

EDI Journal

European Journal for Dental Implantologists



TOPIC

EU Medical Device Regulation

MDR – standing in the way of innovation?



»EDI News: 14th BDIZ EDI Expert Symposium · New Guideline of the 14th EuCC · Investors in the dental sector – threat or opportunity? · Pros & Cons: Short vs. long implants
»European Law: ECJ judgment on patents for medical devices »Clinical Science: Five-year follow-up of immediate restorations »Case Studies: Combined strip technique after vertical ridge augmentation · Benefits of an immediate tissue-level protocol



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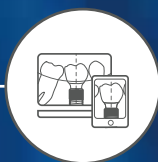
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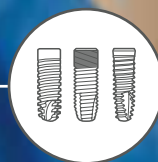
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Turbulent times

Greek mythology tells us how Europe was born. *Zeus*, the Greek father of the gods, had his eye on *Europa*, daughter of the Phoenician king *Agenor*. He turned into a white bull and abducted *Europa* across the sea, to the island of Crete. That “foreign” continent on the other side was later named after her: Europe.

The beginnings of the European Union were based on a widespread desire in Western Europe to secure peace after the Second World War. The USA’s Marshall Plan initiative of 1948 was already based on economic cooperation. This was followed by the foundation of the Council of Europe in 1949 “to uphold human rights, democracy and the rule of law”. The European Coal and Steel Community (ECSC) was founded in 1951, whereas the European Defence Community treaty (signed in 1952) never got off the ground. Then in 1957, in the Treaty of Rome, six ECSC members – Belgium, France, Germany, Italy, Luxembourg and the Netherlands – established the European Economic Community (EEC). Several mergers and transformations ultimately led to the formation of today’s European Union in the Treaties of Maastricht (1993) and Lisbon (2009).

Step by step, cooperation between the European states became closer and expanded into the areas of justice, home affairs, and foreign and security policy. Today there are 28 member states with a total population of half a billion. But the gradual transfer of powers from the nation-states to the supranational organization has also given rise to fears, scepticism and criticism. And this is where we are today. The number of EU sceptics and critics is growing, the numerical strength of pro-European forces is shrinking. Pro-European parties are still in the majority in the newly elected European parliament, but it will be much more difficult to forge alliances following significant losses by the traditional major centre-left and centre-right formations.

Here the EU Commission plays an important role. It is the EU’s executive body, it sets goals and priorities and prepares proposals for legislation. What is the admissible curvature of a banana? Does competition in the European internal market have any limits, and if so, what are they? So far, health care has been a national matter. Nevertheless, in recent years, the Commission has repeatedly tried to include the health sector in the Services Directive, softening it up to competition – constant dripping wears the stone. The question will be whether a new impetus in this direction will come and what influence the newly elected President of the European Commission will exert. The truth is that the health systems of the member states are simply not comparable.

This issue gives you an overview of the results of the European elections in the 28 member states along with a brief analysis. People in the UK also went to the polls – probably for the last time. A hard Brexit is on the horizon. Unfortunately – because there can only be losers on all sides, from an economic point of view.

Dark clouds also hang over the medical device market. The transition period of the EU Medical Devices Regulation will expire in one year, and there is still a shortage of everything: reliable information, Notified Bodies – and optimism.

Of course, this issue of the EDI Journal is not limited to political reporting. Our Pros & Cons section examines long versus short implants, with our two participating experts taking the sharp edges off the battle. And finally, this issue addresses the business structures in our profession, today and in the future. There is a lot of possible middle ground between the individual dental practice and the dental medical care centre (D-MCC) controlled by financial investors.

But do go ahead and take a look for yourself!

Anita Wuttke
Editor-in-Chief



Schematic representation: A perforation of the sinus membrane is sealed with a collagen membrane and two titanium pins.



Buccal view of 18-month follow-up of a combination gingival graft procedure. A considerable amount of KT can be appreciated.

EDI News

- 10 14th Expert Symposium of the BDIZ EDI
- 14 14th European Consensus Conference (EuCC)
- 15 Practice Guideline: Preventing, detecting and treating specific complications
- 22 13th European Symposium of BDIZ EDI in Italy
- 26 Impressions: BDIZ EDI at IDS 2019
- 28 IDS 2019: “Digital” is the magic word
- 30 Quality Guideline – Three questions for ...
- 32 Topic: MDR – standing in the way of innovation?
- 33 Interview with Professor Ulrich M. Gassner
- 36 CED position on MDR
- 38 Professional supervision: No special rules for dental chains
- 40 Interview with Dr Freimut Vizethum on investors in the dental sector
- 42 Pros and Cons: Short vs. long implants
- 44 Analysis of the European election results
- 46 Annual report 2018 of the CED
- 48 ADI Team Congress 2019 in Edinburgh
- 49 Female Dentists in Europe: Dr Kerstin Finger MA
- 52 OMD Gold Medal for Professor Antonio Felino
- 54 International Osteology Symposium 2019
- 56 Europe Ticker

European Law

- 58 Supplementary protection certificate (SPC) also for medical devices?

Clinical Science

- 60 Five-year follow-up of immediate restorations with ceramic-reinforced PEEK
- 64 The “Tattone technique”

Case Studies

- 66 Combined strip technique after ridge augmentation
- 70 Benefits of an immediate tissue-level implant protocol
- 76 An immediate-delayed socket grafting procedure

Business & Events

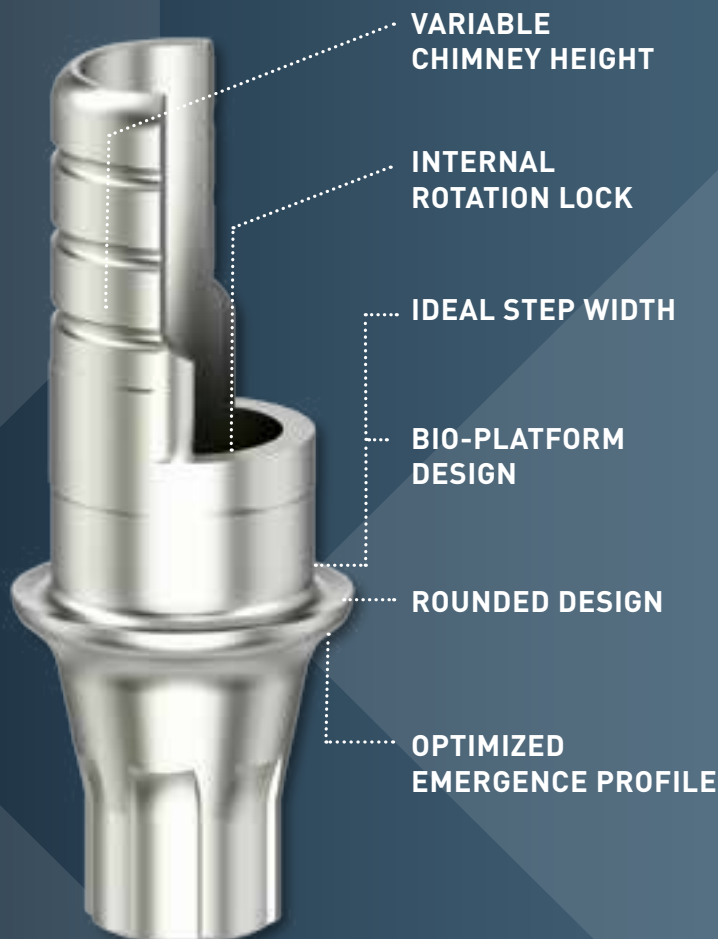
- 82 IDS 2019: Voices from the industry
- 90 Interview with Basil Gürber, Osteology Foundation
- 92 Osstem World Meeting 2019 in Tokyo
- 94 Thommen Workshop at the EAED meeting in Munich
- 95 Farewell Symposium for Professor Daniel Buser, Bern
- 95 Save the date: Geneva Treatment Concept Course
- 96 Interview with Professor Gil Alcoforado, Chair of the EAO annual scientific meeting 2019 in Lisbon
- 97 Save the date: Oral Reconstruction Symposium New York
- 98 One for all – Straumann Group presents its innovations
- 100 Nobel Biocare Global Symposium, Madrid
- 101 Bredent training courses in Armenia and Algeria
- 102 New study results on implants in osteoporosis patients
- 104 Interview with Dr Kyoo-Ok Choi, Osstem Implants
- 105 Interview with Hans Geiselhöringer, Nobel Biocare
- 106 Interview with Professor Michael Gahlert and Dr Stefan Röhling on ceramic implants
- 108 Interview with Edgar Schönbächler, Bien-Air Dental
- 110 Interview with Gene Dorff, Dentsply Sirona Implants
- 111 More than 1,000 scientific studies on ISQ technology
- 112 Anthogyr joins the Straumann Group
- 114 W&H presents new corporate design

News and Views

- 03 Editorial
- 06 Imprint
- 08 Partner Organizations of BDIZ EDI
- 116 Product Studies/Product Reports/Product News
- 130 Calendar of Events/Publishers Corner

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Association of Dental Implantology UK (ADI UK)

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



Ogólnopolskie Stowarzyszenie Implantologii Stomatologicznej (OSIS EDI)

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



Sociedad Espanola de Implantes (SEI)

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



SOCIEDADE PORTUGUESA
CIRURGIA ORAL

Sociedade Portuguesa de Cirurgia Oral (SPCO)

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



Udruženje Stomatologa Implantologa Srbije-EDI (USSI EDI)

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

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14th Expert Symposium of the BDIZ EDI on dealing with complications

From all points of view

“The time of beautiful pictures is over”, that’s how Professor Joachim E. Zöller, Vice President of the BDIZ EDI, had already called for further training events in oral implantology years ago. The 14th Expert Symposium followed this call and focused on possible complications in oral implant treatment. After 2010, the BDIZ EDI dealt with this topic for the second time within the framework of its Expert Symposia and extended the range of topics “Implant Surgery” and “Implant Prosthetics” by legal aspects. A total of about 180 participants attended the two-day symposium, workshop and committee meeting in Cologne.

The BDIZ EDI will celebrate its 30th birthday – and has left its mark in the three decades of its existence, as President *Christian Berger* pointed out. In his short welcoming address he mentioned the milestones of the association since 1989. The exhibition “Impressions from 30 years of BDIZ EDI” was on display at the BDIZ EDI stand at the IDS.

Implant surgery

At the request of many participants from the previous year, the Scientific Director of the Symposium, *Professor Joachim Zöller* (Cologne, Germany) also served as a speaker. He highlighted the difficult topic of nerve injuries and presented the therapeutic options that exist today: from transcutaneous electrical nerve stimulation (TENS) to acupuncture therapy and, in the case of continuity problems, the surgical intervention. He underlined the importance of initiating the suitable therapy with the help of electromyography (EMG). If no reflex is triggered, that is, if the nerve is severed, surgical intervention is necessary. According to *Zöller*, the chance of healing during resection of affected nerve parts and

possibly nerve transplantation is 50 to 60 per cent. However, this does not apply to the lingual nerve, where the prognosis is worse.

The possibilities and limitations of covering recessions at the implant were the topic of *Professor Anton Sculean* (Bern, Switzerland), who presented the Modified Coronally Advanced Tunnel Technique (MCAT) and the Laterally Closed Tunnel Technique (LCT) in his lecture. The variations of the tunnel technique are promising, but the surgeon has to keep in mind to have sufficient bone and attached mucosa. His advice: secure soft tissue before implantation. For smaller soft tissue defects up to 2 mm, good results can be achieved with the coronal advanced flap (CAF), the subepithelial connective tissue graft (SCTG) or GBR. However, there is no evidence for the successful coverage of defects > 3mm.

According to *Professor Robert Haas* (Vienna, Austria), the restoration on four interforaminal or interantral implants with a fixed bridge restoration that cannot be removed by the patient has been part of the standard restoration of the edentulous upper and lower jaw for years. In his lecture, he pointed

Like every year before, Cologne on the Rhine with its famous cathedral, the construction of which began in 1248, was the venue of the 14th Expert Symposium of the BDIZ EDI.



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Christian Berger (left) and Professor Joachim E. Zöller



Professor Anton Sculean, Bern



Professor Robert Haas, Wien



BDIZ EDI legal advisor Professor Thomas Ratajczak, Sindelfingen

out the possible complications specific to the All-on-4 protocol. He showed how the fixed restoration of the edentulous jaw can be achieved more safely and predictably by interantral implantation and how possible complications can be safely eliminated. He made it clear that in the event of a loss, the question was not whether the placement was immediate, delayed or late, but rather when the loss occurred. Smoking plays an important role here, as does a periodontitis.

Legal aspects

When does one speak of failure? A difficult question, which BDIZ EDI legal advisor *Professor Thomas Ratajczak* (Sindelfingen, Germany) tried to answer. The dentist does not owe success, so failure is difficult to define. His version: "Failure occurs when the agreed treatment goal is not achieved and the divergence of the actual state from the desired state is not tolerated." The lack of tolerance in the divergence could be due to the ideas of the practitioner or the patient or to deficiencies or mistakes. On the other hand, the identification of a failure says nothing about its consequences. The medical law expert also dealt with the distinction compared to the treatment error. The failure of the initiated treatment measure alone does not constitute a treatment error, because success is not due. *Ratajczak* listed a number of judgments on this issue, including the one by the OLG (Higher Regional Court) Munich of 14.11.2012 – 3 U 22106/11 and the one by the OLG Koblenz of 04.07.2016 – 5 U 565/16.

Implant prosthetics

MDT Gerhard Stachulla (Bergen, Germany) presented examples of how suboptimally positioned implants could be restored in an adequate way from a prosthetic point of view by adopting appropriate dental technical measures. *Stachulla* stated that despite the many possibilities of pre-surgical

planning, implants were not always placed optimally from a prosthetic point of view.

Biological and technical complications in implant prosthetics were the topic of *Dr Peter Gehrke* (Ludwigshafen, Germany). He mentioned non-detected residual excess cement, which can lead to irreversible inflammatory reactions of the peri-implant hard and soft tissue, as a biological complication. According to *Gehrke*, mechanical complications occur when the fatigue strength of the restorative components is exceeded and, as a result, leads to material failure. Different types of restorations and the associated use of different materials (for example, ceramic/plastics/metal) and treatment concepts (for example, fixed/removable, telescope/bar, pre-fabricated/ customized) hold significantly different risk potentials, said *Gehrke*, the occurrence of fractures, loss of retention and loosening depending on the chosen type of restoration. The classic decision between screw and cement retention must be taken on a case-by-case basis. "I always go for screw retention", is not an universal solution, as *Gehrke* proved by means of various studies.

The day before, the European Consensus Conference (EuCC) had discussed complications and the indication for composite bridges controversially. *Professor Hans-Joachim Nickenig*, speaker at the Expert Symposium, explained the problems in detail. At the beginning of modern implantology, composite bridges were often equipped with stress breakers, which led to an increase in technical and biological complications. "If the anatomical findings require a composite bridge, it is important to fabricate it as a rigid element between tooth and implant", emphasized *Nickenig*. In addition to the permanent cementation on the tooth, the value of the abutment tooth is important for the prognosis, since complications can often be observed earlier in case of endodontically treated or periodontally damaged teeth.



Dr Peter Gehrke, Ludwigshafen(left), and MDT Gerhard Stachulla, Bergen



Professor Hans-Joachim Nickenig, Cologne



Adj. Professor Jörg Neugebauer, Landsberg/Lech



Professor Joachim E. Zöller is President of the Order of Cologne's first carnival society „Die Grosse von 1823“.



In the concluding lecture, *Adj. Professor Jörg Neugebauer* explained the possibilities of reconstruction of hard tissue defects on the implant or after implant loss. Using case studies of implants placed 20 years ago, he demonstrated successful peri-implantitis reconstructions with autologous bone and a follow-up phase of more than ten years.

In the context of peri-implantitis surgery, he warned against the use of non-biological bone graft substitutes because they could accelerate peri-implant bone resorption. In the speaker's opinion, the treatment of bone defects after explantation often requires soft tissue reconstruction in addition to ridge augmentation. According to *Neugebauer*, the most stable results can be achieved with autologous transplants from the retromolar region or an iliac crest graft, depending on the size of the defect. In order to accept these reconstructive surgeries, patients must be made aware of the extensive therapy steps and often sub-optimal results.

Conclusion

The participants of the Symposium rated the topics and speakers with top marks; the important aspects – right up to the legal side – had been impressively highlighted, according to individual voices from the auditorium. The 15th Expert Symposium will again take place in Cologne on 23 February 2020.

AWU ■

14th Expert Symposium 2019

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The European Consensus Conference 2019 (from left): Front row: Adj. Professor Jörg Neugebauer, Dr Stefan Liepe, und Dr Peter Gehrke (all Germany); second row: Professor Hakan Özyuvaci (Turkey), Professor Pavel Kobler (Croatia), Dr Fisnik Kasapi (Republic of Macedonia); third row: Dr Jeroen Peplinkhuizen (Netherlands), Dr Vikas Gowd (India), Dr Peter Ehrl (Germany); back row: Dr Jan Willem Vaartjes (Netherlands), Gerhard Stachulla (Germany), Professor Robert Haas (Austria) und Dr Freimut Vizethum (Germany). Not present: Professor Joachim E. Zöller, Christian Berger, Professor Hans-Joachim Nickenig (all Germany), Professor Anton Sculean (Switzerland), Professor Antonio Felino (Portugal), and Professor Vitomir Konstantinovic (Serbia).

Guideline 2019 of the 14th European Consensus Conference (EuCC)

Preventing, detecting and treating specific complications to optimize patient outcomes

The BDIZ EDI calls for careful planning and proceeding before starting an oral implant treatment. The aim of the new Practice Guideline of the 14th European Consensus Conference (EuCC) under the auspices of the BDIZ EDI is to avoid complications and, if they occur, to treat them properly in order to improve the outcome for the patient. The new eight-page paper is intended to serve dentists working in oral implantology as a recommendation for dealing with complications.

The international 19-member panel of experts at the European Consensus Conference discussed the different treatment concepts in implant therapy, including both surgical and prosthetic approaches.

The conclusions of the EuCC: "The placement of dental implants is a reliable treatment option for restoring the function and aesthetics of the patient. Careful case selection is necessary and the intraoral findings should not be the only ones to be consid-

ered. Due to the wide variety of implant designs and proposed surgical and prosthetic procedures, the individually suggested parameters should be adhered to to avoid complications. All procedures should be performed by practitioners with the necessary up-to-date expertise, education and training."

The working paper was prepared by *Adj. Professor Jörg Neugebauer*, Landsberg, and *Professor Hans-Joachim Nickenig MSc*, Interdisciplinary Polyclinic for Oral Surgery and Implantology, and Clinic and Polyclinic for Oral and Maxillofacial Surgery, Center for Dentistry, Oral Medicine and Maxillofacial Surgery, University of Cologne (Director: *Professor Joachim E. Zöller*). The first draft was examined and discussed by the members of the EuCC according to the following schedule: review of the first draft, registration of alternative proposals, vote on recommendations and levels of recommendation, discussion of points that could not be agreed upon, and final vote.

How to obtain the brochure

The eight-page Guideline 2019 can be ordered as a brochure with a comprehensive bibliography in German or English at a price of 2.50 Euro (incl. VAT, plus shipping costs) from the BDIZ EDI online shop (www.bdizedi.org). Members will receive the Guideline free of charge with the next circular.



Preventing complications to optimize patient outcomes



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Guidelines 2019

**Preventing, detecting and treating specific complications
to optimize patient outcomes**

14th European Consensus Conference (EuCC) 2019 in Cologne

1 March 2019

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Contents#

1 Methods.....	2
2 Problem	2
3 Patient sections	3
4 Surgical techniques	3
High insertion torque	4
Flapless surgery	4
5 Prosthetic procedures	4
Tooth-to-implant fixed partial dentures	4
Fixation of suprastructure	4
6 Conclusion.....	5
7 References.....	5

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Guidelines: Preventing, detecting and treating specific complications
to optimize patient outcomes
14th European Consensus Conference in March 2019
Page 2 of 6

1 Methods

Objective

The purpose of this guide is to provide recommendations for clinicians active in implant dentistry, enabling the prevention, early detection and treatment of complications in order to optimize the patient outcome.

Introduction

All consensus recommendations in this paper should be interpreted as guidelines only. The patient's specific situation is always an important aspect and may justify deviations from the recommendations of this consensus paper.

Background

Implant placement is a proven way to replace missing teeth and to restore function and aesthetics. Nevertheless, complications may occur at various stages of treatment flow. Earlier guidelines covered surgical complications that might be harmful to anatomical structures; a risk analysis; and avoiding implant malpositioning considering further therapeutic needs. This guideline focuses on less frequently encountered risk factors that may arise at various treatment stages.

Literature search

The Cochrane Library, EMBASE, DIMDI and Medline literature databases were used to conduct a systematic search of recent published data. Selective search criteria were used, including terms such as

complication, dental implant, meta-analysis.

The publications identified with the search were screened by reading their abstracts and those irrelevant to the subject were identified and excluded. Those articles found to be potentially relevant were obtained in full-text form. Multiple review papers with meta-analyses were available on the subject.

Procedure for developing the guideline/consensus conference

A preliminary version of this document on which the EuCC based its deliberations was prepared and authored by Dr J. Neugebauer, PhD, and Professor Dr H.-J. Nickenig, MSc, of the Interdisciplinary Department for Oral Surgery and Implantology and Department of Oral and Maxillofacial Plastic Surgery at the University of Cologne, Germany. The preliminary report was reviewed and discussed by the committee members in five steps, as follows:

- Reviewing the preliminary draft
- Collecting alternative proposals
- Voting on recommendations and levels of recommendation
- Discussing non-consensual issues
- Final voting

2 Problem

The outcome of implant therapy depends on the health status of the patient, including his or her medication and nutritional status and the planned procedures and prosthetic restorations. From a surgical point of view, the use of surgical guides and grafting procedures may lead to complications. The recommendations for immediate loading require a high insertion torque, which is also a possible risk factor. From a restorative point of view, the retention type of the

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Preventing complications to optimize patient outcomes



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to optimize patient outcomes
14th European Consensus Conference in March 2019
Page 3 of 6

superstructure may be associated with technical or biological complications. The question of joining natural and implant abutments has also been subject to controversial discussion.

3 Patient sections

Patient expectations

The high number of implant treatments performed today may have deceived patients into believing that there are no longer any contraindications to implant treatment. Implants require a physiological bone metabolism, something that is not a given in the presence of several systemic diseases such as osteopetrosis (Morbus Albers-Schönberg), osteodystrophia deformans (Paget's disease of bone) or fibrous dysplasia. The bone metabolism can also be affected by medications, smoking habits or nutritional status.

Current observations

Case reports have stated that implant treatment is possible for patients with Paget's disease or fibrous dysplasia. For patients receiving antiresorptive therapy, a high incidence of complications in the form of bone necrosis has been reported after tooth extraction, surgical interventions or even as a result of sore spots. However, implant placement, possibly in conjunction with autologous grafting procedures, could produce positive outcomes in osteoporosis patients [16].

Low level of cholecalciferol (vitamin D3) may compromise osseointegration and graft regeneration or lead to progressing peri-implantitis [3]. Patients receiving proton pump inhibitors (PPI) or serotonin reuptake inhibitors (SRI) exhibit higher rates of implant failure [8]. Conflicting results have been reported regarding the effect of glucocorticoids and NSAIDs on implant treatment outcomes [7]

Preventions of complications

- Implant placement is contraindicated in patients suffering from osteopetrosis.
- High-dosage antiresorptive therapy could result in higher rate of BRONJ [17].
- Patients who have been on antiresorptive therapy for osteoporosis for more than three years need a detailed case selection with surgical techniques not requiring intensive bone remodelling [17]. Extensive bone splitting, osteotome techniques or lateral sinus grafts should be avoided.
- In patients with soft bone evident in preoperative radiographs or increased bone resorption, blood cholecalciferol levels should be checked [3].
- In patients with PPI or SRI, the duration and amount of drugs could be investigated before considering a patient for implant treatment [8].
- Patients must be informed that smoking may substantially increase the risk for biologic complications (e.g. peri-implantitis) [4].
- In patients under long-term glucocorticoid medication at high doses, bone-metabolism parameters may have to be evaluated.
- Mild bone malformation in patients with fibrous dysplasia or Paget's disease need a strict indication for dental implants due to a lack of pertinent data.

4 Surgical techniques

Patient expectations

Patients increasingly request immediate fixed rehabilitation in conjunction with immediate implant placement and loading. However, postoperative morbidity should be kept as low as possible.

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to optimize patient outcomes
14th European Consensus Conference in March 2019
Page 4 of 6

Current observations

High insertion torque

Immediate implant placement with immediate restoration is a scientifically proven treatment concept for rehabilitating a failing dentition [6]. Various recommendation on the determination of primary stability have been given, depending on implant designs and the surgical procedures performed, for achieving osseointegration in the context of immediate restoration [18]. A recent RCT on insertion torque showed increased failure and bone resorption rates in the mandible for high insertion torques [14]. Previous meta-analyses have shown that high insertion torques are not correlated with increased bone resorption or implant failure [1, 12].

Flapless surgery

Implant placement using 3D surgical guides is now established, and flapless surgery should reduce the postoperative discomfort. The use of surgical guides based on CBCT technology permits highly accurate implant placement [2, 5]. Compared to free-hand flapless surgery and to the raising of a flap, the outcome of guided flapless surgery was not different in terms of implant failure rates and bone resorption in the hands of experienced treatment providers [11, 20]. Nevertheless, complication such as bone perforation or displacement of the surgical guide may occur [2, 5].

Prevention of complications

- Due to the many different implant designs and recommend preparation techniques, especially in dense bone or in the presence of a thin cortical plate, the manufacturers' recommend insertion torques should be considered.
- Patients benefit from flapless procedures if a proper indication exists in terms of the available bone supply and preoperative 3D diagnostic findings.
- Flapless procedures are subject to a specific learning curve.

5 Prosthetic procedures

Patient expectations

Patients expect a stable prosthetic restoration that meets their aesthetic and functional needs, with minimal complications.

Current observations

A reduction in the number of implants in a given case due to economic or anatomical reasons may be considered by using both teeth and implants as abutments for fixed partial dentures (FPDs). Superstructures can be cemented or screw-retained, both of which can be associated with complications.

Tooth-to-implant fixed partial dentures

A meta-analysis of tooth-to-implant (hybrid) fixed partial dentures (T-I FPDs) reported survival rates of 94.1% after 5 years and 77.8% after 10 years of clinical service [9]. The impact of T-I FPDs and implant-to-implant FPDs in the partially edentulous arch on implant survival rates showed no significant differences for periods up to 72 months [15, 21]. A recent systematic review assessed the effect of rigid and non-rigid splinting between implants and teeth, with overall prosthetic survival rates of 85% and higher risks for tooth intrusion associated with non-rigid connections for observation periods of between 18 and 120 months [19].

Fixation of suprastructure

Depending on the number of implants and the design of available abutments, superstructures can be cemented or screw-retained. Technical or biological complications may occur with

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14th European Consensus Conference in March 2019
Page 5 of 6

either type of retention. A meta-analysis showed no differences regarding loosening of superstructures, changes in marginal bone levels or peri-implantitis [10, 13].

Prevention of complications

- Rigid superstructures should be preferred for T-I FPDs.
- Complications associated with T-I FPDs are encountered mainly at the natural abutment, especially when the teeth are periodontally compromised or root canal filled.
- The form of retention of the superstructure should be chosen by taking function, aesthetics and professional maintenance into account rather than focusing on available techniques.
- To facilitate maintenance, a retrievable superstructure is preferred, but a definitive cementing on natural tooth.

6 Conclusion

Dental implants are reliable treatment options for restoring patient function and aesthetics. Careful case selection is necessary by considering not only the oral findings alone. Due to the great variability of implant designs and surgical and prosthetic procedures proposed, the individual suggested parameter should be followed to avoid complication. All procedures should be performed by treatment providers with the requisite up-to-date expertise and training.

Professor Dr. Joachim E. Zöller
Vice President

Dr. Jörg Neugebauer
Chairman of EuCC

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Guidelines: Preventing, detecting and treating specific complications
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Page 6 of 6

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13th European Symposium of BDIZ EDI in Italy

Intensive days in Verona

The scene: a historic villa just outside Verona. The performance: a congress that explored new approaches from the point of view of oral implantology, approaches that will certainly spur discussion in the professional world. The European Association of Dental Implantologists (BDIZ EDI) had partnered with the European Symposium for the “Veronese Days” this year, held for the fourth time both at the University of Verona and at the congress home in Valpolicella.

The Veronese Days were held under the motto of “Implantology and General Dentistry” and offered an extensive programme for the predominantly German-speaking participants: scientific lectures in English at the University of Verona, live surgery from Switzerland and so-called “table clinics”, that is, small industry workshops that work similar to speed dating. Saturday was reserved for the scientific lectures; there was a special programme for dental assistants. The congress was chaired by *Professors Francesco Nocini* and *Mauro Marincola* (Italy), both of whom are internationally renowned speakers. *Marincola* had previously given several presentations at Expert Symposia of BDIZ EDI and also participated in the European Consensus Conference of BDIZ EDI in 2016, which authored the association’s 11th Guideline entitled “Update: Short, angulated and diameter-reduced implants”.

New approaches, new methods, new materials

While the general-dentistry leg of the European Symposium addressed state-of-the-art endodontics, biofilm management, soft-tissue management,

antibacterial oral hygiene and 3D cephalometric analysis to determine cranial symmetry, the implantological leg focused on ceramic implants and new methods, approaches and materials. *Dr Karl Ulrich Volz* (Kreuzlingen, Switzerland) described methods for bone augmentation with ceramic implants without the use of secondary materials. *Professor Georg-H. Nentwig* (Frankfurt, Germany) showed how to recontour vestibular defects after implant placement using in-situ curable biomaterials, pointing out that this method can make a membrane for stabilization superfluous. *Professor Frank Palm* (Konstanz, Germany) spoke on novel aspects of bone regeneration, focusing on new regeneration materials: a TCP-reinforced collagen foam is thought to stabilize the socket and the soft tissue. *Dr Armin Nedjat* (Flonheim, Germany) demonstrated a direct internal sinus floor elevation. *Professor Marincola* (Rome, Italy) and *Dr Giorgio Lombardo* (Verona, Italy) gave an overview of the short implants available on the market.

The joint panel discussion focused on a question that *Professor Ralf Smeets* (Hamburg, Germany) had asked: Once the tooth is out, when do we get to insert our implant? *Professor Christian Gernhardt*





(Halle, Germany) took up the traditional feud between endodontics and oral implantology – but for him, the two are not at all in opposition to each other. *Gernhard*, who is the president of the German Society for Endodontology and Dental Traumatology (DGET) made it clear that diseased teeth should definitely be preserved as long as possible. *Professor Angelo Trödhan* (Vienna, Austria) demonstrated new methods and instruments used to avoid complications when planning and executing sinus floor elevations and showed how surgeons can keep the Schneiderian membrane intact.



Genotyping ahead of implant placement?

Two lectures were dedicated to the combination of biology and implantology in terms of their complexity and interactions. The topic addressed by *Dr Carolin Stolzer* (Hamburg, Germany) is likely to arouse the minds of experienced implant dentists. Is a genotyping test that measures the genetically determined degrees of inflammation necessary before placing an implant? Or a titanium stimulation test that measures macrophage response to titanium oxide particles? Or even a lymphocyte allergy test? The underlying issue was once again the classic comparison between titanium and ceramics as implant materials. *Stolzer* made it clear that titanium is still the gold standard in oral implantology, but that a biological inflammatory tissue reaction could be caused by particle abrasion, while the risk of abrasion is significantly lower for zirconia. The genotyping test determines the genetic inflammatory potential of a patient. According to *Stolzer*, there is an increased risk of bone resorption with grade IV inflammation.

Miracle vitamin D3?

The second “biological” topic was introduced by *Dr Dominik Nischwitz* (Tübingen, Germany), a dentist and alternative practitioner, namely vitamin D3 and its importance for bone quality. *Nischwitz* is a staunch defender of the beneficial effects of vitamin D3 in combination with vitamin K2 and magnesium on bone quality and supports the intake of

vitamin D3 supplements before an implant surgery. In this combination, he said, vitamin D3 is responsible for transporting calcium to the bones and teeth. It activates two important enzymes, namely osteocalcin (bone Gla protein, BGP), which is responsible for the production of osteoblasts and odontoblasts and plays an important role in the mineralization/remodelling of bones and teeth, and matrix Gla protein (MGP), which prevents calcium from being incorporated into the blood vessels, acting as a so-called calcification inhibitor.

“Small opportunities are often the beginning of great enterprises.” This quote from *Demosthenes* has been characteristic of the history of BDIZ EDI’s European Symposia. Humble beginnings and spurious opportunities have been consolidated into a comprehensive approach that allows communities of dentists to transcend national borders. In BDIZ EDI’s 30th anniversary year, the 13th European Symposium in Verona in early May provided a good example of this, showing how oral implantologists from different countries can benefit from each other’s knowledge.

Top left: Many innovations at the “Veronese Days” – sometimes controversially discussed by the participants. BDIZ EDI and its 13th European Symposium was a cooperation partner of the event. Top right: At the exhibition: BDIZ EDI Managing Director Dr Stefan Liepe, Press Officer Anita Wuttke and Treasurer Dr Wolfgang Neumann. Below: Heads were smoking at the “speed dating” event. Participants moved from table to table. Each table had its own team speaker and its own topic.

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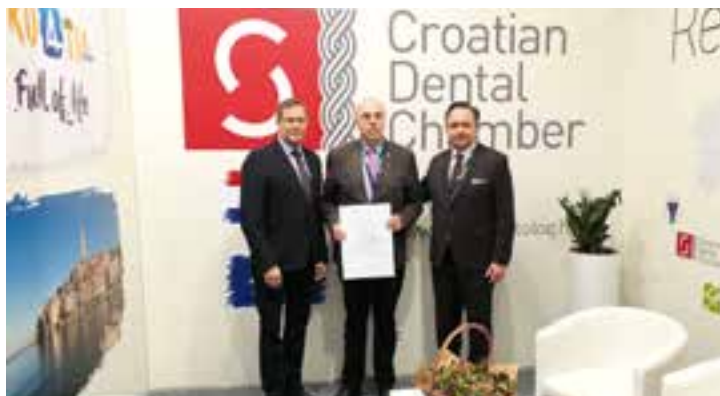
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PLANMECA



The first Expert in Implantology (EDA), Professor Pavel Kobler, received his certificate. Left:BDIZ EDI President Christian Berger, right: Dr Hvroje Pezo, CDC President.



