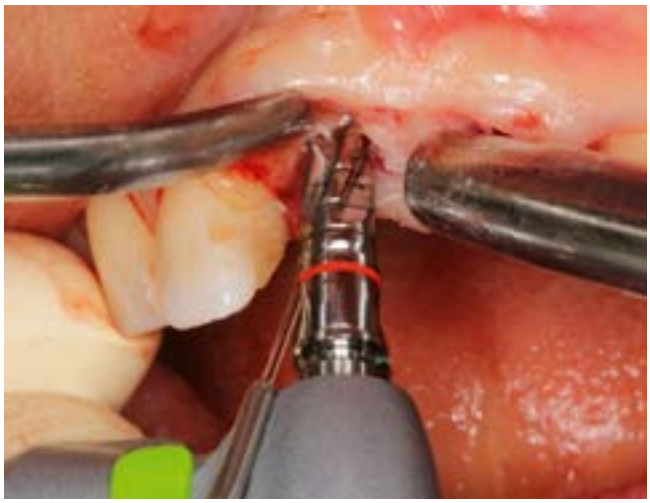


3b I Try-in of the digitally fabricated temporary restoration for the immediate restoration

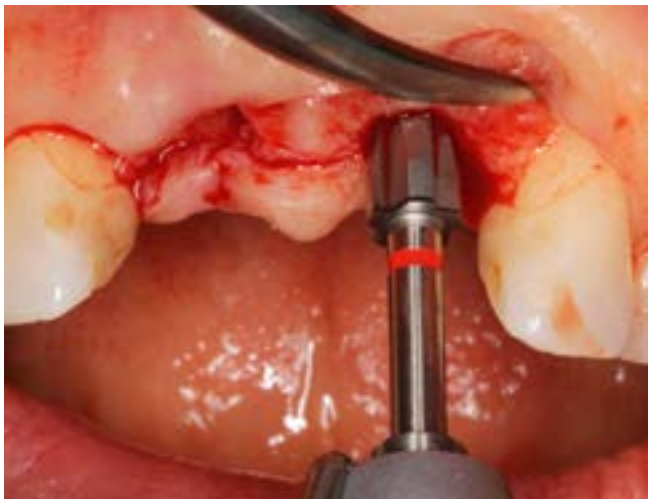
4a I Surgical guide fabricated in the dental practice laboratory with 2 mm drill sleeves



4b I Guided implant setup with minimal flap preparation for subsequent bone chip placement.



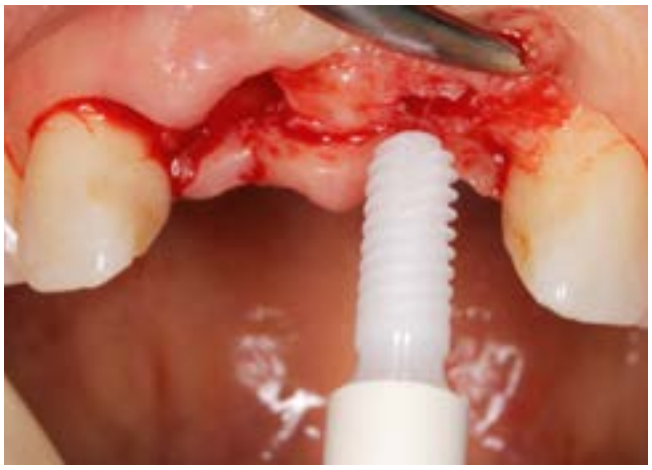
5 I Length preparation with system drill for consolidated harder bone



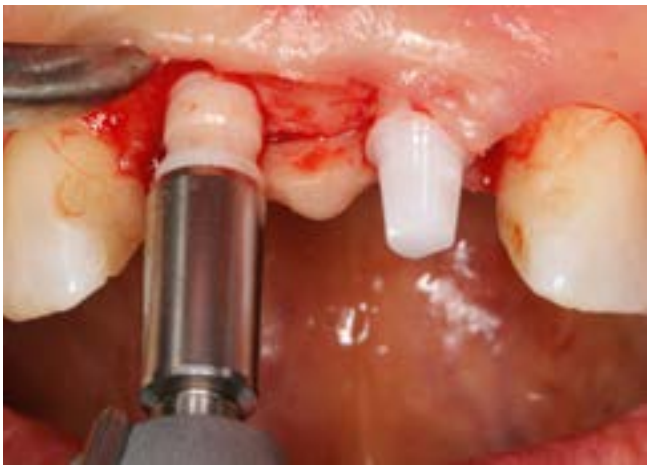
6 I Final preparation to protect the crestal bone

dent medical, Senden) – stand out. These implants can be completely inserted into the jawbone with just a few turns and a a high primary stability can be achieved. Due to the conical design, an interference fit in the bone in terms of internal condensation can be achieved [13, 19]. However, this requires the possibility of adjusting the implant cavity in the harder bone by so-called crestal drills. (Fig. 2–6)

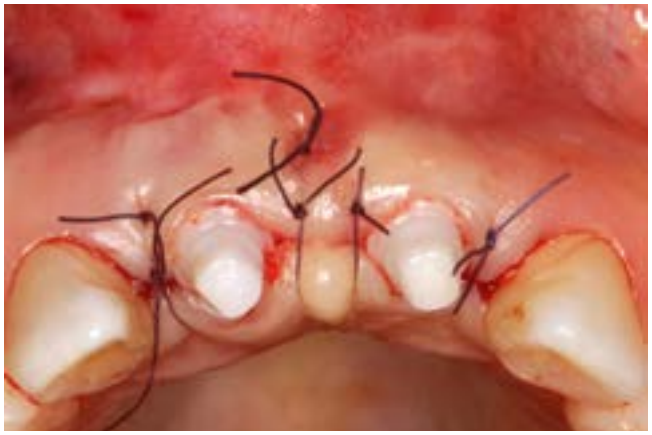
This allows an implant bed preparation according to the bone quality and thus ensures the prerequisite for achieving a high primary stability, which is necessary for an immediate restoration. The implants are



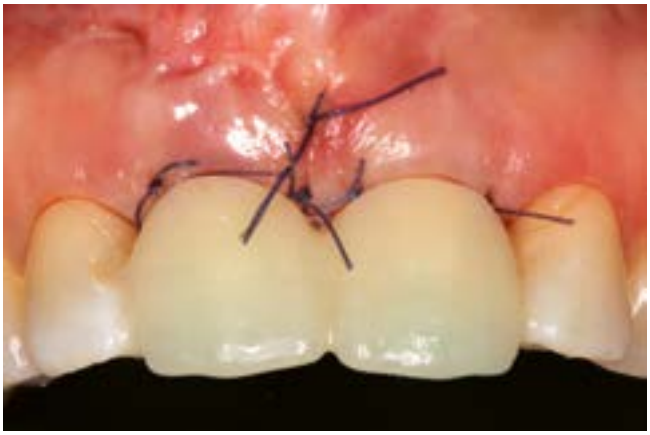
7 I Insertion of the one-piece implant taken from the metal-free sterile package



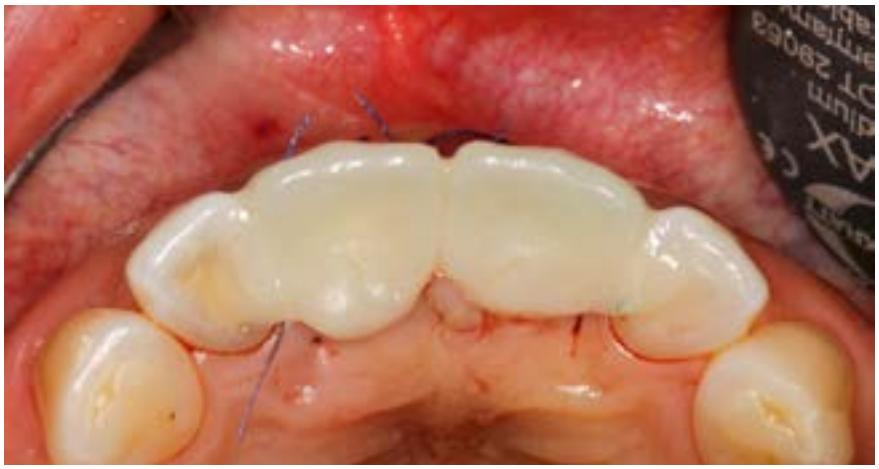
8 I Torque-controlled insertion using the handpiece



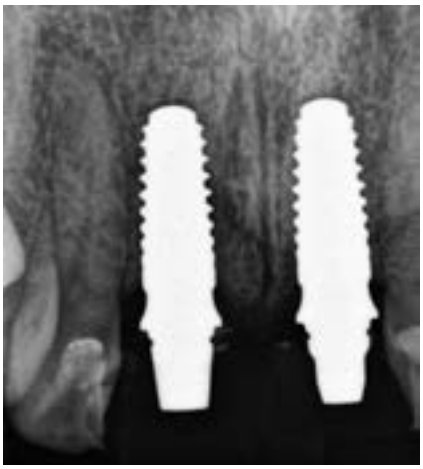
9 I Wound sealing after further peri-implant soft tissue preparation



10 I Embedded CAD/CAM milled acrylic temporary restorations



11 I Fixation of the splinted crowns to the adjacent teeth



12 I Radiological control of the achieved implant position with exact placement of the endosseal portion into the bone

delivered in sterile packaging and their transport holder also allows the first rotations for insertion in the implant cavity. The implant is finally screwed in either with a hand ratchet or the contra-angle handpiece. Torques of approx. 30 Ncm should be achieved and over 50 Ncm should be avoided at all costs [17]. If the implant cannot be fully inserted, it should be removed from the prepared implant bed so that the cavity can be further prepared with the crestal drill (Fig. 7–12).

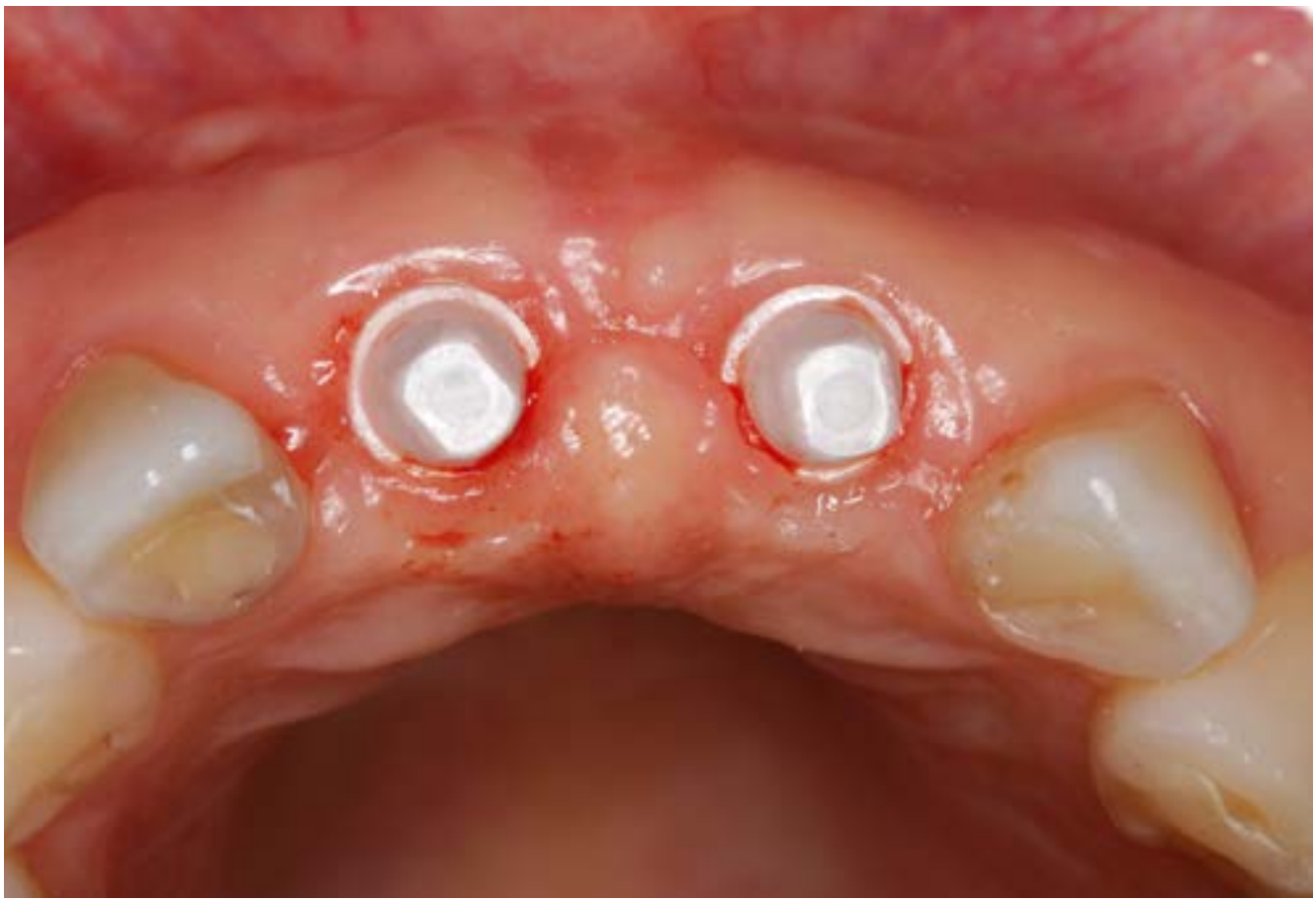
Prosthetic procedure

In the initial phase of one-piece ZrO_2 ceramic implants, almost routine grinding of the abutment portion with special instruments was recommended to adjust the integrated abutment in order to compensate for angulation of the implant or to individualize the gingival contour. Although it has been shown that machining the implant abutment with a diamond of 120 µ grit size allows efficient machining of the mold, fine contouring and smoothing of the surface with a finer grit diamond of 40 µ is time consuming. The labor-intensive machining that is also possible with the current systems, depending on the manufacturer, smoothes and thus hardens the surface of the buildup portion to avoid possible microfractures in the ceramic [14].

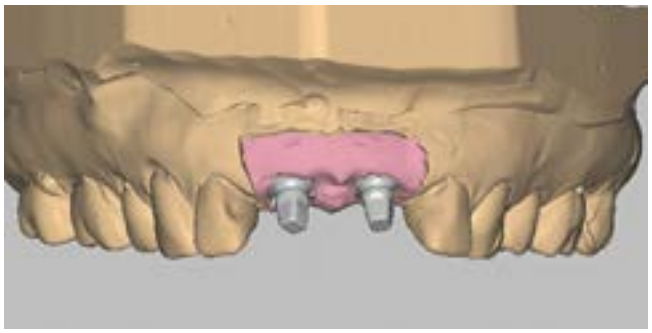
By using three-dimensional diagnostics with the possibility of producing surgical guides, it is possible to insert the implants in such a way that subsequent correction of the abutment portion is only necessary in exceptional cases. During the planning of the therapy, the temporary restoration should already be prefabricated, so it can ideally be placed in an interdental gap with a high friction to the natural teeth. Due to the one-piece implant design, it must be ensured during the osseointegration phase that immobilization of the implants is guaranteed.

The pressure of the tongue or even the direct apposition of the buccal mucosa on the implant can lead to a continuous stimulus in form of micro-movements [4], which can mean a lack of osseointegration [8]. Therefore, it is necessary that multiple implants – especially in terminal situations – are protected by temporary restorations and ultimately a non-functional immediate restoration is achieved. For this purpose, prepared terminal periodontally inconspicuous abutments can also be included as anchors for splinting. In the case of interdental gaps, wide contact points to the adjacent teeth support the stability of the implant. Once osseointegration has been achieved, usually after three months, the temporary restoration is removed, and a conventional or digital impression of the ceramic implant can be taken for the fabrication of the final restoration.

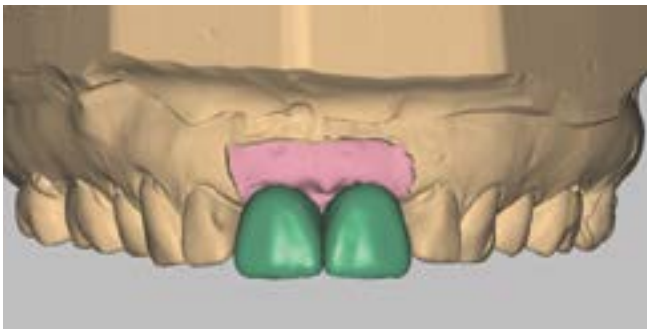
In the more conventional impression, the implant geometry of the uncut abutment is transferred with an impression cap so that a laboratory analog is repositioned by the laboratory for the model fabrication. If the implant abutment has been individualized, the impression is taken as for a prepared tooth stump, optionally also with the careful placement of a thin retraction thread. For the intraoral scan it is important that the implant geometry is stored in the CAD/CAM software database for further processing. This means that the implant body can be used as a scanbody in the dental design software. Thus, high-precision zirconia-based prosthetics can then be fabricated [28] (Fig. 13-19).



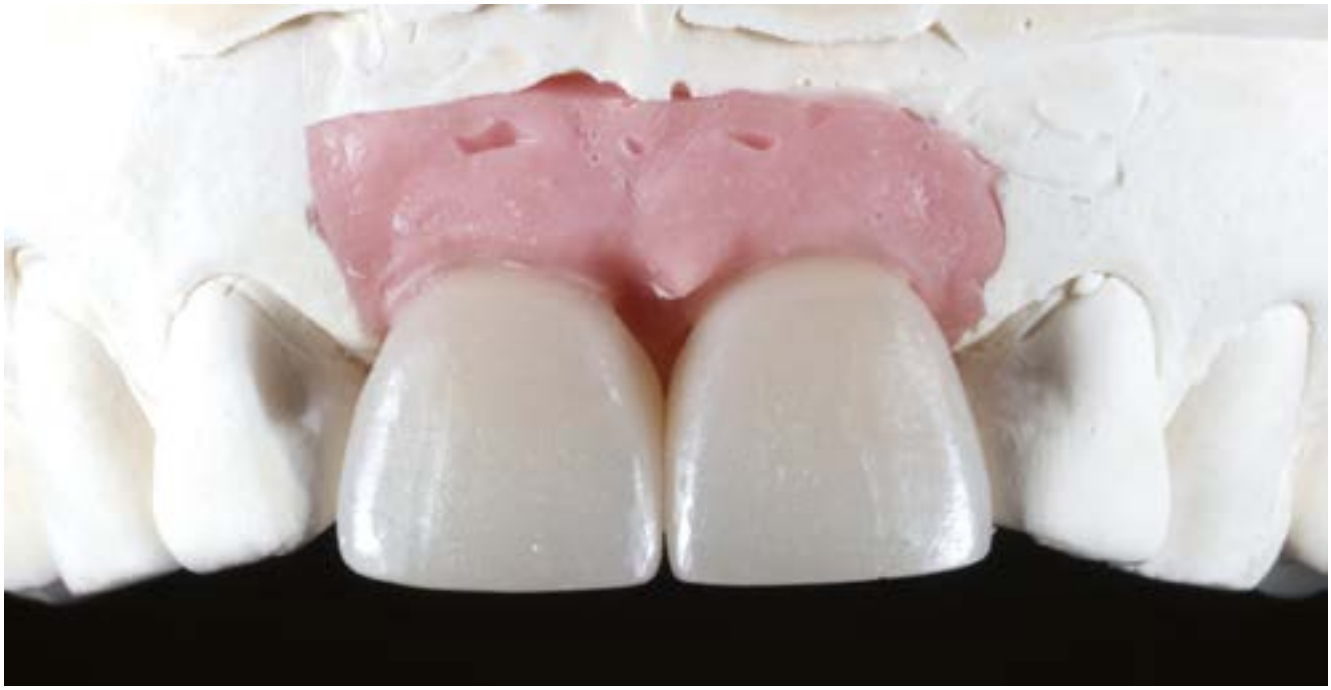
13 I Iirritation-free healed peri-soft tissue around the osseointegrated implant after removal of the superstructure three months after insertion



14 I Digital model with read-in data set for the digital crown manufacturing process



15 I Design of the single crowns made of ZrO ceramics



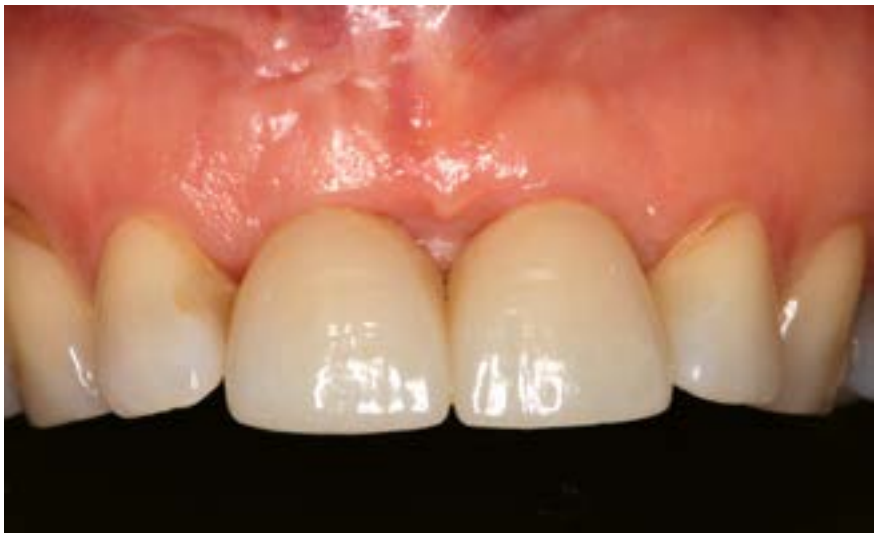
16 I Adjustment and individualization of the single crowns on the master model

Discussion

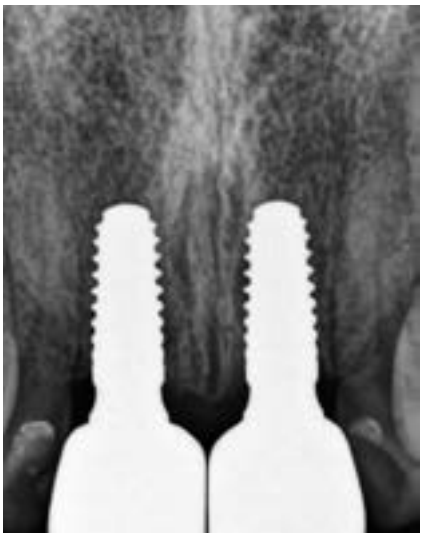
Although titanium implants also show a high therapeutic result in the esthetic field, indications for the insertion of a white implant body are especially for an esthetic restoration with a thin mucosa profile. For esthetic restorations, the requirement to achieve a non-reactive soft tissue attachment to the implant restoration has been available since the days of the application of the first scientifically proven ceramic implants [26]. The positive soft tissue reactions to ZrO_2 ceramics simplify soft tissue management, as there is better adaptation of the epithelium to ceramics than to metal. In addition, the risk of a dark shine-through of a metal body is excluded. Since bacterial colonization on ZrO_2 ceramic is low [21, 25], the risk of peri-implantitis is also reduced.

