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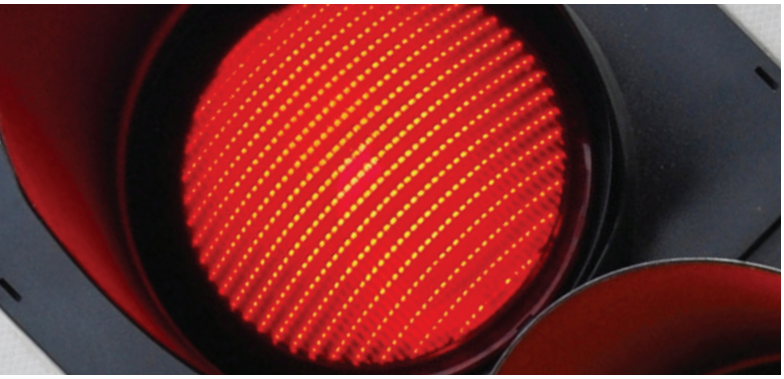
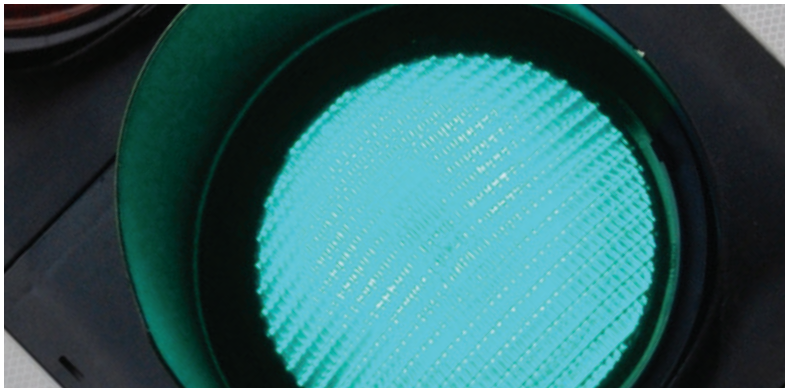


TOPIC

Guideline 2022: Cologne ABC Risk Score for implant treatment



»EDI News: 8th BDIZ EDI Expert Symposium: Periodontal disease · Updated Cologne ABC Risk Score for implant treatment – Guideline 2022 – MDR: waiting is not an option »European Law: ECJ ruling on dispensing over-the-counter medicines in other EU countries »Case Studies: Rehabilitation of a failing central incisor · Immediate implant placement and restoration – a new level of precision · Supporting the osseointegration of ceramic implants · Single-tooth replacement with ceramic implants

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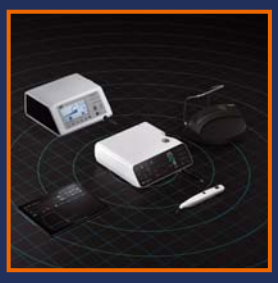

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MDR: Roadblock to innovation

Dear reader,

one year ago, the European Commission ended the due to corona one-year-transition period and the European Medical Device Regulation (MDR) came into effect on 26 May 2021. The comprehensive reform of the entire European medical device law obviously affects also dental practices and dental laboratories and of course the medical device industry.

It was even before the Corona pandemic when BDIZ EDI demanded a delay of two to three years to ensure the MDR's viability. Nothing really happened. In the meantime, all predicted implementation problems came true. Among other things, there is still a lack of Notified Bodies and a non-functional central EUDAMED database. None of the objectives of the MDR can be achieved, even though EUDAMED was postponed. 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 steam of new and innovative products dries up. Our fear still is that especially small and medium-sized manufacturers of medical devices will be at risk.

A few weeks ago the Medical Device Regulation was on the agenda at the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO), where the health ministers of the European member states discussed implementation problems. However, the EU Commission will probably not present any solutions until the end of 2022. BDIZ EDI welcomes the fact that the EU Commission is moving. However, time is too short to guarantee the functionality of the MDR. It's a good thing that the EU Commission and the member states are taking the concerns of clinics, doctors and med-tech companies seriously and striving for pragmatic solutions. But: we need concrete solutions and measures now!

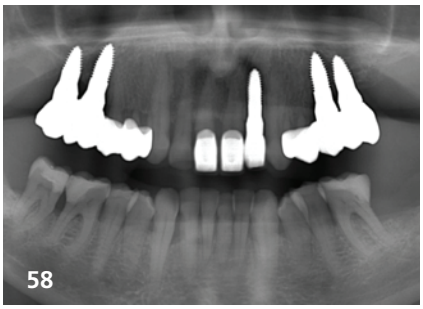
EU Commissioner Stella Kyriakides had to admit that only 1,000 MDR certificates have been issued so far. By the end of the transition period in May 2024, however, some 24,000 certificates will expire. The German Medical Technology Association (Verband Medizintechnologie, BV-Med) is calling for immediate action: increasing number of Notified Bodies, issuing conditional certificates, exemption for niche products and sufficient resources for innovations and finally: more time!

We from BDIZ EDI call again for postponement – otherwise we all would have to swallow the bitter pill: lack of innovation, lack of many medical devices we're using in our offices. Proper treatment of our patient's will then be at risk!

Christian Berger
President BDIZ EDI

Exceptions only in case of special needs
ECJ decision on over-the-counter-medicines

Waiting is not an option
MDR faces bottleneck problems



Radiograph taken with
the restoration in place

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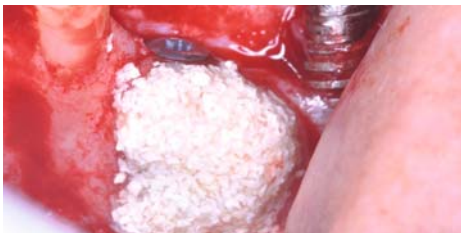

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Partner Organizations of BDIZ EDI

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 (Certy kat Umiejetnosci OSIS), which over 130 dental implantologists have already been awarded.

Sociedad Espanola de Implantes (SEI)

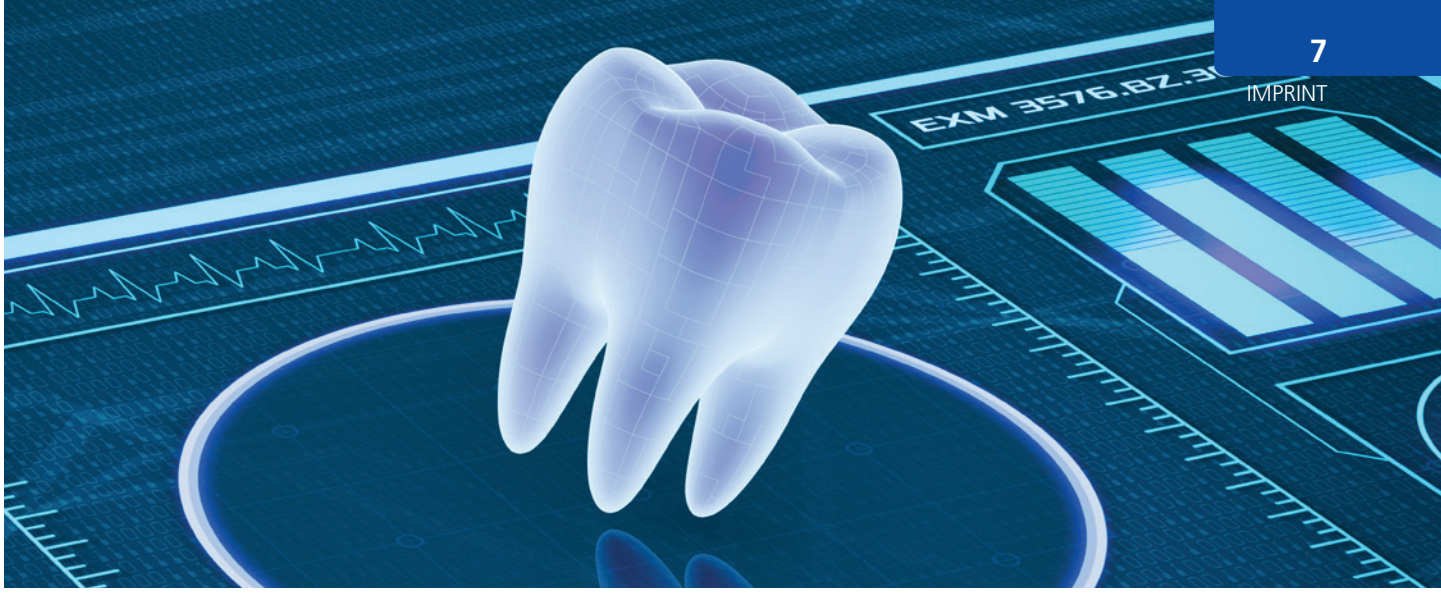
SEI is the oldest society for oral implantology in Europe. The pioneer work started in 1959 with great expectations. The concept of the founding fathers had been a bold one at the time, although a preliminary form of implantology had existed both in Spain and Italy for some time. Today, what was started 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.



Scientific Board

All case reports and scientific documentations are peer reviewed by the international editorial board of EDI Journal.

Chair is Professor Jörg Neugebauer.

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17th BDIZ EDI Expert Symposium: Risk factor periodontal diseases

Covering a wide field

The classic question – to preserve or to implant? – has been driving dentistry for many years. The topic of the 17th Expert Symposium, "Periodontal disease as a risk factor – tooth preservation or implantology?" not only provided interdisciplinary answers to many open questions but also presented new approaches worth discussing. The symposium – live in Cologne again after the Coronavirus hiatus – was moderated by Prof. Joachim E. Zöller.

Periodontal rehabilitation with All-on-4 – Prof. Dr Jörg Neugebauer

Prof. Dr Jörg Neugebauer, Secretary General of BDIZ EDI, delivered the presentation (originally to be held by Dr Wolfgang Bolz, who could not attend owing to illness) on periodontal restoration with All-on-4: edentulism as an opportunity or a risk. The presenter certainly had more than ample experience to highlight the issue, given the several hundred cases treated with this concept at his Landsberg practice that used all common implant systems, provided the appropriate abutments had been inserted. Prof. Neugebauer addressed the topic of how this prosthetic concept performed in periodontally damaged dentitions – How much surgery? How many implants? – by citing several of his own cases. He also took up the question of whether to provide fixed or removable restorations, referring to the 2016 Guideline of the 11th European Consensus Conference of BDIZ EDI that makes recommendations on restorations with short, angulated and reduced-diameter implants. Provided that the specific treatment parameters are observed, this minimally invasive implant approach can be a reliable treatment option in sites with reduced bone volume given the risks associated with the use of standard-dimension implants in combination with augmentation procedures. The All-on-4 and All-on-6 concepts now facilitate fixed restorations on a reduced number of implants. This has the advantage that patients now have to perform oral hygiene for only three interdental spaces instead of ten or twelve. In Neugebauer's view, the following factors are important for all periodontal restorations with All-on-4: the reduction of periodontal risk factors; a standardised procedure that provides stable long-term results; patient motivation and guidance; and an active network consisting of the oral surgeon, the prosthodontist, and the dental hygienist.

Minimally invasive implant treatment for partially edentulous perio patients – Prof. Dr Stefan Fickl

Prof. Dr Stefan Fickl (Würzburg) discussed the interface between periodontology and implantology. Does minimally invasive implant treatment make sense at all in perio patients? Fickl, himself both a periodontist and an implantologist, answered this question in great detail. While implants are a well-documented method for restoring the dentitions of partially edentulous patients, he said, it is known that patients who had lost teeth to periodontitis are at greater risk for implant loss or inflammation around implants. "As clinicians, we very often find ourselves in a position where we have to weigh alternatives, because many of the teeth that are lost these days are lost to severe periodontitis," said Fickl. "We have to decide: are implants feasible in these situations or might conventional prosthetic concepts be preferable?" In partial support of his view, he cited data from a Swedish study by Karlsson et al., who had followed 598 implant patients over 9 years and found that 42% of them had experienced complications. The risk is 1.6 times higher in periodontitis patients, and up to four times higher in partial-arch and full-arch patients. For Fickl himself, one insight had emerged in recent years: "With a high-risk patient, try to be as conservative as possible, try to delay implants – because you are bound to face problems!" – Having presented several additional studies that supported the risk of implantation in periodontitis patients and shared some of his implant cases, Fickl proffered these take-home messages: Biological complications are common in perio patients. Tooth preservation should be preferred where possible. Strict requirements for implant dentistry must be carefully considered. If implants are to be placed, they should be small fixtures with sufficient bone and soft-tissue support, and the implant system chosen also plays a crucial role.

Recession coverage on implants – Prof. Dr Dr Anton Sculean, MS

Prof. Dr Dr Anton Sculean (Bern), attending remotely, talked about options and limitations when covering implant recessions. Citing the differences in biological anchorage between natural teeth and implants, he explained that implants are in direct contact with the bone and that the soft tissue surrounding them is less vascularised than that around teeth, which has to be taken account in soft-tissue surgery. According to Sculean, there are two components to the mucosal seal – connective-tissue integration and the epithelial layer. The former in particular is of major importance if infections arise in this area. Aetiological factors of any soft-tissue recession at implants primarily include incorrect implant placement – too far buccally or labially or, conversely, too far palatally or lingually. Other aetiological factors include the absence of a bony envelope and excessive implant diameters relative to the existing bone supply; an excessive number of implants; insufficient distance between implants, causing the loss of the interimplant papilla; insufficient distance between implants and natural teeth; insufficient mucosal thickness or insufficient attached keratinized mucosa; and, of course, peri-implant mucositis and peri-implantitis. The only appropriate comment if implants are placed too far outside the bony envelope, said Sculean, would be "Mission Impossible" – here the only possible action would be to remove the implant or implants altogether. – What kind of tissue recession, then, remains amenable to coverage around implants? Sculean believes that successful treatment is possible if the dehiscence is no deeper than 2–3 mm, 4 mm at the very most, or if the implant is reasonably firmly positioned within the bony envelope. He then proceeded to present some of his cases using the modified (MCAT) and lateral (LCT) tunnelling techniques. The idea, he said, is not to separate the papillae but to expose this area as part of a mucoperiosteal tunnelling procedure, so that new tissue – such as a connective-tissue graft – can be introduced to reinforce the tissue. The important thing here is tension-free preparation. – For Sculean, tunnelling techniques are a good option for addressing small mucosal defects, as long as the implant is not too far outside the bony envelope, as pointed out previously.

Fig. 1: BDIZ EDI President Christian Berger welcoming the audience. **Fig. 2:** Prof. Joachim Zöller hosting and moderating the 17th Expert Symposium.

Prevention of peri-implant inflammation – Prof. Dr Johannes Einwag

Prof. Dr Johannes Einwag (Stuttgart) reminded his audience that caries, gingivitis and periodontitis are all biofilm-induced diseases. Each bacterium has its ecological niche, and the oral cavity is an ecosystem of its own: "We need to think in biological terms." Einwag believes that a biological equilibrium between the biofilm attack and the immune defence would make sense. Unfortunately, our limited knowledge hampers the possibilities of targeted immune-defence strengthening. What nevertheless remains possible is clear to him: "We must focus on prophylaxis and, hence, on efficient biofilm management. Either strengthen the defences or reduce the attack! In other words: the biofilm must be removed before it becomes pathogenic." – But does periodontitis prophylaxis also apply to implants? Not until 2010 – at a time when implantology was certainly no longer in its infancy – did periodontists discover that yes, peri-implant disease is in fact also biofilm-induced. Einwag deplored the fact that "we have been placing implants for 40 years, yet we had no standard protocol until 2012, or even 2018!" It has now been established that the formation of biofilm on implant surfaces is different from biofilm formation on tooth root surfaces, being intensified by rough implant surfaces. The problem with establishing the prevalence of peri-implantitis, he said, is that there was not even any clear definition until 2018 or 2019. The risk of peri-implantitis in perio patients is elevated by a factor of 5.5 (Schwarz et al., 2021). While the inflammatory reaction does not differ between gingivitis and mucositis (7th European Workshop on Periodontology 2010), given that the sulcus and the marginal epithelium are the same, the situation is completely different for periodontitis vs peri-implantitis, according to Einwag. In periodontitis, the body's own defence mechanisms are triggered via the supporting periodontal tissue, which is absent in peri-implant inflammation. Mechanical biofilm management makes sense if disease can be prevented already at the mucositis stage. Therefore, timely professional tooth cleaning is advisable, rather than waiting until it is time for supportive periodontal therapy. – While Einwag believes that it is advisable to adopt the successful prophylaxis strategies established for natural teeth, he thinks that modifications in detail are required, from interdental space cleaning to using the air/powder/water jet.

Nutritional counselling in the dental setting – Dr Maximilian Gärtner

How does nutrition affect inflammatory reactions? Dr Maximilian Gärtner (Freiburg/Breisgau), a dentist and nutritionist, noted that dietary patterns are considered the greatest risk factor for non-communicable diseases such as diabetes and cardiovascular disease/stroke – ahead of smoking and physical inactivity. As with periodontitis, these are ultimately chronic inflammatory diseases. Gärtner mentioned an overwhelming number of studies looking at the impact of nutrition. All those studies showed that simple carbohydrates – sugars, but also starches – increase oxidative stress. And Germans tend to eat a very starchy diet. Gärtner also examined periodontal parameters. Carbohydrates in particular promote the formation of plaque and the onset and further course of gingivitis, while fats, proteins, fibres, trace elements and antioxidants have the opposite effect. Gärtner's doctoral thesis focused on the effects of a diet optimised for oral health on oral and systemic inflammatory parameters in 30 subjects. The experimental and the control groups both initially had the same plaque values and performed no interdental hygiene. While the control group ate a diet high in carbohydrates, the experimental group ate a diet higher in fibre with nuts, raw vegetables, and vegetables from week 2 (of 8 in total). After 8 weeks, the experimental group showed a shift in macronutrients (protein, carbohydrates, fats) towards less carbohydrates and instead ate more fat and protein, which resulted in a 30% reduction in caloric intake and a significant increase in micronutrients such as vitamin E, K, B6, C, folic acid, and magnesium, and a reduction in salt intake by 70%. There was a 40% reduction in gingivitis in the experimental group, with the control group also achieving a reduction of 20%. To compare with conventional therapy, flossing has no benefit (Bercher et al., 2008), interdental brushing succeeded in reducing gingivitis by 34% (Poktepovic et al., 2013), and the optimal prevention approach shows a 50% improvement (Huguson et al., 2007). The latter study addressed the plaque index, yielding a reduction of 60–80%. "We did not even a 20% plaque reduction," Gärtner said. He therefore questions the "milestone" study by Löe and Theilade that states that if we did not brush our teeth for two weeks, we would get plaque and more inflammation. His dissertation reportedly even made it into the *New York Times*. – Gärtner pointed out that physicians could "prescribe" nutrition therapy. Through interdisciplinary collaboration, patients get a chance to make lasting changes to their diet, given expert support and sufficient time. "In this way, we as dentists – in addition to providing conventional perio therapy – can help our patients view their oral affliction as an opportunity to work on preventing other chronic inflammatory diseases." Gärtner is in contact with health insurers and the German Dental Association (BZÄK) to promote this new approach.

Conclusion

From periodontal rehabilitation to recession coverage and minimally invasive treatment, from prevention of peri-implant inflammation to nutrition as a new topic in the dental practice, the 17th Expert Symposium covered a lot of ground. This highly interesting continuing-education event truly succeeded in captivating its audience while addressing many new aspects of periodontal disease and its causes and treatments, with special reference to implantology.

The updated Cologne ABC Risk Score, as part of the presentation of the 17th Guideline of BDIZ EDI, can be found elsewhere in this issue.

AWU

Preview:

The 18th Expert Symposium will again be held in Cologne, on 19 February 2023. Topic: Update short, diameter-reduced and angulated implants. For more information on the topic, programme and registration, visit the BDIZ EDI website at www.bdizedi.org.

30th European Committee meeting in Cologne

Great demand for continuing education in implantology

Once again, the representatives of the partner associations of BDIZ EDI and invited guests met in 2022 on the occasion of the 30th Expert Symposium to exchange ideas. The one topic that dominated the Cologne meeting in early May was the situation of dentists in the various countries in the wake of the COVID-19 pandemic.

Members of the European Committee at the Dorint Hotel in Cologne.

The Committee consisted of the following participants: Christian Berger, Dr Renate Tischer and Anita Wuttke of the BDIZ EDI, Prof. António Felino (Portugal), Dr Fisnik Kasapi (Macedonia), Dr Davorin Šimunovíc and Dr Deni Milevcic (Croatia), Prof. Vitomir Konstantinovc (Serbia), Dr Zoran Marjanovic (Serbia), Dr Jan Willem Vaartjes (Netherlands) and Dr Eimear O'Connell (United Kingdom).

Reports by the different country representatives indicated that some countries had a shortage of serious events and organisers when it comes to continuing professional development (CPD) in oral implantology. ADI UK President Dr Eimear O'Connell reported that while there were many active providers in her country's CPD market, many young dentists would tend to implant too quickly without having obtained the necessary training. Prof. António Felino emphasized the high quality of dental care in Portugal, but also deplored the "flood" of dental graduates, which that country cannot absorb. In addition, the majority of those graduates would focus on oral surgery. Prof. Vitomir Konstantinovic confirmed for Serbia that the majority of CPD offerings in oral implantology are industry-driven. Dr Zoran Marjanovic, Vice President of USSI EDI, reporting on the Serbian situation, said it was difficult to find the right partners to implement a Curriculum Implantology on the BDIZ EDI model. Dr Fisnik Kasapi of EDI Macedonia lamented the perpetually changing North Macedonian governments that resulted in weak rule-making. At the present time, he reported, the dental association was trying to solve the anaesthesia issue caused by the practice of sedation being restricted to hospitals.

The problem of patients not seeking treatment due to the COVID-19 pandemic appears to be dissipating. There are enough patients – the problem is to find practice staff, said Dr Jan Willem Vaartjes. He is currently taking action against the Dutch antibiotics guideline, which intends to regulate the administration of antibiotics. For Germany, BDIZ EDI President Christian Berger reported on the German facility-based vaccination mandate.

Anita Wuttke thanked all participants for their commitment and cooperation in connection with *EDI Journal*, reporting that there had been a change of publisher. After many years of working with the previous set-up, BDIZ EDI has now switched publisher to OEMUS MEDIA in Leipzig.

AWU

Preview for 2023

The 18th Expert Symposium of BDIZ EDI and, hence, the 31st European Committee meeting will again be held in Cologne, on 18 and 19 February 2023. The BDIZ EDI will also be represented with its own booth at the IDS dental trade fair, to be held 14–18 March 2023 in Cologne.

Updated Cologne ABC Risk Score for implant treatment – Guideline 2022

Risk assessment at a glance

Among the many continuing professional development (CPD) events in the dental field, the Expert Symposium by BDIZ EDI – European Association of Dental Implantologists is an event that sets standards. After ten years, the paper on the Cologne ABC Risk Score has now been revised and updated. The 17th European Consensus Conference of BDIZ EDI (EuCC) conducted this year's proceedings using remote communication technology. Prof. Dr Jörg Neugebauer presented the results at the 17th Expert Symposium in Cologne.

Held in conjunction with the Expert Symposium, the European Consensus Conference (EuCC) discussed the topic "Cologne ABC Risk Score for Implant Treatment" As every year, the results of the Consensus Conference were condensed into a BDIZ EDI Guideline desivzgned to assist dental implantologists in assessing, ahead of time, in advance the individual complexity of a given implantological procedure, thereby contributing to minimizing risks associated with implant therapy.

On 26 April 2022, the EuCC, hosted by Professor Hans-Joachim Nickenig, discussed a working paper submitted by members of the University of Cologne. Using a simple ABC system, possibly and attractively visualized in four colours, clinicians are given the opportunity to assess the risk of their planned implant treatment.

There are four partial scores:
1. Medical history
2. Local findings
3. Surgical
4. Restorative

Each partial score is given a summary rating, with the results – like the criteria – expressed in terms of the colours green, yellow and orange, corresponding to A, B and C (Always – Between – Complex). If two or more criteria for a partial score are assessed as yellow (for B, medium risk), the entire partial score is deemed to be B (yellow, medium risk). Similarly, four yellow or two orange criteria result in an overall partial score of C (orange, increased risk). The ABC classification is defined as follows:

- **A = Always**
  lowest assessed risk, green
- **B = Between**
  medium risk, yellow
- **C = Complex**
  increased risk, orange

Red is reserved for cases where the risk assessment shows that treatment at issue may not be recommended (which is not the same as being contraindicated). "We do not want to issue any contraindications, but if a partial score is red, the therapy in question may not be recommended," Neugebauer said.

The overall patient assessment for the Cologne ABC Risk Score works as follows:

- If all four partial scores are green, the patient case as a whole is assessed as low-risk (A for Always).
- If at least two of the four partial scores are yellow, the patient case is assessed as medium-risk (B for Between)
- If all four partial scores are yellow, the patient case is assessed as high-risk (C for Complex). The same is true if at least two of the four partial scores are orange or yellow.

Compared to the previous version of the ABC Risk Score, Neugebauer pointed out, certain changes have been made, particularly in the area of medication. One innovation was the classification of antiresorptive drugs (ARD). At high doses, the respective partial score is assessed as red: no bone augmentation and no immediate implant placement recommended. Further drugs were included to reflect new developments in recent years. Local findings now incorporate the prevailing occlusal situation.

AWU

Info

The Cologne ABC Risk Score can be determined as a total score for findings and treatment planning or separately for the different partial scores. The Cologne ABC Risk Score developed by the 17th European Consensus Conference of BDIZ EDI is available to members as a download, including literature references, at www.bdizedi.org/en/european-consensus-conference/ or using the QR code in this box.

Bundesverband der implantologisch tätigen Zahnärzte in Europa

European Association of Dental Implantologists

Guideline 2022

Cologne ABC Risk Score for Implant Treatment (Update)

17th European Consensus Conference (EuCC) 2022

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1. Methods

1.1. Purpose

This updated Guideline was designed to help dental implantologists to assess, in advance, the individual complexity of a given implantological procedure, contributing to minimizing risks associated with implant therapy. It is an update of the 2007 Guideline.