BDIZ EDI cooperates with Omnipress, Greece.



Enjoying non-alcohol Caipirinha: Dr Wolfgang Neumann, Anja Rennhack and Dr Stefan Liepe.



Won the first prize: Dr Peter Engel, President of the German Dental Association.



Impressions of the IDS

The BDIZ EDI offers a very positive summary of its participation at the IDS 2019. Many German dentists and their assistants visited the BDIZ EDI booth to get information and advice – and a take-home copy of the new Guideline 2019 of the European Consensus Conference. An international professional audience showed great interest in continuing professional development (CPD), and especially in the Curricula Implantology that the BDIZ EDI organizes in collaboration with the University of Cologne. For representatives of professional associations and societies, especially from Asia, a cooperation with BDIZ EDI was in the focus of many discussions with the members of the BDIZ EDI board and with the team at the IDS booth.

Many representatives of BDIZ EDI's partner associations showed up to learn more about upcoming events, especially the European Symposium, and to get their own English-language copy of the 14th Guideline of the European Consensus Conference.

A hot topic in the legal arena is the Medical Device Regulation (MDR). Legal counsel of BDIZ EDI, *Professor Thomas Ratajczak*, provided additional concrete information in lively discussions.



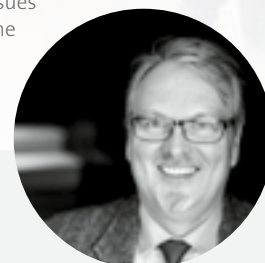
Top: A lot of fun at the wheel of fortune. Centre: Legal advisor Professor Thomas Ratajczak explaining legal issues to dentists from Albania. Bottom: Talk, talk, talk at the booth of BDIZ EDI.

Each of BDIZ EDI's IDS days had its own motto: The list included professional policy, new legislation and the said MDR, quality control and CPD, advanced training, and the information campaign "We want you!". The association's board was represented by *Christian Berger*, *Dr Wolfgang Neumann*, *Dr Stefan Liepe*, *Dr Freimut Vizethum*, *Dr Detlef Hildebrand* and *Professor Joachim Zöller*.

For the first time co-exhibitor at the association's booth: the Croatian Dental Chamber (CDC), which not only offered culinary delights, but also a great deal of knowledge about dentistry in the Balkans. President *Dr Hrvoje Pezo* and Vice President *Professor Pavel Kobler* were present with almost the entire board and many a German-Croatian discussion with representatives of the German Dental Association (BZÄK) took place due to the proximity of the two booths: At IDS, the BDIZ EDI stand is traditionally located opposite the BZÄK stand.

As the IDS approached its end, all printed publications had disappeared, all prizes had been distributed, new cooperative agreements had been announced and potentially new members from Germany and other countries had signed up. All in all, a strenuous but successful IDS week. **AWU** ■

Trends



For Dr Detlef Hildebrand, Secretary General of the BDIZ EDI, the complementation of the fully digital treatment process is an outstanding trend. "It is particularly worth mentioning that digital radiology and digital treatment are now integrating not only in surgery, but also in other areas of dentistry – aesthetics, function, analysis, control – such as DVT/OPG paired with face scan and impression scanning", as he sums up. In implantology, there is a trend towards so-called progressive threads. "These implant types promise higher primary stability for the implementation of so-called immediate restoration concepts". For Dr Hildebrand, greater acceptance of applied biology (PRF/PRP/PRGF) was also a clearly discernible trend at IDS 2019.

Review of 38th International Dental Show in Cologne

„Digital“ is the magic word

Any dentist who did not visit the International Dental Show (IDS) missed something. Without exaggeration, the IDS can be described as the world's leading trade fair for the dental sector. Once again, the organizers achieved record results: 160,000 trade visitors from 166 countries – an increase of 3.2 per cent compared to IDS 2017. There have been minor shifts in content: implant dentistry was no longer the driving force as it had been in previous years. But suppliers in the digital field are outperforming each other: planning, model production, manufacturing processes and more.



The 38th IDS was more international than any other before. After the five fair days, the organizers, GFDI (Association for the Promotion of the Dental Industry), VDDI (Association of the German Dental Industry) and Koelnmesse GmbH reported that exhibitors and visitors were highly satisfied and that IDS had expanded its position as the world's leading trade fair for the dental sector. The forecasts were even exceeded: in terms of the number of trade visitors and the number of exhibitors. 73 per cent of exhibitors from 64 countries came from abroad, as did 62 per cent of visitors from 166 countries – from Argentina, Brazil and Chile to Japan and Korea, Egypt and South Africa, Australia and New Zealand, the whole of Europe, the USA and Canada. Which means that the number of countries of origin also increased by a further 6 per cent.

Keyword: digital practice

There is no way around the digital practice in the future, and the hope of practitioners focusses on a cross-system digital workflow. After all, a completion of the fully digital treatment chain is in sight. Until now, digital radiology and digital treatment have only been used in surgery or implantology, but they are now also moving into other areas: from aesthetics, function, analysis, control to DVT/OPG in combination with face scan and impression scanning to stress tests of the chewing function. According to forecasts, by IDS 2021 at the latest, there will be more digital implant restorations than analogue ones.

Today, virtual models can be used to create virtual set-ups and even plan orthodontic appliances beyond diagnostic aspects. Even endodontics, which were completely analogue until now, "go digital". Today, motors and torques can be controlled via

tablet computers during root canal treatment. The entire procedure can be simulated in advance.

With all the hype surrounding digitalization, it is becoming apparent that dentists and laboratories will not completely abandon analogue procedures. Often, a combination is the best solution: digital impressions, designed on the screen, milled in wax suitable for CAM, pressed traditionally in ceramics and retained conventionally with cement. The rapid technological advances require many detailed decisions – and ultimately, it is the specific patient case that determines the choice of the protocol.

Dentistry leads the way in 3D printing

Dentistry is the absolute leader in the 3D printing sector. This was confirmed at the IDS. The manufacturers and suppliers of more or less meaningful developments literally outbid each other: an individualized 3D printed dental floss holder for prophylaxis, the digitally modelled smile as a template for a printed 3D model as a veneer simulation for an initial aesthetic try-in in the patient's mouth, plastic printing for drilling templates, metal printing for crowns, bridges and denture bases made of non-precious dental alloys or titanium. The entire spectrum of procedures and applications already practiced today was presented: gum masks, drilling templates, cast designs, impression trays, splints (for example orthodontic occlusal splints), transfer keys, aligner foils and long-term temporary restorations made of plastic.

Even more innovations

Of course, the innovations did not confine themselves to the digital sector. The entire product range of new materials for prosthetics was presented at the IDS. The variety has grown considerably over



Impressions of the International Dental Show 2019 in Cologne.

the past 20 years. Alloys play an important role here. Non-precious metal alloys have now gained a strong market position and are used in prosthetics, orthodontics and implantology.

In the field of periodontology, pressure-calibrated periodontal probes met with the interest of trade visitors. In the future, bacterial and DNA tests, including microbial marker tests, may also be used as chairside procedures to improve the assessment of inflammation in the affected periodontal pockets.

The laser has found its way into prophylaxis. The diode laser, in particular, is intended to offer additional possibilities for the killing of bacteria and surface decontamination as a supplement to classical, tried and tested methods.

Hygiene was also a major topic. The processing of sterile goods is an innovative field. At the IDS, modern thermal disinfectors were to be examined, which clearly outshine their predecessors in terms of capacity, and are intended to facilitate documen-

tation and organization for the practice team by means of appropriate interfaces to the digital practice management. Network integration of many functional units, for example autoclaves, thermal disinfectors, ultrasonic devices, are supposed to increase the efficiency of hygiene management.

Conclusion and outlook

The IDS once again proved the innovative power of the dental industry. The leading trade fair seems to set new records unrestrictedly. It will be interesting to observe how the Medical Devices Regulation (MDR), which will be binding next year, affects the industry. Manufacturers are already concerned about the high regulatory requirements to the detriment of development. Small companies and start-ups are particularly affected, as the high approval requirements for medical products will pose major problems for them.

Interview on the BDIZ EDI Quality Guideline for Implantology

Three questions for ...

... BDIZ EDI President Christian Berger. He has been instrumental in revising the Quality Guideline, which first appeared in 2002 and was most recently updated in 2019. It is intended as a set of recommendations for practitioners and patients.



BDIZ EDI President Christian Berger talks about the revised Quality Guideline for Implantology.

What are the benefits of the BDIZ EDI Quality Guideline for Implantology?

Our quality guideline has the status of a recommendation and serves as a tool for self-evaluation and self-assessment, since only the treatment provider himself is familiar with his work and his patients, with all their expectations and problems. He is the only one who can reliably evaluate how the prevailing conditions – which will influence any medical treatment, sometimes decisively so – have affected the treatment result in question, either positively or negatively. The BDIZ EDI would like to emphasize the fact that the criteria are based on evidence from dental science. They can therefore claim validity even in the present political and scientific environment, where scientific evidence unfortunately tends to be disregarded when it comes to defining what constitutes equitable remuneration. Back in the year 2000, the Quality Guideline was a first attempt to highlight the issue of quality in oral implantology in Germany. The Quality Guideline has been consistently modified and updated and will continue to have to be brought up to date as needed.

How about its implementation in actual practice?

First of all: The Quality Guideline does not intend to prescribe or introduce standardized treatment processes or office structures. The dentist's profession is a liberal profession, and it will continue to be up to the dental practitioner himself how he achieves the requisite quality, because this is his responsibility. The Quality Guideline provides a list of six quality criteria for implantological procedures: medical history, examination, treatment planning, patient education, concomitant prevention – as well as implant surgery and implant prosthodontics themselves. These quality criteria are evaluated based on five assessment criteria: What is the indication for the treatment measures suggested? What are the treatment objectives? What are the risk factors influencing the treatment objectives?

Are there any standards related to the treatment measures? What are the indicators for treatment evaluation? This evaluation assigns the treatment result one of the following categories:

A+: Excellent result with no reservations whatsoever

A: Good result, appropriate to aspire to in normal cases

B: Deficient, potentially harmful

C: Unacceptable, alternatives required

The Quality Guideline offers a step-by-step procedure for the application of these quality and assessment criteria, culminating in a list of assessment criteria of the categories A+ to C.

What is the objective behind the BDIZ EDI Quality Guideline for Implantology?

Promoting quality in implantological treatment has been the major goal of the BDIZ EDI for 30 years now. It was no coincidence that in 2001 we won recognition for a formal professional focus on oral implantology for dentists before the German Federal Constitutional Court. Our Quality and Registration (Q&R) Committee tests products and materials. We continue to develop our own biotope of implantological experts and we emphasize the importance of well-trained experts who regularly participate in CPD activities. We also publish the annual Guidelines on current implantological topics as a recommendation for dentists. Of course, we know that a qualitative assessment of dental results is not an easy task, not least because quality aspects are controversial even among many experts in the field. Our objective is to provide implant dentists an appropriately calibrated yardstick that allows them to assess, for themselves and for their patients, the results they have achieved.

Thank you very much for your explanations.

Assessment criteria and categories A+ to C

Category	Description	Implant surgery	Implant prosthodontics
A+	The rehabilitation fully meets the patient's expectations in every respect. Function, fit, comfort and aesthetics are perfect. Accessibility for oral hygiene is impeccable. The implants and their prosthetic restoration do not have a noxious effect but contribute to maintaining the health of the oral and surrounding tissues.	Optimal utilization of the bone supply, no bone loss around the implants detectable on radiographs, healthy peri-implant tissue and attached gingiva around the implants. A customized, structured recall programme has been established. The patient's own oral-hygiene efforts are excellent.	Soft tissue, emergence profile and prosthetic restoration successfully and deceptively imitate the healthy appearance of natural teeth. Chewing function, fit, comfort and aesthetics are perfect. The restorations are not immediately recognizable as such even on closer inspection.
A	The rehabilitation meets the patient's major expectations. Any remaining reservations do not require any modification. Function, fit, comfort and aesthetics are good. Accessibility for oral hygiene is not ideal. No damage to the oral or surrounding tissues.	Good utilization of the existing or augmented bone supply, next to no bone loss around the implants detectable on radiographs, peri-implant tissue exhibits no signs of inflammation. A recall programme has been established; the patient's own oral hygiene efforts are regular and sufficient.	Harmonious transitions between the restoration margin and the implant surface; radiographically well-sealed restoration margin. Multi-contact situation in maximum intercuspation: interference-free canine guidance or group function. The patient is satisfied with the aesthetic appearance and the dentist's performance. The restorations are not recognizable from a normal speaking distance.
B	The rehabilitation does not meet the patient's major expectations; there are objective but reversible deficiencies. Those deficiencies which can be detrimental to the patient's health must be corrected. Deficiencies (e.g., of an aesthetic nature) that do not compromise oral health may be corrected if requested by the patient.	Recognizable bone resorption around implants, deficient peri-implant tissues with signs of inflammation, accessibility for oral hygiene is limited by the restoration. No regular periodontal and radiographic follow-up. The patient's own oral hygiene efforts are irregular and partly insufficient.	Slight gaps or excess material at the restoration margin around the implants, although these can be rectified. Slight occlusal interferences (balance-side contacts, premature contacts on the working side). The patient is not satisfied with the aesthetic appearance and complains about certain shortcomings of the dentist's performance.
C	The rehabilitation does not meet the patient's original expectations on any way. Function, fit, comfort and aesthetics are unacceptable. The implants or restorations cause or have caused significant irreversible damage in terms of function, adjacent teeth or appearance. A failure that can be attributed to inadequate diagnosis or treatment planning, poor execution or technical errors. A new or alternative rehabilitation is inevitable.	Active pathology of the peri-implant tissues due to a lack of osseointegration, disrespect for the biologic width or insufficient accessibility of the restoration for oral hygiene. Advanced or complete loss of retention of the implants within the bone. Follow-up care is neither offered nor organized and performed. Lack of dental awareness on the part of the patient, whose own oral hygiene efforts are generally insufficient.	Massive gaps or excess material at the restoration margins. Massive occlusal interferences, missing contacts in maximum intercuspation, incorrect occlusal plane. Aesthetically unacceptable in terms of shape and shade. The patient does not accept the dentist's performance due to serious deficiencies.

Bibliography

Quality Guideline Implantology , DIN A4, 17 pages and cover
 With a description of six quality criteria and five assessment criteria as well as a description of the assessment criteria and categories A+ to C in an overview.
 Available from the BDIZ EDI online shop at www.bdizedi.org
 (€2.50 including VAT, plus shipping costs)



EU Medical Device Regulation

MDR – standing in the way of innovation?

The European Medical Device Regulation (MDR) came into force on 25 May 2017. It is aimed at increasing the safety of patients in the fields of medicine and medical technology. The manufacturers of medical devices not only have to align their procedures with the new classification rules, but they must also seek approval for the European market from so-called Notified Bodies (for example, NSAI, TÜV Nord or Lloyd's Register) in a complex process.

The worldwide health scandal surrounding breast implants from the French manufacturer PIP was certainly one of the reasons why the Medical Devices Regulation comes with significantly tightened requirements. According to Wikipedia, the manufacturer, which for 20 years had produced about 100,000 breast implants per year, used cheap industrial-grade rather than medical-grade silicone inserts on a large scale after 2001. As reports of ruptured or leaking implants increased in number, marketing and distribution were banned in France and other countries from 2010 onwards. As early as in the year 2000, the US FDA had criticized their production methods and stopped imports into the USA. The Notified Body in Germany that had certified the medical device for the European market had also come under fire.

The new, stricter regulation, which intends to ensure greater safety and quality for medical devices, must be understood against the background of the PIP scandal. Only those products that are class I medical devices escape the complex process of approval by the Notified Bodies. Dental materials are usually assigned to class II – with the exception of implants; implantable devices, including dental implants, are usually subject to the significantly more stringent requirements of class III medical devices.

Anyone wishing to find out more about the new EU regulation through the Federal Institute for Drugs and Medical Devices (BfArM) will be disappointed; there are a few rather succinct pointers to some links, with no support offered beyond that. And that although the new Regulation will have an enormous effect on Germany, which prides itself on its innovative power.

The website of *Professor Ulrich Gassner* of Augsburg University – currently the only holder of an academic chair of medical device law, says the following: “The new European Medical Device Regulation and the new In-vitro Diagnostics Regulation will have considerable effects on German medical device law.

Manufacturers of medical devices and in-vitro diagnostics must establish risk and quality management systems and adapt to changes in technical documentation and labelling. Importers, distributors and authorized representatives must also comply with the new regulations; the Notified Bodies will become monitoring bodies.”

Gassner is the author of two introductory collections of texts on the two new regulations (www.jura.uni-augsburg.de/forschung).

Market survey confirms pessimistic outlook

The industry expects negative effects on the market, and many experts such as *Professor Gassner* share this fear (see interview on the following page). The first results of a market survey conducted by Deloitte, MDR-Competence and the Fraunhofer Institute provide an up-to-date picture of the prevailing sentiment and an appraisal of the predictable consequences of the MDR, which confirm these assessments. Based on the currently available data, the study further differentiates previous assessments by the industry associations Spectaris and BVMed, with the same tenor: Only 15 per cent of manufacturers feel sufficiently informed about implementation of the MDR. 40 per cent of manufacturers will retire existing medical devices currently on the market; 50 per cent

believe that products or product lines will have to be terminated because of the increased requirements; over 40 per cent expect significantly increased product prices; 65 per cent of companies feel compelled to shift resources from development to regulatory issues, at the expense of innovation efforts; and 70 per cent of companies feel uncertain as to whether the Notified Bodies that have assisted them so far will continue to do so to allow all deadlines to be met.

The consequences for the biomedical engineering sector in Germany and Europe are huge: “The figures make it quite clear that in the medium term,

the regulation will result in migration towards the FDA-regulated American market and depletion of the innovation hotspot Germany”, explained *Professor Theodor Doll*, Head of Translational Medical Technology at the Fraunhofer Centre.

“Development costs and time will substantially increase, leading to markedly deteriorating prospects of start-ups and SMEs in this sector”, said *Professor Thomas Lenarz*, Chair of the Board of the German Society for Biomedical Engineering (DGBMT). “Likewise, it will become much less attractive for investors to invest their money in innovative med-tech developments.” **AWU ■**



Interview on the effects of the Medical Device Regulation on the European market

Manufacturers, dentists, patients – all are affected

The EU Medical Device Regulation (MDR) is the sword of Damocles hanging over manufacturers of medical devices and will have an impact on the entire health care system and the economy – including dentists. Pessimism is spreading. Small and medium-sized manufacturers in particular feel overwhelmed by the new requirements. We spoke with Professor Ulrich M. Gassner, Founding Director of the Research Center for Medical Device Law (Forschungsstelle für Medizinprodukterecht, FMPR) at the University of Augsburg, the only research institution of its kind in Europe.

The MDR has been in force since 25 May 2017. Pessimism is spreading throughout the market. But why now? Why not much earlier?

There have been sceptical voices from the beginning. Criticism was levelled at the excessively tight transitional provisions and the fact that hardly any Notified Bodies could be re-accredited in the short time available. But now people are starting to be

more nervous. Warning signals aimed at Brussels are increasing because it is now that the fears are actually materializing. This applies in particular to the bottleneck that has arisen: Numerous observers have remarked that there will be too few Notified Bodies to certify products under the new law as the MDR takes full effect on 26 May 2020.



Anita Wuttke, BDIZ EDI Editor-in-Chief, during her conversation with Professor Ulrich M. Gassner.

Do you share this pessimism?

I tend to. We are already experiencing a significant drop in the number of Notified Bodies. In addition, just like the manufacturers, Notified Bodies are subject to new requirements, which will slow down certification procedures.

Who is particularly affected and what effects do you think this will have on the medical device market in Germany and in Europe?

The major manufacturers have done their homework. But the medical device market is mostly medium-scale in nature. Small and medium-sized enterprises in particular find it difficult to cope with the much more exacting requirements and the associated exorbitant costs. The MDR has already contributed to some concentration tendencies on the market, and this trend will persist. I am aware of small manufacturers who have withdrawn from the market completely or are getting ready to do so. One would rather not have to think about what this means for the affected patients.

How does the regulation affect manufacturers from non-European countries – say from Asia or North America – who export their medical products to Europe?

These manufacturers must adapt to the new circumstances. Incidentally, importers are treated the same as manufacturers with regard to their obligations under the MDR.

Based on estimates by the industry associations Spectaris and BVMed, which are supported by market surveys – including those conducted by the Fraunhofer Institute – it would appear that 40 per cent of companies have already withdrawn their medical products previously on the market. Is the MDR acting as a brake on innovation?

Certainly; added product safety has its price. The higher the regulatory hurdles, the costlier the

certification process, and the greater the delays before an innovative product reaches the patient. Unfortunately, this interrelationship is often overlooked in the public debate. Moreover, it remains to be seen whether the MDR and all its regulations will actually result in greater patient safety or whether the only effect is ever more paperwork.

Who and where are those “Notified Bodies” that approve the consultation procedures in connection with the clinical evaluation for Class IIb medical devices and Class III implants, or monitor compliance with the extensive regulations?

As things stand now (at the end of May 2019), only two Notified Bodies are currently accredited under the new law: BSI (London) and TÜV Product Service (Munich). The respective certification authority is not based on risk classes, but on product categories and technical cross-sectional competencies.

The marketing of products certified under the previous law will have to cease completely by May 2024 at the latest. In your experience, how far have manufacturers come in their implementation of the MDR?

Like I said, the large manufacturers are relatively well prepared. Some small manufacturers seem to prefer to bury their heads in the sand, even though this may often be mostly due to a lack of available qualified staff.

To what extent is dentistry or oral implantology affected by the EU regulation?

Implantologists with in-office laboratories are manufacturers of custom-made products. There are no transitional arrangements that apply to them. As of 26 May 2020, for example, they must meet exactly the same requirements that apply to industrial manufacturers of medical devices with regard to clinical evaluations.

And clinical evaluations are not even all there is to it. Under the heading of “post-market surveillance” (PMS), the MDR demands that implantologists continue to monitor whether their implants are safe and therapeutically useful once implanted and whether there are any incidents related to them. Furthermore, they have to demonstrate that a person responsible for regulatory compliance is available on a permanent and continuous basis.

Professor Gassner, thank you very much for this interesting interview.

This interview was conducted by Anita Wuttke, Editor-in-Chief. ■

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CED position on the implementation of the Medical Device Regulation

Two main concerns

The Medical Device Regulation (MDR) 2017/745 is an essential piece of legislation for ensuring high-quality health care and a cornerstone of patient safety across Europe that will be applicable in all EU Member States from 26 May 2020. The CED supports improvements of the system imposed by the new regulation but also shares two main concerns in relation to the smooth implementation of the MDR by the relevant date.



The Council of European Dentists (CED) is a European not-for-profit association which represents over 340,000 dental practitioners across Europe through 33 national dental associations and chambers in 31 European countries. Established in 1961 to advise the European Commission on matters relating to the dental profession, the CED key objectives are to promote high standards of oral healthcare and dentistry and effective patient-safety centred professional practice.

The CED supports improvements of the system imposed by the new regulation but also shares two main concerns in relation to the smooth implementation of the MDR by the relevant date. These are:

- the implementation of new classification rules for all medical devices;
- the availability and capacity of Notified Bodies across the system.

Possible delays in developing both areas have caused deep concerns amongst the profession about the readiness of the system for May 2020, and the continued availability and timely accreditation of medical devices and therefore, optimal patient treatment options.

Uncertainties over the interpretation of the MDR provisions could result in shortages of medical devices currently used by health professionals on a daily basis; some devices might not be available on the market after May 2020 if their classification and/or accreditation is delayed. This would be

a major issue for the provision of health services across the European Union.

In order to complete the implementation of the Regulation by May 2020, we call on the European Commission and Member States to provide detailed guidance on the classification rules, and to ensure that the necessary systems are ready and the new notification bodies appropriately staffed to take up their work by the early autumn of 2019. It is paramount to enable the start of this work as soon as possible to ensure full functionality of the new system.

The CED furthermore calls for full transparency of information on the safety of medical devices and for public access to the European Medical Devices Database (EUDAMED). Increasing the sharing of device safety information improves traceability and surveillance. In order to ensure the trust and confidence of the public in the way medical devices are regulated, all reports confirming safety should be, in so far as is practicable, publicly accessible.

The CED will monitor the next steps in the implementation of the MDR and remains committed to working with the European Commission through its involvement in the Medical Devices Coordination Group, and to providing other support where needed.

This position was unanimously adopted by the CED General Meeting on 24 May 2019.

Source: Council of European Dentists (CED) ■

According to the MDR, medical devices are classified in different classes with different safety requirements.



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European dentists call for uniform professional supervision

No special rules for dental chains

At its Spring General Meeting in Vienna in late May 2019, the Council of European Dentists (CED) demanded that there should be no special rules for dental chains, but that they should have to be members of the dental chambers and associations, this being the only way to ensure uniform professional supervision in the interest of patient protection.

The representatives of all national dental chambers and associations agreed that individual dentists and dental corporations (as legal entities) had to be subject to the same professional rules and supervision.

As CED President *Dr Marco Landi* pointed out: “We share the concern that the commitment of financial investors, whose primary goal is to maximize profits, will ultimately work against the high quality of dental care and against the interests of our patients.” At its next General Meeting, the CED should therefore clearly adopt the position that all institutions of dental care, whether organized in the form of individual practices, dental corporations or otherwise, must be subject to the same professional regulations and – where applicable – the same type of supervision by professional chambers in order to ensure a high quality of care.

Background

The Council of European Dentists (CED) is an umbrella organization that represents the interests of the more than 340,000 dentists throughout Europe. It consists of 33 national dental associations from 31 European countries, 27 of which are EU member states.

The CED’s spring consultations focused on current developments in health policy at the European level and on the impact of the EU internal market on dental services, linking the issue to the imple-

mentation of the recently adopted EU directive calling for proportionality tests for professional regulations law as well as the decision of the European Court of Justice (ECJ) on dentists and advertising.

As early as November 2018, the CED had adopted a resolution on “Corporate Dentistry in Europe”.

Source: Council of European Dentists (CED) ■



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Workshop: Investors in the dental sector – a threat or an opportunity?

“A bit of equanimity is actually a good thing”

Are all investors just “locusts”? External (private-equity) investors setting up dental chains are likely to labour under this stigma for a good while to come. But in view of the current discussions, the part of the market that is driven by demand is too often overlooked. The editors of EDI Journal recently discussed this topic with Dr Freimut Vizethum, member of the board of BDIZ EDI. On the occasion of the 14th BDIZ EDI Expert Symposium on Cologne in early March, Vizethum, who is an entrepreneur as much as a dentist, held a workshop entitled “Investors in the dental sector – a threat or an opportunity?” A good enough reason to hold the following interview.



Dr Freimut Vizethum

Dr Vizethum, private-equity investors and dental medical care centres are currently the subject of hot debates among members of the dental profession. Which approach did your workshop pursue?

At a time of ongoing changes in many sectors of society, the approach was quite simple. Being well-informed about the facts is a prerequisite for making good decisions. It is precisely this controversial discussion – which, incidentally, I consider to be totally normal, absolutely justified and completely “non-scandalous”, – that should be based on facts. It can and maybe should of course also engage in speculation, provided this is made perfectly clear to all participants.

Differences in the assessment of our reality must be accepted; they reflect the fact that our viewpoints are always subjective to some extent. Many of us hold ideas and convictions associated with current health politics and the dental profession as a whole.

But this is not what my workshop was about, because these topics have been and are being intensively discussed in the trade press, quite extensively so, and it is easy enough to read up on it. The workshop focused on dialogue and discussion, especially of the personal and subjective issues that interest many colleagues.

There seems to be a demand for business models beyond the classical individual practice. Why is that?

This demand is felt every day by every established colleague as a result of the changes in our social environment. To mention only a few keywords, it is based

on the staffing situation, our work-life balance, reconciliation of family and career goals, increasingly amounts of paperwork in the dental office and so on. Over the next ten years, thousands of dental practices will close or be sold. There will be a shortage of willing and capable successors. It would seem that issues such as flexible working hours, increasing specialization, more professional procedures, a renewed focus on “real” dental services may be easier to meet by larger practice organizations, matching the expectations of many younger dentists.

Who were the participants of your workshop, and what are they interested in?

Both dentists in private practice and younger – still employed – colleagues attended the workshop, their curiosity triggered not least by their own personal situation. Many were already quite well-informed. Of course, the topic enjoys extreme media attention, so our colleagues are keen to learn more. From all this, some very simple personal questions arise: What does this apparently great influence of investors and their behaviour (as measured by the space given them in the trade press) mean for my own dental working environment? What could change about my practice, my competitive situation, my personal life?

Why is it so difficult for dentists today to find a successor for their practices?

This is certainly the result of a broad range of factors. For many of the young colleagues inter-

viewed, a whole series of questions still arise ahead of opening their own practice – just not always the same ones as in the past. Taking over an existing practice and gradually growing into the role of the independent dentist is only one scenario. And given not least the increasing mobility in our society, it tends to be a dream hard to turn into reality. Often, the thought of an exit strategy as a creative element of the dental professional life cycle occurs to the entrepreneurial dentist far too late. A further reason could lie in the decreasing willingness on the part of sellers and buyers to commit to decisions at an early stage. If anyone can elect to open shop wherever they want, then unfortunately – depending on the region we are looking at – there are only slight advantages to taking over an existing practice.

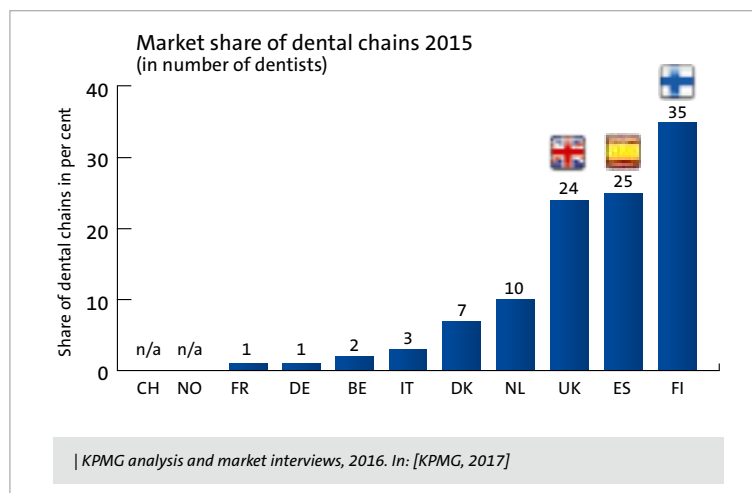
You called your workshop “Investors in the dental sector – a threat or an opportunity?” So what are they, the former or the latter?

A bit of equanimity is actually a good thing. Maybe surprisingly, some very different aspects are involved here. Such “locust periods” have occurred earlier, often in industrial settings, and while we have seen the negative effect of excesses, we have also seen the beneficial effect of the concomitant structural changes. A simple internet search shows that people hold differentiated views of the role of private equity in the economy as a whole. A realization that structural change is easier to achieve with money than without money has certainly played a role.

The “threat” has often been described in our dental trade press in quite drastic terms accompanied by vivid imagery. Who has not seen headlines conjuring up images of “locusts” or “financial sharks” that swallow up and destroy everything?

However, as we all know, trust and a personal relationship with the patient are still the most important assets and success factors in the healthcare sector today. It is therefore extremely difficult to generate growth and healthy long-term returns by “swallowing up and destroying” – as investors are often accused of doing both at the same time.

We should assume that people who are willing to invest a lot of money have a modicum of competence and reflection. We know from many conversations that there are different approaches. Some of these spontaneously seem promising, while others will probably be adapted within a heuristic approach of trial and error. An open question, and one that needs to be examined and answered, is which approach is best suited to one’s own ideas. Based on my own experience with merger and acquisition activities in industry, I recommend my colleagues who want to work out possible implications and examine opportunities for themselves and their prac-



tice to adopt a careful and thoughtful approach. What actually constitutes an opportunity is determined by personal goals and expectations. Here the appearance of investors represents a further aspect that has to be considered as part of one’s own shaping of the future and that of one’s practice – no more and no less.

Grand visions are not the problem. The devil is in the details – careful planning, meticulous implementation, going over the “small print” with a partner who suits you. I can only recommend getting professional advice when looking for the right partner and setting out to negotiate on an equal footing.

Will larger organizations like the dental medical care centres dominate the future of dentistry?

This is a vision that I would meet with a certain amount of scepticism as I look at the current liberal-profession structure of our industry. As the aphorism goes, it’s hard to make predictions, especially about the future. However, as so often, we can simply take a look at other European countries to understand how things can develop.

In England, Spain and Finland, dental chains have existed for decades. Looking at markets of similar size, a possible share of 25 per cent of dentists employed by such chains does not seem too unlikely in the distant future. Conversely, this does not mean the end of the private dental practice, as 75 per cent of dentists will continue to perform their services as liberal professionals or as employees outside any dental chains. Given the German baseline situation of less than 1 in 100 dentists working for dental chains, we probably still have a long way to get there, and no one is likely to embark on that path unless they are convinced of the benefits.

Dr Vizethum, thank you very much for your lucid insights.

AWU ■

Market share of dental chains in Europe in 2015.

Pros and Cons

Short vs. long implants

Are today's "frontlines" still clearly separated – advocates of long implants on one side, advocates of short implants on the other side? Two experts take a stand: Professor Jürgen Becker, Director of the Department of Oral Surgery and Imaging at the University Hospital of Düsseldorf, and Dr Jörg Neugebauer, presenter at numerous European Consensus Conferences on implantology under the auspices of the BDIZ EDI. As so often, it turns out that the views of the two sides are not that far apart – and that the issue is not just a simple question of short or long. This interview was conducted by Anita Wuttke, Editor-in-Chief.