The sensitization of patients by various environmental factors also leads to a lack of acceptance for metallic implants – so that the second patient group is to be seen here – since no interaction with existing metals or alloy components is to be expected when using ceramic implants. However, it must be considered that not all systems offered on the market are free of metallic impurities, as this non-toxic heavy metal is extracted from zirconium minerals such as granite during the production of zirconium oxide ceramics [12].

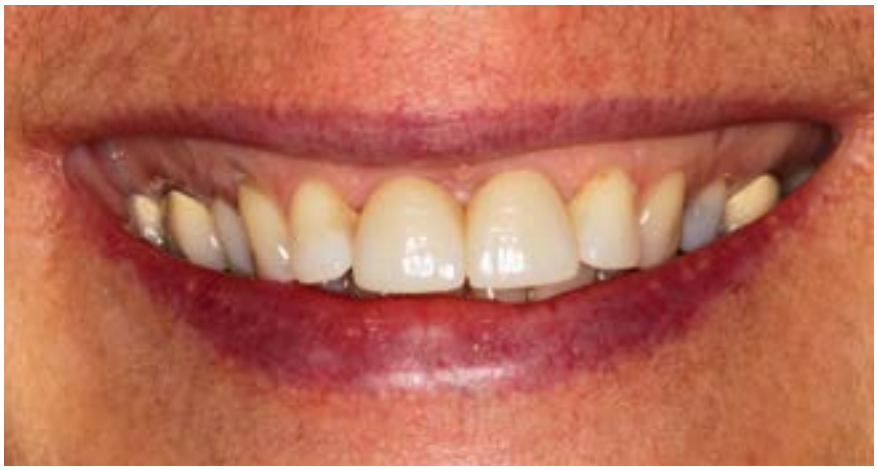
Due to the limited processing possibilities of ceramics, one-piece systems are preferred in order to achieve sufficient long-term stability without complications. This requires an adaptation of the surgical and prosthetic treatment process. Since the implant surface cannot be modified due to the inert material properties as is the case with modern implant surfaces by means of anodic oxidation or radiation and high-temperature etching [5], there is no microporous surface comparable with titanium implants. Nevertheless, the ceramic implants show a micro-rough surface for successful achievement of osseointegration, but a porous microstructure for a shortened healing phase is not possible [7, 24]. Therefore, these implants require the classic osteointegration phase of at



17 I Control of the crowns six months after placement with inconspicuous soft tissue compared to initial findings



19 I Stable bone level after prosthetic restoration



18 I Harmonic soft tissue situation without indication of implantological therapy

least three months. When using immediate loading, care must be taken to ensure a bone-oriented implant bed preparation so that sufficient but also not too high primary stability is achieved in order to prevent micro-movements which cause non-osseointegration [11].

The grinding of ceramic implants with diamond burs of ceramic implants is discussed differently in the literature [2, 10, 15]. The application of CAD-CAM milling technology has shown that machining of zirconia ceramics with a high surface quality is not expected to increase the risk of fracture. Therefore, as observed in the CAD-CAM milling technology, it is important to work with adequate cooling when individually grinding zirconia ceramics in the patient´s mouth[14]. For this purpose, contra-angle handpieces are available today, which can also be used in the surgical area on an implant unit with physiological saline solution. Thus, damage to the soft tissue due to non-physiological osmolarity of the water spray of the normal dental unit is not to be expected. The combination of coarse and fine burs also enables time-effective adjustment of the shape and subsequent smoothing of the surface.

The modification of the implant body with a a new modern thread design and the use of an instrument set that is also suitable for titanium implants enables economic integration of zirconia implants into the implantology practice workflow. By adapting the abutment design with a reduction of the abutment height and additional retention features, an individualization is only necessary in exceptional cases and an intraoral scan can be routinely used for the digital workflow. °

The references are available at www.teamwork-media.de/literatur

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The next generation soft-tissue augmentation material

A breakthrough in xenogenic processing

When choosing a biomaterial, there is a strong demand in clinical practice for predictable outcomes. For over 20 years, LifeCell, a leading global medical technology company, has developed innovative products for use in a wide range of applications. BioHorizons Camlog expands its soft-tissue portfolio to bring NovoMatrix, an innovative soft-tissue augmentation material. NovoMatrix is an acellular dermal matrix derived from porcine tissue intended for soft tissue applications. The LifeCell tissue process is designed to retain the biomechanical integrity of the tissue, which is critical for optimal regeneration.

Dr Marco Cernicchi, a dentist in private clinic in Rome, Italy, who has specialized since 1999 in the field of oral surgery, implantology, specifically in GBR and GTR, TMJ diseases and postural conditions, is a dedicated user of this product. Dr Alina Ion from Teamwork media had the opportunity to learn from Dr Cernicchi how he has achieved good results with this product in his clinic.

Dr Cernicchi, according to your experience, which are the advantages and disadvantages of NovoMatrix compared to autologous tissue transplants?

NovoMatrix is truly the next generation of soft tissue augmentation material! It brings many advantages for both patients and practitioners. First of all, it enables the clinician to avoid removing any tissue from the palate. This obviously means less pain for the patient and a faster surgery (about 30 – 40 % faster). It also provides the opportunity to treat a larger area of the oral cavity, which is especially indicated in patients with recessions throughout the oral cavity.

The only disadvantage is the cost of the material, but if you use it for more than one spot during the same surgery, it pays off well.

NovoMatrix is an alternative treatment option to soft tissue grafts. What other benefits does the product have for the patient?

Avoiding the removal of tissue from the palate ensures a minimal postoperative inflammation and less physical discomfort for the patient, as there is no secondary wound on the palate. It also allows the treatment of multiple teeth in one session, a fact that offers a more comfortable and faster result. So basically it means less stress, pain and time for the patient.

And which are the advantages for the clinician?

The clinician has the possibility to treat a larger part of the mouth and/or more than one site in one step. Due to the time saved and the reduced stress during the treatment, he can focus better and perform a much more precise treatment.

NovoMatrix is ideal for long-term tissue regeneration. Is it also suitable for bone regeneration?

I am more of an implantologist than a periodontist, so I use NovoMatrix more as a membrane or a coverage over my GBR than for its tissue regeneration properties.

Are there any risks or complications that may occur when using NovoMatrix?

Well, the risks are the same as a normal surgery: healing complications, infection or the loss of stability of the graft.

Dr Marco Cernicchi

Please rate the clinical indications of NovoMatrix

NovoMatrix indications include localized soft tissue augmentation procedures for recession defects to increase keratinized tissue around teeth, GBR or ridge reconstruction prior to prosthetic restoration, and guided tissue regeneration for root coverage.

Thank you for your time and your input, Dr Cernicchi

Indications for implants in the premolar and molar region

Benefits of the Ø 6mm wide implant

DAVARPANAH MITHRIDADE[1], RAJBAUM PHILIPPE[2], DAVARPANAH KEYVAN[3]

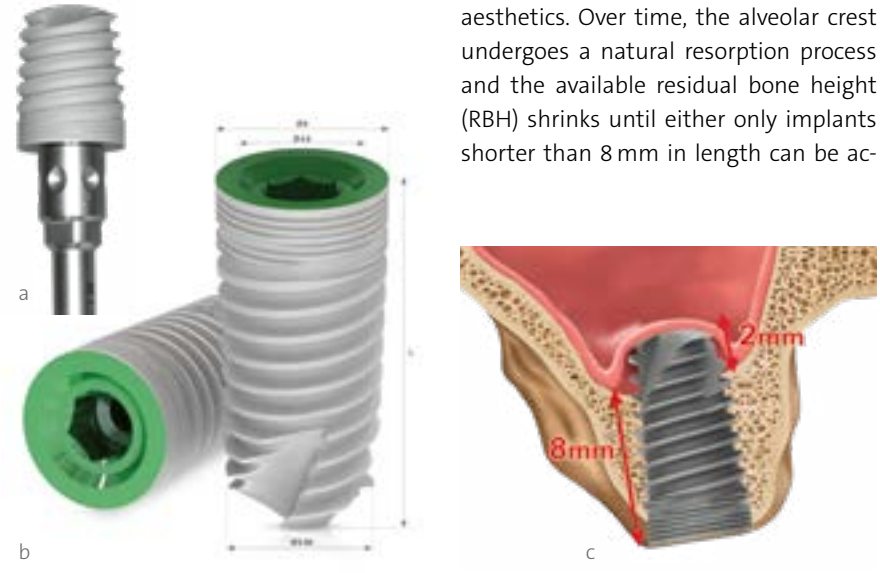
Wide Ø 6 mm implants became clinically available long after standard diameter implants; they have been documented with similar success rates. The aim of this paper is to explore their various indications in the molar region. In addition, the specific surgical attention they require is also addressed.

Introduction

Most dental implants are placed in the posterior area of the oral cavity; they amount to 53.3 % to 65.3 % of the treatments in university settings [1, 2] and 66.5 % in private practice [3]. This region is divided into a premolar and molar area; molars cover 43 – 47 % of the rehabilitations of the region [1, 2]. Among them, the first molars account for 90 % of implant treatment [2]. The 16 – 39 age group experiences the mandibular first molar to be extracted first; the maxillary molar is second [1]. Most frequently, extractions are caused by the failure of an endodontic treatment or follow the fracture of the crown of an endodontically treated tooth that can no longer be prosthetically rehabilitated [4].

Molar extraction is usually not associated with aesthetic issues. Therefore, rehabilitation of these edentulous sites are, unfortunately, not considered with the same urgency as teeth in the anterior region, which are part of the smile aesthetics. Over time, the alveolar crest undergoes a natural resorption process and the available residual bone height (RBH) shrinks until either only implants shorter than 8 mm in length can be accommodated or implant therapy in the upper maxilla requires elevating the sinus membrane and grafting the created space. Patients under 50 are more aware of the loss of the masticatory efficiency. Often, they wish to immediately rehabilitate the newly edentulous site [1, 3]. The large variety of implants which are currently available for implant therapy have been designed to meet the specific needs of every treated site. The dental implants that used to be available during the early 1980s have undergone numerous transforming modifications, which are related to the surface properties, the shape of the implant body, the design of the implant collar, the implant length, the implant diameter and also the geometry of the connection with the abutment. Wide implants of over Ø 4.7 mm were developed by the manufacturers in order to meet the specific demands of the posterior region in terms of biomechanical resistance and better management of the emergence profile of the prosthetic crowns [5, 6, 7]. Implants are considered wide when the diameter lies between 5 to 6 mm; they are labelled ultra-wide when the diameter varies between 7 to 9 mm [8].

The aim of this article is to present the different indications of wide Ø 6 mm implants (Figs. 1a to c) and discuss their surgical uniqueness.



1 I Ø 6 mm Implant. a) 6 mm long implant with a round apex. b) Dimensions of the implant. c) 8 mm long implant; the round apex has been designed to avoid damaging the sinus membrane, while penetrating 1 to 2 mm into the maxillary sinus.

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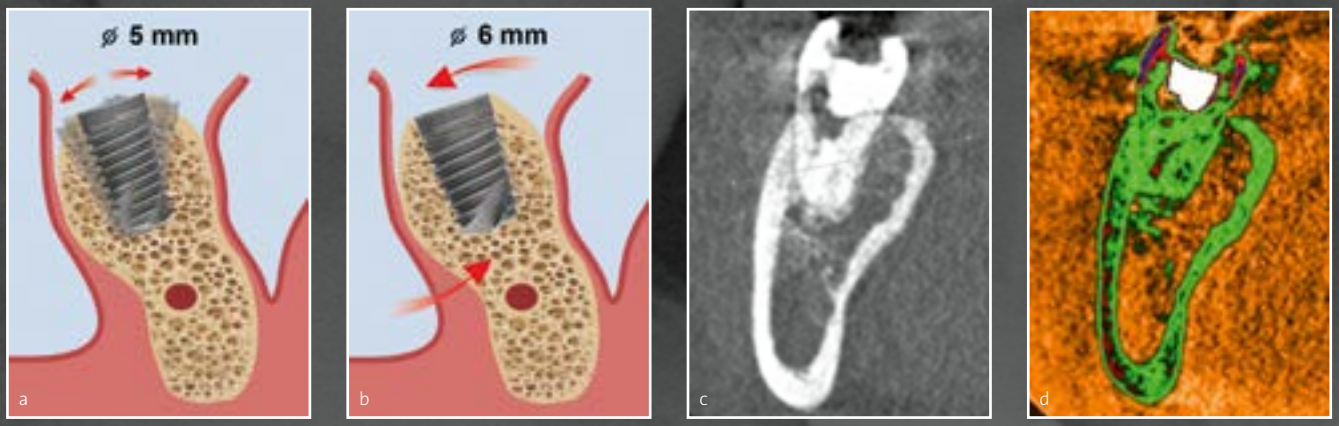
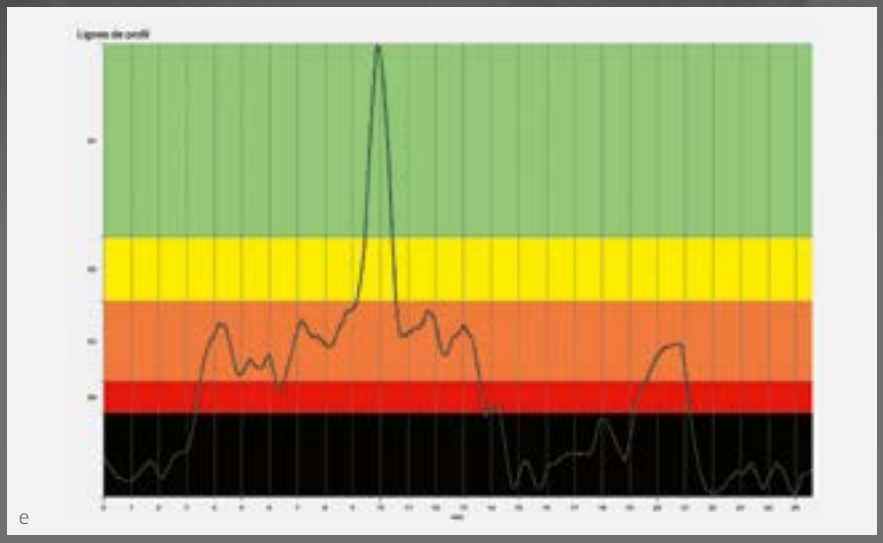
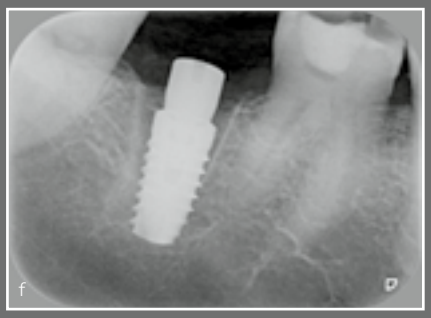
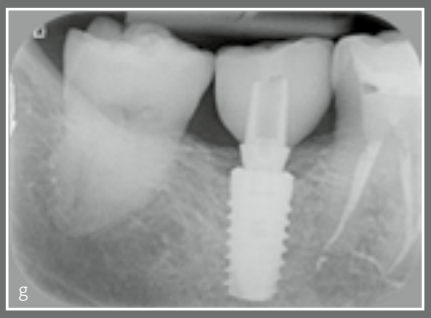








2 I Placement of a Ø 6 mm implant in a site of poor bone density.

a) Illustration showing placement of a Ø 5mm implant with insufficient primary stability.
b) Replacement with a wider Ø 6mm implant providing the desired primary stability.
c) Sagittal section taken at the mandibular second molar showing pronounced internal resorption. The blue line indicates the density profile exposed in the next figure.
d) Sagittal section with various artificial colours representing the different mineral densities. The tooth and the cortical lamellae are in green. In white is the high-density amalgam and in orange is the very poor bone density that covers the whole peri-radicular area and reveals a D5 type density according to Misch classification.
e) Profile of the bone density along the blue line. Apart from the tooth, the amalgam and the bone cortices, the rest of the bone tissue is in black and its density is similar to the noise of the background.
f) Radiograph of the Ø 6 × 11.5mm implant inserted in the post-extraction socket of the second molar.
g) One-year control radiograph. Note the wide diameter implant, the platform-switching feature of the prosthetic abutment and the preserved proximal bone levels.

Indications of wide, Ø 6 mm implants

Implant placement in a site with low bone density

The wide, Ø 6 mm implant may be used an a fortiori rescue implant, in the same way Ø 5 mm implants have been historically used to salvage Ø 4.0 – 4.5 mm implants [4]. This would be the case of a Ø 5 mm implant that has been placed in a healed site or a post-extraction socket in the posterior area and did not achieve primary stability because of a suboptimal drilling sequence or a poor assessment of the local bone quality (Fig. 2a). The surgeon then has the option to go for the next implant diameter, a Ø 6 mm implant, and achieve suitable primary stability (Fig. 2b).

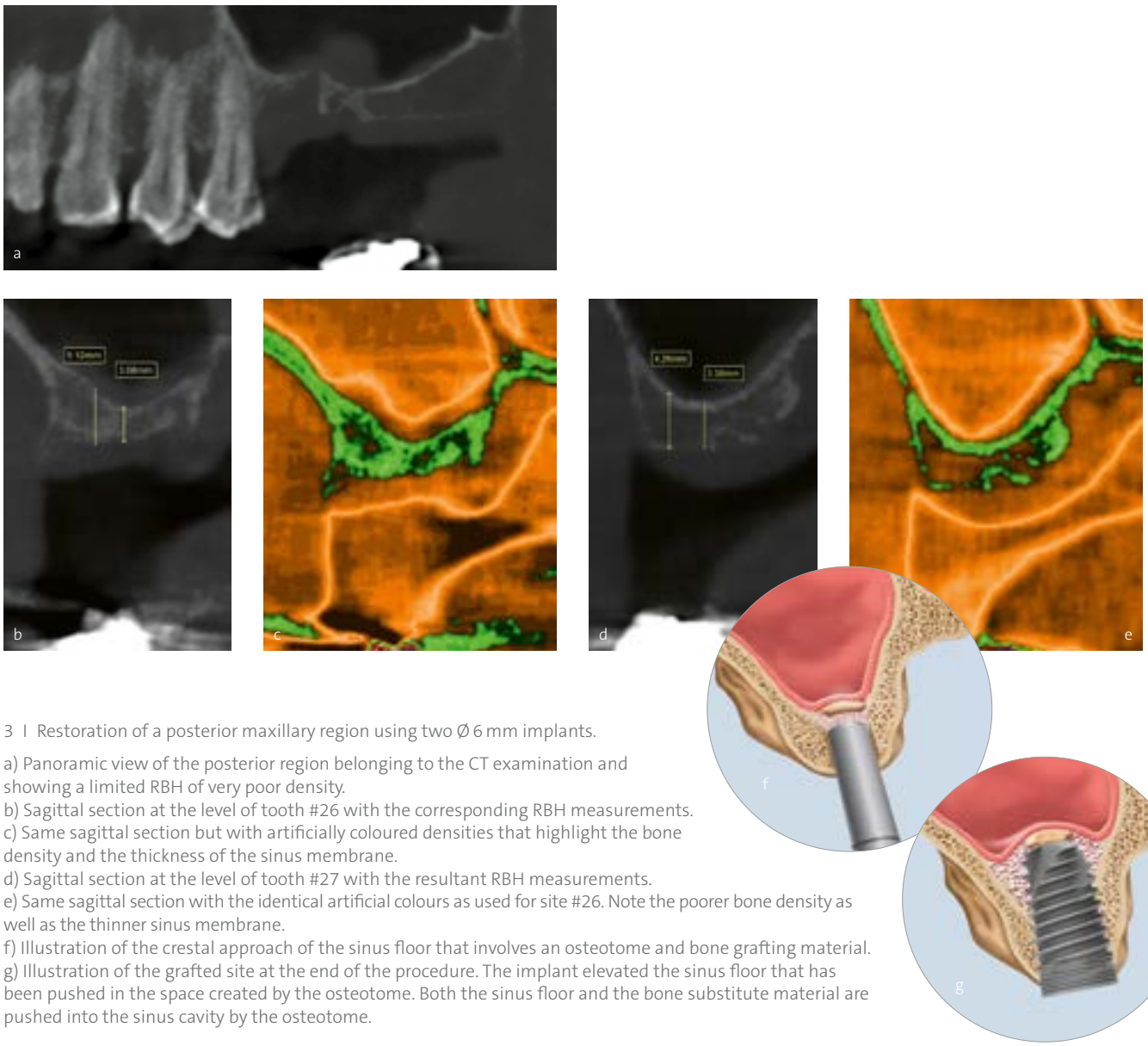
The a priori indication happens when the preoperative computerized tomography (CT) examination taken to treat a to-be-extracted molar site, reveals a poor bone density environment. Better than with a Ø 5 mm implant, one should expect the Ø 6 mm implant to receive stronger bone support from the adjacent cortical lamellae and reach sufficient primary stability. An example of this indication is provided by the 44-year old patient presented in figure 2. The sagittal sections of the CT exam show that the second right molar in the mandible

is experiencing considerable internal resorption. Extraction is required (Fig. 2c). Analysis of the tomographic sections reveals very poor bone density precisely at the level of the planned implant site; depiction of the bone quality with various artificial colours denotes the distinct bone densities (Figs. 2c to e). Revealed are the to-be-extracted tooth, the vestibular and lingual cortical lamellae and the poor mineralized bone volume in between (Figs. 2d to e). The Ø 6 × 11.5 mm implant that has been inserted is sufficiently wide to grasp support from the adjacent cortical bone (Fig. 2f); a 25 Ncm insertion torque has been obtained despite the poor bone quality of the implant bed. The radiographic control taken after one year shows the implant, the large platform-switching feature obtained by the prosthetic abutment that is much narrower than the implant collar and the preserved bone levels on the mesial and distal sides of the implant (Fig. 2g).

