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EDI Journal

European Journal for Dental Implantologists

TOPIC

Update ceramics in implantology

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Changes

"Changes – turn and face the strange" – the lyrics of David Bowie's song are more relevant today than ever. When the Corona virus spread around the world in early 2020, we could hardly weigh its significance for the world. Today, the virus still dominates our lives: privately, socially, economically.

In recent months, continuing dental education in the form of face-to-face events has practically come to a standstill – not only in Europe, but also beyond. Digital seminars dominate the training landscape – what a change! Sitting in front of a monitor and listening to a presentation delivered on a screen is one thing. Experiencing a presentation with a live speaker in a congenial environment of like-minded peers is quite another. The interpersonal aspect, the exchange among colleagues, the social component has almost disappeared.

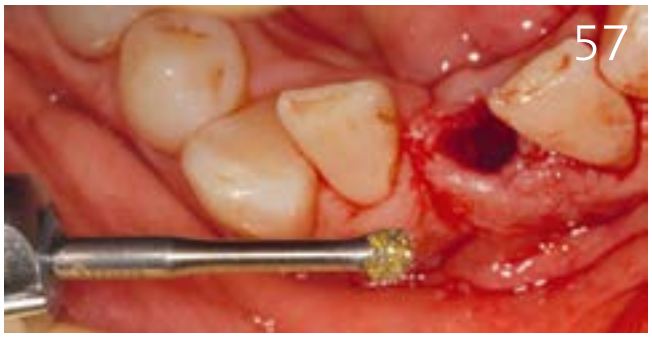
The European Association of Dental Implantologists BDIZ EDI had to postpone last year's European Symposium with EDI Macedonia, which should have taken place in Skopje in May 2020. Instead, we had a digital meeting in May 2021. For the very first time, BDIZ EDI also had to postpone the 16th Expert Symposium – the so called carnival symposium – which traditionally is taking place during carnival season in Cologne. Even worse for the citizen of Cologne: Carnival was not celebrated officially in 2021 which was a heart-breaking experience for the Carnival-enthusiastic people of Cologne.

Whereas the great events in the dental world, like EAO, FDI World Congress etc. were called off within the last months, it's certainly a surprise that the International Dental Show IDS will be taking place 22 to 25 September this year, since the organizing partners, the Cologne exhibition centre and the VDDI – the Association of German Dental Manufacturers – stick to their fair. Due to the ongoing pandemic, the 39th IDS will be far from being as bombastic as its predecessors. Nevertheless, BDIZ EDI will be there – as always. If you want to meet the board and pick up some up-to-date information, please don't hesitate to come by: Hall 11.2, row O, stand 61. We are opposite the stand of the German Dental Association – as always.

The BDIZ EDI is optimistically planning the next Expert Symposium in Cologne on 27 February 2022. The topic will be: Risk factor periodontal diseases – tooth preservation or implantology. In addition, the European Consensus Conference EuCC will update the Cologne ABC Risk Score originally adopted in 2012.

This editorial would not be called "Changes" if there was not a change to announce. BDIZ EDI started digital seminars in April 2020 – at an early stage of the pandemic. Since then, we have organized 40 seminars with renowned speakers and more than 6,000 participants - a great success! In the future, BDIZ EDI will also offer digital seminars for an international audience in English. Further information will follow soon. Stay tuned!

Anita Wuttke
Editor-in-Chief



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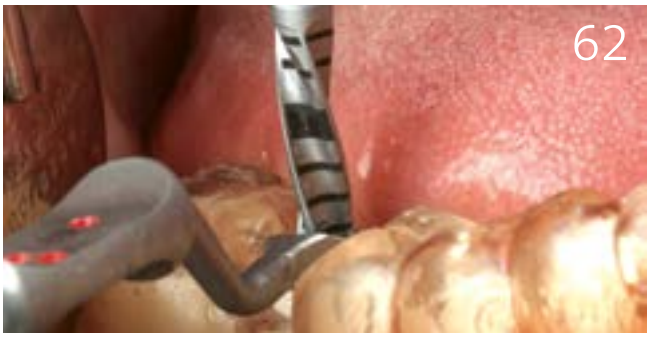

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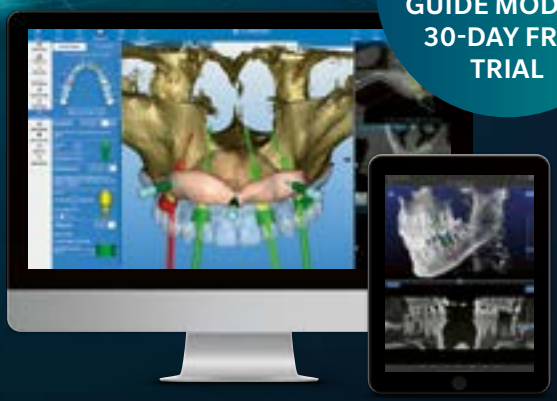

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Michele Manacorda, Bianca Poletti de Chaurand, Alberto Merlone, Giulia Tetè, Francesca Mottola and Raffaele Vinci; Dent J (Basel). 2020 Mar; 8(1): 14.; Published online 2020 Feb 2. doi: 10.3390/dj8010014

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Partner Organizations of BDIZ EDI

Association of Dental Implantology UK (ADI UK)

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

Ogolnopolskie Stowarzyszenie Implantologii Stomatologicznej (OSIS EDI)

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

Sociedad Espanola de Implantes (SEI)

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

Sociedade Portuguesa de Cirurgia Oral (SPCO)

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

Udruženje Stomatologa Implantologa Srbije-EDI (USSI EDI)

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

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Interview with Professor Jörg Neugebauer on the 2021 Guideline

Ceramic solutions for all applications

In February 2021, the BDIZ EDI convened its 16th European Consensus Conference (EuCC) in the form of an online discussion forum. The objective was to update the 2007 consensus paper on ceramics in implant dentistry. The Conference had been prepared and moderated by Professor Jörg Neugebauer for BDIZ EDI. Abutments and superstructures were discussed, as were one-piece and two-piece ceramic implants. In this interview, Professor Neugebauer explains the EuCC procedure as well as the proceedings and results.

Professor Jörg Neugebauer

Professor Neugebauer, what objectives do the Guidelines of the BDIZ EDI pursue?

To provide colleagues with recommendations for action on a current topic in oral implantology that can be easily implemented in clinical practice. To this end, we are looking beyond the German fence. Each EuCC features invited international experts, who deliberate issues with the participants of the Expert Symposium on the relevant topic, striving to find a consensus position.

Who is in charge of preparing the working document?

There is a working document for each Conference, prepared by Professor Joachim E. Zöller, Professor Hans-Joachim Nickenig of the University of Cologne and myself. Most of the time, Hans-Joachim Nickenig and I also jointly moderate the EuCC. This year was the first year, owing to the pandemic of course, that we had an online event, in February, that lasted over three hours.

And when you are done with the Conference, does that mean you have a completed Guideline?

I am sorry to have to disappoint you, but the results of the Conference invariably still need a lot of editing. This time the process was particularly tricky, as the topic offered potential for conflict. But in the end, everyone is satisfied, a consensus has been reached, resulting in the BDIZ EDI Guideline, which is published in two languages.

The topic for 2021 was "Ceramics in Implant Dentistry". Does that mean ceramic implants?

Well, not exclusively; that would be too narrow a scope. Under the heading of ceramics, we also include abutments and superstructures – and of course one-piece and two-piece ceramic implants. This year's Guideline, by the way, is a classic example of how we update Guidelines that became obsolescent. The most recent Guideline on this topic was published in 2007; it was certainly time to update it.

Has there been anything fundamentally new in terms of content?

Not all that much, actually; except that materials have become much more reliable in recent years. This is why the EuCC, for example, has been able to dispel earlier concerns about one-piece ceramic implants. The risk of implant fracture is low for today's commercially available implants. Overload damage during the early healing period can be avoided by splinting or by eliminating functional loads on the temporary restoration. For two-piece ceramic implants, on the other hand, there is a variety of implant abutment designs existing and sometimes the concept of metal-free implant designs will be abandoned. Scientific evidence for two-piece implants is still scarce.

Ceramic implants are now being offered by almost all implant manufacturers, and they seem to become more popular.

Well, in a way. Ceramic is often used as a material for superstructures. In fact, ZrO_2 implants have been around for 20 years. And even if vendors are increasingly offering ceramic implants, their usage is still limited. Many manufacturers offer ceramic implants in addition to their titanium implants. Today's laws and regulations do not make regulatory approval of these implants particularly easy. Recently, one manufacturer discontinued them due to a lack of profitability. The fact is that much fewer ceramic implants are being placed than titanium implants.

What methodology do you use to establish consensus for the Guideline?

The methodology of the BDIZ EDI Guideline – as compared to the classifications offered by Stage

Classification of Guidelines – is probably best described as "consensus-building within an informal process". The selection principle is to ensure to include that the most recent publications for each topic area were included. During the ensuing discussions, further publications that had not been considered initially are added. Our objective is to develop clinically relevant recommendations, taking into account the practical experience of our European participants.

Did the Conference also deal with the so-called titanium allergy, which often surfaces in discussions on ceramic implants?

Yes, indeed; we discussed immunological and biological interactions at the outset. We stick to the hard facts, and we had to conclude that little work has been done in this area. The images frequently presented actually show allergic reactions that do not originate from titanium implants but rather from titanium dioxide – a food colourant that, though approved, must be declared. It is found, for example, in fermented milk products, ice cream, gummy bears and also in mozzarella. Looking at the facts, we have concluded that titanium implants have nothing to do with those allergies; on the contrary, these implants work very well, and they continue to represent the gold standard.

So what is the current status of zirconia implants? Are they really better?

Here and everywhere else there is one golden rule: read the instructions. Taking into account any interactions, we found that commercially available ZrO_2 implants placed according to the manufacturers' instructions achieve good osseointegration and feature good soft-tissue biocompatibility, resulting in high levels of clinical success. Both implant materials work!

Today we are offered a wide variety of one-piece and two-piece implants. How does the EuCC assess their current resilience?

With the one-piece ceramic implants available today, the risk of implant fractures is low thanks to improved materials and demanding regulatory requirements. Overloading during the early healing period can be avoided by eliminating functional loads on the temporary restoration.

There are still too few scientific studies on two-piece implants to issue any reliable statements.

Abutments were also a topic. What were your results for the Guideline?

Here we benefited especially from the contributions on the part of our Dutch colleagues, which once again shows that our Guidelines are improved by our "European" discussions. What was important to the Dutch – and we have consensus here – was that we achieve better aesthetic results with ceramic abutments than with titanium abutments in patients with a thin soft-tissue phenotype. On the other hand, we toned down the importance of biofilm accumulation, because we have concluded one thing: it is not the material that makes the difference, but the surface topography.

What did the EuCC have to say about superstructures in the light of the chipping problem?

We have found that the use of monolithic ZrO_2 ceramic in superstructures has been little studied so far. The reported chipping rates are relatively high for ceramic frameworks with ceramic veneers. Ultimately, however, we hope that, given recent developments in CAD/CAM technology, a better selection of materials and more extensive knowledge will result in better long-term results.

All in all, how would you summarize your view of the "Update on Ceramics in Implant Dentistry"?

Well, we do have ceramic solutions available within oral implantology, both with regard to the implant body and to abutments and superstructures. Of course we do appreciate their high acceptance by patients. On the other hand, it takes a knowledgeable and experienced practitioner to implement the best possible therapy. What is important to me – and here I can speak for the BDIZ EDI – is that our Guideline succeeds in increasing treatment choice, not to stifle it with a lot of confining rules.

Thank you very much for your insightful comments!

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

Update: ceramics in implant dentistry

Bundesverband der implantologisch tätigen Zahnärzte in Europa

European Association of Dental Implantologists

Guideline 2021

Update on Ceramics in Implant Dentistry

16th European Consensus Conference (EuCC) 2021

23 February 2021

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1. Methods

1.1. Purpose

This guideline aims to provide dental and orofacial implantologists with recommendations for the use of ceramics as an implant, abutment, and superstructure material in implant dentistry. It is an update of the 2007 guideline.

1.2. Introduction

This consensus paper covers one- and two-piece implants fabricated from ZrO_2 ceramics, typically placed in accordance with the indications recommended by the Consensus Conference in Implantology (German). Additionally, the use of ceramics as an abutment material or for crown and bridge superstructures is reviewed. All consensus recommendations in this paper should be considered as guidelines only. The patient's specific situation is always an important consideration and may justify a deviation from the recommendations of this consensus paper.

1.3. Background

Ceramics is widely used as material for superstructures on implants. ZrO_2 ceramic implants have now been around for almost 20 years. Even if vendors are increasingly distributing ZrO_2 ceramic implants, their usage is still limited.

1.4. Literature search

The Cochrane Library, EMBASE, DIMDI and Medline databases were used in the literature search performed by the conference host between 15 January and 15 February 2021. For the purpose of updating of the 2007 Guideline, the search was limited to references published 2006 and onwards. The search strategy included search terms such as:

zirconia implant, ceramic implant, dental implant, abutment, superstructure, ceramic, meta-analysis, review, RCT

The 872 literature references returned were then reviewed on the basis of their abstracts; non-relevant literature references were identified and excluded. The parameters for exclusion were: Case reports; studies not related to implant therapy; general, non-dental analyses; theoretical studies not related to clinical practice. For all literature references with (possibly) relevant content, the respective publication was obtained as full text.

The methodology of the BDIZ EDI Guideline as compared to the classification of guideline levels should be rated as "consensus development in informal procedure". Therefore, the selection principle was to ensure that the most recent publications for each topic area were to be included. During the ensuing discussions, further publications that had not been considered initially were added. The objective was to develop clinically relevant recommendations, taking into account the practical experience of the various European participants.

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Update: ceramics in implant dentistry

2. Definitions

One-piece ceramic implants are made from ZrO_2 ceramics with integrated abutments for the retention of crowns, bridges and overdentures.

Two-piece ceramic implants feature a separate implant body and an abutment. The implants may be designed for transgingival or subgingival healing with an inner geometry that stabilizes the abutment by cementation or screw fixation.

Ceramic abutments are used in one piece for insertion into ceramic implants. Two-piece abutments consisting of a ceramic core that is adhesively cemented to a titanium insert are generally used for titanium implant-supported rehabilitations.
Furthermore, one-piece ceramic abutments are available for titanium implant-supported rehabilitations.

Ceramic superstructures can be fabricated as fixed dental prostheses (single-tooth restorations, short- or wide-span implant-supported bridges) using conventional processing methods or CAD/CAM technology.

3. Immunological/biological interactions

- Intolerance/allergies to titanium particles/ions from titanium implants are rare. However, there is a need for controlled and validated studies **[2, 11]**.
- Commercially available implants placed according to the manufacturers' Instructions for Use achieve osseointegration and good soft-tissue biocompatibility with high levels of clinical success **[1, 9, 13, 27, 28]**.

4. Implants

4.1. One-piece implants

- One-piece ceramic implants are available in different designs – parallel-walled or with a flare for immediate-extraction cases **[19, 27]**.
- The risk of implant fracture is low for current commercially available implants **[6, 27]**.
- Overload damage during the early healing period can be avoided by protective guards, by splinting or by eliminating functional loads on the temporary restoration **[5, 8, 10, 16]**.

4.2. Two-piece implants

- Various types of ceramic abutment connections are available, such as adhesive cementing or screw retention with or without an inner metal core **[17, 30]**.
- Fixation of abutments requires a specific protocol according to the manufacturers' Instruction for use **[31]**.
- Scientific evidence for two-piece implants is rare **[7, 15, 20]**.

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5. Abutments

- The peri-implant soft tissue on ceramic abutments appears to provide a better shade match with the soft tissue around natural teeth compared to metallic abutments **[22]**.
- In patients with a thin tissue phenotype, ceramic abutments deliver more favourable aesthetic results than titanium abutments **[32]**.
- Experimental studies show a reduced biofilm adhesion on ceramics than on titanium **[3, 26]**.
- Ultimately, however, surface topography appears to be the primary determinant in the accumulation of biofilm rather than the choice of material **[14]**.
- Abutments for titanium implants should include an implant-abutment connection made of titanium (titanium insert) **[18]**.

6. Superstructures

- Long-term data show remarkable complication rates for implant-supported single crowns and bridges **[21, 23, 25]**.
- The use of monolithic ZrO_2 ceramics for superstructures material has been little studied (only few medium- or long-term data available) **[29]**.
- Frameworks made of ZrO_2 ceramics with a ceramic veneering have a relatively high incidence of chipping. Making these restorations requires attention to specific design principles and special training **[4, 12, 29]**.
- Due to recent developments in CAD/CAM technology, a better selection of materials and more extensive knowledge, improved long-term results can be expected for ceramic superstructures **[24]**.

7. Conclusion

Ceramics are available for all aspects of implant treatment. The implant surgeon and the restorative dentist must have appropriate training to identify the best possible therapy choose for each patient.

Cologne, 23 February 2021

Prof Joachim E. Zöller
Vice President

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8. References

1. Afrashtehfar KI, Del Fabbro M. Clinical performance of zirconia implants: A meta-review. J Prosthet Dent 2020; 123: 419-426.
2. Albrektsson T, Chrcanovic B, Molne J et al. Foreign body reactions, marginal bone loss and allergies in relation to titanium implants. Eur J Oral Implantol 2018; 11 Suppl 1: S37-S46.
3. Astasov-Frauenhoffer M, Glauser S, Fischer J et al. Biofilm formation on restorative materials and resin composite cements. Dent Mater 2018; 34: 1702-1709.
4. Bagegni A, Abou-Ayash S, Rucker G et al. The influence of prosthetic material on implant and prosthetic survival of implant-supported fixed complete dentures: a systematic review and meta-analysis. J Prosthodont Res 2019; 63: 251-265.
5. Balmer M, Spies BC, Kohal RJ et al. Zirconia implants restored with single crowns or fixed dental prostheses: 5-year results of a prospective cohort investigation. Clin Oral Implants Res 2020; 31: 452-462.
6. Bethke A, Pieralli S, Kohal RJ et al. Fracture Resistance of Zirconia Oral Implants In Vitro: A Systematic Review and Meta-Analysis. Materials (Basel) 2020; 13.
7. Borges H, Correia ARM, Castilho RM et al. Zirconia Implants and Marginal Bone Loss: A Systematic Review and Meta-Analysis of Clinical Studies. Int J Oral Maxillofac Implants 2020; 35: 707-720.
8. Borgonovo AE, Censi R, Vavassori V et al. Evaluation of the success criteria for zirconia dental implants: a four-year clinical and radiological study. Int J Dent 2013; 2013: 463073.
9. Bormann KH, Gellrich NC, Kniha H et al. A prospective clinical study to evaluate the performance of zirconium dioxide dental implants in single-tooth edentulous area: 3-year follow-up. BMC Oral Health 2018; 18: 181.
10. Chen J, Cai M, Yang J et al. Immediate versus early or conventional loading dental implants with fixed prostheses: A systematic review and meta-analysis of randomized controlled clinical trials. J Prosthet Dent 2019; 122: 516-536.
11. Chen X, Zhao Y. Genetic Involvement in Dental Implant Failure: Association With Polymorphisms of Genes Modulating Inflammatory Responses and Bone Metabolism. J Oral Implantol 2019; 45: 318-326.
12. de Souza Batista VE, Verri FR, Lemos CAA et al. Should the restoration of adjacent implants be splinted or nonsplinted? A systematic review and meta-analysis. J Prosthet Dent 2019; 121: 41-51.
13. Haro Adanez M, Nishihara H, Att W. A systematic review and meta-analysis on the clinical outcome of zirconia implant-restoration complex. J Prosthodont Res 2018; 62: 397-406.
14. Herrmann H, Kern JS, Kern T et al. Early and mature biofilm on four different dental implant materials: An in vivo human study. Clin Oral Implants Res 2020; 31: 1094-1104.
15. Janner SFM, Gahlert M, Bosshardt DD et al. Bone response to functionally loaded, two-piece zirconia implants: A preclinical histometric study. Clin Oral Implants Res 2018; 29: 277-289.
16. Jung RE, Grohmann P, Sailer I et al. Evaluation of a one-piece ceramic implant used for single-tooth replacement and three-unit fixed partial dentures: a prospective cohort clinical trial. Clin Oral Implants Res 2016; 27: 751-761.