1.2. Introduction

This consensus paper addresses the general aspects (i.e., those aspects not specific to a given implant design) of implant treatment to eliminate diagnostic and therapeutic uncertainties and to avoid complications. All consensus recommendations in this paper should be considered as guidelines only. The patient's specific situation is always an important consideration and may justify a deviation from the recommendations of this consensus paper.

1.3. Background

Since the first elaboration of the Cologne ABC Risk Score, overall medical treatment concepts with a bearing on implant treatment have evolved. For this reason, Partial Score (Medical history) had to be revised extensively- The more strictly implantological partial scores 2 to 4 were revised according to reflect the current state of our knowledge.

1.4. Literature search

The Cochrane Library, EMBASE, DIMDI and Medline literature databases were used to conduct the search. The searching strategy included selected search terms specific to the corresponding fields and issues. The studies returned by the search were screened by reading the abstracts. Studies found to be irrelevant to the subject were identified and excluded on this basis. All articles that were found to be (potentially) relevant were obtained in full-text form. Few if any randomized controlled trials (RCT) or other systematic clinical studies were available on the various topics.

1.5. Procedure for developing the Guideline/consensus paper

A first draft of the Cologne ABC Risk Score (authored by Professors *Hans-Joachim Nickenig, Joachim E. Zöller* and *Jörg Neugebauer,* Interdisciplinary Policlinic for Oral Surgery and Implantology and Department of Oral and Maxillofacial Plastic Surgery, University of Cologne, Director: Professor Joachim E. Zöller) was made available online to the members of the working group on the day of the consensus conference.
The agenda of the Consensus Conference consisted of four steps: Reviewing the preliminary draft; collecting alternative proposals; discussing non-consensual issues; final voting.

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2. Practical application of the Cologne ABC Risk Score

2.1. Introduction

Descriptions in the literature are limited mainly to classifications or scores applicable only to partial aspects of implant therapy (e.g., classifications for indications). There are only few classifications intended to assess the overall risk involved with a potential implantological patient case (e.g., the SAC Classification). The Cologne ABC Risk Score is intended to allow a professional assessment of an individual case with regard to medical history, local findings, surgical aspects and restorative aspects to be made simply and quickly and in a well-structured manner. Only a few scattered RCT on the subject matter of the partial scores were available at the time of the consensus conference. The studies that were available for review were mainly retrospective studies (evidence levels IIb/III), so the level of recommendation of these guidelines falls into class B (indicating "should"-type recommendations).

2.2. Principles of the Cologne ABC Risk Score (see enclosed form)

- Any evaluation or risk assessment using the Cologne ABC Risk 6core is made specifically for an individual patient.
- The Cologne ABC Risk Score can be assessed only by the treating physician (or team of physicians).
- The Cologne ABC Risk Score is unsuitable for assessing risks based on patient records or diagnostic casts.
- The Cologne ABC Risk Score can be determined as a total score for overall findings (medical history and local findings) and treatment planning (surgical and restorative).
- Partial scores of the Cologne ABC Risk Score can be used if appropriate (e.g., for restorative aspects only, in the case of patient referrals).

2.3. Evaluation of the Cologne ABC Risk Score

Each of the partial scores of the Cologne ABC Risk Score should be assessed as completely as possible.

2.3.1 Criteria

- Each criterion or issue within a partial score receives its own appropriate rating, where green stands for A (Always, lowest assessed risk), yellow stands for B (Between, medium risk) and orange stands for C (Complex, high risk)
- Red is strictly reserved for situations where the risk profile indicates that treatment may not be recommended (which is not the same as a contraindication).

2 3.2. Partial scores (Medical history – Local findings – Surgical – Restorative)

- Each partial score is given a summary rating, with the results – like the criteria – expressed in terms of the colours green, yellow and orange, corresponding to A, B and C (Always – Between – Complex).
- If two or more criteria for a partial score are assessed as yellow (for B, medium risk), the entire partial score is deemed to be B (yellow, medium risk). Four yellow or two orange criteria result in an overall partial score of C (orange, high risk).

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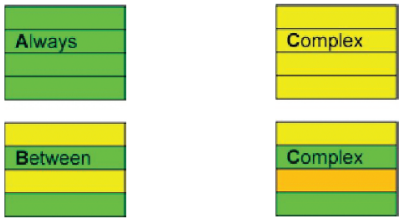
2.3.3 Overall assessment of a given patient case

- If all four partial scores are green, the patient case as a whole is assessed as low-risk (A for Always).
- If at least two of the four partial scores are yellow, the patient case is assessed as medium-risk (B for Between).
- If all four partial scores are yellow, the patient case is assessed as high-risk (C for Complex).
  The same is true if at least two of the four partial scores are orange or yellow.



Cologne, 7 May 2022

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PARTIAL SCORE 1: MEDICAL HISTORY

Health status	ASA classification [11]	ASA = 1, 2	
		ASA = 3	
		ASA ≥ 4	
Pre-existing conditions	diabetes mellitus [5, 15, 17, 18, 44, 45, 54, 55, 61, 78]	HbA1c < 6.5	
		HbA1c 6.5–7.5	
		HbA1c > 7.5	
	irradiated jaw [18, 25, 62, 79, 88]	< 55 Gy	
		< 55 Gy: maxilla or augmented areas	
		> 55 Gy	
		in past 12 months	
	periodontal disease [6, 21, 28, 53, 72, 76, 87]	no evidence of periodontal disease	
		treated or history of periodontal disease	
		inadequate supportive periodontal therapy	
		untreated periodontal disease	
Medications	no medication		
	anti-resorptive drugs (ARD) [7, 16, 40, 63, 67, 77, 81, 85]	lower dose, for osteoporosis (oral and systemic)	
		• low dose with bone augmentation, immediate implant placement	
		higher dose, for the prevention of osseous tumour-related complications	
		• higher dose with augmentation, immediate implant placement	
		high dose, > 4 × yearly for the treatment of osseous metastases	
		• high dose with bone augmentation, immediate implant placement	
		ARD and other infection risks (e.g., periodontal disease)	
		ARD and drug-related cofactors (e.g., immunosuppression)	
	immunosuppression [32, 33, 68]	low dose steroid therapy	
		cytotoxic medication	
	anticoagulation	prophylactic	
		therapeutic	
	proton pump inhibitors [1, 4, 27]		
Smoking [18, 24, 59]	non-smoker		
	mild smoking habit	< 10 cigarettes per day	
	severe smoking habit	≥ 10 cigarettes per day	
Bruxism [10, 22, 26, 49–51, 89]	no		
	yes		
Patient expectations [86]	appropriate		
	over-demanding		

KEY TO COLOURS

Small risk

Medium risk

High risk

Therapy not recommended (no AI)

PARTIAL SCORE 2: LOCAL FINDINGS

Aesthetic risk factors	outside the aesthetic zone		
	smile line [83]	low	
		medium	
		high	
Soft tissue	attached gingiva [14, 56]	adequate	
		inadequate	
	periodontal biotype [3, 35, 43, 46, 75]	thick biotype	
		thin biotype	
	previous surgeries/scar tissue		
Cologne Classification of Alveolar Ridge Defects (CCARD)	no or small defect		
	horizontal, > 4 mm		
	vertical or combined, > 4 mm		
	outside the alveolar ridge		
Jaw position	regular		
	unfavourable		
Periapical lesions, pathologies of adjacent teeth [31, 66, 69]	no		
	present		
Oral hygiene [29]	adequate		
	inadequate		

PARTIAL SCORE 3: SURGICAL

Anatomical risks [38, 80]	none		
	close proximity to adjacent structures (nerves, roots, papillae, etc.)		
Healing period after tooth loss [9, 19, 23, 37]	late implant placement		
	early or delayed implant placement		
	immediate implant placement		
Loading after insertion [13, 20, 37, 73]	conventional healing (at least 8 weeks)		
	early loading (within 4 to 8 weeks)		
	early restoration/loading (within 72 hours)		
Augmentation techniques [2, 57]	Cologne Classification of Alveolar Ridge Defects (CCARD)	no augmentation required	
		horizontal, > 4 mm	
		vertical or combined, > 4 mm	
		outside the alveolar ridge	
	sinus floor elevation [34, 48, 60]	with septae	
		Internal sinus lift with < 2 mm residual bone height	

PARTIAL SCORE 4: RESTORATIVE

Biomechanics [39]	no biomechanical problems expected		
	implant/tooth connection [12, 42, 47, 82, 84]	rigid	
		mobile	
	extension required [36, 70, 71, 74]		
	unfavourable load distribution [65] (crown-to-implant ratio/single-tooth restoration)		
	non-matching implant diameter [52]		
	need for repair, superstructure revision		
	multiple implant systems in same restoration		
Aesthetics [41, 52, 58]	adjacent tooth situation	tooth	
		pontic	
		Implant	
Type of restoration [39, 52, 64]	number and distribution of implants	adequate	
		not adequate	
	fixed restoration	cross-arch fixed restoration	
	removable	bridge design	
Complexity exceeding patient capabilities [64, 86]	handling or cleansability	favourable	
		difficult or impossible	

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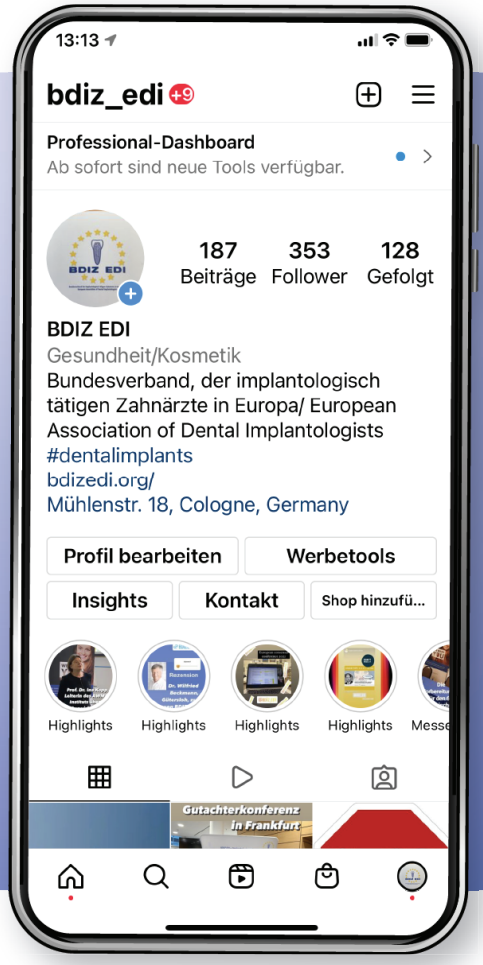
BDIZ EDI active on social media

@bdiz_edi: stay tuned

Instagram, Twitter and Facebook are all about capturing and sharing authentic, relevant and cutting-edge content. Today, the platforms have more than a billion users worldwide, including many dentists, dental technicians and dental assistants. BDIZ EDI seizes the chance to connect with its members and interested dental clinicians as well as collaborating associations and others worldwide via these communication channels. But the association is still at the beginning and needs your support.



More and more dentists and dental practices are using social media to help attract patients and build trust in their services. In fact, there are now several millions of posts online with the hashtag #dentist. As a non-profit organization in implant dentistry, BDIZ EDI is using this conversation and reaches out to dentists and dental practices with its Instagram account @bdiz_edi, its Twitter account @BDIZ EDI and its Facebook account: https://www.facebook.com/bdizediorg/. The primary aim is to improve the information channels on dental-related subjects. The social media accounts form part of a crossmedia campaign, which also incorporates the association's social media activities on Facebook, Twitter, Instagram and YouTube and is to be continued soon with other channels and information platforms like Wikipedia.

To provide information on a pan-European level and throughout, we would urge our members, friends and readers to follow us on the social media channels – so you always know what's going on in implant dentistry. Our topics will cover implant dentistry, hygiene in the dental office and of course new regulations coming from the European Union. Here we also launch information which is published in the EDI Journal in a brief manner. So take the opportunity and stay tuned with the BDIZ EDI social media.

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European Federation of Periodontology in Copenhagen

Most exciting EuroPerio ever

EuroPerio10, the world's leading congress in periodontology and implant dentistry organised in Copenhagen on 15-18 June by the European Federation of Periodontology (EFP), was proven to be the most exciting EuroPerio yet.

Professor Phoebus Madianos, chair of EuroPerio10, said: "EuroPerio attracts the best speakers, scientists, and clinicians from around the world to the Olympic Games of dental congresses. This is the main event organised by the EFP and the growing success of EuroPerio is mainly due to the scientific programme which delivers the present and future in the science and practice of periodontology and implant dentistry."

Key stats:

- More than 7,000 participants from more than 100 countries.
- 66% of participants under 45 years of age and 33% under 35 years.
- Original research presented in over 900 scientific abstracts.
- 41 scientific sessions on emerging issues of interest for practitioners, scientists and academics.
- Over 130 top speakers from more than 30 countries.
- 50% less printed materials than EuroPerio9.

Research was presented on novel topics such as the role of artificial intelligence in the diagnosis and treatment of periodontitis. New evidence was revealed on previously investigated areas including the links between gum disease and heart conditions, diabetes, premature birth and lung function, and the long-term outcome of periodontal treatment. Plus: the first European guideline on how to treat advanced (stage IV) periodontitis.

Professor Andreas Stavropoulos, EFP president, said: "The EFP is the global benchmark in gum health and gum diseases. The main mission of the EFP is to raise awareness about the importance of gum disease and gum health, and our motto is periodontal health for a better life. This is what we communicate to society and to politicians so that we can influence decision making and improve oral health. Our main educational activity is EuroPerio, and this edition has attracted a very young audience, which clearly indicated the interest in periodontology of the young generation of colleagues. While this edition has now closed its doors, we look forward to seeing the dental community at EuroPerio11 from 14 to 17 May 2025 in Vienna, Austria."

European guideline for the treatment of advanced periodontitis

Another highlight was the presentation of the first European guideline for the treatment of advanced periodontitis (stage IV). At the start of the world's leading conference on periodontology, EuroPerio10 in Copenhagen, the European Federation of Periodontology (EFP) presented the first European guideline for the treatment of stage IV periodontitis.

This new S3-level Clinical Practice Guideline (CPG) complements the S3 Guideline on the treatment of periodontitis in stages I to III, published in 2020. It includes recommendations for the treatment of patients with advanced periodontitis that were consented in November at an EFP Clinical Guideline Workshop led by Prof David Herrera (Madrid). "Systematic periodontal therapy alone is not sufficient to stabilize the dentition in severe cases of periodontitis. Therefore, oral rehabilitation usually requires a comprehensive multidisciplinary treatment, including any or all of prosthetic, implantological orthodontic measures", explains Prof Moritz Kebschull (Birmingham), member of the EFP Workshop Organizing Committee and guideline representative of the German Society of Periodontology (DG PARO).

The clinical diagnosis of advanced periodontitis (stage IV) includes five components:

1. Evaluation of the amount of periodontal breakdown and impairment of aesthetics and chewing and speech functions
2. Determination of the number of teeth lost due to periodontitis
3. Determination which of the remaining teeth can be retained
4. Evaluation of all oral factors that may complicate or favour the retention of teeth or the placement of dental implants, such as gaps between teeth or bone availability
5. Assessment of the patient's overall prognosis, including the likelihood of disease progression or recurrence, taking into account risk factors such as smoking and diabetes

"This detailed diagnostic process is essential. It allows us to design a multidisciplinary treatment plan based on what is technically and biologically feasible, as well as cost-effective, taking the patient's preferences and expectations into due account", said Prof Maurizio Tonetti (Shanghai), co-author of the guideline.

Portrait EFP

The European Federation of Periodontology (EFP, www.efp.org) is a non-profit organisation dedicated to promoting awareness of periodontal science and the importance of gum health. Its guiding vision is "periodontal health for a better life."

Founded in 1991, the EFP is a federation of 37 national perio-dontal member societies that represents more than 16,000 periodontists, dentists, researchers, and oral-health professionals from Europe and around the world. It supports evidence-based science in periodontal and oral health, and it promotes events and campaigns aimed at both professionals and the public.

Source: EFP

Marco Landi on the annual report of CED

Former president's perspective

The 2021 annual report not only concludes the year 2021, but also six years of Marco Landi's CED presidency. A few historical events marked these years: terrorist attacks in Brussels, Brexit, the COVID-19 pandemic, European Parliament elections and a new era in health, with the adoption of the first steps towards a European Health Union.

During this time, CED delivered 6 annual reports, 344 mailings, 22 surveys on COVID-19 and 40 approved policy documents, all important for CED lobbying on a national and European level. They reflect the breadth of our work and include dental tourism, corporate dentistry, advertising in dentistry; undergraduate education of dentists and continuing professional development (CPD); patient safety, vaccination and prevention; implementation of the Medical Devices Regulation and use of dental amalgam; eHealth including artificial intelligence in dentistry, access to patient records and online evaluations of dentists and others.

In his report, Landi mentioned two important messages for the dental profession. Firstly, the dental profession was probably at the highest level among all health professionals in tackling the pandemic, being able to deliver oral care at the same high-quality level of pre-COVID times. "The lowest infection rate among dentists is proving that we weren't caught by surprise and unprepared", he said.

Secondly, not only the CED realized that international collaboration and activity is important. The common European effort in the vaccination campaign, even if not equally successful everywhere, and above all the exchange of information on the pandemic evolution in different countries and on sharing protocols between us, has been of utmost importance. Marco Landi: "It proves that we must stay together and support each other: this is not an individual fight."

CED's growing influence

Throughout the last six years CED engaged with various stakeholders. Apart from the regular contact with the European Commission and the European Parliament, the CED was invited in 2021 to become an official stakeholder of the European Medicines Agency (EMA). CED was granted eligibility status and is now officially recognised as representative of the dental profession in the European Union. This is the first time that the European dentists' needs and concerns are represented via direct and formal contact with the EMA and it is a clear sign of the CED's growing influence in the contact with EU stakeholders. Moreover, CED established a close collaboration with the European Centre for Disease Control and Prevention (ECDC), working together on the topic of antimicrobial resistance and more recently on infection control protocols in dental practices.

The CED's relationship with dental organisations was maintained on a regular basis, with the European Dental Students Association (EDSA), the European Regional Organisation of the Fédération Dentaire Internationale (FDI ERO), the Association for Dental Education in Europe (ADEE) and the Federation of European Dental Competent Authorities and Regulators (FEDCAR). "We have been working closely with other healthcare organisations representing doctors (CPME), pharmacists (PGEU), veterinarians (FVE), on interprofessional education and the "One Health" concept and other common topics, such as vaccination", Landi emphasized.

As per Landi there are a strong board, chairs and liaisons, valuable members of the working groups and task forces and an efficient office in Brussels behind the CED activity.

"As the former CED president I look back at the last years with pride for our achievements, but I also look forward to new horizons awaiting our profession. I am confident that the challenges the CED will encounter will be overcome successfully. I wish good luck to the new president and board and all the best to my colleagues and friends", Landi concluded.

Source: CED President's report on 2021

Statement on e-evidence proposal

CED calls for exemption

At their meeting in September 2021, the board of directors of the Council of the European Dentists (CED) examined the developments related to the European Commission's Proposal for a Regulation on European Production and Preservation Orders for electronic evidence in criminal matters COM(2018) 225 (e-Evidence Regulation).

They concluded that the draft of the Regulation as it stands violates patient privacy and presents a serious threat to the ability of dentists to abide by the principles of professional ethics and medical confidentiality which form the core of the patient-dentist relationship.

The CED states in a press release to fully support the Standing Committee of European Doctors (CPME) in their position on the draft e-Evidence Regulation as laid out in the CPME Statement. The consequences of the draft Regulation for dentists would mirror the consequences faced by the medical profession. The CED joins the CPME in calling for an exemption to the scope of the Regulation for professions subject to professional secrecy.

The European Parliament's position on the cross-border gathering of "e-evidence" is confusing, unclear and inconsistent, according to the European Judicial Network, which is made up of EU member states' national contact points for criminal justice cooperation.

The proposed rules on "e-evidence" are intended to make it simpler for national authorities to obtain digital or electronic information held in another jurisdiction for use in criminal proceedings.

It is widely recognised that new rules on this issue are needed, but only with strict safeguards to ensure that data is only handed over in duly justified and necessary cases, and that strong safeguards exist – for example, for doctors, lawyers, journalists, and others with professional secrecy and confidentiality requirements.

The European Parliament adopted its position for negotiations with the Council of the EU in December 2020, making numerous amendments to the Commission's original proposal. Secret negotiations between the Council and the Parliament began recently.

The outcome of the parliamentary procedure was criticised by EDRi for potentially putting at risk the rights of journalists, doctors and lawyers, amongst other things. Meanwhile, the organisation warns, it is likely that the text will be further watered down, as "the Parliament will now have to accept further compromises in its negotiations with the Council."

Judicial practitioners are not happy either – although not necessarily for the same reasons. The European Judicial Network thinks that the Parliament's amendments "are not consistent within the Regulation and in the context of other legal instruments applicable in the EU Member States," and contains potentially confusing, unclear and inconsistent terminology.

Sources: CED press release, Statewatch, EDRi

About EDRi

EDRi is calling itself the biggest European network defending rights and freedoms online. The EDRi network is a dynamic and resilient collective of 45+ NGOs, as well as experts, advocates and academics working to defend and advance digital rights across Europe and beyond. Together, they build a movement of organisations and individuals pushing for robust and enforced laws, informing and mobilising people and promoting a healthy and accountable technology market. Among them is amnesty international.

Europe Ticker +++

Western sanctions on Russia

Frozen supply chain for dental materials

The Russian dental industry is almost entirely dependent on European and U.S. imports of equipment and materials, and now, facing a virtually frozen supply chain, dentists are scrambling to weigh the alternatives of potentially inferior treatments for patients – and having to raise prices. "Getting one's teeth treated has always been a luxury, and now even more so," says Inna, the owner of a dental clinic in the Siberian city of Krasnoyarsk. "No matter how much you care for your patients, it's impossible to keep the same prices." Inna says that every piece of dental equipment and material in her clinic is imported "without exception," listing fillings, implants, prosthetics, crowns, and cement, among other essential items. Where previously these would have been ordered from European suppliers, many in Germany and Italy, now the supply chain has all but dried up. Any chance to get their gloved hands on the supplies that they have relied upon for so long now requires dentists to pay exorbitant prices, but in many instances simply isn't possible. Some dentists were able to stockpile supplies at the beginning of March before many Western sanctions came in. Inna's clinic bought materials for the year ahead. The costliest service that dental clinics in Russia provide is arguably prosthetics, in particular implants. The field of implantology is fully dependent on imports and is now on the brink of going under.

Source: Radio Free Europe

WHO expectation

High levels of COVID-19 in Europe

The World Health Organization said Thursday it expected "high levels" of COVID-19 in Europe this summer and called on countries to monitor the spread as cases tripled in the past month. "As countries across the European region have lifted the social measures that were previously in place, the virus will transmit at high levels over the summer", WHO Europe regional director Hans Kluge told AFP. "This virus won't go away just because countries stop looking for it. It's still spreading, it's still changing, and it's still taking lives." With the milder but more contagious Omicron subvariant BA.5 spreading across the continent, the 53 countries in the WHO European region are currently registering just under 500,000 cases daily, according to the organisation's data. That is up from around 150,000 cases daily at the end of May. Austria, Cyprus, France, Germany, Greece, Luxembourg and Portugal were the countries with the highest incidence rates, with almost all countries in the region seeing a rise in cases. After registering around 4,000 to 5,000 deaths per day throughout most of the winter, Europe is currently seeing around 500 deaths per day, about the same level as during the summer of 2020. "We hope that the strong vaccine programmes most member states have implemented together with prior infection will mean that we avoid the more severe consequences that we saw earlier in the pandemic", Kluge said. The WHO urged people experiencing respiratory symptoms to isolate, to stay up to date with their vaccinations and wear masks in crowded places.

Source: WHO

High energy prizes

Can Europe cope with this?

Energy prices in Europe remain at a record high due to sanctions on Russian oil and reduced gas supplies. Electricity prices hovered around 218 euros per kilowatt hour on the exchanges this June, compared to 74 euros one year ago. And inflation also remains high in the Eurozone at 8.6 per cent. Europe's press worries about what the situation will be in the autumn and winter.

Source: Eurotopics

Oral health care in Europe

Financing, access and provision

Oral diseases are increasingly recognized as one of the most prevalent conditions in Europe, affecting nearly half of the European population. Despite their high prevalence, statutory coverage of dental care is limited in many European countries as evidenced by restricted service packages and high private funding compared to other health services. This Health Systems in Transition (HiT) review investigates a broad range of topics of oral health care across Europe, ranging from oral health and inequalities, coverage gaps, financial protection and unmet needs, preventive community care, workforce, corporate dentistry and cross-border care. The review identifies common trends and challenges in financing, access, coverage and provision of oral health care in 31 European countries and finds that:

- Oral diseases remain an important burden of disease despite decreasing prevalence in all age groups and stronger focus on preventive care.
- Data is lacking on virtually all areas of oral health care, particularly on the underlying causes and the prevalence of oral disease, as well as the effectiveness of community preventive activities and oral health services. This situation impedes informed policy making.
- Private expenditure plays an important role in many countries for covering dental care services. In particular for adults, public coverage is more limited on average than for children and other vulnerable groups.
- Dental care is the most frequent type of care for which people report unmet needs due to financial reasons particularly affecting vulnerable and low-income populations.
- There are large differences in dentists' ratios across European countries, but most countries have seen an increase of dentists which is associated with the growth of the private sector and increased cross-border dental tourism.

Sources: European Observatory on health systems and policies: Health Systems in Transition, Vol. 24 No. 2

Denmarks mink scandal

Cull lacking legal basis

A clear verdict has been reached by the parliamentary commission: the COVID-19 mass mink cull in Denmark lacked a legal basis. Senior officials and members of government now stand accused of serious omissions, and one of the parties that support Prime Minister Mette Frederiksen's social democratic minority government is now calling for new elections this autumn at the latest. For the paper Jyllands-Posten the responsibility clearly lies with Social Democratic Prime Minister Mette Frederiksen: "It is absolutely outrageous that so many civil servants in the most trusted positions in the country are risking disciplinary proceedings. It underlines the seriousness of the mink scandal. No stone must be left unturned. But when it comes to the relationship between the ministers and the civil service, it is not a very bold thesis that the problem Mette Frederiksen claims to want to solve will solve itself once she is gone."