Treatment of a molar site in the maxilla of limited residual bone height and poor density, grafted with a substitute bone biomaterial

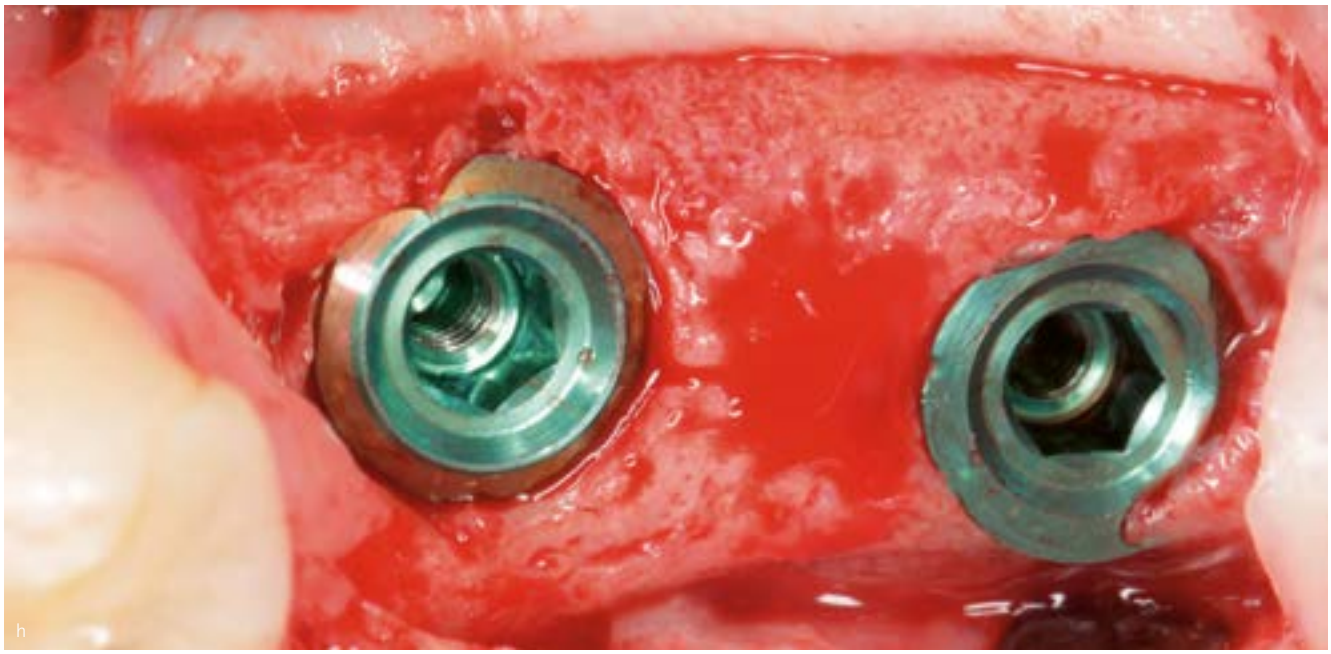
When a site to rehabilitate displays a limited RBH and/or poor density, wide implants larger than Ø 5 mm lead to an increase in the implant surface that comes in contact with the surrounding bone, as well as an increase in the insertion torque.

The case presented in figure 3 illustrates this type of indication. This is the story in which a patient presented to restore the left maxillary molar region after having remained edentulous for several years (Fig. 3a). The CT examination reveals a poor density RBH of 3 – 5 mm below the sinus (Fig. 3b to e). The appropriate treatment protocol of these sites within this RBH range encompasses a crestal sinus augmentation procedure with simultaneous implantation. The crestal approach and elevation of the membrane of the sinus floor are illustrated in figures 3f, 3g. These 3 – 5 mm of bone heights are sufficient to accommodate a Ø 6mm implant with an appropriate insertion torque. Two 8 and 10 mm long Seven (MIS, Israel) im-

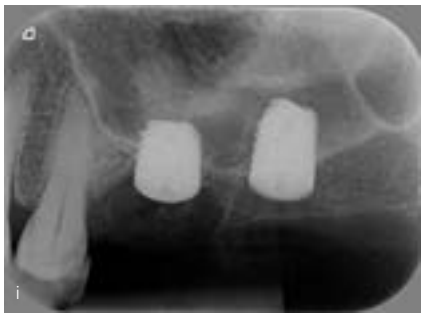


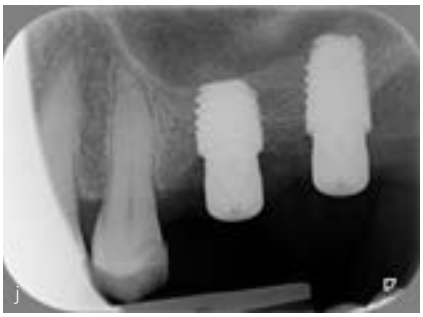
3 I Restoration of a posterior maxillary region using two Ø 6 mm implants.

a) Panoramic view of the posterior region belonging to the CT examination and showing a limited RBH of very poor density.
b) Sagittal section at the level of tooth #26 with the corresponding RBH measurements.
c) Same sagittal section but with artificially coloured densities that highlight the bone density and the thickness of the sinus membrane.
d) Sagittal section at the level of tooth #27 with the resultant RBH measurements.
e) Same sagittal section with the identical artificial colours as used for site #26. Note the poorer bone density as well as the thinner sinus membrane.
f) Illustration of the crestal approach of the sinus floor that involves an osteotome and bone grafting material.
g) Illustration of the grafted site at the end of the procedure. The implant elevated the sinus floor that has been pushed in the space created by the osteotome. Both the sinus floor and the bone substitute material are pushed into the sinus cavity by the osteotome.



h) Occlusal view of the wide, Ø 6 mm implants exposing their corresponding green color coding.
i) Periapical control radiograph following the grafting procedure and implant placement.
j) Periapical control radiograph taken after 7 months of bone healing and after having affixed the multi-unit abutments with a 30 Ncm torque.



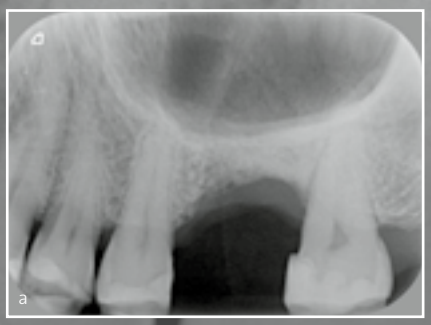


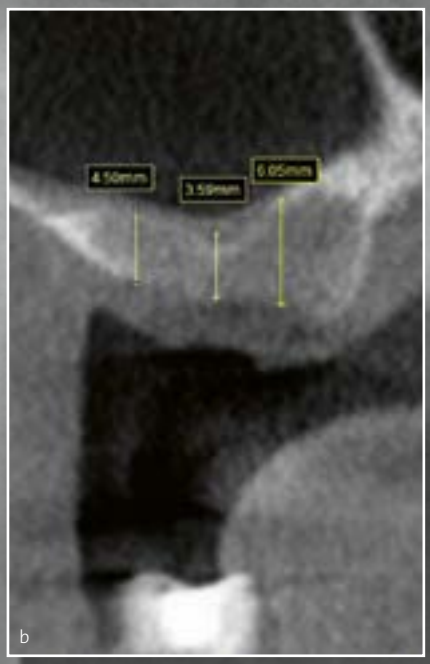
plants are placed with good primary stability. The cover screws are secured in the implant necks and the gingiva is sutured over the implants; Healing is allotted in a submerged fashion for at least 6 months (Figs. 3h to i). After 7 months of bone healing and maturation, the osseointegrated implants are uncovered. The periapical radiographs taken at the end of the second surgical stage show the implants, the multi-unit abutment and the fixed prosthesis (Fig. 3j).

Treatment of a maxillary molar site with limited RBH and poor bone density without grafting procedure

The partially edentulous case presented in this section is similar to the previous one as the RBH is limited and of poor bone density. The aim of the present implantation procedure is to bring the highest percentage of the rough implant surface in contact with bone and achieve the highest primary stability.

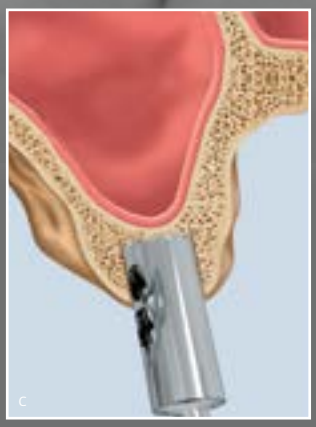
The current clinical situation deals with the restoration of a left maxillary molar where the RBH below the sinus varies between 3.6 and 4.5 mm (Figs. 4a to b). With these bone heights, the crestal approach according to Fugazzotto, with simultaneous immediate implantation may be implemented [9]. The technique involves a trephine of Ø 4.0/Ø 5.0 internal/external diameter; drilling is performed up to approximately one millimetre from the sinus floor. (Fig. 4c). The bone core that is obtained with the trephine is liberated from the sinus floor by a push exerted with a Ø 5.0 mm osteotome. The metallic tool fractures the sinus floor and drives the bone core into the sinus cavity (Fig. 4d). The Ø 6 mm implant is then inserted until final seating in the created implant bed. This brings the bone core deep inside the sinus and detaches further inside the Schneiderian membrane lining the floor of the maxillary sinus (Fig. 4e). By the end of a 6-month osseointegration period, the apical part of the implant which penetrated the sinus is eventually encased in the newly formed bone (Fig. 4f). In the present case, the Fugazzotto technique allowed placement of a Ø 6 × 8 mm Seven implant (Fig. 4g). After the 6-month osseointegration period, a flap is raised, a healing abutment is screwed in the implant neck and the gingiva is sutured around the healing abutment. After soft tissue maturation, a screw-retained single crown with its titanium prosthetic abutment is delivered. The periapical control radiograph taken at the 2-year follow-up shows the Ø 6 mm implant with the newly formed bone at the implant apex that took place without addition of a bone substitute biomaterial (Fig. 4h).

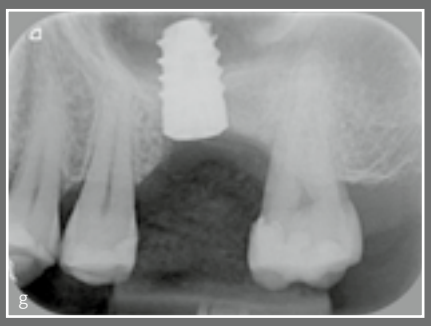


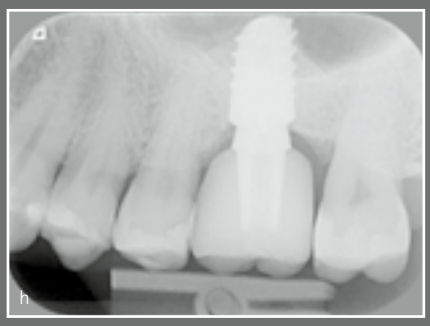


4 I Rehabilitation of a maxillary molar site with a limited RBH of poor bone density without addition of a grafting biomaterial.

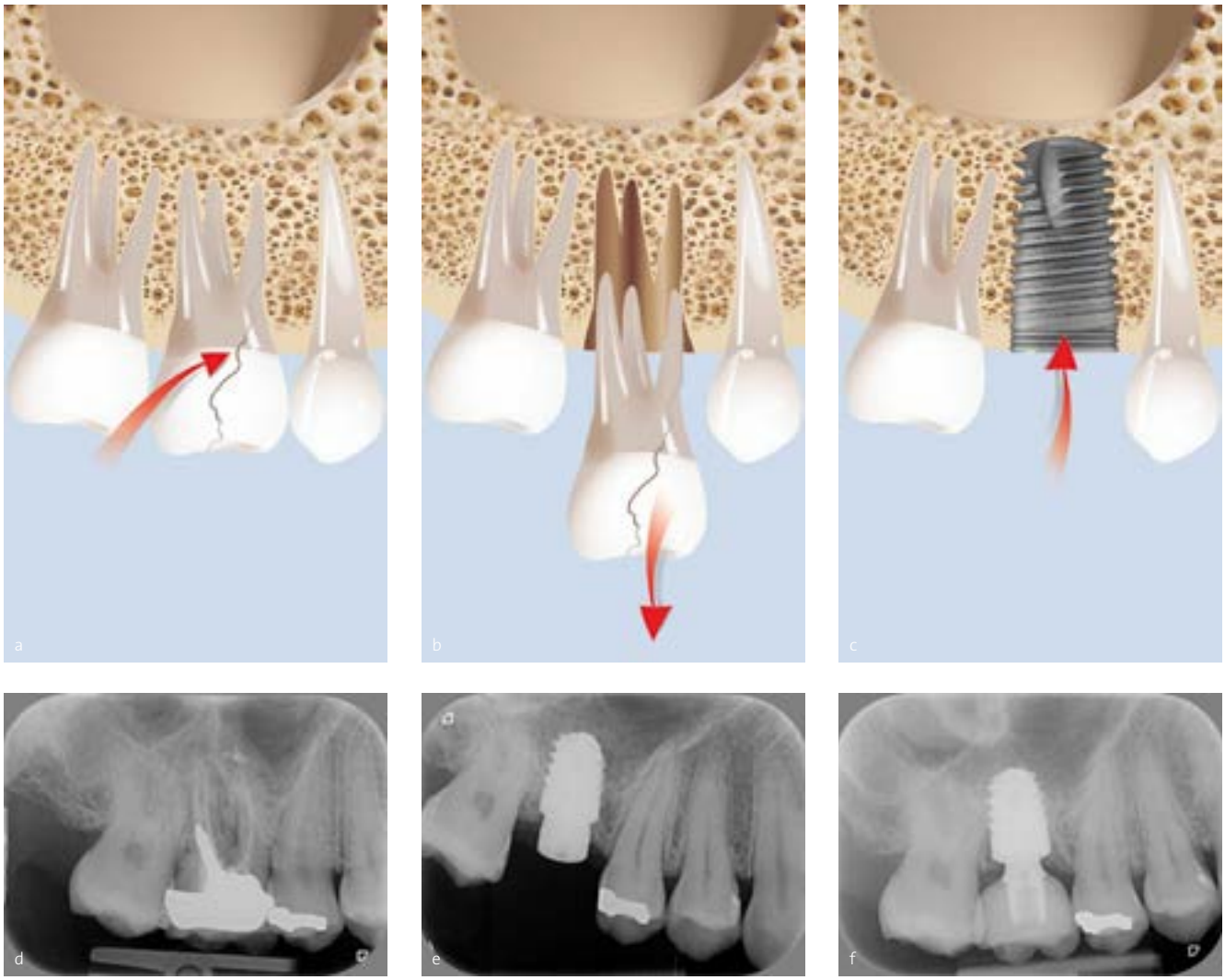
a) Preoperative periapical radiograph showing the reduced bone height below the sinus floor.
b) Sagittal section of the edentulous site showing the available RBH and the corresponding density.







c) Illustration of the crestal approach of the Fugazzotto sinus graft technique with the trephine drilling up to 1 mm below the sinus floor.
d) Release of the bone core inside the sinus through the use of a Ø 5 mm osteotome.
e) As the implant is inserted into the implant bed the bone core is driven deeper in the sinus cavity
f) New formation of bone by the end of the osseointegration period around the apex of the implant. The new bone volume completely accommodates the 8 mm long implant.
g) Postoperative periapical radiograph showing a Ø 6 × 8 mm SEVEN implant inserted according to the Fugazzotto technique. The implant apex largely protrudes into the pristine sinus cavity.
h) Control periapical radiograph taken at the 2-year follow-up. Note the screw-retained crown, the platform switching, the preserved bone levels and the bone covering the apex of the implant.

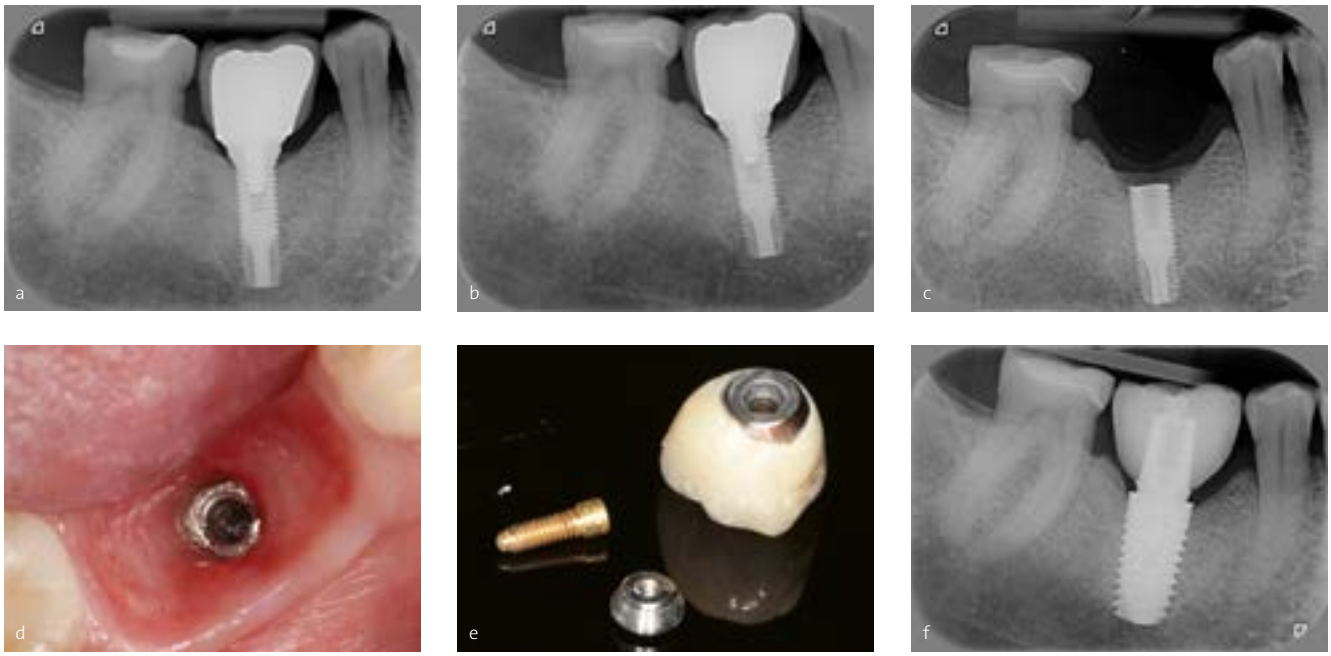


5 I Insertion of a wider diameter implant when a sufficient primary stability cannot be obtained with certainty.

a) Illustration showing a subgingival fracture of a maxillary molar crown.
b) Extraction of the molar.
c) Placement of a Ø 6 mm implant in the extraction socket to rehabilitate the edentulous site.
d) Preoperative peri-apical radiograph of the right maxillary first molar to be extracted.
e) Control periapical radiograph following placement of a Ø 6 × 10 mm implant. The 30 Ncm insertion torque was compatible with a one-stage surgical protocol.
f) Control periapical radiograph taken at the one-year follow-up. Note the preservation of the crestal bone levels, the prosthetic abutment and the wide platform-switching introduced between the abutment and the implant neck.

Replacement of a Ø 5 mm implant with a Ø 6 mm when primary stability is not attained in the maxilla

One of the most relevant indications of the Ø 6 mm implant is to immediately rehabilitate a to-be-edentulous molar site (Figs. 5a to c). From a biomechanical point of view, a Ø 5mm implant is largely able to withstand the mechanical stresses exerted in this posterior area of the oral cavity. Sometimes, a sufficient primary stability is lacking in the post-extraction socket because of the weak dimensions of the inter-radicular septum. Moving to the next implant diameter may solve this issue. Figures 5d to f illustrate the case of a patient that attended the dental office while complaining from an acute pain at the level of the right maxillary first molar (Fig. 5d). A subgingival fracture of the crown of the molar was discovered and extraction of the tooth was required. An atraumatic extraction was performed and the roots left behind a wide socket. Placement of a Ø 5 mm implant did not allow primary stability, so a wider, Ø 6 mm × 11.5 mm Seven implant was chosen to better fill the fresh socket. (Fig. 5e). The periapical control radiograph taken at the first annual follow-up shows the implant-supported crown (Fig. 5f), the large platform-switching feature that allows a better preservation of the initial bone levels and the osseointegrated wide, Ø 6 mm implant.