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Update: ceramics in implant dentistry

17. Koller M, Steyer E, Theisen K et al. Two-piece zirconia versus titanium implants after 80 months: Clinical outcomes from a prospective randomized pilot trial. Clin Oral Implants Res 2020; 31: 388-396.
18. Lin YT, Shen YF, Wei PC et al. Clinical evaluation of two-piece zirconia abutments with bonded titanium inserts for implant-supported restorations. J Prosthet Dent 2020; 123: 449-454.
19. Oliva J, Oliva X, Oliva JD. Five-year success rate of 831 consecutively placed Zirconia dental implants in humans: a comparison of three different rough surfaces. Int J Oral Maxillofac Implants 2010; 25: 336-344.
20. Payer M, Heschl A, Koller M et al. All-ceramic restoration of zirconia two-piece implants--a randomized controlled clinical trial. Clin Oral Implants Res 2015; 26: 371-376.
21. Pieralli S, Kohal R-J, Rabel K et al. Clinical outcomes of partial and full-arch all-ceramic implant-supported fixed dental prostheses. A systematic review and meta-analysis. Clinical Oral Implants Research 2018; 29: 224-236.
22. Pitta J, Zarauz C, Pjetursson B et al. A Systematic Review and Meta-Analysis of the Influence of Abutment Material on Peri-implant Soft Tissue Color Measured Using Spectrophotometry. The International Journal of Prosthodontics 2020; 33: 39-47.
23. Pjetursson BE, Valente NA, Strasding M et al. A systematic review of the survival and complication rates of zirconia-ceramic and metal-ceramic single crowns. Clin Oral Implants Res 2018; 29 Suppl 16: 199-214.
24. Poggio CE, Ercoli C, Rispoli L et al. Metal-free materials for fixed prosthodontic restorations. Cochrane Database Syst Rev 2017; 12: CD009606.
25. Rabel K, Spies BC, Pieralli S et al. The clinical performance of all-ceramic implant-supported single crowns: A systematic review and meta-analysis. Clin Oral Implants Res 2018; 29 Suppl 18: 196-223.
26. Roehling S, Astasov-Frauenhoffer M, Hauser-Gerspach I et al. In Vitro Biofilm Formation on Titanium and Zirconia Implant Surfaces. J Periodontol 2017; 88: 298-307.
27. Roehling S, Schlegel KA, Woelfler H et al. Performance and outcome of zirconia dental implants in clinical studies: A meta-analysis. Clin Oral Implants Res 2018; 29 Suppl 16: 135-153.
28. Roehling S, Schlegel KA, Woelfler H et al. Zirconia compared to titanium dental implants in preclinical studies-A systematic review and meta-analysis. Clin Oral Implants Res 2019; 30: 365-395.
29. Sailer I, Strasding M, Valente NA et al. A systematic review of the survival and complication rates of zirconia-ceramic and metal-ceramic multiple-unit fixed dental prostheses. Clin Oral Implants Res 2018; 29 Suppl 16: 184-198.
30. Spies BC, Fross A, Adolfsson E et al. Stability and aging resistance of a zirconia oral implant using a carbon fiber-reinforced screw for implant-abutment connection. Dent Mater 2018; 34: 1585-1595.
31. Stimmelmayr M, Lang A, Beuer F et al. Mechanical stability of all-ceramic abutments retained with three different screw materials in two-piece zirconia implants-an in vitro study. Clin Oral Investig 2020; 24: 1801-1806.
32. van Brakel R, Noordmans HJ, Frenken J et al. The effect of zirconia and titanium implant abutments on light reflection of the supporting soft tissues. Clin Oral Implants Res 2011; 22: 1172-1178.

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The 22nd Curriculum Implantology has ended

Congratulations to the graduates!

The 22nd Curriculum Implantology of BDIZ EDI and the University of Cologne ended in July 2021 with a final examination. Prior to this, the participants had completed eight modules in the field of oral implantology over a one-year course.

The courses represented a high organizational effort in light of the ongoing corona pandemic. They took place partly online and partly divided into small groups and separated spatially.

The 22nd Curriculum Implantology of the two cooperation partners BDIZ EDI and the University of Cologne has been a long success story. Since 2004, around 600 graduates have received oral implantology training.

"In addition to theoretical presentations, practical demonstrations and first-hand experience during practical exercises or patient treatment are also important for the knowledge transfer," explained Professor Joachim E. Zöller, Director of the Clinic and Polyclinic for Dental Surgery and Oral and Maxillofacial Plastic Surgery in 2004. The Vice President of the BDIZ EDI was and is responsible for the implementation of the teaching objectives and content and has proven over the years that this path has been successfully followed.

Eight modules = one curriculum

Today, the curriculum offers eight modules in two-day courses with observation and supervision by experienced instructors. The goal is to ensure practical relevance.

Therefore, the teaching modules are also subject to constant thematic updating. After successful observation and supervision, the examination for the "Implantology specialization" can be taken if the participant has the necessary experience.

No closed-shop policy

The modules can be booked separately and already completed modules from other providers can also be integrated on request. Professor Hans-Joachim Nickenig, who took over the implementation of the curricula a few years ago and modernized the teaching content, is the contact person for all participants.

The speakers

The instructors have been working in implantology for years and have presented the teaching units with videos and live patient demonstrations. A practical part is included in each course, mostly using realistic practice models or human specimens instead of the usual plastic jaws. "The teaching units always convey the interrelationships between prosthetic and surgical aspects, even if the main topics focus on one or the other specialty," says Zöller. "Due to a limited number of participants – both the BDIZ EDI and the cooperation team of the university attach importance to this – the intensive exchange of experiences with the speakers is guaranteed."

RED/AWU

The successful graduates of the 22nd Curriculum Implantology at the University of Cologne with their instructors Professor Joachim Zöller and Professor H. J. Nickenig.

Start of the 23rd Curriculum Implantology

The 23rd Curriculum Implantology starts in October 2021. Due to the great demand, BDIZ EDI and the University of Cologne have set up a second group. Therefore, it is still possible to register at the BDIZ EDI office: office@bdizedi.org

Further information is available on the BDIZ EDI website: www.bdizedi.org

The eight modules of the next BDIZ EDI Curriculum Implantology

Module 1

Fundamentals of oral implantology

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

+ external speakers

Module 2

Indications, diagnosis and treatment planning

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

Workshop I: *Surgical and prosthetic protocols*

+ external speakers

Module 3

Implant systems, instruments, advanced diagnosis

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

Workshop II: *3D workshop with interactive planning*

Demonstration of different instrument sets

Case presentations by participants I

Module 4

Implant prosthetics I and minimally invasive surgery

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

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

Modified bone splitting using Piezosurgery

Case presentations by participants II

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

Module 5

Augmentation I: Regional bone augmentation

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

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

Exercise in customized bone regeneration

Case presentations by participants III

+ external speakers

Module 6

Implant prosthetics II and soft-tissue management

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

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

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

Case presentations by participants IV

Written examination

Module 7

Augmentation II: Bone grafting and distraction

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

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

+ external speakers

Case presentations by participants V

Module 8

Recall – Coping with complications – Future perspectives

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

+ external speakers

Final exam

Steinbeis University Berlin

Professorship for Jörg Neugebauer

Jörg Neugebauer, a specialist in oral surgery from Landsberg am Lech, Germany, has been appointed Professor of Digitization in Dentistry at Steinbeis University Berlin on 1 March 2021. Neugebauer has been active on the board of BDIZ EDI for many years and is especially responsible for the Qualification (Quality) and Register Committee (Q&R Committee), which is in control of quality management in the practices and of material testing.

Professor Günter Dhom, member of the academic senate, awarded the certificate of appointment on 30 July 2021, on the examination module of the master's program in implantology and periodontology. In his lively and entertaining inaugural lecture, Professor Neugebauer highlighted the various aspects of the digitalization in dentistry based on his extensive practical experience and his scientific activities to date.

Jörg Neugebauer was awarded the venia legendi for dentistry and oral and maxillofacial surgery in 2009 for his habilitation thesis on "Design and Treatment Parameters for the Successful Immediate Restoration of Dental Implants". He has worked at the University of Cologne since 2001. There, he first successfully completed his residency for oral surgery and laid the scientific foundations for his habilitation. Prior to this, Neugebauer worked for many years in the dental industry, most recently as Head of Product Development and Clinical Research in a renowned company.

Professor Jörg Neugebauer receives the certificate of professorship from Professor Günter Dhom.

While the beginning of his scientific work at the University of Cologne was mainly the experimental research to validate individual implant systems for special indications – such as immediate loading – the scientific work concentrated on the comparison of different implant systems and in particular on the reliability of the respective products.

The results of these studies have been published regularly in the two journals of the BDIZ EDI: in the German-speaking countries in "BDIZ EDI konkret" and throughout Europe in the English "EDI Journal". The "Comparison of the torque accuracy of different dental surgical units in implantology" and the "Comparison of the torque accuracy of implantological hand ratchets" – to name two research papers – received a great deal of attention among experts.

He was an early follower of digitization in dentistry. While working in the dental industry, he supervised a project on radiological data management in implantology, but at the time, this was way too far ahead of its time. In Cologne, Professor Zöller's working group was intensively involved in three-dimensional diagnostics using DVT, so that Neugebauer was able to present various surgical techniques with digital surgical preparation – not only in implantology. His work in the dental practice has also led him to pursue the optimization of the documentation system for running a paperless practice, so that the 100 employees at two locations can now successfully use digital techniques for routine patient care.

In addition to his clinical activities, he is well known as an international speaker and scientist, now successfully supervising over 60 PhD students

and quite a few Masters students. Next year, he will chair the Academy of Osseointegration Summit 2022 in Chicago.

For many years, Professor Neugebauer has been preparing in the BDIZ EDI the contents of the expert symposia in Cologne together with Professor Joachim E. Zöller, as well as the consensus papers, which have been published every year since 2006 as practice guidelines on a current issue in implant surgery and implant prosthetics. He also moderates the European Consensus Conference (EuCC), which discusses and consents this working paper.

As head of the scientific advisory board, he evaluates the submitted scientific articles for the editorial team of "BDIZ EDI" konkret and "EDI Journal".

AWU

On the occasion of the 75th birthday of Dr Hans-Jürgen Hartmann, Chairman of the BDIZ EDI from 1993 to 2000

Co-founder of the BDIZ

Dr Hans-Jürgen Hartmann was Chairman of BDIZ from 1993 to 2000 and was also one of the founding members of the professional organization. On the occasion of the former chairman's 75th birthday on 19 July 2021, President Christian Berger expressed his thoughts in a personal letter.

Dear colleague Dr Hartmann,

More than 30 years ago you co-founded the BDIZ. Without the will and the assertiveness of the nine founding colleagues, the association would not have achieved that implantology – in addition to scientific recognition – quite quickly gained the professional political significance that characterizes it to this day. We were and still are serious partners for various German federal ministries, for private health insurers, for dental bodies and now also for institutions on the EU level. Whenever the interests of dentists working in implantology are affected, we get involved. This was the case under your auspices, and we are continuing that legacy.

As a founding member and as chairman in the years 1993 to 2000, you stood up for structured implantology continuing education, for quality in implantology, for a high standard of expertise, for dentists with specialized training in implantology, for the enforcement of implantology as a focus of activity at the German Federal Constitutional Court – and not to forget: for performance-based remuneration.

I am very glad that you have faithfully supported our association over all these years. As a founding member, you helped shaping the BDIZ's stormy beginnings and, as chairman, you steered the association in the right direction. I can assure you that we have taken this as a mandate to continue to stand up courageously and innovatively for the interests of dentists working in implantology, despite paternalism from politics and business.

He was one of nine like-minded colleagues who met in Frankfurt/Main, Germany, 32 years ago to give implant dentistry a political voice: Dr Hans-Jürgen Hartmann is a founding member of the BDIZ EDI and was chairman of the association from 1993 to 2000, when the BDIZ was not yet Europe-oriented.

On behalf of the Board, I wish you good health, joie de vivre and continued enjoyment for our profession. Do celebrate in the circle of your loved ones, the BDIZ EDI celebrates in spirit with you!

Happy birthday and many more years of beautiful life!

Yours sincerely
Christian Berger
President

30th Anniversary: The Expert Symposium for Regenerative Dentistry

Review and preview on oral implantology

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

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

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

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

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

Lots of workshops in Fuerteventura

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

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

Travel organization and registration

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Lectures, workshops and hands-on in a relaxed atmosphere

16th Experts Symposium: Fuerteventura instead of Cologne

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

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

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

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

Cases are also discussed with the speakers during the breaks

Relaxing after an interesting day of training

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

Full house during Professor Joachim Zöller's lectures.

Interview with Dr Tröltzsch on sinus lift

Large approaches belong to the realm of myths

The elevation of the maxillary sinus floor in the upper jaw – sinus lift for short – requires biological and anatomical knowledge. In this interview, Ansbach, Germany based oral and maxillofacial surgeon Dr Markus Tröltzsch discusses methods and materials for this technique.

Dr Markus Tröltzsch, dentist and maxillofacial surgeon

Dr Tröltzsch, you mention in your lecture for the BDIZ EDI that during the sinus lift, some things can backfire. What do you mean by that?

There is a lot of advertising on social media that gives the impression that the sinus lift is a simple procedure where you just "push in" a bit or everything succeeds anyway due to maximally large approaches. But this is far from the truth. Complications can certainly occur during a sinus lift and, of course, sometimes things may go wrong for me, too.

Therefore, I wanted to present in my lecture the risks that the sinus lift can entail. The outcome is determined by the interaction between the surgeon and the patient, the surgical skills of the practitioner, the self-assessment, the materials and planning, and on the other hand the diseases, the compliance and the financial willingness of the patient. In the end, it is the case assessment that counts.

Which are the risk factors the practitioner should or must necessarily consider?

Obviously, the medical aspect must be considered when assessing a case. There are many factors that can play a role here: antiresorptives, radiation, metabolic diseases, smoking or whether periodontitis or peri-implantitis are present.

It is also essential to consider the anatomical aspect. There is a defect – and the fewer walls the area has, the higher the regenerative effort and the higher the demands on the skill of the surgeon. With the sinus lift or the reconstruction of the alveolar ridge in the maxilla, if we allow the skeletal envelope, i.e. the soft tissue, to collapse, the effort will be correspondingly higher.

Many posts on social media in the category sinus lift show a large opening of the sinus wall for a better view. How do you rate this aspect?

It's a myth that you must tear big holes in the bone wall to get a good view and then just push something in from the side. If we consider the biology of healing, we need as many limitations as possible. So, it makes no sense to expand the access to the maximum. On the contrary, the smaller the access to the sinus, the more stable the prognostically achievable result, the better the patient's healing and the greater the bony healing tendency.

However, this of course varies from case to case, and sometimes a large approach may be necessary. Interestingly, healing problems very often occur in

the area of the window. In the sinus lifts I've already done this year, I haven't had a single case where a problem developed in the area where I remained in the bony tissue. An infection, a dehiscence, a wound healing disorder always develops where the facial wall is missing. The defect should be big enough so that we can operate well and safely, but not larger.

In your lecture, you discuss anatomy in detail. What should be considered in the anatomy of the maxilla?

If we look at the sinus' anatomy, we notice that the vestibular and palatal bones are often actually not equally high. This means that we are led to believe that the alveolar ridge is higher on the X-ray than it actually is. Regarding the structures we are confronted with during the sinus lift: there are several areas where we can "meet" relatively large caliber vessels – up to the facial artery.

But even the smaller vessels can cause us problems, because they can hardly be closed. Because they are embedded in the bone, they cannot be ligated. We can reach them poorly and must try to seal them somehow.

The vessels of Schneider's membrane can cause us even more problems. There are effects that almost seem like corona mortis. If we encounter a massive venous plexus in the Schneider's membrane and do not recognize it in time in order to cauterize or ligate it, hemorrhages in the maxillary sinus that are difficult to control can occur. Therefore, my appeal is to create sinus defects only in the size that we actually need for a safe sinus lift – by this, I do not mean a mini keyhole, but opening up the entire sinus laterally is dangerous from an anatomical point of view and often fraught with complications with regard to the wound healing result.

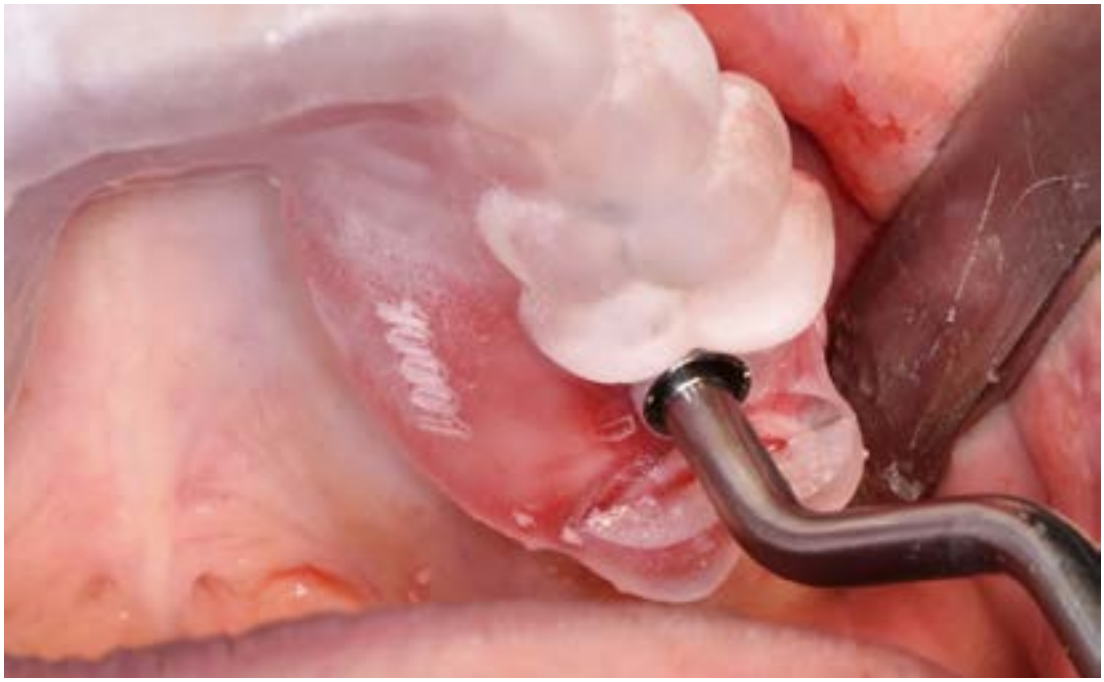
Which bone substitutes work, which do not and what about autogenous bone?

On this question I refer to the S2k Guideline for Germany regarding the implantological indications for the use of bone substitute materials. The sinus lift is described as follows: "When performing a sinus lift, the practitioner can use all available materials and techniques with comparable success rates. In a two-stage procedure, a bone substitute with resorption stability may be advantageous."

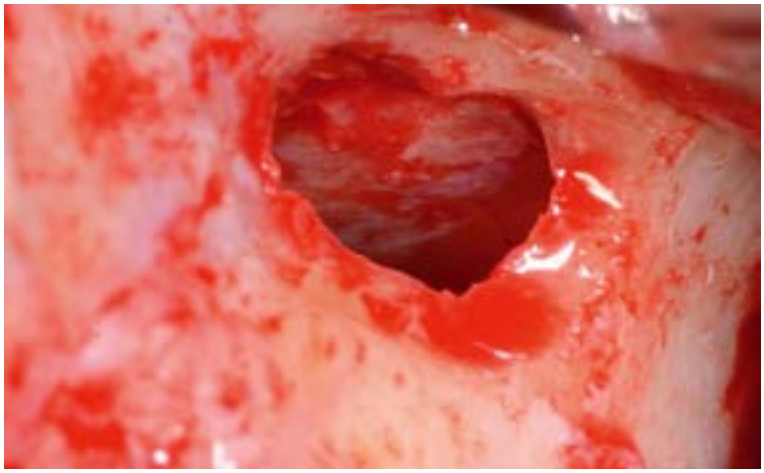
In my opinion, it is completely irrelevant for the survival of the implants whether we implant in a pure bone substitute sinus lift or in a sinus lift with a mixture of autogenous bone chips. However, since lateral co-augmentation is often performed, the bone chips are very important to me. I personally do not see any indication for purely autogenous sinus lifts because we have to create an additional harvesting defect.

Let's move on to the technique. When is the internal sinus lift indicated?

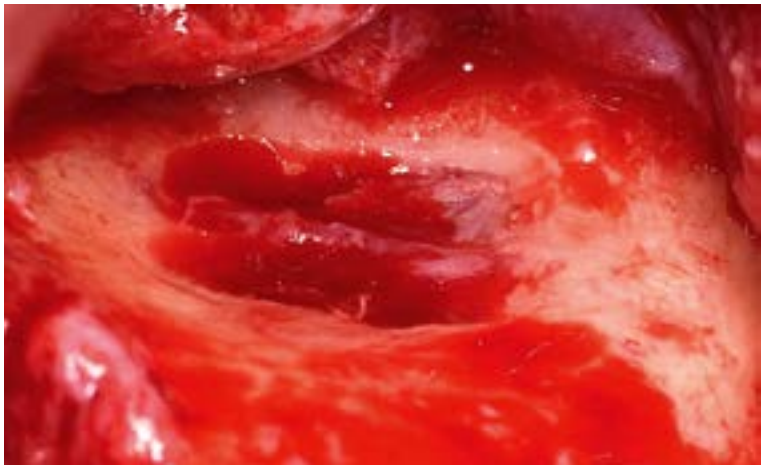
An example: we have a well-developed alveolar ridge after ridge preservation. A guided implant placement, e.g. implant length of 10 mm, is to be performed and we have only 8.5 mm bone height.