Source: Eurotopics

Europe Dental Implants Market

To Surpass USD 2.5 Billion by 2028

Geographically, the Europe dental implants market is segmented into Germany, the United Kingdom, France, Italy, Spain, and the rest of Europe. The United Kingdom accounts for the largest market share in the Europe dental implants market owing to the presence of a strong dental healthcare system along with favorable reimbursement policies. Furthermore, rising demand for dental surgeries with increasing prevalence of various oral diseases is also propelling the demand for dental implants in the United Kingdom. However, France and Germany also account for a substantial market share.

Source: BlueWeave Consulting

EU Council presidency

France handed over to Czech Republic

France handed over the rotating EU Council Presidency to the Czech Republic. Under France's leadership, the focus was on issues such as the energy transition, the regulation of digital services and border protection, and Paris also called for a united stance on Russia's war against Ukraine. For Europe's press the results are mixed. The French president did not shine on every front during the six-month presidency, Le Monde comments: "The fact that the balance sheet is positive in many areas should not prevent us from questioning the limits of Emmanuel Macron's leadership role in a Europe where the balance of power is shifting. The desire of France's head of state 'not to humiliate' Russia and his efforts to maintain an open line to the Kremlin have weakened his authority in an area of the continent – Poland and the Baltic states – that advocates continuing the war until Russia is defeated, whereas France, Germany and Italy favour a more moderate course."

Source: Le Monde

ECJ ruling on dispensing over-the-counter medicines in other EU countries

Exceptions only in case of special medical needs

If a drug may be sold without prescription in one EU member state, this does not automatically mean that it may also be dispensed in other EU states, according to a decision by the European Court of Justice (ECJ) in Luxembourg.

A drug that is not subject to medical prescription in one member state may only be marketed in another member state if that state or the EU Commission also authorises its marketing. According to the ECJ ruling, exceptions are only possible if a special medical need exists.

The ECJ proceedings were triggered by a legal dispute in Hungary. A Hungarian company, Pharma Expressz, contested an official order to halt the distribution of certain medicinal products not covered by a special procedure. The competent Hungarian court requested an ECJ interpretation of the EU Medicinal Products Directive.

Under Hungarian law, the marketing of medicinal products that do not have a marketing authorisation granted by Hungarian authorities or the European Commission is subject to strict conditions. As the ECJ noted, the law stipulates that such uses for therapeutic purposes must be notified to the Hungarian authorities by the prescribing physicians, who must additionally obtain an opinion from these authorities on the intended application.

Violation of EU law?

Pharma Expressz had challenged the decision of the Hungarian authorities before the Fővárosi Törvényszék (Metropolitan Court of Appeal, Hungary), which asked the ECJ to clarify whether requiring compliance with these formalities ahead of marketing the respective medicinal products in Hungary where the same products were approved for dispensation without medical prescription by another member state, was not contrary to European Union law.

No distribution without authorisation

The ECJ pointed out that under the Medicinal Products Directive, a medicinal product may not be placed on the market in a member state unless and until marketing authorisation has been granted by the competent authority of that member state or by the Commission in accordance with the centralised procedure provided for that purpose. Thus, if a medicinal product does not have either (1) a marketing authorisation granted by the competent authority of the member state in which it is offered or (2) a marketing authorisation granted in accordance with the centralised procedure, it may not be dispensed in that state – regardless of the fact that the product may be legally available without a medical prescription in another member state.

No application filed for recognition

The ECJ further notes that the procedure for mutual recognition of a marketing authorisation as provided for in the Medicinal Products Directive is performed under strict conditions and requires for the holder of a marketing authorisation for a given medicinal product in one member state to submit an application for recognition of that authorisation in the other member state or states – which does not describe the circumstances of the case at hand. Consequently, not only does the Medicinal Products Directive not require that, if a medicinal product has been authorised by one member state to be marketed as a non-prescription medicinal product, this product must also be regarded as a non-prescription medicinal product by another member state in which no pertinent marketing authorisation has been issued – on the contrary; the Directive precludes that very possibility.

Exception properly implemented in national law

Finally, the ECJ noted that the formalities established by Hungarian law appeared to be the transposition into Hungarian law of an exception provided for in the Medicinal Products Directive, which allows the dispensation of medicinal products in a member state in order to meet special medical needs, even in the absence of a marketing authorisation granted by that state or by the Commission.

However, since Hungary has properly transposed (implemented) this exception by introducing the above formalities, these formalities cannot be classified as quantitative restrictions on imports or as measures that have an equivalent effect with regard to the principle of the free movement of goods.

Sources: ECJ press release of 8 July 2021
Judgment in Case C-178/20

Did you ever know…

…that BDIZ EDI

…offers online seminars for all associated partner organisations for free and on demand? There's still a strong need of information among dentists and implant dentists all over Europe. Topics can be infection control, hygiene, but also a need for updates on peri-implantitits, on digital Implantology, short, angulated and diameter-reduced implants, on bone augmentation and many more.

For more information contact our office:
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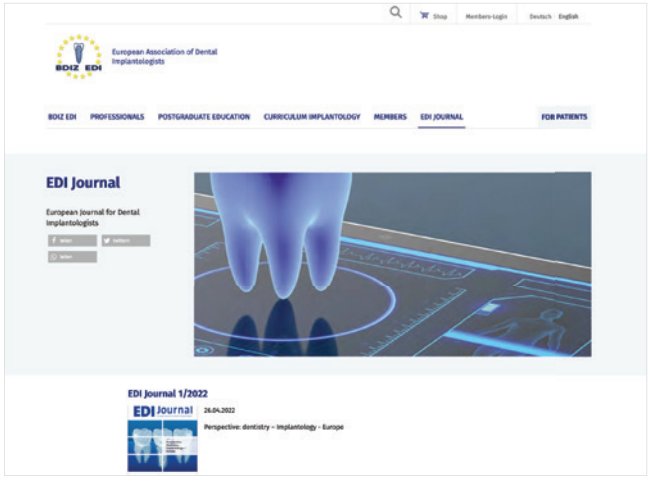

…that EDI Journal

…covers the hot topics in the field between science, human medicine and dentistry? For example: EDI Journal 4/2020 gave exciting insights into stem-cell research, especially when it comes to regrowing teeth. In 1/2021 we gave a glimpse on the value of vitamin D in dentistry and the possible necessity of supplementing the substance when it comes to augmentation and/or implantation. Don't miss the editorials in EDI Journal for the dental office.

For more information see https://bdizedi.org/en/edi-journal/

…that BDIZ EDI

…will hand out once a year a guideline on specific implant topics. 2022 the European Consensus Conference (EuCC) under the auspices of BDIZ EDI discussed the Cologne ABC Risk Score on implant therapy (paper is being published in this issue). 2023 topic will again be the short, angulated and diameter-reduced implants.

For more information see https://bdizedi.org/en/european-consensus-conference/

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European Medical Device Regulation (MDR)

Waiting is not an option

The Medical Device Regulation was on the agenda at the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) in mid-June, where the health ministers of the European member states discussed implementation problems. However, the EU Commission will probably not present any solutions until the end of 2022. "It is a good thing that the EU Commission and the member states are taking the concerns of clinics, doctors and med-tech companies seriously and striving for pragmatic solutions. But: Waiting is not an option! We need concrete solutions and measures now and cannot wait until the EU Commission's next status report in December 2022", said Dr Marc-Pierre Möll, Managing Director and board member of the powerful German Medical Technology Association (Verband Medizintechnologie, BV-Med), commenting on the outcome of the meeting.

Only 1,000 MDR certificates issued so far

BV-Med welcomes the fact that EU Commissioner Stella Kyriakides has recognized and identified the problems at the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) and that a full 18 member states have spoken out in favour of pragmatic solutions. Only 1,000 MDR certificates have been issued so far, said the Commissioner. By the end of the transition period in May 2024, however, some 24,000 certificates will expire. She said that action must be taken quickly and decisively, that manufacturers must submit applications, while the Commission must also ensure that sufficient capacity is available on the part of the Notified Bodies. Kyriakides referred to solutions already discussed: relieving the burden on Notified Bodies; focusing on MDR certifications; easing the transition for manufacturers; working with hybrid audits. The Commission is monitoring

MDR-related developments and will provide an update at the next meeting, to be held at the end of the year. "However, what is needed now is not announcements, but harmonized and pragmatic solutions across Europe involving the medical device industry, as suggested by Austria", Möll said. "This is where the Commission has a responsibility – now and not in December 2022."

BV-Med supports the statements by the Irish representative and by Dr Thomas Steffen, German secretary of state, that the EU Commission must coordinate Europe-wide solutions and ensure simpler solutions and the cutting of red tape. "But we need these measures now. We need action, not announcements", Möll insisted.

BV-Med proposes "conditional certificates"

BV-Med had already presented three potential solutions the week before the meeting to address the problems in implementing the MDR:

- Increased capacity: increasing resources at Notified Bodies; expediting notification of additional Notified Bodies
- Expedient deployment of existing capacities: pragmatic grandfathering-in transfer of "legacy devices" (existing products under the old MDD guidelines) by issuing conditional certificates; exemptions for niche products; sufficient resources for innovations
- More time: postponing the deadlines if the measures cited are not sufficient

According to BV-Med, capacity bottlenecks at the Notified Bodies are the main problem. Increasingly, applications by manufacturers are rejected for lack of capacity, or existing long-term contracts are being terminated. The average duration of the certification process is about 18 months. Given a transition period until May 2024, this would mean that business decisions – such as on what medical devices should be withdrawn from the market – would have to be made by the third quarter of 2022 at the latest. "If we don't take political action, healthcare will be jeopardized, and we may completely lose an estimated 10 per cent of manufacturers in Germany and Europe – especially small and medium-sized ones who account for 30 per cent of the overall product inventory and for much of the power of innovation. That's why we need solutions now!"

At the EPSCO meeting, the Medical Device Regulation was also on the agenda. The problems with the implementation of the EU MDR were discussed extensively. However, concrete solutions and measures on the part of the EU Commission are not expected to be presented until the end of 2022.

AWU

BDIZ EDI's point of view

It was even before the Corona pandemic when BDIZ EDI demanded a delay of two to three years to ensure the MDR's viability. Unfortunately, the MDR has been in force since 26 May 2021. All predicted implementation problems came true. BDIZ EDI welcomes the fact that the EU Commission is moving. However, time was too short to guarantee the functionality of the MDR. Among other things, there is still a lack of Notified Bodies and a non-functional central EUDAMED database. None of the objectives of the MDR can be achieved, even though EUDAMED was postponed. 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 steam of new and innovative products dries up. Our fear still is that especially small and medium-sized manufacturers of medical devices will be at risk.

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 whichachieve 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 intendedto 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 notified 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.

Customised 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.

Customised 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 customised products are, for example:
- ready-made teeth
- industrially produced attachment elements
- implant components.

Customised 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 customised 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 customised 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.

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BDIZ EDI

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

Manufactured by / manufacturing address

Prescribed by

Name and address of the prescribing dentist

Medical device (type)

Precisely describe specification and/or product as per MDR and if appropriate give additional information e.g. order number, hardware and materials.

Patient's name to include specific patient number

This custom-made product is used for the above patient only.

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

This date

Released on

Provided by

Released by (proprietor dental lab)

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

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Certification as an EDA Expert in Implantology

Qualification for experienced implantologists

For many years, BDIZ EDI has been catering to experienced and well-versed oral implantologists by offering the certification exam for EDA Expert in Implantology. Jointly with the European Dental Association (EDA), BDIZ EDI regularly invites interested dentists to take the certification exam, which we would like to present in this article.

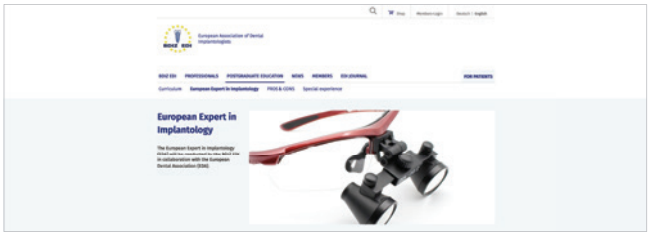
That quality is of paramount importance to BDIZ EDI is no secret. BDIZ EDI has demonstrated this in many different areas – legal and accounting, materials testing, postgraduate education, the annual Guidelines of the European Consensus Conference (EuCC) on current implantological issues and finally the qualification of court experts. BDIZ EDI also supports dental education with its Curriculum Implantology that introduces aspiring dentists and young implantologists to this dental specialty in eight well-organized modules.

Admission requirements for the certification exam

Certification as Expert in Implantology requires very good to excellent skills and knowledge. Candidates must meet the following admission requirements:

- 250 EDA-recognized continuing education/training hours in various sub-disciplines of implantology
- Submission of ten documented, independently performed implantological treatment cases
- At least five years of professional activity, primarily in the field of implantology.

Specific experience and primary activity in the field of implantology must be documented by at least 400 implants inserted and



150 implants restored within the past five years. Candidates who already obtained qualifications in oral implantology (eg from other professional societies) may submit the appropriate credentials with their application for certification as EDA Expert in Implantology.

The exam

Candidates meeting all the requirements will be admitted to the examination. The examination board of BDIZ EDI and EDA consists of recognized specialists. The exam has a theoretical and a practical part, both of which must be completed successfully. The procedure is as follows: The theoretical part of the exam will start with a discussion of the documented cases. In addition, candidates are expected to answer questions related to oral implantology and closely associated fields. The theoretical examination usually takes no longer than 60 minutes; it may be administered to candidates in groups. The practical part of the examination covers one or more recognized, state-of-the-art treatment method or methods and/or treatment plans covering some aspect of oral implantology. Candidates will be informed of the respective topic two weeks before the exam date. Candidates are responsible for providing the required materials and instruments on the day of the exam. The examination as a whole is subject to a fee to cover the cost incurred by the examination board.

New EDA Experts in Implantology are nominated by the president or vice president of the EDA certification committee.

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More information

To register for the next certification exam, please go to www.bdizedi.org and select English > Professionals > Expert or write to the BDIZ EDI office in Cologne at office@bdizedi.org.

Applicant's address:

Full name: .....

Full address: .....

.....

.....

E-mail: ..... Date: .....

Forward by mail or fax to:

European Association of Dental Implantologists (BDIZ EDI)
Mühlenstr. 18
51143 Köln
Germany

office@bdizedi.org
Fax: +49 2203 9168822

Certification exam: EDA Expert in Implantology
Application for accreditation

I hereby apply for the EDA Expert in Implantology certification exam (EDA = European Dental Association).
I am qualified for this exam as defined below:
Member of BDIZ EDI ☐ yes ☐ no
Member of the following Societies/Associations: .....
I am: ☐ a dental clinician ☐ an oral surgeon ☐ a maxillofacial surgeon
I meet the training requirement of 250 hours of postgraduate education. ☐ yes ☐ no

Education and experience:

Surgery:

Inserted implants:	☐ less than 400	☐ more than 400
Sinus lift:	☐ yes	☐ no
Close to nerve:	☐ yes	☐ no
Advanced atrophy of the jaw:	☐ yes	☐ no
Soft-tissue augmentation:	☐ yes	☐ no
Bone augmentation:	☐ yes	☐ no

Prosthodontics:
Implant-supported restorations: ☐ less than 150 ☐ 150 or more
During the exam, I will be able to present documentation for 10 treatment cases. ☐ yes ☐ no

I understand that the examination board will review my qualifications and vote to accept or reject my application. Furthermore, I declare that all images I present are my own and that the implants have been inserted and prosthetically restored by me.

....
Applicant's signature Date

Having successfully passed the exam and paid the requisite fee, I will be certified as EDA Expert in Implantology.

Part 2 and conclusion of the overview of the portrayal of the dental profession in German feature films

Dentists in German motion pictures

Fig. 4: Stadtgespräch ("Talk of the Town", 1995), still image. Originally a TV production (ZDF). Directed by Rainer Kaufmann, with August Zirner as a dentist. © Buena Vista International. Courtesy of Herbert Klemens, Filmbild Fundus.

West and East Germany (1964–1989)

In the mid-1960s, cinema and dentistry were moving in different directions. Dentistry broke new ground with technical innovations such as turbines (about 1965), laser instruments (after 1970) and surgical microscopes (after 1975) [Strübig, 1979]. The film industry had to cope with an increasing number of theatre closures. TV, while not the only culprit, played a major role in this development on both sides of the Iron Curtain. The two German states employed different strategies to support the film industry [Faulstich, 2005; Müller, 2016].

Nevertheless, the incidence of dentist characters in films – about one per year – remained unchanged in this quarter-century period. But especially West German cinema experienced a serious decline in respectability for the dentist characters depicted. Dentists were almost always featured in B pictures, soft porn and nonsense thrillers – dentists as slapstick figures incarnate. A welcome relief

No.	Title	Year	Director
4–1	Und sowas muss um acht ins Bett ("In Bed By Eight")	1964	Werner Jacobs
4–2	Alfons Zitterbacke (DEFA) ("Alfons Zitterbacke"; DEFA)	1966	Konrad Petzold
4–3	Kinderarzt Dr. Fröhlich ("Dr Fröhlich, Paediatrician")	1971	Kurt Nachmann
4–4	Wenn die prallen Möpse hüpfen ("When plump boobs bounce")	1973	Ernst Hofbauer
4–5	Eva und Adam (DEFA) ("Eve and Adam"; DEFA)	1973	Horst E. Brandt
4–6	Nelken in Aspik (DEFA) ("Carnations in Jelly"; DEFA)	1976	Günter Reisch
4–7	Der kleine Zauberer (DEFA) ("The Little Magician"; DEFA)†	1977	Erwin Stranka
4–8	Einer muß die Leiche sein (DEFA) ("Someone Has to Be the Body"; DEFA)	1978	Iris Gusner
4–9	Deutschland bleiche Mutter ("Germany Pale Mother")†	1979	Helma Sanders-Brahms
4–10	Nicki* (DEFA) ("Nicki"; DEFA)*†	1979	Günther Scholz
4–11	Aber Doktor (DEFA) ("Well, Well, Doctor"; DEFA)	1980	Oldrich Lipský
4–12	Der Keiler von Keilsberg (DEFA) ("The Boar of Keilsberg"; DEFA)	1980	Peter Hill
4–13	Die Pinups und ein heißer Typ ("The Pinups and a Hot Guy")	1981	Yoel Silberg
4–14	Gemischter Salat – French Dressing (verschollen) ("Mixed Salad – French Dressing"; film has been lost)	1981	Erwin Kneihsl
4–15	Frevel (verschollen) ("Mischief"; film has been lost)†	1981	Peter Fleischmann
4–16	Die Olympiasiegerin ("The Olympic-Winning Lady")†	1983	Herbert Achternbusch
4–17	Super ("Super")	1983	Adolf Winkelmann
4–18	Die lieben Luder (DEFA) ("Dear Sluts"; DEFA)	1983	Helmut Krätzig

Table 4: Feature films with dentist motif (1964–1989).

DEFA = Deutsche Film AG, East Germany
** Featured dentist is a woman*
† Film appears to actually have shown in English under this title [translator's note]

from this depressing state of affairs was the West German drama film Deutschland bleiche Mutter ("Germany Pale Mother", 1980) by Helma Sanders-Brahms; the film title alludes to a poem of the same name by Bertolt Brecht with the famous line "What have your sons done to you?" This retrospective recounts the tragic love story of Lene and Hans, who married and had a child shortly before the start of World War II. By the time Hans finally returns from captivity, self-confident Lene is no longer the "little wifey" he thought he left. But Lene cannot win the ensuing relationship struggle and "loses her face", cinematically expressed by the appearance of facial paresis. To prevent the progression of the supposedly odontogenic paralysis, all her teeth are expertly removed in infiltration anaesthesia in a depressingly protracted scene. Scholars of film history interpret the female lead as an allegory of a Germany violated by the Nazi era and the war [Sanders-Brahms, 1981]. The tooth extraction scene represents the frightening climax of an emancipation drama – a documentary image of the time, personifying an strong-willed woman symbolically silenced by mutilating her dentition, with the (male) dentist acting as a vicarious agent of a patriarchal society.

The role of the dentist found an interesting niche in East German cinema. No fewer than three chil-

No.	Title	Year	Director
5–1	Der Streit um des Esels Schatten (DEFA) ("The Dispute About the Donkey's Shadow"; DEFA)†	1990	Walter Beck
5–2	Schramm ("Schramm: Into the Mind of a Serial Killer")†	1993	Jörg Buttgereit
5–3	Stadtgespräch ("Talk of the Town")	1995	Rainer Kaufmann
5–4	Die Apothekerin ("The Pharmacist")†	1997	Rainer Kaufmann
5–5	Zurück auf Los* ("Return to Go")†	2000	Pierre Sanoussi-Bliss
5–6	Suck my Dick* ("Suck my Dick")*†	2001	Oskar Roehler
5–7	Mutti – der Film* ("MoM – The Movie")*	2002	Klaus Purkart et al.
5–8	Halbe Treppe ("Grill Point")†	2002	Andreas Dresen
5–9	Frau fährt, Mann schläft* ("Woman Driving, Man Sleeping")*†	2004	Rudolf Thome
5–10	Mädchen Mädchen 2 – Loft oder Liebe ("Girls on Top 2")*†	2004	Peter Gersina
5–11	Glück auf halber Treppe ("Halfway Landing Happiness")	2005	Thomas Jacob
5-12	Check it out (verschollen) ("Check It Out"; film has been lost)	2005	Michael Stelzer

Table 5: Feature films with dentist motif (1990–2005).

DEFA = Deutsche Film AG, East Germany
** Featured dentist is a woman*
† Film appears to actually have shown in English under this title [translator's note]

dren's films presented a dentist character, and an even female dentist appears in Nicki ("Nicki", 1979) [Schenk, 1994].

Quite a few films from this period are still accessible films, but their overall characterisation can be brief. Any dentists shown almost always play only a supporting part, designed mainly to entertain the audience. The dentist character is generally marginalised, and it is hardly possible to make any general statements about the film's authenticity, implicated character types, or dramaturgical functions. Strikingly, whereas more than 20 per cent of real-world dentists in West Germany and more than 50 per cent in East Germany were female at the time [Groß, 2019], the female dentist in Nicki remains the only representative of its gender.

Germany after reunification (1990–2005)

After the pivotal fall of the Berlin Wall (1989), screen heroes increasingly appeared on digital media rather than on celluloid. Like all of East Germany, the country's only film company, DEFA, had become history. Film theatres adapted to growing competition from VHS tapes, DVD discs and other electronic media by presenting new architectural ventures and globalised offerings [Trümper, 2006]. At the same time, the digital transformation made for radical changes within the practice of dentistry [Davidowitz/Kotick, 2011]. Basic research became paramount, while patients' needs, the range of dental specialties, and the overall economic framework also changed significantly.

But dentist parts continued to be sidelined in social satires, family tragedies, thrillers, and even a horror film (Table 5). However, a new level of realism had set in to replace earlier aberrations (Fig. 4), and the cliché of the (supposedly) wealthy dentist began to crumble. The "quota" of close to one dentist character per year remained constant as the female share increased somewhat. Out of thirteen relevant productions one featured a female dental student and four featured a female dentist, with Hannelore Elsner, Ulrike Folkerts and Doris Dörrie (Fig. 5) among the most prominent actors. These female dentists were shown as urban, professional and empathetic and almost invariably worked with an assistant – just like their male colleagues, who were mostly cast in supporting roles. Tooth extrac-

tion also experienced a cinematic renaissance, now under perfect hygienic and anaesthetic conditions. In a world of hepatitis B and AIDS infections [Hardie, 1983; Modarresi-Tehrani, 2000], face masks, gloves and protective eyewear had become as much a standard part of the dental attire in films as the back-closure gown had once been. Directors now actively sought to document for audiences the dental standards that had been achieved. However, both male and female screen characters had long been overshadowed by their television competitors. More than twenty dentists were depicted in TV films and series of the same period [Petzke, 2009].

The 21st century (2006–2018)

The new millennium offered cinema dentists less and less room on the big screen (Table 6). This is partly due to the continuing popularity of their TV counterparts. But the previously stable theatrical "quota" of one dentist character per year dropped significantly (4 in 15 years). There were also gender fluctuations; while the first five years still featured an astonishingly high proportion of female dentists (5 out of 8) (Fig. 6), their male colleagues again dominated the cinematic scene again in the following years (3 out of 4), although the only film depicting a female dentist at least showed her in the lead role.