6 I Fracture of a standard diameter implant placed in the site of a mandibular molar.

a) The periapical radiograph taken during crown delivery shows a standard diameter implant with its widened collar rehabilitating a first molar site.
b) Control periapical radiograph of the implant at the 11-year follow-up. Moderate bone loss is noted on the distal side of the implant down to between the first and second thread.
c) Periapical radiograph of the implant that fractured during year 14. The fracture materialized below the implant collar at the level of the first thread. The proximal bone levels reached the second threads.
d) Occlusal view of the fractured implant. Note the healthy soft tissue.
e) Fractured components. Note the implant collar that endured the fatigue fracture, the crown and the retaining screw.
f) Periapical radiograph of the Ø 6 mm wide implant placed after removal of the fractured standard implant with its crown. Note the more appropriate emergence profile of the crown and the large platform-switching feature.

Replacement of a fractured standard implant restoring a molar site

When the dental implantology community started to endorse restoring teeth in the molar area, only standard Ø 3.75 and Ø 4 mm implants were available on the market (Fig. 6a). Fracture of these standard implants may take place fairly soon after installation, but it can also occur after several years of function. Figure 6a shows the case of a first mandibular molar restored with a standard Ø 4 mm implant with a Ø 5 mm wide collar design. This shape was specifically used to restore the posterior region with a more suitable emergence profile. This implant functioned many years without displaying the typical steep bone loss caused by occlusal overload or showing any other significant bone damage (Fig. 6b). During the year 14 of function, the implant lost its crown. The periapical radiograph revealed that the implant neck fractured below the first thread level due to fatigue (Figs. 6c to e); implant removal could not be avoided. The standard implant was removed with a Ø 5 mm trephine and a Ø 6 × 11.5 mm Seven implant was placed. Restoration of the molar better met both the biomechanical and prosthetic requirements (Fig. 6f). The wide platform-switching feature introduced here by the use of a prosthetic abutment that fits Ø 5 mm implants facilitates superior preservation of the peri-implant bone levels.

Discussion

Wide diameter implants were made available to the market by the end of the 90s as rescue implants, to be used a fortiori in two indications. The first was when the primary stability of a standard diameter implant could not be obtained. The second was to replace an implant explanted next to a fatigue fracture [5]. At the beginning of the clinical use of wide implants, some practitioners reported significantly higher failure rates for the wide diameter implants compared to the standard ones, of up to 20 % [10]. However, more recent meta-analyses of the wide diameter implants have shown that the increased failure rates were specifically involving machined surface implants that were used as rescue implants [7, 8]. When wide implants with a rough surface were used in a priori indications rather than in a posteriori ones, the failure rates of the wider implants were found identical to the standard ones. Reviews of the literature focusing on these diameter implants documented an average crestal bone loss of 0.57 mm measured at the one-year control and a cumulative survival rate of 97 % at five years

[7, 8]. What is noteworthy, is that not all implants wider than Ø 5 mm should be placed in the same category because only wide Ø 5 to Ø 6 mm implants were clinically investigated and taken into consideration. Ultra-wide Ø 7 – 9 mm implants seem to be prone to higher failure rates, 3.7 % compared to 1.45 % for wide implants of lesser diameters [8].

Before the widespread use of the wide diameter implants, healed molar sites were rehabilitated with a standard diameter implant placed in the middle of the edentulous space [5, 6]. This solution was not optimal because:

1) it was subject to biomechanical fractures arising after an unforeseeable period of time (Fig. 6),
2) the prosthetic management of the emergence profile of an 8 – 11 mm wide prosthetic crown, relying on a standard Ø 4 mm implant was an impossible task for the lab technician [11]; in addition it complicated the routine hygiene maintenance of the patient. In those days, another solution was proposed and included two standard or narrow diameter implants tilted one toward the other to support the bulky molar crown [5, 6]. However, this configuration also was coming at the cost of an increased difficulty for the patient to maintain a sufficient standard of hygiene.

Similarly, when post-extraction sites were treated within the frame of an immediate implantation protocol, one of the molar roots had to be selected to receive the standard diameter implant. The position and the direction of this implant were unable to meet the prosthetic requirements of this kind of placement.

Wide, Ø 6 mm implants have the advantage of offering a larger contact surface with the surrounding bone, whether when placed in a fresh extraction socket or in a healed site. This is the reason why some implant systems include 5 to 6 mm long implants only when the diameter is wide. These dimensions are more specifically indicated in molar sites of low residual bone height and/or poor bone density. Alongside their increased mechanical resistance, they allow for a better management of the emergence profile. The wide Ø 5 mm and Ø 6 mm implants share the same diameter for the prosthetic abutment supporting the crown. The platform-switching that results is larger for the Ø 6 mm compared to the Ø 5 mm, meaning it is better shaped to avoid peri-implant crestal loss.

All these consideration do not mean that placing a wide Ø 6 mm implant in a mandibular or maxillary extraction socket of a molar is simple and does not require a learning curve to master it. The SAC Classification (Straightforward, Advanced, and Complex) grades this implant placement as C for Complex [8]. A prosthetically driven surgery in these sites means that the most suitable location for implant placement is often in the inter-radicular septum. The size of these septa are limited; some practitioners even require an available, inter-radicular bone septum of 2.5 to 3 mm before accepting to engage in immediate implant surgery [8]. The first drills may slip on the narrow inter-radicular crestal bone and the following ones may change orientation during the subsequent drilling. The shape of the implant bed may switch from round to oval and fail to provide a sufficient primary stability. To overcome this impediment, some authors proposed to use piezo surgery tips [12], to finish preparing the bony implant bed with osteotomes, to drill through the crown still in place before extraction [13] or to use specific drills conceived to densify the local bone [7]. Despite all the above aspects pointing toward surgical complexity, the clinical studies that surveyed these wide implants placed in post-extraction sockets, rarely reported more failures during the osseointegration period compared to implant placed in healed sites [7, 8].

It is recommended to fill the peri-implant spaces with a low-resorbable bone substitute material; the aim is to achieve a 2 mm wide vestibular and lingual/palatal cortical plate by the end of the osseointegration period. This thickness should ensure an efficient bone support to the overlying soft tissues in the longer term.

Finally, it is advised to position the implant collar 2 mm below the vestibular plate of the socket in anticipation of the vertical bone loss that will necessarily occur during the early physiological remodelling process.

Conclusion

Wide, Ø 6 mm implants were made available for implant therapy later in time than narrower diameter implants. Their success rates are similar to the standard diameter implants.

They are indicated in the molar area of the mandible and the maxilla when:

- The bone quality is insufficient to stabilise a Ø 5 mm implant and it is necessary to seek support from the vestibular and lingual cortical tables.
- The RBH is limited and a larger implant surface is sought after in order to increase the overall bone-implant contact surface.
- The second mandibular or maxillary molar have fused roots, unlike the first molars that present divergent roots. In such cases, immediate implantation of Ø 5 mm implants often leads to compromised primary stability.
- In the posterior region of the maxilla, their wide and round apex reduces the risk of damaging the Schneiderian membrane of the sinus during a bone grafting procedure with sinus floor elevation via the crestal approach with either the osteotome technique or Fugazzotto's.
- A standard diameter implant is fractured or is removed because of crestal bone loss caused by overload, and an immediate larger implant is indicated.

In fresh extraction sockets, the surgical technique is not straightforward; the surgeon must go through a learning curve to get the skills and get acquainted with the specific tools and methods that will help attaining the desired primary stability in these sites.

The references are available at
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Minimally invasive approach to implant treatment in the posterior maxilla

Re-evaluating sinus lifting as first choice

GABOR TEPPER MD, DMD, PHD[1], CHRISTIAN JARRY DDS, MS, PHD[2,3]

Implant-supported rehabilitation of the edentulous jaw represents a highly predictable and widely accepted therapy [1]. However, implant placement in the atrophic posterior maxilla is frequently challenged by sinus pneumatization and alveolar bone resorption after tooth loss. To increase available bone volume, guided bone regeneration using the sinus membrane as a natural barrier – sinus floor elevation surgery – has been established [2].

Introduction

Among others, iatrogenic perforation of the maxillary sinus membrane during membrane elevation represents one of the most frequent intraoperative complication in an average of 20 % of sinus floor augmentation surgeries [3, 4] and increases the risk of postoperative sinusitis owing to bacterial contamination or graft migration into the sinus cavity. Some factors may contribute to the potential impact of membrane perforation and complication rates, including the lack of proper surgical training, decreased membrane thickness [5, 6], and complex sinus morphology [7], which require careful consideration of the treatment method.

Sinus lift procedures are regularly indicated with the goal to have regular sized implants placed in the maxillary posterior region following axial position [8]. Early descriptions of implant placement in the way to create axial loading of the implant were derived from theories that were applicable to natural teeth for which the goal is to place forces down the long axis of the teeth. With implants, this force application may be somehow irrelevant, because the complex forces of compression, tension, and shear exist macroscopically at each thread of the implant and microscopically at every undulation of the microscopic surface of the implant [9].

For the last decades, the dental implant industry has invested heavily into research and development to allow less invasive treatment options in areas of poor bone quantity and quality. The use of short implants as well as tilted implant placement have been proposed as alternatives to avoid bone augmentation for the accommodation of standard implants along with long-term evidences. In the same direction, more clinicians recognize that efforts, morbidity, increased cost and treatment time to allow a vertical osteotomy to house the implant in a similar way to that of the natural teeth are frequently perceived as an over-treatment and started adopting alternative options [10, 11, 12].

This case report demonstrates a patient presenting limited maxillary posterior bone availability which has been successfully treated with the use of short implants and through non-axial implant placement in the tuberosity area as patient centric alternative to avoid sinus lifting procedures.

Initial situation

Forty-nine-year-old male patient, with no smoking habits, general good health and oral condition presented to the office with the main complaint of continuous pulsating pain on tooth 25 for over 7 days and also the desire to replace the absent tooth 26 and 27 with dental implants. During intraoral examination it was possible to assess tooth 25 with mobility and restored with a PFM crown presenting the porcelain layer considerably worn out. After radiographic examination it was possible to notice tooth 25 with adequate crown adaptation and a root canal with no endodontic treatment history. Regions 26 and 27 presented pneumatization of sinus floor with remaining vertical bone availability significantly reduced (Figs. 1 and 2).

Treatment planning

The patient was presented with 2 treatment options that are scientifically and clinically validated:

Option 1

- Tooth 25: Removal of the prosthetic crown, endodontic treatment, intraradicular retentive post, and placement of a new crown restoration.

[1]University of Vienna Medical School, [2]Praxis Institute / Brasilia-Brazil, [3] Institute Straumann AG

Region 26 and 27: Sinus lift via lateral window and bone grafting (bovine sourced xenograft), (six months healing time of the grafted site)
- Tooth 26: Implant placement
- Tooth 27: Implant placement (twelve weeks healing time to initiate the prosthetic phase)

Option 2
- Tooth 25: Extraction with immediate implant placement.
- Tooth 26: Implant placement of a short implant.
- Tooth 27: Non-axial implant place¬ment in the tuberosity area to maxi¬mize implant engagement.

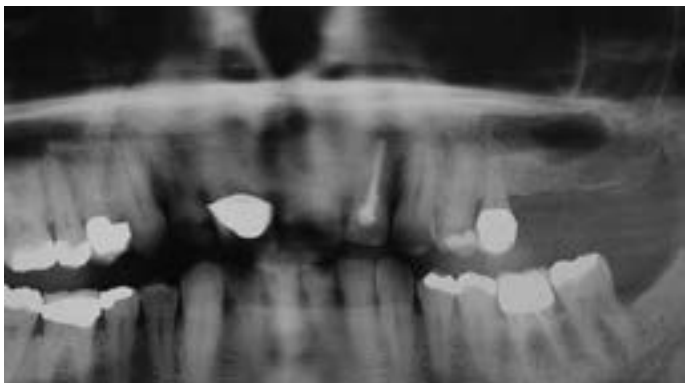
After a healing period of six weeks, the restorative phase can be initiated.

The patient claimed chronic and recurring sinusitis in the past, and the option with sinus lifting procedure was discarded. On top of that, after considering all costs associated, all surgical interventions, and the considerable amount of time needed to complete treatment motivated the patient to choose option 2.

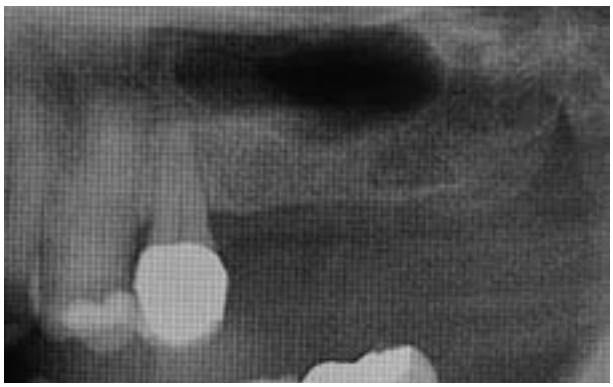
Surgical phase

Under local anesthesia, intra sulcular incision was done on tooth 25 to minimize the trauma to the soft tissue contour during the extraction. Supra crestal incision followed from the distal of tooth 25 until the end of the tuberosity, and a muco-periosteal flap was elevated to expose the crestal bone.

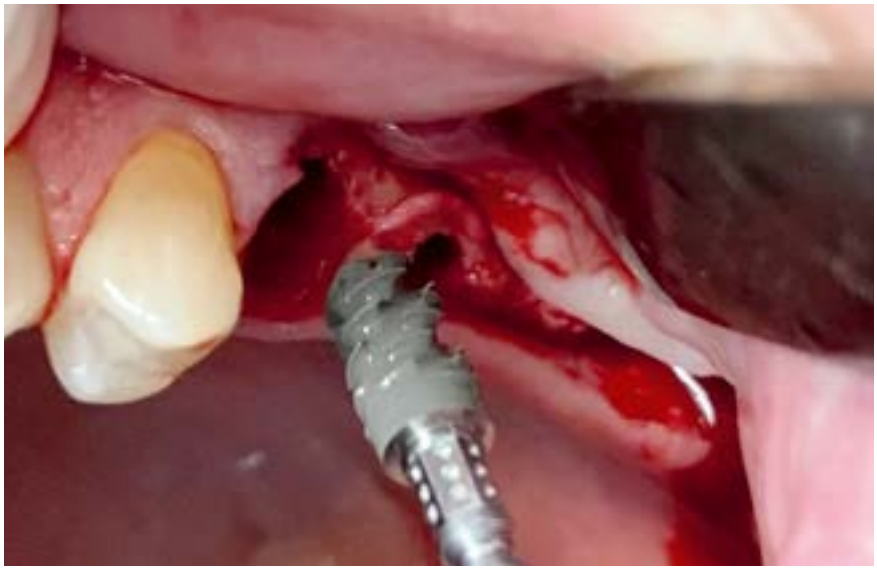
On site 25, a periotome was used around the sulcular ligaments to minimize the need for lateral forces with the forceps during the extraction in the attempt to preserve as much surrounding bone as possible. Considering there was not much room apically to gain implant engagement in native bone without perforating the maxillary sinus floor, it was decided for placement of Straumann BLX implant 5.0 mm × 12 mm directly into the socket without any osteotomy facilitated by the implant's engaging thread design. Initially inserted with the use of the handpiece at 25 rpm and taken to the final position with the use of ratchet and torque control device, reaching a final torque value of 80 Ncm (Figs. 3 and 4).



1 I General good oral health – Panoramic radiograph



2 I Close-up view on radiograph examination sites 25, 26 and 27

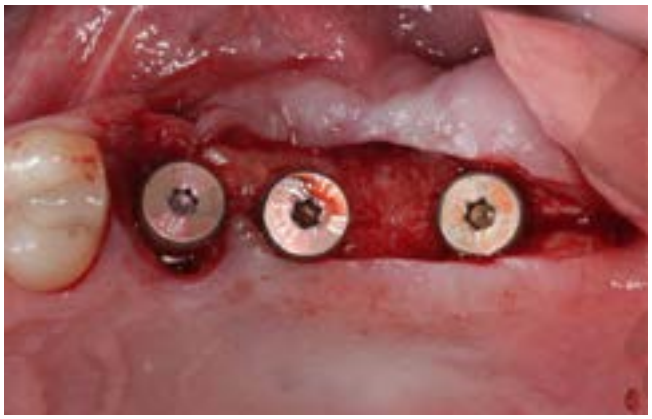


3 I Straumann BLX Implant ∅ 5.0 mm x 12 mm ready for placement on site 25

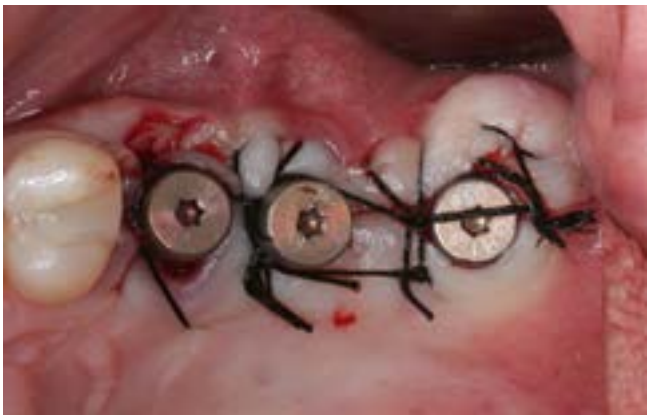
4 I Torque value of 80 Ncm reached measure with surgical torque control

5 I Straumann BLX Implant ∅ 5.0 mm x 6mm ready for placement on site 26

6 I Straumann BLX Implant ∅ 5.0 mm x 14mm ready for placement on site 27



7 I RB/WB Healing abutments in position allowing a one stage surgical approach



8 I Inter-locking continuous sutures

On site 26, we performed a 6 mm depth osteotomy sequence according to the manufacturer step-by-step for soft bone type and a short implant, a Straumann BLX 5.0 mm × 6 mm was placed with final torque measured in 50 Ncm (Fig. 5).

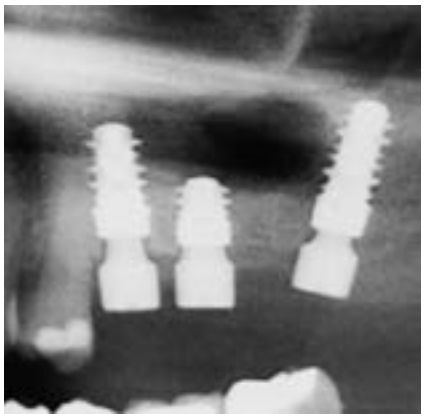
For site 27, a non-axial osteotomy with an apical orientation towards the distal was performed to bypass avoiding the maxillary sinus and benefiting from the tuberosity available bone to an osteotomy depth of 14 mm. A Straumann BLX of 5.0 mm × 14 mm implant was placed reaching a torque value of 50 Ncm (Fig. 6).

All three sites received a transgingival healing abutment in a one stage surgical approach without the need for a second surgical intervention to expose the implants. Continuous interlocking sutures were applied to bring the soft tissue in close contact with the healing abutments (Figs. 7 and 8).

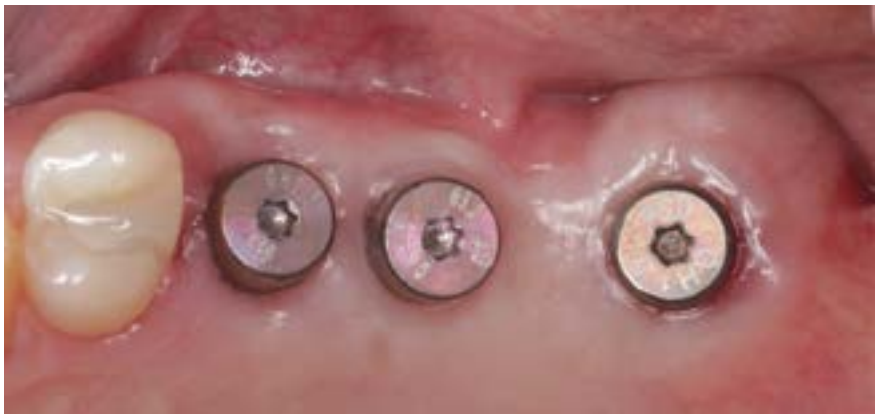
Prosthetic steps

After 6 weeks, it was possible to verify outstanding soft tissue healing response which then all implants were assessed for adequate osseointegration after a radiographic examination (Fig. 9 and 10).