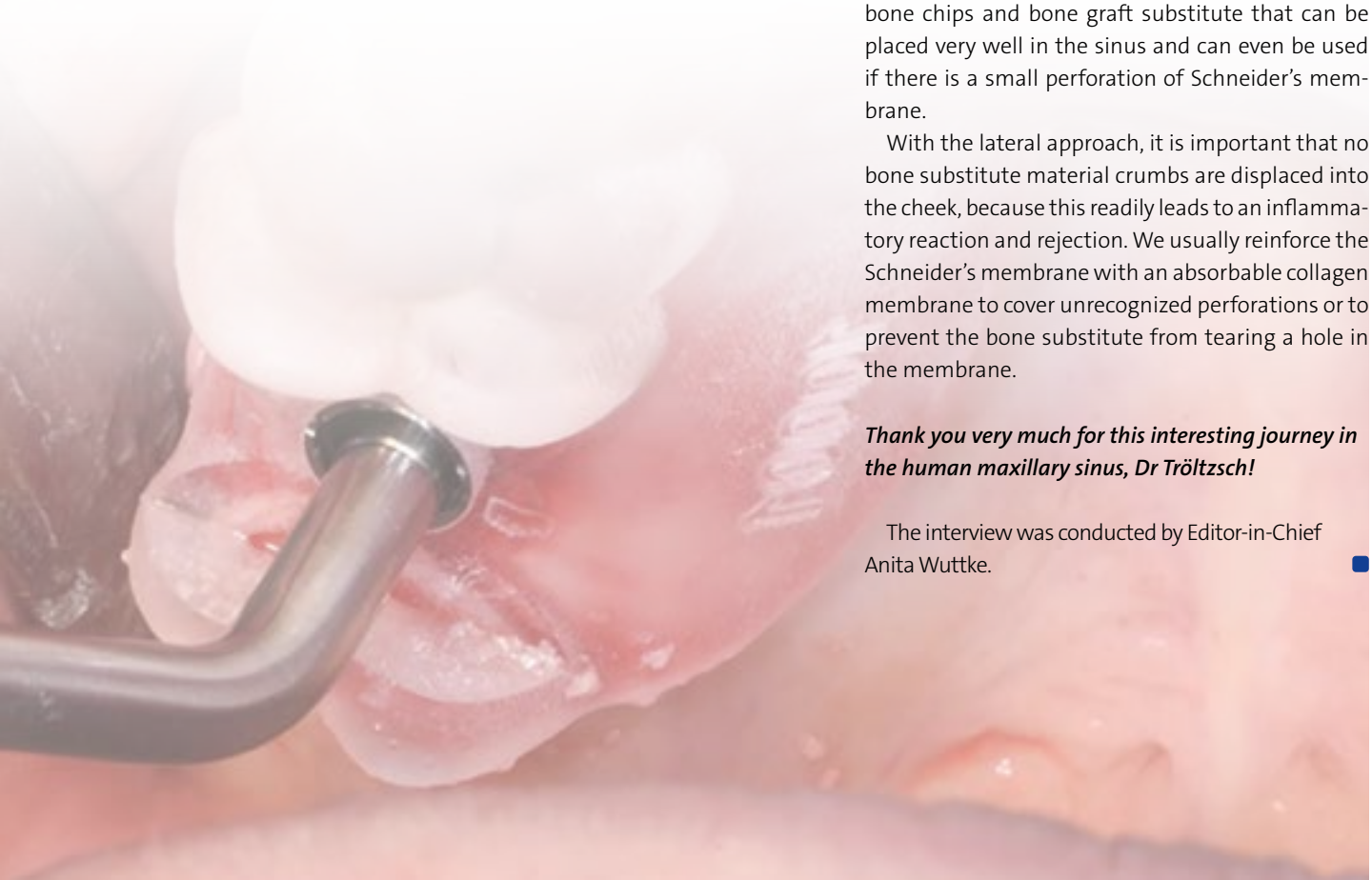
Internal sinus lift with the aid of the guided template during implantation



Classic window in the lateral sinus wall, made with a safescraper and finished with a diamond bur



Complication source: intraosseous vessel of the lateral sinus wall



For me, that is the indication for an internal sinus lift. With this procedure, we basically just push the maxillary sinus floor and Schneider's membrane cranially. The advantage of the internal sinus lift is: it runs with the implantation. The disadvantage is: it is done without visibility. If I use a hammer for this, as suggested in some textbooks, the patient will usually not be happy about this and the control whether Schneider's membrane is not perhaps damaged is very limited. Therefore, the internal sinus lift is a technique that we use to gain 1 to 2 mm extra. It is not predictable for larger augmentation. What length is sufficient for implants in the maxilla is another matter for discussion.

How do you perform the "real" sinus lift with lateral approach?

In our practice, we no longer use the classic methods of creating a window with the piezo tool or working with the bur because it causes bone chip loss. As stated in the above guideline, we know that it is beneficial to mix our bone graft substitute with bone chips.

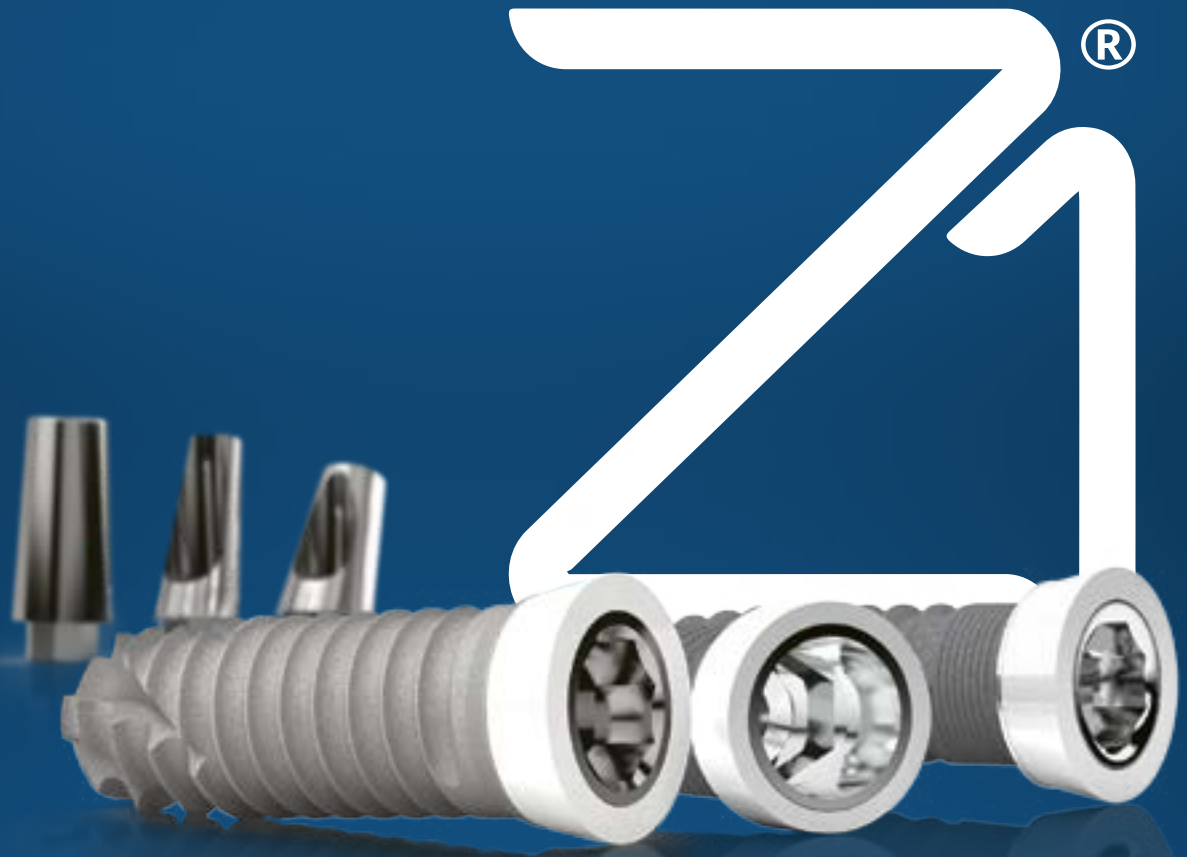
Thus, we visualize the facial wall of the maxillary sinus and prepare the access up to Schneider's membrane with an instrument that can be used to collect the bone chips, e.g. the safescraper.

With the large amount of autogenous bone chips – which we can mix with PRF if it is available – and otherwise just with the bone graft substitute, we then obtain something very useful like the sticky bone, which is a cohesive mixture of autogenous bone chips and bone graft substitute that can be placed very well in the sinus and can even be used if there is a small perforation of Schneider's membrane.

With the lateral approach, it is important that no bone substitute material crumbs are displaced into the cheek, because this readily leads to an inflammatory reaction and rejection. We usually reinforce the Schneider's membrane with an absorbable collagen membrane to cover unrecognized perforations or to prevent the bone substitute from tearing a hole in the membrane.

Thank you very much for this interesting journey in the human maxillary sinus, Dr Tröltzsch!

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



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Because of a strict hygiene concept there will be no close get-together as in former years. But Board members will be available to answer all the questions and a big flat-screen TV will show BDIZ EDI can support implant dentists.

39th International Dental Show in Cologne from 22 to 25 September 2021

Meeting point implantology

Training and education are top-notch. Like a well-trained avalanche dog, BDIZ EDI tracks down what is missing from the practice of oral implantology in terms of (continuing) education and European networking among dentists. Meet the "activists" behind the scenes – at the stand of BDIZ EDI at the IDS 2021 in Cologne (Hall 11.2, Stand O 61).

"Our Meeting Point Implantology is designed to bring together the different types of competence and skills and to showcase the support which BDIZ EDI can offer oral implantologists", says BDIZ EDI President Christian Berger. This includes the "We want you" campaign, aimed at young professionals – including the proven Curriculum Implantology, whose individual modules can be combined as needed by dentists interested in the field.

New Guideline of the European Consensus Conference: "Update Ceramics in Implantology"
At the end of February 2021, the European Consensus Conference (EuCC) under the auspices of BDIZ EDI met online due to the pandemic. The result: Our 16th Guideline is ready; this year's topic is about dealing with ceramics in implantology to include implants, abutments and suprastructures.

Get the new publications

There are not only the two outstanding magazines on implant dentistry available at the stand but also all new papers, just like the Quality Guideline, the guideline 2021 on Update ceramics in implantology, implant maintenance brochure and many more.

International visitors come to the BDIZ EDI stand – not only for small talk

At IDS, the consensus paper will be available hot off the press; it is published in German and English. The previous Guidelines on immediate loading (2006), ceramics as an implant material (2007), peri-implantitis (2008), three-dimensional imaging (2009), complications (2010), short and angulated implants (2011), the Cologne ABC Risk Score for implant treatment (2012), the Cologne Classification of Alveolar Ridge Defects (CCARD) (2013), avoiding the malpositioning of implants (2014), treatment of peri-implant inflammation (2015), short, angulated and diameter-reduced implants (2016), digital workflow in implant dentistry (2017) and last year's paper on patient-oriented treatment concepts in oral implantology can be downloaded from www.bdizedi.org.

Common congress in Cologne

Coming up next is the 17th Expert Symposium of BDIZ EDI in Cologne in February 2022. Visitors of the BDIZ EDI stand will receive information about the agenda and the side programme. Cologne is worth visiting and synonymous with culture and of course the famous carnival.

Questions? We like to provide answers!

Of course, the BDIZ EDI board will be present on site: Presidents Christian Berger and Professor Joachim E. Zöller, Treasurer Dr Wolfgang Neumann, Secretary-General Dr Detlef Hildebrand and Secretary and Managing Director Dr Stefan Liepe as well as the entire team.

AWU

Don't miss BDIZ EDI
in Hall 11.2, Row O, Stand 61

BDIZ EDI at IDS 2021: Programme 22 to 25 September 2021

Wednesday, 22 September 2021
EU regulations

- Information on the MDR
- EU legislation on medicinal products and EU directive on the recognition of professional qualification
- BDIZ EDI's work in the EU committee

Thursday, 23 September 2021
Postgraduate education and quality in implantology

- BDIZ EDI's continued education, symposiums, workshops, and curricula
- BDIZ EDI's new guidelines of the European Consensus Conference (EuCC)
- Indication classes of the Consensus Conference Implantology
- BDIZ EDI's quality guideline
- The BDIZ EDI online seminars

Friday, 24 September 2021
Meet the Board of BDIZ EDI

- Special day for international guests

Saturday, 25 September 2021
We want you!

- Benefits for European members of BDIZ EDI
- Meet the Experts

Certification as an EDA Expert in Implantology

Qualification for experienced implantologists

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

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

Admission requirements for the certification exam

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

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

Specific experience and primary activity in the field of implantology must be documented by at least 400 implants inserted and 150 implants restored within the past five years. Candidates who already obtained qualifications in oral implantology (e.g. from other professional societies) may submit the appropriate credentials with their application for certification as EDA Expert in Implantology.

The exam

Candidates meeting all the requirements will be admitted to the examination. The examination board of BDIZ EDI and EDA consists of recognized specialists. The exam has a theoretical and a practical part, both of which must be completed successfully.

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

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

AWU

More information

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

European Association of Dental Implantologists

Applicant's address:

Full name _____

Full address _____

_____

_____

E-mail _____ Date _____

Forward by mail or fax to:

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

office@bdizedi.org
Fax: +49 2203 9168822

Certification exam: EDA Expert in Implantology
Application for accreditation

I hereby apply for the EDA Expert in Implantology certification exam (EDA = European Dental Association).

I am qualified for this exam as defined below:

Member of BDIZ EDI ☐ yes ☐ no

Member of the following Societies/Associations: _____

I am: ☐ a dental clinician ☐ an oral surgeon ☐ a maxillofacial surgeon

I meet the training requirement of 250 hours of postgraduate education. ☐ yes ☐ no

Education and experience:

Surgery:

Inserted implants: ☐ less than 400 ☐ more than 400

Sinus lift: ☐ yes ☐ no

Close to nerve: ☐ yes ☐ no

Advanced atrophy of the jaw: ☐ yes ☐ no

Soft-tissue augmentation: ☐ yes ☐ no

Bone augmentation: ☐ yes ☐ no

Prosthodontics:

Implant-supported restorations: ☐ less than 150 ☐ 150 or more

During the exam, I will be able to present documentation for 10 treatment cases. ☐ yes ☐ no

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

_____ _____

Applicant's signature Date

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

The commercial processing of your personal data on this form is based on the EU General Data Protection Regulation (GDPR – Regulation (EU) 2016/679 of 27 April 2016), Article 6 f GDPR by the European Association of Dental Implantologists (BDIZ EDI), Mühlenstr. 18, D-51143 Cologne/Germany. You have the right to obtain information about personal data concerning you (Article 15 of the GDPR). You can also request the correction (rectification) of incorrect data (Article 16 of the GDPR). More information: Privacy Statement on www.bdizedi.org.

Europe Ticker +++

UK AND CORONAVIRUS

Infections rise again

New coronavirus infections reached 32,181 end of August and 50 deaths were recorded. In comparison, there were 26,476 new positive cases one day before and 48 deaths in 24 hours. There was a delay noticed, said the Standard, before the latest coronavirus data was made available to the public on the official website. As a further 50 people died in 24 hours, it took the UK death toll total to 132,535. Separate figures published by the Office for National Statistics show there have been 156,000 deaths registered in the UK where COVID-19 was mentioned on the death certificate. Besides this, Italy has dropped quarantine for vaccinated British travellers.

Source: The Standard

Effects of soda on teeth

Pop causes cavities?

Soda tends to contain a lot of sugar with no significant nutritional benefit, according to 2017 researchTrusted Source, and drinking too much is often linked to obesity. An occasional soda might not be a big deal, especially if followed up with some water to rinse the mouth, says Healthline, an oral health platform dedicated to supporting the understanding of oral health issues in easy to understand language. Drinking a lot of pop, teeth may pay the price. Teeth are vulnerable to sugars in all the foods and beverages that people are consuming. Even after one swallows a mouthful of soda, the sugary residue remains behind on (and in between) the teeth. The bacteria in the mouth sense the bounty of sugar and begin feeding on it. They do this by producing acids that basically attack the teeth. Over time, these acids can wear away at the enamel on teeth. This erosion can make the enamel thinner and more vulnerable. Weaker enamel can lead to more cavities, according to a 2015 studyTrusted Source. It can even expose part of the dentin, the sensitive middle layer of the tooth that covers the pulp at the center. According to the American Dental Association ADA, a dental sealant is a thin coating that attaches to the surface of your back teeth and can help keep cavities from forming.

The same 2015 animal studyTrusted Source that suggested regular fluoride treatments for people who are more vulnerable to cavities also recommended dental sealants on teeth, especially on the molars.

Source: healthline.com

Photo: Jaime Perez/Pixabay

International study shows the impact of pandemic

Huge decrease in organ transplants

The number of solid organ transplants fell dramatically around the world between 2019 and 2020, researchers have found, highlighting the widespread impact of the COVID-19 pandemic on health services and patients. As the pandemic surged, hospitals were forced to delay potentially life-saving organ transplant surgery, because of resources such as intensive care beds being needed for COVID patients and because of concerns including whether it was safe to treat transplant recipients in hospital. Now an international study, published in the journal Lancet Public Health and presented at the European Society for Organ Transplantation (Esot) congress 2021, has showed the overall number of kidney, liver, lung, and heart transplants from human donors fell by 31 % during the first wave of COVID-19 across 22 countries. The overall drop was almost 16 % by the end of 2020, with more than 11,200 fewer transplants carried out. "Temporal trends revealed a marked worldwide reduction in transplant activity during the first three months of the pandemic, with losses stabilising after June, 2020, but decreasing again from October to December 2020," the team wrote. The study looked at the number of the transplants carried out in each country until the end of 2020, starting from

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the point in the year at which 100 COVID cases were confirmed. These figures were then compared with those for the same time period the year before. ›› The results showed that the impact of the pandemic varied across countries: while there was a 9.86 % overall drop in the number of organ transplants carried out in Canada during that period, corresponding to 227 fewer transplants; there was a 66.71 % drop in Japan, where 1,413 fewer transplants were carried out. Kidney transplants were the most affected, with a 19.14 % decrease when all 22 countries were taken together, corresponding to 8,560 fewer transplants. The team said this was "probably due to the non-immediate life-saving nature of this surgery and the possibility to postpone procedures". Researchers said that while some countries experienced large reductions in transplant numbers others did not even though hard hit by COVID, meaning further analysis is required on a regional, national and global level to understand the differences.

Source: Guardian, UK, Lancet Public Health

FDI World Dental Federation

Word Dental Congress 2022 in Mumbai

FDI World Dental Federation (FDI) looks forward to welcoming all attendees to Mumbai, India, for the 2022 FDI World Dental Congress (WDC) from 29 September to 2 October. FDI is delighted to co-host this meeting jointly with its member, the Indian Dental Association. Held under the theme 'Reunite and Rebuild Dentistry in the City of Dreams', the Congress aims to, finally, bring delegates together in a face-to-face WDC after two years of disruption to in-person networking and learning opportunities. The WDC is a flagship continuing-education event for FDI, strengthening ties and fostering collaboration within the global oral health community. The 2022 WDC offers a unique opportunity to meet with leaders within the oral health profession from around the globe. To advance the art and science of dentistry, this congress will deliver a cutting-edge scientific program, interactive forums, and a dental exhibition attended by the most prominent figures in the dental industry. The dental profession and the dental industry are essential partners in delivering oral health to populations around the world. Bridging the gap between the two is even more important today, as new materials and technology are developed to accommodate the latest treatment philosophies.

Source: FDI

Photo: Jaskaran Singh/Pixabay

WHO on diabetes care

Dialogue with the private sector

The World Health Assembly resolution endorsed, in May 2021, marks an historic milestone in collective efforts to address the global diabetes epidemic, which urges member states to raise the priority given to the prevention, diagnosis, and control of diabetes as well as the prevention and management of risk factors such as obesity (WHA74). Another milestone is the establishment of the Global Diabetes Compact (GDC), which provides an opportunity for the global diabetes community to come together to address the barriers in accessing insulin and its associated health technologies. WHO is convening biannual private sector dialogues with representatives from international business associations, and the pharmaceutical and health technology industry. The dialogues focus on mobilizing commitments and contributions by the private sector toward the noncommunicable diseases (NCDs) response on NCDs to achieve SDG target 3.4, 3.8 and 3b. The first meeting took place in February 2021 and focused on access to insulin and its associated health technologies for diabetes. The second, begin of September 2021 focused on the same topic. Further meetings planned for 2022 will address the other major noncommunicable diseases (cardiovascular disease, cancer, lung diseases, oral health, rehabilitation, sensory impairments and disability). The dialogue will encourage inputs and confirm commitments and contributions from pharmaceutical and the associated technology product industry to support WHO's activities to strengthen and improve access to medicines and technologies for diabetes, including achievements possible by December 2021.

Source: WHO

17th EXPERT SYMPOSIUM OF BDIZ EDI

SAVE THE DATE

RISK FACTOR PERIODONTAL DISEASES

Tooth preservation or implantology

Update of the Guideline: Cologne ABC Risk Score

Sunday
27th February 2022

Dorint hotel | Pipinstr. 1 | 50667 Cologne

IMPLANTOLOGY &
CARNIVAL IN COLOGNE

BDIZ EDI
Bundesverband der implantologisch tätigen Zahnärzte in Europa e.V.
European Association of Dental Implantologists

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How the MDR affects clinical innovation and niche products

Back to the Stone Age

The Medical Device Regulation (EU) 2017/745, or MDR for short, has been binding on medical technology companies since 26 May 2021. Improving patient safety while facilitating innovation was what this regulatory framework intended. But physicians and dentists sometimes have a very different experience. Four of them reported for us what the Regulation means in their environment, describing their ideas, their hopes and, above all, their disappointments.

Professor Brigitte Stiller is medical director at the Clinic for Congenital Heart Defects and Paediatric Cardiology at the University Cardiological Centre Freiburg-Bad Krozingen in Germany. Calmly and soft-spoken, the paediatric cardiologist and intensive-care specialist describes how her team performs cardiac catheterization procedures even on newborns. Even premature babies weighing only two kilograms can have special cardiac catheters inserted in their blood vessels – barely two millimetres in diameter! – from the groin or neck and advanced all the way to the heart. How carefully the groin must be approached for insertion in order not to jeopardize the leg's arterial blood supply. How fraction-of-a-millimetre precision is required when operating on young hearts to successfully burst open closed valves or to keep vital vascular connections or critical-vessel stenoses open for an extended time using individually dimensioned stents. How life gets a second chance before it has really begun.