When are long implants the better choice?

Professor Jürgen Becker

In my department, "long" implants are those longer than 11 mm. Implants longer than 15 to 16 mm are not part of our inventory. Due to the good prognosis of implants 8 to 10 mm in length, the use of longer implants is rarely indicated – such as when implants are immediately placed in fresh extraction sockets where they have to cover the entire length of the original root. For me this is now the major indication for which I still use implants longer than 11 mm.

Dr Jörg Neugebauer

Today, implants 12 to 14 mm in length are already considered long implants. Even diameter-reduced implants, the so-called mini-implants, require stabilization in the local bone, so implants 12 or 14 mm long are used here as well. Depending on the anatomical situation, implants for standard indications can require bone augmentation, but this is associated with higher complication rates, especially in the case of vertical defects.

When would you consider short implants?

Professor Jürgen Becker

In my department, the routinely used implant has a length of 9 mm in the posterior region and (usually) 11 mm in the anterior region of the maxilla. We use shorter implants, less than 6 mm, in the posterior region to increase the number of available abutments where this helps avoid vertical bone augmentation. For us, short implants are 6 to 7 mm long; implants 4 to 5 mm in length would be "ultra-short" implants.

Dr Jörg Neugebauer

We have used short implants in our practice for over ten years, the first time after a failed vertical augmentation with further loss of local bone, which made a short implant necessary. On

that occasion we were able to achieve long-term success with the stable fixed restoration on 5-mm implants. Since then, the range of indications has become wider, not only in the posterior mandible but, and especially, in the maxilla, where an internal sinus lift can facilitate a fixed implant-supported rehabilitation even with a very limited bone supply. In our practice, the terms short and ultra-short implants are therefore used almost synonymously, since short implants with a length of 5.2 mm are now the ones we use most frequently.

Since every implant requires a certain amount of mechanical stability, short implants are placed if the alveolar ridge is still sufficiently wide, which will often be the case in vertical atrophy. Short implants combined with a reduced diameter does not work.

What do you think of angulated and diameter-reduced implants?

Professor Jürgen Becker

We use diameter-reduced implants currently in the mandible and in the maxillary posterior region to increase the number

of available abutments, with the result that lateral augmentation is not indicated in fewer cases. Of course, we must also

consider whether these reduced-diameter implants have been approved for these indications by the manufacturer. Looking at your second question about angulated implants, the implants we have been talking about are two-piece implants with a diameter of, for example, 3.3 mm. Implant inclinations are actually a different topic. There are standard protocols, such as the “all-on-four” protocol, where manufacturers and clinicians prefer angulated implants for anatomical reasons; as clinical studies have shown, the long-term results that have been achieved have been very good. For me, another topic is the accessibility of angulated implants for oral hygiene. I think we need more research on how the periodontal parameters related to oral hygiene behave after an extended period in function.

Bottom line: Short vs. long implants?

Professor Jürgen Becker

implant lengths quite naturally play an important role, because an implant that is 13 or 15 mm long is more difficult to explant and results in more pronounced bone loss than a shorter implant. Furthermore, clinical studies have shown that longer implants around which peri-implant bone loss has occurred tend to exhibit higher fracture rates. In other words: Using longer implants is not necessarily helpful because the fracture risk increases. And this is the primary reason why we now work with a standard length of 9 to 11 mm: In the event of failure, these implants are easier to remove – and the bone defects associated with the explantation can also be augmented more easily.

Dr Jörg Neugebauer

By using short implants, extensive vertical augmentation or sinus floor elevation using a lateral window technique and bone substitute grafts can be avoided, especially in the posterior region. The insertion of long implants also entails a risk

Dr Jörg Neugebauer

We increasingly use angulated and diameter-reduced implants in combination for “fast & fixed” or “all-on-four” restorations. Especially the anterior mandibular ridge will often present very narrow and accommodate only 3.5-mm implants. The angulated implants in the posterior region can also be used with diameter-reduced implants, although – depending on the design – higher bone-loss rates may be observed. For this reason, we prefer implants with a diameter of at least 3.8 or 4 mm, depending on the system, in the centre of masticatory activity to accommodate the angulated abutments.

of injury to neighbouring anatomical structures, which is less likely with short implants. Enough studies have now shown that an anchorage ratio of 1 : 2 relative to the crown length can produce stable long-term results.

However, the mobile lingual mucosa on the implant presents a limitation in the case of short implants in the posterior mandible. Careful planning and meticulous surgical procedures can help avoid relative movements at the floor of the mouth around the implant. Such movements can trigger peri-implantitis and subsequent bone resorption through “pumping effects”. However, the same problem also becomes apparent following vertical bone augmentation to facilitate the insertion of longer implants, since the mucosa usually has to be mobilized lingually to cover the bone graft.

In our experience, many patients with ultra-short implants can still be treated minimally invasively despite unfavourable baseline conditions, allowing dentists to apply less risk-filled procedures that are gentler on the patient.

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Dr Jörg Neugebauer



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A brief analysis of the European election results

So where, please, is the middle ground?

Europe has cast its vote – and there is some good news: Voter turnout has not been this high in 20 years. According to the EU Parliament (EP), it was 51 per cent for Europe as a whole. Europe seems to have moved more into the spotlight, probably not least due to the eternal Brexit discussions in and with Great Britain and the current progress on climate change and environmental protection, which especially young voters seem to find unsatisfactory.

The second piece of good news is that the parties on the right and left ends of the spectrum did not perform as well as predicted. And thirdly: EU-friendly parties will probably still make up two thirds of the members (MEPs) of the new EP, even though the established contenders suffered significant losses. The European People's Party group (EPP, Christian Democrats and conservatives) remains the strongest force in the EU Parliament with 24 per cent of the vote (–4.9%), followed by the Progressive Alliance of Socialists and Democrats (S&D) with 19.4 per cent (–5.5%). While the German Greens polled a sensational 20 per cent in Germany, the showing of the Greens/European Free Alliance (G-EFP) in the other EU countries, at +2.3 per cent, was not as strong, so that they will be only the fourth strongest force in the EP behind the Alliance of Liberals and Democrats (ALDE), if you count in *Emmanuel Macron's* party *La République en Marche*.

427 million eligible voters in 28 member states

The major centre-left and centre-right parties, traditionally strongest, are the main losers in this election. EPP and S&D have lost their majority in the EP. Nevertheless, pro-European parties as a whole are still in the majority. Because of the poor performance of his CDU/CSU party in Germany, *Manfred Weber* is no longer expected to be a shoo-in for the office of EU Commission President. The Greens and Social Democrats have brought their own candidates into play – *Frans Timmermans* (Netherlands) and the liberal competition commissioner *Margrethe Vestager* (Denmark).

German dentists fear that if the EVP's top candidate is unable to win, it will be difficult to stand up for the preservation of the liberal professions in Germany, with its institutions of self-government and its fee schedules and professional codes.

Right-wingers move forward in France, Italy, Poland, Hungary, and Slovenia

While the feared shift to the right did not occur throughout Europe, the nationalist party of *Marine Le Pen* is still ahead in France, as expected. In Italy, a plurality of the vote went to right-wing populist *Lega*, whose leader *Matteo Salvini* wants to align the European right in a fight against the EU in its present form. In Poland, the governing national conservative party *Law and Justice (PiS)* was ahead; in Slovenia, the opposition right-wing nationalist of the *SDS*. As expected, Prime Minister *Viktor Orbán's* right-wing nationalist *Fidesz* party won the European elections in Hungary.

A slap in the face for the Czech Social Democrats

Prime Minister *Andrej Babiš's* populist *ANO* party once again became the strongest force in Czechia, while the Social Democrats, who are the junior partners in a coalition government with *ANO*, suffered a heavy defeat.

Liberals ahead: Slovakia, Denmark, Ireland, Estonia, Latvia, and Luxembourg

A majority of the Slovaks, the Danes, the Luxembourgers, the Irish, the Estonians, and the Latvians voted in favour of liberal parties. Looking at who is the strongest force in each of the 28 member states therefore not only illustrates the success of some right-wing parties, but also the collapse of the traditionally strongest centre-right and centre-left.

Spain, Portugal, and Malta to the Social Democrats

In Spain, the Social Democratic *PSOE* clearly emerged victorious not only from the recent national elections on 26 April (28%) but also from the EP elections (32,8%). In Portugal, Prime Minister *António Costa's* *Partido Socialista (PS)* received

33.7 per cent of the votes. Malta voted social democratic at over 50 per cent of the vote.

Mudslinging in Greece

Greece made the headlines on election night with the announcement of snap elections in June, triggered by the clear victory of the conservative opposition, Nea Demokratia under *Kyriakos Mitsotakis*, at 33 per cent. Prime Minister *Alexis Tsipras*' Syriza polled just under 24 per cent. European issues did not play a role in the Greek election campaign, which was marked by defamatory statements and personal recriminations.

Spectacular victory for Kurz in Austria

Chancellor *Sebastian Kurz*' conservative ÖVP polled a whole 34.9 per cent (+7.95%). The right-wing FPÖ polled only 17.2 per cent (-2.5%), while the SPÖ, the Social Democrats, got 23.6 per cent (-0.5%). Austria's European elections were overshadowed by a serious government crisis. In the wake of the so-called Ibiza affair, Vice Chancellor *Heinz-Christian Strache*, and subsequently all FPÖ ministers, had to resign, followed by *Sebastian Kurz* himself after a vote of no confidence.

Brexit party clear winner in the UK

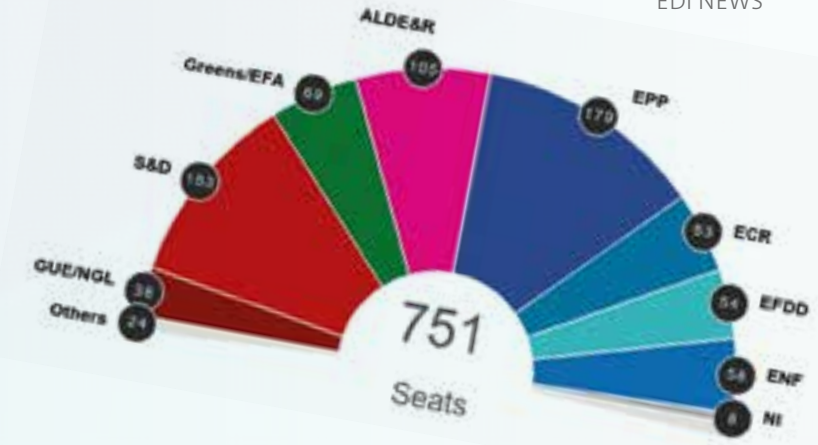
The Brexit party, founded just a few weeks ago, is the clear winner in the European elections in the UK. The EU-critical party of *Nigel Farage* received about 30.5 per cent, a third of the vote. The pro-European Liberal Democrats proved to be the second strongest force, polling almost 20 per cent. British society is deeply divided on the Brexit issue. The parties that argued for withdrawal without an agreement performed about as strongly as parties that wanted a second referendum with a view to the UK remaining in the EU.

Netherlands, Sweden and Finland: social democratic, but ...

In the Netherlands and Sweden, the Social Democrats have asserted themselves as the strongest force. *Frans Timmermans*'s party received 18.1 per cent of the vote, while in Sweden Prime Minister *Stefan Löfven*'s Social Democrats received 23.6 per cent. Nevertheless, the big winners in Sweden are the right-wing populists led by *Jimmie Åkesson*, who polled 15.5 per cent of the vote (+5.7%) In Finland, the right-wing populists fell short of expectations. Here the Greens and Social Democrats could call themselves winners with gains of 6.7 per cent and 2.3 per cent, respectively.

Belgium: Separatists take the victory

In Belgium, the Nieuw-Vlaamse Alliance won the European elections with only 13.5 per cent of the



Composition of the European Parliament based on available provisional or final national results published after voting has finished in all Member States, based on the structure of the outgoing Parliament.

Political groups in the European Parliament	Number of seats	% of seats
EPP - Group of the European People's Party (Christian Democracy)	179	23.63%
S&D - Group of the Progressive Alliance of Socialists and Democrats in the European Parliament	193	25.77%
ALDE&R - Group of the Alliance of Liberals and Democrats for Europe + Renew Europe + LIBERAL	105	13.99%
Greens/EFA - Group of the Green European Free Alliance	69	9.19%
ECR - European Conservatives and Reformists Group	53	7.07%
ENF - Group of National and Freedom Group	56	7.42%
EFDD - Group of Freedom and Direct Democracy Group	54	7.19%
GUE/NGL - Confederal Group of the European United Left - Nordic Green Left	24	3.18%
NI - Non-attached Members	8	1.07%
Others - Newly elected Members not affiliated to any of the political groups set up in the outgoing Parliament	24	3.18%

Source: EPDP, according to Parliament's rules of procedure. Political groups shall consist of at least 50 Members elected in a third-round electoral system.

Composition of the European Parliament 2019–2024

votes. This separatist party demands the independence of Flanders from Belgium. Right behind them in second place came the right-wing extremist separatist party Vlaams Belang, with 11.4 per cent.

A view of the Balkans

In Bulgaria, the conservative ruling party GERB (part of the EPP) of Prime Minister *Boiko Borisov* was the clear winner. In Romania, the ruling Social Democrats (PSD) lost the European elections, receiving 25.8 per cent of the vote, while three competing opposition parties together received 65.7 per cent. In Croatia, the national-conservative Croatian Democratic Union (HDZ) was ahead of the Social Democrats (SDP).

Conservatives win in Germany, Lithuania and Cyprus

Despite heavy losses, the CDU/CSU won the EP elections in Germany. In Lithuania, the conservative TS-LKD came in ahead of the Social Democrats. In Cyprus, the winner of the elections is the Democratic Rally (DYSI), the conservative Cypriot democratic movement, despite heavy losses.

Editors/miscellaneous sources ■

Annual report 2018 of the Council of European Dentists (CED)



“Putting issues that concern dentists on the political agenda”

“Over the years the CED has worked intensely on improving EU legislation and putting issues that concern dentists on the political agenda.” CED president Dr Marco Landi (Italy) gives a review of the year 2018. One of the main issues of the CED is focussing on its concern that profit-driven interests which underpin the business model of some corporates and chains may impact patient safety overall.



Dr Marco Landi

“We dedicated significant attention to this topic in the resolution on corporate dentistry in Europe”, says *Dr Landi*. The resolution was adopted in November 2018. Before, in May 2018, the CED adopted the revised statutes and internal rules which also included a change in the categories of membership. The CED now has full members, affiliate members and observers. Albania is the most recent member, having joined the CED on 1 January 2019 as an observer.

Dental materials and medical devices

This new working group emerged from the combined working group Amalgam (Chair *Dr Susie Sanderson*, UK) and other restorative materials, and working group medical devices (Chair *Dr Edoardo Cavallè*, Italy). The mandate was approved by CED delegates at the 2018 May General Meeting in Tallinn. The working group focused on advancing the CED work on the implementation of the Mercury Regulation, the Medical Device Regulation and the reverse of the ban on tooth whitening in persons under 18 in the EU. The WG drafted the CED CAD/CAM Statement highlighting the right of dentists to not be defined manufacturers under the Medical Device Regulation. The WG will look into an emerging issue concerning the classification of nanomaterials under the Medical Device Regulation.

Task forces

The task force on antibiotics continued to be involved in the joint action on AMR and Healthcare Associated Infections (JAMRAI) and has been working with the European Center for Disease Control (EDC) and other stakeholders on survey for healthcare professionals. Chair: *Dr Hans Schrangl*, Austria.

The internal market task force continued advocating for dentists as liberal professions in the EU and focused on promoting the CED position on the draft Proportionality Test Directive, drafting a CED position on corporate dentistry and following the developments in the field of advertising by healthcare professionals. Chair: *Dr Alexander Tolmeijer*, the Netherlands. Third task force on communications contributes to CED political work through lobbying, advocacy and reputation and capacity building. In 2018, focus was put on the website, organization of public events, and preparation of the annual report and the manifesto for 2019 European elections.

Policies 2018


The CED policies adopted at a glance:

- CED position on dental professions in ESCO
- CED resolution on dental practice and third parties in Europe
- CED resolution on data sharing as part of eHealth
- CED resolution on antimicrobial resistance – update
- CED resolution on corporate dentistry
- CED medical devices regulation – CAD/CAM Statement

Preview 2019

Dr Landi: “While constantly being involved in the ongoing discussion at the EU level, we also look into the priorities and barriers for young graduates, and engaging more actively with the new generation is one of the main priorities for the CED for coming years.”

Source: Council of European Dentists (CED) ■



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The ADI Team Congress 2019 in Edinburgh, UK

Living up to expectations

The ADI Team Congress 2019 delivered an exciting lecture programme this May, with a line-up of national and international speakers sharing their knowledge and passion for excellence in implant dentistry. Set against the beautiful backdrop of Edinburgh, the event catered to all members of the dental team involved with the field of dental implants, ensuring there was something for dentists, dental hygienists and therapists, dental nurses and practice managers, dental technicians, and students. ADI UK is associated partner of BDIZ EDI.

Dr Abid Faqir, ADI President, commented: “We were so pleased to provide such a high quality educational event for ADI members and non-members. The feedback we have received so far has been extremely positive and it has highlighted the calibre of the speakers we invited. It is also great that so many dental nurses, practice managers, dental hygienists, dental therapists, technicians and students got involved with their own dedicated programmes, which were equally well received.”

The event commenced with a morning of Corporate Forums, whereby dental implant-related companies invited professionals to discover the latest innovations in their portfolios.

Following a warm welcome by *Dr Abid Faqir* – who thanked various individuals and companies who’s hard work had made the ADI Team Congress possible – the Plenary Programme got off to a flying start. Continuing until Saturday lunchtime, this programme was presented by leaders in the global dental implant field, including *Istvan Urban*, *Lyndon Cooper*, *Alessandro Agnini* and *Andrea Agnini*, *Markus B Blatz*, *Wael Att*, *Markus Hurzeler*, *Craig Misch*, *Daniele Cardaropoli*, and *David Guichet*, to name but a few.

David Offord, a dentist in attendance, commented: “The ADI Team Congress 2019 has been a first-class conference. The standard of the speakers was exceptional and it is a tribute to the association that such eminent international figures are willing to travel to our event and share their knowledge. Well done to all the ADI team!”

“It has been a fantastic Congress again. I particularly enjoyed the Hygienists’ & Therapists’ Programme, which provided the latest techniques and research for maintaining and treating dental implants. I’m already looking forward to attending the next Congress in two years!” said *Stella Galer*, dental hygienist.

“It has been a pleasure to attend a series of lectures and to have learnt fundamentally from them all. In fact, I have learnt masses, making this great value for money. I have many years of experience in dental technology and so it is fantastic that I could attend and still learn so much from so many different sessions”, was the feedback of *Stephen Harrison*, dental technician.

In addition to the lectures, the ADI Team Congress featured a major exhibition with more than 50 companies in the field demonstrating the

latest products and technologies. The various submissions for this year's Poster Award were also displayed, with the winner announced on Saturday morning as *David Furze* for his poster entitled "Aesthetic outcomes of implant supported crowns with and without peri-implant conditioning using fixed provisional prosthesis, a randomized clinical study – three-year results". Further still, the ADI was keen to acknowledge the hard work and dedication of its past Presidents, offering prestigious honorary memberships to the following individuals in recognition for all they have done for the association (Presidential term in parentheses):

- *Philip Freiburger* (1992 – 1993)
- *Roy Sennett* (1994 – 1995)
- *Paul Stone* (2003 – 2005)
- *Anthony Bendkowski* (2007 – 2009)
- *Stephen Jacobs* (2009 – 2011)
- *Cemal Ucer* (2011 – 2013)
- *Philip Friel* (2013 – 2015)
- *Craig Parker* (2015 – 2017)



The internationally renowned speakers of the Plenary Programme obviously captivated the audience.

As if all that wasn't enough, the congress dinner maintained its legendary status with another fantastic evening enjoyed by congress participants at the National Museum of Scotland. The ADI Team Congress 2019 certainly delivered on everyone's high expectations. ■



Female Dentists in Europe

Ethically motivated and always curious

This issue is about a dentist from Germany who grew up in the German Democratic Republic and still lives and works in East Germany. The professional career of Dr Kerstin Finger is characterized by a great social commitment. How a dentist from the East German workers' and peasants' state made her way to the Federal Republic with its social market economy is demonstrated by her journey through life.

Name: **Dr Kerstin Finger MA**
 Profession: **Dental Specialist for General Stomatology**
 Age: **59**
 Family: **married, two grown-up children, several grandchildren**
 Active: **Member of BDIZ EDI, DGZMK (German Society of Dentistry, Oral and Maxillo-facial Medicine), DGAZ (German Society for Geriatric Dentistry), VDZÄ (Association of Female Dentists)**

Why did you decide to become a dentist?

Originally, I wanted to study medicine and become an anaesthetist. But I was not admitted to university in the GDR in the first place. After one year as a nurse in the department of internal medicine, I was admitted to study dentistry. The subject was not foreign to me, because my grandfather was a dentist with his own practice. After the birth of my daughter at the end of the second academic year, I gave up my original intention to switch to the "great medicine" after the Physikum (preliminary

medical examination). Today I am very happy with this decision. What remained was my interest in surgical subjects. So I chose a topic from the field of oral surgery for my Ph.D., which I earned during my specialist training.

How did your career as a dentist and your involvement in professional policies get started?

In 1984, I started my work in a typical polyclinic of the GDR, where I completed my doctorate in 1988 and my specialist dental training in October 1989. The opening of the border in November 1989 was one of the greatest gifts and a huge opportunity for my further professional development. First of all: I always had the dream of running my own practice with the idea of a dentistry as I imagined it to be ethical and professional. I immediately pursued this plan from the beginning of 1990, and together with four other colleagues who were equally enthusiastic about the project, I set up with my private practice on the territory of the new federal states at the end of 1990, even before BEMA (the evaluation standard for dental services in Germany) was introduced. My first practice was therefore still based on the "Preußische Gebührenordnung" (Prussian Fee Schedule), which was valid for independent dentists in the GDR.

While preparing for my private practice, I quickly realized that it was important to join forces with like-minded, active and experienced colleagues in order to strengthen the opportunities for independent and freelance work. Shortly after the reunification, there were still strong tendencies towards maintaining the polyclinics and it was by no means clear that we would experience a huge wave of private practices in such a short time. This path led me to the FVDZ (Free Association of German Dentists). For a long time, I was actively involved in shaping professional policy there and served as a deputy federal chairwoman for four years.

When and why did you decide to become a member of the BDIZ EDI?

Even before the foundation of my own practice and my involvement in the FVDZ, my path led me to the BDIZ EDI. This was due to the far-sightedness of *Professor Brinkmann* and *Dr Engels*, who were responsible at the time. At the end of November 1990, the BDIZ EDI held its annual congress in Dresden and offered its colleagues from the new federal states the opportunity to participate at a reduced fee. Although this was still half of my monthly salary back then, it was about a new territory, about dental implantology! I was very interested, especially as it was by no means an established topic at the universities at that time. Something that came out

of practice, which was very exciting for me. I took advantage of several training courses and enjoyed the cooperation among colleagues.

In practice, I did not integrate implant dentistry into my office because I was very busy with the general dental care on site and there were not enough cases for my needs. Nevertheless, I was able to translate my knowledge into competent consultations and to establish a trustful cooperation with local oral surgeons. For a long time, I did not know that colleagues who were not actively involved in dental implantology were accepted into the BDIZ EDI. When I learned that you don't necessarily have to be active in implant dentistry, I immediately became a member.

You have become popular in the media as a dentist who travels across the country with a mobile practice to treat patients in remote regions. What is your motivation?

In the 35 years I've been working by now, I've treated entire generations of families. From many conversations, I understood that there is a need for treatment of the elderly, but due to mobility restrictions and the need for care, access to the dental practice is difficult or even impossible. Here in the Uckermark, 80 per cent of those in need of care were cared for at home at the time, and there is a clearly limited infrastructure due to an extremely low population density. As far as this group of people is concerned, I am a student of *Professor Klaus Dörner* (editor's note: *Professor Dörner* reformed psychiatry), who in these cases suggests to focus on the weakest and to develop appropriate solutions. It was an ethical motivation and at the same time curiosity as to whether it could work and whether those affected would accept it. They have accepted it!

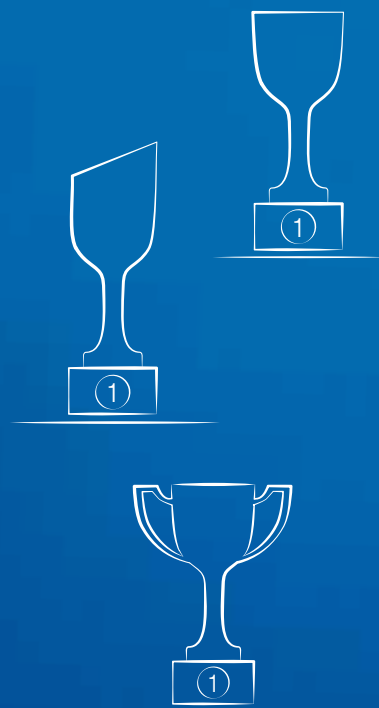
What are your hobbies?

I like to develop and design all kinds of projects; I have started to study Cultural Sciences out of sheer pleasure, and I like to do handicrafts.

Many thanks for the interview and the excursion into the recent history of Germany.

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Highest award of the Portuguese Dental Association OMD

Gold Medal for António Felino

Professor António Felino, dentist, full professor at the Faculty of Dental Medicine at the University of Porto and former Deputy Director of the faculty, has been awarded with the Gold Medal from the Portuguese Dental Association (OMD).

The Gold Medal of OMD is the highest distinction of this institution, and the decision to honour *Professor Felino* was unanimously adopted by the Board of Directors of the OMD, by proposal of *Orlando Monteiro da Silva*, President of the Portuguese Dental Association (Ordem dos Médicos Dentistas) and former President of the FDI World Dental Federation (2011–2013).

The OMD Gold Medal can only be attributed to individuals who, whether or not they are dentists, have contributed in a relevant and unequivocal manner to the development of dental medicine in Portugal, whether at a technical and scientific level or for the benefit of Public Health.

President Orlando Monteiro da Silva (left) awarding the OMD Gold Medal to Professor António Felino.



For many years, *Professor Felino* has been an active member of the European Committee of BDIZ EDI (European Association of Dental Implantologists). Some stepstones of his impressive career: He was President of the Scientific Committee of the APMD and the OMD from 1998 until 2009. Designated in 1999, he served as President of the College of Oral Surgery and since 2017 of the Constitutive Committees of the Oral Surgery Specialty of OMD.

The ceremony to celebrate 20 years of the Ordem dos Médicos Dentistas (OMD) in the Parliament of Lisbon was led by the chair of the General Assembly of the OMD, *João Caramês*, and included speeches by the current Minister of Health, *Marta Temido*, and two former portfolio owners, *Maria de Belém Roseira* and *António Correia de Campos*. *Marta Temido* stressed the importance of oral health and promised to continue the work that has been developed to integrate dental medicine into the National Health Service. The Minister also made a point of leaving a few words of appreciation for the exemplary role of the OMD and its staff, always dedicated to patient service and oral health.

At the end of the ceremony, the Gold Medals of the OMD were awarded to professors *António Vasconcelos Tavares* and *António Felino*, distinguishing their paths, exceptional in the relevance of decades to the service of the profession.

Source: OMD, Portugal ■

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International Osteology Symposium in Barcelona 2019

“Welcome to the next reGeneration”

In April 2019, Barcelona was the place to be for everybody interested in oral regenerative therapies, with the International Osteology Symposium attracting 2,800 scientists and clinicians from all over the world. The congress covered the latest technologies, developments and techniques in the field of oral regeneration and included hands-on workshops, the Research Forum, the first Case Session at an International Osteology Symposium and the launch of The Box app.

The International Osteology Symposium was held for the sixth time end of April. 2,800 participants from more than 70 countries around the world attended the congress in Barcelona, which is organized by the Osteology Foundation every three years.

The scientific programme

Together with the Foundation's Education Committee, the two Chairmen of the symposium, *Professor Christoph Hämmerle*, Switzerland, and *Professor Maurício Araújo*, Brazil, put together a programme covering all aspects of oral regeneration, including the latest developments in techniques and technologies, whilst also giving the next generation of experts the opportunity to present.

During the symposium in Barcelona, *Hämmerle* explained: “The world of dentistry is developing quickly in many ways. On the one hand, advancements in dental medicine, biological understanding and technical progress allow us to improve treatment planning, patient communication, therapy execution, reconstructive surgery, and patient care. These developments deeply affect the field of oral tissue regeneration. On the other hand, the dental care providers change. The young generation of dentists is primarily made up of women and the typical “one dentist – one practice” model is disappearing, making room for larger group practices which are often organized as part of chains.”

Araújo added: “I strongly believe that in the fast-moving world that we live in today, we have to be dynamic and interactive when delivering information and education. One new interactive format is the case competition where every clinician had the possibility to share their cases with a specific



audience and to exchange ideas with other colleagues. We tried to inspire the participants with novelties and advances, but without forgetting the predictability and humanity.”

Linking science with practice in regeneration

Discussing the next generation of technologies, developments and techniques also includes covering the latest results from research. Part of the symposium programme was dedicated to science. More than 288 posters were displayed in the poster exhibition – and the authors of the six best abstracts in both clinical and basic research presented the content of their posters in the Research Forum on Friday. In addition, the outcome of the XIII European Workshop of the European Federation of Periodontology in collaboration with the Osteology Foundation, a consensus conference on bone regeneration, was presented and discussed. All with the goal of ensuring that clinicians can orientate themselves in the science of regeneration.

Sold-out workshops

The five hands-on Osteology workshops were run by renowned specialists. The participants were

eager to improve their practical skills in the workshops and to learn new things. Demand for the workshop with *István Urbán*, Hungary, was so high that it was held for a second time in the afternoon. During the workshop called “Management of soft and hard tissues during bone augmentation”, participants were shown the theoretical and practical



armamentarium in a very systematic way, allowing them to successfully use the “sausage technique” in their practice. *Urbán* summarized: “The participants were given a broad and systematic overview of the topic. The sausage technique is a predictable technique, and an easier and less-invasive surgery than harvesting bone blocks. The participants trained their dexterous abilities and learned the ‘sausage technique’ under my guidance in the hands-on part of the workshop.”

For the first time: Case Session and Competition

Prior to Osteology Barcelona, participants were invited to submit a clinical case to “The Box” and participate in the first Case Competition at an International Osteology symposium. 178 cases in six competition categories were submitted. The jury assessed the cases based on the outcome and criteria such as creativity and originality of the treatment, and the biological principles behind the technique. The winners in each of the competition categories received a free registration for the congress and presented their case in the Case Session on Friday afternoon to a targeted audience. *Araújo* explained: “With this interactive format,

participants got the opportunity to get the best out of their cases. They shared their knowledge and expertise, discussed the cases with colleagues from all over the world and got recognition of the excellent work they do.”

Creating a better experience

At Osteology Barcelona, the Osteology Foundation launched “The Box app”. Previously, only a web-based version of the platform was available. The participants had the opportunity to ask questions to the speaker, read abstracts, browse through the posters submitted and view the congress programme. Among these features, an Augmented Reality interface was also integrated into the app. During the congress, participants had the opportunity to scan pictures around the congress and in the Osteology booth – once scanned, additional content appeared on the smartphone and was merged both online and offline. Real added-value to the content!

Facing the future

When asked about how the Osteology Foundation has developed since the last International Osteology Symposium in Monaco in 2016, the President of the Foundation, *Mariano Sanz*, said: “The Osteology Foundation’s main mission is to link science with practice in the field of oral regeneration and therefore, as new scientific advances and technologies have developed in this field during these last three years, the Osteology Foundation has significantly widened its scope.”

The congress in the beautiful city came to its end. Barcelona perfectly combines modernity, culture, freshness and the light of the Mediterranean Sea. All of this, combined with the quality of the scientific programme and professional networking of the Osteology Foundation’s International Symposia, was a great cocktail for a successful event.

RED ■



Mariano Sanz, President of the Osteology Foundation, during the International Osteology Symposium in Barcelona.

Europe Ticker +++

EU pushes eHealth and mHealth

Digital transformation throughout Europe

Within the framework of its competences, the European Union is committed to increasing the dissemination of electronic (eHealth) and mobile (mHealth) health services. The EU wants to become particularly active in three areas: Citizens across the EU are to obtain secure access to complete electronic files containing their health data. Furthermore, the exchange of health data for research purposes is planned to be improved in compliance with existing regulations. And finally, the development and use of digital tools (for example, dedicated apps) will be encouraged.

Source: EU Parliament ■

member associations, the World Medical Association is a strong voice of physicians worldwide. It is the Chair of Council's task to lead the organization both politically and organizationally.

In his new role, *Montgomery* succeeds *Dr Ardis Dee Hoven* (USA) in his new role. *Dr Mari Michinaga* (Japan) was elected Vice Chair of Council, while *Dr Ravindra Sitaram Wankhedkar* (India) has been elected treasurer.

Source: German Medical Association ■

France wants to abolish "numerus clausus"

A way to resolve the shortage of doctors in the countryside?

France wants to abolish restrictions on the number of medical students. At the end of March, the National Assembly in Paris approved a bill to this effect, which the Senate must discuss. The delegates voted by 74 votes to 4 in favour of abolishing access restrictions for medical studies from 2020 onwards. This reform would promote a greater diversity of profiles among students, build bridges between courses and encourage an increase in the number of students, said Health Minister *Agnès Buzyn*. "The abolition of the *numerus clausus* is a measure of common sense", she wrote on Twitter. as it says the draft law on the selection procedure for medical studies. "The whole process will remain challenging and selective in order to ensure a high level of competence for future healthcare professionals", as it says the draft law on the selection procedure for medical studies. The move affects, among others, the medical, pharmaceutical and dental university programmes. The aim is to increase the number of trained doctors by 20 per cent and thus bring more doctors to rural regions.