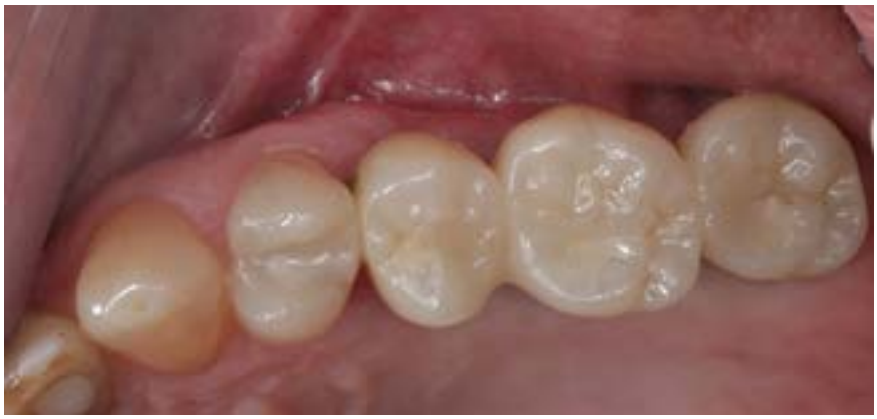
Open tray impression posts were connected to the implants and elastomer material was injected around the impression posts as well as the impression tray in a one-step impression taking. After model manufactoring in the laboratory,



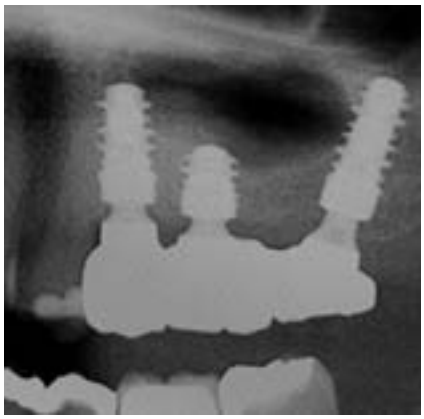
9 I Radiographic examination after 6 weeks



10 I Soft tissue condition after 6 weeks healing



11 I Final bridge in position – occlusal view



12 I Final radiographic exam confirming osseointegration and optimal prosthetic seating.

a ceramic layer was then applied onto the milled framework with proper staining and glazing process after. As a final step, the restoration was then seated directly onto the implants, when occlusion and proximal contacts were checked. The prosthesis was torqued to 35 Ncm on all screws, and they were then protected with PTFE tape and light curing composite (Fig. 11).

Outcome

In the final radiograph, we can see the complete osseointegration of all implants and the stable crestal maintenance around the implant placed immediately after extraction, the short and the non-axially placed implant positioned towards the tuberosity (Fig 12).

The patient is completely satisfied with the aesthetic and functional side and how minimally invasive and the reasonably short time the entire treatment took.

Discussion

It is still important for the practitioner to learn and to perform surgical techniques for sinus lifting to serve the patients with absolute indicated situations in the maxillary posterior region. Sinus augmentation requires a high degree of manual dexterity to avoid the most common complication, which is a puncture or rupture of the sinus membrane. Recent scientific literature reports rates of sinus membrane perforations at sinus lift surgeries using a lateral window approach with consecutive loss of graft material and successive sinusitis between 25 % and over 50 % of all cases [12].

In times of immediate gratification, patients expect efficient low trauma affordable solutions based on abundant information available in digital channels. Reducing the number and duration of visits, especially in times of ongoing pandemic, minimizing patient exposure, and surgical interventions are of additional benefit and value.

The use of short implants and angulated placement in the tuberosity with splinted screw-retained prosthetics offers, a reliable and predictable way to avoid a significant number of sinus lifting procedures [13].

The percentage of sinus lift procedures and consequent complications that can be spared must be further investigated, and guidelines must be defined.

The references are available at www.teamwork-media.de/literatur

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Two years post-loading results of a multicenter, randomized controlled split-mouth trial comparing implants with acid-etched (SA) and new hydrophilic (NH) surface

A randomized controlled evaluation on different implant surfaces

MARCO TALLARICO, DDS, MSC[1,2,3], NICOLA BALDINI, DDS, PHD[4], FULVIO GATTI, DDS[5,6], IRENE IERIA, DDS[7]

A multicenter, randomized controlled split-mouth trial was aimed to compare SA surface implants (SA group) and implants with a newly developed bioabsorbable apatite nanocoating surface (NH group). Outcomes were the two-years implant and prosthetic survival rates, any biological or mechanical complications, insertion torque at implant placement, and the implant stability quotient (ISQ).

Introduction

Implant stability is one of the most important factors that may affect osseointegration during the healing period [1]. After that, marginal bone loss has been used for several years to measure the implant success. Implant failure can be classified in early or late, depending on its time of occurrence [2–4]. Early failure occurs prior the definitive prosthesis delivery, as consequence of a lack of integration with the bone, while, late failures occurs after definitive prosthetic loading [5].

In the last years, dental industry introduced in the market implants with modified surfaces with the aim to enhance the osseointegration, reducing the risks of implant failure and complications during the osseointegration period (early implant failure) [6, 7]. According to the scientific literature, the risk of implant failure is improved in immunocompromised patients, immediate loading, immediate implants, and posterior maxilla [8, 9]. In these clinical scenario, hydrophilic surface could provide faster and stronger osseointegration, allowing to reduce the overall implant failure [10, 11]. However, a recent systematic review reported no statistically significant differences between conventional and novel hydrophilic surfaces [10, 11]. A possible explanation could be the insufficient data regarding the novel implant surfaces. Hence, the aim of this split-mouth randomized controlled trial was to compare early implant failure and implant stability of one-stage Hiossen ET III implants (Deutsche Osstem GmbH, Germany) with its new hydrophilic (NH) surface, compared with Hiossen ET III implants (Deutsche Osstem GmbH, Germany) with the well-known SA surface at the two years follow-up. The null hypothesis was that there is no difference between groups. The following trial was reported according to the STROBE statement.

Materials and Methods

This study was designed as a multicenter, split-mouth, randomized controlled trial of parallel groups with two arms and independent outcome assessment, conducted between November 2017 and May 2018. The study was registered in the clinicaltrial.gov (NCT03649100) after approval from the Institutional Review Board of the Aldent University, Tirana, Albania (3/2018). The 2013 Helsinki declaration was adhered too.

The inclusion and exclusion criteria were in Table 1 on page 50. Patients were clearly informed about the clinical procedures, the materials to be used, the benefits, potential risks and potential complications, and they gave an informed consent before including in the study-Surgical protocol was reported in a preliminary report of the same study [12]. In brief, a single dose of antibiotic was administered prophylactically one hour before surgery. Hiossen ET III implants

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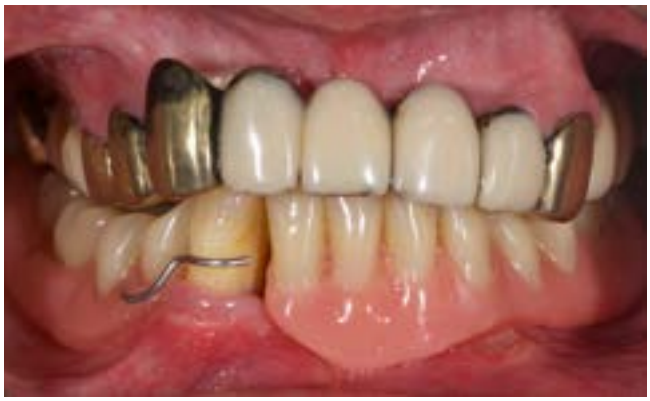
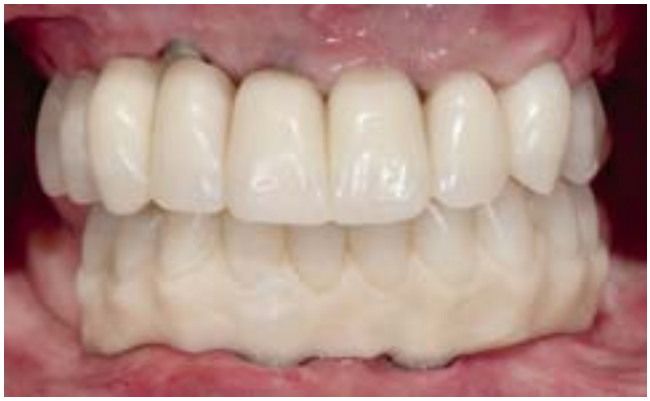
[3] Private practice in Rome, Italy
[4] Department of Periodontics and Implantology, University of Siena, Italy
[5] Department of Biomedical, Surgical and Dental Sciences, Unit of Oral Surgery, San Carlo and San Paolo Hospital
[6] University of Milan, Milan, Italy
[7] Private practice, Rome, Italy

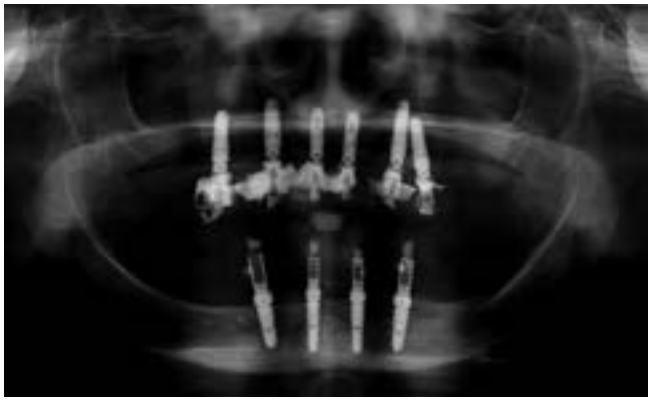


1 I Initial situation

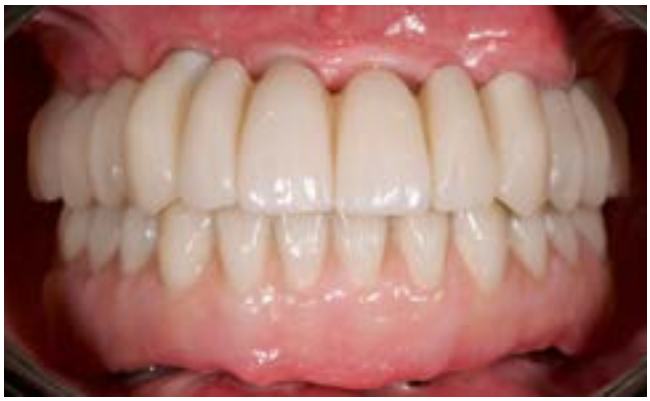
2 I Surgical templates



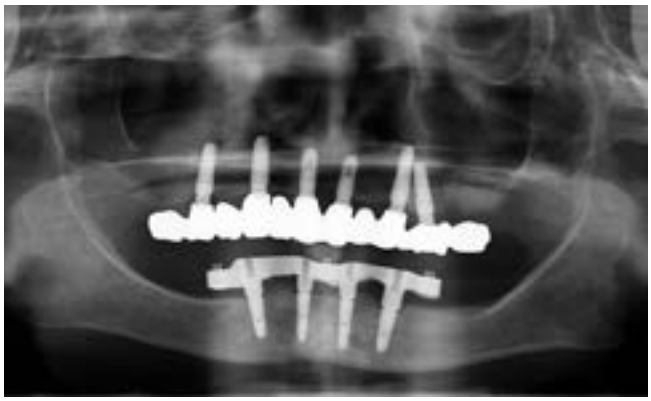
3 I Immediate loading



4 I Orthopantomograph (NH implants in the maxilla)



5 I Definitive restoration (Zirconia-composite)



6 I Ortopantomograph two years after loading (NH implants in the maxilla)

were placed under local anesthetic in the planned anatomic sites, according to the drilling protocol recommended by the manufacturer (Deutsche Osstem GmbH, Germany). The SA (SA group) or NH (NH group) were randomized after implant site preparation, immediately before implant placement (one-stage protocol). Two to three months after implants placement patients receive single screw-retained restorations. Periapical radiographs were taken at the definitive prosthesis delivery (Figs. 1 to 6).

The outcome measures were implant and prosthetic survival rates, any biological or mechanical complications that occurred during the entire observation period, the insertion torque at implant placement, and the implant stability quotient during osseointegration.

Success rates of the implants and prostheses were evaluated by an independent assessor according to established criteria [12]. The implant stability quotient (ISQ) was measured and recorded using a smart peg (Type 47 cod. 100478, Osstell,

Exclusion criteria	Inclusion criteria
Positive medical findings (such as stroke, recent cardiac infarction, severe bleeding disorder, uncontrolled diabetes, or cancer)	Healthy patients
Psychiatric therapy	Aged 18 years or older
Pregnancy or nursing	Two implants to be rehabilitated
Smoking > 10 cigarettes per day	Full mouth bleeding and full mouth plaque index ≤ 25%
Insertion torque < 30 Ncm	Sufficient bone to allow placement of at least 11.5 mm-long implants
Untreated periodontitis and/or poor oral hygiene	Bone width of at least 6 to 8 mm for the placement of a regular platform Hiossen ET III implant
Acute and chronic infections of the adjacent tissues or natural dentition	
Previous radiotherapy of the oral and maxillofacial region within the past 5 year	
Postextractive implants (at least 3 months after tooth extraction)	

Table 1 I Exclusion and inclusion criteria.

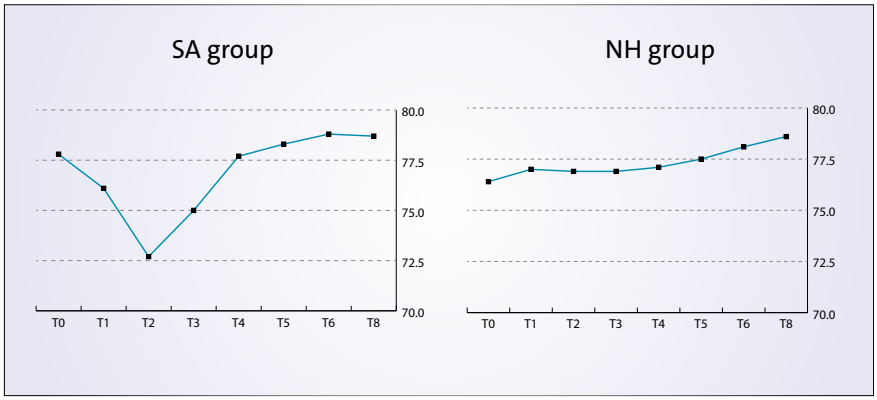
Sweden) connected to the implants, and the Osstell Mentor device (Osstell). Measurements were taken at implant placement, and every week up to 8 weeks after implant placement. A blind outcome assessor collected the data (EX), according to a previously published study [12].

Complications and failures were compared using the Fisher's exact test. Comparisons between groups (SA versus NH), and between jaws (maxilla versus mandible) were made by unpaired t-test, while the comparison between baseline (T0) and the last follow-up (T8) was made by paired t-tests to detect any change during the follow-up. Pearson's correlation coefficient was used to evaluate the correlation between insertion torque at implant placement and ISQ value 8 weeks after implant placement. All statistical comparisons were two-tailed and conducted at the 0.05 level of significance. The patient was used as the statistical unit of analysis.

Results

A total of 29 patients (22 females and seven males, with a mean age at implant insertion of 59.9 ± 11.3 years) were treated according to the allocated interventions, and followed up to two years after loading. No patient dropped out. A total of 58 implants (29 with SA surface and 29 with SA surface with the newly developed bioabsorbable apatite nanocoating) were placed. Eighteen patients were rehabilitated in the maxilla and 11 in the mandible. Two years after loading, no implant and no prosthesis failed. Two weeks after implant placement, two Hiossen ET III SA implants showed a small mobility with an ISQ values lower than 55 (49 and 51, respectively). The healing abutments were replaced with cover screws and the implants were left to heal undisturbed up to eight weeks after their placement. Nevertheless, no statistically significant difference was reached ($p = 0.491$). In both the implants, the healing abutments were replaced with a cover screw and the implants were left to heal submerged for six weeks (up to eight weeks after implant placement).

The mean insertion torque ranged between 35.0 and 45.0 Ncm (mean of 40.5 ± 3.23 (38.17 – 41.83) Ncm in the SA group and 40.48 ± 3.49 (38.02 – 41.98) Ncm in the NH group). The difference between groups was not statistically significant ($p = 0.981$).



7 I Comparison of mean ISQ values between groups (healing phase)

The comparison between ISQ values were reported n Figure 7.

There was a statistically significant difference between groups at the second week after implant placement (T2) with higher values in the NH group (P = 0.041). Similar results were found in the maxilla (P = 0.045), but not in the mandible (P = 0.362). Overall, the ISQ values improved in both groups during the entire follow-up (8 weeks), with statistically significant difference in the NH group (P = 0.019), but not in the SA group (P = 0.266). A positive correlation was found between initial insertion torque and ISQ with higher value in the NH group (0.73 versus 0.66). Correlation was stronger in the mandible (SA = 0.71; NH = 0.86) compared with the maxilla (SA = 0.52; NH = 0.55).

Discussion

The purpose of the present research is to update a previous research providing the two years follow-up data. In this study, the mean ISQ experienced during the osseointegration period improved in both groups, with statistically significant difference only in the NH group. Therefore, it can be assumed that implants with the hydrophilic surface (NH) could reduce possible complications that may occur during the first week of healing, by avoiding the ISQ drop back. This phenomenon could be exploited to improve implant survival and success rates in case of immediate loading, poor bone quality, and immunocompromised patients.

In the literature, there are several researches, including systematic reviews that reported conflicting results (13-19). So it is not easy to understand the potentiality of newly developed surfaces. A possible explanation for these results could be different surfaces treatments provided by different implant companies. Moreover, most of these study were performed in animal, or in ideal clinical conditions. New implants surfaces have been introduced in the present days for the purpose of improving the bone to implant interface as well as improving bone integration and reducing the timing of this process. Nevertheless, it would be desirable that researchers will provide well conducted studies even in problematic conditions, were newly developed surfaces could make the differences. These are not only immediate loading, poor bone quality (i.e. posterior maxilla), and immunocompromised patients (i.e. type II diabetic patients), but also in case of indirect bone healing, such as guided bone regeneration and post-extractive implants (20). In these clinical scenarios, the implant surface is not in direct contact with the bone. Therefore, active implant surfaces able to promote healing process could improve the overall osseointegration process, reducing the healing period and, as a consequence, reducing possible biological complications.

Conclusion

The NH implants showed encouraging results in term of implant stability, success and survival rates and are a viable alternative to SA surface, as they seem to avoid the ISQ drop during the remodeling phase.

Implants with NH surface could be finally suggested as gold standard in problematic clinical scenario, such us immediate loading, immediate implants, immunocompromised patients, and one-stage guided bone regenerations. Results remain stable up to two years after loading. Further researches are needed to evaluate the potential benefit of NH surface implants in problematic clinical situations.

The references are available at www.teamwork-media.de/literatur

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Report of a retrospective multi-center study of the early phase of implantological rehabilitations

Performance of a novel implant design

DR MANFRED NILIUS M.SC.[1, 2], JÖRG WINTERHOFF[3], PROFESSOR GÜNTER LAUER[4]

Numerous studies show an increased risk of complications or even loss of an implant in the early phase of implant rehabilitation. The purpose of this study was to evaluate the clinical performance of implants with a novel design (SICtapered, SIC invent AG).

1. Abstract

Materials and methods: In six private dental clinics 118 SICtapered Implants (SIC invent AG) were placed in 64 patients covering a variety of indications. They were retrospectively clinically assessed at six different stages, from implant placement to checkup after prosthetic restoration. For the very first cases treated within the scope of the present study, a follow-up period of up to 32 months has been reached. Thus, all cases include the early phase after implant placement. As a consequence, the results deliver scientific insight into the clinical reliability of the implants in exactly the period which is most critical in terms of osseointegration and marginal bone loss.

Results: Implants featuring the novel design outperform the early phase success rates reported in literature and reach a rate of 99 %. This result is confirmed by clinical as well as by radiological evidence. The radiological evaluation consistently shows a positive bone level stability. The bone resorption rates are substantially equivalent to the stage-related applicable criteria of Misch and Albrektsson which are internationally accepted.

Conclusion: Based on the results of the present study, this novel implant design exhibits positive effects which manifest themselves in both clinical and radiographic examinations and, in addition, in patients' satisfaction. The clinical performance in the early, critical phase shows a low degree of complications. The implant survival rate and the bone level stability meet high values which can be found in the referenced literature.

2. Introduction

Implantological treatment has been used for many years as a reliable method to compensate tooth loss and to help patients regain functional chewing comfort and a good quality of life. The long-term success rates published in the literature can be considered scientifically validated, but there remains a low risk of complications or even failure, which is very important for an individually affected patient. Consequently, the choice of treatment procedure and implant system should meet up-to-date standards in safety and predictability.

The largest clinical implant study in Europe by M. Krebs et al. 2013 [1], including more than 12,500 implants assessed, confirms good long-term success. Applying Kaplan-Meier statistics the cumulative survival rate (CSR) was 93.3 % after 204 months. The study proved a generally high implant survival rate. It also revealed and stated that a relatively high percentage of the failures occurred in the first year after implant placement and before prosthetic restoration.

These findings about implant loss in the early phase were affirmed by another large study by Knöfler et al. 2019 [2] including 10,165 implants. Most of the implant losses occurred during the healing period in the first months up to two years. The one-year survival rate of all implants was 97 %. Similarly, Lemmerman and Lemmerman stated that for 1003 implants, 75 percent of the implant losses occur in the early phase [3]. According to this knowledge from the literature, the first 1–2 years seem to be the most vulnerable time span in the life of an implant.

The aim of this study is therefore to analyze the clinical performance of the novel implant in this sensitive period of time and to come to a conclusion about the clinical reliability.