Ingenious developments

Stiller weighs her words with the same care she uses when treating her little patients. But her tone changes to raptures as she starts talking about neonatal stents. She and her team developed, together with a medium-sized medical technology company, a vascular support that grows with the patient. Previously, stents had to be removed and replaced after a few years in major open-heart surgery using a heart-lung machine. The novel baby stents, by contrast, are inserted through a femoral artery and can still be dilated with a balloon after several years, depending on the child's physical development. "The flexible hook-and-loop mechanism is ingenious. It was specially developed for very small babies to give them a gentle start in life", says Stiller, adding that this could thus make the initial intervention much easier. Could reduce the number of risky follow-up interventions. Could increase the chances of survival. "Could." Stiller has to stay with the subjunctive. Although multicentre studies have been approved, the company's downstream cost is no longer commensurate with potential revenue. Further development has been halted. "Neonate stents aren't mass-market products. They will be used for just a handful of procedures every year", Stiller reminds us, her voice back in matter-of-fact mode. But every one of her syllables breathes deep disappointment. "It's a shame we can't make this work."

Patient "protection" at the expense of patient and treatment safety

The MDR has been binding since 26 May 2021 after a four-year transition period, which had been extended because of COVID-19. Under the MDR, it takes much more time and costs at least twice as much to bring new medical devices to market. Among other things, manufacturers must collect and document more data, provide evidence and – depending on the risk class and degree of innovation – initiate clinical studies. When the MDR was launched in 2017, memories of the PIP breast-implant scandal were still fresh, and they reverberate in the new rules.

"Patient protection is always and undeniably paramount", agrees Julia Steckeler, joint managing director of Medical Mountains, with Yvonne Glienke. "But if patient protection comes at the expense of advanced patient and treatment safety, then there is something wrong with the system." Medical Mountain's headquarters is in Tuttlingen, in southwestern Germany. The city on the upper Danube has been dubbed the "world centre of medical technology". Well over 300 companies make surgical instruments, implants, endoscopes and other medical products. "Research and development have been scaled down noticeably", Glienke reports from her network, "because no one has any idea about whether investing in innovations will eventually pay off."

“No one has the courage to submit products to registration”

No one can say exactly how many promising products and processes fall by the wayside. But there are examples from clinical reality. In the operating theatres, impulses to develop new or improved products arise from practical experience. This is also the case in Professor Wolfram Lamadé’s work. Pancreas surgery is considered high-risk. Secretions can leak into the abdominal cavity and “digest” other organs, as Lamadé, head physician for general and visceral surgery at the Helios Clinic in Pforzheim describes it – with life-threatening complications as a result. The state of the art is to divert the flow to the stomach or small intestine, a complicated and certainly not harmless undertaking. Wolfram Lamadé has an idea: a tissue adhesive could present a secure barrier, keeping the fluids away from the surrounding tissue. This would make procedure be easier for the surgeon, but – more importantly – safer for the patient. Despite successful initial tests, their industry partner backed out because the economic risk is just too great even for a group generating billions in sales every year. Wolfram Lamadé shakes his head. “No one has the courage to submit products to registration anymore.”

This does not just apply to new developments but also to existing products. Conformity cannot be declared for the life of the product range but must be periodically renewed. The MDR has tightened the requirements for documentation and evidence considerably, even for products that have been on the market for decades without any changes and without any reported incidents. “Manufacturers think twice about taking on the effort of re-certification”, says Glienke, “especially for products for rare indications, which sell relatively few units.”

New developments made much more difficult

Professor Oliver Muensterer, head of the paediatric surgical clinic and polyclinic at Dr. von Hauner’s Children’s Hospital in Munich, is familiar with these cases. “Until recently, one manufacturer had offered us a whole arsenal of differently sized instruments for paediatric surgery”, he reports. “But suddenly only one standard size was still available. The trend is shifting towards products that can be used in paediatric and adult settings alike. “Half a millimetre doesn’t seem much at first, but it makes a big difference whether a baby is operated on with a 3.5- or 3.0-mm instrument.”

A similar situation exists with staple suture devices. In the U.S., one such device with a diameter of 5 mm was launched specifically for children. In Europe, the development of a similar product was

Photo: bvmed/aesculap AG

The MDR affects all areas where medical devices are used – including digital robotic microsurgery.

Photo: bvmed

Sensor for heart failure telemonitoring implanted via a catheter

discontinued. The math just does not add up for the manufacturer. New developments, especially in the field of paediatric surgery, are made considerably more difficult. "I can already see us operating like our pre-predecessors", says Muensterer. "It's like going back to the Stone Age."

Easier in the U.S.: once approved, always approved

For specific legacy products, the cost of re-approval can run into the hundreds of thousands, according to the calculations of Professor Nikolaus Haas, who is the director of paediatric cardiology and paediatric intensive care at Ludwig Maximilian's University in Munich and the current president of the German Society for Paediatric Cardiology and Congenital Heart Defects (DGPK). "Companies in the U.S. don't have to worry about this, as there the principle applies: once approved, always approved", with drastically unequal treatment and market distortion as a result. So when some products previously offered by German or European suppliers are taken off the market, they are replaced by American ones instead. "Which can easily cost ten times as much", says Nikolaus Haas.

And in the absence of proven products, paediatric surgery and many other fields are moving backwards, towards "old", riskier methods – which confirms Muensterer's assessment. For example, in paediatric cardiology, there was a special balloon catheter that had been used worldwide for decades to save the lives of newborns with a specific heart defect and make surgery possible. "This catheter is no longer available because it is not profitable for the U.S. company to sell it here." As a result, he says, numerous babies have died because there is no comparably good product on the market. "It is five past twelve", says Haas. "A disaster, to put it mildly."

All four agree that the medical technology companies cannot be blamed. The MDR rules make it increasingly difficult to come up with economically viable concepts. "Society must ask itself whether it is morally justifiable not to approve innovations", says Muensterer, making the implications clear and giving vent to his disappointment. "A child we can operate on, if everything goes smoothly, can look forward to 70 or 80 good years of life." However, if new, improved – or even established – instruments are unavailable, this will cost the health care system dearly, with great losses in terms of quality of life for many individuals. "But these long-term consequences are simply not being adequately addressed".

Re-shaping the regulatory framework now to make innovation feasible again – especially for niche products – will pay off in terms of money and offer ethical benefits. However, as Wolfram Lamadé adds, this is countered by the primate of business, the pressure to realize savings that is inherent in the system, a pressure that weighs equally on manufacturers and physicians. "This will do more harm than good."

Role model U.S.: old rules for legacy products

Steckeler mentions that pragmatic solutions already exist. In the USA, for example, there are so-called "grandfather clauses" and "pre-amendment devices", in a market known to place great emphasis on safety. In simple terms, products that were placed on the market before the introduction of new regulations continue to be subject to the old rules. "This system could also be applied to existing products under the MDR", Steckeler suggests, provided there are no defects or substantial changes to the product itself. Also modelled on FDA rules, "orphan devices" could solve the problem of speciality products: separate specifications for medical devices that are manufactured in small numbers and for very specific applications. In such cases, it would be conceivable to successively collect the clinical data required by the MDR via the use of CE-marked instruments. Otherwise, clinical studies would have to be initiated. "This item puts a huge load on niche products and makes them go way over budget. It's an almost classic no-go criterion, especially for small and midsize companies."

"Unless something changes, new developments will not be pursued at all, or else will be approved first, or even exclusively, in non-European markets," summarizes Steckeler. "Each of these issues ultimately impacts patient care across Europe." Lamadé goes one step further in his assessment: "That there is a need for control and that safety is paramount are undisputed facts. However, obviously excessive regulation of new products can no longer be justified with 'patient protection'. Restricting innovation produces deaths."

Source: Medical Mountains, article published on DeviceMed Online on 18 June 2021

Patent

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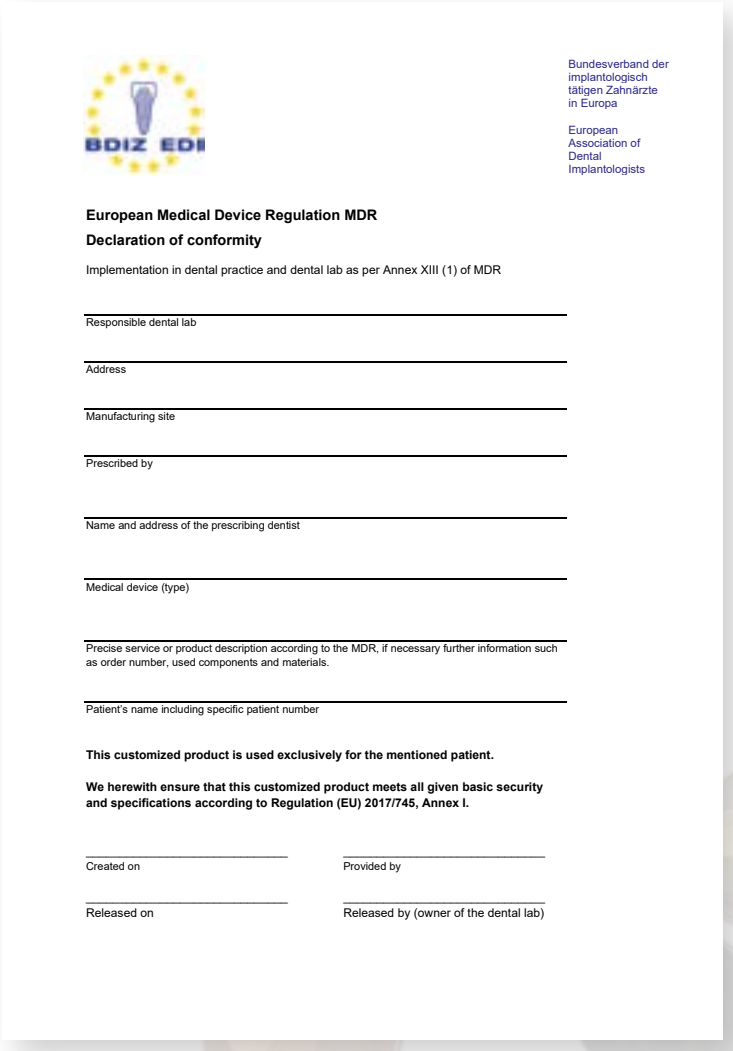
According to Article 15 MDR and IVDR

Person responsible for regulatory compliance (PRRC)

In this series, BDIZ EDI provides the necessary documents for meeting the requirements of the European Medical Device Regulation MDR step by step. In this issue we provide you with second document practice owner and/or dental lab owner need to meet the requirements in article 15 of MDR and IVDR (In-vitro Diagnostic Device Regulation).



Bundesverband der implantologisch tätigen Zahnärzte in Europa

European Association of Dental Implantologists

European Medical Device Regulation MDR
Declaration of conformity

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

Responsible dental lab

Address

Manufacturing site

Prescribed by

Name and address of the prescribing dentist

Medical device (type)

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

Patient's name including specific patient number

This customized product is used exclusively for the mentioned patient.

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

Created on

Provided by

Released on

Released by (owner of the dental lab)

Declaration of conformity

Whereas manufacturers (more than 50 persons) shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices it is different for small enterprises like dental practice or dental laboratory. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.

Below, you will find the second document BDIZ EDI has prepared and makes the necessary form available on the website: www.bdizedi.org/en/

The PDFs are interactive, meaning they can also be filled out electronically. For more information, please contact us: office-munich@bdizedi.org

AWU

MDR forms online

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

Bundesverband der implantologisch tätigen Zahnärzte in Europa

European Association of Dental Implantologists

European Medical Device Regulation MDR

Person responsible for regulatory compliance (PRRC)

according to Article 15 MDR and IVDR (In-vitro Diagnostic Device Regulation)

PRRC responsible to meet requirements for the dental practice and the dental lab[1]

Name and address of the dental practice/dental lab

Authorized representatives:

Authorised representatives shall have **permanently and continuously at their disposal** at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications

☐ a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline,
and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

☐ four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Roles and responsibilities of the person responsible for regulatory compliance within a manufacturer (paragraph 3)

- *the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;*
- *the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;"*
- *the post-market surveillance obligations are complied with in accordance with Article 10(10) [Article 10(9) of the IVDR];*
- *the reporting obligations referred to in Articles 87 to 91 [Article 82 and 86 of the IVDR] are fulfilled;*
- *in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV [Section 4.1 of Annex XIV of the IVDR] is issued.*

Person responsible	*Owner of Practice/Lab*
Date and signature	*Date and signature*

[1] "Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal."

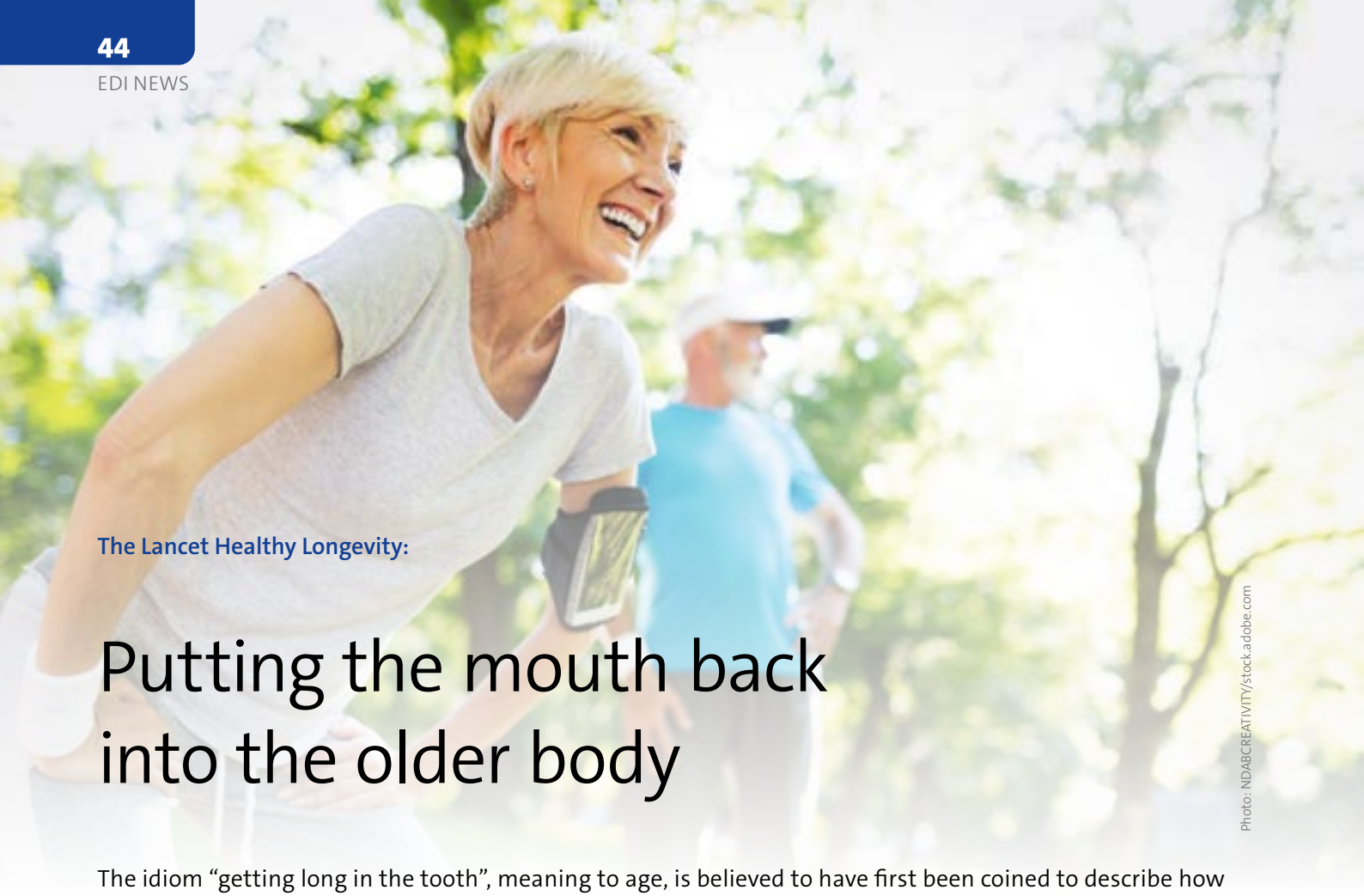


Photo: NDABCREATIVITY/stock.adobe.com

The Lancet Healthy Longevity:

Putting the mouth back into the older body

The idiom "getting long in the tooth", meaning to age, is believed to have first been coined to describe how horses' teeth seemed to grow as their gums shrunk with age, but is increasingly becoming an accurate descriptor of human ageing. Receding gum lines resulting from untreated oral disease means that as we age, we also become literally long in the tooth.

The burden of oral disease in older people is global and increasing. The Lancet published a Review and Personal View both examining the unique – and neglected – challenges that maintaining good oral health poses to older people.

Oral health is much more than sparkling white teeth. In 2016, the FDI World Dental Federation General Assembly approved a new definition of oral health to reflect its multifaceted nature and importance. Oral health is now defined, amongst other things, as including "the ability to speak, smile, smell, taste, touch, chew, swallow, and convey a range of emotions through facial expressions with confidence and without pain, discomfort, and disease of the craniofacial complex".

Oral health indicators

For older people especially, there is a direct link between oral and general health, with oral health being both a predictor and marker of frailty. In their review, Vittorio Dibello and colleagues carry out a systematic review on the association between oral health indicators and frailty among older adults (aged older than 60 years) and identified 12 oral health factors that were found to contribute to frailty.

12 oral health factors

The interplay between oral health and frailty is probably mediated by nutritional status: having fewer teeth, reduced masticatory force, or oral pain is likely to reduce nutrient intake, with frailty developing from muscle wasting and bone weakening. This occurrence probably produces a negative feedback loop, with sarcopenia then reducing the ability to chew and swallow. Notably, oral health of older people has been shown to decline when they first enter assisted living irrespective of their previous health status; although the exact causes are unknown, possible reasons include side effects of polypharmacy (e. g. having a dry mouth), or an inability to carry out personal dental care from physical or mental disability. Furthermore, frailty is not the only systemic condition affected by poor oral health. In their personal view, Jay Patel and colleagues discuss evidence showing the interplay between periodontitis and common chronic inflammatory diseases of ageing, aspiration pneumonia, and cardiovascular disease.

2019 Global Burden of Diseases study

There is a growing unmet burden of oral disease that needs to be addressed, especially in older people.

The 2019 Global Burden of Diseases study estimated that oral disorders contributed 8 million years lived with disability among people aged 50–74 years. This burden has almost certainly increased because of the COVID-19 pandemic, which has reduced routine access to dental care and disproportionately affected older people. The world is gradually awakening to this issue. On May 27, 2021, the World Health Assembly passed its first ever resolution on oral health, recognising it as an issue of global concern, and urging member states to address causes of oral disease, especially as they overlap with other non-communicable diseases (diets high in sugar and alcohol, use of tobacco), and to enable better access to dental care.

In low-income and middle-income countries, there is a high burden of preventable oral disease. Untreated oral diseases have more than doubled between 1990 and 2017 in low-income countries and affect about 3.5 billion people. Half of all countries, mainly low-income and middle-income countries, spend less than $10 per person each year on oral health. There are strong economic arguments for recognising the importance of oral health: the global economic burden due to poor oral health and disease is about US$ 545 billion, and as the global population ages, this economic burden will almost certainly increase. However, unlike other preventable, non-communicable diseases, oral health is rarely discussed in the context of global health or ageing populations. To a large degree, this is because of the separation of dental care from other routine medical interventions, leading to dental health practitioners to call for "the mouth to be put back in the body", i. e. for recognition of the important role that oral health plays in general health.

Cross-talk necessary

Oral health typifies the issues which face older people navigating health-care systems. Like many diseases, oral health is crucial for ensuing general health, yet dental care is separate and siloed from general medical practice. To ensure that older people receive affordable access to dental care, health-care systems need to reform to ensure cross-talk between dental and general medical practitioners: we must put the mouth back in the older body.

Source: Editorial, August 2021, The Lancet
Permitted to reprint by the Lancet

Council of European Dentists CED

Recommendation on vaccination

State authorities should recognise the valuable role dentists can play in promoting vaccination and in the provision of vaccines, within their scope of competence, particularly amongst healthy patients given the large number of citizens who visit their dentist annually. To support their efforts, they should be offered opportunities for continuing education and training on vaccination in accordance with national recommendations.

This resolution outlines the CED position on vaccination, especially for HPV, AMR and it points out the importance of vaccination in the fight against COVID-19. Moreover, the document calls for support of vaccination programmes at national and European level, in the best interest of all Europeans.

Vaccines

Immunisation through vaccination is the most efficient and cost-effective public health measure to prevent communicable diseases. Goal 3 of the UN 2030 Agenda for Sustainable Development (SDG) – "ensure healthy lives and promote well-being for all at all ages" – stresses the importance of access to and use of vaccines for the health of all people. Alongside this, the European Council published its recommendation on strengthened cooperation against vaccine-preventable diseases [1] in 2018 to initiate action at EU and national level, including to help tackle vaccine hesitancy, support research and development and strengthen EU cooperation on vaccine-preventable diseases. From a public health point of view and for prevention purposes, CED also calls for the full vaccination of dental staff, free of charge and regularly testing their antibody status.

HPV and oral cancer

The Human papillomavirus (HPV) is a very common disease, infecting more than 80 % of the population at some point in their life [2]. Many of the infections will not cause serious harm but some of the HPV strains can lead to cancer. HPV 16 is the most carcinogenic strain and the most frequent type detected in HPV related cancers in Europe [3]. It is estimated that 5 % of cancers are caused by HPV [4]. Many citizens and policymakers are aware that HPV causes cervical cancer, but HPV is also the main cause for cancers in different parts of the head and neck, especially the oropharynx. More than 70 % of cancers in this area of the back of the tongue, the soft area at the back of the roof of the mouth, tonsils and back wall of the throat are caused by HPV [5]. This number is expected to increase further over the next years, also due to a decline in tobacco-related oral cancers [6]. Men are more likely than women to de-

Photo: Torsten Simon/pixabay

velop this type of cancer. 13,800 cases are diagnosed in the EU annually, with 11,000 found in men and 2,800 in women [7].