Source: dpa; www.forschung-und-lehre.de ■

EDU study programme in medicine

Malta says no

According to the Maltese Ministry for Education and Employment and the German Medical Association, there are still a number of open questions regarding



World Medical Association elects new Chair of Council

A German at the helm

The new Chairman of Council of the World Medical Association (WMA) hails from Germany, where he had served as President of the German Medical Association for many years. At the Council meeting in Santiago de Chile in late April, *Professor Frank Ulrich Montgomery* was unanimously elected to lead the association during the next two years. "Global health care is facing major challenges that require the commitment and cooperation of the international medical profession", said *Montgomery*. In particular, the revision of the International Medical Ethics Code, the vaccination issue and the training and continuing professional development of medical practitioners will be important topics on the WMA agenda in the next few years. With its 112 national

Photo: pikabay.com/Mariamichelle



the establishment of a privately organized course of medical studies in Malta. EDU Medical, a company operating from Germany but registered in Malta (a brand of Digital Education Holdings) had announced that it was offering a mostly online medical degree course. Future students will never have to set foot in Malta but are said to still end up with a Maltese degree. Even as applications for this study programme are already being solicited, the German Medical Association believes that the quality and structure of this study programme still give rise to unresolved issues. In Malta, a professional license for physicians to practice requires successful completion of a course of medical studies, but in addition also a pertinent license by the Medical Council of Malta. According to the Minister, Malta will not issue such a license on the strength of an EDU degree as currently offered. The Ministry has asked a group of experts to address the issues related to EDU Medical's offering. The Standing Committee of European Doctors (CPME) is to be involved in the work of the expert group to advise on issues relating to the recognition of qualifications.

Source: Various media ■

[Appointment of Dr Michael Frank \(Germany\)](#)

The FDI has a new European regional President

A new President was appointed at the General Assembly of the European Regional Organization (ERO) of the World Dental Association (FDI), which took place in Frankfurt am Main at the end of April. The previous President of the ERO, *Dr Anna Lella* (Poland), was succeeded by erstwhile President-Elect *Dr Michael Frank* (Germany), President of the Regional Dental Chamber of Hesse (LZKH), a dentist in private practice in Lampertheim on the Rhine and a member of BDIZ EDI. The ERO is a sub-organization of the FDI and represents the interests of dentists

from 53 European countries. The aim is the free choice of treatment and a dentist-patient relationship without interference by third parties. The General Assembly of the ERO takes place within the framework of the FDI World Congress. The European Regional Organization (ERO), together with the representations of the Asia-Pacific (APRO), Africa (ARO), Latin America (LARO) and North America (NARO) regions, is one of the FDI's sub-organizations. Since four of the seven most important industrial nations are part of Europe, the influence of this continent in the FDI is similarly extensive as in world politics. The influence of the European dental profession, and in particular of the German delegation, can be felt above all in the main topics they bring to the international debate. At present, this is primarily the question of adequate medical care for people who are underserved by European standards.

Source: ERO, BDIZ EDI konkret 4/2018 ■

[FDI to elect a new Council in San Francisco](#)

Dr Peter Engel standing for President-Elect

The President of the German Dental Association, *Dr Peter Engel*, is standing for election as President-Elect of the World Dental Organization (FDI). The elections will be held at the FDI World Dental Congress at the Moscone Center in San Francisco, California. According to an interview in the German trade journal *Deutsche Zahnarztwoche*, *Engel* wants to integrate more closely the FDI's current focal issues, such as oral health, antibiotic resistance, malnutrition, sugar reduction and health systems – in line with their importance in the area of health policy, at the same time stressing the importance of a strong link with general medicine.

Source: *Deutsche Zahnarztwoche*;
German Dental Association ■



Dr Michael Frank



Dr Peter Engel

Supplementary protection certificate also for medical devices?

The ECJ has decided: The two are clearly separate

Patents can be granted for medical devices as well as for medicinal products. This means that they will be protected for a period of 20 years from the date of filing. Since the patent application for new medicinal products is filed while the development process is still ongoing, while the marketing authorization is actually granted much later, the actual period of protection is actually reduced.

Regulation (EC) 460/2009 of the European Parliament and of the Council dated 6 May 2009 introduced a supplementary protection certificate (SPC) for medicinal products. The European Court of Justice (ECJ), in its judgment dated 25 October 2018 (C-527/17), had to decide whether this SPC could also be granted for a medical device containing a substance as one of its integral parts that, if used separately, could be regarded as a medicinal product in the decision of 25 October 2018 (C-527/17).

The case

Boston Scientific, a med-tech manufacturer, is the holder of a European patent that relates to the use of medicinal substances designed to reduce restenosis following angioplasty. Paclitaxel, the active medicinal substance, is also used for treating certain cancers and is marketed under the name of Taxol. The patent protects, inter alia, the use of Taxol in a preparation intended to maintain an expanded luminal area in blood vessels.

Boston Scientific had already obtained a CE certificate for the Taxus medical device, a stent coated with the drug Paclitaxel. In the context of the mandatory certification procedure, the drug was also assessed in accordance with Section 7.4 (1) and (2) of Annex I to Directive 93/42/EEC (the Medical Device Directive).

In March 2011, Boston Scientific filed with the German Patent Office (DPMA) an application for a supplementary protection certificate (SMC) in relation to Paclitaxel on the basis of the patent already issued, and of the CE conformity certificate issued for the medical device. The DPMA rejected that application in February 2016, one of the grounds cited being that the product, under Regulation 469/2009/EC of 6 May 2009, required but did not have marketing authorization (MA).

Boston Scientific brought an action against that decision before the German Federal Patents Court (Bundespatentgericht). According to the applicant, the medicinal product had already undergone an administrative authorization procedure under the Medicinal Products Directive, as the competent medicinal products authority had already reviewed the safety and usefulness of Paclitaxel in relation to its use in the medical device. The mandatory certification procedure should therefore be regarded as an authorization procedure equivalent to the MA procedure laid down in the Medicinal Products Directive.

The German Federal Patents Court observed that the medicinal product indeed had an MA for the treatment of certain cancers, but no formal authorization procedure for the purpose envisaged in the patent. As the substance formed an integral part of a medical

device, an evaluation pursuant to the Medical Device Directive had been performed. While the procedures followed were different, that evaluation related to the safety, quality and usefulness of the substance incorporated. That evaluation was equivalent, as regards the test criteria, to the procedure required for the authorization of a medicinal product. The court therefore held that the certification procedure for medical devices incorporating a medicinal substance should be regarded as an administrative authorization procedure pursuant to Article 2 of Regulation 469/2009/EC.

Given the Member States' inconsistent practice in this regard, the German Federal Patents Court referred the following question to the European Court of Justice (ECJ) for a preliminary ruling:

Must Article 2 of Regulation 469/2009/EC be interpreted as meaning that, for the purposes of that regulation, an authorization under Directive 93/42/EEC for a combined medical device and medicinal product within the meaning of Article 1(4) of Directive 93/42/EEC is to be treated as a valid marketing authorization in accordance with Directive 2001/83/EC, where, as part of the authorization procedure laid down in Section 7.4(1) of Annex I to Directive 93/42/EEC, the quality, safety and usefulness of the medicinal product component has been verified by the medicinal products authority of a Member State in accordance with Directive 2001/83/EC?



Photo: Florian Bauer/stock.adobe.com

The ECJ judgment

The ECJ came to the conclusion that Article 2 of Regulation 469/2009/EC must be interpreted as meaning that a prior authorization procedure under the Medical Device Directive cannot be treated in the same way as an MA procedure even if that substance was evaluated in Section 7.4(1) and (2) of Annex I to Directive 93/42/EEC.

The ECJ reasoned that it is clear from the actual wording of that Article 2 that an SPC may only be issued if the product had undergone an MA procedure as a medicinal product. If the product is a substance pursuant to Article 1(4) of the Medical Device Directive, that is, if it forms an integral part of a medical device, it may not be regarded as a medicinal product capable of being the subject of an MA procedure as laid down in the Medicinal Products Directive (see para. 27 and 28 of the ECJ decision).

Medicinal products, according to Article 1(2)(b) of the Medicinal Products Directive, are substances or combinations of substances that may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis (para. 30).

Medical devices, by contrast, according to Article 1(2)(a) of the Medical Devices Directive, are any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose, inter alia, of diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap, and

which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (para. 31).

The terms “medicinal product” and “medical device” are therefore mutually exclusive. A product that falls within the definition of a “medicinal product” under the Medicinal Products Directive cannot be a “medical device” under the Medical Devices Directive. For a valid differentiation, the principal mode of action of the product should be considered.

A substance which forms an integral part of a medical device and performs an action on the human body that supplements that of the device is still not a medicinal product. This substance therefore cannot fall within the scope of Regulation 469/2009/EC (para.35).

The ECJ further held that the testing of a substance that forms part of a single integral product within the framework of the certification procedure is not comparable with the procedure that must be followed for a medicinal product approval. Section 7.4 (1) and (2) of Annex I to Directive 93/42/EEC state that such a substance must be tested by analogy with the methods specified in Annex I to Directive 2001/83/EC. However, the substance is not independently tested in this procedure; rather, the test is based on the intended purpose of the medical device.

For this reason, too, the ECJ did not regard the examination within the framework of the certification procedure as tantamount to an evaluation of the medicinal product as provided for in the Medicinal Products Directive. Such a

substance does not fulfil any of the conditions laid down in Article 2 of Regulation 469/2009/EC (para. 40).

A SPC cannot be issued for such medical devices.

Summary and conclusion

The ECJ has clearly rejected the legal opinion voiced by the German Federal Patent Court and once again emphasized that a product can either be a medicinal product or a medical device, but not both. This fundamental separation applies even to combination products. The issuance of a supplementary protection certificate is thus not possible for such medical devices.

Whether this interpretation is appropriate is another question. In fact, certification for a combination product is likely to take longer, so a need for protection could well be construed. However, the ECJ’s interpretation is understandable given the clear distinction that the law requires. ■



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Five-year follow-up of immediate restorations with ceramic-reinforced PEEK

A safe and predictable long-term treatment protocol

PROFESSOR JOSÉ EDUARDO MATÉ SÁNCHEZ DE VAL¹, MURCIA, SPAIN

Ceramic-reinforced PEEK materials have been developed to improve the shade and mechanical properties of dental restorations. One of these materials is BioHPP (bredent group, Senden, Germany). Abutments are made by overpressing a titanium base with the BioHPP material, resulting in monolithic hybrid abutments with threaded screw-holes in the titanium part for long-term stability and a resilient body made of ceramic-reinforced PEEK. The objective of this article is to present a follow-up and re-evaluation of patients treated with immediate restorations using abutments made of BioHPP, in a five-year follow-up period.

Introduction

Immediate restorations for dental implants are an effective and predictable treatment modality for which there is a broad scientific evidence base. They can be safely included in the practitioner's standard treatment portfolio [1]. Close study of the properties of the new materials has given rise to the development of treatment protocols that are precise and stable; they include the concepts of platform switching and the retention of the initial attachment.

This approach is particularly interesting in the aesthetic zone, where patient expectations are high. To achieve a highly aesthetic result, the dentist must be able to make use of a broad range of solutions that guarantee long-term stability of the restorations, high survival rates and stable peri-implant soft tissues [2]. Among the new materials, PEEK reinforced with ceramic offers very promising results in terms of physical and mechanical properties as well as biocompatibility.

The surface of the material offers excellent conditions for a healthy peri-

implant soft-tissue attachment. It is bacteriostatic, lowering the prevalence of peri-implant mucositis. An ideal modulus of elasticity avoids component fracture and allows a progressive transmission of masticatory forces. Finally, the material is highly biocompatible and does not promote irritation or inflammatory reactions [3].

Removing and re-connecting abutments has been shown to be a critical factor in the onset of crestal bone loss and the formation of micro-spaces where pathogenic bacteria can be trapped [4]. In addition, the concept of platform-switching has provided an extra margin of safety for anchoring soft tissue with diameter differentials of approximately 0,2 mm, which is an effective way to stabilize the peri-implant environment [5,6].

This article presents a five-year follow-up and re-evaluation of patients treated with immediate restorations using abutments made of BioHPP, a ceramic-reinforced PEEK material.

Material and methods

Study design

This study evaluated an implant-placement protocol featuring immediate loading of implants using abutments made of ceramic-reinforced PEEK (BioHPP SKY elegance abutment; bredent, Senden, Germany). Of the 48 implants (blueSKY, bredent) placed in healing bone, 32 received SKY elegance abutments (test group) and 16 received titanium abutments (control group).

A randomization scheme was generated using the www.randomization.com website. The Ethics Committee of the University of Murcia (Spain) approved the study protocol, which followed guidelines established by Council Directive 2013/53/EU).

Surgical protocol

The research protocol called for recruitment of subjects from patients referred to the Department of General Dentistry of the University of Murcia over an 18-month period. All patients in need of

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anterior oral rehabilitation that would include the placement of a single implant were invited to participate in the study, which was overseen by the institutional review board.

Additional inclusion criteria were sufficient bone height and width to allow the placement of implants with a minimum diameter of 4.1 mm and a minimum length of 10 mm, and an occlusal pattern that allowed for bilateral stability. Study participants were required to present with at least 3 mm of soft tissue vertically to establish an adequate biologic width and to reduce bone resorption. Exclusion criteria included severe maxillomandibular skeletal discrepancies, uncontrolled diabetes, haemophilia, metabolic bone disorders, a history of renal failure or radiation treatment in the head or neck region, ongoing chemotherapy, pregnancy, drug or alcohol abuse, poor oral hygiene, insufficient bone volume at the recipient site and the need for bone augmentation prior to implant placement.

- **Surgical procedure:** A full-thickness incision was made with a No. 15c blade, combining an intrasulcular with a crestal incision in the palatal area. A flap was elevated and the bone was exposed using periosteotome. A blueSKY implant (bredent) was placed using the manufacturers prescribed placement protocol. The site was sutured with simple interrupted sutures with a 4-0 polypropylene element.

- **Postsurgical care:** All patients (AINE) received ibuprofen 400 mg once every eight hours for three days as anti-inflammatory treatment, and chlorhexidine digluconate gel 0.12 % once every twelve hours for two days after surgery.
- **Implants:** 48 blueSKY implants (bredent) 3.5–4 mm in diameter and 10–12 mm in length were placed crestally in the premolar region of the maxilla.
- **Abutments:** 48 BioHPP SKY elegance abutments were connected at the time of implant placement (immediate loading). These abutments are hybrid abutments with a body made of BioHPP moulded directly onto the titanium base without a gap. These abutments must be placed only once in immediate-restoration cases, since they combine the properties of a temporary and a definitive abutment; in other words, it is not necessary to change abutments.
- **Restorations:** All crowns were Cerec (Dentsply Sirona, Bensheim, Germany) crowns made from the definitive material cemented with self-curing RelyX universal cement (3M Espe, Seefeld, Germany). All the implants were restored using a platform-switching protocol. Figures 1 to 4 show an example case.

Analysis

- **Follow-up period:** All measurements were taken five years after implant placement and compared with baseline data.

- **Radiological analysis:** Standardized radiographs were taken by means of a one-position paralleling system and analyzed using ImageJ software (Wayne Rasband, USA). The distance between platform and the point of first bone contact was recorded.
- **ISQ stability analysis:** Stability measurements were made at baseline to assess whether the implants were sufficiently stable to permit immediate loading. An ISQ value of 65 was assumed as the minimum value required. ISQ values were taken using Osstell Mentor (Osstell, Göteborg, Sweden).
- **Mucogingival analysis and clinical findings:** The bleeding index for the implants was recorded by special peri-implant probing. Post-insertion loss of peri-implant mucosa and any height loss were also recorded. Values for bleeding on probing (0 = no bleeding, 1 = bleeding) were recorded at one, three and five months. The depth of insertion was measured with a conventional plastic probe by the same examiner. The results represent the means of six measurements.
- **Statistical analysis:** Values were recorded as means \pm standard deviation and as medians. A non-parametric Friedman test was applied to compare samples values. The level of significance was set at $p < 0.05$.



1a to d | Case example: Preoperative image with vertical fracture of the tooth. Tooth extraction with odontosection.



2a to d | Case example: Images of implant positioning at crestal level, attachment placement and milling.
3a and b | Control image at one year and five years after surgery.

Results and discussion

General findings

Visual and clinical inspections showed good stability of the tissues, no attach-

ment loss of the soft peri-implant tissue, and a very low prevalence of inflammation or bleeding on probing. All patients were greatly satisfied with their treatment results and with the speedy

procedure. In addition, patients judged the fact that the treatment could be completed in a single phase as a great advantage.

		5 months	5 years	P value
First bone contact to platform (mm)	Mean ± Sd	1.17 ± 0.87	1.21 ± 0.63	0.23
ISQ value (%)		71.43 ± 3.01		0.12
Bleeding on probing (0–1)		0.06 ± 0.02	0.10 ± 0.01	0.14
Insertion length (mm)		4.11 ± 1.02	3.96 ± 1.36	0.11

Table 1 Linear measurements on the radiological analysis and clinical values analyzed. Comparison between control at five months and five years. Significant differences for $p < 0.05$



4a and b | Radiological control at five months and five years.



5 | Image obtained from a project of experimental analysis in animals (tissue preservation by means of Elegance abutment. 2018).

Analyses

A comparison of the results (Table 1) showed no significant differences between the measurements at baseline (five months) and the five-year follow-up. The radiological analysis showed similar values at five months (1.17 ± 0.87) and at five years (1.21 ± 0.63). Nor did the results for bleeding on probing exhibit any significant differences ($p = 0.14$). The depth-of-insertion results were also similar at five months (4.11 ± 1.02) and at five years (3.96 ± 1.36).

The combination of an abutment that does not have to be removed and the hybrid ceramic-reinforced PEEK material yields excellent results. The preservation of crestal bone and the good peri-implant soft-tissue attachment are demonstrated in Figure 5.

Conclusions

With the limitations of this clinical study, it can be concluded that the

technique of immediate loading ceramic-reinforced PEEK abutments is predictable and stable over time from an aesthetic and clinical point of view.

The type of material used, together with the single-phase treatment concept produced excellent clinical and aesthetic results. Combined with the results of experimental studies, whose histological images corroborate the present results, it can be said that the protocol presented here is a safe and predictable long-term treatment protocol. ■

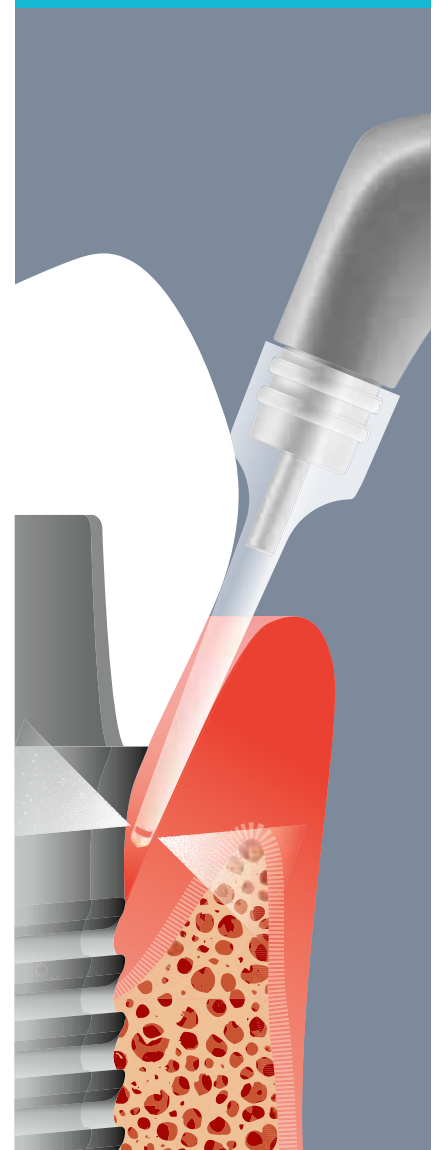
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Management of sinus membrane perforations

The “Tattone technique”

PASCAL VALENTINI¹, GEORGE EID¹, JEAN-MICHEL FERRANDI¹, DAVID ABENSUR¹, TIZIANO TESTORI²

One of the most frequent complications which is encountered with maxillary sinus grafting is the perforation of the sinus membrane. Several techniques have been reported for the management of this complication. In this technical note, the authors present a method for the repair of a membrane perforation adjacent to the medial wall of the sinus cavity, an indication that makes the success of all previously described techniques unpredictable. The sealing of the perforation is possible by using titanium tacks for stabilizing the membrane against the medial wall.

Modern implantology continues to extend the limits of possible indications for our patients. The advent of short implants has allowed the expansion of therapeutic strategies, but post-extraction atrophy of the alveolar bone in the upper jaw may result in the lack of height between the sinus floor and the alveolar ridge to plan rehabilitation with implants, even with short ones.

In the early 1980s [1], *Boyne and James* proposed a sinus graft technique by means of a lateral approach with autologous bone in order to increase the bone volume beneath the sinus.

Today, the use of biomaterials in the form of granules as graft material is fully validated by the scientific community [2-4].

However, the surgical procedure via the lateral approach may entail complications, above all perforation of the sinus membrane. Leakage of the graft material through the perforation can lead to sinusitis due to the blockage of the ostium by granules [5].

For all interventions, the prevalence of perforations of the sinus mucosa is between 7 to 35 per cent [6]. This rate can be reduced using piezoelectric surgery [7,8].

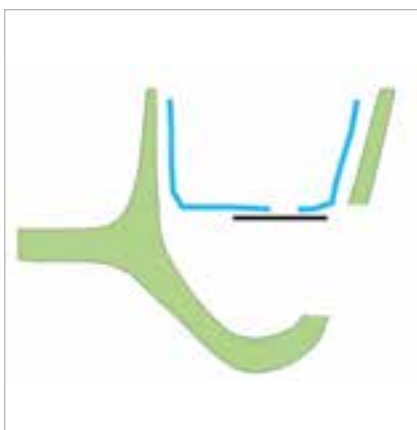
Management of sinus membrane perforations

For the treatment of perforations smaller than 5 mm, when the membrane is torn, it is possible to consider suturing it with resorbable material [9]. This option appears difficult to implement in the case of a very thin membrane. Today, the most frequently used method is sealing of the rupture outside its edges with a resorbable membrane [10-12].

However, the use of a resorbable collagen membrane may not be effective. In fact, despite the use of resorbable membranes, sinusitis can occur [13]. This is likely due to improper use of these

membranes. The objective of the present article is to propose a new approach, the Tattone technique, for the management of perforations of the sinus membrane in order to complete the existing therapeutic arsenal and thus increase the success of procedures.

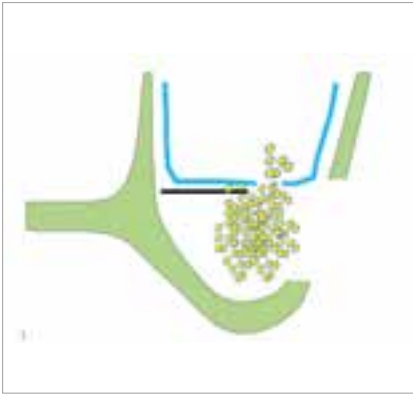
Literature [11] reports a prevalence for sinusitis of 31.4 per cent in cases of membrane perforation despite intra-operative closure with resorbable membranes. The technique usually suggested [6] consists of sealing the perforation with a resorbable collagen membrane that extends beyond the edges of the perforation but remains entirely inside the sinus cavity (Fig. 1). There is, thus, a risk of leakage of grafting material through the perforation when the graft material is injected, which can cause the collagen membrane to be displaced (Fig. 2) beyond the edges of the perforation. It is therefore necessary to stabilize this membrane in order to prevent it from moving during the placement of the material [10]. To avoid such displacement, it would be necessary to introduce part of the collagen membrane in contact with the perforation, leaving part of it outside, attached to the external aspect of the buccal wall with one or



1 | The collagen membrane is inserted above the perforation.

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2 | The collagen membrane is moved away from the perforation.



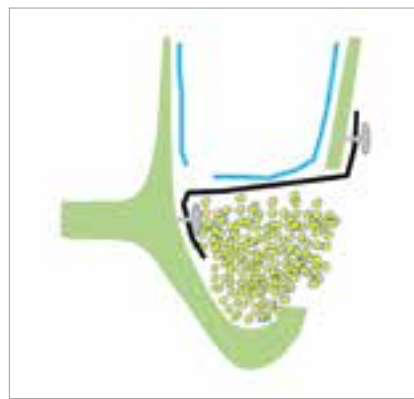
3 | The collagen membrane is stabilized above the perforation.



4 | As the perforation is adjacent to the medial wall, the sealing is not effective.



5 | Two titanium pins on the medial wall.



6 | The perforation is perfectly sealed.



7 | Coronal cut showing one pin in the medial wall.

more titanium pins (Fig. 3). This option is valid when the perforation is located away from the medial wall of the sinus.

The Tattone technique

However, this solution is not usable if the tear is in contact with the medial wall. In such case, the zone in contact with the medial wall cannot be hermetically sealed, and there is a risk of leakage of material (Fig. 4).

The “Loma Linda pouch” [14] may then be an option, but the risk is that this pocket may detach from the medial wall when the patient breathes. There is thus a risk of the sinus membrane getting between the medial wall and the graft, which may cause a displacement of the graft buccally and thus disrupt the osteoconduction due to the absence of

contact between the graft and the bone wall. The solution consists in cutting the collagen membrane (Bio-Gide, Geistlich, Wolhusen, Switzerland) so that it is in contact with the medial wall, where it is then pinned (Titan Fix, Geistlich) (Fig. 5) while the external part can also be pinned to the vestibular wall (Fig. 6). While avoiding loss of granules through the perforation, this technique makes it possible to optimize the contact surface between the graft and the medial wall without the collagen membrane getting in between.

In addition, the double fixation of the membrane allows better stability of the blood clot around the particles of the xenograft and hence better healing. Of course, the pins are not removed (Fig. 7).

Conclusion

It is important to consider the location of the perforation in order to adjust the use of the collagen membrane and to make it effective to prevent graft loss. ■

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

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Keratinized tissue augmentation with a xenogenic collagen matrix in an open healing situation

Combined strip technique after vertical ridge augmentation

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A xenogenic collagen matrix designed to increase the amount of keratinized tissue can be used in conjunction with autologous tissue to treat complex mucogingival defects, reducing the amount of autologous graft needed. The patient benefits from a shorter surgical time and a reduced morbidity.

The minimum amount of keratinized tissue (KT) around dental implants ensuring peri-implant health is a widely debated topic [1]. Several in vitro and clinical studies have demonstrated a critical threshold value of 2 mm mucosal width [2–9]. Souza et al. evaluated the influence of peri-implant KT on peri-implant tissue health in 80 patients/270 implants [1]. The findings demonstrated that the level of brushing discomfort was significantly higher in sites with < 2 mm of KT. Additionally, it was shown that implant sites with < 2 mm of KT exhibited 50 per cent more plaque and 25 per cent more bleeding on probing than sites with ≥ 2 mm of KT. Meta-analysis demonstrated also that the presence of KT is associated with less mucosal recession and attachment loss [10].

Surgical strategies

Surgical techniques aimed at augmenting the width of KT and deepening the vestibule include an apically positioned flap or a vestibuloplasty procedure [11]. Although the short-term outcome of these procedures is favourable in many cases, there is a typical rebound within a few months and the achieved tissue gain is lost [12]. To achieve more stable results, soft tissue autografts, for example free gingival grafts or subepithelial connective grafts were recommended [12].

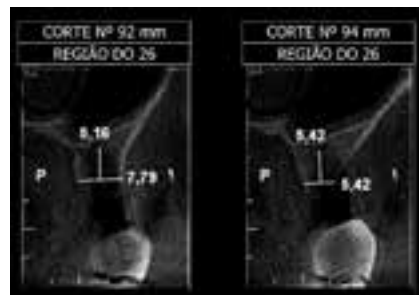
However, the use of autografts has several disadvantages. The quantity and

quality of tissue that can be retrieved vary depending on the shape of the palatal vault and the patient's sex and age [13] as well as on anatomical factors such as a thick alveolar process, exostosis, and the palatine nerves and blood vessels [14–16]. More importantly, harvesting autologous soft tissues from the palate is usually associated with additional risks,

such as numbness or infection, and especially with significant patient morbidity [17,18]. This is mainly true when there is a need to graft large mucosal areas, for example in case of major bone augmentation procedures. This usually results in a severe translocation of the mucogingival line and loss of vestibule, even limiting the mobility of the lip [12].



1 | Periapical radiograph demonstrating the vertical bone defect.



2 | CT scan image of region 26 (pontic) with insufficient crestal bone height.



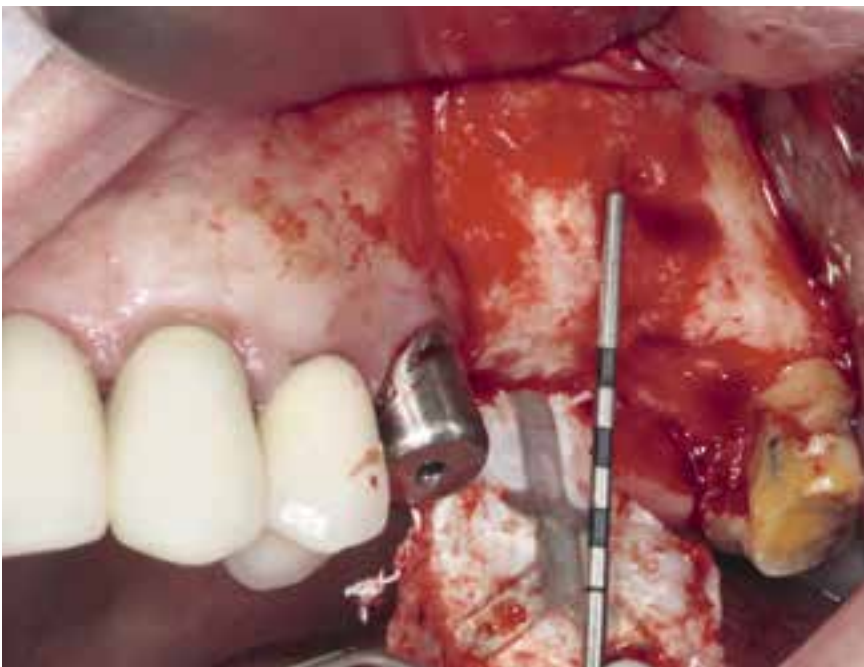
3 | Buccal view of a vertical defect in the maxillary first molar region.



4 | A 1:1 mixture of particulate autologous bone and Geistlich Bio-Oss placed under a TR-PTFE membrane (Cytoplast Ti-250, Osteogenics Biomedical).



5 | Stabilization of the graft and membrane with fixation titanium screws (Pro-Fix, Osteogenics Biomedical).



6 | 8 mm vertical bone regeneration, nine months postoperatively. A 4,3 x 10mm implant was installed in the newly regenerated bone. The posterior implant (27) was lost, removed and immediately replaced by another 4,3 x 10 mm implant in the same surgery.

Different soft tissue substitutes from several origins and for diverse clinical indications are now available. They can be used together with or instead of autologous tissues to reduce patient morbidity [12,19,20].

Based on the study of *Urban* et al. [12], the following case report describes a treatment protocol that combines a strip of free gingival autograft with a two-layer xenogeneic collagen matrix (Geistlich Mucograft; Geistlich Pharma, Wolhusen, Switzerland), to deepen the vestibule and increase the width of KT between

implants placed in a vertically augmented ridge. Geistlich Mucograft has been intensively investigated for augmenting keratinized tissue around implants. In pre-clinical and clinical models, the matrix demonstrated the ability to promote immediate blood clot stabilization, leading to early vascularization and facilitation of the soft tissue cell ingrowth and an excellent integration with surrounding tissues [21,22].

The case shows a step-by-step description of the treatment procedure adopted, from diagnosis to conclusion.

Case report

The case is presented to demonstrate a feasible solution for treating a severe mucogingival distortion after vertical augmentation, by increasing the width of KT. To alleviate the need for an extensive autograft harvest, a technique of combined grafts is used by taking advantage of a two-layer xenogeneic collagen matrix in an outpatient setting.

A 51-year-old male patient was referred for a graft procedure to correct a vertical bone defect in the region of the first molar (26) between two previous installed implants (25,27) (Figs. 1 to 3).

The initial treatment plan consisted of a vertical ridge augmentation of the region of interest using a guided bone regeneration (GBR) technique as previously described by *Urban* et al. [23,24] Composite bone grafts in a 1:1 mixture of particulate autologous bone and deproteinized bovine bone mineral (DBBM, Geistlich Bio-Oss; Geistlich Pharma), covered with a titanium-reinforced high-density polytetrafluoroethylene (TR-PTFE) membrane were used (Figs. 4 and 5).

At the re-entry, nine months after the vertical bone augmentation procedure, an 8 mm bone gain was observed, and a 4,3 x 10 mm implant (Replace Select, Nobel Biocare, Zurich, Switzerland) was installed in the newly regenerated bone. The implant in the posterior position (27) was lost but removed and immediately replaced in the same surgery (Fig. 6).



7 | Occlusal view of the mucogingival distortion with loss of KT, three months after the implant surgery.



8 | Horizontal incision on keratinized tissue parallel to the mucogingival junction, on the palatal side of the ridge. Split thickness flap to reposition the mucogingival line apically.



9 | Strip gingival graft, removed from the palate.



10 | The xenogeneic collagen matrix (Geistlich Mucograft), already trimmed, being placed over the recipient site.



11 | Buccal view of the combination graft: strip gingival graft and xenogeneic collagen matrix sutured over the recipient site.



12 | Buccal view, seven days after the combination graft.



13 | Buccal view, 15 days of healing, with the newly formed tissue in the grafted region.

At three months after the implant placement, a significant mucogingival distortion with loss of KT was visible (Fig. 7) and the patient was treated with the combined strip technique. A horizontal incision on the keratinized tissue par-

allel to the mucogingival junction on the palatal side of the ridge, and a split thickness flap to reposition the mucogingival line apically were performed (Fig. 8). An autologous free gingival graft of suitable dimensions to cover the recipient defect

was harvested and sutured immediately (Fig. 9). The remaining part of the recipient site was covered with Geistlich Mucograft, sutured in place and left exposed for healing (Figs. 10 and 11).