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[2] University Hospital „Carl Gustav Carus", part of the Technical University Dresden, Department of Oral and Maxillofacial Surgery, Dresden, Germany
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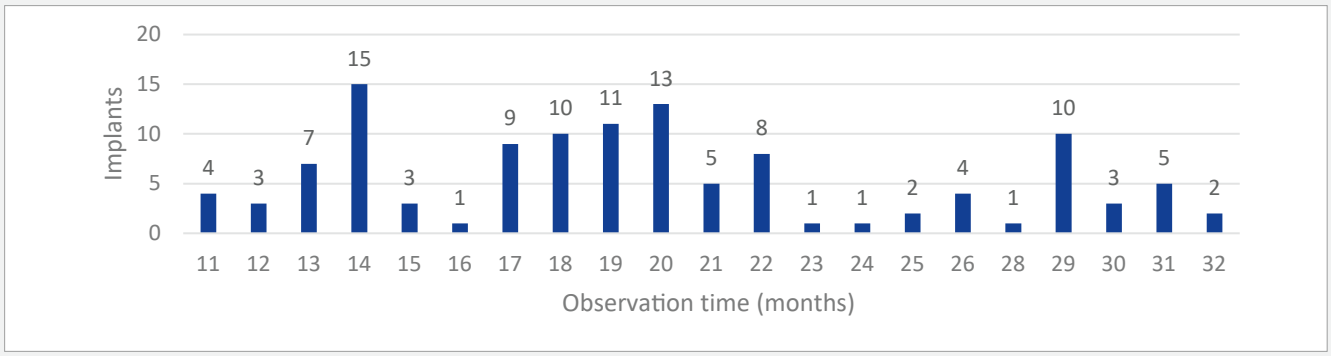
[4] University Hospital „Carl Gustav Carus", part of the Technical University Dresden; Public Law Institution of the Free State of Saxony



1 I Number of the implants being under observation (y-axis) for n months (x-axis)

The SICtapered Implants have been on the market since the 2nd quarter of 2018 and can therefore already have follow-up periods of up to 2 ½ years. During this period of time, the clinical behavior in the early phase (pre-prosthetic) and in many cases also in the subsequent prosthetic restoration phase can be reliably mapped. The cases will continue to be followed in the future so that the next part of the study will aim to deal with the long-term performance.

3. Materials and methods

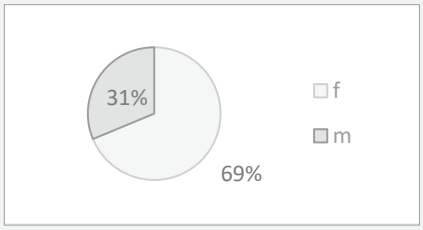
The clinical performance of the novel implants, a relatively new range of implants that came onto the market in 2018, is to be examined.

The study is designed as a retrospective observational study. The data was collected in 6 private dental clinics (see 7.) All practitioners have been practicing for years with a focus on implantology. One of the 6 dental clinics is an academic teaching practice of the University of Berne, Switzerland.

The patients received the implants in the time period between April 2018 and December 2019. Thus, the observation periods today range from 11 months to 32 months, with the average being 20 months, according to the following distribution (Fig. 1):

The practitioners made it possible to have a complete view of their treatment files and X-rays so that all of their SICtapered Implant cases since April 2018 have been recorded.

64 patients are included in this study: 20 male and 44 female patients (Fig. 2).



2 I Distribution of the patients referring to gender

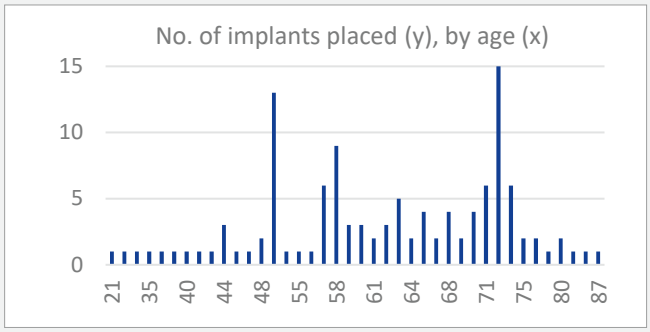
The age of the patients ranged from 21 years to 87 years. The average age was 60 years.

The implant distribution related to the patients by age is as follows (Fig. 3 and 4):

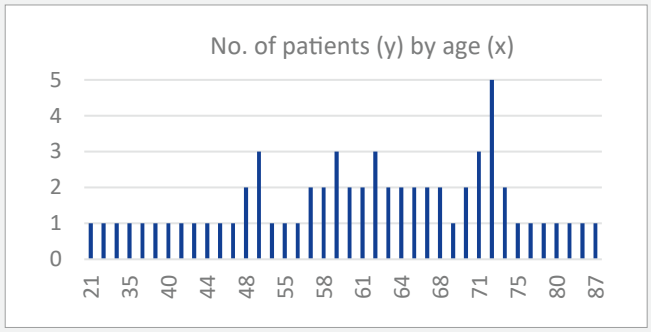
Inclusion and exclusion criteria

Patients of all ages and genders were treated. All implantological indications and prosthetic needs were accepted as well as all bone qualities ranging from D1 to D4, including cases, where bone augmentation measures were needed, ranging from marginal gap filling to huge bone block augmentation. All implant areas in upper and lower jaw were accepted (anterior, canine, premolar, molar region). Accordingly, no specific exclusion or inclusion criteria were applied but general contraindications (such as inappropriate medical/psychological/behavioral conditions) as well as local contraindications (such as, e.g., insufficient oral hygiene, oral tissue disorders, etc.) were considered according to good implantological practice [4] for treatment decision. Patients who met these contraindications were excluded from this study.

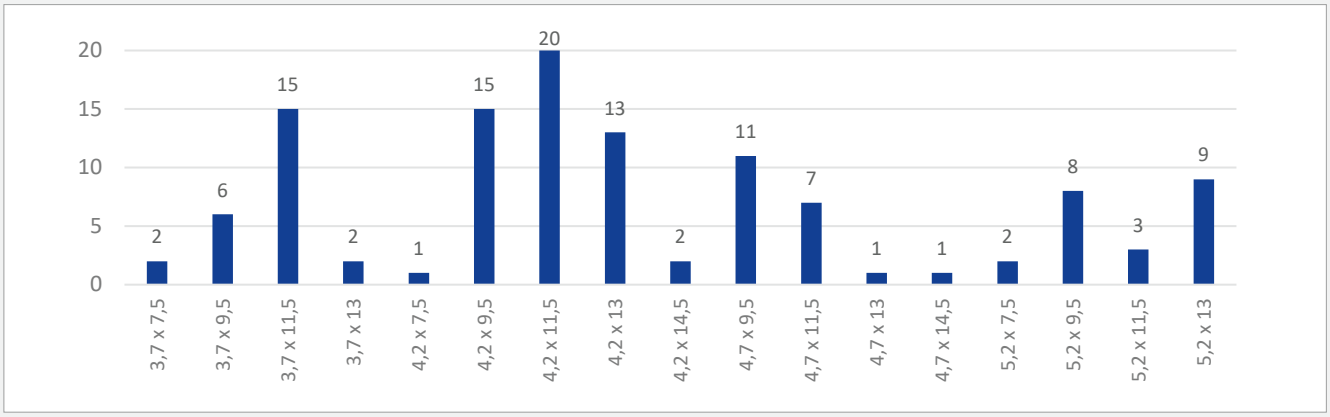
Consequently, three patients have been excluded from the cohort (of originally 67 patients) from the retrospective assessment because of strong individual reasons: One patient suffered from a long-lasting heavy attack of a diabetic disorder



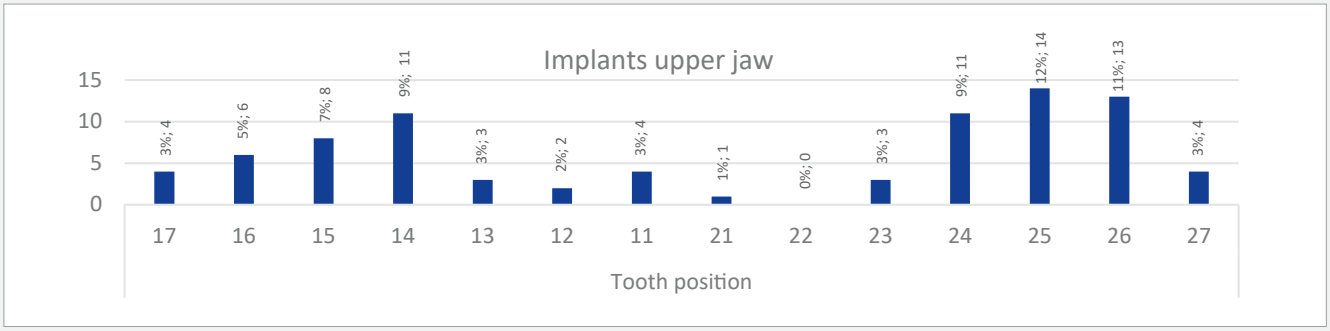
3 I Number of the implants placed referring to the age of the patients.



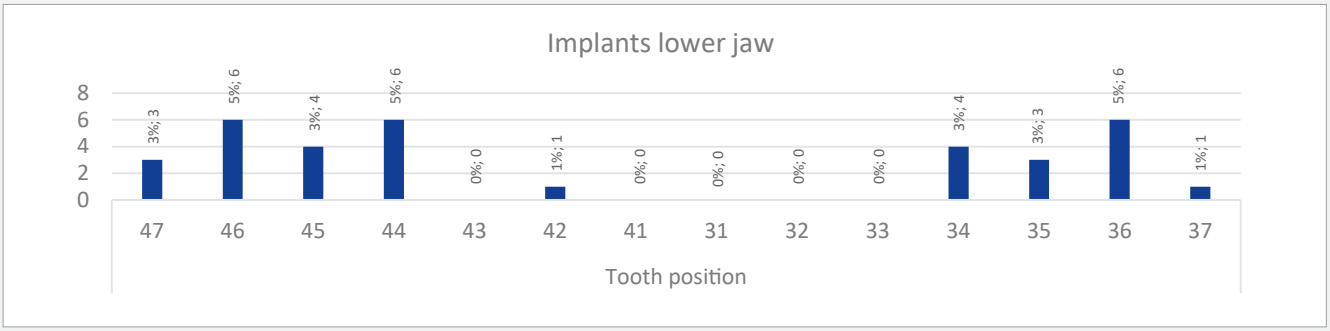
4 I Number of the patients referring to their age



5 I Number of implants placed (y-axis) having a combination of diameter/length as stated (x-axis)



6 I Distribution in percentage and number of the implants in the upper jaw referring to the area of placement



7 I Distribution in percentage and number of the implants in the upper jaw referring to the area of placement

that caused multiple wound healing disturbances, ending up with involvement of the oral cavity and limbs (toe amputation). One patient fell into an intolerable bad oral hygiene level and heavy smoking during healing phase. One patient failed to comply with using a splint to protect an implant just inserted but chewed on the gums in that area and chewed the implant into the sinus maxillaris. These events are, from a medical viewpoint, not related to the implant properties. Consequently, those patients have been excluded from the assessment in order to not distort the statistical results.

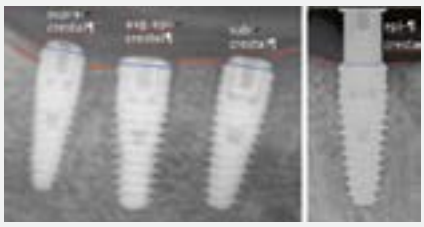
In all, 118 implants of all available dimensions (diameter x length) of the SICtapered Implant were placed according the following distribution (Fig. 5).

Implant selection and place of insertion (jaw, position) strictly followed medical indications (Figs. 6 and 7).

This results in following distribution by placement area (Table 1):

The implants were placed in all situations from extraction sockets to healed sites. In 82 (69 %) of the cases, bone augmentation measures were performed (Table 2).

The implant placement depths were chosen according to bone condition and restoration planning needs, following current implantological standards (Table 3 and Figs. 8 and 9).



8 and 9 I Different types of implant positioning relative to the alveolar crest

upper molar area	23 %	molar area*	36 %
lower molar area	14 %		
upper premolar area	37 %	premolar area*	52 %
lower premolar area	14 %		
upper anterior/canine area	11 %	anterior/canine area	12 %
lower anterior/canine area	1 %		

*When summing up upper area + lower area, certain deviations are due to rounding differences.

Table 1: Distribution in percentage of the implants inserted referring to the placement area.

augmentative measures performed before implant placement					
sinus floor augmentation in Implant area	sinus floor augmentation adjacent to implant area	vertical/horizontal augmentation in implant area	vert./horiz. augmentation area adjacent to implant area	implant-bone gap filling	none
29 (25 %)	8 (7 %)	26 (22 %)	3 (3 %)	16 (14 %)	36 (31 %)
82 (69 %)					

Table 2: Number and percentage of the implants requiring augmentative measures

subcrestal	**epicrestal**	**average epicrestal**	**supracrestal**
16	19	64	19
14 %	16 %	54 %	16 %

Table 3: Number and percentage of the implants referring to the implant placement level

healing method applied to n (x %) implants (number of implants and percentage based on the total of all implants)		
closed	open, with gingiva shaper	open, with provisional crown
92 (78 %)	18 (15 %)	8 (7 %)

Table 4: Different post-implant-placement healing procedures

prosthetic restoration type				
single crown	crown (bridge)	bar (denture)	locator (denture)	none*
43	57	6	8	4
36 %	48 %	5 %	7 %	3 %

*'none' includes the implants which have not yet been prosthetically restored and the 1 implant loss

Table 5: Different types of prosthetic restoration

Samples of placement depths:
- supracrestal: implant shoulder above bone level
- epicrestal: implant shoulder on bone level
- avg. epicrestal: inclined situation with some parts of implant shoulder below, equal or above – but in avg. on bone level
- subcrestal: implant shoulder below bone margin

The bone cavity preparation and the placement of the implant were performed according to the manufacturer's instruction.

After implant placement, different healing procedures were applied (Table 4):
- closed healing (with a second surgery later on for implant uncovery, on average 23 weeks after placement)
- open healing with gingiva shaper
- open healing with provisional crown

All open healing cases were checked for adequate primary stability before the decision was made in favor of the open healing procedure. Primary stability was achieved in 100 % of the cases planned for open healing or direct provisional restoration.

After the healing period, the implants were prosthetically restored as shown below (Table 5).

4. Data assessment and consolidation

4.1. Data assessed and follow-up times

A total of 118 implants in 64 patients were assessed. The treatment data and the respective clinical findings were extracted from the patients' medical records. More than 250 X-ray images, which had been taken at different treatment stages, were also evaluated.

t_0	implant placement		date of surgery
t_1	post-surgical period		avg. 9 days after surgery
t_2	implant uncovering period		avg. 23 weeks after implant placement
t_3	prosthetic restoration period	impression/scan	avg. 28 weeks after implant placement
		placement of restoration	avg. 30 weeks after implant placement
t_4	follow-up check 1		avg. 37 weeks after implant placement
t_5	follow-up check 2 → latest check		avg. 70 weeks, → up to 135 weeks after i.p.

Table 6: Time schedule for baseline and follow-up examinations

However, practitioners prefer different time intervals between implant placement and follow-up treatments/examinations. So the present study focuses on those data which were recorded in a substantially uniform way at the following points in time (Table 6).

The investigations at the points in time specified above covered the fields 'clinical status', 'radiological status' with their implantology-relevant subsections and 'patient satisfaction'.

4.2. Specifics and limitations

General aspects of the data collection

In Germany and Switzerland, patients' records are subject to the legal obligation to precisely document the course of treatment as well as all negative occurrences, such as complications, adverse effects, patient complaints etc. There is no obligation to document positive remarks, such as patient satisfaction etc. Nevertheless, many remarks of this kind are voluntarily entered into the records.

In accordance with this legal situation, the absence of negative entries for a documented treatment step was counted as 'no complications' but was not added to the explicitly positive entries.

It will be understood, that in a retrospective study we have to deal with heterogeneous data. The patient record entries from the six private dental clinics differ from each other in one way or another. Therefore, in particular the free-text statements of the practitioners in the patient records were assigned in a suitable manner to the corresponding categories of the international standards applied. These categories are listed below (Chapter 4.3).

Specifics of implant figures in different observation periods

Not all implants underwent every follow-up check, therefore the number of implants in some of the result tables differ from the number of total implants (118).

Depending on medical needs (e.g., the need to take an X-ray image), the time they are in place, the stage of prosthetic restoration etc., some records cannot be found in the implantologists' patient files. For example, an implant with open healing procedure and immediate restoration will not appear in the checkup phases from 'uncovering period' to 'prosthetic placement'. Furthermore, some patients underwent certain follow-up treatments such as the post-surgical check at their family dentist.

Especially some prosthetic-related treatment stages and respective follow-up checks have not been performed in the implantologists' practices for all implants, but some of them were prosthetically restored and intermittently checked in the referral dentists' practices. For this reason, the number of implants examined during the respective assessment stages may differ from the total number of 118 implants observed in this study.

Radiologic data

The radiation protection ordinances in Germany and Switzerland allow patiens' exposure to X-rays only if this kind of diagnostics is following a diagnostic or treatment need and if no other comparably reliable method can be used. Therefore, in the present study not all practitioners took X-ray pictures at all stages of the treatment. (Example: In a case with irritation-free clinical appearance – such as, e.g., stable implant with low sulcus depth and no inflammation etc. – some practitioners consider an X-ray avoidable). For this reason, at some observation stages the number of radiologically assessed and clinically assessed implants may differ from each other.

The radiographs have all been assessed and cross-checked against the entries in the patient records.

Clinicians in their daily workflow don't assess radiologic data according to international classifications but according to the clinical relevance for the case. The huge variety of individual entries in the patient records have therefore been consolidated to the most relevant findings, i.e. whether and how much bone resorption is visible in the follow-up phases vs. status of implant placement, categorized in the practice-oriented grading as described in the following (Table 7).

4.3. Suitable international assessment criteria

In the literature, numerous different standards and criteria are used to assess the success of implants, but these are only comparable to a limited extent.

Exemplary internationally used standards according to R. Buch et al. 2003 [5] include the Albrektsson criteria (T. Albrektsson et al. 1986 [6]; T. Albrektsson & F. Isidor 1994 [7]); Jahn-d'Hoedt criteria; Buser criteria; NIH criteria; Naert criteria. In 2007, the ICOI Pisa Consensus Conference proposed the criteria according to Misch which have been in use since then (Misch et al. 2008) [8]; (M. Thöne-Mühling et al. 2011) [9].

For reasons of general dissemination and awareness, this study not only re-

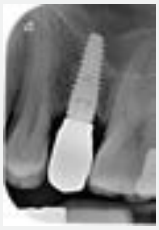
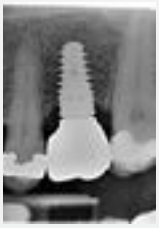
practically-oriented classification	corresponds to findings	sample X-ray images
stable bone level vs. insertion	bone level at follow-up in average height the same as at implant placement stage (with a tolerance of +/- 0,5 mm due to different beam angles and/or different X-ray machines, e.g. OPT vs. IO)	 10 I bone level stable, unchanged (versus epicrestal insertion situation)
slight superficial bone resorption vs. insertion	bone level at follow-up in average ≤ 1.5 mm below status at implant placement (tolerances see above)	 11 I 0.7 mm recession at an 11.5 mm implant (vs. epicrestal insertion situation)
noticeable but not critical bone resorption vs. insertion	bone level at follow-up in average ≥ 1,5 and ≤ 3.5 mm below status at implant placement (tolerances ± 0.5 mm see above)	 12 I 1.6 mm recession mesial at a 9.5 mm implant (vs. epicrestal insertion situation)
critical bone resorption/failure/loss	worse than above, (≥ 4mm) in worst case failure/loss	 13 I bone loss > 50 % of length (no suchlike picture available from this study, sample with other implant brand)

Table 7: Bone resorption categorized in a practice-oriented grading

ports the practice-internal criteria noted by the participating clinics but also the international criteria of Albrektsson and Misch.

4.4. Albrektsson Criteria

The Albrektsson criteria [6, 7, 9] state:

1) After 5 years of loading, the implant survival rate should be at least 85 %, after 10 years at least 80 %.
2) The individually unblocked implant is clinically stable.
3) The radiograph shows no continuous peri-implant translucency.
4) The vertical bone loss should be less than 0.2 mm per year after the first year under load.
5) There are no permanent and/or irreversible symptoms such as pain, infection, neuropathy, paresthesia, or injury to the mandibular canal

and check for fulfillment/non-fulfillment.

4.5. Misch Criteria

The criteria according to Misch [8, 9] assess the success of the implant in 4 levels:

1) Success (optimum health)
   neither pain nor pressure-sensitivity under functional load, no mobility, < 2 mm radiographic bone loss since implantation, no exudation.
2) Satisfactory survival
   no pain under functional load, no mobility, 2–4 mm radiographic bone loss, no exudation.
3) Compromised survival
   Sensitivity to functional stress/load, no mobility, 4 mm radiographic bone loss, but less than ½ of the implant length, PD > 7 mm, possible exudation.
4) Failure
   Pain with functional load, mobility, radiological bone resorption, less than ½ of the implant length, exudation that cannot be treated, implant cannot be prosthetically treated (sleeper), implant no longer in situ.

4.6. Criteria application

The standards according to Misch and Albrektsson are internationally accepted and widely used for the assessment of implant success [5, 9]. However, they are designed in such a way that their criteria predominantly refer to implants which are already prosthetically restored.

criterion and area / phase	t_0	t_1	t_2	t_3	t_4	t_5	remarks
1 (clinical)	-	-	-	-	-	-	criterion is related to 5 years
2 (clinical)	-	-	+	+	+	+	
3 (radiological)	-	+	+	+	+	+	
4 (radiological)	-	-	-	-	-	-,+	t_5 depending on observation time
5 (clinical)	-	+	+	+	+	+	

Table 8: Elements of ALBREKTSSON Criteria (Chapter 4.4) applicable in respective phase

criterion and area / phase	t_0	t_1	t_2	t_3	t_4	t_5	remarks
1 (clinical/radiological)	-	+*	+*	+	+	+	* 'load' n.a.
2 (clinical/radiological)	-	+*	+*	+	+	+	* 'functional load' n.a.
3 (clinical/radiological)	-	+*	+*	+	+	+	* 'functional stress' n.a.
4 (clinical/radiological)	-	+*	+*	+	+	+	* 'functional load' n.a.