The HPV vaccination is the best way of preventing people from catching the virus and potentially developing one of the cancers caused by HPV. Vaccinations are among the most cost-effective public health interventions and can contribute to the efficiency of and cost-savings in health care systems.

All EU member countries recommend the vaccination, but not all recommend them for boys/men and girls/women [8]. This can lead to the vaccination not being reimbursed in some healthcare settings. Since males face the same risks of catching an HPV infection, they should have the same access to the vaccination as females. In the end, the more people – boys and girls, men and women – are vaccinated, the less likely it will be for those who are not vaccinated to catch the virus, i.e. creating a herd immunity.

Vaccination and antimicrobial resistance

With Antimicrobial Resistance (AMR) responsible for an estimated 25,000 deaths per year in the EU and incurring EUR 1.5 billion per year in healthcare costs and productivity losses in the EU, it is imperative to acknowledge the role vaccines have in the fight against AMR [9]. Vaccinations are a very effective way to prevent people from getting infected in the first place, consequently avoiding the use of antibiotics. It is crucial that the existing vaccines are used efficiently to reduce such preventable diseases and even death caused by AMR. Additionally, it is critical to develop new vaccines to treat especially those diseases that are caused by now antibiotic-resistant bacteria, like multi-drug resistant tuberculosis (MDR-TB), and those common diseases for which no vaccine exists so far, for instance Group A Streptococcus.

COVID-19 and vaccination

The COVID-19 pandemic, also known as the coronavirus pandemic, is a global pandemic of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [10]. With more than 152 million cases confirmed and more than 3.2 million deaths attributed to COVID-19 by May 2021, it is one of the deadliest pandemics in history [11]. Vaccines are a critical tool in the battle against COVID-19. With vaccination being proved to be a safe and effective process, it is essential that all healthcare professionals are the first to get vaccinated against COVID-19 when they have the opportunity to do so, their health being paramount for the functioning of the health systems, even more so in times of crisis. They must also help promoting vaccination against COVID-19 among the general public, as builders of public trust with the professional responsibility to protect patients by encouraging them to get vaccinated.

CED position

The CED appreciates the work done at national and EU level to promote vaccinations and to counter online misinformation and fake news about vaccinations.

The CED

- stresses that healthcare workers, including dentists, play a key role in working towards the goal of improved vaccination coverage rates;
- supports an inclusive approach to HPV vaccinations so that both boys and girls receive coverage, creating a herd immunity that also protects the most vulnerable;
- supports the EU's public awareness initiative on vaccination during the European Immunisation Week;
- supports the EU's work on countering online vaccine misinformation, including the upcoming vaccines information portal, and developing evidence-based information tools and guidance to support Member States in responding to vaccine hesitancy, which is of particular importance for Member States with active anti-vaccine groups;
- recommends that vaccination should be free of charge, be included in the national immunisation schedules, in compliance with national rules, administered at a young age and before the first sexual encounter;
- recommends vaccination as the most effective tool to prevent AMR as well as being the most successful and cost-effective public health intervention;
- supports vaccination as a safe and effective tool against COVID-19 and underlines the key role of healthcare professionals as builders of public trust;

Adopted at the CED General Meeting in June 2021

The references are available at www.bdizedi.org/en/europe

INTRODUCTION

The Council of European Dentists (CED) is a European not-for-profit association which represents over 340,000 dentists across Europe. The association was established in 1961 and is now composed of 33 national dental associations from 31 European countries.

A key objective for the CED is contributing to the protection of public health and vaccination is a key factor for achieving this.

Did you ever know ...

... that

... the European Association of Dental Implantologists BDIZ EDI is collaborating with European associations and societies in implant dentistry? Beyond the European borders there is a collaborating coming up with the EDI India to train and educate professionals around Hyderabad, India within a fellowship program. More is coming up soon.

Photo: Mohammed Sohail Khan - stock.adobe.com

... that

... the BDIZ EDI is collaboration partner to implant associations and societies in Europe to organize the European Symposium on an annual basis? 2021 collaboration partner was EDI Macedonia. Due to the Corona pandemic the event originally planned for May 2020 in Skopje had to be postponed but was presented online at the end of May 2021. Motto was: implantology from A to Z with participants from BDIZ EDI board and European Committee members of BDIZ EDI. Next is coming up 2022.

Photo: nikitamaykov - stock.adobe.com

... that

... the BDIZ EDI is looking very carefully to watch what is going on in Europe – European Commission and the European Parliament and also the European Court of Justice – to recognize in an early stage how politics, regulations, directives, decisions regarding the dental practice may change. BDIZ EDI is to take some action by intervening or informing about consequences thereof.

ECJ ruling on professional qualifications, part 2

Recognition of qualifications becomes easier across the EU

In its decision of 8 July 2021 (C-166/20), the European Court of Justice (ECJ) once again interpreted Directive 2005/36/EC, Articles 1 and 10(b). The issue was to determine, among other things, whether professional training that had not been fully completed in one Member State (home state) and had then been completed in another Member State (host state) in accordance with the regulations of the home state is to be regarded as a valid professional qualification as defined by Directive 2005/36/EC.

The case

The applicant, who is from Lithuania, had successfully completed four years of pharmacology studies in the United Kingdom in July 2013 and received a master's degree in pharmacology. To practice the profession of pharmacist in the UK, a twelve-month internship is additionally required. Having successfully completed a six-month internship in a pharmacy, the applicant returned to Lithuania for personal reasons.

In July 2014, she applied to the competent Centre for Quality Assessment in Higher Education in Lithuania for a certificate of equivalence of her British diploma with a Lithuanian master's degree, the degree usually awarded following integrated pharmacology studies. The requested certificate was issued with the caveat that it did not constitute a recognition of professional qualifications, for which the Ministry of Health would be exclusively responsible.

In August 2014, she applied to the Ministry of Health for recognition of her professional qualification. The Ministry responded that while her course of studies was duly documented, her professional qualification was not, adding that it was unclear in which Member State the remaining six-month internship needed to be completed. The applicant enrolled in the University of Health Sciences in Lithuania, completing a second six-month pharmacology internship. The university issued her a certificate in May 2015 that confirmed she had completed the internship.

She then applied to the competent office of the Ministry of Health for a license to practice as a pharmacist, relying on the university's certificate. She was informed in June 2015 that a document had to be submitted confirming the recognition of her professional qualification in Lithuania. The applicant again applied to the Ministry of Health for recognition of her professional qualification and submitted the Lithuanian certificate.

The application for approval as a pharmacist was rejected in July 2015. In July 2017, the Ministry of Health also refused to recognize her professional qualification. It found that the applicant did not hold a professional qualification as a pharmacist in an EU Member State. The applicant appealed the rejection, and when her appeal was denied, she brought an action before the Vilnius Administrative Court. The court of first instance dismissed the claim as unfounded in February 2018, whereupon the applicant appealed to the Supreme Administrative Court.

The Supreme Administrative Court asserted that according to the British law, the applicant met all requirements for a professional qualification as a pharmacist in principle, and if she had completed her education and training in a Member State, she would also have acquired the professional qualification of pharmacist, which is eligible for automatic recognition according to Article 21 of Directive 2005/36/EC. However, since the applicant could not base her application on that provision, it was necessary to examine whether Article 10(b) of Directive 2005/36 was applicable to cases where an applicant had not been able to secure evidence of formal qualifications as the requirements for obtaining the professional qualification had been satisfied not in a single Member State but across multiple Member States, one of which was the host Member State.

Photo: By Cédric Puisney from Brussels, Belgium - European Court of Justice - Luxembourg, CC BY 2.0, https://commons.wikimedia.org/w/index.php?curid=34942382

Furthermore, the court wanted to clarify whether the competent authority was obliged in this situation to assess the content of all documents submitted and whether the certified training complied with the regulations on professional education and training in the host country and, if necessary, to apply compensation measures. The Supreme Administrative Court stayed the proceedings and referred the following questions to the ECJ for a preliminary ruling:

1. *Should Article 10(b) of Directive 2005/36/EC [...] be interpreted as being applicable in a situation where a person has not obtained formal evidence of qualifications because he or she has potentially fulfilled the requirements necessary for obtaining the professional qualifications in several Member States of the European Union rather than in a single one? In such a situation [...] should [...] Directive 2005/36/EC be interpreted as obliging the institution recognizing qualifications to assess the content of all the documents submitted by the person which can demonstrate professional qualifications and whether they comply with the requirements set in the host Member State for obtaining the professional qualifications and, if necessary, to apply compensation measures?*
2. *In a situation such as that in the present case [...] should Articles 45 and 49 TFEU and Article 15 of the Charter be interpreted as obliging the competent authorities of the host Member State to assess the professional training of the applicant and to compare it with the professional training required in the host state, and also to assess the content of the documents submitted which can demonstrate professional qualifications and whether they comply with the requirements set in the host Member State for obtaining the professional qualifications, and, if necessary, to apply compensation measures?*

The ECJ's decision

Regarding the first question, the ECJ concluded that Directive 2005/36/EC, and specifically Article 10(b), does not apply if the person seeking recognition of a professional qualification cannot show formal evidence of any qualifications that would enable him or her to pursue a regulated profession in the person's country of origin.

In justification of its conclusion, the ECJ stated that the mutual recognition of professional qualifications serves to enable the holder of a professional qualification to take up and practice a regulated profession in a country other than his or her country of origin, under the same conditions as a national of that country. However, this presupposes education and training that qualifies the applicant to practice a regulated profession in the country of origin – regardless of whether the training profession is eligible for automatic recognition or the general recognition regulation (recital nos. 25 ff.). Article 10 of the Directive cannot require the host Member State to examine the applicant's formal evidence of qualifications if the applicant does not possess a qualification required for practicing the profession in the Member State of origin (no. 28).

Regarding the second question, the ECJ held that Articles 45 and 49 TFEU as well as Article 15(2) of the Charter of Fundamental Rights (CFR) must be interpreted to the effect that the authorities of the host Member State have to assess the referenced skills in the context of the recognition of professional qualifications and compare them with those required in the host Member State for access to the relevant profession even in cases where the applicant cannot show a (completed) professional qualification even though relevant professional skills were acquired in the Member State of origin and in the host Member State. If these skills correspond to those required in the host Member State for the practice of the profession, they must be recognized.

Otherwise, proof of the undocumented knowledge and skills may be required. The competent authority must assess whether the knowledge acquired is sufficient. If substantial differences are found between an applicant's formal education and training and that offered in the host Member State, the authorities may set compensation measures to make up for any differences (no. 42).

By way of explanation, the ECJ pointed out that, in principle, all EU citizens have the freedom to seek work and to establish themselves in other Member States (Article 45 of the TFEU, free movement of workers; Article 49 of the TFEU, freedom of establishment). Hence, if an applicant applies for a professional licence and the licence depends on a diploma, professional qualification or practical experience, the authorities of a Member State must take into account all diplomas, examination certificates and other qualifications as well as relevant professional experience and compare them with the knowledge and skills required by national law (nos. 31–34).

According to the ECJ, the fact that the Directive on the Recognition of Professional Qualifications contains a special regulation does not preclude the applicability of the general regulations. According to Article 53(1) of the TFEU, directives are intended to facilitate the recognition of professional qualifications, but not to make recognition more difficult in cases not covered by the directive (no. 36).

The host Member State must also comply with its obligation to examine cases that do not fall within the scope of Directive 2005/36/EC. If the examination of the evidence leads to the conclusion that the knowledge and skills meet the requirements under national law, this must be recognized as sufficient evidence. Otherwise, proof of the undocumented knowledge and skills may be required. Compensatory measures may otherwise be required (nos. 39–41).

Summary

It should therefore be noted that a professional qualification can only be (automatically) recognized if a professional qualification has actually been acquired. This would also appear obvious in substance, because otherwise recognition of the qualification would not fall within the scope of Directive 2005/36/EC.

Nevertheless, even cases in which all the requirements for a professional qualification were not fully met in the country of origin must also be examined by the competent authority in the host Member State. The authority must then examine whether the education and training completed abroad is comparable to the training provided domestically. Where significant differences are found, compensatory measures will have to be undertaken.

As a rule, it will be easier to complete the professional qualification in the country of origin if at all possible; especially for members of professions subject to automatic recognition – such as physicians, dentists or pharmacists – this will make it much easier to practice the respective profession in the host Member State.

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Demonstration of synergy between an innovative implant design and a novel biomaterial

Implant and alloplast synergy in the anterior mandible

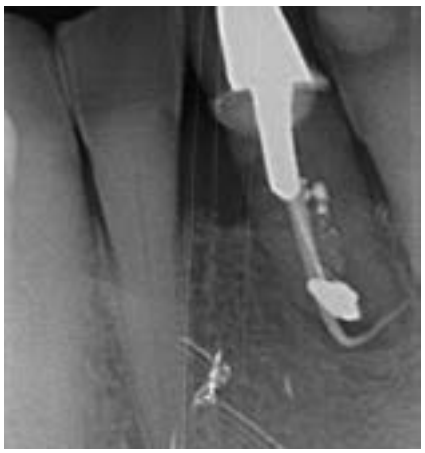
DOMINIC O'HOOLEY, FFGDP (UK), BDS (LIVERPOOL), MFDS RCS (ENG), MFDS RCPS (GLASG), LEEDS, UK

Intraoral host bone regeneration within the labial portion of the anterior mandible can be unpredictable, affected by many factors including host healing, the bony envelope dimensions labial to the implant shoulder, surgical technique and patient compliance pre, peri and post operatively. This case study demonstrates the first use of a novel implant design together with a ß-tricalcium phosphate (ß-TCP) particulate alloplast graft material in the anterior mandible with immediate placement and loading.

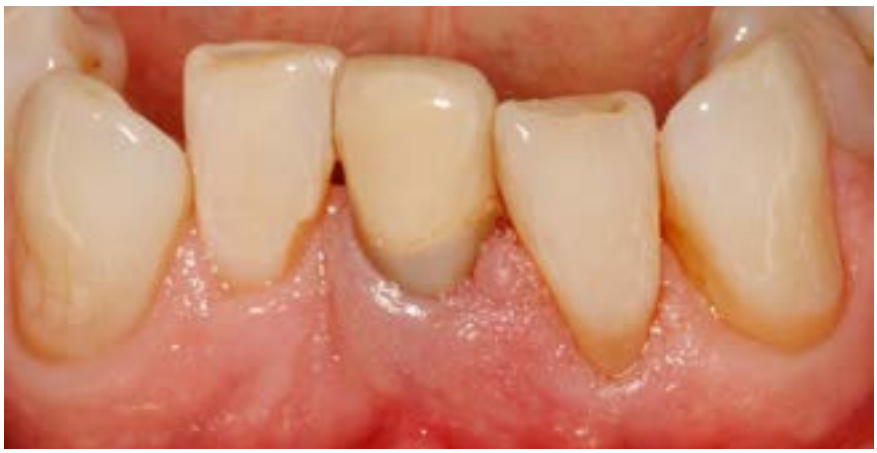
Case report

A 76-year-old male patient, non-smoker, with a non-contributary medical history presented with a painful lower left central incisor tooth 31, the lower right central incisor 41, being removed in childhood. A reduced incisal dimension between the lower canines was present with no diastemata. The symptomatic tooth had become tender to biting pressure and had previously been orthograde root treated with a subsequent apicectomy using amalgam as a retrograde filling material (Figs. 1 to 4). At presentation, the tooth was tender to percussion with grade 1 mobility. No increased probing depth or suppuration was noted, either on the affected tooth 31, or elsewhere in the mouth. A diagnosis of chronic apical periodontitis secondary to suboptimal orthograde and retrograde root treatment was made for tooth 31 and the tooth was given a hopeless prognosis.

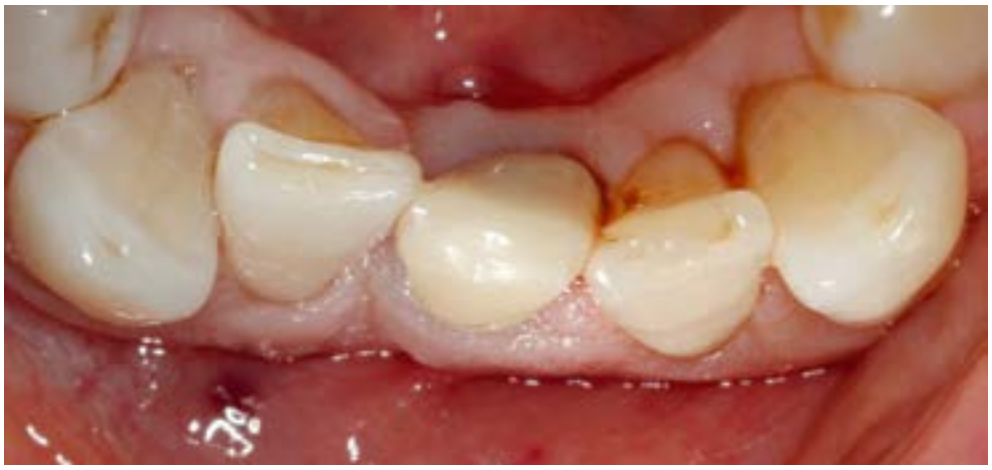
An immediate placement/loading implant treatment plan was proposed. The initial treatment plan involved the fabrication of a PMMA Shell provisional crown designed based on the approved digital 3D-printed diagnostic wax-up for immediate loading; a pre-extraction small field, sectional CBCT scan on the lower anterior mandible; an atraumatic extraction of tooth 31 with meticulous degranulation and curettage; and an immediate implant placement using a novel implant with internal angle correction.



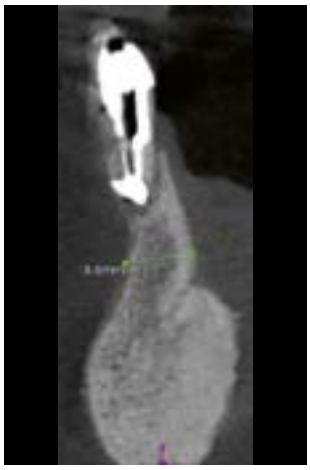
1 I Initial situation – periapical radiograph shows tooth 31 with apicectomised root, extruded anterograde root filling material, amalgam retrograde root filling, post crown with off-centre post positioning.



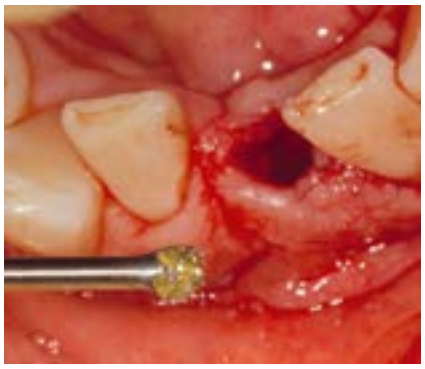
2 I Initial presentation shows thick biotype with stippled keratinised attached mucosa, a vertical linear scar visible at site of historically extracted tooth 41 and a composite labial repair to the cervical margin of the 31, post-crown.



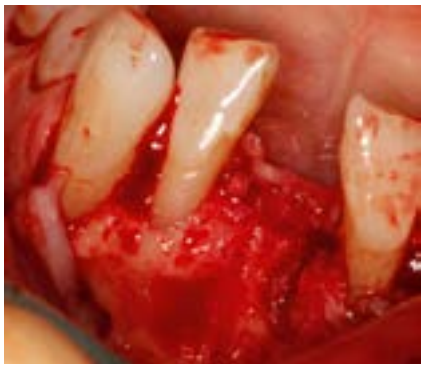
3 I Initial presentation occlusal view shows loss of ridge with associated with linear gingival scar at site 41, mild imbrication of remaining lower incisors and mild tooth surface loss with a major attrition component on the incisal edges of the lower anterior teeth.



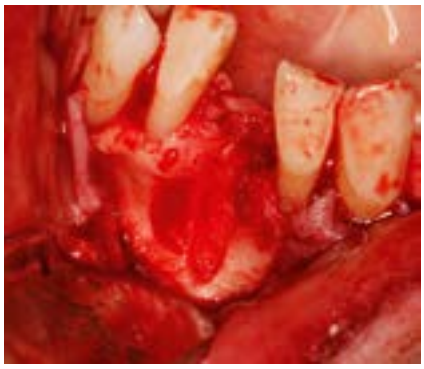
4 I Sectional CBCT showing very thin labial plate and labio-lingual morphology of the bony ridge at tooth 31



5 I Prior to mechanical degranulation of the socket 31



6 I Full thickness muco-periosteal flap with papillae sparing release incisions distal to canines. Granulation tissue visible within vertical bony cleft associated with extracted tooth 41



7 I During further mechanical degranulation showing a reduction in granulation tissue

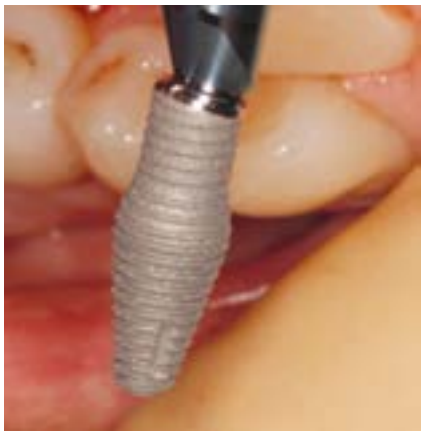
A simultaneous bone grafting with an in-situ hardening synthetic resorbable bone substitute was then used, composed of ß-TCP and calcium sulphate (CS), according to Fairbairn and Leventis [1–4] and simultaneous loading of the implant with the PMMA provisional crown which is modified at chairside.