The majority of more recent productions belonged to the drama genre; the rest had a mostly humorous tone. The dental profession itself was rarely the focus of dramatic entanglements. Only in Was bleibt ("What Remains", 2012) did the financial venture of opening a dental practice fuel the overarching conflict. In the other four recent productions, dentists' activities were characteristically stigma-

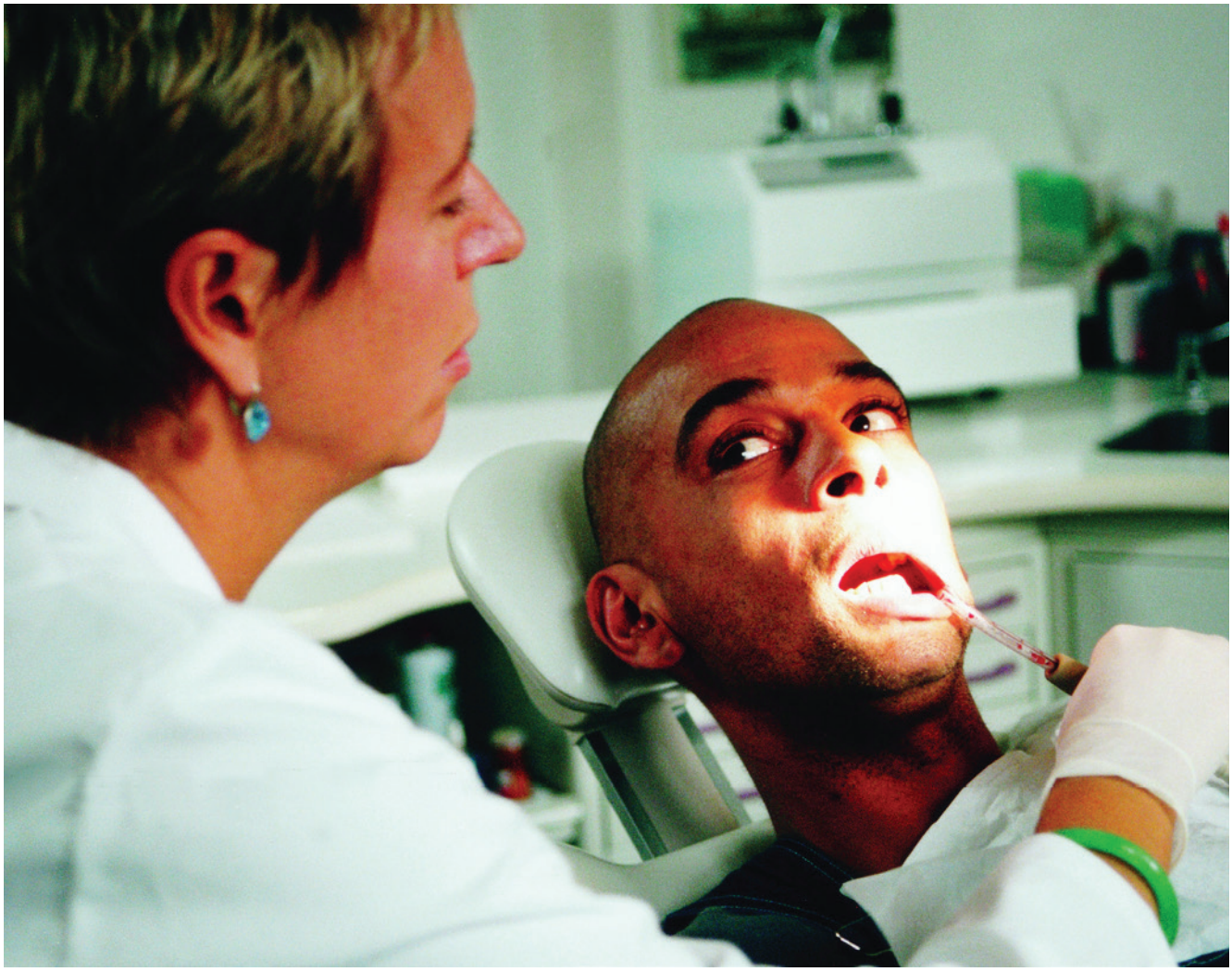

Fig. 5: Zurück auf Los! ("Return to Go", 2000), still image. ö Filmproduktion GmbH in cooperation with ZDF. Directed by Pierre Sanoussi-Bliss, with Doris Dörrie as a dentist. © Pro-Fun. Courtesy of Herbert Klemens, Filmbild Fundus.

No.	Title	Year	Director
6–1	Was bleibt* ("What Remains")*	2012	Hans-Christian Schmid
6–2	Lügen und andere Wahrheiten ("Lies and Other Truths")	2014	Vanessa Jopp
6–3	Schneeflöckchen ("Snow Flake")†	2017	Adolfo J. Kolmerer, William James
6–4	So viel Zeit ("Comeback")†	2018	Philipp Kadelbach

Table 6: Feature films with dentist motif (2006–2018).

DEFA = Deutsche Film AG, East Germany
** Featured dentist is a woman*
† Film appears to actually have shown in English under this title [translator's note]

tised – as a rather oppressive daily routine, part of a mundane life better left behind, or the essence of a petrified life to break away from. In Lügen und andere Wahrheiten ("Lies and Other Truths", 2014), dissatisfied patients torment an already stressed dentist to the point where treatment incidents occur (a slip of her drill). The dentist suffers a nervous breakdown due to her mishap and has to be calmed down by a paramedic.

Dentist in films thus did not seem to lead much of a fulfilling professional life, feeding a negative connotation; moreover, filmmakers readily and repeatedly exploited the pain and fear component associated with dental treatment for dramaturgical purposes. Unsurprisingly, it was mostly the dental drill that became an object of fear. Schneeflöckchen ("Snow Flake"), went so far as to show the dentist being tortured with his own instrument by two crooks who had barged into his practice. And in So viel Zeit ("Comeback", 2018), the dentist character even intimidates an adversary by threating extraction: "[or else] ... I'll pull out all your teeth one at a time without anaesthesia." This intentional staging of dental treatment as a moment of fear seems to have been borrowed from the US cinema tradition [Mariño, 2017] that had hesitantly found its way into the German cinematic landscape.

Nevertheless, the fictional dentists, their treatment rooms and their instrument are still portrayed in an authentic light, with attention to detail and proper hygiene. The treatments themselves are not accorded much space. The audience sees two short sequences with caries treatments, and once a prosthetic procedure is hinted at as a crown is being adjusted. Finally, in Schneeflöckchen ("Snowflake", 2017) a patient sits in the waiting room with a circular lip and cheek retractor in place, in anticipation of professional tooth cleaning.

The last 15 years have once again transformed the image of dentists and dentistry on the screen. The significant decline in extant productions, in addition to competition from TV movies, is owed to the emergence of increasingly elaborate TV and streaming series. The earlier minor boom in screen dentists seems to be fading. However, given the limited number of films produced, this may be a historical blip and may well change again.

Conclusion

Across more than a century of cinema history, dentists have been and continue to be present on the screen. Famous and less famous directors devoted themselves to the character or role, represented by quite a few famous actors. Across all cinematic incarnations – including German TV productions – more than 100 of these characters were created. Both male and female dentists appeared in almost all genres, with comedies their preferred screen biotope, even though dental activities and treatments per se contain no exhilarating elements – the silent film era excepted. Screen dentists generally acted in supporting roles and were often shown in the exercise of their profession. The role of dentist has been put to versatile dramaturgical uses, and it is probably no overstatement to say that dentists play "the most important supporting role in German cinema history".

Advances in dentistry are certainly reflected in those fictional representations, if rarely without considerable delay. Throughout the period considered, conservative and surgical treatments were more or less equally prominent while prosthodontics and prophylaxis were marginalised and orthodontics and oral surgery were ignored altogether – not least because the inherent rules of the screen film prevailed over the experience of dental practice.

Fig. 6: Mädchen, Mädchen 2 – Loft oder Liebe ("Girls on Top 2", 2004), still image. Directed by Peter Gersina, with Karoline Herfurth as an aspiring dentist. © Constantin Film. Courtesy of Herbert Klemens, Filmbild Fundus.

With few exceptions, screenwriters and directors long denied female dentists a cinematic presence, whether in the Nazi era or in the postwar period, whether the West or the East, all the while their share of practising dentists has been steadily increasing in real life. Only since the mid-1990s have female film dentists become part of the norm. Motion pictures not only reflect specific aspects of reality; they also create their own reality. By virtue of their powerful images and stories, they shape the image of a professional group. All in all, the fictional treatment providers appear professional and authentic – and are still appreciated by audiences today.

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A periodontal and restorative success formula

Rehabilitation of a failing central incisor

Dr Rita Singh, Nepal

Introduction

Rehabilitation in the anterior zone with implant-supported restorations is a daunting task. Implant-supported rehabilitation in the anterior maxilla requires seamless merging of the restoration with the existing gingival architecture. Therefore, prosthetically driven implant placement is of utmost importance in achieving the aesthetic goal. Implant success is not limited to osseointegration alone but is mainly dependent on the aesthetic outcome. Another important factor influencing success of the procedure is the quality of hard and soft tissue available at the time of treatment planning. This periodontal assessment is the crux of aesthetic zone management in cases which require augmentation procedures with immediate implantation. The hard and soft tissue form the peri-implant seal which is crucial for the long-term success of the implant restoration. Immediate implantation has become the preferred option for cases in the anterior zone, as it prevents post-extraction ridge collapse and hence maintains optimum bone and soft-tissue quantity and quality for favourable outcomes. Immediate provisionalisation of the implant maintains acceptable function and aesthetic appearance simultaneously, providing a template for soft-tissue contouring and maturing until a definitive restoration can be integrated. The implant serves as a placeholder to prevent migration of neighbouring teeth and extrusion of opposing teeth. Favourable implant success, peri-implant tissue response and aesthetic outcomes can be achieved with immediately placed and provisionalised maxillary anterior single implants.[1] A favourable visual result is a combination of a well-planned and executed surgical technique along with good prosthetic choices and operator skill. The following case report showcases the complete rehabilitation of an ailing maxillary central incisor with an implant-supported restoration.

Case report

The patient presented with the chief complaint of discomfort and mild mobility of the maxillary left central incisor and gave a history of trauma to the same jaw region about ten to twelve years before that had led to avulsion of the same tooth, following which the tooth was replanted. The right central incisor showed purple discoloration and required endodontic retreatment (Fig. 1)

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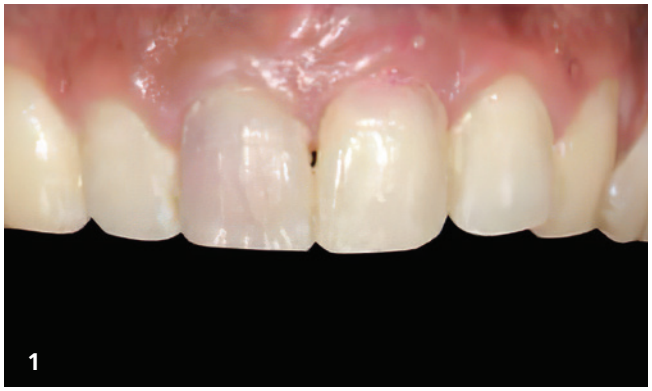
Radiographic investigations

A CBCT scan was done for planning the treatment. Tooth #21 revealed a fenestration in the middle third of the root (Fig. 2). Based on the clinical and radiographic findings, extraction of tooth #21 with immediate implant placement and loading was decided on. A putty index was made to record the existing morphology of tooth #21. Guided bone regeneration and



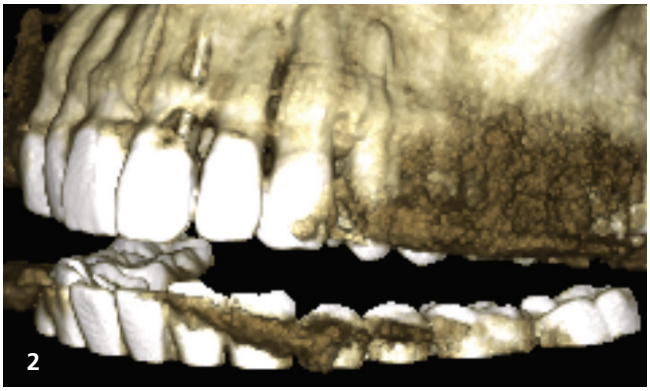
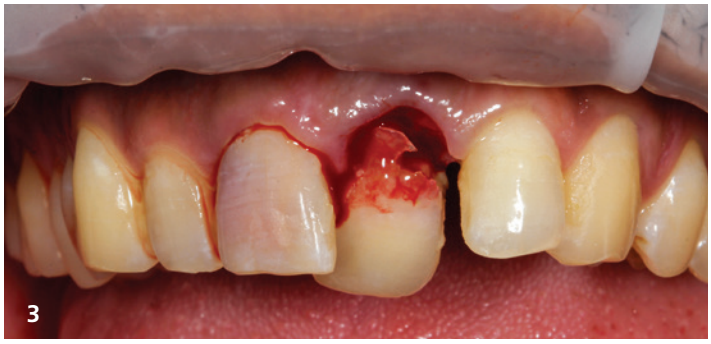
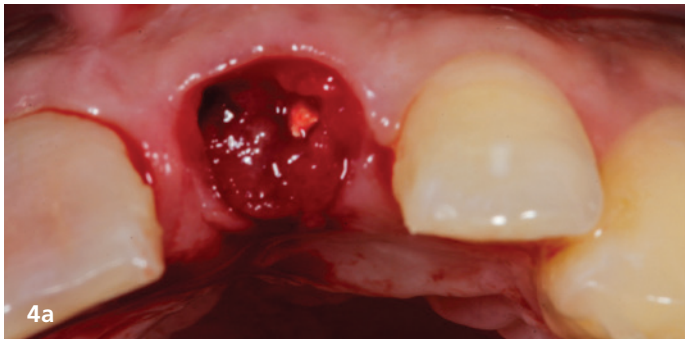
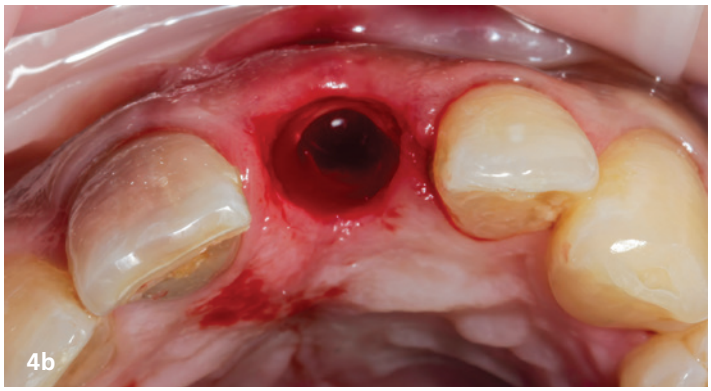
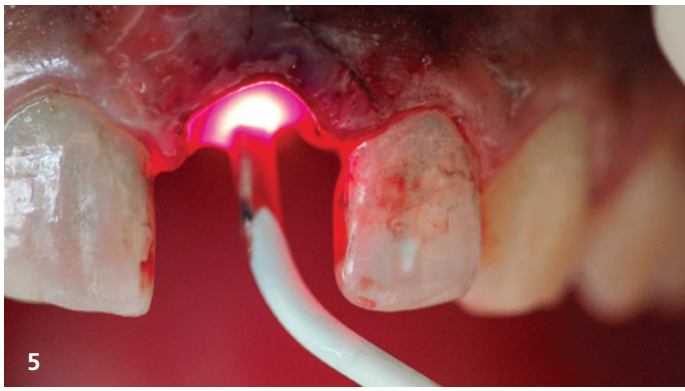


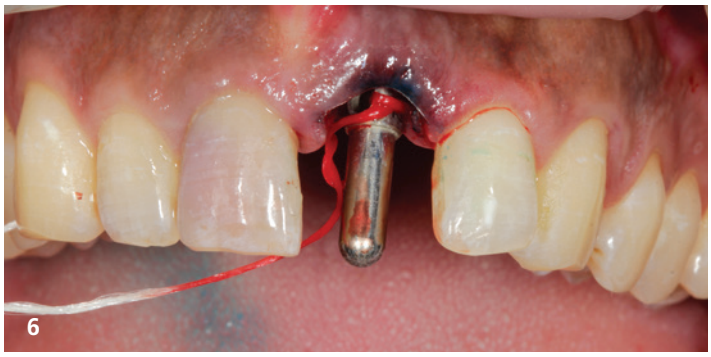
Fig. 1: Pre-op clinical image showing the affected teeth #11 and 21. **Fig. 2:** CBCT evaluation showing fenestration at tooth #21.











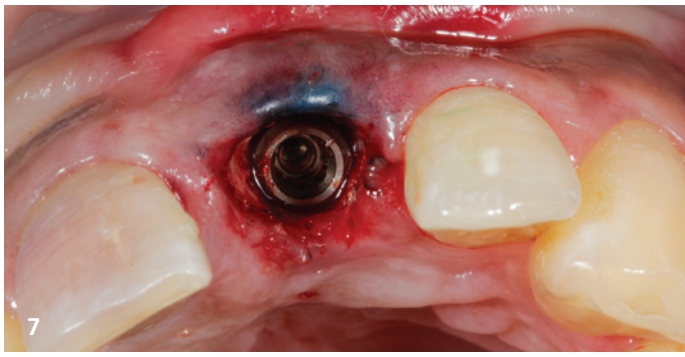


Fig. 3: Fractured cervical portion of tooth #21. **Fig. 4a:** Granulation tissue after extraction. **Fig. 4b:** Extraction socket after mechanical debridement. **Fig. 5:** HELBO antimicrobial photodynamic therapy. **Fig. 6:** Verifying implant position and angulation. **Fig. 7:** Implant placement 4 mm below the gingival margin, respecting biologic width.

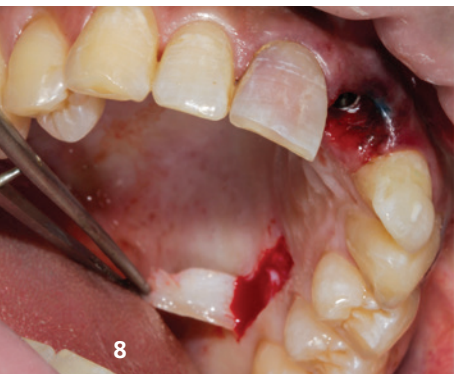
soft-tissue surgery were planned for the fenestration defect and augmentation of the thin gingival tissue for ensuring a good peri-implant seal.

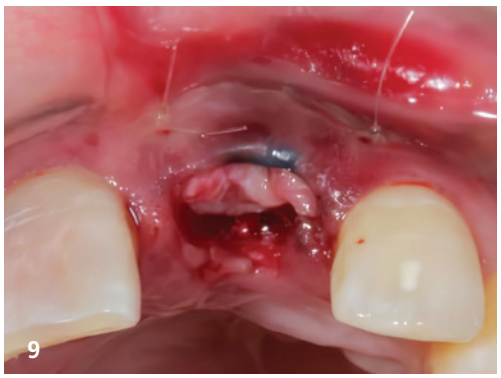
Procedure

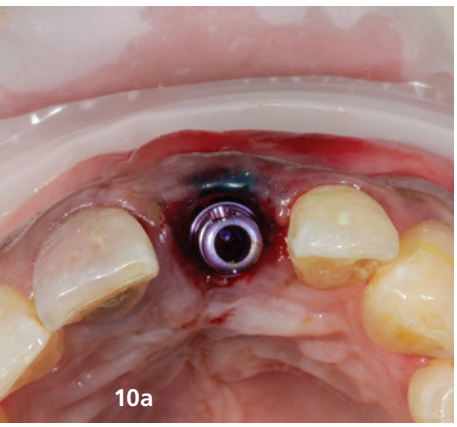
The procedure was flapless in order to minimise hard- and soft-tissue trauma. The fractured portion of the tooth was gently removed with a tweezer and the remaining root was atraumatically luxated (Fig. 3). Thorough curettage was done to ensure the total removal of the granulation tissue (Figs. 4a & b). To ensure complete disinfection of the site, antimicrobial photodynamic therapy was done using the HELBO laser (bredent medical). Blue photosensitiser (methylene blue) was applied inside the socket and left *in situ* for 60 seconds to stain the bacteria. After the dye had been rinsed off, the socket was then exposed to the HELBO TheraLite diode laser for 1 minute (Fig. 5). This ensures focused antibacterial action by singlet oxygen molecules, destroying bacteria in the biofilm.

The implant osteotomy site was prepared with sequential drills, and 3D position verified with paralleling tools (Fig. 6). The implant (copaSKY, 4 × 12 mm; bredent medical) was placed with sufficient primary stability (torque of 45 Ncm), facilitating predictable immediate loading of the implant. The implant was placed 4 mm below the gingival margin to accommodate biologic width (Fig. 7).

A free gingival graft was harvested from the palate, de-epithelialised and stabilised under the labial gingiva, as the existing labial tissue appeared thin (Fig. 8). The connective tissue graft was then stabilised with a sling suture using #6/0 Deme-







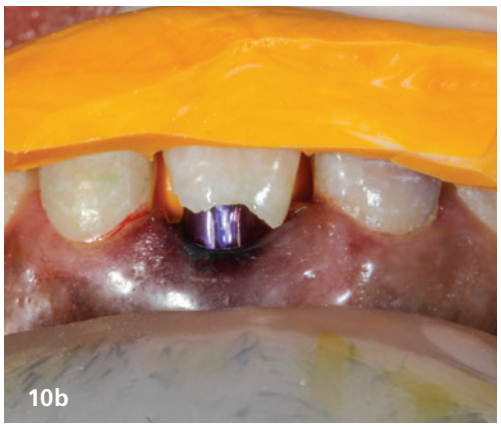


Fig. 8: Free gingival graft obtained from the palate. **Fig. 9:** De-epithelialised free gingival graft (connective tissue) stabilised in a pouch. **Fig. 10a:** CopaSKY exso abutment placed for provisionalisation. **Fig. 10b:** Putty index with extracted tooth for relining over the abutment. **Fig. 11:** Provisional crown highly polished extra-orally.

DIOX polydioxanone resorbable monofilament thread (Demetech; Fig. 9).

The extracted tooth was relined with flowable composite and used for the provisionalisation on an copaSKY exso abutment using the previously fabricated putty index (Figs. 10a & b). The screw-retained provisional restoration was polished extra-orally and the abutment screw torqued to 15 Ncm (Fig. 11). The screw access channel was plugged with PTFE and composite and kept out of occlusal contact.

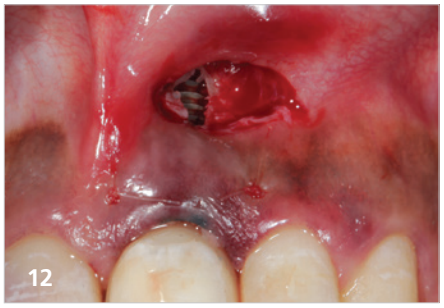
Guided bone regeneration was done at the site of the fenestration to ensure bone filling of the defect. Guided bone regeneration provides an environment conducive to bone formation. A membrane is applied to exclude non-osteogenic tissue from interfering with bone regeneration. A semilunar incision was made on the mucogingival junction to expose the area of fenestration (Fig. 12). After debridement, 50/50 NonDemin mineralised cortical and cancellous human allograft (0.5 cm^3; Impladent), along with autogenous bone, was mixed together with injectable platelet-rich fibrin to make sticky bone, which was then packed on the exposed implant side and later covered with a resorbable collagen bilayer membrane, and the flap was sutured with the same aforementioned suture thread (Figs. 13 & 14). An immediate postoperative radiograph was taken (Fig. 15).

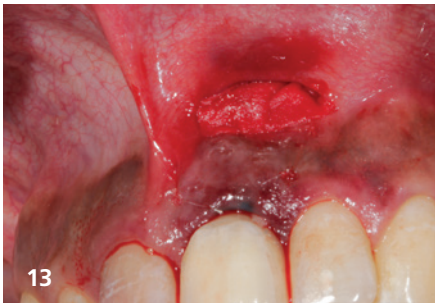
Instructions regarding diet and oral hygiene were given to the patient. The patient was also instructed to avoid any wedging force on the anterior teeth. Subsequently, during the osseointegration period, endodontic re-treatment of the right central incisor was completed, enabling fabrication of both crowns together during the restorative phase.

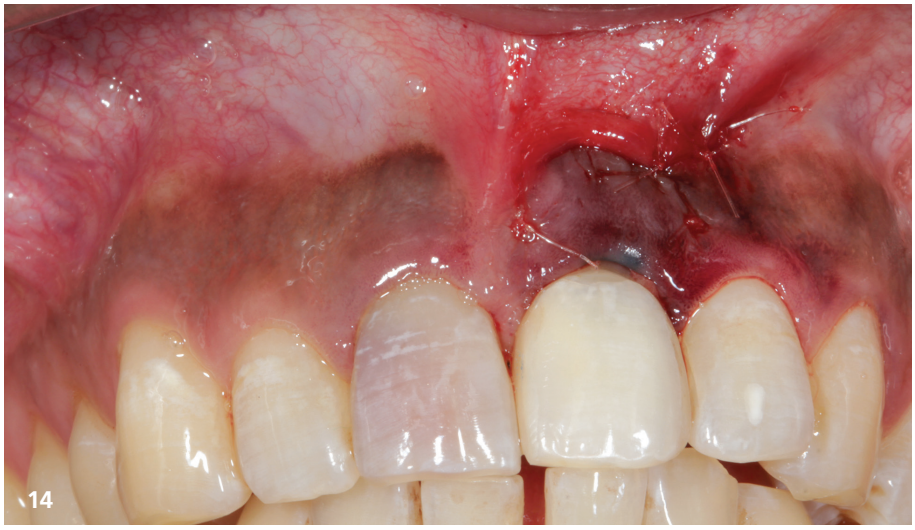
Prosthetic phase

The screw-retained provisional crown was removed after four months, revealing healthy underlying tissue with well-maintained gingival contours (Figs. 16 & 17). The resonance frequency analysis performed with the bredent penguinRFA revealed an implant stability quotient value of 86, indicating sound osseointegration and implant stability. An analogue impression was taken with customised impression copings to register the soft-tissue contour (Fig. 18). The crowns were digitally fabricated by the technician (Fig. 19). For the implant crown, a titanium base was used and a single zirconia crown with a palatal screw access channel was fabricated. In addition, the adjacent tooth #11 was prepared for a definitive zirconia crown. The definitive implant crown was cemented extra-orally, steam-cleaned, torqued to 25 Ncm and plugged with PTFE and composite intra-orally (Fig. 20). A postoperative radiograph was taken after the definitive restoration, and an excellent aesthetic outcome was achieved (Figs. 21 & 22).

Clinical examination after six months revealed a healthy peri-implant mucosa and no bleeding on probing. The patient was satisfied with the results (Fig. 23). Furthermore, a six-month postoperative radiograph revealed maintained crestal bone levels (Fig. 24).