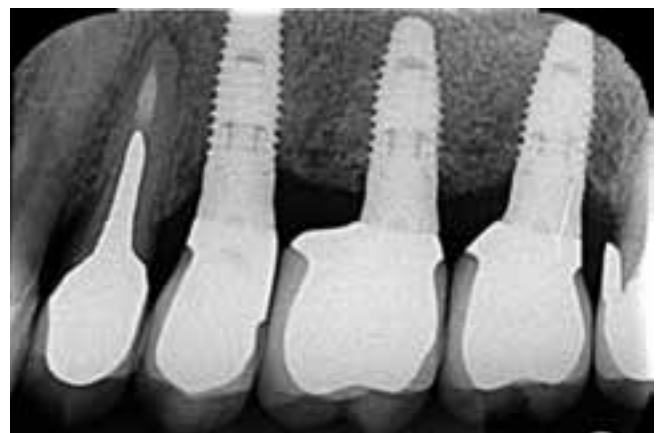
14 | Occlusal view of the KT around the implant abutments, when placing the final metal-ceramic crowns, 18 months after the combination gingival graft.



15 | Occlusal view of the final metal-ceramic crowns.



16 | Buccal view of the 18-month follow-up of the combination gingival graft procedure. A considerable amount of KT can be appreciated.



17 | Periapical radiographs after 18 months of loading demonstrating stable crestal bone and an improvement in the crestal bone at the distal of implant 25 due to the bone graft procedure.

An almost complete healing of the wound was visible at seven and fifteen days postoperatively, with newly formed tissue in the grafted region (Figs. 12 and 13). The final crowns (IPS d.Sign; Ivoclar Vivadent, Schaan, Liechtenstein) were placed 18 months after the combined gingival graft procedure. A significant amount of KT was visible and periapical radiographs demonstrated stable crestal bone and an improvement in the crestal bone at the distal of implant 25 (Figs. 14 to 17).

Conclusions

The influence of the width of KT around implant-supported restorations, both on implant survival and on the stability of peri-implant tissues, is still controversial. However, several studies have shown that a width of KT <2 mm is associated with higher plaque accumulation and gingival inflammation, and with significantly higher mucosal recession [5]. To

overcome this problem, different surgical techniques and materials have been proposed, such as the most frequently used apically repositioned flap plus the application of autologous graft harvested from the palatal or allograft materials. However, none of these substitutes proved to be up to the gold standard connective tissue graft or free gingival graft, reporting significantly inferior results [25,26].

A xenogeneic collagen matrix, such as Geistlich Mucograft, has compensated for this deficit. It demonstrates the ability to promote immediate blood clot stabilization, leading to early vascularization. This feature facilitates the soft tissue cell ingrowth and an excellent integration with surrounding tissues [21,22]. Several clinical studies show that the gain in KT with this matrix is comparable to a connective tissue graft [27] or a free gingival graft [28]. In addition, there is no harvest-site morbidity [27,28].

This clinical case showed how to treat a complex mucogingival defect using the combination of strip gingival grafts and a xenogeneic collagen matrix in an open healing setting. The case proved that this matrix can be used as an effective, safe and optimal alternative to autologous grafts. It has the advantages of having an unlimited availability in terms of quantity and consistent quality, and the patient benefits from a reduced morbidity and a shorter surgery time. ■

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

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A post-extractive implant case with a CAD/CAM solution on a zirconia collar tissue-level implant

Benefits of an immediate tissue-level implant protocol

DR RÉGIS NÈGRE, RODEZ, FRANCE

The main challenge with post-extraction implant cases is the preservation of native bone. It's important to maintain as much of the bone as possible, in order to ensure that the implant has sufficient primary stability. The immediate implant placement protocol further helps to preserve the natural bone volume [1,2]. Delayed implant placement protocols require a waiting time of three to four months after the extraction for bone healing before implant placement. During this time, the patient can lose a significant amount of bone height and width [3–5] if no bone regeneration is performed. The immediately placed implant has a “tent” effect, supporting soft tissue volume [6] to encourage regeneration where necessary, and leading to higher implant stability compared to conventional implant placement techniques [7].

The protocol carried out and the material used in this case allowed the restoration of the patient's smile in just two stages: a surgical one and a prosthetic one. The approach with only two steps offers several benefits. The patient only needs to attend one 40-minute appointment for extraction and implant placement, and a second 40- to 50-minute appointment for impressions and the manufacture and fitting of the CAD/CAM restoration.

Case presentation

A 35-year-old female patient presented with a previously restored molar that

was causing problems. Upon X-ray, a very long post was identified in the existing crown, as was an apical lesion (Figs. 1 and 2). This gave the molar a hopeless prognosis and extraction was therefore indicated. The option of extraction with immediate implant placement was discussed and agreed on with the patient.

During the first appointment, the crown and the post were removed (Fig. 3). The three remaining roots were separated in order to perform the most atraumatic extraction possible (Figs. 4 to 6). It has been suggested that this helps to preserve the interradicular bone (Fig. 7)

and facilitates primary stability of the implant when placed [8,9]. The roots were then extracted and the socket cleaned in order to remove any infection.

The pilot drill was used to mark the entry point of the implant in the bone, located in the centre of the remaining interradicular bone (Figs. 8a and b). A 5 mm diameter tissue level dental implant with a 6 mm diameter platform and 2.5 mm height zirconia collar (Z1; TBR, Toulouse, France) was placed (Fig. 9), followed by the cover screw (Fig. 10). Almost all of the recommended drilling sequence was used – preparation stopped short of the



1 | Radiograph demonstrating long crown post and apical infection.



2 | Intraoral view before treatment.



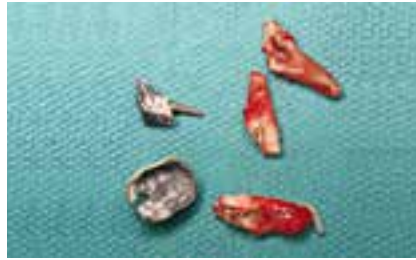
3 | Crown removal.



4 | Inlay core removal.



5 | The roots are separated to allow for a more atraumatic extraction.



6 | The extracted roots.



7 | Preservation of the interradicular bone.



8a | Drilling ...



8b | ... and preparation of the socket.



9 | Immediate placement of the Z1 implant (TBR) under the cemento-enamel junction of the adjacent teeth.



10 | Cover screw placed.



11 | Preparation of the PRF and allogeneic graft material.



12 | Grafting material placed and wounds sutured.

final drill in order to under-prepare the soft bone for higher primary stability. In position 26, we often deal with D3 or D4 bone, making the design of the implant threads of vital importance for the outcome of the restoration.

The efficient threads of the tissue-level implant promote stability, encouraging success even in high risk or limited bone situations. Another benefit of this surgical technique is that the clinician can decide on the most suitable depth

of the implant and thus the position of the zirconia collar in contact with the soft tissue.

From 15 years of experience with this technique, the author has learned that placing the zirconia collar 1 mm beneath the cemento-enamel level on both the palatal and buccal aspects, leads to improved aesthetics. According to *Dr Joseph Choukroun's* protocol [10], I-PRF (Injectable Platelet-Rich Fibrin) and an allogeneic bone grafting material were

placed to improve bone quality, quantity and healing (Fig. 11). An A-PRF (Advanced Platelet-Rich Fibrin) membrane was placed over the top to protect the bone graft and implant. The wound was then closed with O-shaped sutures, being sure not to create any tension in the soft tissue so as to prevent bone resorption (Fig. 12). The patient was prescribed antibiotics, anti-inflammatories and painkillers to aid comfort and healing.

Follow-up

Four months later the patient returned for her follow-up appointment. The X-ray demonstrated no bone loss and perfect osseointegration of the implant within the surrounding bone. Ideal healing of the soft tissue around the zirconia

collar could be seen and the zirconia collar had integrated well with both the bone and gingiva to produce a very good emergence profile (Fig. 13). This made restoration simpler through CAD/CAM protocols, as a titanium base and scan-body could be placed onto the zirconia

platform in order to take a digital impression (Figs. 14 to 17). The use of a chair-side CAD/CAM workflow made treatment quicker – the restoration could be designed, manufactured and placed in a single appointment – more accurate and more comfortable for the patient.



13 | Four months post surgery.
14 | Cover-screw removed.



15 | Titanium base ...
16 | ... and scan body placed.



17 | Digital impression.

18 | The work area is reduced with the software.

19a | Virtual articulator ...



19b | ... used to check occlusion.

20a | Implant position ...

20b | ... and crown are designed digitally.



21 | Pre-drilled e.max block.



22 | Precision fit with the Z1 implant.



23



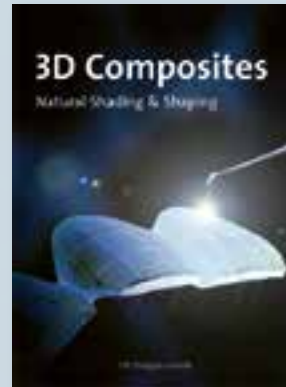
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23 | The crown is milled ... 24 | ... and finished.

Using digital design software, the work area was reduced to the immediate region of the implant (Fig. 18), while both arches were put into the virtual articulator to check occlusion (Figs. 19a and b). The restorative design was performed on the virtual implant (Figs. 20a and b). The software is very intuitive and automatically recognizes the type of implant solution used. The restoration was then fabricated from an IPS e.max bloc (Ivoclar Vivadent, Schaan, Liechtenstein) and the final touches were made (Figs. 21 to 24).

3D Composites – Natural Shading & Shaping

by Ulf Krueger-Janson



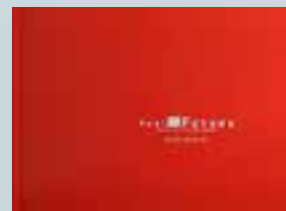
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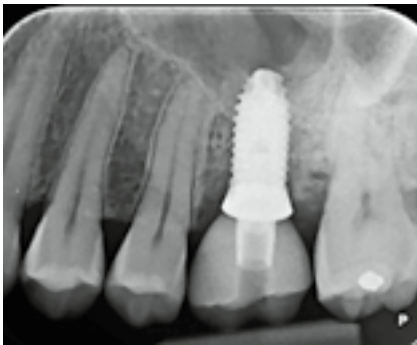
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25 | Screw-retained crown in the patient's mouth.

26 | The screw-hole is filled with composite.



27 | Post-treatment radiograph.

28 | Creeping attachment of gingiva after six months of crown placement.



29 | Papilla repositioning ...

30 | ... and final restoration after six months of crown placement.

The comparison between a tissue level surgical technique versus a bone level surgical technique shows a considerable advantage. In this case, the CAD/CAM-fabricated crown is fixed directly on the implant platform. However, if we had to opt for a bone level surgical technique, this same crown would have been cemented onto the shoulder of an abutment. The selected surgical technique is therefore much less invasive for soft tissues. On the one hand, it does not constrain or mobilize the gingival tissues once the implant has been placed, and on the other hand, zirconia has aesthetic and antibacterial properties superior to titanium. In this technique, the combination of using a zirconia collar at soft tissue level and a CAD/CAM-fabricated crown ensures a ceramo-ceramic con-

tinuity, significantly improving the aesthetics of the restoration.

The final restoration was screwed into place with a torque of 30 Ncm (Fig. 25). Composite was placed to fill the screw access hole and complete the occlusal surface of the crown (Fig. 26). Figure 27 shows the post-treatment radiograph, Figures 28 to 30 demonstrate papilla formation and creeping attachment along the emergence profile after six months of crown placement.

Discussion

A wider platform implant was used in this case, as this was appropriate for restoring a molar tooth. It creates a more natural-looking soft tissue emergence profile and this in turn makes oral hygiene easier to achieve for the patient in the long-term.

The author only uses a zirconia collar height of 2.5 mm, as this is the ideal size to ensure that it remains 1 mm below the periodontal tissue. The zirconia collar provides a natural barrier to infections as the gingiva adheres to it, protecting the implant, the bone, the gum and therefore, the overall restoration [11]. All of this together ensures the long-term stability and survival of the dental implant. ■

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An immediate-delayed socket grafting procedure

Helping the host regenerate hard and soft tissues

MINAS LEVENTIS^{1,2}, PETER FAIRBAIRN^{1,3}, ANNETTE LINDNER⁴

This case report highlights the use of a bioactive in situ hardening synthetic resorbable bone substitute composed of beta tri-calcium phosphate (β -TCP) and calcium sulfate (CS) for alveolar ridge preservation, following a modified immediate-delayed socket grafting technique. Both the staged approach along with the biological and biomechanical properties of the grafting material helped the host to regenerate vital bone and newly-formed thick keratinized soft tissues, thus minimizing the complexity of the procedures and leading to a predictable and successful outcome.

Case report

A 63-year-old female patient, non-smoker, with non-contributory medical history, presented with a non-conservable mandibular right first premolar due to extensive caries and periapical pathology (Figs. 1 and 2). After thorough clinical and radiological examination, a delayed implant placement treatment was proposed. The treatment plan involved:

- extraction of the failing tooth,
- alveolar ridge preservation with grafting of the socket six weeks after extraction,
- implant placement four months after grafting,
- uncovering of the implant three months after placement and subsequent loading with a final screw-retained crown.

The extraction was performed under local anaesthesia without raising a flap. Firstly, the crown was removed using forceps and the decayed root was carefully mobilized



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⁴ CTA - Cell Tissue Analysis, Medical Center, University of Freiburg, Freiburg, Germany



4 | The post-extraction site; note the loss of the buccal plate and the thin buccal soft tissues.



5 | Periapical x-ray immediately post-extraction.



6 | Debridement of the socket using EthOss degranulation burs.

and removed, using periostomes and thin elevators in order to minimize the injury of the surrounding soft and hard tissues (Fig. 3). However, due to the extensive caries and the non-favourable anatomy of the root, the extraction was very difficult, which resulted in complete loss of the thin buccal bone plate and loss of the buccal keratinized soft tissues crestally (Figs. 4 and 5). Thus, the socket was thoroughly curetted and debrided of any soft tissues, using Lucas hand bone curettes and degranulation burs (EthOss EK

Strauss Degranulation Bur Kit, EthOss Regeneration Ltd, Silsden, UK), followed by rinsing with sterile saline (Fig. 6). The post-extraction site was then allowed to heal by secondary intention.

After six weeks, the site was covered by newly-formed soft tissues, while the complete loss of the buccal plate during the extraction resulted in severe atrophy of the ridge in the horizontal dimension (Fig. 7). Under local anaesthesia, a site-specific papillae-sparing full thickness flap was raised using

vertical releasing incisions, without including the papillae of the adjacent teeth (Fig. 8) as described by *Greenstein and Tarnow* [1]. After flap elevation, all granulation tissue was removed and the socket was grafted utilizing a self-hardening fully resorbable synthetic bone grafting material (EthOss, EthOss Regeneration Ltd, Silsden, UK), consisting of β -TCP (65%) and CS (35%), as described by the authors in a previous publication [2]. No barrier membranes were used (Figs. 9 and 10).



7



8



9



10

7 | Clinical view six weeks after the extraction. The host already regenerated soft tissues to cover the socket.

8 | Site specific papillae-sparing flap to expose the socket. Note the lack of buccal bone.

9 | The socket was grafted with β -TCP/CS (EthOss). No membranes were used.

10 | Periapical x-ray post-op.



11 | Clinical view four months post-op.



12 | Periapical x-ray four months post-op.



13 | Adequate regeneration of hard tissues at re-entry four months post-op.



14 | The only way to evaluate the quality of the regenerated bone is to harvest a trephine bone biopsy. The bone sample was harvested from the centre of the regenerated site, so there is no old bone there, just newly-formed regenerated hard tissue.



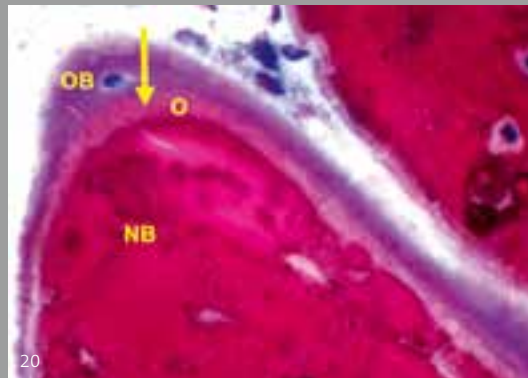
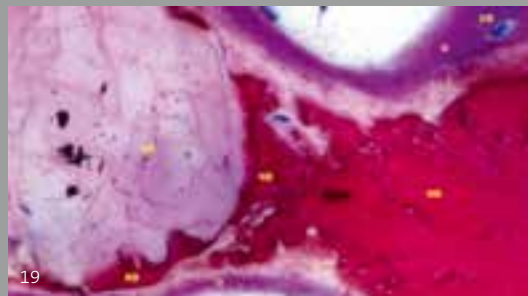
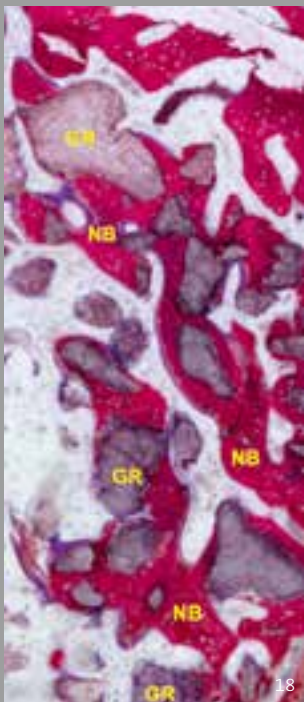
15 | Implant placed at the correct 3D positioning.



16 | Additional veneer grafting with EthOss.



17 | Repositioning and suturing of the full-thickness flap.



18 | Histological analysis of the sample showing pronounced bone regeneration. Dense trabecular network of new bone (NB) with tightly integrated EthOss granules (GR). Undecalcified ground section; stain azure II/pararosaniline staining, original magnification x50.

19 | Regenerated bone (NB) in contact to a dissolving EthOss granule (GR). Osteoblasts (OB) form osteoid (O). Connective tissue shows no signs of inflammation. Undecalcified ground section; stain azure II/pararosaniline staining, original magnification x400.

20 | Osteoblasts (OB) form osteoid (O). In some areas, a brighter space (arrow) between blue osteoid and red new bone can be observed. This might be a sign of different calcification stages in bone formation. Undecalcified ground section; stain azure II/pararosaniline staining, original magnification x630.

The mucoperiosteal flap was repositioned and sutured without tension with 5-0 sutures (Prolene, Ethicon, Johnson & Johnson, Somerville, NJ, USA). Antibiotic therapy consisting of 500 mg amoxicillin every eight hours for five days was prescribed. The sutures were removed after a week. The patient did not wear any prosthesis during the healing period.

The post-operative healing was uneventful. After four months, the architecture and the dimensions of the ridge were adequately restored and the site was covered with keratinized epithelium (Fig. 11). A periapical x-ray at this point in time showed the consolidation of the grafting material, resulting in bone regeneration at the site (Fig. 12). A site-specific full thickness flap was elevated revealing that the grafted area was filled with regenerated hard tissue (Fig. 13). Prior to implant placement, a bone core biopsy was taken (Fig. 14) with a depth of 7 mm from the centre of the site using a trephine drill with a diameter of 2.3 mm (Komet Inc., Lemgo, Germany). Following the harvesting of the bone sample, the preparation of the bony bed was completed and a 3.75 mm x 10 mm tapered implant (Paltop Advanced Plus,

Paltop Dental Solutions Ltd, Israel) was placed at the optimal position (Fig. 15). After placing the cover screw, the site was again grafted with a small amount of EthOss to cover the exposed implant threads buccally (Fig. 16). Again, no barrier membranes were used. After releasing the periosteum, the flap was repositioned and sutured tension-free using the same kind of sutures as in the previous procedure (Fig. 17). There was no need for a frenectomy, as the adjacent frenum was not applying any tension to the site when mobilizing and pulling the patient's lower lip. Antibiotic therapy consisting of 3 g amoxicillin one hour pre-operatively and 500 mg amoxicillin every eight hours for five days post-operatively was prescribed. The sutures were removed after an uneventful seven-day healing period.

The trephine bur with the bone biopsy inside was fixed in 4% formalin for five days, rinsed in water and dehydrated in serial steps of ethanol (70%, 80%, 90%, 100%), remaining for one day in each concentration. The specimen was then infiltrated, embedded and polymerized in resin (Technovit 9100, Heraeus Kulzer, Wehrheim, Germany) according to

the manufacturer's instructions. After polymerization, the sample was cut in 500 µm sections using a precision cutting machine Secotom 50 (Stuers, Ballerup, Denmark). The sections were mounted on acrylic slides (Maartin, Freiburg, Germany) and grounded to a final thickness of approximately 60 µm on a rotating grinding plate (Stuers, Ballerup, Denmark), and subsequently stained with Azur II and Pararosaniline (Merck, Darmstadt, Germany), which allowed for a differentiation between graft granules, pre-existing and newly formed bone. Imaging was performed with an Axio Imager M1 microscope equipped with a digital AxioCam HRC (Carl Zeiss, Göttingen, Germany). Histologically the analyzed biopsy contained newly-formed bone, residual grafting material, and vascularized uninfamed connective tissue. No necrosis or foreign body reactions were detected. The graft particles were surrounded and in contact with trabecular bone, while active osteoblasts forming osteoid could be identified, demonstrating persistent osteogenesis (Figs. 18 to 20).

After three months, the healing was uneventful (Figs. 21 and 22) and a small



21 | Clinical view three months after implant placement.



22 | Periapical x-ray three months after implant placement.

crestal incision was utilized to expose the implant and a healing abutment placed. The patient had to travel and came back three months later for the restoration of the implant. At this point of time, clinical examination revealed that the ridge was adequately reconstructed, with increased bulk and thickening of the keratinized soft tissues (Fig. 23). The secondary stability of the implant was measured by resonance frequency analysis (Penguin^{RFA}, Integration Diagnostics Sweden AB, Göteborg, Sweden). An ISQ (Implant Stability Quotient) value of 75 was recorded, demonstrating high stability (Fig. 24). An open-tray impression was taken and the final screw-retained crown was fitted and torqued at 35 Ncm, resulting in a successful outcome, regarding aesthetics and function (Figs. 25 and 26).

Discussion

The atrophic changes of the alveolar ridge that are triggered by tooth extraction are extensively documented in animal and human studies, describing that horizontal bone loss of 29 to 63 per cent and vertical bone loss of 11 to 22 per cent can be observed during the first six months after tooth removal [3,4]. Grafting the post-extraction sockets at the time of tooth extraction with a bone grafting material constitutes a predictable and reliable way to limit the resorption of the alveolar ridge. Such alveolar ridge preservation measures involve the use of a wide variety of bone grafts, barrier membranes and biologically active

materials, and many different surgical techniques and protocols have been proposed [5,6]. When placing a grafting material into a socket immediately after extraction, a clinical decision has to be made as to whether the site will heal under secondary intention or a flap will be raised and advanced to cover the grafted socket. The clinician has to decide which approach is preferable. The first approach involves the risk of the biomaterial being washed out in the oral environment, while the second method may lead to distortion of the vestibule and the coronal displacement of the buccal keratinized gingivae. This iatrogenic loss of the buccal keratinized soft tissues will alter the soft tissue profile of the site and may influence in a negative way the health status of the supporting tissues around the dental implants [7].

For the above-mentioned reasons, in the presented case an immediate-delayed socket grafting was performed and the socket was filled with the biomaterial not immediately after the extraction, but six weeks later. Although an additional clinical step was added in the overall treatment, it is of great clinical importance that the six-week healing period after the extraction enabled the production of adequate newly formed keratinized tissues, achieving tension-free primary closure and protection of the socket graft throughout the healing and regeneration phases. Moreover, as the graft was not placed immediately into the socket, the risk of an infection and graft loss may be decreased.

In a recent systematic review of randomized controlled clinical trials analyzing the outcomes of flapless socket grafting, *Jambhekar et al.* [8] reported that after a minimum healing period of twelve weeks, sockets filled with synthetic biomaterials had the maximum amount of vital bone (45.53%) and the least amount of remnant graft material (13.67%) compared to xenografts and allografts. The histological findings of the present case are in accordance with the above findings as pronounced regeneration of vital bone and small amounts of dissolving graft particles were observed four months after the socket grafting procedure.

In the presented case, a synthetic fully resorbable grafting material (EthOss) consisting of β -TCP (65%) and CS (35%) was used in order to preserve the alveolar ridge and enhance the regeneration of high quality vital bone, as shown in preclinical and clinical studies published by the authors [9–15]. The bioactive β -TCP element, apart from being osteoconductive, shows an osteoinductive potential which might further improve host regeneration of bone in the healing process [16–18]. The CS element is bacteriostatic and produces an in situ self-hardening grafting material that doesn't need additional stabilization with the use of collagen membranes or other meshes. In this way, the CS acts as an "integrated barrier membrane", halting the ingrowth of soft tissue during the early phases of bone regeneration. Both CS and β -TCP are fully resorbable bone



23 | Maturation of the soft tissues. Note the zone of thick keratinized soft tissues that have been regenerated by the host to cover the reconstructed high quality bone around the implant.



24 | ISQ measurement revealing high secondary stability of the implant.



25 | Final result.



26 | Periapical x-ray after fitting the screw-retained implant crown. The grafting material is turning over, being replaced by the regenerated bone.

substitutes, leading to the fast regeneration of vital host bone without the long-term presence of residual graft particles. The CS element will resorb over a three-to-six-week period, thus creating a vascular porosity in the β -TCP scaffold for improved vascular ingrowth and angiogenesis, while the β -TCP element resorbs by hydrolysis and enzymatic and phagocytic processes, usually over a period of 9 to 16 months.

In the presented case, the self-hardening bioactive β -TCP/CS bone graft was covered only with the mucoperiosteal flap. Periosteum has an immense osteogenetic potential and plays a pivotal

role in bone graft incorporation, healing and remodeling, as it contains multipotent mesenchymal stem cells that are capable of differentiating into bone and cartilage, and provides a source of blood vessels and growth factors [19,20].

Conclusion

A modified immediate-delayed socket grafting approach using a bioactive self-hardening fully resorbable synthetic grafting material resulted in successful clinical, radiological and histological results. The spontaneous soft tissue healing after the extraction, and the thick keratinized soft tissues that the host

regenerated to cover the reconstructed high quality bone around the implant were key factors for the success of the presented treatment modality. ■

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

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International Dental Show in Cologne

IDS 2019: Voices from the industry

Once again, the International Dental Show in Cologne proved to be an absolute crowd-puller and lived up to its reputation as the world's leading trade fair for the dental sector. Over 160,000 visitors from 166 countries flocked to Cologne, 73 per cent of them coming from abroad. The EDI Journal asked exhibitors specialized in dental implantology about their impressions and their personal bottom line. Their statements reveal a huge satisfaction from all sides.

The 2019 edition of the International Dental Show was a historic moment for Anthogyr, as we had the pleasure of announcing that we are joining the Straumann Group. This news has been really positively received by our customers and we have been very warmly welcomed by the Straumann Group team. Our most important product launch was the presentation of AxIN, a major innovation in single restorations. AxIN is a customized screw-retained zirconia tooth with a built-in screw, featuring 0° to 25° angulated access with a 2 mm diameter narrow



channel. The fact that it functions without glue or sealing cement sparked a lot of interest. As to our overall impression of this year's IDS, we found that it was a great event and we had the opportunity to meet a huge number of people. The change of hall this year and the announcement of our integration into the Straumann Group brought us a lot of additional visibility at the fair. We also took advantage of this IDS to present our latest Anthogyr film.

www.anthogyr.com

Bego Implant Systems is on the right track! The months of planning and development have paid off: our new products inspire our customers worldwide. In our spacious lounge, we were able to present our company and our products in peace and quiet and, despite the lively atmosphere, had concentrated discussions with customers and interested parties from all over the world. Our exhibition stand, including the Carrera racetrack as an entertaining sidekick, gave visitors the opportunity to take



a breather from the exhausting everyday work at the fair. We were able to inform our partners from the media world about innovations and the future of our company at more than well attended press conferences. Our conclusion of IDS 2019: It was successful, exciting and inspiring! And that is why we say, "Thank you, stay healthy and see you in 2021 in Cologne!"

www.bego.com



Photo: Koelnmesse GmbH, IDS, Thomas Klerx

At this year's IDS, we presented a new therapeutic alternative for the rehabilitation of the atrophic jaw, the new line of BTI implants 3.0. It is a minimally invasive option for the rehabilitation of narrow ridges, especially in case of total or partial edentulism. The line has a prosthodontic platform and body diameter of 3 mm and is available in different lengths. Its main advantages are less surgical intervention, shorter treatment time and better acceptance by the patients. The visitors at our booth acknowledged the new implant line with great interest and very positively. Altogether, we found that

the whole exhibition enjoyed strong popularity and we were happy to welcome plenty of guests at the BTI booth. The public was also very interested in our Endoret (PRGF) technology and our prosthetic solutions related to digital workflow. IDS 2019 has also been an opportunity to talk to dentists personally and to identify their current needs in a direct way. Thus, the event turned into a perfect tool to evaluate the situation of the market.

www.bti-biotechnologyinstitute.com



At IDS 2019, Camlog announced the launch of the Progressive-Line implant and offered dental professionals the opportunity to test it right away with the established Conelog connection. The feedback for the new implant line, which has been geared to high primary stability and to facilitate modern treatment concepts, was thoroughly positive by those who experienced the Progressive-Line firsthand. Testers realized the "exceptional grip and stability" as the product's clear benefits, which

underlines results both from in-vitro studies and practical clinical use in the prelaunch phase with more than 1000 implants. The Progressive-Line will be available with the popular Camlog and Conelog connection. We are very pleased to confirm that the IDS 2019 was a great success for us and that our innovative products were very well received by the visitors.

www.camlog.com



We are very satisfied with this year's IDS. Our company presented significant innovations in the field of implant dentistry and ceramic materials: Under the slogan "It's my choice", we introduced our worldwide unique tiologic Twinfit implant system with its revolutionary abutment switch that allows for the restoration of two prosthetic connection geometries – conical and platform – on a single implant. Excellent additions: the high-strength ceraMotion LiSi lithium disilicate ceramic for pressing and the



new ceraMotion One Touch finalization pastes Pink and No Limits for characterizing all-ceramic monolithic restorations made of zirconia and lithium disilicate. During our „ceraMotion meets tiologic Twinfit“ Come-together Lounge, our new products were thoroughly inspected and discussed by our many visitors. We are very pleased to say that we achieved the goals that we had set ourselves for this IDS.

www.dentaurum.de



The expectations were high for the European market launch of Acuris conometric concept. The solution had already proven to be a real-game changer in redefining retention of the crown on an implant-supported abutment in other markets.

"When a true innovative solution or product hits the market, it is very exciting to meet the clinicians and technicians, to see their expectations and how it will fit their clinic and patients," said a Dentsply Sirona Implants senior product trainer and specialist. "The best way to understand an in-

novative new concept is to try it. I saw this happen, how fast and easy the dental professionals learned the new concept because it really is as easy as it sounds." Over 100 people attended the workshop on this innovative conometric concept that uses friction instead of screws or cement to place the crown in seconds rather than minutes with a unique Fixation Tool.

Acuris is available for Astra Tech Implant System, Ankylos and Xive and is part of the comprehensive portfolio from Dentsply Sirona Implants.

www.dentsplysirona.com

Once again, IDS proved to be an invaluable date in the diary for our team here at EthOss Regeneration, giving us the chance to meet with our existing partners, make new connections and celebrate our company's rapid success story which has seen us enjoy fast, international growth since attending IDS in 2017. We signed three new agreements at the event, with distributors in Spain, Israel and Columbia, taking our international presence to more than



35 markets worldwide. It was great to return to the show this year and to demonstrate our strong position in the market and plans for future growth, too, as more customers realise the advantages of using modern synthetics during the bone grafting process, for both practitioners and patients alike.

www.ethoss.dental

We from mectron, the Italian based inventor and producer of the original Piezosurgery, celebrated our "40 years anniversary" at this year's IDS. With typical Italian pasta, Espresso and other specialties, the huge number of worldwide customers were welcomed at the booth, dominated by large picture of the Ligurian coast, the home of mectron. For the first time, we also presented our prophylaxis



product range in a dedicated prophylaxis corner. Many visitors, especially dental assistances, tested our air-polishing and ultrasound units and were impressed by the gentle scaling thanks to the unique soft mode. The overall result, never achieved before, confirmed that – after 40 years – mectron is still a technological market leader.

www.mectron.com

After five exciting and intensive days at the fair, we can offer a very positive summary. The IDS again proved to be one of the most important international trade fairs and an excellent platform for networking in the dental sector. This year, we had even more national and international visitors than before.