Antibiotic prophylaxis with 3 g amoxycillin was given one hour prior to surgery, with chlorhexidine mouthwash used for two minutes at the time of surgery. Under local anaesthesia, atraumatic flapless tooth extraction was performed using both elevators (Helmut Zepf Medizintechnik, Germany), and extraction forceps (Devemed GmbH, Germany) trying to avoid plastic flexing of the labial and lingual plates of intact bone. Immediately post extraction the socket was debrided of granulation tissue using both Lucas curettes (Hu-Friedy Group, USA), and degranulation burs (EthOss EK Strauss Degranulation Bur Kit, EthOss Regeneration Ltd, UK) (Fig. 5).

After completion of degranulation, the socket was evaluated and a dehiscence was detected labially. A full thickness muco-periosteal flap with mid crest mandibular and papillae sparing incisions distal to both canines was raised using microsurgical instrumentation (SM69 & SM67 blades, Swann Morton, UK), with periosteal release to mobilise the flap using microsurgical instrumentation (SM65 blade, Swann Morton, UK) (Fig. 6). Further meticulous curettage followed with both hand instruments and degranulation burs.

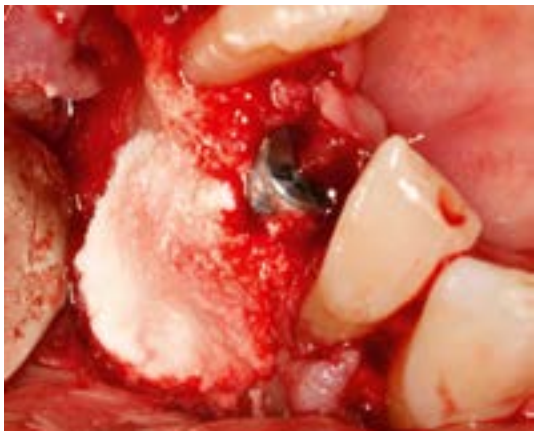
A deep narrow bony defect was noted labially with a smaller deep cleft coronally associated with the previous extracted tooth 41 (Fig. 7). An osteotomy was created using a sharp Inverta spade drill followed by a 3.7 mm twist drill (Southern Implants (PTY) Ltd, South Africa), to create an undersized Osteotomy within the original bony envelope for a Southern Inverta Deep Conical Co-Axis 12° 3.5 mm–4.5 mm implant (Southern Implants (PTY) Ltd, South Africa), a novel implant design with an inverted body shift and internal angle correction.

This implant system was originally designed for placement in the maxillary anterior region, with the inverted body shift design creating a wider diameter at the apical portion of the implant to help create high primary stability, whilst the smaller diameter cylindrical coronal portion reduces the facial-crestal gap distance [5–11]. However, these benefits can also be applied to immediate place-

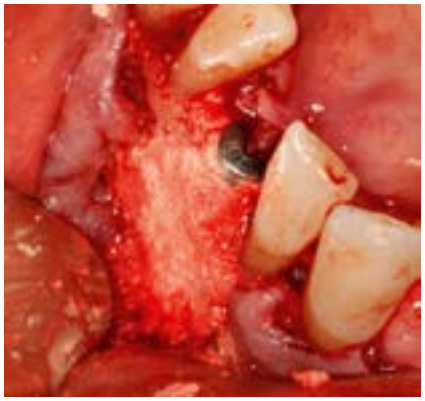


8 I Southern Inverta Deep Conical 12° Co-Axis implant in its carrier prior to placement

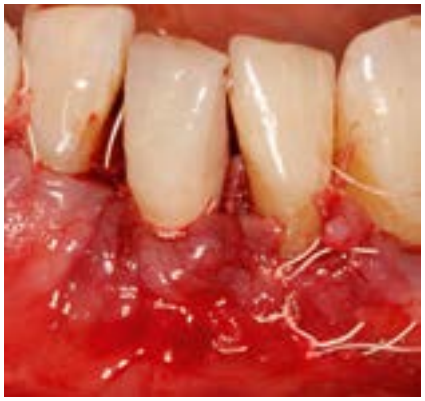
9 I Implant position showing large buccal dehiscence with thread exposure but implant within original bony envelope



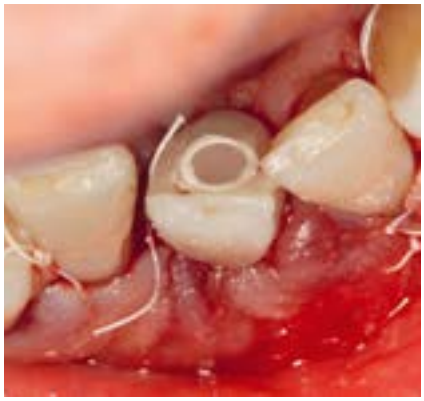
10 I Initial EthOss 0.5 cc placement prior to shaping



11 I EthOss shaped to cover exposed implant threads and adjacent bony defect. Note: not overbuilt



12 I Provisional crown fitted at 20 ncm to implant and flap repositioned tension free using 5.0 PTFE sutures (Omnia)



13 I Lingual screw channel occluded with SilverPlug (Silveraid), and Venus Flow (Kulzer)

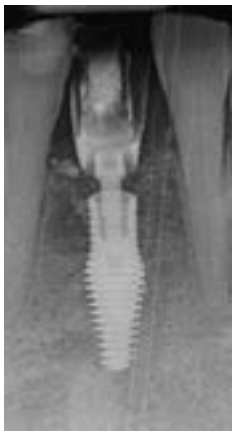
ments in the mandible, as is shown in this case (Fig. 8).

The implant was placed to the ideal position at 75 ncm, with excellent primary stability (Fig. 9). A 4 mm healing abutment was placed prior to site augmentation with a resorbable synthetic bone grafting material (Ethoss; Ethoss Regeneration Ltd, UK), a novel biphasic bone substitute consisting of ß-TCP (65 %) and calcium sulphate (CS, 35 %) (Fig. 10). 0.5 cc of the material was hydrated with 0.9 % sterile saline, mixed and partially dried, according to manufacturer's instructions and placed directly over the exposed implant threads and labial defect. Gentle pressure for 3 – 5 minutes with a piece of sterile gauze, "set" the material (Fig. 11). The tissue flap was repositioned and tacked with initial 5.0 PTFE sutures (Omnia S.r.l., Italy) (Fig. 12), prior to the healing abutment being removed and replaced by a Peek engaging cylinder to 20 ncm (Southern Implants (PTY) Ltd, South Africa).

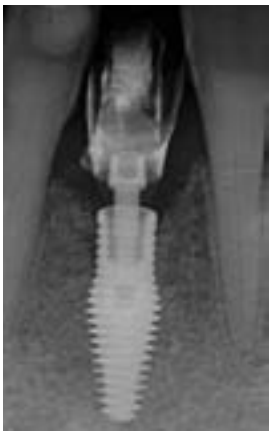
The PMMA shell provisional crown (BDT Ltd, UK), was positioned and attached to the PEEK cylinder using flowable, light curing composite resin (Venus Flow; Kulzer GmbH, Germany) (Fig. 13), followed by its removal, modification and finishing at chairside using polishing disks (Super-Snap; Shofu Dental GmbH, Germany). The healing abutment was replaced, and the patient relaxed during this procedure. The finished provisional crown was fitted to 20 ncm, with SilverPlug (Silveraid, Italy) followed by Venus Flow placed to occlude the lingual screw channel. Careful occlusal analysis ensured the crown was not in occlusion in either centric or excursive occlusal positions.

The patient followed the post-operative instructions regarding oral hygiene and a soft diet assiduously until review for suture removal at 14 days post-surgery. Excellent initial healing was observed (Fig. 14).

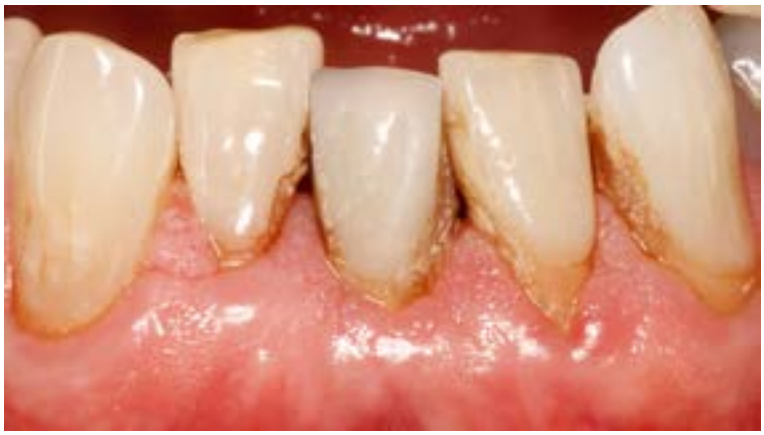
Due to the COVID-19 pandemic and UK lockdown restrictions, the patient was unable to attend for a further review for thirteen months. Via telephone consultation he reported no problems and at thirteen-month review the provisional implant restoration had assimilated well into the oral scheme and the patient was masticating his normal diet with normal function. A periapical radiograph showed no bone loss around the implant (Fig. 15). Probing depths were measured at ≤ 2 mm around the implant at tooth 31. Supra-gingival calculus was noted (Fig. 16), and oral-hygiene instruction and supra-gingival debridement was performed (Figs. 17 and 18) prior to the impression for the definitive screw-retained crown being scheduled.



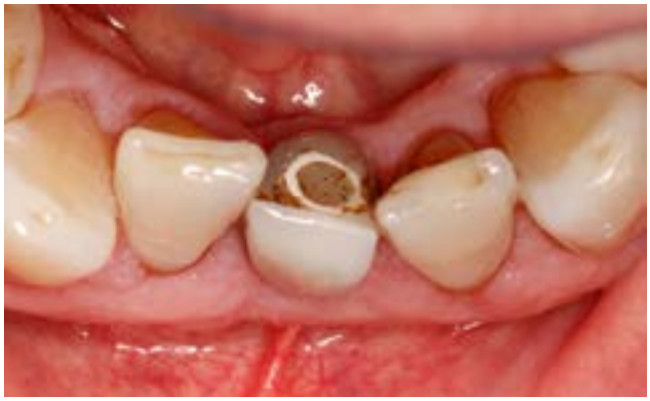
14 I Periapical radiograph immediately post implant placement



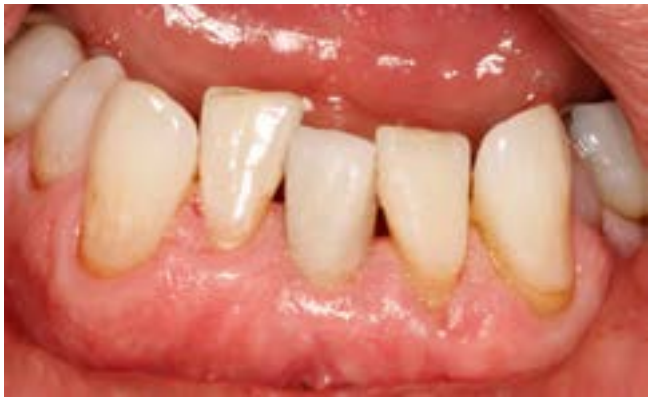
15 I At thirteen-month review. Periapical radiograph showing no bone loss on the implant



16 I Minimal changes to attached gingivae associated with implant at tooth position 31, or repositioned flap



17 I Improved ridge width with minimal evidence of preoperative vertical gingival cleft at site 41 tooth



18 I After removal of supra-gingival calculus and oral hygiene instruction

At sixteen months post implant placement the impression was taken using a custom tray open at the 31, with a modified impression coping and machine mixed one-stage addition cured silicone impression material (Flexitime light and Flexitime Dynamix putty base, Kulzer GmbH, Germany). A custom screw retained crown abutment (Atlantis Crown Abutment, Dentsply Sirona, USA), was bonded at the laboratory with a monolythic zirconia crown, which was delivered to the mouth and fitted to 35 ncm. SilverPlug (Silveraid), and Venus Flow (Kulzer), were used to occlude the lingually placed screw channel (Figs. 19 to 23). A post fit periapical radiograph shows a well-fitting restoration with an ideal emergence profile (Fig. 24).

Discussion

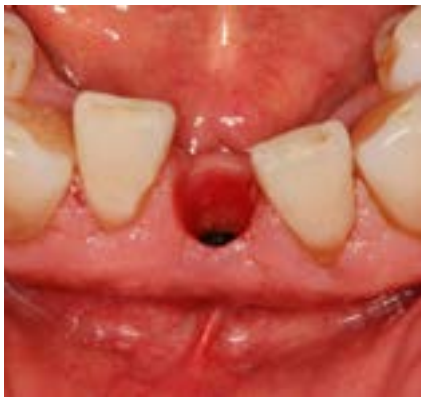
This is the first example of this novel implant design being used in the anterior mandible and the case presents its use with a bioactive alloplastic ß-TCP and CS material, in an immediate placement and loading implant protocol.

The premise of the novel implant design features include that the innovative body-shift inverted morphology allows enhanced apical bone engagement for immediate loading, whilst the narrower coronal portion allows a chamber for the formation of endosteal bone labially by increasing both the jump gap distance and the space between the coronal labial implant shoulder and the labial cortical plate position.

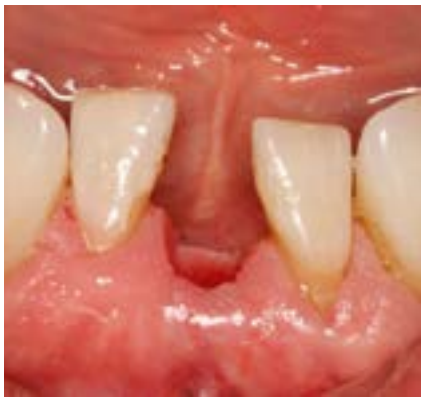
The bioactive ß-TCP and CS combination produces a grafting substrate that self-hardens, with the CS having a barrier function, preventing soft-tissue ingress during the early phases of bone regeneration. The CS resorbs in a three-to-six-week window dependent of individual patient physiology, and as it resorbs, it creates interlinked porosities within the ß-TCP scaffold for angiogenesis.

The ß-TCP component resorbs over a 6 – 12 month period due to a combination of phagocytosis, hydrolysis and enzymic action. As both it and the CS are fully resorbable bone augmentation materials, host bone is regenerated without the presence of residual graft particles.

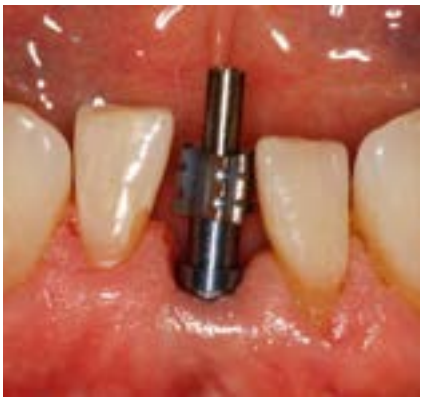
This case study shows amendments from the published protocol [2] where these materials are used in a delayed immediate procedure. Here, immediate placement and loading are used with simultaneous grafting for improved preservation of host hard tissue along with up-regulated host-regeneration [1].



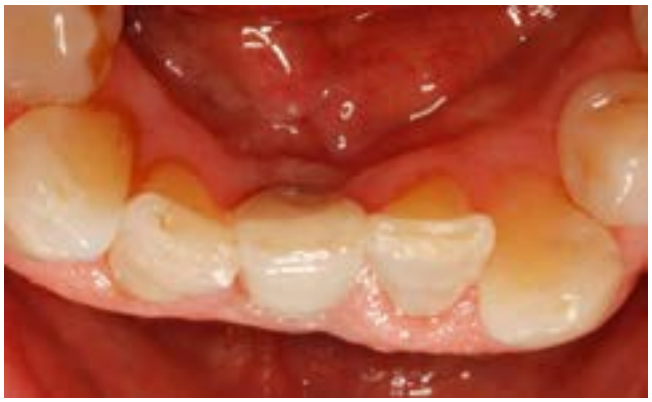
19 I Immediately on removal of provisional crown showing healthy mature gingival collar and preservation of optimal soft tissue and ridge form



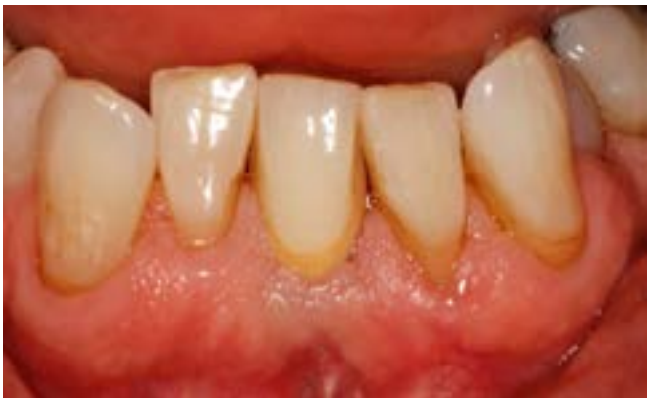
20 I From the labial showing the papillae



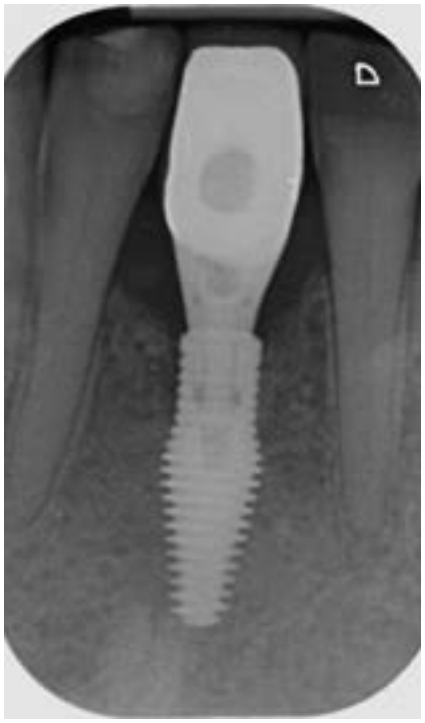
21 I The impression coping screwed into the implant



22 I The definitive crown, occlusal view



23 I The definitive crown, labial view



24 I Check periapical radiograph showing well-fitting restoration and the stable bone level sixteen months after implant placement and augmentation

The ß-TCP graft constituent shows both osteo-conductive, but also, osteo-inductive potential, which enhances host bone regeneration during the healing period. The self-hardening nature of the material meant graft stability whilst in contact with the host periosteum. The narrow chimney portion of the novel implant design with its internal angle correction allowed increased graft volume within the original bony envelope, facilitating ideal screw channel position for a screw-retained restoration without the use of ASCs with their associated deficits, or having to use a cement-retained solution with its associated issues.

For further reading regarding the science specific to bioactive calcium phosphates and their clinical applications, the readers may refer to papers published in previous issues of the EDI Journal and other international journals [1–4, 12–16].

To conclude, the use of this novel implant design in conjunction with immediate placement and loading and the use of a fully resorbable bioactive alloplastic graft material may have provided a synergistic result here, with a very successful outcome for this patient. It is essential that clinicians are well versed in the surgical procedures they employ and understand the specific properties and handling characteristics of the grafting protocols that they elect to use, so that they can optimise the biological mechanisms of host regeneration in each individual implant procedure, and improve both predictability and long-term success of their implant practice.

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

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2.5 mm diameter implants as a predictable treatment

Narrow diameter implants in severe bone resorptions

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A narrow diameter implant (NDI) is an implant with a diameter ≤ 3.5 mm and is clinically indicated for extreme horizontal bone resorption areas [1–4].

Classically, these implants are reserved for the lateral and mandibular incisors, but the role of NDIs is changing [5]. The new protocols in implantology and the emergence of new NDI implants have brought about a conceptual change in the use of these implants, and now NDI implants are used in the posterior and anterior regions to avoid complex surgical procedures [6–9]. However, the long-term use of NDIs in the posterior maxilla and mandible is not well documented, and it is unclear when these implants can be used successfully and when they cannot.

Some studies show a significantly higher failure rate with NDIs than with wider implants. Survival of NDI could be influenced by several variables (prosthesis, loading, surgery) [10]. Thus, surgical planning and prosthesis design could be the key to success.

The aim of this study is to evaluate different prosthetic combinations of 2.5 mm diameter implants using finite element analysis and to provide surgical and prosthetic indications to achieve the success of the treatment in different patients and situations. In configuration 2, with distal and mesial loading in an axis of 30° and in the vertical direction about the implant axis, the results are the same as in configuration 1.

Material and methods

To evaluate the bone stress when a narrow diameter implant (NDI) is placed and loaded, we perform a finite element analysis with two configurations of the diameter of the implants and three cases in each configuration with different loading schemes. In all cases the implants were splinted.

The configurations of the implants in the cases analysed were:

- Configuration 1: A 2.5 mm diameter implant in the mesial region splinted to a 4 mm diameter central implant and a 5 mm diameter distal implant.
- Configuration 2: One implant each with a diameter of 2.5 mm in the mesial and central region and a distal implant with a diameter of 5 mm. This configuration of implants was loaded in three points (mesial load, central load an distal load) with two directions of load (vertical load and 30°).

Results

Configuration 1

With a distal load in an axis of 30° in relation to the implant axis, this configuration of implants generates 40 MPa of tension in a crestal bone. The same configuration with a distal load perpendicular to the implant axis generates a reduction in the tension of crestal bone superior to 50 %, with a resultant tension of 15 MPa (Fig. 1).