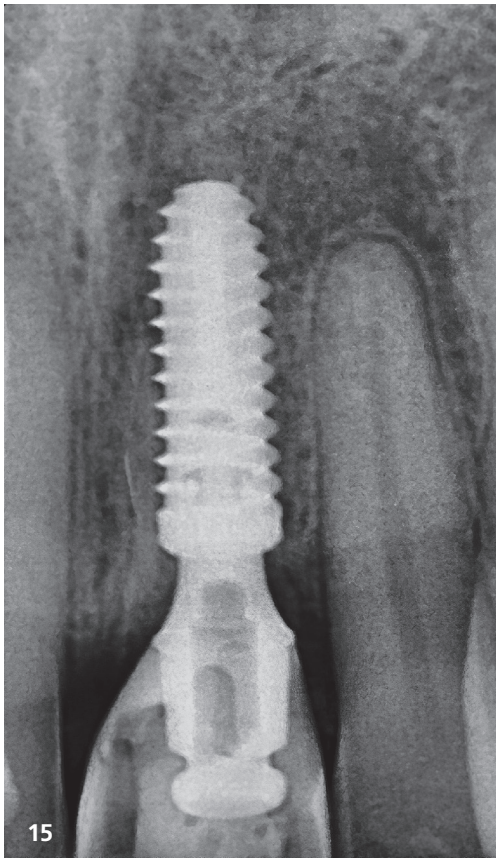
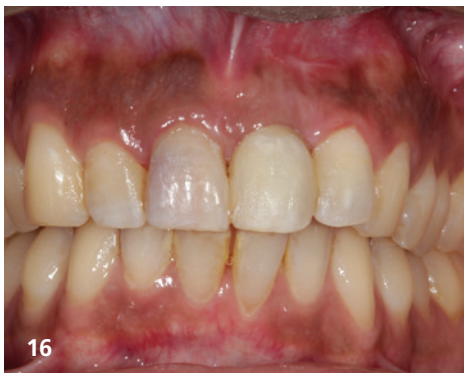
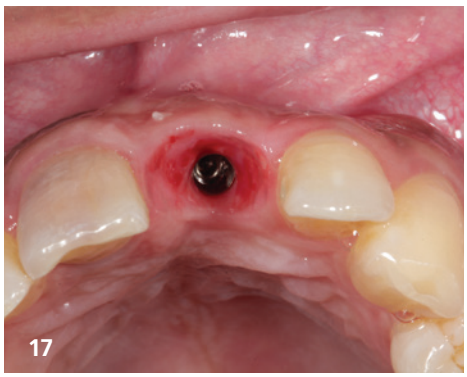


Fig. 12: Fenestration exposed with semilunar incision. **Fig. 13:** Guided bone regeneration done with bone grafting material and a membrane. **Fig. 14:** Tension-free closure. **Fig. 15:** Immediate post-op radiograph after seating of the provisional crowns.

Discussion

Post-extraction ridge collapse is an inevitable process. Human re-entry studies have shown horizontal bone loss of 29–63% and vertical bone loss of 11–22% after six months after tooth extraction.[2] Type 1 implant placement was planned and executed in this case.[3] Apart from preventing this bone collapse, immediate placement and restoration of a single implant in the aesthetic zone has several proposed benefits, including reduced overall treatment time, fewer surgical procedures, less traumatic surgery and greater patient satisfaction.[4] However, immediate placement of implants in infected sockets is debatable. This may be indicated for replacing teeth lost because of chronic periapical lesions with a history of endodontic failure when appropriate preoperative procedures are undertaken to clean and decontaminate the surgical sites.[5] The use of antibiotics and chemotherapeutic agents has been suggested as adjuncts, but they have limitations related to their release mechanisms and the induction of bacterial resistance over time.[6,7] Antimicrobial photodynamic therapy has gained much attention as a non-invasive and biocompatible approach that can be employed to prevent biological complications associated with implants.[8] HELBO antimicrobial photodynamic therapy was done as an adjunct to mechanical debridement of the granulation tissue in this case. Novaes et al. showed better results for immediately placed implants decon-





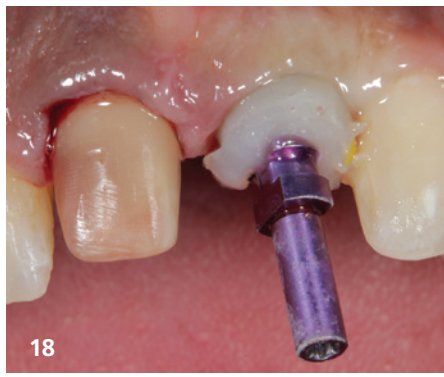
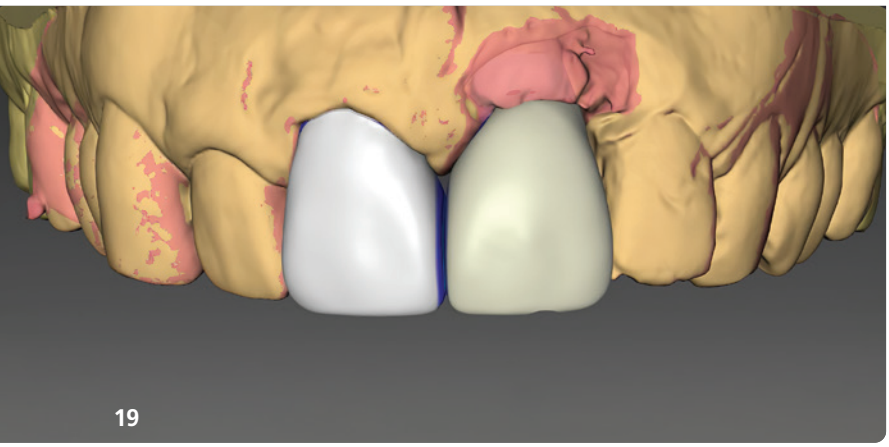


Fig. 16: Four-month post-op clinical evaluation, showing maintenance of the gingival contours. **Fig. 17:** Removal of the prosthesis revealed heathy underlying tissue. **Fig. 18:** Customised impression coping for recording soft-tissue contour.



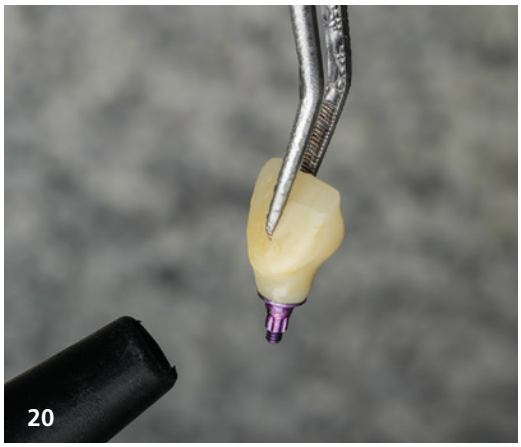
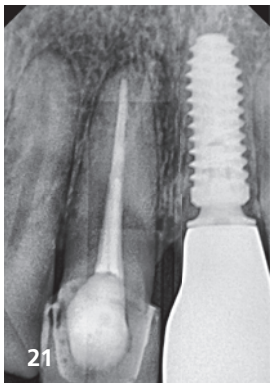


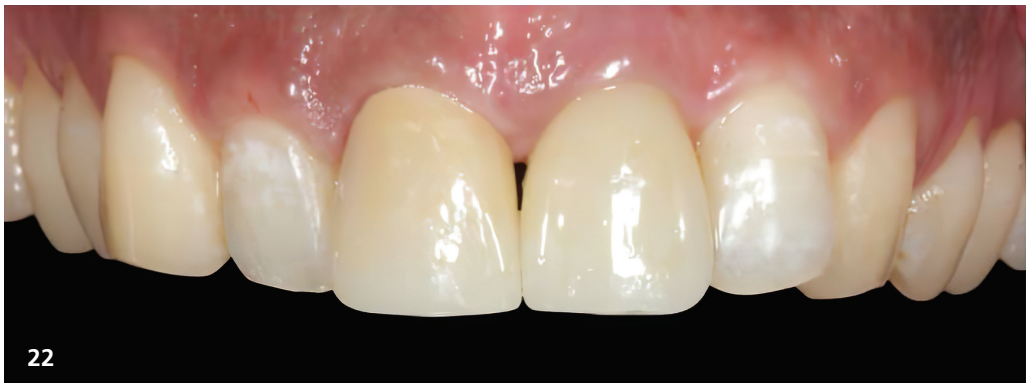
Fig. 19: Digital fabrication of crowns. **Fig. 20:** Steam-cleaning of the definitive implant crown.

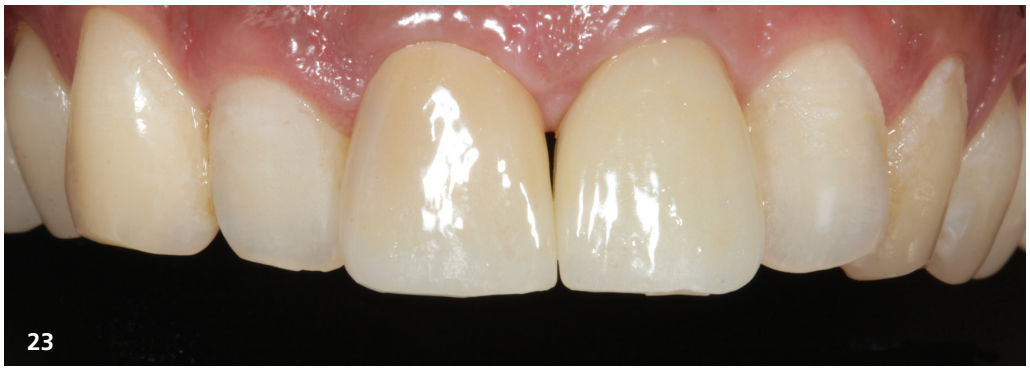
taminated by debridement associated with antimicrobial photodynamic therapy.[9] The sites treated with mechanical debridement and antimicrobial photodynamic therapy led to osseointegration of the implants without evidence of inflammation; conversely, evidence of peri-implantitis was observed where antimicrobial photodynamic therapy was not used.[9]

Since the primary stability in this case was 45 Ncm, immediate loading was done. Studies have demonstrated that insertion torque value alone can be used as a benchmark for single crown immediate loading of implants placed in fresh extraction sockets if the attested insertion torque value score is > 30 Ncm.[10] Excellent primary implant stability is an absolute requirement for immediately loading an implant with a provisional restoration. It is dependent on bone density and quality, implant design and surface, as well as the technique and accuracy of the osteotomy preparation.[8]

The implant system used was selected due to its virtue unique osseo connect surface, owing to which the neck of the implant supports soft-tissue attachment, thereby preventing bacterial infiltration and providing protection for the implant. The sandblasted and etched surface enhances rapid osseointegration. It features a back-taper design, which has a positive influence on the marginal bone level, and a self-tapping double thread, which is impor-







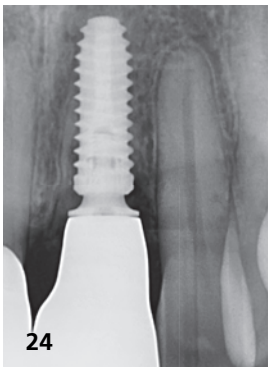


Fig. 21: Immediate post-op radiograph after placement of the definitive crowns. **Fig. 22:** Definitive restorations of teeth #11 and 21. **Fig. 23:** Six-month follow-up clinical image. **Fig. 24:** Six-month follow-up radiograph.

tant for the predictable attainment of high primary stability. The copaSKY implant system employs platform switching. Platform switching refers to placement of an abutment of a smaller diameter than that of the implant platform. This minimises crestal bone loss, as the inflammatory infiltrate is moved away from the crestal bone.[11] The self-tapping double thread achieves faster insertion of the implant with lower heat generation and bone condensation.[12] Sandblasted and etched implants with a self-tapping thread in a cylindrical and conical hybrid design show statistically higher insertion and removal torque values compared with machined implants, along with enhanced primary stability.[13]

Soft-tissue augmentation with a de-epithelised free gingival graft was done, as the gingival biotype was thin. Autogenous soft-tissue procedures ensure good blood supply to the graft with predicable results. The long-term stability of pink aesthetics around dental implant prostheses has been strongly correlated with adequate peri-implant soft-tissue thickness, that is, a thick peri-implant biotype.[14,15] When a thin biotype is diagnosed, a subepithelial connective tissue graft or a free gingival graft can be used to prevent potential long-term recession of the facial mucosal margin or permeation of a greyish discoloration from the implant.[16–18]

The case in discussion, shows satisfactory short-term results at 6 months based on all the above-mentioned clinical procedures and scientific considerations.

Conclusion

Complexities of anterior implant rehabilitation can be combated with thorough diagnosis and holistic treatment planning. Immediate implant placement with immediate loading is made more predictable with photodynamic therapy, especially in infected sockets. Guided bone regeneration and soft-tissue augmentation reinforce the foundation of the peri-implant seal, which is essential not only for long-term implant success but also for the harmony of the gingival architecture. Successful anterior implant rehabilitation is a combination of periodontal and restorative mastery.

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Literature

About …

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Immediate implant placement and restoration – a new level of precision

Dr Markus Sperlich and Dr Mathias Sperlich, Germany

Patients increasingly seek shorter and less invasive treatments that minimise physical and psychological limitations. This finding was confirmed by current studies and forward-looking analyses,[1] indicating a growing demand for efficient immediate implantological and restorative solutions. Extensive information are now accessible online, so today's patients are much more aware of existing implant placement and restoration options. In this article, dentists Markus Sperlich and Mathias Sperlich discuss the immediate implantological treatment concept.

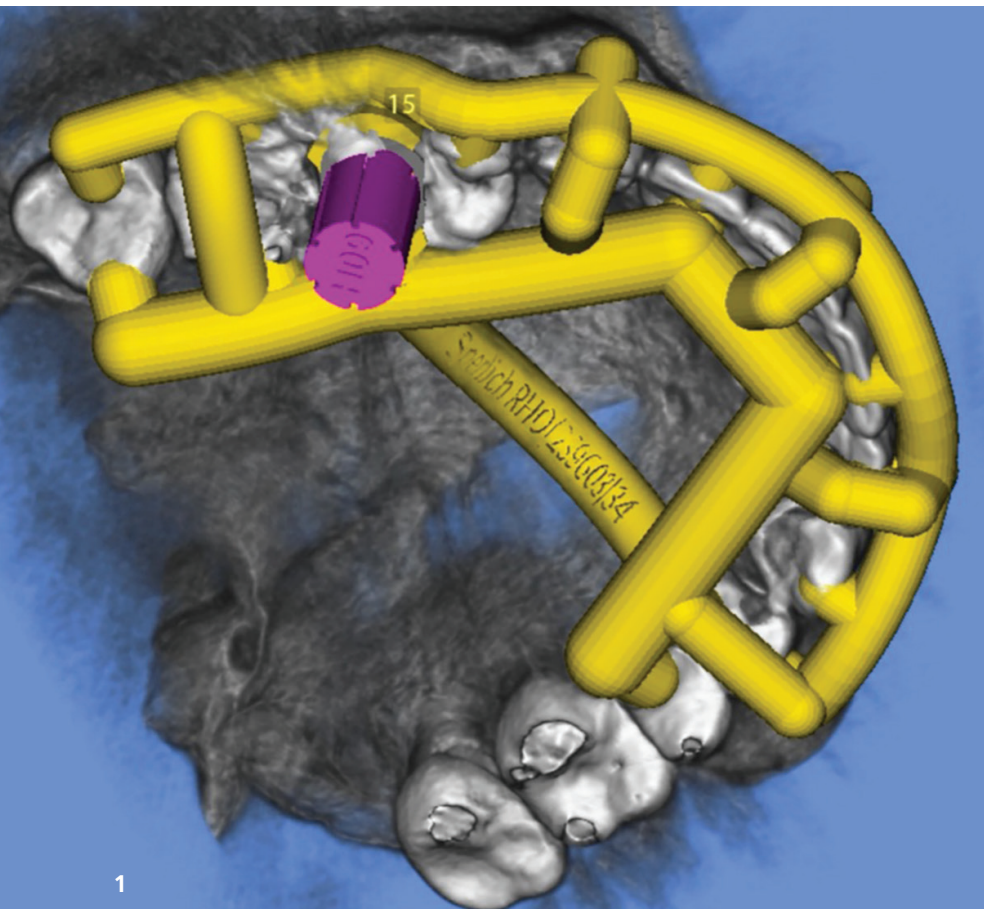

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Fig. 1: Three-dimensional implant planning in SMOP Swissmeda.

The implantological treatment concept of immediate implant placement and restoration is a favourable option that preserves the patients' biological and physiological environment to the maximum extent possible. This approach can significantly shorten overall treatment times and lower the cost.[2] The procedure is atraumatic, reduces healing times, and allows for rapid rehabilitation. This helps patients achieve a better oral health-related quality of life. Physiologically, this treatment concept can significantly reduce the dimensional changes of the marginal bone walls that occur when teeth are extracted.[3,4]

Immediate implant placement – a clinical case series

In a case series, 20 non-salvageable teeth were immediately replaced with implants (Straumann BLX), which were then immediately restored with preoperatively fabricated CAD/CAM crowns. Three-dimensional preoperative implant planning was performed in all cases, using the SMOP Swissmeda planning system (Fig. 1) to determine the ideal prosthetically guided implant position for immediate restoration. The surgical guide was designed and the dimensions for the prosthetic superstructure was defined based on the abutment geometry. The STL data of the prospective implant position were generated by the SMOP three-dimensional implant planning system and imported directly into CAD software (exocad with high evidence; Fig. 2). Based on the data, the matching restoration was CAM-fabricated preoperatively based on the exocad design. In all cases of this series, transocclusally screw-retained acrylic single crowns were fabricated preoperatively.

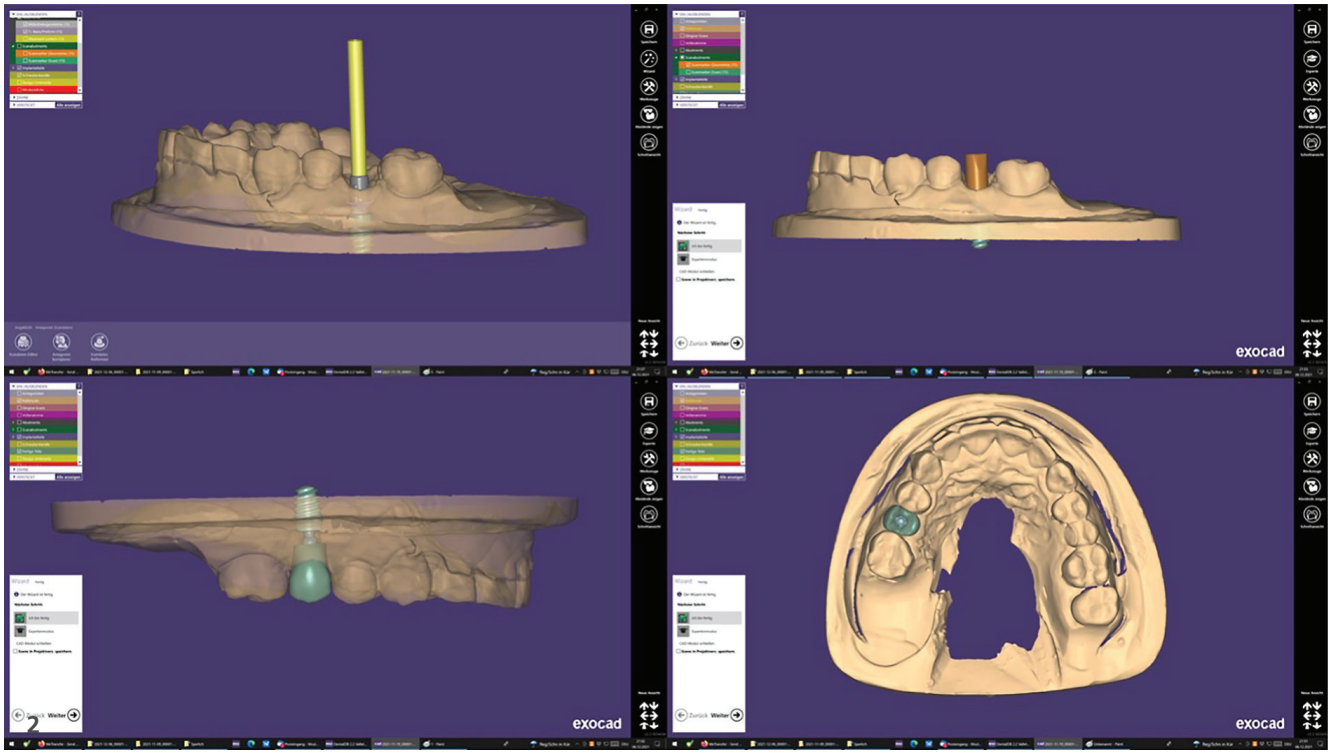
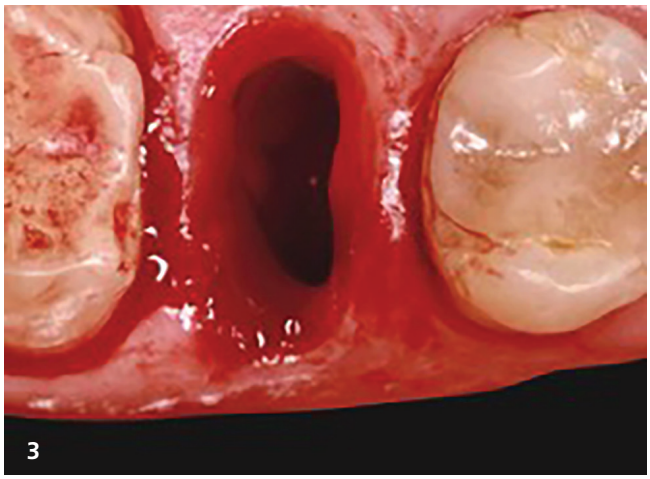


Fig. 2: Designing the preoperatively fabricated restoration in exocad.

Clinical workflow

To begin, the affected teeth were extracted atraumatically (Fig. 3), followed by alveolar management and immediate placement of a suitable implant (Fig. 4). If an insertion torque greater than 35 Ncm was achieved, the implant was then immediately restored with a transocclusally screw-retained crown, which had been fabricated preoperatively. Prerequisites for this surgical procedure include an intact post-extraction socket, healthy soft-tissue conditions, and the absence of inflammation, as well as patient compliance.[5]

Three-dimensional planning is essential to performing the workflow described.[6–8] Only template-guided insertion allows the implant to be surgically placed so that the vertical height and rotational orientation of the internal connection matches the digital design. For this purpose, the TorcFit connection of the Straumann BLX implant has to be exactly reproduced surgically. The H07/H09/H11 insertion tools (Figs. 5 & 6) specially developed at our practice define the stop height on the sleeve canal of the surgical template as well as the correct vertical implant position, angulation and rotational alignment of the TorcFit's internal connection (Fig. 7) by way of a positioning marker. This procedure avoids subsequent adjustments of the immediate restoration. It eliminates manual and



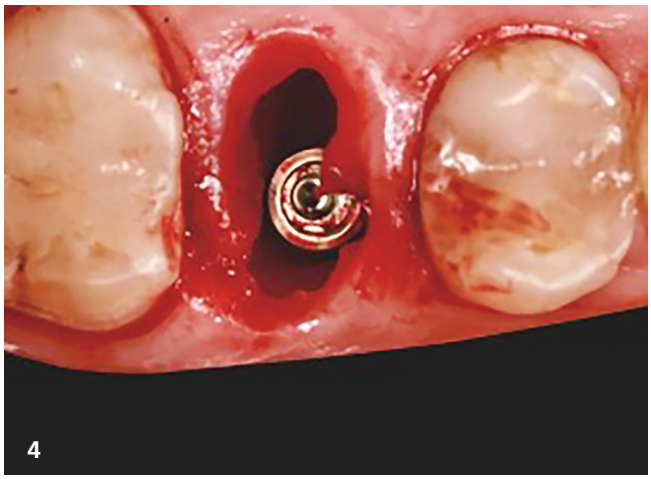
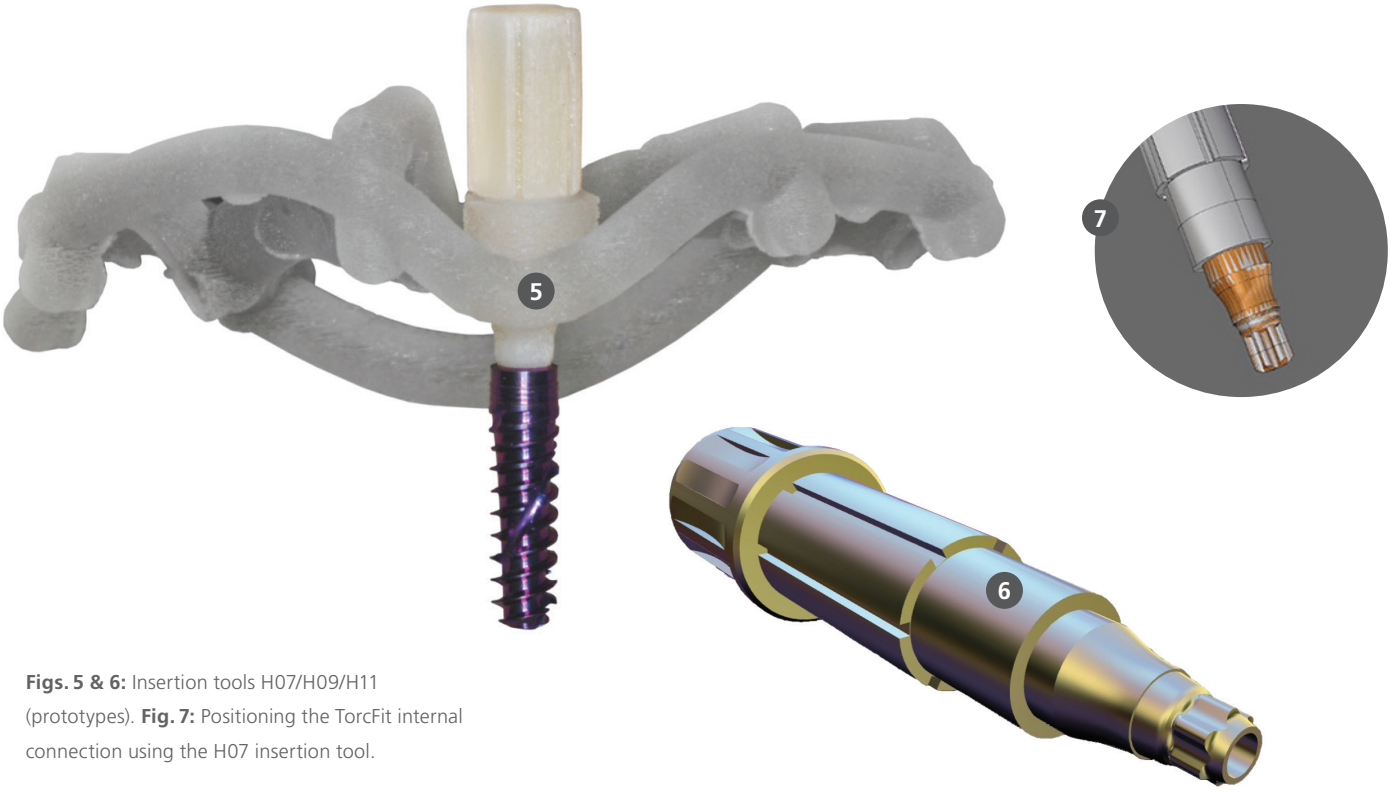


Fig. 3: Atraumatic tooth extraction. **Fig. 4:** Immediate implant placement.