Our focus was on the titanium base ASC Flex for angled screw channel as well as the new abutment connections especially for the Asian market. The completion of our Procone portfolio and our one-

piece implant Minicone also attracted numerous visitors to our booth. With our 360° Virtual Reality movie, we were able to give visitors a first impression of our production facilities. Our multi-media table was very well received, too: Visitors and clients were delighted to get information in form of videos, PDFs and 3D pictures at the same time in a modern way.

www.medentika.com



Integrated workflows set the pace at this year's IDS and this was reflected both in our booth concept and in our IDS highlights. "More independence for the dentist" – that's the motto according to which medentis medical has designed its innovations. These include ICX-Royal, a complete system for implant-supported dental prostheses that makes life much easier for dental laboratories, and ICX-Independent, a five-axis milling machine from a

German manufacturer with which standard abutments from the catalogue are shipped to the lab at the click of a mouse. Magellan-X, a cloud-based implant software that is managed via an app, aroused great enthusiasm among many visitors, as did the hourly life surgeries which were displayed on a giant screen at our booth.

www.medentis.de



The International Dental Show in Cologne remains the true global platform for us to show innovation, as well as meet customers and partners from all around the world. This year's show was no different as we introduced the "Mucointegration era" to implant dentistry with the reveal of our new surfaces Xeal and TiUltra. Another milestone was clearly the presentation of DTX Studio suite; a single digital

platform that empowers the entire treatment team to seamlessly connect workflows. The feedback from the market to these innovations was exceptional and we are looking forward to unveiling even more at our own symposium in Madrid at the end of June.

www.nobelbiocare.com



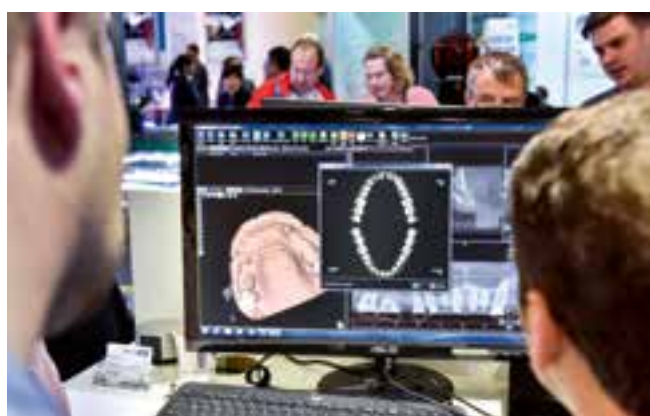
One of the highlights for MIS at this year's IDS was the reveal of the Connect system, a one-time abutment, which enables a prosthetic procedure at any level of the connective tissue. Dr Norre of Belgium gave a few short talks about the Connect and its advantages which attracted many visitors. Our team also enjoyed showcasing their best-selling Seven implant system, as well as the V3, C1 and the MGuide system. The crowds of doctors who visited the booth were excited to learn about the products and engaged with our team who were

happy to present and explain the advantages of each one. Last but not least, the colorful and musical announcement for the next Global Conference, planned for May 2020 in Marrakech, Morocco, was a highlight at our booth. Everyone enjoyed a wonderful show of drumming and belly dancing and got a sneak peek into what's planned for the big scientific conference, awaiting them next year.

www.mis-implants.com







Meeting clinicians and partners from all over the world in Cologne in March confirmed the need for a tool to support clinical decisions with objective data. These discussions perfectly fit with Osstell's evidence-based approach, providing technology supported by over 1,000 studies and the possibility for Osstell users to provide their patients with an evidence-based treatment to optimize time to teeth. The launch of the Osstell IDx Pro at the IDS was very



well received. Osstell Connect – the exclusive online service accessible to all Osstell users – safekeeping Osstell ISQ data and providing relevant key insights allowing clinicians to enhance their implant treatment performance, based on more than 150,000 implant stability measurements – sparked visitor's deep interest, as actionable insights enable “factfulness” about the osseointegration of an implant.

www.osstell.com

IDS 2019 was a turning point for Osstem Implant as we were not only able to present our broad range of implant-related products but we also introduced our company as a digital leader. Our visitors were surprised by our full line-up of digital dentistry equipment, including CBCT, milling machines and 3D printers. The consecutive live lectures supported by real clinical cases using this equipment convinced the audience of the excellence of our products. Our team wel-



comed 13,000 visitors at our booth – 30 per cent more than at the previous IDS – and a quarter of them had in-depth consultations with our staff. It was our special pleasure to give them an enjoyable memory of the IDS with various events including Korean traditional games and lucky draws. Overall, it was a very successful event and we would like to thank all visitors for joining us and showing such great interest.

www.osstem.de

This year's IDS was a big step forward for us – we had significant new products to introduce in all key categories. We are happy to now offer the most comprehensive overall solution for digital dentistry available. At the center of it all is our all-in-one software Planmeca Romexis. The new version 6 of the software elevates usability to a whole new level and truly makes your work flow in every way. To showcase the actual benefits of our full product offering,



we had gathered a great group of expert speakers to give presentations at our IDS stand throughout the week. This was met with much excitement, as the speakers' enthusiasm for digital dentistry was simply contagious and their insight inspirational. We are already looking forward to the next IDS in 2021 – the year Planmeca will celebrate its 50th anniversary.

www.planmeca.com

On more than 1,000 m², the different brands of the Straumann Group presented over 50 launches and innovations – motto: #ChangeEstheticDentistry. At the heart of the Straumann presence was the stunning “Arena of Confidence” which served for customer hospitality and presentations. On each day of the IDS, it hosted several live-streamed expert lectures on hot topics such as artificial intelligence, implant immediacy, ceramic implants and full-



arch rehabilitation, intraoral scanners, 3D printing, clear aligners, and next-generation dentistry. Launch highlight was undoubtedly the Straumann BLX Implant System, a new portfolio for immediacy protocols. Customer feedback on the event was overwhelmingly positive, reflected also in the fact that the demand for direct purchases of Straumann products was higher than ever before at a trade fair.

www.straumann.com

TBR has specialized in the design, manufacture and marketing of unique dental solutions for over 30 years. This year, IDS focused on the latest generations of CAD-CAM technologies in dental offices and laboratories: a great opportunity for us to present our high-quality products. The unique Z1 tissue level implant with zirconia collar, which incorporates soft tissue management, delivers unequalled clinical results while facilitating surgical and prosthetic procedures. A game-changing technology à la française! In addition to the possibilities of-

fered by the Z1 implant, CAD/CAM prosthetic restorations, combined with radiological and surgical planning, are streamlined by planning kits and open libraries, providing high levels of accuracy. The philosophy of TBR is clear: sharing the same ambitions with dentists to offer patients the best possible functional and aesthetic restorations.

www.tbr-implants.com



At IDS 2019, TRI presented various digital innovations. The remarkable highlight was the introduction of the world's first digital implant with a completely new connection called matrix. With the TRI Digital Implant and the matrix connection, it will be possible to place the 3D-printed or CAD/CAM milled prosthesis directly on the implant without using an abutment. This revolutionary concept was definitely the main attraction for visitors at the TRI stand.

The IDS is always an important trade show for us and we were again able to inspire many visitors with our innovations, enabling us to create new and interesting contacts as well as connections. And we were really overwhelmed by the positive feedback on the TRI Digital Implant.

www.tri.swiss



IDS 2019 – a great success for W&H! Our entire trade fair appearance was intended to present W&H as a solution provider. Our “Solutions for Dental Professionals” make the work of dentists more interconnected, easier and safer. Our latest innovation – Smart Solutions – attracted a great deal of attention. Smart Solutions help to optimize workflows in the dental practice. Our new ioDent system, the smart W&H solution for efficient treatment management turned out to be a special IDS highlight.

Our new fair booth, with its completely new look and feel with a lucid and inviting design, also provided a further “wow” experience. The new corporate design helped to make all of our product innovations tangible for our visitors and their lively interest showed that W&H occupies an important place on the map of innovations.

www.wh.com



The International Dental Show, the leading global dental trade fair, attracted an amazing number of visitors from all over the world – and we have the impression that many of them were also present at our booth! Very important for us was the successful launch of the GenTek Genuine Dental Restorations and Open Digital Workflow, a cooperation of Zimmer Biomet Dental and Zfx. These innovations offer a new portfolio of digital restorative components with genuine connections for Zimmer Biomet implants and are now available in Spain, Portugal,

France, Italy, and Germany. At our booth, we also presented several Digital Workflow Stations with live performances of renowned speakers demonstrating the iTero IOS Scanners. They were supported by Zimmer Biomet dental Digital Specialists and Zfx CAD/CAM Specialists who also trained and instructed the many interested visitors and customers.

www.zimmerbiometdental.com



The Box app launched in Barcelona

Augmented reality = augmented possibilities

The motto of the Osteology Foundation is “Linking Science with Practice in Regeneration“. However, the Foundation not only regards itself as a specialist in the field of regeneration, but also as a pioneer in the application of state-of-the-art technology to promote theoretical and practical knowledge. Latest proof: the launch of an app that provides access to the Foundation’s knowledge platform – The Box – from mobile devices, and works with a new feature. At this year’s International Osteology Symposium in Barcelona, the EDI Journal spoke with Basil Gürber, Communications Coordinator of the Osteology Foundation, about the latest achievement.



Basil Gürber,
Communications
Coordinator of the
Osteology

The Osteology Foundation has launched the new The Box app in Barcelona. Can you briefly explain what is so special about this app?

Gladly! We have different functionalities: a news feed function, a symposium function where you can browse the programme and ask the speakers individual questions, and our “special gimmick”, the AR Interface. AR means augmented reality. This is how we want to bridge the gap between offline content and online content. The app scans an image in the “real” offline world, and once you have scanned it, additional content is displayed on your mobile phone. That might be a video, pictures, or a 3D object connected with a link where you receive further information on the topic, or other options.

How does this work in concrete terms? What tools do you need and what’s in it for the user?

It’s very simple: You only need an appropriate picture and The Box app. You scan the image with the app and you will immediately see the same image on your screen, but with a video in the background that conveys any kind of additional information.

Wanna try?

1. Download the app free of cost from Google Play store for Android or App Store for iOS. Just search for Osteology Foundation – The Box.
2. Open the app, log in, choose the AR icon and scan the picture to the right.
3. Enjoy your AR experience!



The Osteology Foundation focuses on scientific research and advanced training. To what extent can AR as a tool contribute to that objective?

There are various possibilities, both in theoretical and in practical training. For example, in a brochure or book that you want to use to communicate knowledge, you can link a picture to an image gallery which appears when you scan the picture with the app. This means that the printed work offers an infinite number of further content in addition to the existing text. There are also fantastic possibilities in practice, and some of them are already being used today. A great example: During a treatment, a mentor gives instructions to his trainee over a long distance. The trainee wears AR glasses and sees the instructions of his mentor live on the glasses and can thus implement them directly on the patient.

Do you see other advantages of AR applications?

In addition to the possibilities in the field of online education, which I have just described, there is also a lot to be said for AR in the offline world: You can enhance or complement textbooks, some of which already seem somewhat “dusty” today, with additional content and thus offer added value for the user. Furthermore, it guarantees that contents are always cutting-edge, since they can be updated and adapted at any time: If the information “behind” an image is no longer up to date, the content can be upgraded in the background without the reader holding the book in his hands having to buy a new edition.

Thank you very much, Mr Gürber, for the the fascinating insights and outlook.

MT ■

AxIN®

CUSTOMISED SCREW-RETAINED TOOTH

INNOVATION

Choose your new restoration

To respect the anatomy of the natural tooth, Anthogyr has created **AxIN®**. This **Simeda®** zirconia customised screw-retained tooth requires neither adhesive nor sealing cement. Take advantage of its free Angulated Access from 0° to 25° and of its straight \varnothing 2 mm channel to optimise the prosthetic design. A smart way to preserve the incisal edges and constraint areas. Whether you are a practitioner or a prosthetist, choose aesthetic results and biological safety of your single-unit restorations regardless of the sector.

AxIN®
A **Simeda®** solution



Osstem World Meeting in Tokyo, Japan

The answer is: digital!

Osstem Implant has successfully finished its 2019 Osstem World Meeting on 11 and 12 May in Tokyo, Japan. 1,200 dentists from 35 countries flew all the way to Tokyo to participate in the 12th meeting of its kind that took place under the motto “Digital Leader Osstem Implant”. The whole symposium was live-broadcasted through its own online platform Denple in four languages – English, Russian, Japanese and Chinese –, enabling the event to be followed by 40,000 dentists all over the world.

On day one, four hands-on workshops were conducted with a focus on topics ranging from digital guided surgery to crestal approach sinus augmentation to guided bone regeneration (GBR). Pre-registered participants took the opportunity to learn the best possible solutions on each topic using Osstem’s special and easy-to-use surgical kits together with valuable clinical experiences shared by four globally renowned lecturers. As a special feature, all the hands-on materials used during the workshops originate from Osstem Implant itself.

The symposium day was divided into four sessions with six lectures and two live surgeries. The first session was started by *Professor Changjoo Park*, South Korea, who introduced digital guided sinus surgery with Osstem OneCAS Kit. *Professor Park* was followed by *Dr Patrick Wu*, Hongkong, who gave a lecture about immediacy protocols titled “Moving towards the immediate loading using full digital workflow”.

In the second session, *Dr Torii Akimaro*, Japan, conducted a live surgery on a male patient in his fifties, suffering from hypertension. By applying intravenous sedation and digital guided sinus surgery using OneCAS Kit, *Dr Akimaro* successfully lifted the sinus membrane and placed implants on the sites 24 and 26 within limited time, amazing the audience.

The participants showed great interest in all lectures; the large lecture hall was always completely filled.



Dr Sooyoung Lee, Korea, opened the third session by giving a lecture on “Digital workflow for implant dentistry”, which drew a roadmap for those who are not yet familiar with digital procedures.

The third session was continued by a speech of *Dr Han Choi*, New Zealand, who introduced different approaches on “Complete arch implant placement and immediate loading using full digital workflow” with Pic Camera.

Session four concluded the attractive symposium with two lectures and a live surgery. The evidence-based presentation on “Management of soft and hard tissue for implants” by *Dr Fulvio Gatti*, Italy, and the fascinating speech by *Dr Marcus Lastimado*, USA, on “Enhancing full arch tilted implant therapy with OneGuide surgery” kept the attention of the audience until the end and lead over to the highlight of the day, a live surgery conducted by *Dr Kanayama Takeo*, Japan. *Dr Kanayama* conducted a guided surgery in a severely atrophied edentulous mandible of a female patient in her eighties, whose residual bone height above the inferior alveolar bone was less than 1 mm. With the help of OneGuide, he could successfully finish this difficult case.

A question & answer round at the end of every session offered the audience an opportunity to dig deeper into specific issues and to enter into a close dialogue with the speakers.

“It was very meaningful that we could globally introduce our excellencies in digital fields”, said *Tae-kwan Eom*, CEO of Osstem Implant Co. Ltd., adding that “the whole lectures will be available for re-watching on Denple (www.denple.com) as of June.”

The next Osstem World Meeting will be held in Istanbul, Turkey, in June 2020. ■

More information

www.osstem.de

Your Solution Provider,

OSSTEM IMPLANT



CAS KIT
Sinus Surgery



ESSET KIT
Narrow Ridge



OSS Builder
Bone Defect



ESR/EFR KIT
Post Failure

Thommen Medical workshop at the EAED Spring Meeting in Munich, Germany

Questions in daily work – and viable answers



The speakers of Thommen's EAED workshop (from left): Dr Christopher Köttgen, Professor Irena Sailer, Dr Ueli Grunder, and MDT Nicola Pietrobon.

On the occasion of the 33rd Spring Meeting of the European Academy of Esthetic Dentistry (EAED), which took place from 23 to 25 May 2019 in Munich, Thommen Medical as a Gold Sponsor came up with a very individual workshop format. In the classy ambience of the Grand Hotel Bayerischer Hof, the truly practice-oriented concept met with great response from an interested and actively participating audience.

No sophisticated PowerPoint presentation and none of the usual frontal lectures: In the precious atmosphere of the “princely” conference room, the speakers sat at eye level with the audience and discussions were held at exactly the same level. But before things could get started, a lot of chairs had to be brought in, as many more interested guests than expected flocked in continuously. Which in fact did not harm the atmosphere, but rather confirmed the familiar spirit of this special workshop.

The speakers, each as a representative of their own field, had gathered to find answers to questions that occur in the daily work of practitioners. *Professor Irena Sailer*, Head of the Division of Fixed Prosthodontics and Biomaterials at Clinic of Dental Medicine of the University of Geneva, Switzerland, represented the scientific side, while *Dr Christopher Köttgen*, implant dentist with a private practice in Mainz, Germany, and *Nicola Pietrobon*, Master Dental Technician from Zurich, Switzerland, acted as representatives of the practical side. *Dr Ueli Grunder*, well-known and experienced dentist from Zollikon, Switzerland, proved to be an adept moderator who, with only a few questions, sparked lively and sometimes controversial discussions between the speakers themselves as well as between the speakers and the audience.

The different views were already reflected in the answers to the first question: Is a monolithic full zirconia bridge on six or seven implants a sensible solution for a fully edentulous jaw? *Professor Sailer* pointed out that there was still no literature and only little practical experience with this kind of restorations. *Sailer* underlined that careful polishing

was essential to prevent damage on the opposite dentition. *Pietrobon* as a dental technician pointed out that there are no stress breakers in a monolithic zirconia bridge, which increases the risk of fractures considerably. Since chipping can also occur with metal ceramic, but is easier to repair, he still advocates the latter type of restoration. *Dr Köttgen* added that the cost factor plays a very important role, too, and that he usually takes decisions only after a personal consultation with the patient.

In the course of the following two hours, the controversial and productive discussions continued on other topics: experiences with the “One Abutment One Time” concept, principles of veneering, the reconstruction of lost contact points between crown and natural tooth or the choice of the suitable loading protocol. Particularly wide was the range of opinions on the subject of the digital workflow, which not only showed a visible generation gap, but also the sometimes opposing positions of dentists and dental technicians. In the end, *Dr Grunder* summed up the conclusion on digitalization in implant dentistry in one common denominator: “The development is not stoppable and the right time to get into digital is NOW, even if many dentists and technicians still ask for more user-friendliness.”

During the following “Apéro”, the discussions continued not only on a professional, but also on a private and familiar level. A straightforward workshop concept with real benefits for the practical work of every practicing dentist. IL ■

More information

www.thommenmedical.com

“High-class implantology – think global, act local”

More than 20 speakers and moderators from all over the world, 750 participants and a large number of industry representatives met in Bern at the last weekend of May to attend the farewell symposium in honour of Professor Daniel Buser.



Long-time companions (from left): Andrea Mombelli, Dean Morton, Daniel Buser, Urs Belser, David Cochrane, Mario Rocuzzo, German Gallucci, Hans-Peter Weber, and Urs Brägen.

The tightly packed and high-quality scientific lecture programme kept the audience spellbound from early in the morning until late in the afternoon. During the breaks, the visitors could feast on the culinary delicacies and satisfy their curiosity

about the latest trends and product developments in the industrial exhibition.

Needless to say that the top-class speakers seized the opportunity not only to present their own exciting clinical insights but also to highlight the extraordinary relevance of *Professor Buser's* life work. With his rare and very own combination of scientific and clinical expertise and didactic commitment, he significantly contributed to the excellent reputation that the Dental School of the University of Bern has acquired internationally during his 20 years as Head of the Clinic for Oral Surgery and Stomatology. As befits an occasion of this importance, the festive part was not neglected either. The scientific programme concluded with an aperitif and was followed by an evening programme that was a highlight in itself. 450 participants sat down at the festively set tables and enjoyed an delicious gala dinner. Many companions from teaching and research, former and current students and long-standing partners had prepared special and very personal praises and words of farewell that rounded off the banquet and turned the evening into a memorable and moving event. **MT** ■

Geneva welcomes you

With great pleasure, the University of Geneva would like to announce that the next Geneva Treatment Concept Basic Course, now running in the fifth year, will take place from 9 to 13 September 2019 in the University of Geneva brand new dental school.

This very popular course is aimed to international dental professionals who would like to be introduced to the fixed restorative treatment concept, starting from the noninvasive restorative philosophy over minimally invasive restorations to fixed reconstructions.

Besides theoretical lectures, case presentations and live demonstrations, the participants will have the opportunity to enhance their practical clinical skills in order to be able to apply the demonstrated types of treatment procedures to their patients.

The course will not only be highly educational both theoretically and practically, but also inspiring.

The Geneva Treatment Concept Team is very much looking forward to welcoming participants in Geneva and sharing with them the great location, outstanding quality sights and the many attractions Geneva has to offer in September 2019. ■

More information and registration
www.thegenevaconcept.org



Photo: allard1/stock.adobe.com

Interview with Professor Gil Alcoforado, Chair of the Scientific Committee of the EAO Annual Scientific Meeting 2019

Welcome to Lisbon!

The European Association for Osseointegration (EAO) has elected Lisbon, the charming capital of Portugal, as the venue of its 28th Annual Scientific Meeting, taking place from 26 to 28 September 2019.

The EAO congress is a truly global event, and the Scientific Committee is delighted to welcome Brazil as this year's invited country. Matching the landmark of the city, the impressive Ponte 25 de Abril, a suspension bridge spanning the river Tagus, the motto is building a "Bridge to the future" of implant dentistry.

Professor Gil Alcoforado, Secretary General of the EAO Board of Directors and Chair of the Scientific Committee, proudly presents the event that will take place in his home country.



Professor
Gil Alcoforado

The upcoming EAO will take place in beautiful Lisbon. What else can one expect of the EAO programme?

The presidency of a meeting of this kind has to follow guidelines common to all annual congresses of our association. We try to have new themes debated as well as new speakers on stage. One of the rules says not to repeat speakers from one year to another. There are always exceptions, but we try to make them as infrequent as possible, and when it happens, there must be a strong reason. From then on, the responsibility of building the scientific programme resides in the person of the President of the Congress, assisted by the Vice President and by all members of the Scientific Committee specifically designated for this congress by the President.

When I set out to do this task, which seemed initially unsurmountable, I decided to ask myself what problems I would like to be solved by "experts",

problems that arise on a normal day to day basis in an oral implant clinic. This is how I began to envision the scientific programme on the very same day Lisbon and Portugal were designated as the venue for this congress, two and a half years ago.

We will have plenary sessions, three in total, and 16 parallel sessions, running on Thursday afternoon and full-day on Friday and Saturday. In addition to these sessions, we will also have an oral communication session, previously scrutinized by a jury, and poster presentation sessions. Here we will have to consider that it is a strong appanage of EAO to choose all these sessions freely without any interference from our sponsors.

However, in order to meet the aspirations of these same sponsors, who help to make this event possible, sessions "sponsored" by the companies are held at lunch time and after the main programme. These

sessions always attract a lot of people since the sponsors always bring in top speakers, thus making the entire scientific programme of the congress even more appealing.

We have high-class speakers from 20 different countries, and we are expecting attendees from 80 to 90 countries. This diversity is becoming very usual in EAO Annual Congresses and gives our events a very special and different flair and atmosphere.

Are there any special highlights that you would recommend?

The main sessions always feature very renowned speakers and very enticing subjects. The first one at the opening of the congress on Thursday is called “New avenues in implant dentistry” where both stem cells and the future of bone regeneration are discussed. The second main session will present three different methods to overcome the fact of a non-existing buccal plate after an extraction before placing an implant, which is a very common situation, especially in the aesthetic area.

Since Brazil is the official “invited country”, we will have a session set up by “Brazilian speakers and friends”. We should note that all lectures will be given in English, including those which are organized by the Portuguese associations, which include SPEMD, SPPI, SOPIO and SPERO.

Parallel to these sessions, we have organized a special session called “My first implant” which is dedicated to young dentists who want to start getting into the field of oral implantology. We will also be offering a course for dental assistants where they will be able to learn about how to prepare a surgical room for implant therapy, how to prepare the implant patient and the implant instrumentation and post-op recommendations.

I think we have assembled a very special blend of subjects and speakers to ensure a very successful meeting and I am very much looking forward to welcoming our visitors in Lisbon.

Thank you very much for your time and the interview, Professor Alcoforado. ■

20/20 Vision – Global Symposium in 2020

The Oral Reconstruction Foundation is pleased to announce the theme and venue for the 2020 Oral Reconstruction Global Symposium. With a world-renowned lineup of speakers from all dental disciplines, the Symposium themed “20/20 Vision” will cover a wide range of contemporary issues in implant dentistry and tissue regeneration. The Symposium will take place from 30 April to 2 May 2020 at the iconic New York Marriott Marquis Hotel in New York City.

A joint European-American scientific committee consisting of well-known experts such as *Dr Edward P. Allen, Professor Fernando Guerra, Dr Craig Misch, Dr Myron Nevins, Professor Robert Sader, and Professor Irena Sailer*, will head the Oral Reconstruction Global Symposium 2020.

A diverse programme

A multitude of breakout sessions and hands-on exercises on topics such as digital workflow, immediate full-arch treatment, L-PRF applications, hard and soft tissue grafting, immediate placement and temporization, prevention and management of peri-implant diseases, business practices, and many more are planned. The Symposium will include lectures on extraction site management, tissue

regeneration, digital workflow, long-term sustainability, and experts’ discussions of challenging cases.

The Global Symposium offers a great opportunity to stay abreast of the latest treatment options while enjoying time with colleagues in the heart of Times Square.

Attendance will be limited to maintain an environment conducive to learning. Early registration is recommended. ■



■ **More information and registration**

www.orfoundation.org/globalsymposium

Straumann Group presents change-making innovations at the 38th IDS in Cologne

One for all

The Straumann Group comprises multiple brands and partners, which combine to provide total solutions in aesthetic dentistry across continents, customer groups and price segments. Most of the brands and partners were present at the IDS and in close proximity. Anthogyr, ClearCorrect, Dental Wings, Medentika and Neodent all had separate booths, while the largest exhibition stand was devoted to Straumann. Once again, Straumann used a huge truck to demonstrate its suite of digital solutions.

At the heart of the Straumann presence stood the “Arena of Confidence,” which served for customer hospitality and presentations. On each day of the IDS, it hosted several lectures given by experts and KOLs and streamed live on the internet. The topics ranged from Artificial Intelligence, implant immediacy, ceramic implants and full-arch rehabilitation, to intraoral scanners, 3D printing, clear aligners, and next generation dentistry. Highlight of Straumann’s presence at the IDS was the launch of BLX, an innovative implant line for immediacy protocols.

A game changer in implant dentistry

Several years ago, Straumann began working with world-leading experts with the goal of developing the most advanced fully-tapered implant system. BLX is the result. Its innovative design, combined with Straumann’s proven Roxolid and SLActive technologies, creates a unique next-generation implant system that brings a new level of confidence to implantology. Designed for immediacy, it is suitable for all treatment protocols – from immediate to conventional placement and loading – to suit the

In the impressive “Arena of Confidence”, Frank Hemm, Head of Marketing & Education, outlined the characteristics of Straumann’s new BLX implant line to the EDI Journal.



The new BLX implant line comes with a simplified but versatile portfolio, featuring one connection and under-contoured prosthetics. Moreover, the BLX concept relies on a mix of unique and totally new drills called VeloDrill.

dentist’s preference. BLX is designed to optimize primary stability in all bone classes, to simplify restorative workflows and to achieve predictable outcomes, even in complex cases. It is available in a full range of diameters and lengths, together with a simplified versatile prosthetic portfolio.

The full market release of BLX in Europe started at the IDS and was supported by a research and development programme that was initiated several years ago and includes a large non-interventional clinical programme to evaluate the implant’s performance in everyday clinical practice. Together with BLX, Straumann is launching an innovative drill concept, called Straumann VeloDrill. The main advantages are reduced heat generation, high drilling stability and time savings.

“The special haptic of the new BLX implant during insertion has proven to be a true USP”, said *Frank Hemm*, Head of Marketing & Education, to the EDI Journal after the official launch. “This has also convinced users of competing products who we included as testers during the clinical programme of the development phase.” Another impressive feature of the new BLX, according to *Hemm*, is the special thread design that cuts excess bone and redistributes it along with the implant, which leads to a high bone to implant contact and minimizes overcompression. “With the BLX, we are closing a gap in our implant product range and we have thus taken another big step towards our goal of serving the personal preferences of every single clinician and practitioner”, concluded *Hemm*. ■

[More information
www.straumann.com](http://www.straumann.com)

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That's
NEVER been
seen before!



ONE IMPLANT – TWO ABUTMENTS.

conical platform

Nobel Biocare Global Symposium Madrid, Spain

Reshaping implantology with a new implant solution

At its Global Symposium in Madrid, Nobel Biocare presents a new implant system designed to challenge conventional methods of dental implant care. Developed in collaboration with an international network of researchers from acclaimed international institutions, the new Nobel Biocare N1 system will feature not only a new biologically driven design, but also a unique site preparation method that was created with the goal to further reduce complexity and streamline workflows during implant and restorative procedures. Experience gained from clinical use of this new concept over the last 18 months has indicated it to be more efficient than currently used drilling protocols.

The new Nobel Biocare N1 system marks the next step in the latest wave of innovation coming from Nobel Biocare, which began with the introduction of the Xeal and TiUltra surfaces for abutments and implants at the International Dental Show in Cologne in Germany. Both surfaces will be also available on the new system, which is planned for release in CE markets in fall 2019. Dental professionals have the opportunity for a pre-launch experience with this step forward in implant dentistry at the Nobel Biocare Global Symposium in Madrid.

One of three global meetings to be held over the next three years, the symposium in Madrid hosts over 60 internationally acclaimed experts of whom several will, among other important advancements in implant dentistry, share their experience with the Nobel Biocare N1 system. From enhancing aesthetics and improving long-term clinical outcomes to implementing a fully integrated digital workflow, participants have plenty to learn and discover about how to bring their clinical skills to the next level. A number of special hands-on workshops further shows them how to best implement the latest dental solutions into their own practice.

Hans Geiselhöringer, President of Nobel Biocare, said: "Where others in the market attempt to imitate, we innovate. With the exclusive showing of the new Nobel Biocare N1 implant system at our Madrid symposium, Nobel Biocare is starting to prepare dental professionals for a new chapter in dental implant care. In Madrid, the future of implant dentistry will be revealed."

The Nobel Biocare Global Symposium in Madrid takes place at the Madrid Marriott Auditorium Hotel & Conference Center from 27 to 29 June. A full review of the event will be published in the next issue of the EDI Journal. ■

More information

nobelbiocare/global-symposia



Advanced training in Armenia and Algeria

The use of implants in tooth restoration is an increasingly popular topic worldwide. bredent medical, the German specialist for implant prosthetics and implant solutions, responds to this development by intensifying its commitment to train dentists in emerging regions of the world. Most recent examples: two very successful training courses in Armenia and Algeria.

The two courses were conducted by bredent in cooperation with the IFZI-Institut (Nuremberg, Germany) and its founder, *Professor Manfred Lang*, in Armenia's capital Yerevan and in Annaba, a town on the northeastern coast of Algeria. In Armenia, the three-day course took place in the newly opened Centre of Excellence in Dental Education of the Yerevan State Medical University (YSMU). The training centre has 24 phantom workstations and was officially inaugurated with this implant simulation course. In the future, implant phantom courses will be held there at regular intervals by certified IFZI trainers from Armenia and Georgia. In Algeria, the course was held in collaboration with Annaba University as part of the postgraduate Oral Implantology programme. The enthusiasm and commitment of the numerous participants are the best proof that bredent has hit the nerve of time with its advanced training initiative. ■



Professor Manfred Lang supports the participants very individually and in detail; on the left photo with participants from Algeria, on the right one during the course in Yerevan.

More information

www.bredent-medical.com
www.ifzi.de

Reinforcement of the TRI management team

TRI continues to expand and so does the management team. Since the beginning of June, Dr Stefan Hund took over the role of CEO at TRI. Former CEO and founder Tobias Richter is continuing his involvement as active Chairman of the Board.

Dr Stefan Hund brings extensive experience in top management strategy consulting to the dynamic TRI management team. After several years with PWC and *Arthur D. Little*, he joined the in-house strategy department of Hilti AG. He pursued his career in several strategic and operational management functions in Hilti's headquarter in Liechtenstein. *Dr Hund* holds a Master's Degree in Business Engineering from K.I.T. and a Ph. D. from Vienna University of Economics and Business, is an avid mountain climber, and enjoys experiencing the globe's cultural diversity after living in seven countries.

With reinforcement in this position, the company aims to further accelerate its growth. TRI is

already present in more than 50 countries worldwide and has just attracted a lot of attention with the launch of the groundbreaking innovation TRI Matrix – the world's first digital implant. With the combination of leadership and sales skills of *Dr Stefan Hund* paired with the existing expertise of the management team, TRI is ready for the next growth step towards "No. 1 digital implant company". ■



Dr Stefan Hund



Tobias Richter

More information

www.tri.swiss

Latest clinical results on osteoporotic patients

Good prospects for osteoporosis patients

According to the definition of the Consensus Conference 1993, osteoporosis is a systemic skeletal disease characterized by loss of bone mass and microarchitectural destruction of bone tissue with a consequent increase in bone fragility and tendency to fracture. Hence, osteoporosis tends to be considered as a contraindication for the insertion of dental implants as it may possibly lead to higher failure rates. A recently published long-term study comes to positive conclusions.

Dentsply Sirona Implants had already dedicated a lecture to the risk management of patients with osteoporosis at last year's Ankylos Congress in Berlin. Professor *Natasha Ihan Hren* from the University of Ljubljana, Slovenia, dealt with the topic in a detailed lecture. She concluded that osteoporosis is not per se a contraindication for oral implant therapy. However, there are prerequisites that should be strictly adhered to. She recommended, among other things, a prolonged time between placement of the implant and prosthodontic loading, and pointed out that not only the implant surface, but its overall characteristics were of crucial importance. In her conclusion, *Ihan Hren* also emphasized

that long-term studies were still inconsistent and that additional randomized controlled clinical trials were still needed.

In this context, a step forward has just been taken. The results of a recently published five-year study* indicate that patients with osteoporosis show similarly good results to a control group without osteoporosis. OsseoSpeed implants (Astra Tech Implant System) with the fluoride-modified, nano-structured OsseoSpeed surface were evaluated after up to five years and the patients in the osteoporotic group showed similarly good bone and soft tissue response to the healthy control group. In both groups, the mean marginal bone loss was only 0.09 mm overall. The patients in this study were diagnosed with osteoporosis but had not yet received medication against bone resorption (that is, bisphosphonates). The study concludes that female osteoporosis patients can be treated with dental implants and the clinical outcome is expected to be as good as for non-osteoporotic women.

Due to the gain in quality of life and the functional benefits of dental implants, these results can be considered very encouraging for osteoporosis patients. ■



"It is necessary to inform the osteoporotic patient about the risk of implant failure or MRONJ." Professor *Natasha Ihan Hren* at the Ankylos congress in Berlin.

*Temmerman A, Rasmusson L, Kübler A, Thor A, Merheb J, Quirynen M: A Prospective, Controlled, Multicenter Study to Evaluate the Clinical Outcome of Implant Treatment in Women with Osteoporosis/Osteopenia: 5-Year Results. *J Dent Res*. 2019 Jan;98(1):84-90. doi: 10.1177/0022034518798804. Epub 2018 Sep 11.

More information

www.dentsplysirona.com

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Click and you're done. That's what the final restoration is like with Acuris—our new conometric concept. Instead of cement and screws, it relies on friction retention to secure the crown onto the abutment. Just click once on the crown with our unique Fixation Tool, and that's it. Placement takes seconds rather than minutes and the procedure couldn't be easier.