When the load is changed to the central point of the configuration, the results of the tension in the crestal bone are the same (with a vertical component and 30°) (Fig. 2). However, when the load is changed to the mesial point of the configuration with a vertical component, the tension in the crestal bone decreases to 20 MPa and increases to 90 MPa with a load in an axis of 30° with respect to the axis of the implant (Fig. 3).

Configuration 2

With a distal and mesial load in an axis of 30° and in a vertical direction in relation to the implant axis, the results are the same as with configuration 1. However, the results of configuration 1 and 2 with the central load are completely different. With a central load in 30° angle with respect to the implant axis the crestal tension was 65 MPa and with vertical load in a central area the result was 30 MPa (Fig. 4).

In figures 5 to 16, we show a clinical rehabilitation case with narrow implants according to configuration 1.

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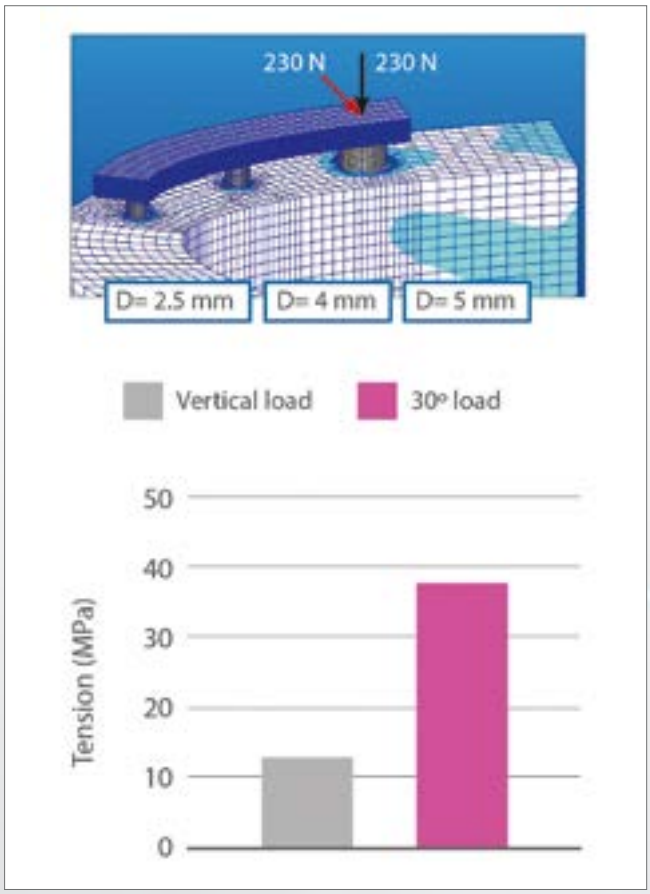
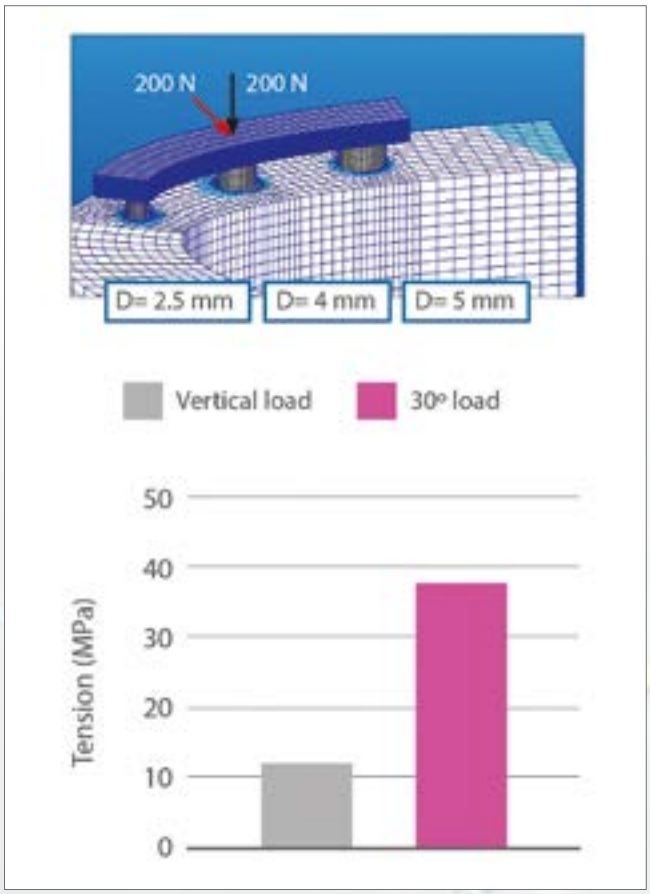
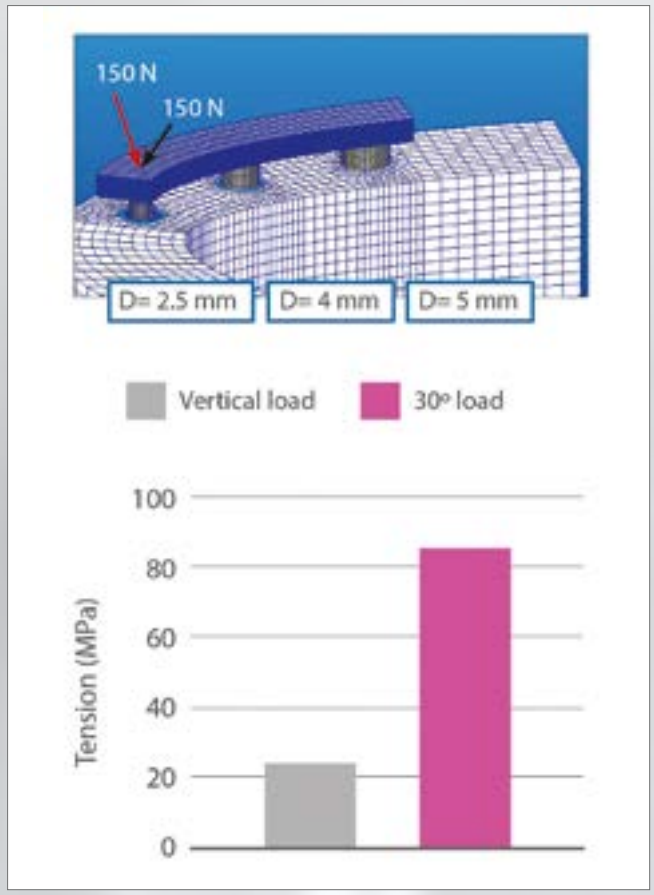
[2] Clinical researcher, Eduardo Anitua Foundation, Vitoria, Spain.
[3] University Institute for Regenerative Medicine and Oral Implantology–(Fundación Eduardo Anitua), Vitoria, Spain.



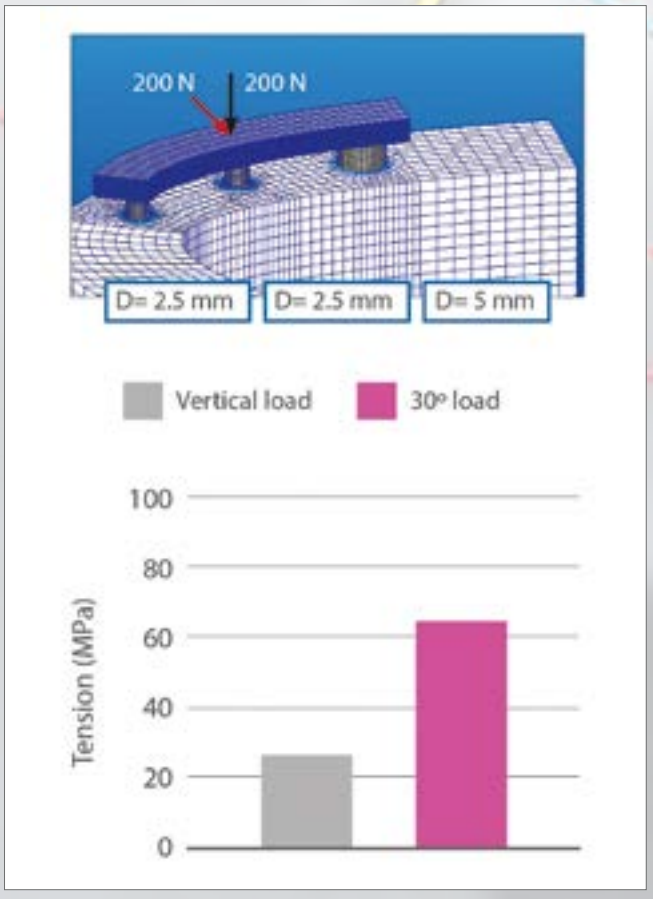
1 I Configuration 1 with a distal load (vertical and 30°)



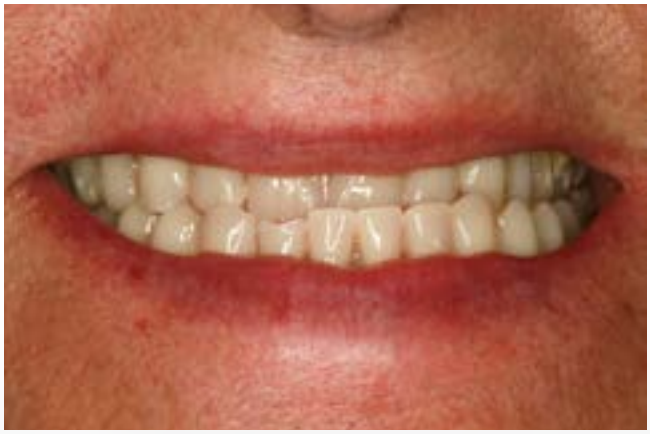
2 I Configuration 1 with a medial load (vertical and 30°)

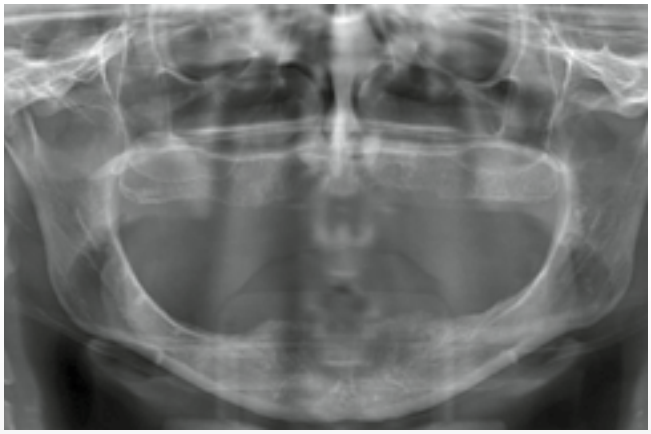


3 I Configuration 1 with a mesial load (vertical and 30°)



4 I Configuration 2 with a medial load (vertical and 30°)



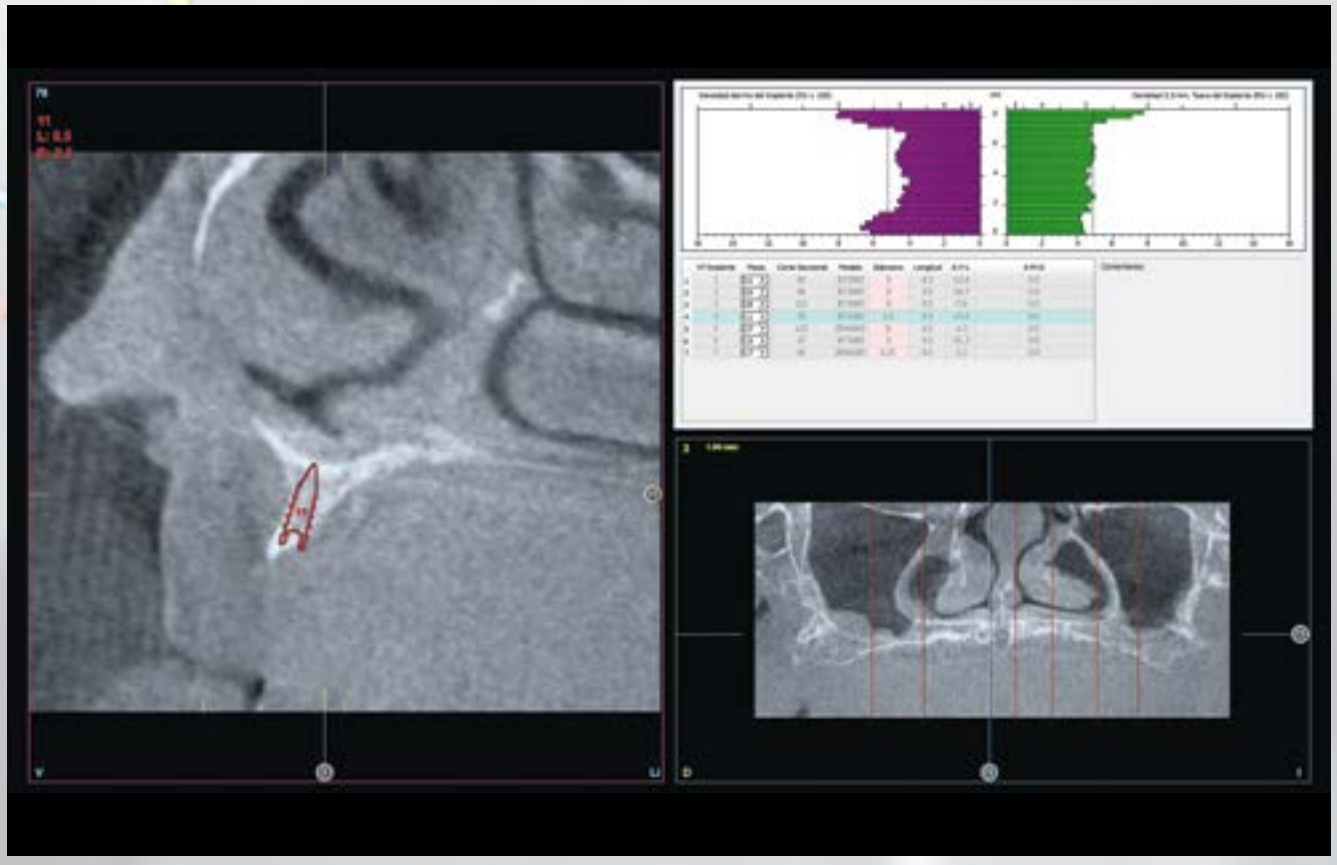


5 and 6 I Initial findings

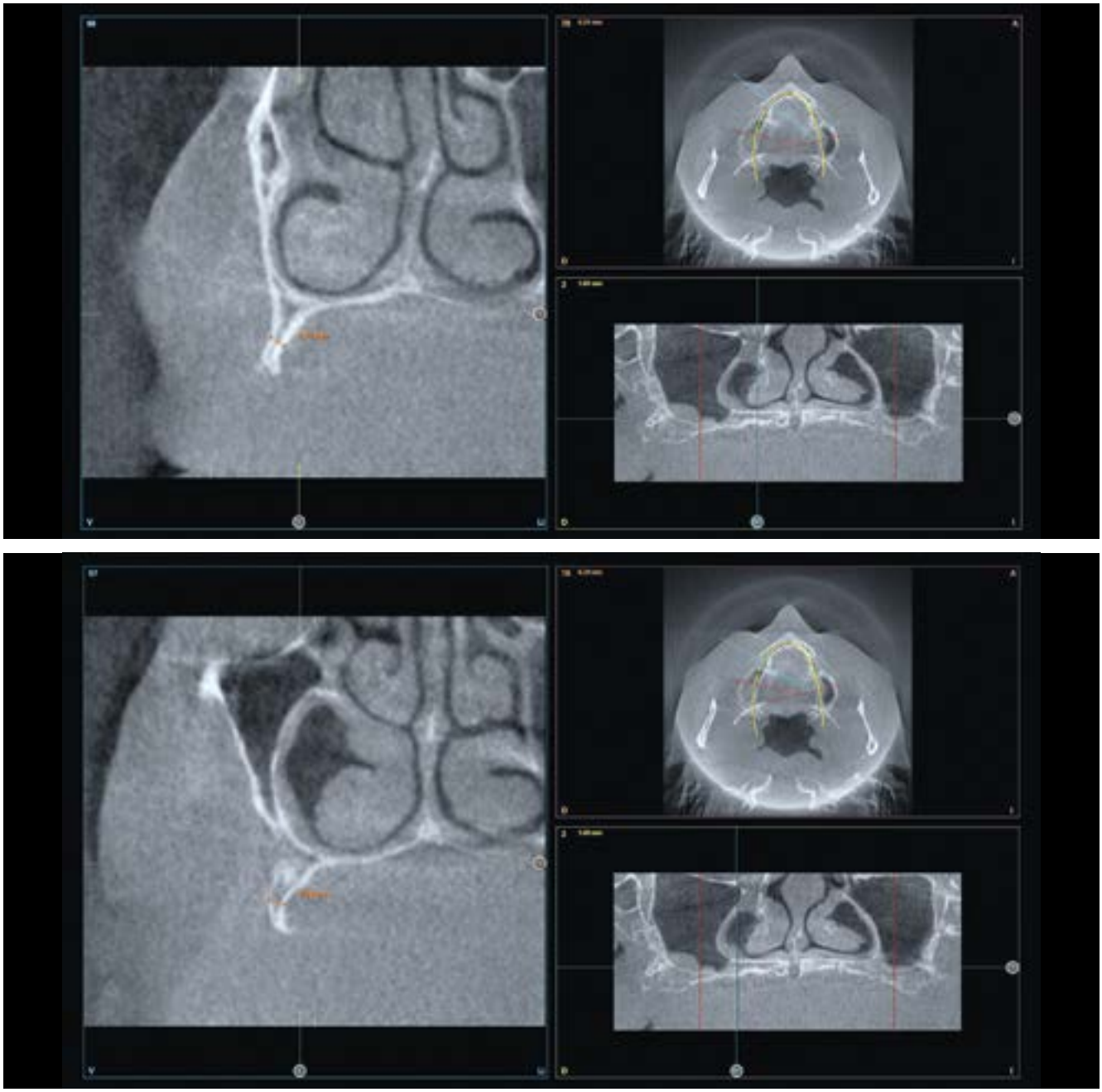
Discussion

Narrow diameter implants allow rehabilitation of areas of horizontal atrophy, avoiding more complex surgical techniques.

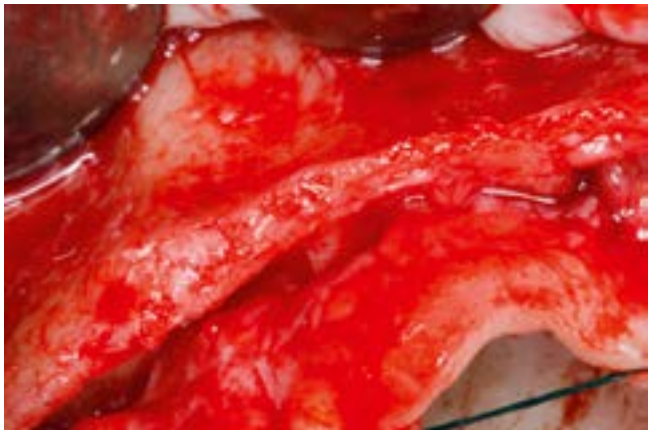
Some publications have reported an implant survival rate higher than 90 % for 3.0-mm and 3.3-mm implants [11 – 13]. The papers evaluating the NDI recommended splinting these implants using the prosthesis. Splinting the implants would reduce the lateral force on the crestal bone (and thus crestal bone loss) [14, 15]. In this work, this hypothesis is confirmed. Splinting the implants is a good approach to reduce the crestal tension in the bone and the crestal bone loss, but the best results are obtained with only a 2.5 mm diameter implant in the implant bridge. When two implants with 2.5 mm of diameter were integrated in the same rehabilitation, the more injurious force was the center loading. With this concept, we have several alternatives for treatment in cases of horizontal atrophy with NDI as a support for the splint. Multiple implants or other techniques are not necessary to achieve greater bone width.



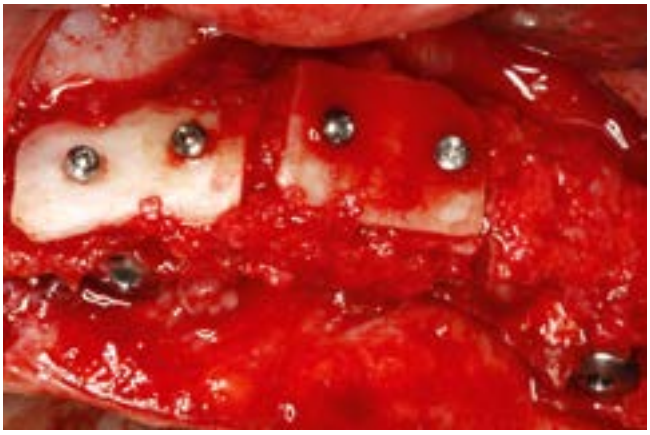
7 I In some areas, the residual ridge shows an extreme bone resorption in width – as seen in the CBCT.



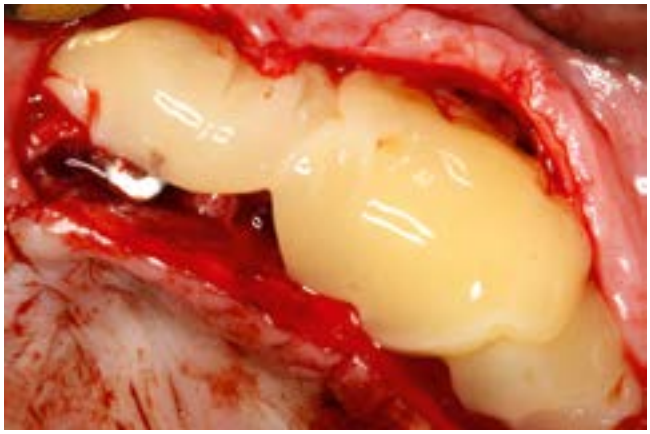
8 and 9 I In some areas, the residual ridge shows an extreme bone resorption in width – as seen in the CBCT.