Figs. 5 & 6: Insertion tools H07/H09/H11 (prototypes). **Fig. 7:** Positioning the TorcFit internal connection using the H07 insertion tool.

Figs. 5–7: © Formherr Industriedesign Braunschweig

chemical manipulation of the surgical site and allows undisturbed initial healing. The surface of the inserted crowns retains their final polished texture created in the laboratory (Fig. 8), and patients are spared extended additional prosthetic procedures.

The success rate of immediate treatment is equivalent to other approaches.[9] The following parameters are crucial for success:[10] patient selection, bone quality and quantity, implant design, an insertion torque greater than 35 Ncm,[11] H07/H09/H11 insertion tools and, of course, surgical experience. A basic prerequisite for this workflow is digital implant planning, as described above.[7]

Success rates of preoperatively fabricated restorations

In the case series described above, the preoperatively fabricated restorations achieved 95% accuracy of fit, where any added needed intraoperative manipulation of the restoration was counted as a failure. The survival and success rates of the implants were 100% after 18 months (Figs. 9 & 10). The prosthetic success rate of the preoperatively fabricated immediate restorations was 90%. In two cases, the crown detached from its adhesive base during the first six postoperative months. In a review paper, the authors compared the different implant placement and loading protocols.[12] That paper showed that immediate placement in conjunction with immediate loading had a success rate of 98.4%. Conventional

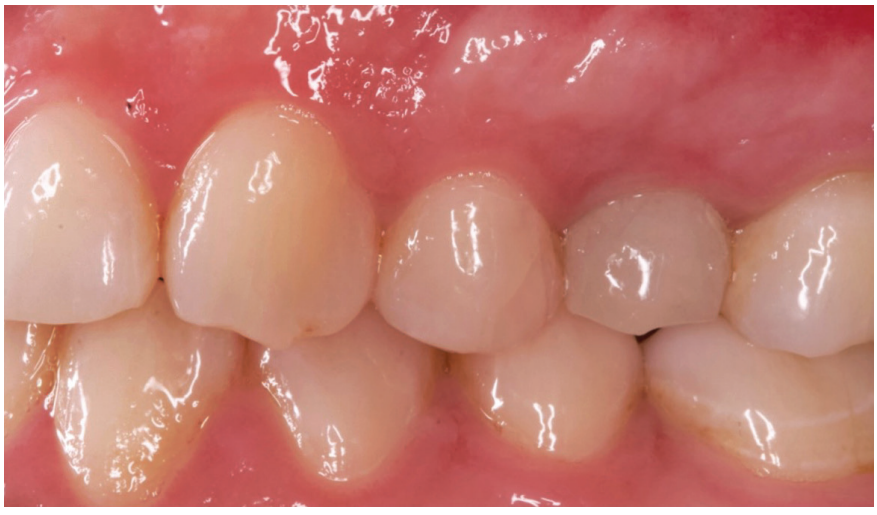


Fig. 8: Preoperatively fabricated CAD/CAM crown 25.

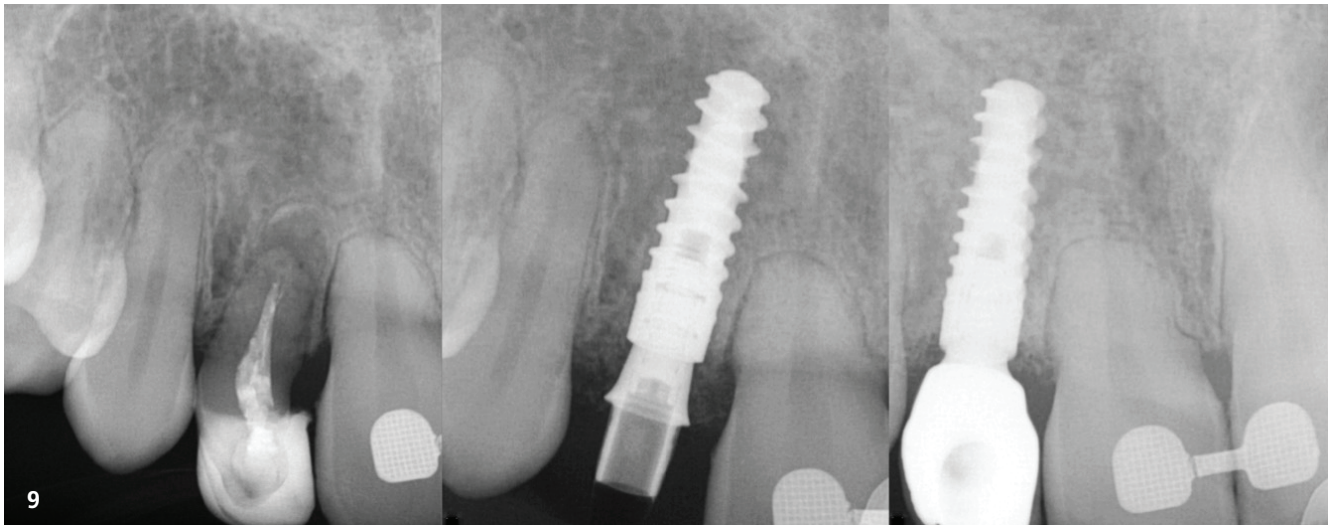


Fig. 9: Radiographs taken at different stages.

protocols of late implant placement combined with conventional loading have a success rate of 97.7%. It should be noted, however, that there was a, sometimes substantial, difference in the level of evidence between the papers included when comparing the individual protocols. Immediate placement data were limited to clinically documented data.

Conclusion

Advantages of the workflow described include maximum patient satisfaction, shorter treatment times and optimum preservation of existing biological structures. Successful implementation is contingent on strict adherence to the listed requirements and on sufficient surgical experience. Further scientific studies with high evidence are needed to confirm and consolidate these results.

Dr Markus Sperlich

Dr Mathias Sperlich

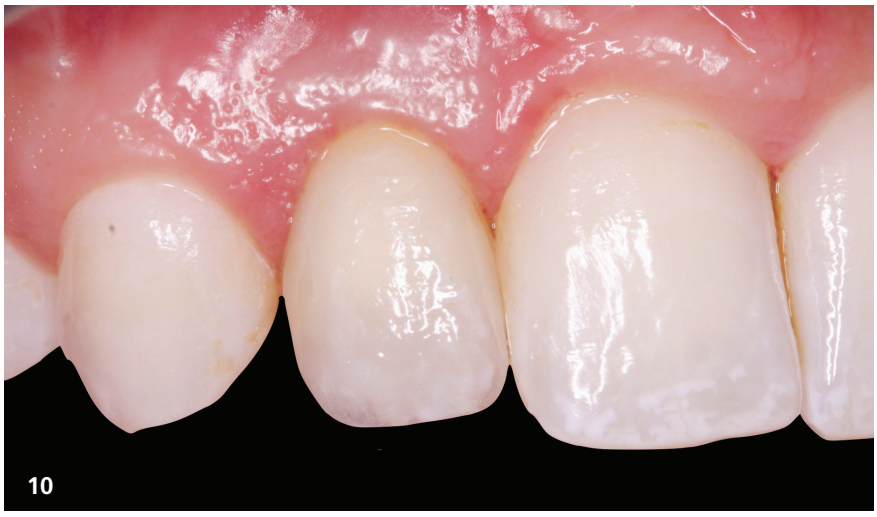


Fig. 10: Clinical follow-up at 18 months.

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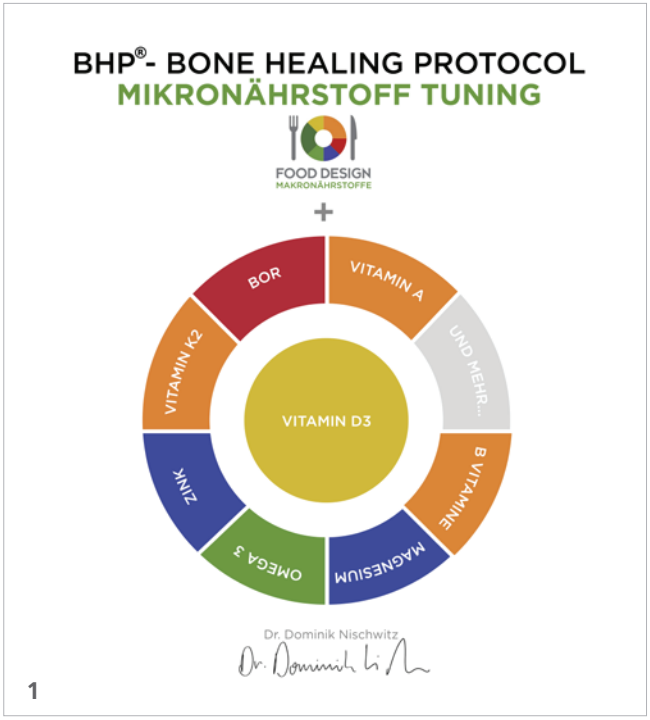
Literature

Supporting the osseointegration of ceramic implants

Dr Dominik Nischwitz, Germany

In traditional oral surgery and implantology, the focus is on implant healing and on the local prerequisites for maintaining or building bone and soft tissue. But our prevailing perspective rarely transcends the oral cavity. Traditionally, we distinguish four potential mechanisms of bone formation: osteoinduction (growth factors), osteoconduction (bone replacement materials as "placeholders"), distraction osteogenesis and guided tissue regeneration (membranes, shell technique, etc.).[1]



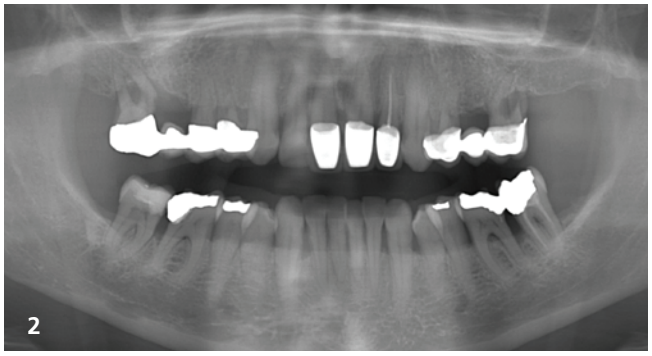


Fig. 1: Overview of the Bone Healing Protocol. **Fig. 2:** Orthopantomograph taken prior to surgery.

In biological dentistry, we draw on our experience and knowledge from functional medicine and nutritional science and employ targeted micronutrient therapies to support the systemic requirements ahead of planned surgery and for subsequent bone and tissue regeneration.

Local preconditions

Local preconditions for smart bone and soft-tissue regeneration include the decontamination of the surgical site (breath, saliva) and the activation of local growth factors (IGF-1, osteoblasts, plasma proteins, etc.) by drilling and by providing bleeding spots for bone stimulation, as well as the use of smart biomaterials such as platelet-rich fibrin (PRF) membranes to improve the extracellular matrix and optimise the bone and soft-tissue situation.

The use of microinvasive techniques such as piezosurgery, the use of ozone, navigated implant placement and improved imaging technologies (such as cone-beam computed tomography, CBCT) have brought enormous advances in dental craftsmanship. The trend is clearly towards aesthetics and health. Far from remaining a taboo subject, ceramic implants are the future of oral implantology. Nevertheless, only about one per cent of surgeons insert ceramic implants. Based on his ten years of clinical experience (with over 4,000 ceramic implants placed), the author can safely assert that more surgical but especially systemic information is needed to achieve even better healing rates.

Ceramic implants heal without inflammation – but this is actually crux of the matter. Hardly any of us are truly familiar with the biochemistry of the entire human body. In ceramic implantology, it is important to incorporate insights from functional medicine, nutrition and micronutrients in order to prepare the body for a "remodelling phase", and this is why

much of our focus is on improving our patients' lifestyles. Both systemic preparation for the surgical intervention and a targeted follow-up are of the utmost importance.

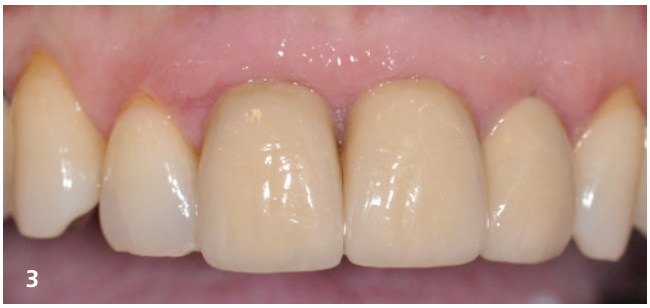
Smart bone and soft-tissue management

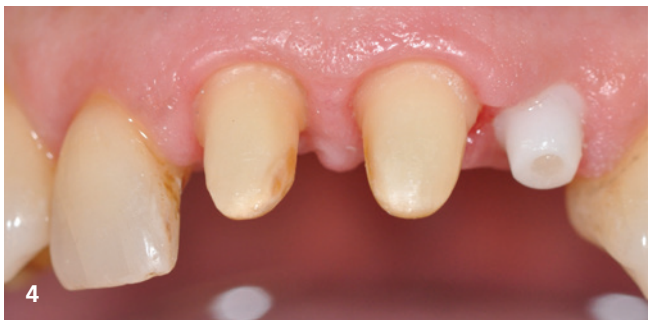
Systemic preconditions: Surgical preparations and dietary changes. An improper diet with sugar, wheat, refined cooking oils, conventional dairy products ("Core Four disease agents") and other food intolerances promote the body's general tendency to develop inflammatory reactions and macro- and micronutrient deficiencies, meaning that insufficient proteins and amino acids, the fat-soluble A, D3, E and K vitamins, the water-soluble B and C vitamins, and minerals such as zinc and magnesium as well as healthy omega-3 and omega-6 fatty acids will be available for building and regenerating tissue and bone.[2] Our goal is to prepare patients for surgery as effectively as possible. The focus is on providing the right macronutrients and avoiding as many stressors as possible. The "Core Four disease agents" should be strictly avoided. More than one hundred years ago, Dr Weston Price researched different peoples all over the world. He documented his research in his book "Nutrition and Physical Degeneration"[3]: People who ate a species-appropriate diet were virtually immune to tooth decay. Their descendants, who had already been exposed to industrially processed foods, were already suffering from the typical signs of degeneration due to a lack of nutrients. The most important macronutrient for building tissue (bone, soft tissue, muscles, etc.) is protein.

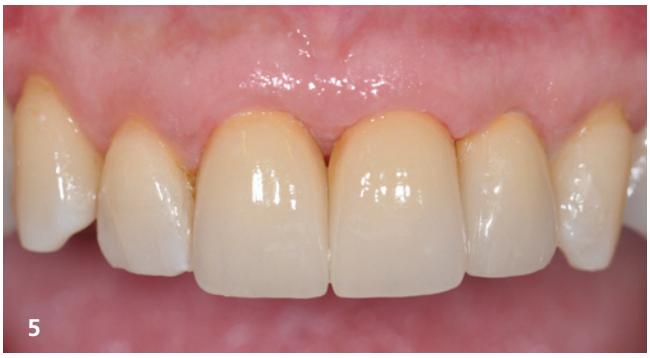
Proteins and amino acids – life's building blocks

There are twenty proteinogenic amino acids, but only eight of them actually have to be ingested with the diet. These so-called essential amino acids are isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan and valine. The body is capable of building any protein from these eight amino acids – provided it has enough raw material available.

Numerous studies have demonstrated a link between inadequate bone formation, reduced bone density and delayed fracture healing on one hand and deficiencies in proteins and amino acids on the other. The older the patients, the more significant the correlation. Dayer et al. (2006), in an animal study, found that titanium implants osseointegrated less readily in protein-deficient rats (< 1 g/kg body weight).[4,5] The torque required to explant an implant from a rat's bone after six to eight weeks was around 43% lower in protein-deficient rats than in the animals with sufficient protein in their diet (= 1 g/kg body weight).[4] Hannan et al. found a clear association over four years between bone loss and insufficient animal protein in the diet, based on data from 391 women and 224 men participating in the Framingham Osteoporosis Study.[6] The greater the protein deficiency, the more pronounced the loss of bone mass at the femur and spine. No negative effect of excess protein on bone healing was observed.[6]







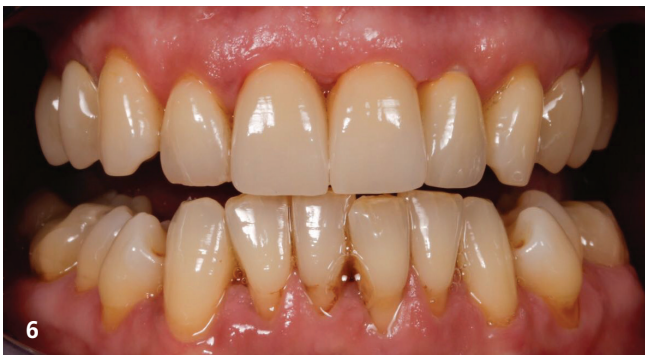


Fig. 3: Intra-oral situation prior to surgery. **Fig. 4:** Preparing for implant placement. **Figs. 5 & 6:** Status following delivery of the restoration.

Consequently, our main focus is on an adequate protein supply. Since no deficiency of macro- and micronutrients should be present in the acute regeneration phase, we recommend a daily protein intake of 1.5 to 2 g/kg body weight. To alkalize the body, a serving of vegetables is recommended with every meal. Healthy fats such as omega-3 and a variation of monounsaturated and polyunsaturated fatty acids should also be present. Collagen powders, essential amino acids, bone broths and protein shakes

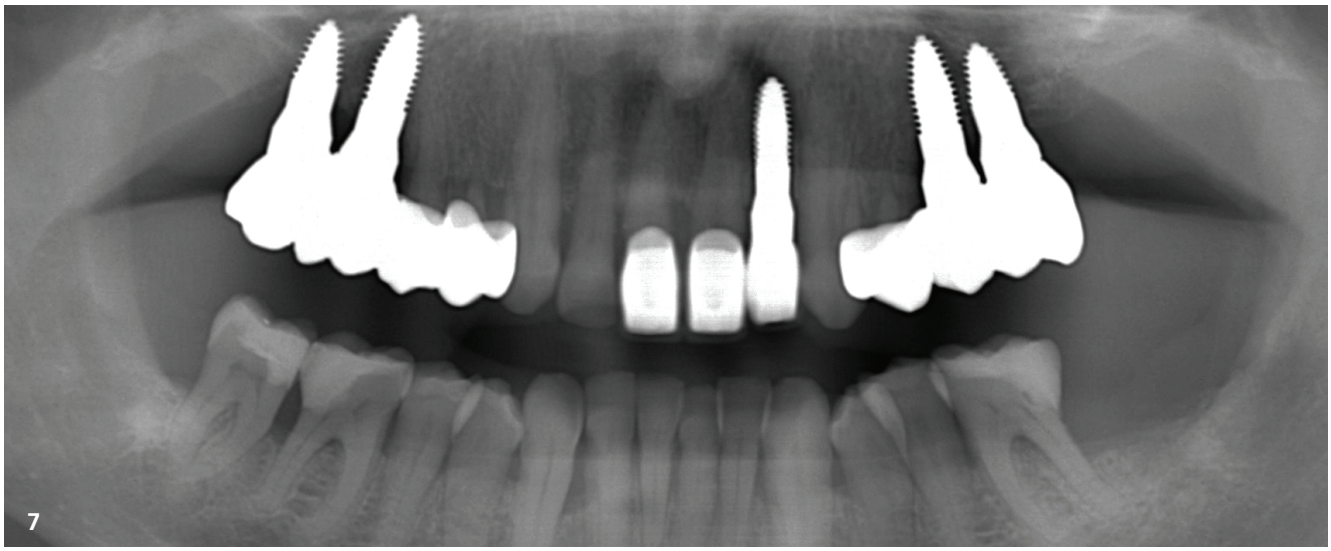


Fig. 7: Radiograph taken with the restoration in place.

make it easier for patients to meet their daily protein requirements.[7–17] In our practice, systemic support for patients through targeted nutrition and supplying the appropriate nutrient supplements has become standard practice as a vital component of the surgery treatment.

Micronutrients

The foundation of the Bone Healing Protocol is high-dosage vitamin D3. Before surgery, we measure the patient's blood vitamin D3 levels. For optimal sustenance, we aim for a preoperative level of at least 60 ng/ml.[18] Numerous studies have shown that vitamin D3 is a critical factor in bone and tooth regeneration.[19–23] This vitamin activates two enzymes that are critical for bone mineralisation: osteocalcin (BGP) and matrix Gla protein (MGP). To prevent calcium from causing the calcification of arteries, these enzymes are activated by another important co-factor, vitamin K2 (MK-7).[24]

Another co-factor is magnesium, which is implicated in over 400 metabolic processes.[25] Zinc is involved both within the immune system and as a co-factor in the activation of the vitamin D3 receptor.[26] The trace element boron doubles the half-life of vitamin D3.[27] Since micronutrients work synergistically, there should be no shortage of B vitamins, vitamin C or digestive enzymes as well as omega-3 fatty acids in the postoperative period.

Conclusion

In addition to the very delicate classical surgical craft of dentistry, we harness the power of insights from functional medicine and nutrition. In this way, we support the body's own healing powers and ensure better tissue and bone healing – and thus, of course, better integration of the ceramic implants. The result: fewer failures and healthier and happier patients.

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Literature

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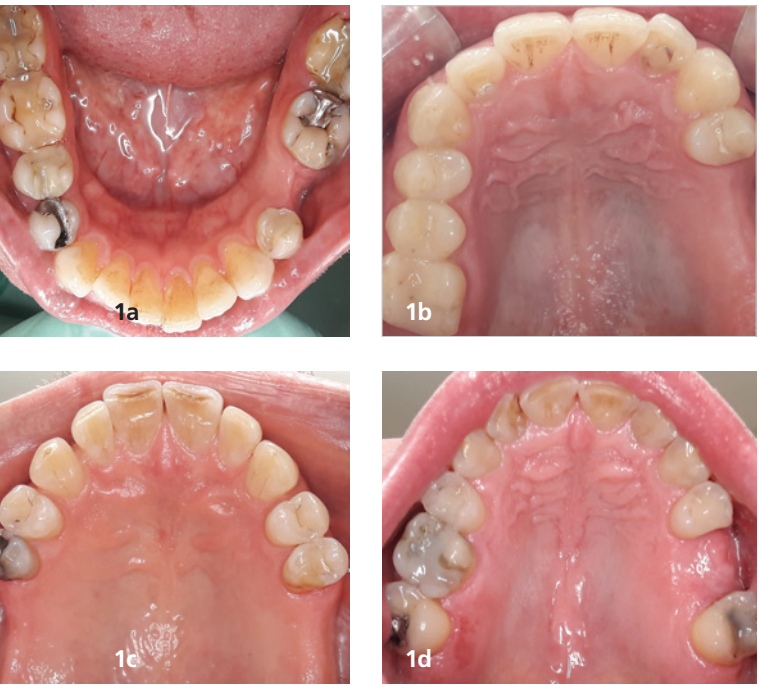
A case series

Single-tooth replacement with ceramic implants

Professors Curd Bollen & Paul Tipton, UK



Figs. 1a–d: Pre-op situation in all four patients. Case 1 **(a).** Case 2 **(b)**. Case 3 **(c).** Case 4 **(d)**.

Introduction

Dental implants have helped to improve quality of life for our patients. The material of choice for implants remains Type IV titanium, whose mechanical and biological properties have been proved.[1] Yet, this material is not exempt from complications. Firstly, these metallic implants show aesthetic limitations when used in the anterior region, especially in patients with a thin gingival biotype. Examples are the possible appearance of a metallic margin in case of gingival recession and a greyish discoloration due to translucency of the peri-implant mucosa.[2,3] Secondly, studies have reported immunological reactions to titanium particles, leading to biological complications.[4] Others have demonstrated allergic reactions to titanium, reporting a prevalence of 0.6%.[5] Thirdly, it must be taken into account that the number of patients demanding metal-free implants has been increasing during recent years. For these reasons, non-metallic alternatives to titanium have emerged. The first ceramic implants arrived on the market more than 40 years ago.[6] They were made of alumina, a material prone to fracture when loaded unfavourably, and so they are no longer available on the market.[7] More recently, yttrium tetragonal zirconia polycrystal (Y-TZP) became the material of choice for the manufacture of ceramic implants. It is characterised by a high resistance to fracture, a low modulus of elasticity, a low affinity to plaque and high biocompatibility.[8,9] In this series of four cases, the CERALOG system (BioHorizons Camlog) was used. CERALOG implants are manufactured from Y-TZP.[10] The CERALOG system provides all the necessary elements to permit retention of any type of prosthesis upon these implants, ranging from single crowns to a full-arch restoration. In this case series, the treatment indication was single-tooth implants.

Case series report

Four patients were selected for this case series (Table 1). All of them wanted or needed replacement of one or two teeth with ceramic dental implants. All the patients were in good general health.

Table 1: Patients' data.

	Sex	Age (years)	Health status	Smoking status	Periodontal health	Diastema location
Case 1	Male	52	ASA I	No	Healthy	#35
Case 2	Male	43	ASA I	No	Healthy	#25 & 26
Case 3	Male	57	ASA I	No	Healthy	#16 & 26
Case 4	Male	61	ASA I	No	Healthy	#26

Table 2: Implant specifications.