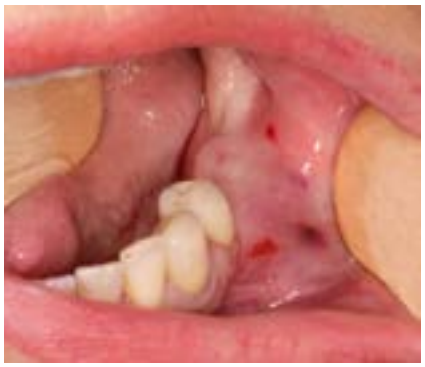
Table 9: Elements of MISCH Criteria (Chapter 4.5) applicable in respective phase

Since there are no general and comparable standards for evaluating the success of the implant in the 'intermediate steps' of an implant treatment, in the present study the standards outlined above were applied in a tailored way. In each follow-up examination exactly those subitems of each criteria were assessed which obviously made sense at the respective point of time (Tables 8 and 9).

In the tables below showing the results of the follow-up examinations the categories are consistently tagged with the extension '(app.c.)' for 'applied criteria', e.g. 'Albrektsson (app.c.)' or 'Misch (app.c.)'.

5. Exemplary presentation of the clinical approach

In order to briefly illustrate the clinical approach, a typical treatment is shown as performed in the context of the present study.



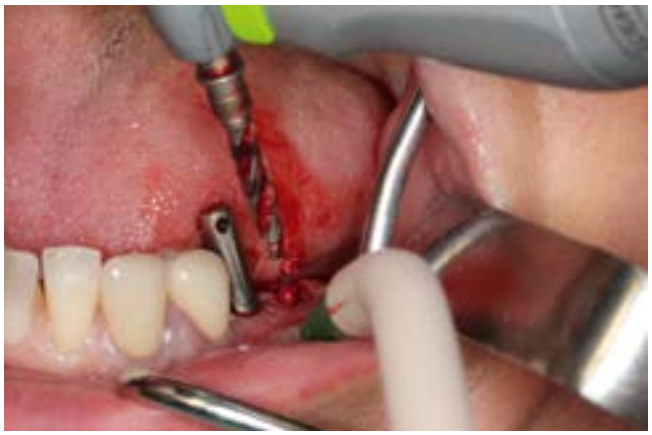
14 I Pre-operative view

The patient had lost two teeth (35 + 36) and, as a result, was in need of two implants (Fig. 14). In addition, two crowns (33 + 34) had to be replaced. The treatment comprised inserting two implants (SIC tapered, SIC Invent, Basel; Figs. 15 to 18), temporary restoration (Figs. 19 and 20), and final restoration with two tooth-borne and two implant-borne crowns (Figs. 21 to 25).

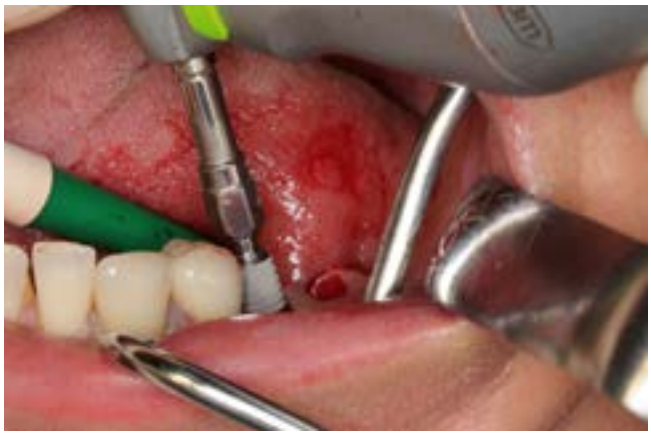
6. Results

In the following, the assessment results on clinical performance, radiological performance and patient satisfaction are described and statistically evaluated.

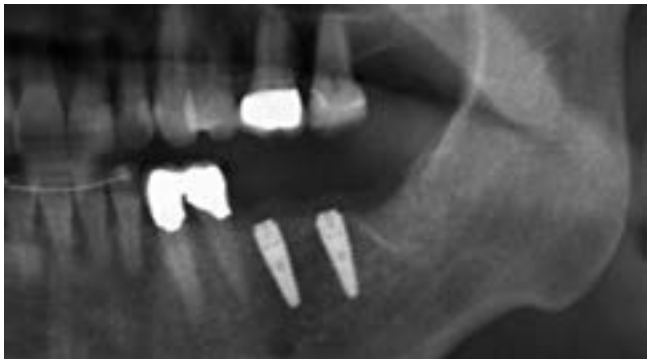
The statistics are kept on an implant basis. Calculating on a patient basis would be imprecise, as some patients have multiple implants with different findings.



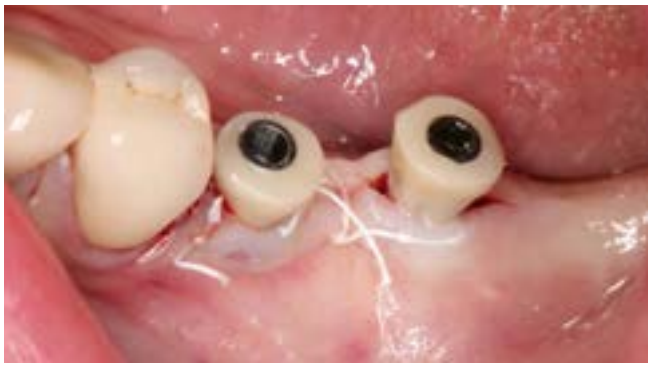
15 I Passage of the drill at implant site of 36



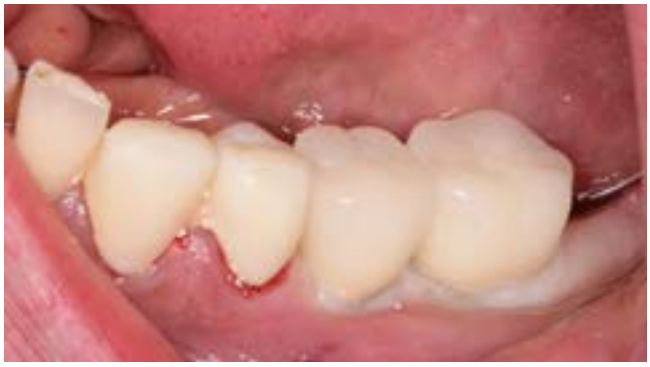
16 I Insertion of the implant at implant site of 35



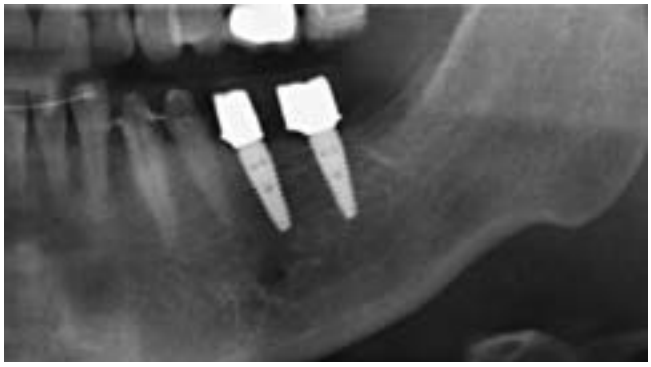
17 I Post-OP X-ray control



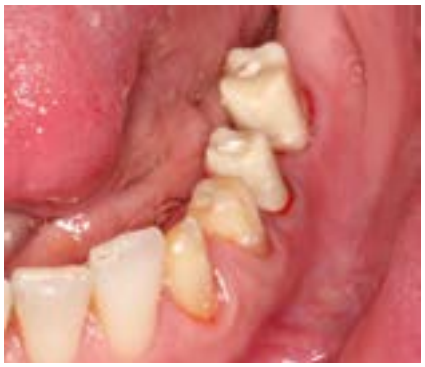
18 I Reapproach, individualized (PMMA) abutments for soft tissue management

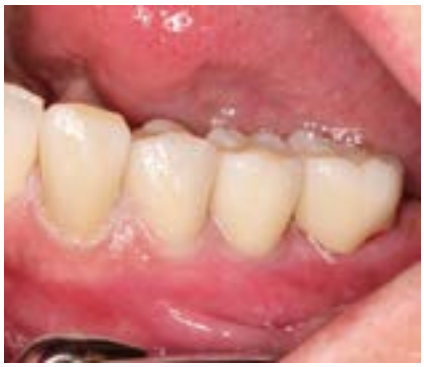


19 I Adhesively luted provisional crowns (33, 34, 35, 36)

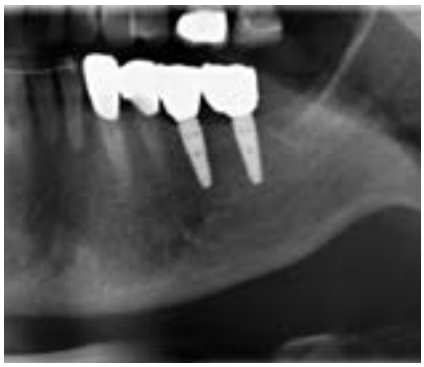


20 I X-ray control after placement of the long-term provisional crowns (35 weeks after implant placement, t_3)

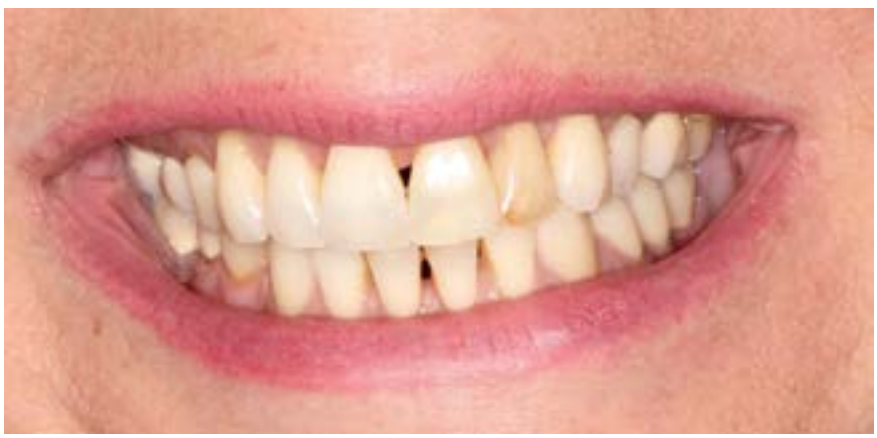




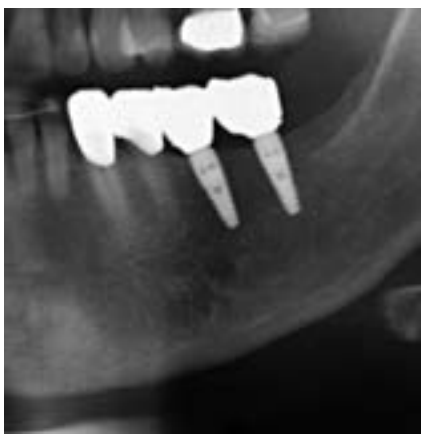
21 and 22 I Placement of the four crowns, two of them tooth-borne (33 + 34) and two implant-borne (35 + 36)



23 I X-ray control after placement of the final ceramic restorations (prosthetic check 1, 57 weeks after implant placement, t_4)



24 I Final result: the clinical outcome after prosthetic restoration and maturation of the tissue



25 I Final X-ray control (prosthetic check 2, 135 weeks after implant placement, t_5)

For reasons of clarity, the following tables only show the implants applicable to the respective observation phase. For more detailed information such as patient numbers or implants that cannot be evaluated for a phase, please refer to the links at the end of the article.

6.1. Follow-up examinations at specific points during the observation period

6.1.1. t_0 – Implant placement surgery
All implant placements could be performed according to the planning and following the manufacturer's treatment protocol.

Although 69 % (82 impl.) of the 118 implant placements were performed in conjunction with bone augmentation procedures, no complications or adverse effects were reported in any case.

No patient mentioned dissatisfaction at this stage.

Wound management could be realized as planned in all cases, according to the closed or open healing procedure.

6.1.2. t_1 – Post-surgical check
The post-surgical check was done on average 9 days after implant placement. All implants were in place and free of problems. No complications or adverse effects were reported.

98 % of the implants showed no irritations or complications at the post-operative follow-up visit; only 2 % showed temporary minor post-operative irritations, such as superficial inflammation, slight swelling or discomfort which were stage-appropriate to the extent of the surgery (Table 10). Patient satisfaction was high, no dissatisfaction was expressed (Table 11).

6.1.3. t_2 – Implant uncovering phase
The implants which underwent closed healing procedure were uncovered on

t_1

post-surgical period t_1 average time after implant insertion: 9 days					
clinical assessment t_1	**clinical findings from practice records**				
implants assessed at that stage	positive remarks about situation	no pathological findings noted	temporary minor irritations	persistent irritation/ inflammation or failure	
108	88	18	2	0	
100 %	81 %	17 %	2 %	0 %	
clinical criteria acc. Misch (app.c.)				**clinical criteria acc. Albrektsson (app.c.)**	
1: 'success (optimum health)'	2: 'satisfactory survival'	3: 'compromised survival'	4: 'failure'	Albrektsson criteria fulfilled	Albrektsson criteria failed
108	0	0	0	108	0
100 %	0 %	0 %	0 %	100 %	0 %

Table 10 I Clinical results of follow-up examination, on avg. 9 days after implant insertion

patient satisfaction t_1	**satisfaction-related entries from practice records**			
implants recorded acc. this parameter at that stage	patient proactively expresses satisfaction	no criticism noted	patient asks for improvement	patient unsatisfied
108	40	68	0	0
100%	37%	63%	0%	0%

Table 11 I Patient-satisfaction-related entries from practice records, on avg. 9 days after implant insertion

t_2

uncovering period t_2 average time after implant insertion: 23 weeks					
clinical assessment t_2	**clinical findings from practice records**				
implants clinically assessed	positive remarks about situation	no pathological findings noted	temporary minor irritations	persistent irritation/ inflammation or failure	
88	21	65	1	1	
100 %	24 %	74 %	1 %	1 %	
clinical criteria acc. Misch (app.c.)				**clinical criteria acc. Albrektsson (app.c.)**	
1: 'success (optimum health)'	2: 'satisfactory survival'	3: 'compromised survival'	4: 'failure'	Albrektsson criteria fulfilled	Albrektsson criteria failed
87	0	0	1	87	1
99 %	0 %	0 %	1 %	99 %	1 %

Table 12 I Clinical results of follow-up, on avg. 23 weeks after implant insertion

average 23 weeks after implant placement (Table 12). All implants were in place, but one had to be explanted due to missing osseointegration at that stage. All other implants were stable, well osseointegrated and free of problems.

The uncovering procedure caused temporary minor inflammatory irritation in only one case but even in this case it did not result in any complications.

Only the patient who lost an implant expressed dissatisfaction. In no other case any criticism has been noted.

6.1.4. t_3 – Prosthetic restoration phase

The prosthetic restoration phase started on average at 28 weeks after implant placement with the impression taking or optical scan and ended approximately 30 weeks after implant placement with the placement of the superstructure (crowns, bridges, dentures with bars or locators).

The assessment results in detail from this stage are as follows (Table 13-15):

6.1.5. t_4 – Prosthetic follow-up 1 check

The prosthetic follow-up check 1 took place on average at 37 weeks after insertion. It covered the performance of implants and of those prosthetic restorations, which had already been placed, according to the detailed criteria, see table below (Table 16):

6.1.6. t_5 – Follow-up 2 check

The last follow-up period started with the final check that took place on average 70 weeks after implant placement but was extended to mid-December 2020, the date when this report was finalized (Table 18a-b and 19).

t3

prosthetic placement period t_3 average time after implant insertion: 28 – 30 weeks					
radiological assessment t_3	**radiological findings from practice records**				
implants radiologically assessed	stable bone level vs. insertion	slight super-ficial bone resorption vs. insertion	noticeable but not critical bone resorp-tion vs. insertion	critical bone resorption/ failure/loss	
79	67	11	1*	0	
100 %	85 %	14 %	1 %	0 %	
radiological criteria acc. Misch (app.c.)				**radiological criteria acc. Albrektsson (app.c.)**	
1: 'success (opti-mum health)'	2: 'satisfactory survival'	3: 'compromised survival'	4: 'failure'	Albrektsson criteria fulfilled	Albrektsson criteria failed
78	1* (3mm)	0	0	79	0
99 %	1 %	0 %	0 %	100 %	0 %

Table 13 I Radiological results of follow-up, on avg. 28-30 weeks after implant insertion

* same implant

clinical assessment t_3	**clinical findings from practice records**			
implants clinically assessed	positive remarks about situation	no pathological findings noted	temporary minor irritations	persistent irritation/ inflammation or failure
106	22	84	0	0
100 %	21 %	79 %	0 %	0 %

clinical criteria acc. Misch (app.c.)				**clinical criteria acc. Albrektsson (app.c.)**	
1: 'success (opti-mum health)'	2: 'satisfactory survival'	3: 'compromised survival'	4: 'failure'	Albrektsson criteria fulfilled	Albrektsson criteria failed
106	1	0	0	106	0
99 %	1 %	0 %	0 %	100 %	0 %

Table 14: Clinical results, on avg. 28-30 weeks after implant insertion

patient satisfaction t_3	**satisfaction-related entries frompractice records**			
implants recorded	patient proactively expresses satisfaction	no criticism noted	patient asks for improvement	patient dissatisfied
106	31	75	0	0
100 %	29 %	71 %	0 %	0 %

Table 15: Patient-satisfaction-related entries from practice records, on avg. 28-30 weeks after implant insertion

t_4

prosthetic follow-up 1 t_4 average time after implant insertion: 37 weeks					
radiological assessment t_4		**radiological findings from practice records**			
implants radiological assessed		stable bone level vs. insertion	slight super-ficial bone resorption vs. insertion	noticeable but not critical bone resorp-tion vs. insertion	critical bone resorption/ failure/loss
28		26	1	1 (see t3)	0
100 %		92 %	4 %	4 %	0 %
radiological criteria acc. Misch (app.c.)				**radiological criteria acc. Albrektsson (app.c.)**	
1: 'success (opti-mum health)'	2: 'satisfactory survival'	3: 'compromised survival'	4: 'failure'	Albrektsson criteria fulfilled	Albrektsson criteria failed
27	1 (see t_3)	0	0	28	0
96 %	4 %	0 %	0 %	100 %	0 %
clinical assessment t_4		**clinical findings from practice records**			
implants clinically assessed		positive notes about situation	no pathological fin-dings noted	short term minor discomfort	persistent irritation/ inflammation or failure
90		25	64	1	0
100 %		28 %	71 %	1 %	0 %
clinical criteria acc. Misch (app.c.)				**clinical criteria acc. Albrektsson (app.c.)**	
1: 'success (opti-mum health)'	2: 'satisfactory survival'	3: 'compromised survival'	4: 'failure'	Albrektsson criteria fulfilled	Albrektsson criteria failed
89	1	0	0	90	0
99 %	1 %	0 %	0 %	100 %	0 %

Table 16: Radiological and clinical results, on avg. 37 weeks after implant insertion

patient satisfaction t_4	**satisfaction-related entries frompractice records**			
implants recorded acc. this parameter at that stage	patient proactively expresses satisfaction	no criticism noted	patient asks for improvement	patient dissatisfied
90	18	71	1	0
100 %	20 %	79 %	1 %	0 %

Table 17: Patient-satisfaction-related entries from practice records, on avg. 37 weeks after implant insertion

t_5

follow-up t_5 average time after implant insertion: 70 weeks					
radiological assessment t_5		**radiological findings from practice records**			
implants radiologically assessed at this stage		stable bone level vs. insertion	slight super-ficial bone resorption vs. insertion	noticeable but not critical bone resorp-tion vs. insertion	critical bone resorption/ failure/loss
21		17	4	0*	0
100 %		81 %	19 %	0 %	0 %
radiological criteria acc. Misch (app.c.)				**radiological criteria acc. Albrektsson (app.c.)**	
1: 'success (opti-mum health)'	2: 'satisfactory survival'	3: 'compromised survival'	4: 'failure'	Albrektsson criteria fulfilled	Albrektsson criteria failed
21	0*	0	0	21	0
100 %	0 %	0 %	0 %	100 %	0 %

*the 1 implant mentioned in t3 and t4 has timewise not yet reached this (t5) observation period

Table 18a: Radiological results, on avg. 70 weeks after implant insertion

t_5

clinical assessment t_5	clinical findings from practice records			
implants clinically assessed	positive remarks about situation	no pathological findings noted	temporary minor irritations	persistent irritation/ inflammation or failure
46	9	37	0	0
100 %	20 %	80 %	0 %	0 %

clinical criteria acc. Misch (app.c.)				clinical criteria acc. Albrektsson (app.c.)	
1: 'success (optimum health)'	2: 'satisfactory survival'	3: 'compromised survival'	4: 'failure'	Albrektsson criteria fulfilled	Albrektsson criteria failed
46	0*	0	0	46	0
100 %	0 %	0 %	0 %	100 %	0 %

Table 18b: Clinical results, on avg. 70 weeks after implant insertion

*see remark under previous table

patient satisfaction t_5	satisfaction-related entries frompractice records			
implants recorded acc. this parameter at that stage	patient proactively expresses satisfaction	no criticism noted	patient asks for improvement	patient dissatisfied
46	5	41	0	0
100 %	11 %	89 %	0 %	0 %

Table 19: Patient-satisfaction-related entries from practice records, on avg. 70 weeks after implant insertion

6.2. Entire observation period

At the end of this study, not all study implants had reached the same age (see section 3) and correspondingly not all reached the same follow-up stage. For an overall evaluation of all implants at the end of this study (Dec. 2020), the records of the latest available follow-up were assessed to obtain a final status information for each implant. The table below shows the consolidated results of the performance of the implants examined over the study period according to the respective latest follow-up and most recent records in the patients' files (Table 20).

clinical and radiological

clinical appearance and functionality according to latest practice records			
implants assessed	implants in place and functional, without constraints	implants in place and functional, with minor tissue recession	implant failure/loss
118	115	2*	1
100%	97%	2%	1%

overall evaluation and classification (merged clinical and radiological) according to applicable criteria of Misch					
implants classified	classifiable				not classifiable**
	1: 'success (optimum health)'	2: 'satisfactoy survival'	3: 'compromised survival'	4: 'failure'	
97	94	2*	0	1	21
100%	97 %	2%	0%	1%	

*1 implant is the same case as in the detailed tables above (stable since t3) + 1 implant with moderate bone recession (2.5 mm) detected only after t5 in the most recent X-ray, therefore doesn't appear in the previous tables

overall evaluation and classification (merged clinical and radiological) according to applicable criteria of Albkretsson			
implants classified	classifiable		not classifiable**
	fulfillment of criteria	no fulfillment of criteria	
97	96	1	21
100%	99%	!%	

**implants which have not reached both, clinical and radiological follow-up in at least t3 stage or higher cannot be assessed for combined overall classification. (see links at the end of the article)

Table 20: Overall radiological and clinical results at the end of the study

In the overall assessment, not all 118 implants could be clearly assigned to the applicable Misch or Albrektsson criteria over the entire observation period due to the absence of sufficient X-ray images at the respective follow-up periods (see link at the end of this article).