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Acuris Conometric concept is available for Ankylos, Astra Tech Implant System and Xive.

[Retention redefined.](#)
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 **Dentsply
Sirona**
Implants

Interview with Dr Kyoo-Ok Choi, founder and chairman of Osstem Implant, Seoul, South Korea

On the way to the top

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 over 70 countries worldwide. But the company's ambitions go even further. At the IDS in Cologne, the EDI Journal had the opportunity to meet the founder and chairman of the company, Dr Kyoo-Ok Choi, and to ask him about the history and the future of his company.



Dr Kyoo-Ok Choi and
EDI Journal Project
Manager My To

Osstem Implant is the first dental implant company in Korea. How did you get into this business?

As a dentist myself, I always wanted to help other dentists to practice better and to manage their dental office more efficiently. My wish developed to the idea of founding a dental company, which can help more dentists with more solutions. Eventually, on 8 January 1997, Osstem Implant was born. My initial idea also became the philosophy of our company: "Provide the best value to customer and patient."

Since its foundation, Osstem has experienced an amazing growth. What are the main driving forces?

One reason for our success is that I am a dentist myself, so we know what dentists really need. Secondly, our continuous R&D investments widely contribute to our success. We have been investing more than 7 per cent of our annual sales on R&D since our foundation. Currently, we have more than 400 researchers, dedicated to the continuous improvement of our products as well as new product development. Last but not least, Osstem offers high-quality products with a great convenience at a reasonable price, which means that we provide every dentist easy access to high quality products.

Where are you now and where do you see the future of Osstem Implant in the international market?

We are ranked number 1 in the Asia-Pacific region and number 5 globally. At the same time, among the global Top 5 players, Osstem implant has been showing the highest growth rate with 16 per cent of CAGR for the last five years. This makes me confident that we will soon be the most influential company in the dental market.

What significance does the European market have for Osstem?

The European market has always been very significant for us, but at the same time, we have been

recognizing it as the most conservative and difficult market. Strategically, as an initial step of our globalization, we firstly targeted the Asian and the American market, where we now account for about 15 per cent and 5 per cent of market share respectively. In the meantime, since our first step here in Europe in 2006, our network has been steadily growing and we are now providing our products in 29 European countries with the help of our solid partners. Now we are planning to strengthen our activities in Europe, so you will see Osstem more often than ever.

How will you convince European users to choose the products of Osstem Implant?

With various solutions and an unbeatable quality-price ratio. We have a range of special surgical kits that other companies do not offer and which are very helpful for dental practitioners. These special kits can be an entry product for new customers. Secondly, as I mentioned before, our reasonable price will lower the entry barrier to our high quality products. Once practitioners experience our products, they will realize what I mean.

Osstem Implant is also very active in training and education. What is your vision for this field?

To secure long-term stability, implants should be well placed by properly trained dentists. That's why we founded the AIC Training Center in 2000, and we are proud of the fact that more than 65,000 dentists have already been trained with our programme. For the last three years, we have been working on a global implant course, called "Master Course", a 24-day lecture and hands-on course with extensive and exclusive material and various online content. It has been successfully launched in Korea last year and is now being applied globally from this year.

Thank you very much, Dr Choi, for your time and your insightful answers.

MT ■

Interview with Hans Geiselhöringer, President of Nobel Biocare Systems

A real game changer

Many companies use the leading dental trade fair IDS as an opportunity to announce groundbreaking news and developments. This year's show was no exception. Often, however, these announcements do not stand up to intensive scrutiny. The EDI Journal spoke with Hans Geiselhöringer, President of Nobel Biocare Systems, about what a real innovation is and the ambitions his company pursues.

Like many others, Nobel Biocare has promised to present revolutionary breakthroughs at this year's IDS. Has your company fulfilled the promise?

The new surface technology that we are introducing is a real breakthrough. The terms “revolutionary” or “groundbreaking” are often used quite carelessly in our industry, but the result of what we have developed together with leading researchers and in cooperation with over 20 universities is a real game changer.

Besides osseointegration, where we have achieved extremely excellent results, we now also focus on the mucosal area at the interface between implant and abutment. We call it the “Mucointegration era” and we have developed two special surfaces, TiUltra and Xeal, which specifically address the improvement and acceleration of tissue integration on all levels, from the abutment to the implant apex. Both surface chemistry and surface topography, made possible by our decade-long expertise in anodization technology, play an important role in this context.

The fact that these surfaces are golden does not mean that we intended to create a golden surface, it just turned out that this kind of anodization showed the best possible results when it comes to osteoconductivity and cell adhesion. This, of course, leads to aesthetics that are even better than what we expected when we started the project five years ago.

Are there any special shortcomings in the protocols that have prompted NB to devote itself once again to the subject of implant surfaces?

There are no shortcomings from that point of view. The success rates in dental implantology are extremely high, among the highest in all of human medicine, with proven protocols and experienced clinicians. The success rates are near 100 per cent, depending on which publication and time frame you look at.

The improvements we are addressing with the new surfaces are aimed at ensuring that even complex situations can be loaded in a shorter time and with the same success rates. Even patients in difficult situations can be treated more quickly because the new surfaces help the body to regenerate as quickly as possible and to produce a tight seal around the implant – the mucointegration in question – to prevent the penetration of bacteria or other contaminants. Every patient wants to leave the practice as quickly as possible with a temporary restoration and to be able to chew, laugh and talk again. This is what we try to achieve: a fundamental improvement of the clinical workflow – reducing treatment time and invasivity, while ensuring long-term maintenance.

After all, I believe that long-term maintenance will be moving into the focus more and more. This does not only include durable osseointegration and mucointegration, but also long-lasting aesthetics, which again require healthy mucosal and gingival conditions. The more implants we see, especially in younger patients, the more important it will be that the implant and the associated prosthetic restoration still perform optimal after 30 and 40 years. Our customers and their patients are in the center of everything we do here at Nobel Biocare



At the IDS 2019, Hans Geiselhöringer, President of Nobel Biocare Systems, answered the questions of the editorial team of EDI Journal.

and the prime motivation behind the new surfaces; we believe they represent a significant improvement over what is now referred to as established surfaces.

Nobel Biocare has designed a very extensive educational programme for the next three years. What can visitors particularly look forward to at the next Global Symposium?

Training and education have always been an important pillar of what we do at Nobel Biocare, but I think it's more important than ever. On the one hand, more and more young and less experienced dentists are placing implants because it has become the standard of care. On the other hand, the traditional treatment methods are constantly subject to so many changes and improvements that continuous training is simply indispensable. As a progressive and responsible company, we feel obliged not only to develop great innovations, but also to educate users accordingly. And we have a very clear concept: peer to peer. Our customers are trained by leading clinicians and practitioners, not by us as a manufacturer and dealer. We really value the fact that clinicians and practitioners who have had ex-

tensive experience with our innovations actually do the trainings and serve as speakers at our upcoming Global Symposia. Of course, visitors to the Madrid Global Symposium which will take place at the end of June can also be very excited and look forward to the introduction of our new Nobel Biocare N1 implant, which is designed to challenge conventional methods of dental implant care and will help more clinicians to provide implant restorations with immediate function and shorter time-to-teeth.

The new European Medical Device Regulation, which will come into force in 2020, is currently shaking up the entire dental industry. What is Nobel Biocare's position on this?

We welcome initiatives like the EU Medical Device Regulation in 2020 and are confident it will result in supporting manufacturers like Nobel Biocare which put huge emphasis on scientific documentation, validation of their products and the safety of patients.

Thank you very much for your time and the interesting interview, Mr Geiselhöringer. MT/IL ■

Interview with Professor Michael Gahlert und Dr Stefan Röhling DDS

Focus on ceramic implants

Today, many patients wish to be treated with restorations that are as metal-free as possible. As a result, ceramics are becoming increasingly popular as a dental material, even for implants. Professor Michael Gahlert, Munich, and Dr Stefan Röhling, Lörrach (both Germany), talked to EDI Journal Project Manager My To about the past, present and future of ceramic materials in implant dentistry.

Ceramic implants are becoming increasingly popular. What do studies reveal about their success?

Gahlert: Ceramic implants are a hot topic. Many manufacturers of titanium implants have recognized this development, and more and more universities and independent practices are doing research in this field. This creates more scientific evidence of ceramics as an implant material. On the occasion of the ITI Consensus Conference 2018 in Amsterdam, we prepared a consensus statement on one-piece ceramic implants. According to this consensus, the products tested proved to be reliable over an obser-

vation period of two years. At the annual meeting of the German Association of Oral Implantology (DGI) 2018, I presented the first preliminary results of our prospective long-term study of one-piece ceramic implants over five years [1]. With a survival rate of 97.5 per cent and a 97.2 per cent success rate, we are in a very good range overall. In the long-term study, we adopted the success criteria of *Buser et al.* The study involved the Klinikum Stuttgart, the Hannover Medical School and my private practice in Munich with *Professor Kniha* [2].

More and more manufacturers are entering the market. Where do you see the differences in the offered products?

Röhling: One difference is the availability of scientific and evidence-based data which are not offered for all available ceramic implants. Besides, the products differ in terms of material composition and manufacturing processes. This has an considerable influence on the stability of the material. The processing method of the surfaces is quite decisive. It cannot simply be transferred from titanium to ceramics. And the manufacturers differ in their quality standards. During the production of ceramic implants, the material must not be damaged. For me, as a user, it is important to know that the manufacturer's quality standards ensure a flawless production process.

What should be considered with regard to the surface of ceramic implants?

Röhling: The surface is one of the crucial factors for the implants to grow into the bone tissue. At present, the vast majority of implants has a micro-rough surface. But there are still differences between the manufacturers. That's why it is necessary to check existing study data on osseointegration and the surface of ceramic implants. These data allow to draw conclusions as to whether the product in question integrates as reliably as a titanium implant, the current gold standard.

There has been a substantial development of the production process. How do you judge the current risk of implant fracture, for example?

Röhling: In fact, a lot has improved in this respect. In our systematic review, we could show that the fracture rate for commercially available implants is currently 0.2 percent, which is very low. For example, this value corresponds to that of titanium implants over a period of five years. The risk of fracture has diminished significantly and will certainly no longer be an issue in clinical use with modern products.

What about two-piece implants?

Röhling: The development shows that companies are launching more and more products with a two-piece design. This clearly reflects the trend in implantology. But study data on two-piece implants are still sparse at the moment. This doesn't mean it wouldn't work. It just means that these products are new and are still being examined.

Are there any clinical indications where one-piece implants are preferable to two-piece implants?

Gahlert: Experienced implantologists know that one-piece implants can achieve fantastic results.

This is also due to the fact that the one-piece ceramic implant supports the soft tissue, which is a great advantage in the highly aesthetic area, especially in the case of implant placement with simultaneous bone or soft tissue augmentation. We have documented excellent results with transgingival one-piece implants over many years.

Is there a relationship between the incidence of peri-implantitis and the implant material?

Gahlert: We claim that in the future, peri-implantitis will no longer occur in ceramic implants. That's a bold statement, but clinical experience allows us to make it. It is an empirical value from our clinical experience. But we have also considered evidence-based scientific data by comparing peri-implantitis in titanium and ceramic implants in a trial.

Röhling: Periimplantitis is multifactorial. An important factor is the accumulation of biofilm, which depends on the surface and the material. This is where the difference between ceramic and titanium comes into play. According to our scientific findings to date, microrough ceramic surfaces show significantly less microbial biofilm accumulation than microrough titanium surfaces. Smooth surfaces showed the same results. In a recently published animal study, we were able to show that in cases of bone resorption caused by inflammatory processes, bone loss was significantly lower in ceramics compared to titanium. So these are two important points that could point towards clinical benefits.

Why do patients choose ceramic implants?

Gahlert: Many patients come explicitly to our practice for ceramic implants. They have had amalgam or gold removed and now ask for a ceramic restoration. Other patients have a proven titanium intolerance reaction and see a new perspective in the restoration with ceramic implants. Some prefer a tooth-coloured implant instead of a grey metal implant. These are clear reasons. For me, ceramic implants are meanwhile a sine qua non for the highly aesthetic region.

Röhling: This trend reflects the development that has been taking place in dentistry for many years: away from metals and towards metal-free reconstructions. Amalgam, for example, but also gold and metal crowns are disappearing; veneered metal-ceramic crowns are increasingly being replaced by all-ceramic restorations. This is an unstoppable trend that will soon include implants as well.

Thank you very much, Professor Gahlert and Dr Röhling, for your time and the insightful interview. ■



Professor Michael Gahlert



Dr Stefan Röhling DDS

Interview with Edgar Schönbächler, CEO Bien-Air Dental, Biel, Switzerland

“Technology is no end in itself”

For almost three generations, the developer and manufacturer of instruments for various applications in dental medicine has been in family hands. This year, the traditional Swiss company is celebrating its 60th anniversary. CEO Edgar Schönbächler talked to the EDI Journal about the company’s beginnings and its impressive path to becoming an internationally operating dental manufacturer.



Bien-Air CEO Edgar Schönbächler told the EDI Journal – among other things – how his company got its name.

Mr Schönbächler, Bien-Air is celebrating its 60th anniversary in 2019. How did the company start?

The beginnings of the company actually lie in the famous “garage”. One day, our company founder *David Mosimann* talked to a dentist friend of his who complained about the unreliability of his dental instruments. This was not only the initial spark for the technician *Mosimann* to find a remedy, but also the basis for the philosophy of the company that was founded soon after: to listen to users and act accordingly. *Mosimann* developed the first reliable turbine, which was one of the company’s bestsellers for about 50 years: the famous air-driven Gyro turbine. Looking for a name for his young company, *Mosimann* combined the good functionality of the device (“bien” is French for “well”) and the operating principle by air, which resulted in “Bien-Air”. That’s how the history of the company took its course!

How big is Bien-Air today and where do you see its strengths in today’s dental market?

Even after 60 years, we are still a family business, organized in a holding structure with two operational units: the “historical” dental business, and Bien-Air Surgery which has been existing for about 20 years and uses the same proven technology to manufacture instruments for other clinical applications, such as ENT surgery and aesthetic-plastic surgery.

Our company has more than 400 employees worldwide, working in our headquarters in Biel, Switzerland, or in one of our eight branches in the USA, Japan, China and the most important European countries. We plan to open a new branch in Brazil in 2019, as we have identified great potential there and want to offer our Brazilian customers even better service through local support.

In addition, there are about 90 service centers in countries where we have no branches but sell through local specialist dealers. These centers are

very important for us because the long service life of our equipment requires reliable service. In some cases, we see equipment that is older than 25 years and that the dentist wants repaired because he is so satisfied with it. Of course, we are very happy to provide this service because it is an important line of our business and it is a way of demonstrating our proximity to our customers.

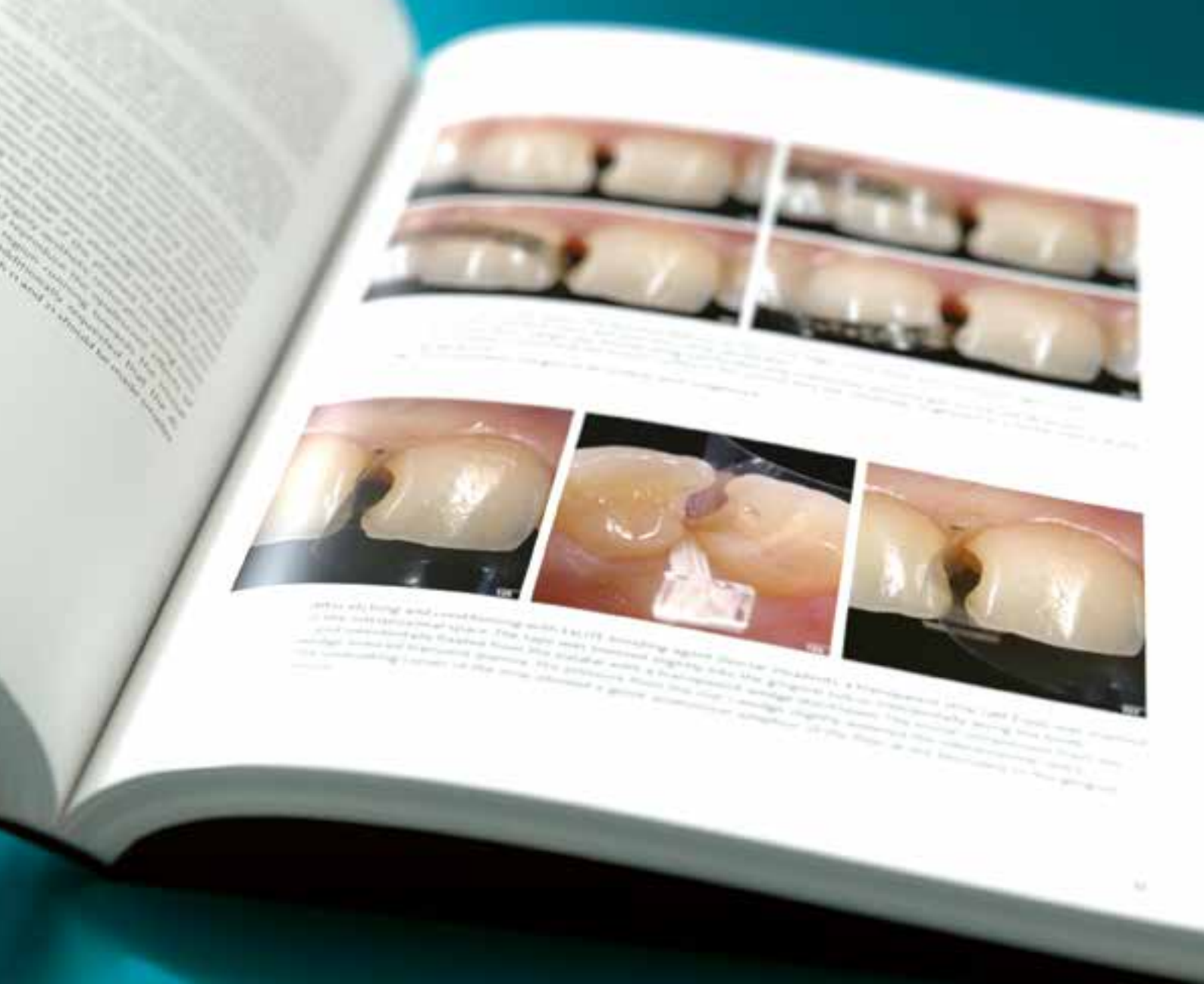
Bien-Air has developed some very innovative products in recent years. Can you tell us more?

We have always been working innovatively throughout our history. Recently, we have focused on the iChiropro, where we have launched something that never existed before: an iPad-based medical device. It’s a completely evolutive system, which is controlled by an app that can be downloaded free of charge from an App store. The user virtually receives a new instrument, a new motor, with every new version of the app. That means that our products are still based on our proven motor technology and handpieces, but now have a complete digital control system that allows them to integrate seamlessly into the digital workflow of today’s modern dental practices. Another advantage of the new iChiropro is the fact that it allows the practitioner to document and export the entire treatment process, and to communicate it to the patient, all of which are essential requirements today.

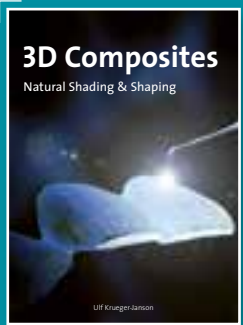
With this device we are certainly going in the right direction, but we are also not neglecting that we have been trying for 60 years to make the life of dentists as simple as possible. Technology is no end by itself. We don’t want to bring complications into the dental practice, we want to simplify the workflow with the help of technology. That is our philosophy, which we will continue to pursue.

Thank you very much for taking the time to talk to us, Mr Schönbächler.

MT ■



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Interview with Gene Dorff, Group Vice President Implants at Dentsply Sirona

“We are a customer-focused company”

At the beginning of 2019, Dentsply Sirona streamlined its business structure: The previous ten business units were reduced to two segments, Equipment & Consumables, which comprise four new Dental Product Groups responsible for the overall direction and strategy of Dentsply Sirona's products, including marketing, product management, R&D and clinical affairs. Gene Dorff, previously Group Vice President Restorative, is in charge of the new Implants division. At the IDS 2019, he gave the EDI Journal a summary of the insights he gained so far, and his vision for the future.



Enthusiastic about his new position: Gene Dorff, Group Vice President Implants at Dentsply Sirona, during the interview with EDI Journal Project Manager My To.

You have stepped into the big footsteps of Lars Henrikson. What can you say after your first months in office?

It's an honour to follow *Lars Henrikson*. I worked with him in the Dentsply Sirona management team for a number of years and I always enjoyed our cooperation.

In my first months in my new role as Group Vice President Implants, I had the opportunity to meet many of our employees and I found them to be very passionate, very excited about what they do. There is a real sense of purpose and meaning in the Implants division of Dentsply Sirona which I find very refreshing and very inspiring. I am also very excited to see that many of the things that we are doing as a company in the area of innovation, such as our new products Azeno and Acuris, are really working well. On top of that, I am building my team and my presence in Implants and that, too, is a lot of fun.

With Astra Tech Implant System and Atlantis, two main products of Dentsply Sirona are coming from Mölndal, Sweden. How important is the Mölndal location and how often will you be there?

When you think of Dentsply Sirona Implants, we are located in several places: We are headquartered in Mölndal, Sweden, and we have production sites in Mölndal, as well as in Hanau, Germany, Hasselt, Belgium, Waltham, USA, and Tokyo, Japan. And MIS, our value-price implant, is headquartered in Haifa, Israel. In fact, I am responsible for all these locations. As Dentsply Sirona is headquartered in the USA in Charlotte, North Carolina, I will be travelling a lot

between these locations but I will definitely spend plenty of time in Mölndal, which is our greatest Implants presence with the highest concentration of employees.

Dentsply Sirona is a very large corporation. Don't you think that smaller companies are much nearer to the patient and at the same time more flexible and more agile?

The answer to the first part of the question is no – I think being close to the market is not affected by the size. It's about your commitment and if you want to be close to the market. At Dentsply Sirona, it's part of our DNA to be in close contact to the clinician and to the market place.

I come from a sales and marketing background and when I first entered the dental industry 15 years ago, I needed to learn the business, so I built up a network of dentists with whom I spent many lunches and dinners so I could learn about dentistry and how dentists think.

When our CEO *Don Casey* joined the company, the very first thing he said was, “I don't hear the word ‘customer’ frequently enough in this company.” *Don* is a very charismatic person and he is truly engaging in the market place. So he is out there talking and working with clinicians very often. I would definitely say that we are a customer-focused company.

As to the second part of your question: you're right. The scale of a company does tend to create some challenges with speed. If you're a larger company, processes may be slower, but scale also ensures the quality of what you're doing. Of course there are many small companies that create great new products. Many companies are very fast and quick to move, but they also tend to fall behind when it comes to validating their products, under-

standing clinical needs, thinking about the sustainability of their products and live up to their value proposition. As a big company, we can do a great job at that. We have a huge network of clinicians that we can reach, markets we can go to ensure that if we create something, it is of truly high quality.

Azento is the first complete single-tooth replacement kit. Is this the first step towards a “kit solution” for many other indications?

It is a first step. As a company, we are becoming much more solution-focused; that means everything from putting products in a kit to integrating our software in digital solutions to thinking about how many of our other products might work together. Solution does not mean it has to be in a box, it does mean things need to work together in a complementary fashion.

We started with the single tooth restoration because it represents 80 per cent of all tooth replacements, but what we really intend to create is a workflow solution. When you go for larger indications, the part of the lab becomes more important. That means that the connectivity between the different partners, the collaboration and communication in the implant treatment team needs to be smooth and trouble-free. That is not an easy thing

to reach if you want to do it in a quality way. But we will definitely go for other indications, and it's something we are looking forward to.

DS has presented a firework of international events and trainings in recent years. Will this continue?

Yes, we will definitely continue on this path. Clinical education is important to what we do and it's also a great vehicle to stay in touch with our customers. We might not have major events like the Implants World Summit Tour every year, but we will have them when we think it is the right time.

In addition, our three global education centres – in Bensheim, Germany, in Charlotte, USA, and in Taipei, Taiwan are dedicated education centres that are in operation every day with opinion leaders and educators training dentists in everything from prosthetics to implant surgery to restorative procedures and prevention. Keeping those centres busy and full, keeping the curriculum in those centres interesting for clinicians, that's a big part of our strategy right now. So there is a lot of effort and commitment in education and you will continue to see that in the future.

Thank you very much, Mr Dorff, for your detailed and interesting answers.

MT ■

Batting a thousand

Osstell, the company that developed the original ISQ technology, today announced that since March 2019, there are now over 1,000 scientific studies and publications evidencing Osstell's special ISQ technology using the original SmartPegs.

Osstell has worked exclusively and systematically with an evidence-based approach since its inception more than 20 years ago, constantly reviewing research to share knowledge and improve its proprietary technology to best serve clinicians and their patients. Osstell has collected all of this important work in a convenient way and made it accessible in its regularly updated searchable database, where all scientific research relating to Osstell and Osstell ISQ is compiled, now including over 1,000 scientific, peer-reviewed studies and publications.

Helping clinicians provide patients with optimal time to teeth is the top priority for Osstell and its users. Osstell has also invented and developed Osstell Connect, an online service enabling clinicians to compile, analyze and make well-informed

and objective decisions based on their Osstell ISQ readings, utilizing evidence-based data from thousands of fellow ISQ users worldwide.

“On behalf of Osstell and all users of Osstell ISQ, I would like to thank all the research and clinical community for their invaluable contribution over the years, making Osstell ISQ the widely accepted evidence-based clinical standard for measuring implant stability and assessing osseointegration”, says *Jonas Ehinger*, CEO, Osstell.

Osstell has announced this milestone at the IDS in Cologne, Germany, and at the Annual Meeting of the Academy of Osseointegration in Washington, DC.

More information

www.osstell.com



You can access the Osstell database directly via the above QR code.

Anthogyr joins the Straumann Group

A mutually beneficial relationship

The Straumann Group and its partner Anthogyr have signed an agreement that paves the way for Straumann to increase its stake in Anthogyr from 30 per cent to full ownership. Privately-held Anthogyr provides Straumann Group with an additional range of attractively-priced high-quality implant solutions. The successful partnership since 2016 has enabled Straumann to tap into the non-premium implant segment in fast-growing emerging markets like China and Russia.

Anthogyr adds a high-quality attractively-priced European brand to the Group's portfolio, supporting its strategy to penetrate the attractive non-premium implant segment. With a history of almost 30 years in implantology, Anthogyr is a well-established brand that develops, manufactures and sells high quality, innovative, implant and CAD/CAM solutions. Its comprehensive portfolio addresses the upper value implant segment and includes fully and apically tapered designs, as well as parallel-walled tissue and bone level implants. The company has a strong clinical network of key opinion leaders in its home market, where it is the largest supplier of non-premium implant solutions.

The partnership between the two companies dates back to early 2016, when Straumann acquired a 30 per cent stake and took over Anthogyr's business in China.

"Our companies are a good cultural fit and our partnership over the past three years has been very successful. Anthogyr provided us with timely footholds in the non-premium implant segments in China and Russia, where we have been able to

generate strong growth with the brand. Our goal is to drive its international expansion together with Neodent, Medentika and our other brands, offering customers and their patients high-quality implant solutions with a broader range of price options than other companies can offer", said *Marco Gadola*, CEO of the Straumann Group.

"Straumann provides us with the global platform and resources we need to expand internationally. We have already expanded our state-of-the-art manufacturing capacity in preparation for future growth and will benefit from the Group's global sales, marketing and distribution capabilities. We are immensely proud of our union with the world's leading implant company and are convinced that it will add value for our staff, customers and patients", confirmed *Eric Genève*, President & CEO of Anthogyr. ■

More information

www.anthogyr.com
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Marco Gadola, CEO Straumann Group



Eric Genève, CEO Anthogyr

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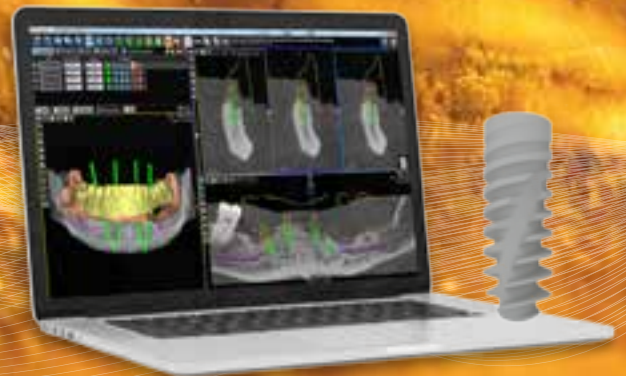
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New corporate design for W&H

Simple. Clear. Modern.

W&H has a fresh new look: The renowned medical technology company has adopted an original, contemporary corporate design to go with its new strategic orientation.

Under the motto “Simple. Clear. Modern.”, W&H has created an image showing that the company is ready to take on the future. New logo, new font, more designs and colours – perfect for all digital channels. The aim of the relaunch was to achieve a gentle, but still clearly noticeable change that would outwardly reflect the rapid development of the W&H Group whilst staying close to the W&H core values .

“W&H has developed from a supplier of products into a provider of solutions, and is offering more and more digital solutions to support everyday practice. W&H’s product range boasts innumerable innovations, with products that are easy to use, reliable, and feature a modern design. This is exactly what should be reflected by the corporate design. The new design strengthens W&H’s profile in relation to its

competitors. W&H has also defined individual brand identities for the new business areas W&H Med and W&H Vet,” says *Anita Thallinger*, Director of Marketing, on the subject of the new corporate design.

W&H logo remains the central element

The corporate design, produced in collaboration with Austrian designer *Gerhard Andraschko-Sorgo* and his design and advertising agency “Linie 3”, immediately catches the eye. The central element of the W&H logo, the hexagon shape, remains the same. However, the design is now clearer and more focused. Together with the new corporate font “Neue Helvetica World”, W&H’s look has been given a new burst of energy thanks to a range of additional colours that complement the traditional apple green, as well as a modern image and design language.

In order to create a clear distinction between the two new business areas W&H Med (human medicine) and W&H Vet (veterinary medicine), the former features a dazzling cyan blue, and the latter an eye-catching turquoise green.

Experience W&H online

For W&H, usability for customers is essential. Which is another factor that influenced the new corporate design. As part of the relaunch, the website has also been revised. It is now fully responsive, looks much more modern and offers additional space for products and digital content. Large images and a new navigation tool make browsing much easier and encourage customers to explore the world of W&H.

“Our international websites have featured the new corporate design since the middle of March. By the end of the year, the new corporate design will be visible across all channels and countries”, says *Anita Thallinger* on the relaunch of the wh.com website. ■



New logo, new font, more designs and colours: The new corporate design of W&H fits all digital channels.



More information

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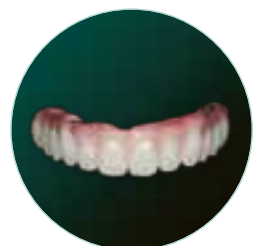


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Osstell Beacon

The latest instrument in resonance frequency technology

The need for an objective measure of primary stability remains an important issue with clinicians ever keener to determine if an implant is suited to early or even immediate loading. Osstell, the global leader in implant stability measurement and osseointegration progress monitoring has launched the next leap in the evolution of implant diagnostics with the introduction of Osstell Beacon. Dr Michael R. Norton, specialist in Oral Surgery, Adj. Professor at the University of Pennsylvania, and Past President of the Academy of Osseointegration (AO), has been using RFA for many years and has published and lectured widely on the value of RFA and its role in immediate loading protocols. In this article, he describes the development of the RFA technology and the use of the new device.

Osstell introduced Resonance Frequency Analysis (RFA) for clinical use 2001. This technology measures lateral stiffness and is recorded in Implant Stability Quotient units (ISQ) which range from 1 to 100, although the clinically relevant scale ranges from approximately 35 to 90. Initially RFA was very much seen as a research tool, allowing detailed longitudinal evaluation on increasing or decreasing stiffness of an implant in bone over time. The technology was somewhat cumbersome and generally made it impractical for daily use. However, with improvements in both the transducer design and subsequently instrument design, RFA became a more user-friendly tool that could be employed by clinicians in private practice.

The first such instrument, the Osstell Mentor, was quickly superseded by the Osstell ISQ. This instrument had the unique advantage of using a wireless transducer and have a memory capacity to allow multiple readings to be stored. Some years later the Osstell IDx was launched. This instrument could also be used as a Quality Assurance and audit tool, allowing multiple data on the implant brand, tooth position, need for grafting and so on, to be stored in the instrument using a touchscreen interface and also uploaded to the Osstell Connect website by Wifi connectivity.

As the older Osstell ISQ needed to be replaced and Osstell wanted to offer also a wireless device with integrated display and measuring tip, Osstell recently launched its new Osstell Beacon which set out to combine simplicity, with the audit capacity of the IDx and the reliability for attaining a reading seen with the Osstell ISQ.

The Osstell ISQ replaced the first ISQ measuring device, Osstell Mentor.



The Osstell IDx is a fast and non-invasive system that provides the accurate and objective information needed to proceed with confidence.

However on this occasion the instrument would take advantage of Bluetooth capability and automatically upload data to a personalized account on the new Osstell Connect website. This website allows the clinician to enter as much or as little data on the implant, the tooth position, the type of loading, and any other related data that might be deemed to be of value, and the ISQ values are displayed both on the Beacon itself and also automatically uploaded to the patient's records on the Osstell Connect website. In order to create this connectivity, the tool is primed by the motion of simply picking up the Beacon and connects via a USB dongle that can be plugged into the computer.

In addition to the above, the Beacon is ergonomically and attractively designed, providing a visual output by means of a red, amber, or green light to give the clinician an instant appreciation for the degree of stability attained by the implant. Once set down on the bench top and left motionless, the Beacon automatically switches off to preserve battery life.

The Osstell Beacon is light weight and really very easy to use. Combined with the wireless SmartPegs that have been in existence for some years now, this instrument has truly become the first choice objective tool for assessing implant stability, not just at the time of implant placement, but on subsequent occasions to build up a clear image and appreciation for gain in stability over time. The results can be seen graphically on the patient's own data page in the clinician's account on the Osstell Connect website when two or more readings are taken.