	Position	Implant diameter	Implant length	L-PRF	Insertion torque
Case 1	#35	4 mm	12 mm	No	35 Ncm
Case 2	#25	4 mm	12 mm	No	30 Ncm
	#26	4 mm	8 mm	No	25 Ncm
Case 3	#16	4 mm	8 mm	Yes	25 Ncm
	#26	4 mm	10 mm	Yes	30 Ncm
Case 4	#26	4 mm	10 mm	Yes	30 Ncm

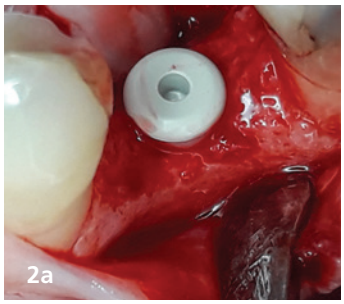
Examination

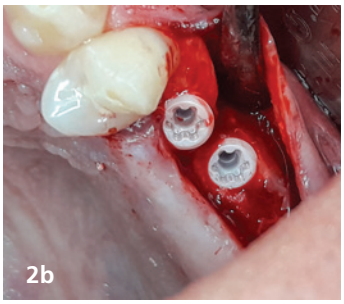
In all cases, the tooth or teeth to be replaced had been extracted at least one year before the dental implant surgery. In none of these cases was socket preservation or ridge preservation performed at the time of extraction. Moreover, all the patients had good oral hygiene. In all but one patient, radiographic analysis was performed by CBCT, supplemented with subsequent digital implantpositioning (SICAT and Sidexis, both Dentsply Sirona; Fig. 1).

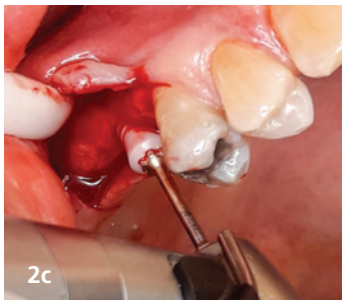
Surgery

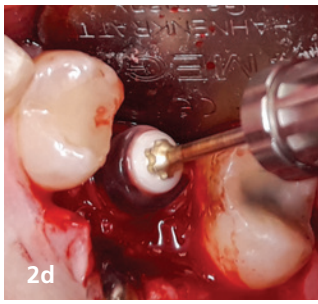
Two-stage surgery was performed for all six implants. All surgeries were performed without sedation or preoperative systemic antibiotics. In two of the four cases, leucocyte- and platelet-rich fibrin (L-PRF) was used during the intervention (IntraSpin, BioHorizons; Table 2). In all cases, the exact CERALOG pre-tapping (maximum: 15 rpm) and drilling protocols (maximum drilling speed: 550–800 rpm) were used. All the implants were placed manually to a maximum torque of 35 Ncm. After the insertion of the implant, a PEEK cover screw was inserted into the implant (Fig. 2). The soft tissue was sutured tightly with an atraumatic resorbable suture material. No postoperative complications were reported. The patients were asked to rinse with chlorhexidine twice a day for one week postoperatively (PERIO-AID, 0.05%, DENTAID). A healing time of three months in the lower jaw and five months in the upper jaw was respected.

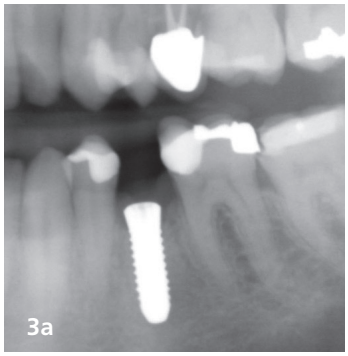
After three months (Case 1) and five months (Cases 2, 3 & 4), the second-stage surgery was performed under local anaesthesia. Healing abutments (PEEK material with titanium screw) were placed to a maximum force of 15 Ncm (Figs. 3–6). All the implants showed excellent stability (measured using the Periotest, Medizintechnik Gulden) and were completely osseointegrated. Radiographic examination confirmed the latter findings.

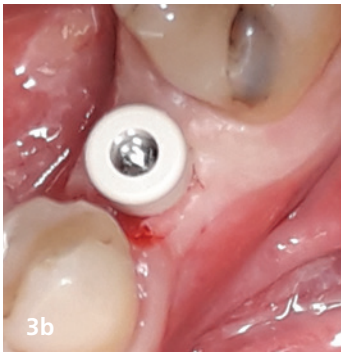


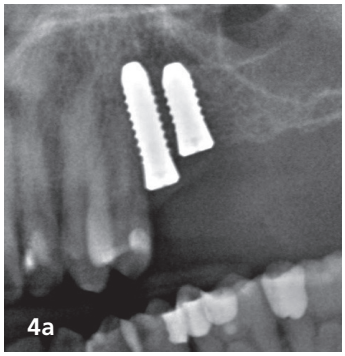


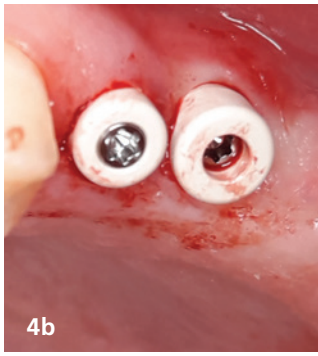




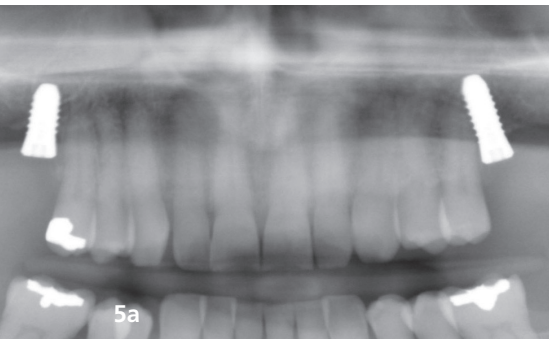
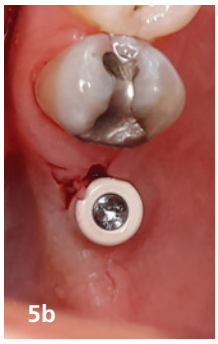
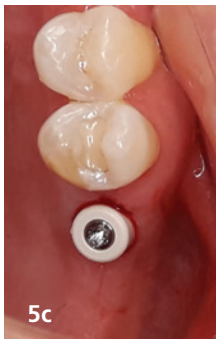
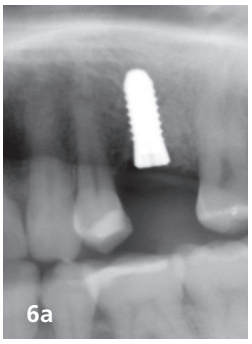
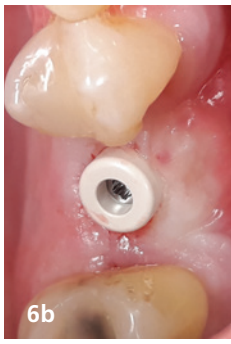








Figs. 2a–d: PEEK cover screws inserted into the implants. Case 1 **(a)**. Case 2 **(b)**. Case 3 **(c)**. Case 4 **(d)**. **Figs. 3a & b:** Radiograph after three months **(a)** and healing abutment in place (**b**; Case 1). **Figs. 4a & b:** Radiograph after five months **(a)** and healing abutments in place (**b**; Case 2).

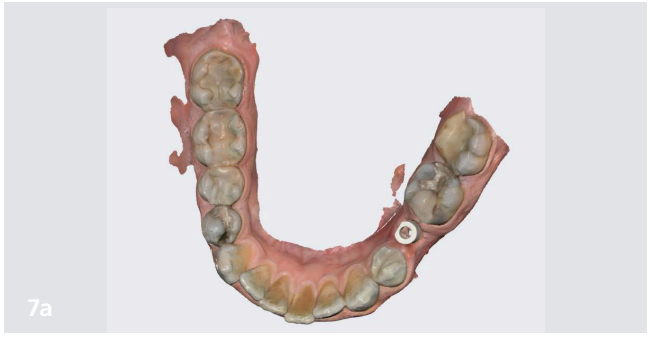
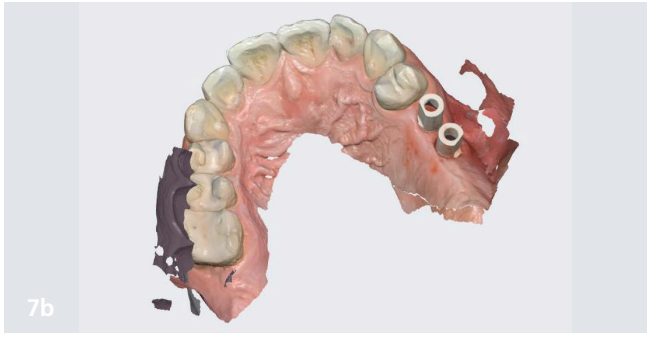
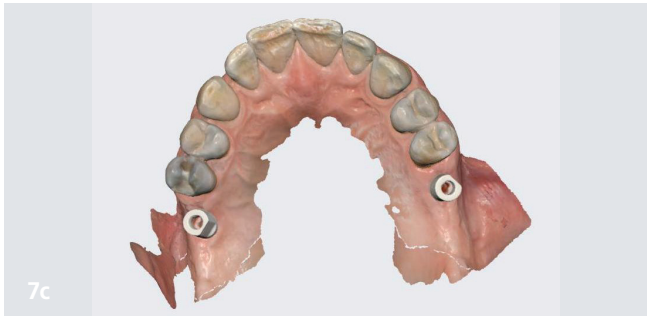
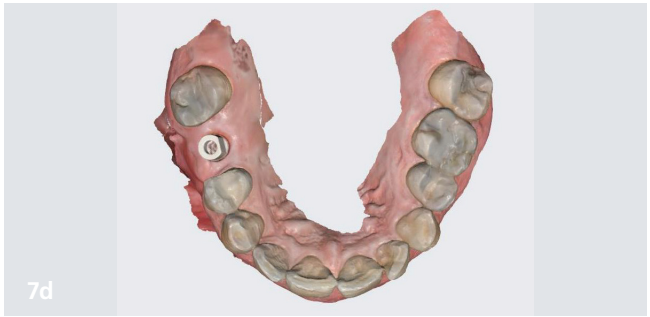
Figs. 5a–c: Radiograph after five months **(a)** and healing abutments in place (**b & c**; Case 3). **Figs. 6a & b:** Radiograph after five months **(a)** and healing abutment in place (**b**; Case 4).

Digital intra-oral scanning

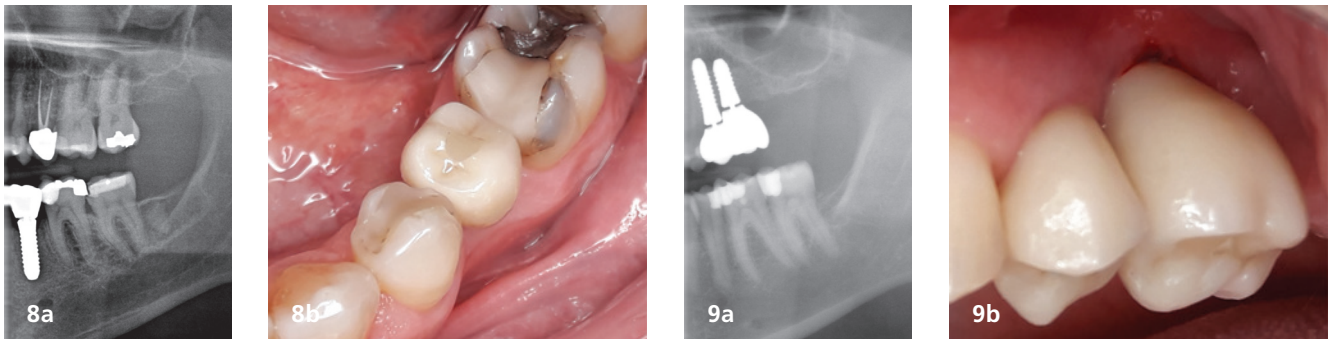
One week after the second-stage surgery, the intra-oral scanning was performed using a Medit i500 scanner (Medit) following the scanning protocol prescribed by the company (Fig. 7). After the removal of the healing abutments, CERALOG scan bodies (PEEK–titanium alloy screw) were inserted into the implants. After the scanning procedure, the original healing abutments were reinserted. Shade determination was digitally carried out with a Rayplicker (Borea). For the planning of the prosthetic restoration, polyphenylsulphone selection abutments were used. All the crowns were ordered digitally from the same dental laboratory. For all the crowns, a ceramic material was selected.

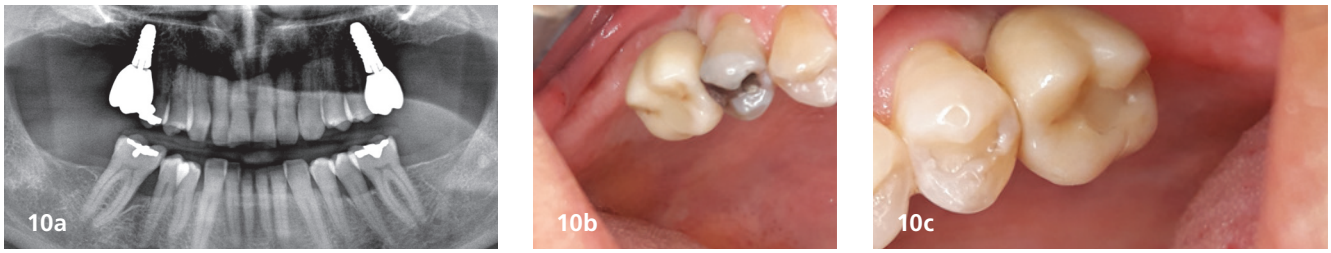
Crown installation

On average, two weeks after the scanning procedure, the crowns were available for placement. PEKK abutments were used. All the crowns were prepared as screw-retained superstructures. Since the four patients strictly wished for a bio-holistic approach, the six titanium abutment screws were replaced with six gold abutment screws (Holisticor screws). These gold screws were tightened to a maximum torque of 15 Ncm. When titanium abutment screws are used, a maximum toque of 25 Ncm should be applied. As recommended by the company, all the screws were retightened to the corresponding torque (15 Ncm) after at least 5 minutes. The screws were protected with PTFE tape, and the remaining screw openings were filled with a composite material of the same colour as the zirconia crown. The occlusion was checked and adjusted where necessary (occlusal concepts included no guidance on the implant-retained restorations and very light intercuspal contact as verified with occluding paper). Oral hygiene instructions were given, focused on interdental cleaning with interdental brushes. A final control radiograph was taken. The PEKK abutment is not radiopaque, and therefore the distance between

Figs. 7a–d: Digital intra-oral scans after the second-stage surgery. Case 1 **(a)**. Case 2 **(b)**. Case 3 **(c)**. Case 4 **(d)**.



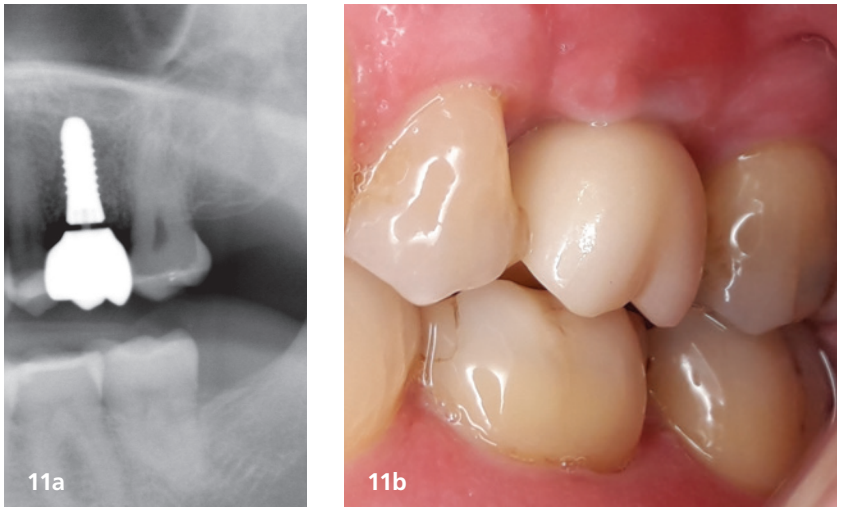


Figs. 8a & b: Final control radiograph of the implant position **(a)** and final intra-oral situation for Case 1 **(b)**. **Figs. 9a & b:** Final control radiograph of the implant position **(a)** and final intra-oral situation for Case 2 **(b)**. **Figs. 10a–c:** Final control radiograph of the implant position **(a)** and final intra-oral situation for Case 3 **(b & c)**.

the implant and crown can easily be determined in the radiograph: the abutment is correctly positioned in the implant when the gap between the implant shoulder surface and the lower edge of the crown measures 0.55 mm in the radiograph (Figs. 8–11).

Conclusion

All the patients were happy with the results of the therapy: the functional and aesthetic outcome was satisfying. The only remark was the long duration of the complete therapy for the upper jaw cases. Owing to the extended osseointegration period of five months, the complete therapy took more than six months. From the practitioner's point of view, there was no major difference in comparison with the use of titanium implants, besides the following of the strict guidelines from the manufacturer. CERALOG implants seem to be an adequate and stable alternative to titanium implants in the replacement of lateral teeth in the upper and lower jaws.



Figs. 11a & b: Final control radiograph of the implant position **(a)** and final intra-oral situation for Case 4 **(b)**.

Author details

Literature

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Modern implantology concepts in september in Konstanz

EUROSYMPOSIUM 2022

On September 23rd and 24th 2022, the EUROSYMPOSIUM will take place for the seventeenth time under the scientific direction of Prof. Dr Dr Frank Palm/Konstanz. The program is thematically broad again and aligned to the informational needs of practitioners.

The recognizable normalization of the current pandemic situation also opens up good prospects for the EUROSYMPOSIUM to be held in Konstanz on Lake Konstanz in the fall.

The traditional implantology event will offer a special platform for collegial exchange and know-how-transfer. Once again, this year, in addition to the scientific lectures on Saturday, there are going to be three live surgeries in the pre-congress program on

Friday and a BBQ later on. The organizers have been guided by the professional interests of practitioners themselves and, under the theme "Modern implantological concepts – fast, esthetic, predictable, safe", have been focusing on the special challenges in everyday practice.

The congress will take place entirely on the grounds of the Konstanz Clinic in the modern conference rooms of hedicke's Terracotta (lectures, seminars, broadcasting of live surgeries). The accompanying industrial exhibition will also be located there throughout the entire period. The live surgeries will be broadcasted from the MKG-Ambulanz Konstanz.

Note: The event will be held in accordance with the applicable hygiene guidelines!

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More information

The dental industry is celebrating a special reunion in Munich: the Oral Reconstruction International Symposium (ORIS) 2022.

More information

Dreams and reality – treatment concepts and trends

While innovation is driven by people who have a dream to improve, in the end who is better positioned to show what reality is, than a scientist presenting evidence-based data? The eminent scientific committee and internationally renowned speakers vouch for a differentiated and pioneering program, addressing dental professionals from all walks of implantology.

Hot topics for all tastes

The symposium features eight sessions with a wide range of hot topics, proven and contemporary concepts as well as the latest technologies. The world-renowned speaker line-up guarantees the highest quality of lectures and state-of-the-art workshops.

Expect an inspiring program with a lot of opportunities to network with like-minded professionals.

Bavarian Night:
Munich and all of Bavaria are inseparably linked with the Oktoberfest. Celebrate with us on Friday, 14 October in the evening in one of the most traditional restaurants in the heart of the Bavarian state capital! Join us for an unforgettable event.

A 12-month follow-up

Delayed immediate implant placement and direct soft-tissue management

Dr Haki Tekyatan, Germany

This follow-up after 12 months concerns the current clinical and radiological condition of a case previously documented in a published report,[1] more specifically an implantological treatment in region #12. In summary, endodontic treatment of tooth #12 had failed, the tooth was not worth preserving and it was thus extracted in a minimally invasive manner. Local bone and alveolar management were carried out using bio-functionalised (injectable platelet-rich fibrin or A-PRF) CERASORB Foam (curasan), a biomimetic, regenerative β-tricalcium phosphate collagen matrix. Six weeks after the alveolar management, delayed immediate implantation was carried out using a surgical guide and implant position was confirmed via an intraoperative scan. The scan was used to produce a new, special individualised PEEK healing abutment. Another six weeks later, implant exposure and direct soft-tissue management took place in the healing phase with the special PEEK healing abutment. Finally, the fitting of a ceramic crown was carried out. This allowed the creation of favourable conditions under appropriate circumstances and with targeted procedures in order to achieve an aesthetic, prognostically reliable and predictable result. A clinical examination and a radiographic follow-up were carried out after 12 months (Figs. 1 & 2).

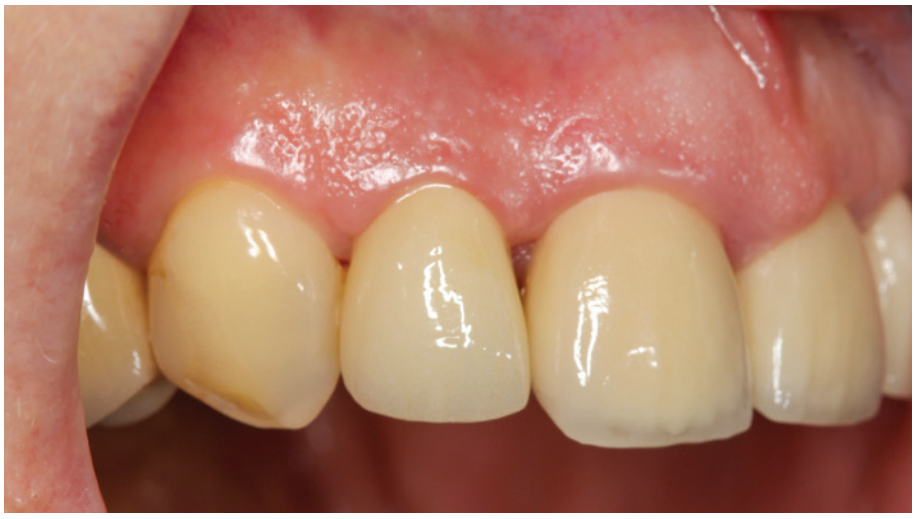
Conclusion

The expectations of our implantology patients are very high, particularly in the aesthetically relevant area. It is of particular importance to use targeted procedures and methods to preserve soft tissue and bone for long-term functional and aesthetic success and to ensure the prerequisites for this. In our case, the 12-month follow-up showed stable clinical and radiological conditions to continue ensuring an aesthetic, safe and predictable result.

About CERASORB Foam

The precise filling of bone defects has an important influence on bone regeneration. In this context, the biomimetic, fully resorbable, hydrophilic and malleable β-tricalcium phosphate collagen matrix CERASORB Foam scores highly in every respect.

CERASORB Foam is a matrix of porcine collagen (Type I) and highly porous pure-phase β-tricalcium phosphate granules (CERASORB M, CERASORB Classic) of different sizes and densities. The granules are embedded in the collagen and are fixed by its fibres.



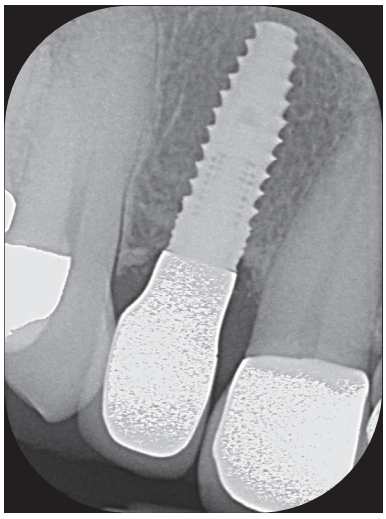


Fig. 1: Clinical situation 12 months after restoration. Stable, non-inflamed soft-tissue conditions. Distally almost complete and mesially partial formation of papillary structures. **Fig. 2:** Radiograph 12 months after restoration. Stable, well-developed osseous structures could be seen around the implant, along with complete integration of the implant. CERASORB Foam had been completely resorbed and replaced by endogenous bone.

Convenient to use

The collagen gives CERASORB Foam its particularly user-friendly properties. Moistened with blood from the defect or mixed with platelet rich fibrin (PRF), the initially dry material can be modelled and then positioned precisely and comfortably in the defect.

Synergy effects through the CERASORB collagen matrix

Collagen has a high binding capacity for physiological fluids. The resulting large area of contact with the surrounding vital bone allows bone-forming cells to integrate the material and facilitates the absorption of nutrients and proteins. This allows collagen to support bone regeneration early on.

The special CERASORB collagen matrix can hold a granulate content of 85% by weight and thus ensures high volume stability after degradation of the more quickly resorbable collagen. The high porosity of the granules in turn offers a stable scaffold for the newly forming bone.

Complete bone regeneration

CERASORB Foam is completely degraded and replaced by autologous bone. Degradation of the biomaterial with the simultaneous formation of new bone leads to the restoration of healthy bone. Resorption occurs in several phases and can easily be followed using radiography.

Literature

1 Tekyatan H. Delayed immediate implant placement and direct soft-tissue management. implants. 2021;3:6–12.

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Case report

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NSK

Finding the right time for implant loading

Today, the trend in implant dentistry is to have a short or no healing period at all before loading the implant. If conditions are not optimal, poor primary stability may increase the risk of implant failure. The Osseo 100 measures implant stability and osseointegration to provide sufficient information to decide when to load an implant. This is particularly important when working with shorter treatment time or managing risk patients.

The peg is excited by magnetic pulses and vibrates due to the stiffness in the contact area between the bone and the implant surface. Once attached to an implant, magnetic pulses cause the MulTipeg™ to vibrate. The instrument measures the frequency of the vibration and translates it to an ISQ scale value between 1 and 99. The higher the ISQ value, the better the stability. Measurements can be made without unnecessary impact since the equipment does not come into physical contact with the implant or abutment.

The device is also available as Osseo 100+: It can be connected via Bluetooth® to Surgic Pro2 to share and manage the data of those measured ISQ scores.