Nevertheless, all implants – except for a single case of an early implant loss – are still in place and clinically performing (Tables 21 and 22).

6.3. Conclusion

Compared to the results known from literature and the findings of the studies listed in section 2, the survival rate of the novel implant design in the early phase (99 %) surpasses the rate described (97 % after one year) in the most actual large study by Knöfler et al. [2].

The radiological evaluation consistently shows a positive bone level stability with bone resorption rates that are substantially equivalent to the stage-related applicable criteria of Misch [8] and Albrektsson [6, 7] which are internationally accepted [5, 9, 10].

This novel implant design exhibits positive results in the clinical, radiographic, and patient satisfaction areas based on the study results.

The clinical performance examined in the early critical phase seems to have a low degree of complications in accordance with the referenced literature.

For reasons of clarity, the tables in section 5.1 and 5.2 only show the implants applicable to the respective observation phase. For more detailed information, such as the numbers of implants or patients [I and (P)] that cannot be evaluated for a phase, please scan the QR-Code below:

Also, you can find a list of individuals and participating clinics to whom I would like to express my gratitude by scanning the QR-Code below:

The references are available at www.teamwork-media.de/literatur

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	acc. prosthetic-related entries from practice records					
prosthetic restoration	implants recorded acc. this parameter at that stage	prosthetic restoration in place and fully functional	prosthetic restoration in place with minor constraints (e.g. sharp edges, occlusion corrections, denture pressure points, etc.)	prosthetic restoration in Place, but with possible risk	Failure of prosthetic restoration and/or implant Loss	prosthetic restoration not (yet) provided
	118	111	2	1*	1	3
	100%	94%	2%	1%	1%	2%

*this is the single implant listed in t3 and t4 under 'satisfactory survival' with the bone recession of 3 mm

Table 21: Overall prosthetic results referring to practice records

	satisfaction-related entries from practice records				
patient satisfaction	implants recorded acc. this parameter at that stage	patient ‚proactively' expresses satisfaction	no criticism noted	pat. asks for improvement (due to minor discomfort)	patient dissatisfied (heavy discomfort or failure)
	118	24	90	3	1
	100%	20%	76%	3%	1%

Table 22: Summary of patient-satisfaction-related entries from practice records

Scientific survey on the topic of ceramic implants

Ceramic implants are increasingly establishing their place in modern dental implantology as a supplement to the treatment spectrum with titanium implants. A growing interest can be observed not only on the part of health-conscious patients, but also dentists are increasingly interested in the biological advantages.

Promising short- and medium-term data on the successful use of ceramic implants are now available. Nevertheless, the topic is still controversial in some cases due to the lack of corresponding long-term data. Above all, however, there is a lack of comprehensive knowledge from the practical use of ceramic implants and experience from daily dental practice. .

The European Society for Ceramic Implantology (ESCI) wants to change that: with its European and worldwide survey, the organization wants to find answers to the most important questions and to provide insight into the daily use of ceramic implants. The survey is intended to offer valuable information for further development and to make an important contribution to the reliable use of ceramic implants.

The questionnaire was designed by the ESCI Scientific Advisory Board and is aimed at dentists, oral and maxillofacial surgeons and dental technicians. The results of the survey will be scientifically evaluated by the ESCI and published in appropriate journals or sent directly to the participants upon request. The ESCI guarantees a serious, independent and novel processing of the answers without commercial aims. No data relevant to data protection will be collected. Participants and answers remain completely anonymous.

We look forward to your participation! Please acces the survey directly via https://esci-online.com/en/survey-ceramic-implantology/ or simply scan the QR code below with your cell phone.

More information
www.esci-online.com

Optimal time to teeth

The fully digital 13th Osstell ISQ Annual Symposium will be held on 16 September 7 pm – 00 am (CET, Paris) and will gather an exciting line-up of international speakers. The speakers will discuss how to provide each implant patient with optimal time to teeth – with confidence and predictability.

In the first session, Dr Tara Aghaloo will discuss the transition from primary to secondary stability, and how important it is with case selection and proper treatment planning in patients with medical risk factors.

She will be followed by Dr William Martin who will share his extensive clinical experience utilizing the Osstell technique and online OsstellConnect platform in a university clinic setting,

Dr Stephen T. Chen will share his research in timing of implant placement after extraction to obtain predictability, Finally, we will investigate the future of the dental industry with Dr Kyle Stanley, implant dentist and surgeon, where he will present on the exciting topic of AI – Artificial Intelligence – in dental implantology. can assist you as a clinician to obtain better clinical results with your patients.

After each lecture there will be a live Q&A-session and before the final panel discussion, Dr Marcus Dagnelid will also show live surgery to further display the Osstell technique.

Participants will have the opportunity to earn up to five continuing education credits, watch live surgery, interact with the speakers and network with their peers digitally.

For dental professionals who are unable to attend, the symposium sessions will be available to watch on demand.

More information and free-of-charge registration
www.osstellcampus.com

20 years BTI – Science – Health – Humans

This year's BTI Day was one of the first live congresses in the pandemic year 2021. About 100 participants met in Frankfurt Airport in mid-April to attend the congress under the motto "Science – Health – Humans". No less than Dr Eduardo Anitua came all the way from Spain to host the event.

The congress day was divided into the main podium and a practical course for the dental team. Once more, the BTI day presented the latest developments in implantology and regenerative medicine. In addition to a variety of topics, such as the latest advances in surgery and prostheses for the treatment of various pathologies, Dr Eduardo Anitua's two lectures were the highlight of a high-level congress day. He spoke about Endoret PRGF technology, developed by the BTI research team for the therapeutic use of growth factor-rich plasma (PRGF), and prosthetic solutions related to digital workflow. One of the main topics in his lecture was the alveolar ridge preservation, on which he presented some recent RCTs[1] that examined four groups: blood clot, allograft + collagen membrane, xenograft + collagen membrane, and Endoret (PRGF). He was able to demonstrate that after three months, the percentage of new bone formed was significantly higher with PRGF than with the others means.
In addition to the founder and scientific chairman of BTI Dr Anitua, renowned speakers spoke about PRGF in combination with autologous stem cells, guided surgery options of immediate implant loading, PRGF and implants and more. Speakers included Professor Önder Solakoglu, Dr Christoph Wenninger, Professor Fred Bergmann and Dr Oliver Zernial.

AWU

Dr Eduardo Anitua

[1] Stumbras A, Galindo-Moreno P, Januzis G, Juodzbalys G. Clin Implant Dent Relat Res. 2020 Oct 20
Stumbras A, Januzis G. Kubilius R, Gervickas A, Juodzbalys G. J Oral Implantol. 2020 April 21

New dates for the 5th MIS Global Conference

Following the long-awaited announcement on the new dates for the 5th MIS Global Conference, the MIS team is hard at work getting ready for Marrakech, Morocco, where the company will be hosting this next event.

As major global events were affected by the COVID-19 pandemic, which led to uncertainty and rescheduling, the conference is now planned for 19 – 22 May 2022, and will include a three-day scientific program of lectures by world-renowned experts, hands-on workshops, as well as exciting social celebrations.

World-class speakers and experts in their field

As in previous global conferences, the scientific committee is determined to present the most relevant and important topics and cases as part of the scientific program. Speakers have been carefully selected to bring forth new concepts, breakthroughs and a view into their vast collective experience and knowledge.

Exotic views and spellbinding entertainment

With a location such as Marrakech, conference guests can count on being met with a rich pallet of beautiful and colorful sights, exotic tastes and smells, and unique experiences that will never be forgotten. The meticulously planned and spectacular evening celebrations, which are a part of every MIS global conference, are sure to be part of this next, highly anticipated event.

More information
www.marrakech.mis-implants.com

The product information produced editorially in the following sections is based on information provided by the manufacturer and has not been checked for accuracy by the editor.

Z1 implant by TBR Dental

Giving you confidence in implantology

The Z1 implant, combining a titanium body and a zirconia collar, offers the advantage of being a tissue level implant as well as using materials optimized for the tissues with which they are in contact.

Tissue Level implants require only one surgery, which saves time for the practitioner and is also more comfortable for the patient. In addition, its transgingival position allows the practitioner to easily see the connection and thus facilitate his work. Moreover, it allows a healing of the soft tissues of first intention as well as a simultaneous healing of the hard and soft tissues, thus saving treatment time and improving final aesthetic. Finally, the absence of mobility between the abutment and the implant at the bone level avoids the bone loss that can be associated with it [1].

Dental implants must integrate with the three surrounding tissues - the bone, connective tissue and epithelial tissue. The main challenge involved with the implant's periodontal integration is the long-term stability of the implant/tissue interface.

The titanium body of the Z1 implant, combined with its sandblasted and etched surface, allows a good integration of the implant into the bone tissue. It also provides good mechanical properties to the implant.

The transgingival zirconia collar protects the bone from bacterial infiltration. Indeed, zirconia reduces bacterial colonization compared to titanium [2]. This is the reason why the zirconia collar can be considered as an antibacterial shield. In addition, the adhesion and proliferation of fibroblasts is improved [3] leading to a strong attachment between the soft tissues and the zirconia collar, ultimately leading to a natural reconstruction of the papillae and thus to an optimal esthetic result. This last item is accentuated by the zirconia color that is similar to the one of natural teeth, which will avoid the grayish coloring of the gingiva so that the final restoration will be close to a natural tooth [4].

[1] N. Broggini et al., « Peri-implant Inflammation Defined by the Implant-Abutment Interface », J. Dent. Res., vol. 85, no 5, p. 473-478, 2006.
[2] L. Rimondini, et al., « Bacterial colonization of zirconia ceramic surfaces: an in vitro and in vivo study », Int. J. Oral Maxillofac. Implants, vol. 17, no 6, p. 793 798, déc. 2002.
[3] A. E. Bianchi, M. Bosetti, G. Dolci, M. T. Sberna, F. Sanfilippo, et M. Cannas, « In Vitro and in Vivo Follow-Up of Titanium Transmucosal Implants with a Zirconia Collar », J. Appl. Biomater. Biomech., vol. 2, no 3, p. 143 150, 2004.
[4] A. Kim et al., « Abutment Material Effect on Peri-implant Soft Tissue Color and Perceived Esthetics: Abutment Effect on Soft Tissue Esthetics », J. Prosthodont., vol. 25, no 8, p. 634 640, déc. 2016

More information
www.tbr.dental

Osstem Ergonomic chair

Product
Ergonomic dental treatment chair

Indication
Dental treatment for patients

Distribution
Deutsche Osstem GmbH
Mergenthalerallee 35-37
65760 Eschborn
Germany
eu.osstem.com

Osstem Implant's K3 is a dental unit chair which was designed to provide comfort and convenience for dental professionals, assistants and patients. The chair has been successfully sold in 38 countries and is the best-selling dental chair in the Korean market with a market share of over 50 percent. It has been available in Europe since 2017 and has been sold more than 30,000 times worldwide.

The chair is characterised by features as below:

- The dentist's element has a 4.3-inch LCD display, which provides all the necessary information. The tabletop contains an instrument tray, a mouse-pad and a holder for documents, so that the dentists always have all the tools and information they need.
- The assistant unit is designed to reduce work steps and allow more efficient treatment. The user-friendly control panel combined with the ergonomic design maximizes comfort and efficiency throughout the treatment.
- The K3 features a wide seat and back support with easily adjustable head and arm rests to provide patients with a comfortable sitting position. The hydraulic motor provides smooth movement. The surgical light has 6 brightness levels and produces a shadow-free light thanks to a unique reflector. A special filter removes blue light waves that would affect the fillings hardening.

Zimmer Biomet Dental Accura Line

Product
Customized meshes

Indication
Guided bone regeneration

Distribution
Biomet 3i Dental Ibérica S.L.U.
C/Tirso de Molina, 40
08940, Cornellà de Llobregat
Spain
www.zimmerbiometdental.com

Zimmer Biomet expanded its dental product portfolio to include customized products for guided bone regeneration procedures for select markets in Europe. The new AccuraMesh and AccuraPlate product lines include customized meshes made of Titanium or PEEK (Polyetheretherketone) and customized PEEK plates in different size variations.

Zimmer Biomet's AccuraMesh and AccuraPlate are designed using a fully digital workflow. Data from 3D medical imaging devices combined with modern Computer-Aided Design (CAD) software and state-of-the-art Computer-Aided Manufacturing (CAM) processes result in high-quality customized medical devices for guided bone regeneration procedures[1]. AccuraMesh and AccuraPlate products are recommended in certain complex cases, such as horizontal and/or vertical ridge augmentation procedures, where space maintenance may be needed to ensure undisturbed healing after grafting with bone graft particulates[2]. Among other product features, AccuraMesh and AccuraPlate products contain pre-planned positions for bone fixation screws and are terminally sterilized. The launch of the new AccuraMesh and AccuraPlate products broaden Zimmer Biomet Dental's portfolio of customized bone grafting solutions, which already includes Puros Allograft Customized Blocks.

"We are proud to introduce even more tailored solutions to clinicians and patients as part of our already broad regenerative portfolio," says Indraneel Kanaglekar, Vice President and General Manager, Zimmer Biomet Dental. "Offering four different patient-specific product options now positions Zimmer Biomet as the market leader in the segment of customized bone grafting solutions."


PEEK AccuraMesh


PEEK AccuraPlate


Titanium AccuraMesh

[1] Cruz N et al. Materials (2020) 13:2177.
[2] Titanium AccuraMesh IFU latest revision, PEEK AccuraMesh IFU latest revision, PEEK AccuraPlate IFU latest revision.

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Fellowship status / diplomate status in implantology

☐ Yes ☐ No ☐ Organization .....

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(For information on BDIZ EDI Directory of Implant Dentists see overleaf)

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Calendar of Events

	Event	Location	Date	Details/Registration
8/2021	**30th Euro Dentistry Congress**	online	23–24 August	eurodentistry.dentalcongress.com/
9/2021	**ITI World Symposium 202ONE**	online	1–3 September 2021	iti.org
	Oral Health Research Congress	Hybrid congress: online/ Brussels, Belgium	16–18 September 2021	ced-iadr2021.com/registration/
	International Dental Show IDS	Cologne, Germany	22–25 September 2021	ids-cologne.de

Due to the Coronavirus spread, many events have been postponed or cancelled. Other events only take place online. Please check the official websites or contact the organizers to see if the dates are confirmed.

EDI Journal – Information for authors

EDI Journal – the interdisciplinary journal for prosthetic dental implantology is aimed at dentists and technicians interested in prosthetics implantology. All contributions submitted should be focused on this aspect in content and form. Suggested contributions may include:
- Original scientific research
- Case studies
- Product studies
- Overviews

Manuscript submission
Submissions should be made in digital form. Original articles will be considered for publication only on the condition that they have not been published elsewhere in part or in whole and are not simultaneously under consideration elsewhere.

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The photos should have a size of 10x15 cm, the image or graphic files must have a resolution of 300dpi. Tiff, eps and jpg file formats are suitable. Radiographs, charts, graphs, and drawn figures are also accepted.
Captions should be brief one or two-line descriptions of each illustration, typed on a separate page following the references. Captions must be numbered in the same numerical order as the illustrations.Tables should be typed on a separate page and numbered consecutively, according to citation in the text. The title of the table and its caption must be on the same page as the table itself.

References
Each article should contain a minimum of 10 and a maximum of 30 references, except in unusual circumstances. Citations in the body of the text should be made in numerical order. The reference list should be typed on a separate sheet and should provide complete bibliographical information in the format exemplified below:
[1] Albrektsson, T.: A multicenter report on osseointegrated oral implants. J Prosthet Dent 1988; 60, 75-82.
[2] Hildebrand, H. F., Veron, Chr., Martin, P.: Nickel, chromium, cobalt dental alloys and allergic reactions: an overview. Biomaterials 10, 545-548, (1989)

Review Process
Manuscripts will be reviewed by three members of the editorial board. Authors are not informed of the identity of the reviewers and reviewers are not provided with the identity of the author. The review cycle will be completed within 60 days. Publication is expected within nine months.

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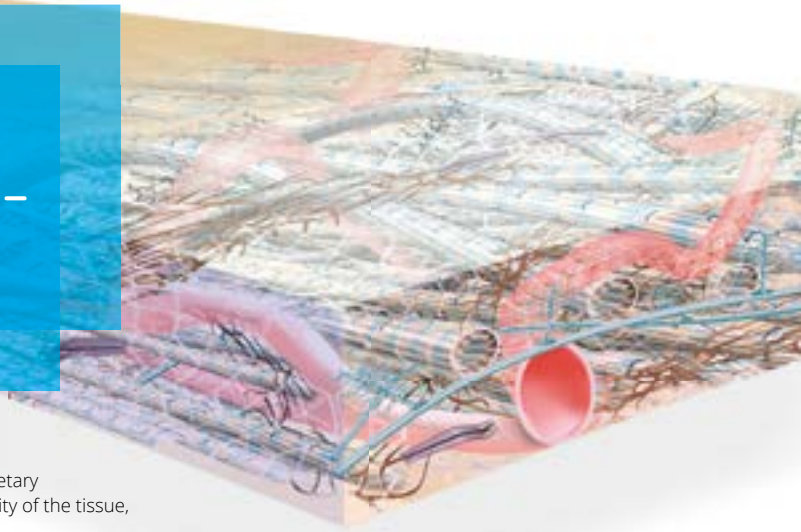
NovoMatrix™ Reconstructive Tissue Matrix – the next generation material



NovoMatrix™ Reconstructive Tissue Matrix is an acellular dermal matrix derived from porcine tissue intended for soft tissue applications. The proprietary LifeCell™ tissue processing is designed to maintain the biomechanical integrity of the tissue, which is critical to support tissue regeneration.

Indications
- Localized gingival augmentation to increase keratinized tissue (KT) around teeth and implants
- Alveolar ridge reconstruction for prosthetic treatment
- Guided tissue regeneration procedures in recession defects for root coverage

Product features
- Consistent thickness (1 mm)
- Pre-hydrated
- Controlled source

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Before use, physicians should review all risk information, which can be found in the Instructions for Use attached to the packaging of each NovoMatix™ Reconstructive Tissue Matrix graft. NovoMatrix™ is a trademark of LifeCell™ Corporation, an Allergan affiliate. ©BioHorizons. All rights reserved.
Not all products are available in all countries.

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Bone tissue augmentation

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MinerOss™ A The allograft for outstandingly fast bone remodeling [1]

The scientific evidence shows that allografts are the second best option to patient's own bone compared to other bone substitutes. [2]

Benefits of MinerOss™ A human bone substitute [1, 3–5]
- Optimal osteoconductivity
- Fast graft incorporation
- Complete remodeling potential

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[1] Wen et al. J. Periodont. 2019, 1, 734.
[2] Schmitt et al. Clin Oral Implants Res. 2013, 24, 576.
[3] Kloss et al. Clin Oral Implants Res. 2018, 29, 1163.
[4] Solakoglu et al. Clin Implant Dent Relat Res. 2019, 21, 1002-1016.
[5] Kloss et al. Clin Case Rep. 2020, 8, 5.
References available at: www.biohorizonscamlog.com/references_minerossa

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LEADING REGENERATION

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Biomaterials

Geistlich Bio-Oss® Collagen 50mg

A little innovation can make a big difference

Preserves 92 % horizontal bone volume[1]

NEW SIZE

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1 Cardaropoli, D. et al. IJPRD 2014;34:631-637. (clinical study)