At a glance it is also possible to see when the implant was placed, when ISQ readings were taken, the length of healing time and the nature of the surgical protocol and loading protocol. By clicking on the implant data tab one can also garner information on the brand and specific type of dental implant used, and its dimensions.

One should not underestimate the dentolegal value of being able to draw on such a pool of data as well as the benefits accrued through building an auditable database not just for the individual but potentially for the profession, from the immense amount of data that could be available through Osstell, from many thousands of implants. As such the use of the Beacon without the use of the Osstell Connect database seems to this author to be a missed opportunity. ■

*Norton M.R. Resonance Frequency Analysis: Agreement and correlation of implant stability quotients between three commercially available instruments. Int J Oral Maxillofac Implants. 2019;34:215-222.



The Osstell Beacon helps to objectively determine implant stability a matter of seconds.



Example of a patient data page.



Example of an implant data page.

[More information](#)

www.osstell.com

Interview with Dr Bernhild-Elke Stammnitz, Langen, Germany

A splendid digital experience

Dr Bernhild Stammnitz has been running her own dental practice for 15 years. Her team consists of a total of three doctors, assistants, a dental laboratory and a prophylaxis department. Dr Stammnitz has been involved with digitization in dentistry since very early times and was one of the testers of the new Primescan intraoral scanner. She shares her experiences with the innovative device with the readers of the EDI Journal.

Had you ever worked with an intraoral scanner before or taken digital impressions? How did your workflow look like before Primescan?

I already had my first experiences with taking digital impressions during my studies. At the time, it was far from being perfect, but I found that the idea behind it was groundbreaking. In the early days of digital impressions, we still asked ourselves which indications it could really be used for, whereas today we ask ourselves: Where can it not be used? In my own practice, which I have been running since 2004, I began offering CAD/CAM technology for my treatments from the very beginning.

What are the obvious advantages that you have been able to recognize?

Well, first of all, everything goes much faster now. In order to understand it, one only must consider the various steps of the procedure: laying out trays of various sizes and trying them for size. Afterwards, all of them must be reprocessed for reuse. Next step: The material for taking the impression has to be selected, and it might not work perfectly in the first round, so you might have to repeat some steps. All of that can be omitted if you use digital impressions. Furthermore, it is a way to more sustainability, because there is no waste that has to be disposed of, the need to store materials is reduced, and – this is very important to me – the dentist can focus his attention more on the patient. Digital technologies are also a great communication tool. During digital impressions, the patient sees his own intraoral situation on the screen, and he can far better understand where and why the treatment is necessary.



In her practice, Dr Stammnitz works together with her master dental technician, Josef Kopping, and her dental technician apprentice, Sanja Seibel. Their work is facilitated by accurate impressions with Primescan.



Dr Bernhild-Elke Stammnitz has been using the new Primescan intraoral scanner from the very beginning and is very convinced of its advantages.

How well can Primescan be integrated into your workflow? What noticeable improvements have you observed with Primescan in your everyday work?

I have already been taking digital impressions for a long time, so there were no fundamental changes in my workflow. Taking impressions was already good before, but now it is even better. For example, with Primescan, scans can be taken even in situations where the patient shows signs of periodontally compromised teeth, which are characterized by long crowns and exposed roots. If subgingival preparations need to be made, the scanner can also reach those situations. Until now, that was a popular argument against digital impressions. Another important improvement is the representation of the preparation margins. This is very important for the further processing of the scan, because on one hand, it simplifies the design and the production if the restoration is fabricated in the practice. On the other hand, the scan reliably delivers all the information that the technician needs. He can work on the model, and he can set the occlusion and articulation with ease.

Is Primescan “the end of the line”, that is, the perfect intraoral scanner?

I can see a noticeable development in Primescan and it allows me to do exactly what I want to do: to scan intuitively, without having to worry about a perfect scanning strategy. Therefore, Primescan is already fulfilling wishes that users have expressed for a long time – beginning with the touch display of the acquisition center, all the way to the accuracy of the scan. My absolute favourite is the buccal bite on both sides, because now I can treat many different indications in all four quadrants. It saves time during the treatment, and it also reduces the overall number of visits in the practice. I like to carry out individual splint treatments, which is made possible by these quick, accurate scans. The dental technician is provided with work documentation that is simply perfect. The time-consuming precision impression has been replaced by Primescan’s accuracy scan.

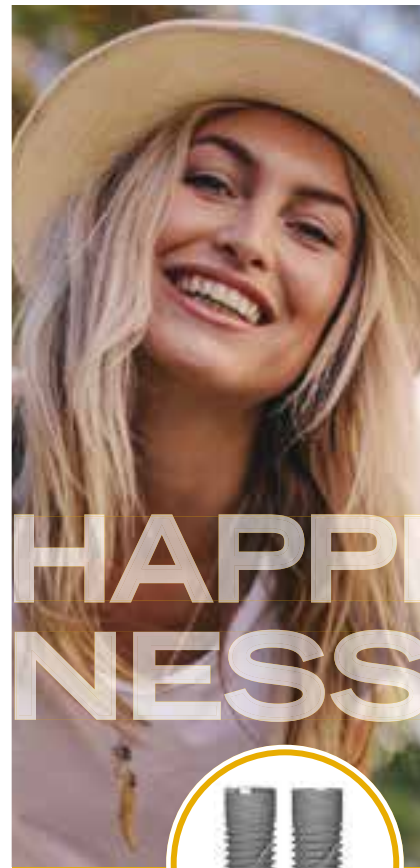
Do you still see room for improvement?

Something I would still like to see is the possibility of comparing different scans, for example, in order to examine possible movements of teeth or to diagnose a recession over time. Although this is already possible with OraCheck, it would be even easier to handle as part of the Connect or Cerec software. Irrespective of that, taking impressions with Primescan provides noticeable added value, both clinically and economically. The advantage for the patients, who really appreciate the “digital experience” and talk about it to others, is also very important to me.

**Thank you for sharing your experiences with our readers,
Dr Stannitz. MT ■**



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Interview mit Dr Frederic Hermann MSc, Zug, Switzerland

An implant for all clinical situations

Dr Frederic Hermann MSc, owner of a private dental practice and experienced implantologist, was one of the first users of the new Progressive-Line implant system from Camlog. EDI Journal Project Manager My To spoke with the practitioner about his experiences with and the advantages of the new system.



Dr Frederic Hermann MSc has tested the new Camlog Progressive-Line implant system and is very satisfied with the outcomes.

Dr Hermann, you already gained experience with the new Progressive-Line implant system before its market launch. What can you tell us about it?

In June 2018, we began the clinical documentation phase of the new Progressive-Line implant system in our practice, in collaboration with Camlog's R & D department. To date, we have documented approximately 80 implants in a balanced ratio of different clinical indications. We documented the primary stability of the implant depending on the bone quality (performed with the iChiropro surgical unit) and a follow-up of the bone stability with the Osstell ISQ.

In addition, relevant parameters were collected during the healing phase using an observation and documentation sheet. Currently, half of the implants are already in the post-prosthetic documentation phase. Our experience with regard to safe primary stability and reliable osseointegration is downright positive.

Where do you see the advantages of the system, especially in clinical applications?

Progressive-Line impresses with its innovative apically tapered conical macro design with a special thread and at the same time the proven prosthetic interface of the Camlog line. This means that these implants allow to achieve a reliable primary stability in the surgical phase. The system is particularly suitable for difficult conditions such as immediate implant placement, reduced alveolar ridge width, concave alveolar ridges or soft bone in the maxilla.

Due to the crestal anchoring thread, we also see an advantage in the placement of implants with a simultaneous open sinus floor elevation with a very reduced residual bone height of 2 to 3 mm. In most cases, the achieved primary stability is so high that immediate provisional treatment or loading is possible. This enables us to meet patients' increasing demands for shorter treatment times and to offer them efficient treatment procedures.

This efficiency also manifests in the reduction of drilling steps through a flexible drilling protocol. For example, in soft bone, we usually don't need more than three drilling steps to insert the implant and achieve excellent primary stability due to less preparation of the implant bed. In many cases it is possible to do without the additional use of non-ablative methods. But the new Camlog Progressive-Line has not only proven itself in soft bone. Thanks to the innovative "Dense Bone Drill", implants can also be inserted in hard bone (D1) without exerting too much pressure on the cortical structures. This is a very important aspect if you want to use one implant system for all indications.

The prosthetic interface is another aspect of the mentioned efficiency. Thanks to the unchanged and proven Camlog or Conelog interface, practitioners can use the prosthetic parts they have on stock. This means significant time and cost savings for existing users. In addition, they can choose between the Camlog or Conelog prosthetic interface. The latter is suitable for subcrestal positioning of the implant due to the conical internal connection and the integrated platform switch.

What is your summary of the new implant system?

In summary, I can say that the clinical indications have been expanded with regard to simultaneous procedures, that is, simultaneous implant placement and augmentation. This is due to the already mentioned primary stability in difficult anatomical situations. In many cases, we can also consider immediate restoration or immediate loading of the implant. The adaptation of the drilling protocol to the respective situation enables an efficient placement, the existing Camlog prosthetic interface guarantees the familiar handling. All this with an implant that we can use in all clinical situations.

Thank you very much, Dr Herrmann, for sharing your experiences.



Interview with Dr Germano Filippini, Gavardo, Italy

More flexibility means more safety

Dentaurum Implants advertises its new tioLogic Twinfit implant system with a maximum flexibility in prosthetic restoration. Dr Germano Filippini is an experienced specialist in implant dentistry and one of the first to use the new implant system in his private practice. EDI Journal Project Manager My To wanted to know whether the system actually delivers in practice what it promises in advertising.

In the implant market there is no shortage of “revolutionary innovations”. What, in your eyes, is really new in the tioLogic Twinfit system?

The flexibility. Flexibility in implant placement and prosthetic flexibility. The new design of the implant enables a placement with a complete biological respect of the bone. The new implant system with the disposable depth stops assures safety during the preparation of the implant bed, leaving great room for manoeuvre when the bone requires an unconventional preparation.

Prosthetic flexibility means the possibility of choosing between two different connections, based on the patient’s clinical situation and the type of aesthetic restoration we wish to perform. This kind of flexibility guarantees long-term success.

You are one of the first users of tioLogic Twinfit. Have you already come across a case where you decided to change the approach during the treatment and used a different connection from the one originally planned?

I am an advocate of the conical connection and when I can, I don’t give it up. However, I had a case where the aesthetic requirements of the patient were high: upper right lateral incisor, very little adherent gingiva. In order to be able to manage the emergence profile in the best aesthetic way (it was made of ceramic rather than metal, which was visible through the gum), I opted for a switch connection that allowed me to manage the emergence profile in the best possible way.

Why is it advantageous to make the final decision on the appropriate connection at a later stage of the treatment?

I believe it is always a great added value to be able to choose the best prosthetic solution according to the clinical situations present at the time of surgery. Even more, I can choose and intervene again if, over the years, unforeseen aesthetic complications arise.

Usually, where there is light there is also shadow. Would you recommend the systematic tioLogic Twinfit without reservation?

Definitely! The system as a whole is a complete solution and does not disappoint expectations. Flexibility, surgical safety, digital workflow and prosthetic solutions in accordance with clinical requirements certainly position this implant line among the most complete on the market today.

Thank you very much for the interview, Dr Filippini.

MT ■



Dr Germano Filippini is convinced of the merits of Dentaurum Implants’ new tioLogic Twinfit System. Here during his conversation with EDI Journal Project Manager My To at the IDS 2019.

Zimmer Biomet and Zfx announce the launch of GenTek

Easy. Fast. Genuine.

Zimmer Biomet and its affiliate Zfx announce the European launch of GenTek, a new restorative digital product line for Zimmer Biomet dental implant systems. GenTek products and workflows will bring clinicians, dental laboratories and milling centers the restorative solutions that best address patients' needs and maintain the integrity of clinically proven implant connection designs.

Zfx offers quality CAD/CAM restorative components for the industry's most popular dental implant connections. Now, for the first time, clinicians can be confident that GenTek components are designed with genuine Zimmer Biomet implant connection specifications. The GenTek portfolio is comprised of scanbodies, Ti-bases, pre-milled abutment blanks and accessories, which are part of an open digital workflow. The solutions were designed in close collaboration with Zimmer Biomet Dental, ensuring the highest level of accuracy in its implant-connection designs.

"With the growing adoption of digital technologies and open architecture workflows in the European market, Zimmer Biomet Dental in collaboration with Zfx strives to be a valuable partner to our customers by introducing genuine restoration components that are part of an open digital workflow," said *Daniele Landi*, Vice President, EMEA.

A comprehensive product line

A highly accurate digitization of the implant positions in the patient's mouth or from the laboratory model is possible with the Zfx GenTek Intraoral Scanbodies and GenTek Desktop Scanbodies. Their genuine titanium connection base ensures a precise fit with the implant connection for optimal scanning results. Scanning accuracy is also supported by the PEEK material used in the scanbodies, which provides a favourable surface for optical scanners without the need for spray.

Zfx GenTek Digital Scan Analogs are also available, featuring a proprietary anti-rotation functionality, a first of its kind 3-in-1 digital analog. They function as digital analogs in 3D printed models, scanbodies and conventional analogs used in a stone model.

For the production of hybrid abutments and hybrid abutment crowns, Zimmer Biomet Dental offers Zfx GenTek Ti-Bases equipped with proven Friction-Fit and SureSeal technologies along with its

special Gold-Tite screw. The genuine Ti-bases meet geometrical requirements for Sirona Cerec blocks for chairside milling and inLab CAD/CAM solutions and offer high restorative flexibility as they may be combined with various materials including oxide ceramics, glass ceramics and PMMA.

One-piece titanium custom abutments may be produced in the dental laboratory using Zfx GenTek pre-milled abutment blanks. They have a pre-fabricated genuine connection to ensure accurate fit and superior performance with the implant connection. As the blanks are compatible with Zfx Inhouse5x and all milling machines that work with Medentika PreFace abutment holders, many partner laboratories will be able to provide the desired genuine abutment.

The use of genuine restorative components is instrumental in safeguarding the physical integrity of implant-based restorations. By ensuring a precise fit and tight seal between the components, the potential for biological and technical complications such as tissue inflammation, screw joint failure and screw loosening may be mitigated. In this way, the genuine connection can contribute to the long-term prosthetic stability. ■



More information

www.zimmerbiometdental.com
www.zfx-dental.com

Xeal and TiUltra surfaces from Nobel Biocare

Entering the era of Mucointegration

Nobel Biocare invited dental professionals to join the Mucointegration era with the launch of the Xeal and TiUltra surfaces at the International Dental Show (IDS) in Cologne. Applied to not only implants but also abutments, these new surfaces were created to optimize tissue integration at every level for the purpose of improved implant treatment outcomes.

Based on its decades-long expertise in applied anodization technology, Nobel Biocare has understood that for optimal integration of dental implant restorations, different tissues demand different surfaces. While osseointegration is fundamental for the long-term function of implant restorations, soft-tissue integration is often overlooked. Dense soft-tissue contact with the abutment, however, can act as a barrier to protect the underlying bone [1–4]. To maintain long-term tissue health and stability, surface chemistry as well as topography of the new Xeal abutment was specially designed to facilitate soft-tissue attachment to the abutment. Backed by data from a clinical study with two-years' follow-up, the Xeal surface has demonstrated a significant increase in soft-tissue height compared to machined abutment surfaces [5]. Available for the On1 Base and Multi-unit Abutment from Nobel Biocare, dental professionals in Europe can now experience the benefits of this pioneering surface in their own practice.

Developed with the ultimate goal of early osseointegration and long-term bone stability in mind, the ultra-hydrophilic, multi-zone implant surface, TiUltra, is taking anodization technology a step further. Going beyond just roughness, the surface chemistry was optimized with the goal to positively influence its interaction with cells and ultimately osseointegration. TiUltra's topography has also been reimagined to gradually change from a minimally rough and non-porous collar to a moderately rough and porous implant apex thus respecting the natural transition from hard, dense cortical bone to cancellous bone [6]. The TiUltra surface will be available with Nobel Biocare's NobelActive and NobelParallel Conical Connection implants. Combined with the Xeal abutment surface, dental professionals have a new complete solution for soft-tissue health, bone protection and fast osseointegration at their disposal. To ensure that every

implant and abutment is delivered in pristine condition, the surface chemistry and hydrophilicity of both Xeal and TiUltra is preserved with a protective layer that dissolves upon contact with fluids. "Having mastered osseointegration for decades, Nobel Biocare is taking tissue integration to a new level. With the launch of Xeal and TiUltra at IDS Cologne we are not only advancing our leadership position in surface technology but also opening a new era for implant dentistry, that of Mucointegration", *Hans Geiselhöringer*, President of Nobel Biocare, commented at launch. "Our focus has always been on the patient. These new solutions are supported by clinical evidence including a two-year clinical trial." Dental professionals in CE markets are the first to get access to the new surfaces, followed by other regions around the globe in 2019.*

A unique insight into the scientific evidence already available on the new surfaces has been published in a dedicated supplement of the journal *Clinical Implant Dentistry and Related Research* released online in April. This is accessible via the QR code below.

* Availability in other markets pending on product registration and clearance.

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



This QR code leads you directly to the supplement "A New Era in Mucointegration and Osseointegration Driven by Surface Chemistry".

Surfaces have been reimagined to optimize tissue integration from the abutment to the implant apex.



More information

www.nobelbiocare.com/surface



BTI offers exclusive solutions to simplify the treatment of the atrophic jaw

Think small

Transversal and vertical bone defects are a common phenomenon encountered by dentists and often involve the use of invasive bone augmentation techniques which increase treatment times, surgical morbidity, and related costs. Recent advances in the design of BTI implants and biomechanical research have enabled the development of implants with reduced diameter and length, thus introducing simplified protocols in the treatment of cases of bone resorption, such as immediate placement.

Extensive scientific evidence (over 15 years of publications on the subject) prove the predictability of implants with reduced diameter and length, suggesting survival rates similar to, or even greater than, those of implants with standard length and diameter. Furthermore, in cases of severe resorption, BTI proposes the use of minimally invasive bone augmentation techniques such as alveolar ridge expansion or transalveolar sinus elevation, which simplify the surgical procedure and minimize the post-operative period for the patient.

Narrow BTI implants (3.0)

These implants are characterized by a 3 mm prosthodontic platform, body diameters of 2.5, 3 or 3.3 mm, and a self-tapping apex to displace the bone without generating apical compression and obtain excellent primary stability. A drilling sequence of increasing diameter, low revolutions (75–100 rpm), and no irrigation is used to insert these implants, which enables the socket to be kept in the best biological conditions. In addition to collecting bone marrow, it is a cell carrier with angiogenic activity used together with plasma rich in growth factors (Endoret-PRGF) to obtain particulate graft. The primary indication of these implants is the treatment of total and/or partial edentulisms with transversal alveolar atrophies without the need for previous bone augmentation steps, under the condition of sufficient residual bone volume.

Depending on the diameter of the implants, the narrow implants are indicated to solve single cases affecting lower, lateral, or upper incisors, as well as dental agenesis. Their use also covers the treatment of crests with severe defects together with a bone augmentation technique and the use of autologous and heterologous particulate grafts to obtain an adequate bone volume and height.

Extra-short BTI implants

The extra-short BTI implants are available in various prosthodontic platforms with lengths of 5.5 and 6.5 mm. The apex of these implants has a greater surface that favours primary stability without compressing the compromised anatomical regions (maxillary sinus and dental nerve).

The main modification applied to the drilling sequence used for these implants is the introduction of a front cutting drill characterized by a cylindrical morphology similar to the apex of the short implant, with an exclusively apical cutting ability that allows the user to maintain a safety margin from the mentioned anatomical structures.

This drill is indispensable for the preparation of the sockets in which these implants will be inserted, besides allowing crestal access to the maxillary sinus in cases of severe resorption.

The ultra-short BTI implants are indicated to treat edentulisms with vertical atrophies by means of immediate placement protocols or bone augmentation techniques (elevation of the transalveolar sinus) when the residual bone height is insufficient.

To solve the possible limitations resulting from resorbed bones (poor revascularization and low cellularity), BTI suggests the use of the Endoret-PRGF technology due to its high regenerative potential and therapeutic versatility.

Endoret-PRGF is a 100 per cent autologous technology based on the use of platelet-rich plasma obtained from the patient's own blood. It allows for obtaining a series of therapeutic formulations (fluid, clot, graft, and membrane) that are highly useful in the rehabilitation of atrophic jaws. ■

More information

bti-biotechnologyinstitute.com

BioHorizons Camlog expands its soft-tissue portfolio



NovoMatrix – the next generation soft-tissue augmentation material

When choosing a biomaterial, there is a strong demand in clinical practice for predictable outcomes. For over 20 years, LifeCell, a leading global medical technology company, has developed innovative products for use in a wide range of applications. BioHorizons Camlog expands its soft-tissue portfolio in partnership with LifeCell to bring NovoMatrix, an innovative soft-tissue augmentation material, into the European market. Full market release of this product will take place at the Oral Reconstruction Foundation Symposium in New York City in April 2020.

NovoMatrix is an acellular extracellular dermal matrix consisting of tissue-engineered porcine material. It is a breakthrough in xenogeneic processing ensuring a structurally intact, undamaged scaffold that supports cell and microvascular ingrowth. The proprietary tissue processing allows for rapid revascularization, cell repopulation and minimal inflammation. NovoMatrix comes pre-hydrated and ready to use and offers a true alternative to autogenous soft-tissue grafts and current products on the market. The NovoMatrix indications include guided tissue regeneration procedures in recession defects for root coverage, localized gingival augmentation to increase keratinized tissue (KT) around implants and natural teeth, and alveolar ridge reconstruction for prosthetic treatment.

The expert's opinion

Dr Edward P. Allen, Dallas, Texas, USA, one of the pioneer users of NovoMatrix, says: "The biggest problem for a clinician with soft tissue grafting is the treatment of multiple tooth areas in one patient, which we see very often. When using palatal tissue only, we have got limitations in how much can be done in a single visit. The new product – NovoMatrix – allows the treatment of multiple teeth in one time without using the palate. That provides a more comfortable outcome for the patients because they don't have a secondary wound in the palate.

The problems from the patient's standpoint are post-op care and of course any complications or discomforts associated with the procedure. The tunnel technique is a minimally invasive technique that

provides a more rapid healing response and less discomfort for the patient. Using NovoMatrix means that there is no harvest of the palate which considerably reduces complications or discomfort associated with that particular part of the procedure.

The advantages of NovoMatrix over the existing products, certainly over allografts, are the consistency of the physical properties and the handling characteristics. The advantages over other xenografts is that NovoMatrix is not a resorbable collagen membrane; in fact, it is integrated wholly providing an increase in tissue thickness and function with a physiologic outcome. So the tissue is integrated rather than resorbed.

NovoMatrix graft exhibits uniform physical characteristics and great surgical handling, enhancing its ease of use in the tunnelling technique. This results in an excellent clinical outcome with minimal post-operative swelling and inflammation." ■



More information

www.camlog.com

OssBuilder titanium mesh from Osstem Implant



Easy and efficient GBR with a 3D preformed titanium mesh

Guided Bone Regeneration (GBR) is one of the essential techniques for the successful implant treatment in vertically or horizontally deficient alveolar bone. With OssBuilder (previous name: SmartBuilder) from Osstem Implant, clinicians and practitioners can expect predictable and stable results.

Titanium is a biocompatible precious metal that is the most commonly used material for dental implants. Thanks to its good ductility as well as excellent biocompatibility, it is also widely used in various oral and maxillofacial treatments. However, titanium has rarely been used in GBR due to its difficult handling and the high risk of exposure. Since 2012, Osstem has been offering OssBuilder, a preformed titanium mesh, which effectively solves these weaknesses.

Simple and less invasive placement

OssBuilder can be directly connected to the implant, without any additional fixation of the membrane. Firstly, an anchor that serves as a bridge between the implant and OssBuilder is connected to the implant, and the final fixation is done by connecting either a healing cap or a cover cap on top of the OssBuilder after its placement (see illustration to the left). There is no need for additional fixation on the edge of the mesh. With the help of OssBuilder, shortened chair time and easier soft and hard tissue management can be ensured.



The pore structure of the membrane is designed to optimize the diffusion of natural fluids and growth factors throughout the tissue without letting soft and hard tissue form cell occlusions.

Easy handling with various options of 3D preformed membranes

OssBuilder is easy to handle, thanks to its optimized preshaped design. As the design reflects the cases frequently observed in actual clinical practice, it can be directly applied to the patient without additional bending or trimming. Moreover, there are different options and sizes of OssBuilder, which can be chosen depending on the bone defect condition of the patient.

The lateral type is ideal for various horizontal and vertical bone augmentation procedures including simple socket extractions, fenestration and dehiscence cases. The jaw type is applicable for severe bone loss, when alveolar bone needs a regeneration of 5 to 10 mm. Both types feature smooth edges and preformed dome shapes, minimizing potential exposure through the soft tissue.

Predictable results with excellent volume maintenance

The key to a successful GBR is to maintain the space and volume during the GBR period. The OssBuilder titanium mesh has a high strength, which can effectively maintain the volume by protecting the space from external stress.

According to *Dr Marco Tallarico*, an experienced practitioner who has been using OssBuilder for several years, "using OssBuilder with simultaneous implant placement to provide the space necessary for bone augmentation of alveolar bone defects results in a good bone stability, a good soft tissue quality and a predictable success of the implant treatment and the prosthetic restoration." ■

[More information](#)

www.osstem.de

bredent copaSKY

With new prosthetic components for the ultra-short copaSKY titanium implant, bredent medical offers further treatment options for patients with reduced bone availability. The specialist for sophisticated prosthetic solutions again relies on the proven high-performance polymer BioHPP. The ceramic-reinforced material reduces the masticatory forces that otherwise act directly on the implant. Prefabricated BioHPP abutments are available in straight and 17.5° angled form, there is a prefab for the digital workflow, and the laboratory can also fabricate its own individual abutments using the for 2 press process.

Dentists have always been working very efficiently and economically with the “exo – extended solution” abutment line, as the impression abutment also serves as the final abutment. With exso, impressions of straight and angled implants can be taken precisely with an impression coping cap. The technician uses the exso abutment as the definitive abutment after model fabrication.

In addition to the popular uni.cone series, bredent medical now also offers bridge and bar abutments for the ultra-short copaSKY which allow screw-retained bridges to be be screwed directly into the implant – even with a compensation of an 20° angulation. ■

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

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EDI Journal is the first and only European professional journal of its kind, written for all clinicians with distinct interest in dental implantology. This publication aims at uniting European dentistry in a common effort, to establish appropriate standards and to help open up new markets.

The specific dental section of this periodical offers a wealth of original work, case reports, scientific research and other articles presented by authors from countries all over Europe, all helping to make this top-quality platform a truly international voice in the dental profession. Product innovations are covered in depth. And for the first time ever, dental implantologists are offered exhaustive information on important ancillary themes such as European standards, quality guidelines, legal issues, questions of remuneration and professional specialization.

Information on upcoming events of importance to dental implantology and on training, continued education and professional growth opportunities are also regular features of **EDI Journal**.



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Calendar of Events

	Event	Location	Date	Details/Registration
9/2019	FDI Annual World Dental Congress	San Francisco USA	5–8 September 2019	FDI World Dental Federation) www.fdiworlddental.org
	Geneva Treatment Concept Basic Course	Geneva Switzerland	9–13 September 2019	University of Geneva thegenevaconcept.com
	EAO 2019 Annual Scientific Congress	Lisbon Portugal	26–28 September 2019	EAO European Association for Osseointegration congress.eao.org/en/
	ITI Congress Italy	Riccione Italy	26–28 September 2019	ITI International Team for Implantology www.iti.org/congressitaly
10/2019	Dentsply Sirona World	Las Vegas, NV USA	3–5 October 2019	Dentsply Sirona www.dentsplysironaworld.com
	1st European Congress for Ceramic Implant Dentistry	Zurich Switzerland	11–12 October 2019	European Society for Ceramic Implantology ESCI www.esci-online.com
	Osstem HiOssen European Seminar	Prague Czech Republic	18–19 October 2019	Osstem Implant www.osstem.de
11/2019	Swedental 2019	Stockholm Sweden	13–15 November 2019	Stockholmsmässan www.swedental.org
	ADF 2019 French Dental Association Annual Meeting	Paris France	26–30 November 2019	Association Dentaire Française www.adf.asso.fr
4/2020 5/2020	Oral Reconstruction Global Symposium	New York City USA	30 April–2 May 2020	Oral Reconstruction Foundation www.orfoundation/globalsymposium
	ITI World Symposium	Singapore	14–16 May 2020	ITI International Team for Implantology www.iti.org/worldsymposium2020/
	MIS Global Conference	Marrakech Morocco	14–17 May 2020	MIS Implants www.misimplants.com

EDI Journal – Information for authors

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

- Original scientific research
- Case studies
- Product studies
- Overviews

Manuscript submission

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

Manuscripts

Pages should be numbered consecutively, starting with the cover page. The cover page should include the title of the manuscript and the name and degree for all authors. Also included should be the full postal address, telephone number, and e-mail address of the contact author.

Manuscripts can be organized in a manner that best fits the specific goals of the article, but should always include an introductory section, the body of the article and a conclusion.

Illustrations and tables

Each article should contain a minimum of 20 and a maximum of 50 pictures, except in unusual circumstances. Our publishing house attaches great importance to high quality illustrations. All illustrations should be numbered, have a caption and be mentioned in the text.

The photos should have a size of 10x15 cm, the image or graphic files must have a resolution of 300dpi. Tiff, eps and jpg file formats are suitable. Radiographs, charts, graphs, and drawn figures are also accepted.

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References

Each article should contain a minimum of 10 and a maximum of 30 references, except in unusual circumstances. Citations in the body of the text should be made in numerical order. The reference list should be typed on a separate sheet and should provide complete bibliographical information in the format exemplified below:

- [1] Albrektsson, T.: A multicenter report on osseointegrated oral implants. *J Prosthet Dent* 1988; 60, 75-82.
- [2] Hildebrand, H. F., Veron, Chr., Martin, P.: Nickel, chromium, cobalt dental alloys and allergic reactions: an overview. *Biomaterials* 10, 545-548, (1989)

Review Process

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

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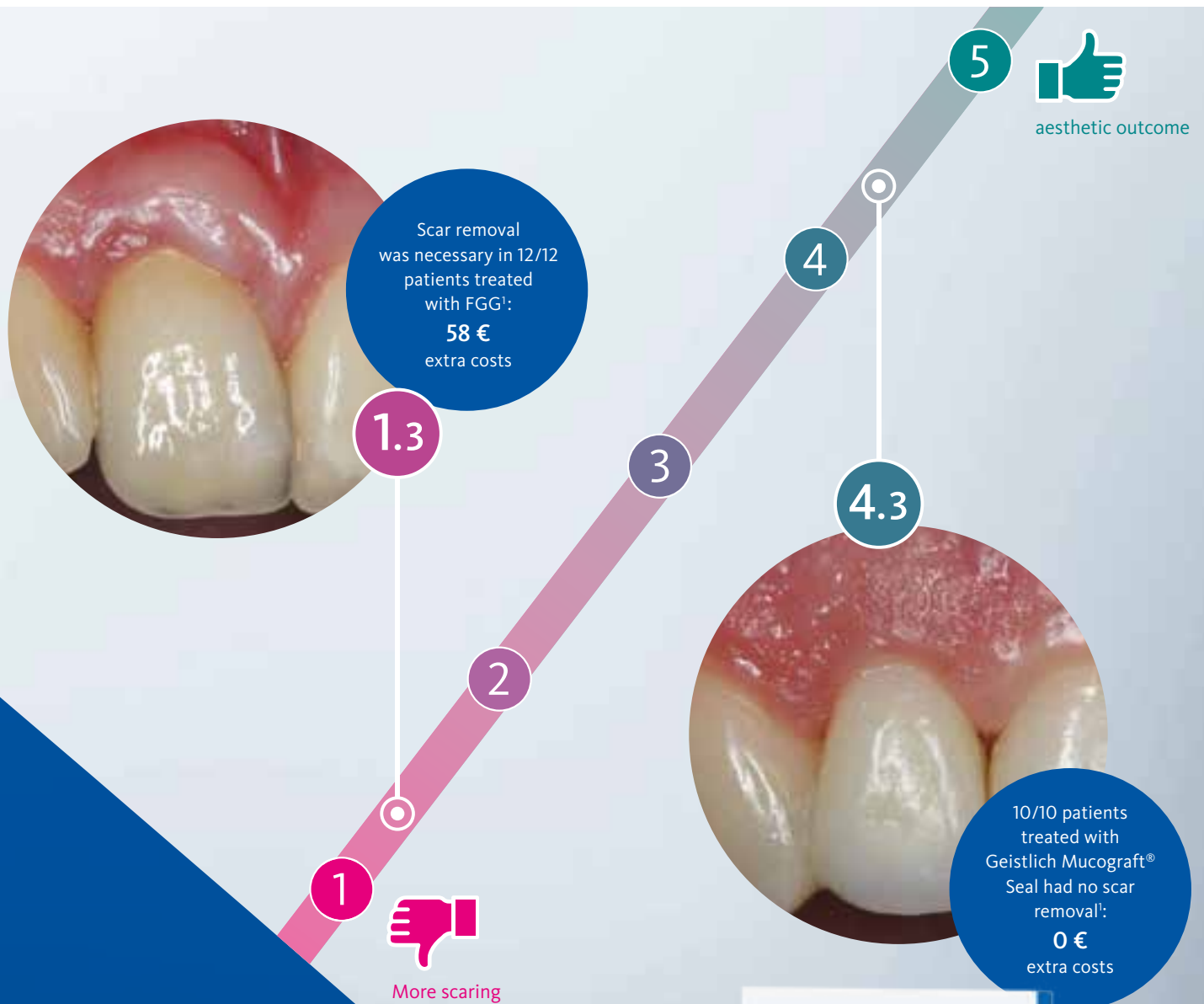
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¹ Fickl S. et al. International Journal of Periodontics & Restorative Dentistry, 2018, 38(1):1-7