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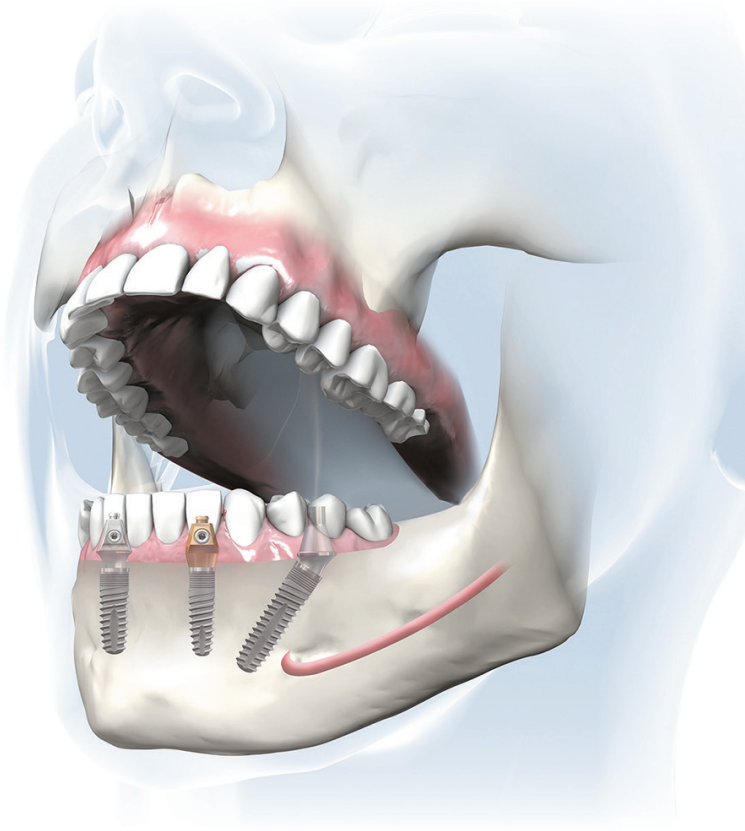
bredent medical

Immediate implant placement: Better than ever



More than 500 dental practices and clinics in more than 20 countries offer SKY fast & fixed immediate restoration therapy.

With its SKY fast & fixed implant system, bredent paved the way for its international success some 15 years ago. Since then, the company has continuously developed its system together with users. It is not ony a new product, but also a very special and innovative form of therapy: patients who become edentulous can be completely restored with a small number of implants. And this can be done in just one day and with a success rate of over 98 per cent. This is because, in contrast to delayed implantation, immediate implantation preserves the surrounding soft and hard tissue and achieves a correspondingly better osseointegration.

"We saw SKY fast & fixed as a holistic therapy from the very beginning. Thus, at the beginning, the main task was to develop a reliable protocol with our clinical partners in order to be able to provide patients with a bridge in a few hours," says Roland Benz, Product Manager at bredent medical. The first comprehensive manual was published in 2008. In the meantime, it has been revised several times and today, of course, also includes the integration of the implant system into different, digital workflows.

It is the details that counts

The components of the SKY fast & fixed system have also undergone a continuous development process. The abutments have become narrower and more tailored so that there is no more bone collision during insertion. The existing, valuable bone therefore no longer has to be removed. With the transversal screw connection, the german manufacturer offers a special solution for appealing aesthetics in the anterior region, as the occlusal screw channels are omitted here. The closure pin of the screw channel facilitates the fixation of the temporary bridge in the mouth so that complications due to resin in the screw channel can no longer occur.

These and many other special features have been developed by bredent together with users over the past years to round off the SKY fast & fixed therapy.

Competent partner throughout the entire process

With SKY fast & fixed, bredent not only offers a coherent form of therapy: Users can count on the company as a competent partner throughout the entire workflow. On the one hand, because bredent with its product variety can offer practice groups and Medical Care Centers complete solution packages that fit together smoothly. On the other hand, because the READY FOR USE platform also makes communication with external partners such as laboratories child's play. It gives the practitioner the possibility to upload his patient data securely to the READY FOR USE platform and to choose an experienced, specialised planning centre. The centre creates a planning proposal, which is corrected and confirmed by the practitioner. The surgical guide and the temporary restoration are then fabricated on the basis of this approved planning.

Win-win situation

For more than 15 years, the use of SKY fast & fixed has led to a win-win situation for all parties involved. The patient benefits from a short treatment with the best prospects of success. For the practice, the investment in the immediate restoration brings the maximum increase in added value. The treatment time compared to classical implantology is at least halved and more patients can be treated. Due to the comparatively short treatment time, there is much less organisational work for the practice and the patient.

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Fig. 1: JM Lee, Executive Managing Director of Osstem Europe.

Interview with JM Lee, Executive Managing Director of Osstem Europe

Osstem Europe: New European headquarters in Prague

As one of the fastest growing implant manufacturers in the world, the South Korean company Osstem Implant provides dental implants and related products to patients in more than 70 countries. Now the company opened the doors to its new headquarters in Prague. In an interview, JM Lee, Executive Managing Director of Osstem Europe, talks about the company's motivation and their plans for the European market.

Osstem Implant was founded in South Korea in 1997. Why did you choose Prague as the location of your new European headquarters?

There were several reasons for choosing the Czech capital. It is geographically in the centre of Europe, and we wanted to be able to support our 41 partners across the continent even better and use the multi-cultural environment and thus this great pool of talents for our organisation. The expansion of our infrastructure and the ability to offer a wider portfolio of products and provide a total solution was another reason for Prague. Now we have a service centre, a training centre, and a logistics service. And of course, we wanted to be able to strengthen our presence in the German market and have the space for our direct sales in Germany.

What significance does the European market have for Osstem?

The European market has always been significant for us, but at the same time we have been recognising it as the most conservative and difficult market. Strategically, as an initial step of our globalisation, we targeted the Asian & Pacific Region, where we successfully grew into one of the market leaders. Thanks to our strong presence in those markets,

Fig. 2: Dr Mukesh Soni, Course Director of Practical Implantology, UK (second from left), JM Lee, Executive Managing Director of Osstem Europe (third from left), Ben Nahab, CEO of Dental Direct UK (third from right) and Prof. Marco Tallarico, President of AIC Italy (second from right).

we were able to achieve our market position as the fourth biggest dental implant manufacturer worldwide, accounting for 8% of the global market share.

What makes Osstem Europe special compared to other major competitors?

I would say our various solutions and unbeatable value-for-money ratio. We have a range of special surgery kits that other companies do not offer. For example, the CAS Kit for sinus surgery, the ESSET Kit for narrow ridge and the ESR Kit maintenance kit. These special kits can serve as an entry product for our new customers. Furthermore, we offer high-quality products at a reasonable price.

Since the foundation of our company, we have been continuously investing 7% of our annual sales on R&D and recently we have even increased this share up to 11%. We pursue the philosophy of our founder: "Provide the best value to the dentist and patient." Once the practitioners experience our products, they will realise what I mean.

What are your plans for the future of Osstem Europe, and what developments can your customers perhaps look forward to this year?

We have plans of launching new products such as a new implant system, new implant surface treatments, GBR and of expanding our impression materials line-up. Additionally, continuous online and offline education courses will take place; for instance, Osstem OnDemand and Osstem OnSite. And finally, our annual event "The Osstem-Hiossen Meeting" in Rome will be held on 28 and 29 October 2022.

Interview
video excerpt

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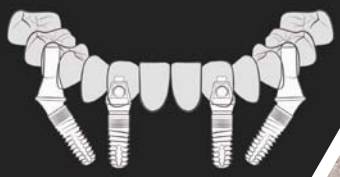
Fig. 3: Prof. Marco Tallarico giving the first lecture in the new training centre.

SKY
fast & fixed



TEAMWORK

FAST. WELL-COORDINATED. EFFICIENT.

United in strength: for predictable and convincing results in full-arch restorations!
Scan and integrate our standardised protocol.

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DENTAL INNOVATIONS
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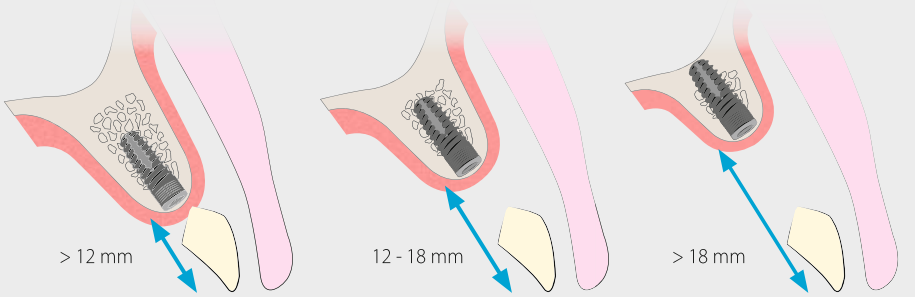
THE SUCCESS FORMULA IN THE PRACTICE

Standardisation = Success

Standardised processes in everyday routine allows you to focus on what is essential. The SKY fast & fixed full-arch restoration makes it possible to manage approx. 80% of the cases with a standardised protocol. This enables you and your team to focus on the peculiar aspects of the each case.

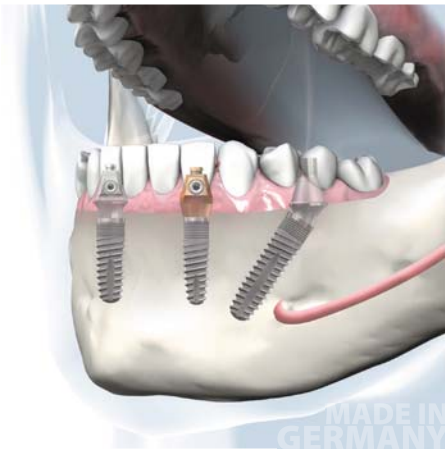
Distance between incisal edge and implant platform[1]



Bridge without artificial gingiva | **Bridge with artificial gingiva** | **Bridge, fixed yet removable**

The symbiosis of routine and learning curve

Practice makes perfect. This principle can be applied to almost all areas of life and can be extended to the SKY fast & fixed therapy. The key to success is a well-coordinated team and a certain degree of routine in order to be able to grasp the complex procedures. Every single step must be perfect so that fast and atraumatic management of the patient is ensured. A standardized treatment protocol supports this. By regularly repeating the steps, the surgical assistant quickly understands what needs to be done with the right armamentarium, subsequently giving you more time to fully concentrate on the procedure. Our experienced medical product specialists are available to assist you with thefirst set of cases and boost your confidence.



SKY fast & fixed – Pioneer in implant-supported full-arch immediate restorations.

Predictable and guaranteed results

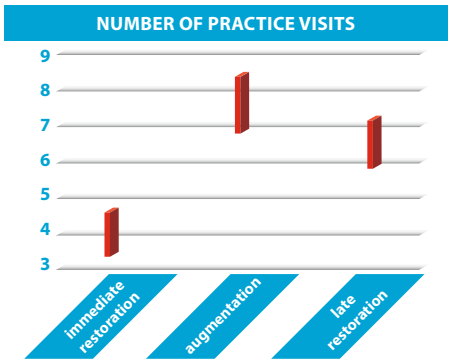
Unrealistic and false promises before treatment usually lead to disappointment for the patient which could have a wide variety of consequences. Standardisation allows you to avoid this problem, as you can make precise statements and plan an appropriate restoration before treatment on the basis of the existing bone structure. Consequently, the patient knows what to expect right from the start. According to Dr. Ali Tunkiwala[1], the reference values above are helpful in this context.

Increased economic efficiency

Beside guaranteeing success and securing routine processes, standardisation provides other advantages too. Preparing a cost estimate is considerably simplified, as more than 80% of the dental supplies and instruments are the same and only a few patient-specific features need to be considered. Above all, this reduces the risk of exceeding the allowable maximum cost. At the same time, you avoid undesired post-treatment cost and guarantee your patients predictable reliability on the basis of a fixed price. With growing experience and routine, you can reduce the total treatment time and your patient can immediately enjoy social life again! In addition, unplanned patient visits due to dehiscence or other complications are reduced to a minimum by the immediate fixed provisional bridge on implants. In the best case, you will only see your patient during the recalls.

Success for practice and patient

Routine, standardized procedures and increased cost-effectiveness – the SKY fast & fixed therapy offers both your practice and your patients some major advantages. Achieve maximum satisfaction through time-saving workflows and immediate, improved quality of life for your patients. Integrate it into your practice now!



Advantages of immediate restorations compared to augmentation and late restorations.

[1] Tunkiwala, A., Kher, U., & Vaidya, N. H. (2020). "ABCD" Implant Classification: A Comprehensive Philosophy for Treatment Planning in Completely Edentulous Arches. Journal of Oral Implantology, 46(2), 93-99; 46(2), 95.

For more information, simply scan the QR code or visit us at www.bredent-implants.com.

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Osstem Europe

Precise and fast VPS impression material

Osstem Europe, the European headquarters of Osstem Implant, one of the most dominant implants sellers worldwide, has launched HySil Plus, a precise and fast V.P.S. impression material with a light, heavy, and mono (medium) body.

In the development of HySil Plus, Osstem Implant has focused its research capabilities on factors such as quality and ease of use of the impression, thus focusing on aspects such as hydrophilicity, tensile strength, setting time and ejection force.

HySil Plus has been optimised for the needs of both practitioner and patient. It spreads into the microscopic areas of the oral cavity, achieving a tear-free result.

Moisture in the oral cavity affects the accuracy of the impression. In order to take the most accurate impression of the patient, excellent hydrophilicity is required – this is easily achieved with Osstem's new material. Hydrophilicity has been improved by minimising the contact angle with moisture. As a result, even in the presence of blood and saliva, HySil Plus flows easily into the smallest detail and captures it. Since HySil Plus becomes less viscous under loading than other products, it is possible to take more precise impressions with its excellent thixotropy.

The correct viscosity ratio also reduces the risk of the impression material falling into the oral cavity.

Not only has the curing time been shortened to the shortest among competing products, but the time for the patient to hold the impression has also been reduced. This in turn increases the practitioner's satisfaction by minimising setting time and increasing the accuracy of the impression.

Normally, the delivery of heavy impression material requires considerable force when loading the tray, but HySil Plus is easy and smooth to deliver due to the significantly reduced delivery force.

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Dentaurum

The new fixing screw – development for the digital workflow

Fig. 1: The new fixing screw.

Fig. 2: tioLogic® TWINFIT titanium scan abutments.

Improvements always start in the detail. True to this motto, the innovators at Dentaurum Implants have developed the fixation screw. It allows the new titanium scan abutments to be inserted safely and precisely. This ensures that the abutment is correctly inserted, even in areas that are difficult to view – without additional X-rays.

The new fixing screw has a shortened thread and can therefore only grip if the scan abutment is correctly lodged in the implant. If there are even the slightest deviations, the thread will not find a grip and the dentist will immediately notice that readjustment is necessary.

Perfect placed insertion is ensured even under poor visibility or with raised gingiva. Deviations in the digital impression will be minimized. The new fixing screw is also anodized in red to make it easier to perceive. Dentaurum Implants is actively committed to environmental protection. Besides the certification according to DIN EN ISO 14001 and EMAS, the reduction of disposables is an integral part of the concept.

With the new HLD coating, it has been possible to make the scan assemblies and scan caps completely scannable without powder or spray. After using, the articles can be sterilized in the thermal disinfector. With the titanium material, the abutments are robust and resistencially stable, making them more durable and environmentally friendly.

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Immediate implant placement in focus

Better now than later

For patients there is usually no doubt: implants placed directly after an extraction, requiring no separate surgical procedure, are an attractive option. But how does the peri-implant tissue react to immediate implant placement? And how does this technique compare to delayed or late implant placement protocols? We are taking a look at a selection of studies to answer this question.

In their cross-sectional analysis, Parvini et al. investigated the prevalence of peri-implant disease following immediate implant placement and immediate loading. A total of 47 partially edentulous patients with 64 implants were included in the study. Standardized surgical and prosthetic protocols were used for all patients (including flapless atraumatic extraction, bone-level implants with platform switching, immediate provisional restoration with screw-retained abutments and bisacrylate composite resin crowns). Following surgical procedures performed between 2008 and 2017, the inserted implants studied had been in situ for two to ten (4.23 ± 1.7) years.

The clinical evaluation included probing depths, soft-tissue recession, suppuration, implant mobility and the width of the keratinized mucosa, in addition to the plaque index and bleeding on probing. Where clinical signs of peri-implant inflammation were present, panoramic radiographs were also taken to detect any changes in marginal bone levels.

Peri-implantitis is rare

At the patient level, healthy peri-implant conditions prevailed in 38.3% of individuals. In the remaining 61.7%, researchers found peri-implant disease. The majority of these cases (57.5%) were diagnosed as peri-implant mucositis, with only 4.2% of subjects showing peri-implantitis. At the implant level, healthy peri-implant conditions prevailed around 48.5% of fixtures. Another 48.5% of implants were affected by peri-implant mucositis, and 3% by peri-implantitis.

Based on these findings and given the limitations of this study, the authors conclude that immediate implant placement and immediate loading are associated with a high success rate after two to ten years.

Immediate implant placement in compromised extraction sockets

A 2021 systematic review examined treatment outcomes after immediate implant placement in compromised extraction sockets. The authors looked at implant survival rates and other success parameters, such as marginal bone levels or soft-tissue conditions.

Their literature search, which included reports published to January 2021, identified 43 studies to include in their analysis. In total, data covering 3,436 subjects and 5,148 implants over a period of 8 to 120 months were considered. Of these implants, 4,804 were immediate implants, with 3,305 of the latter placed in compromised extraction sockets. A flapless approach was used in 18 of the studies included, while a mucoperiosteal flap was reflected in 25 studies. Only 2 studies used both techniques.

An option for pre-damaged extraction sockets

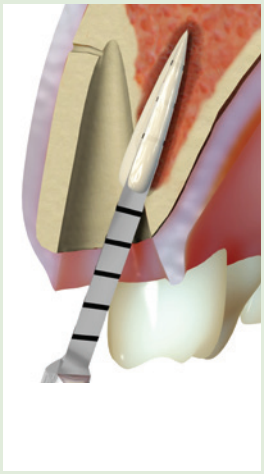
While all 43 studies reported the incidence of implant loss, 22 publications additionally addressed marginal bone loss, 9 addressed instances of soft-tissue recession, and only 3 studies zoomed in on aesthetic parameters. A total of 106 implants placed immediately in compromised extraction sockets were lost, compared to 19 lost implants in intact extraction sockets. The resulting survival rates were 96.79% and 98.73%, respectively, so the review's discussion section stated that there had been no significant differences in survival rates. The conclusion was that immediate implant placement in compromised extraction sockets does not appear to adversely affect survival and success rates compared to non-compromised sockets.

High survival rates regardless of timing

Aiquel et al investigated the extent to which the timing of implant placement and loading affects implant survival and biological success parameters in a systematic review. They analyzed 14 studies with at least 10 patients rehabilitated with multi-unit restorations supported by at least two implants and followed for at least three years. Implant survival rates and at least one biological parameter were reported in all studies included.

Based on the definitions of different times of implant placement and loading proposed by Gallucci et al. and Siebers et al., the authors assigned all studies to one relevant category. In this system, implant placement and implant loading can

Minimally invasive immediate implant placement



The MIMI procedure is a flapless implant insertion protocol that also provides for immediate implant placement, developed by Dr. Armin Nedjat between 1994 and 2006. In the MIMI nomenclature, immediate placement is designated a MIMI 0. A characteristic feature of MIMI 0 is that a new implant bed is created rather than inserting the implant into the extraction socket. Scan the QR code on the left to view an immediate implant placement procedure using the MIMI 0 protocol.

For teeth with a single root, such as the incisor shown on the upper left, a new implant bed is created by drilling at an angle different from that of the extraction socket. The empty extraction socket can then be filled with, for example, autologous bone replacement material obtained from the patient's extracted tooth using the Smart Grinder procedure.

For molars with two or three roots, drilling is performed into the bifurcation or trifurcation. This requires the pilot hole and, if necessary, its first extension hole to be drilled with conical triangular drills at low speed. The cavity is then prepared with condensers of ascending diameter until a torque of approximately 20 Ncm is achieved, which also indicates what the diameter of the implant should be. For example, if a torque of 20 Ncm was achieved with the condenser with a diameter of 4.3 mm, an implant with a diameter of 4.5 mm should be selected. Scan the QR code on the right to view an immediate implant placement procedure using the MIMI 0 protocol.

be immediate, early or delayed, resulting in nine possible combinations (e.g., immediate placement with early loading or delayed placement with immediate loading).

The studies included covered five of the nine defined categories, including immediate and early loading after immediate placement and all three loading times following delayed placement. With the exception of one prospective cohort study, in which immediate placement and loading were performed (survival rate: 90%), all groups exhibited survival rates of more than 90% over study periods of 3 to 15 years after surgery. Based on these findings, and given the prevailing limiting factors, the authors concluded that all timing combinations for placement and loading produced high survival rates.

Positive results following immediate placement

Arora et al took a closer view at immediately placed and provisionalized implants. Their prospective study covered 30 patients with single-tooth implants in the anterior maxilla and documented hard- and soft-tissue changes as well as aesthetic outcomes using the Pink Es-

thetic Score (PES). In their study, the surgical procedure was flapless following augmentation of the bony gap between implants and buccal bone walls.

The average increases in bone height over a follow-up period of two to five years were 0.18 ± 1.38 mm (p = 0.85) in the mesial region and 0.34 ± 1.40 mm (p = 0.22) in the distal region. The average soft-tissue loss was 0.05 ± 0.64 mm in the mesial papillary region and 0.16 ± 0.63 mm in the distal papillary region, and the midfacial recessions was 0.29 ± 0.74 mm, deemed to be beneficial by the study authors as none of these values turned out to be statistically significant.

The authors concluded that by using a flapless technique, immediately placed and restored implants in the anterior maxilla yielded positive results in terms of osseointegration and of hard- and soft-tissue outcomes and aesthetics.

Reduced incidence of soft-tissue recession

The retrospective analysis by Noelken et al found evidence for an improvement of the facial soft-tissue level after immediate implant placement. They provided 26 patients with recession of the marginal gingiva on a non-salvageable anterior maxillary tooth (13 to 23) with an immediate implant. Extraction and implant placement were performed using a flapless technique, and facial bone defects were augmented with autologous bone. Exactly half of the patients also received connective-tissue grafts.

After an average 45 months, the authors found a significant reduction in soft-tissue recession from 1.8 to 0.9 mm in the group of patients without a connective-tissue graft. In the group of patients treated with a connective-tissue graft, this reduction was even more pronounced – from 2.3 to 0.5 mm. Additionally, a significant improvement in PES values was evident in both groups. None of the implants investigated were lost, although a marginal bone loss > 1 mm was observed around 5 implants without a soft-tissue graft.

The authors considered the clinical results as evidence that immediate implant placement could improve facial soft-tissue levels and aesthetics patients with initial gingival recessions of 1 to 3 mm. This effect was more evident in cases with more pronounced recession and additional connective-tissue grafts.

Conclusion

Some practitioners still consider immediate implant placement too risky, but the studies discussed here take a much more promising view of this technique. While the authors of the cited reviews uniformly express a desire for a broader data base, their conclusions suggest that immediate implant placement is far more reliable than the still relatively small number of immediate procedures would suggest. Given the smaller number of treatment sessions that eases the psychological and financial burden on patients in particular, immediate implant placement should be considered as a treatment option more frequently.

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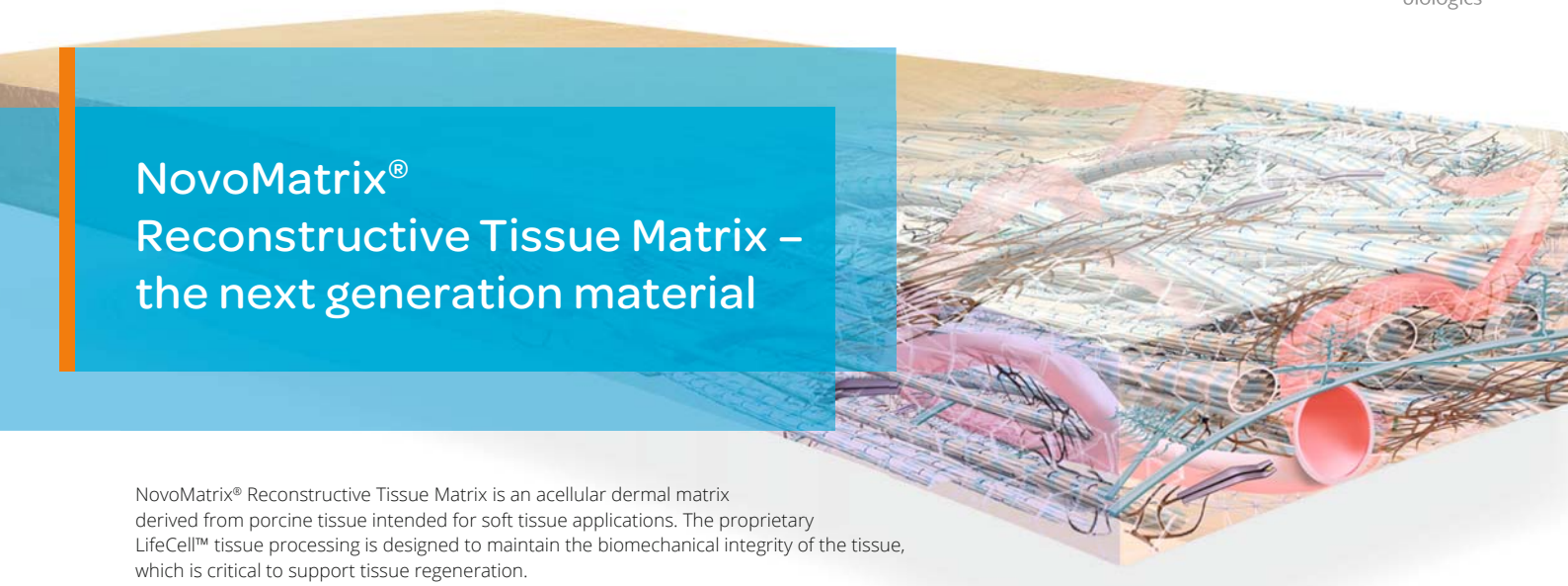

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