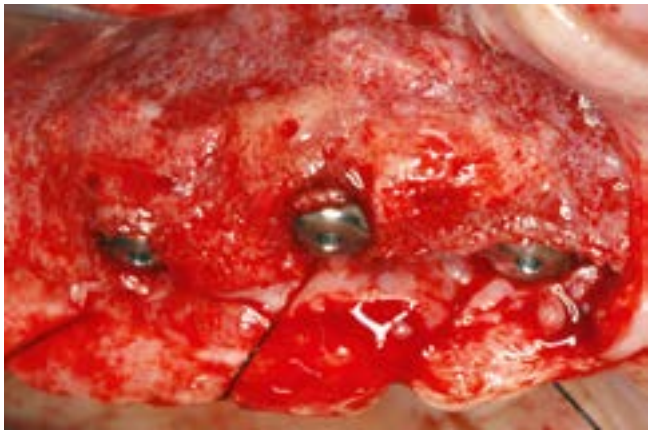
10 I Actual situation of the bone during surgery



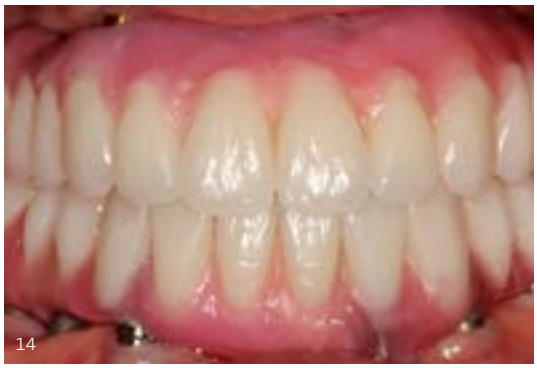
11 I Implants placement, combined with block bone grafts to improve the bone width



12 I Placement of autologous fibrin membranes obtained with PRGF-Endoret (fraction 1 activated and retracted) covering the entire surgery before suturing the soft tissues



13 I Surgical re-entry for the completion of the second phase and the start of implant loading



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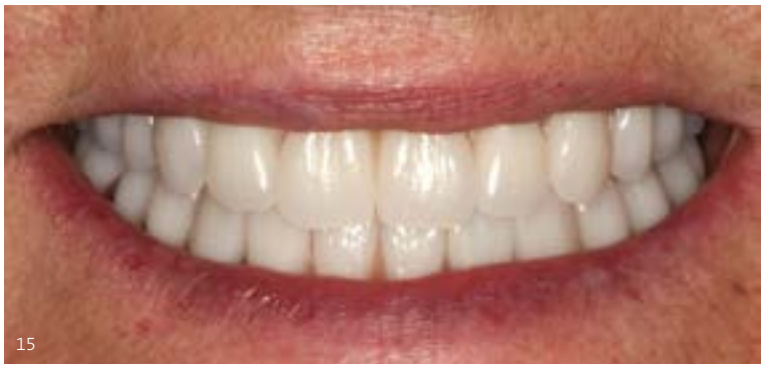

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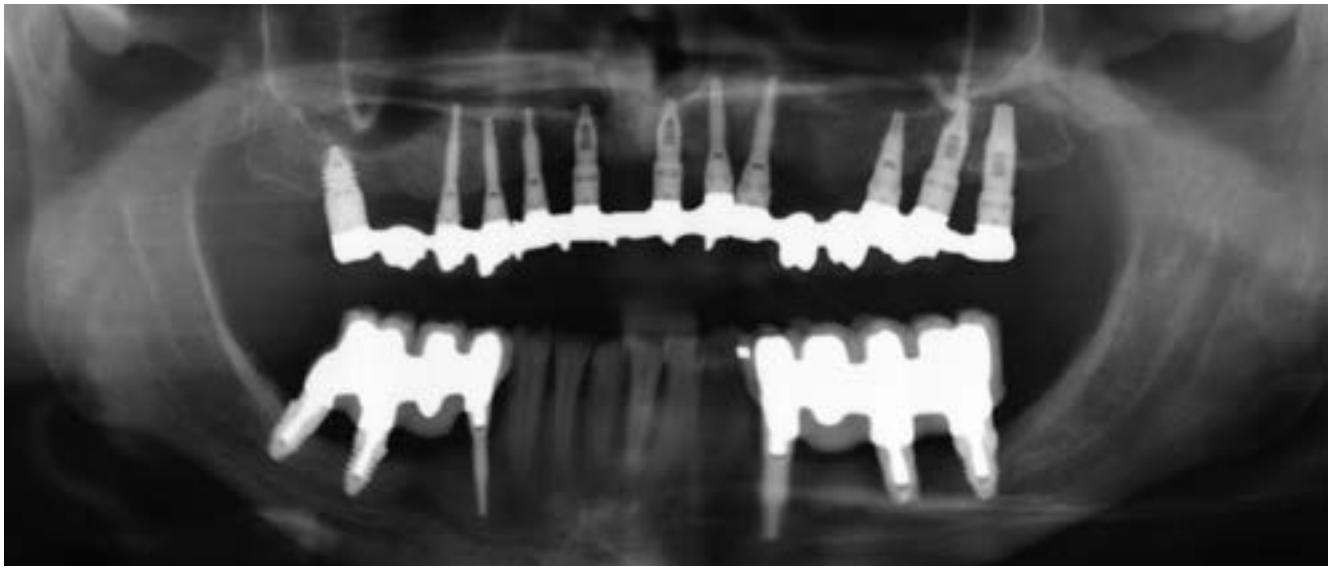

14 and 15 I Final images of the patient with the restoration
16 I Panoramic X-ray after 10-year follow-up

Conclusions

Implants of 2.5 mm diameter can be a predictable alternative with less morbidity for patients with severe horizontal atrophies than other techniques for increasing the bone volume. The distribution of the tension in splinted prosthesis is correct and reduces the crestal bone loss.

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

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Tissue-level implants as a practical option for implant-based rehabilitation

Integration of the digital workflow for a novel hybrid implant

ANDRE CHEN[1, 2], ELENA CERVINO[1, 3], JOANA RODRIGUES[1, 4], JOÃO BORGES[1, 4]

Implant dentistry is a clinically established procedure in the dental field with high survival and success rates, both in partially and completely edentulous procedures [7, 19]. Despite this standard treatment, biological problems such as mucositis and peri-implant disease have increased their incidence and prevalence over the years [4, 6].

Introduction

The rough surface incorporation contrasted to the smooth or machined microgeometry of pioneer dental implants, creating a higher bone to implant contact (BIC) and survival and success rates [22]. The negative side was the potential site for the bacteria colonization.

Marginal bone loss was part of the clinical definition of success and was described as normal at 1.5 mm to 2 mm in the first year and 0.1 to 0.2 mm in subsequent years [1]. Mostly related to supracrestal machined dental implants, these criteria were considered a success due to the absence of clinical symptoms or general problems for the patient.

The onset of periimplantitis for this type of implant treatment was low (1.2%) on the 8-year data [14].

The rough surface implants change the perspective of marginal bone remodeling, since exposure of this surface to oral environment and bacteria may create situations of faster infection (although with mixed results in literature) [21] and progression of peri-implant disease and clinical symptoms [5].

Various attempts were made to control the marginal bone remodeling, the platform switching [10, 23], the one-abutment one-time concept [18], the biomaterial selection [2] and the surgical modified less invasive procedures [20].

Hybrid designs of supracrestal dental implants provide several biological advantages and features that have been evidenced throughout the years.

The tissue and bone stability may be attributed to the supracrestal position of the microgap and the presence of machined collar in contact with the soft tissues, influencing the formation and size of the biological width [8, 9].

They contrasted with the subcrestal implant placement where the biological width forms at the abutment level (subcrestal) and not in the implant polished collar (supracrestal) [11, 12].

The macro-geometry of the implants and the surface technology will be further developed to improve primary stability and bone and soft tissue response. The good clinical performance of the cylinder implant was replaced for easier clinical apical tapered and conical solutions [16].

Higher torque values needed in bone type 3 or 4 led to aggressive designs with the introduction of progressive threads designs and self-cutting edges that allow a better engagement with the trabecular bone [13].

These new generations of dental implants were associated with a subcrestal approach, that in maxillary anterior regions may have an advantage but in other (posterior maxilla or posterior mandible), may originate biological altered healing, leading to marginal bone remodeling and exposing the implant to the oral cavity bacteria [3].

The combination of having a microgap in a tissue level position with enhanced primary stability brings advantages at different clinical stages of implant-supported rehabilitation [8].

Digital technology has created new workflows that use multiple machines to achieve better results and long-term outcomes [15].

From treatment planning to final prosthetic placement, these improved procedures correlate very well with tissue-level implants and provide accurate 3D position especially in depth (apico-coronal position and buccal-palatal position) [24].

This case report demonstrates the incorporation of digital techniques into all phases of implant-supported rehabilitation of a novel supracrestal hybrid macrogeometrically machined collar implant.

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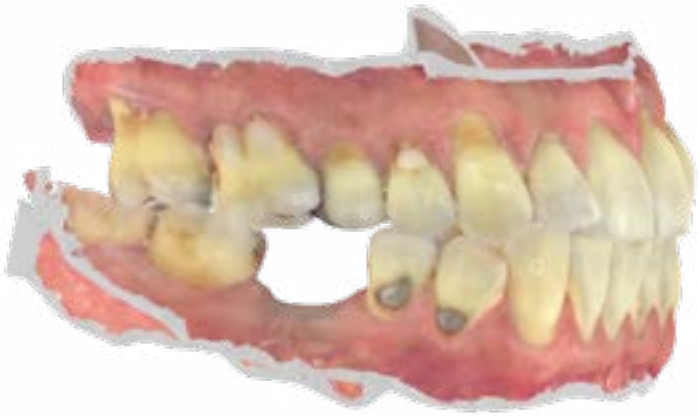
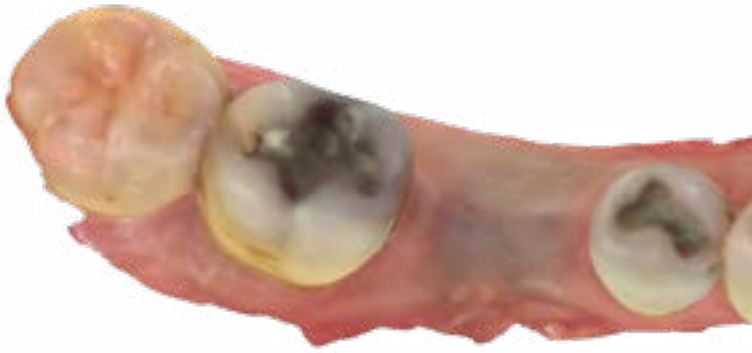
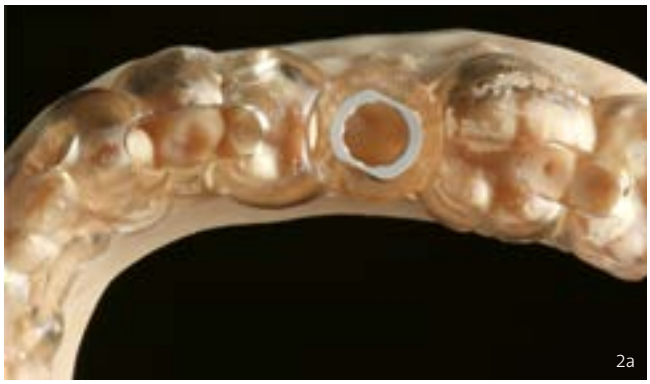
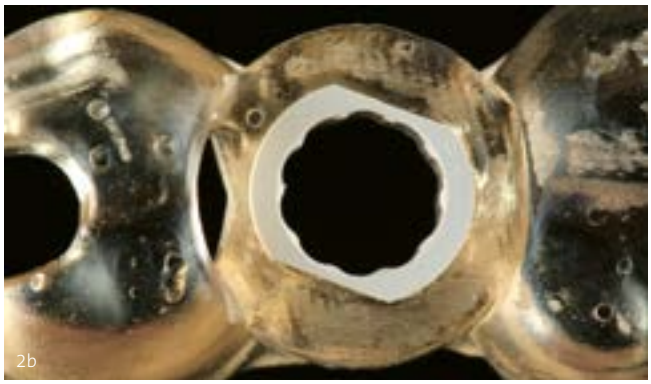


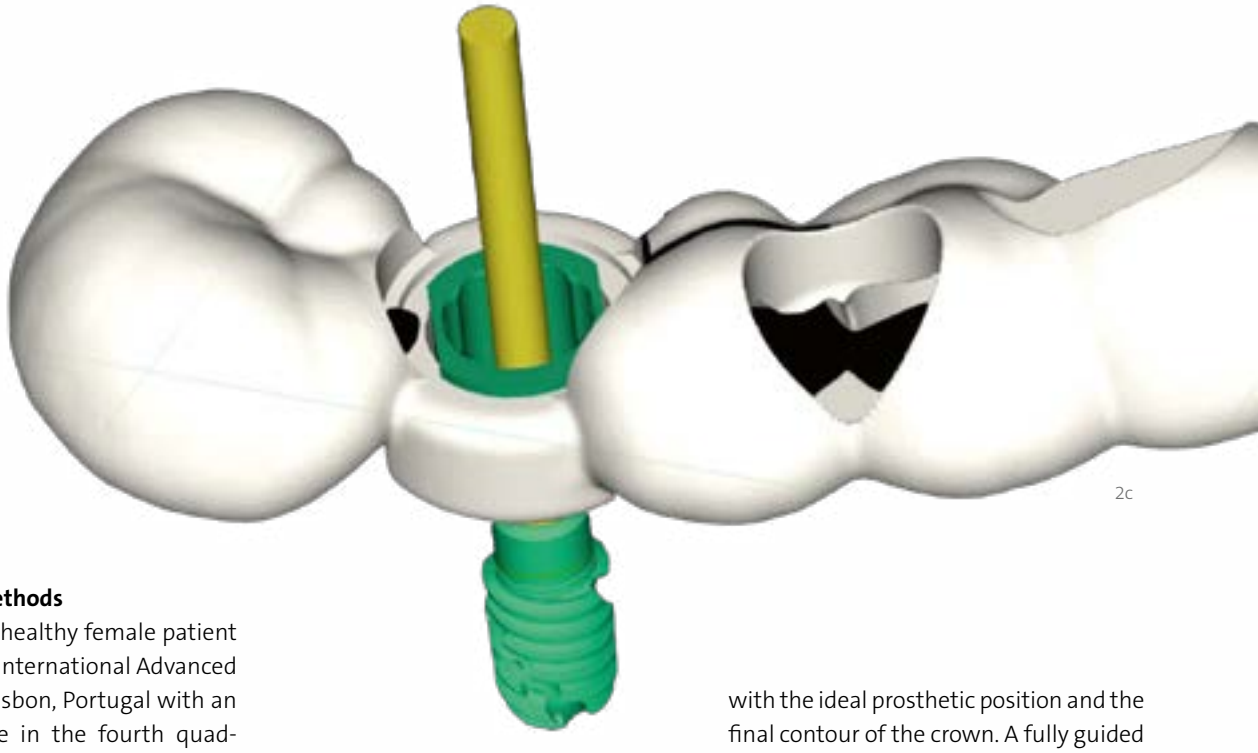


1a and 1b I Initial situation





2a, b and c
Fully guided surgical template planning and 3D printed



Materials and methods

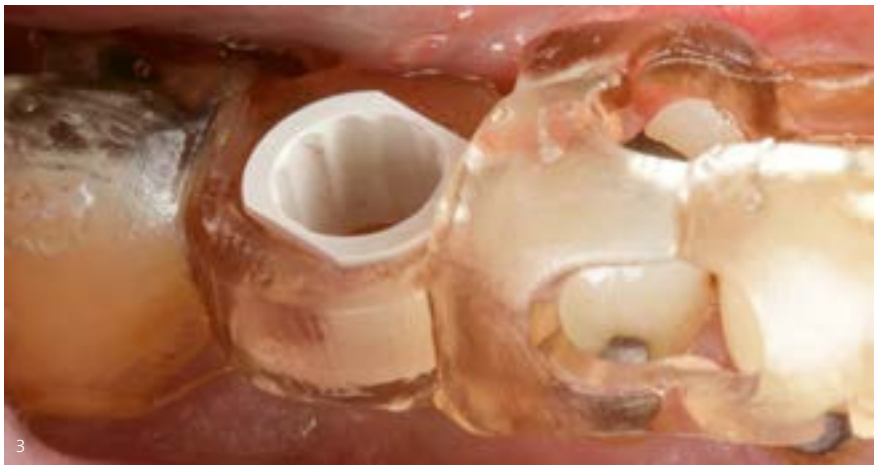
A forty-year-old healthy female patient presented to the International Advanced Dentistry (IAD), Lisbon, Portugal with an edentulous space in the fourth quadrant, due to tooth extraction (46), requiring an implant-supported rehabilitation (Figs. 1a and b).

Bone availability was assessed with a localized CBCT (Planmeca Romexis), allowing a proper digital planning and workflow.

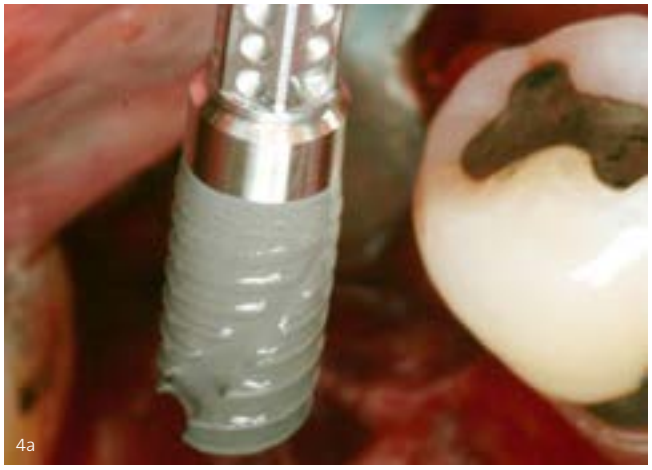
The CoDiagnostic tools (Dental Wings) were used for 3D positioning of the novel TLX NT implant (SLActive, diameter 4.5 mm, length 10 mm, Institut Straumann AG, Switzerland) in accordance with the ideal prosthetic position and the final contour of the crown. A fully guided surgical template was fabricated using the Straumann P20 series 3D printer (Straumann Cares P series) and a 5 mm diameter sleeve was inserted. (Figs. 2a to c)

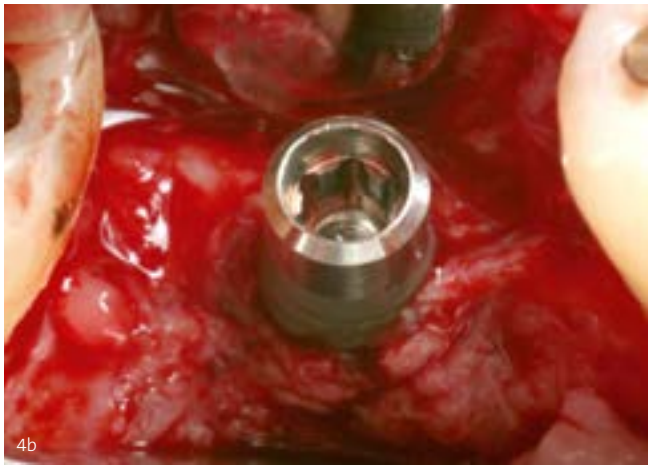
A temporary PMMA screw-retained crown was manufactured accordingly following the Straumann Cares visual design.

3 I Checking surgical guide

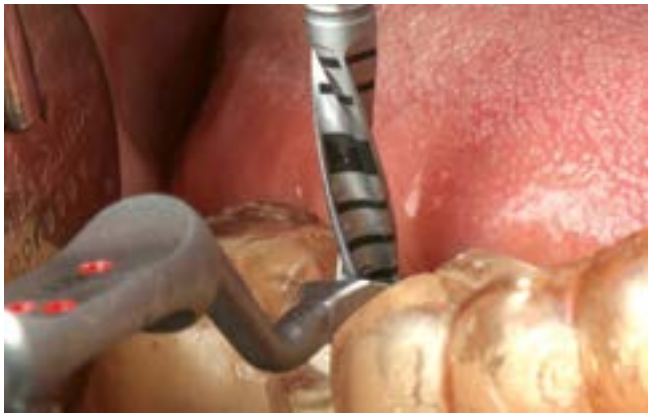


4a and b I Surgical procedure

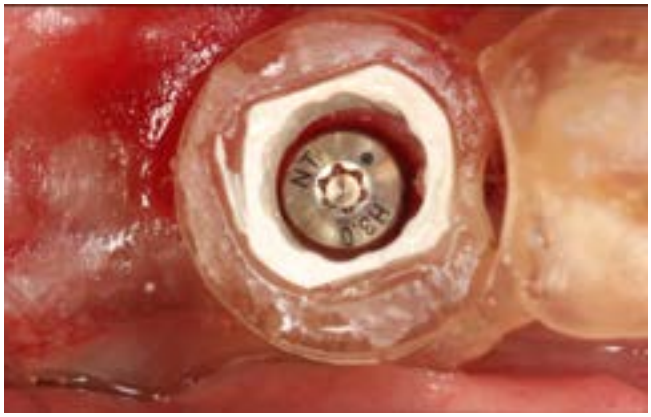




5 I TLX fully guided surgery drilling protocol



6 I Implant placement



Surgery protocol

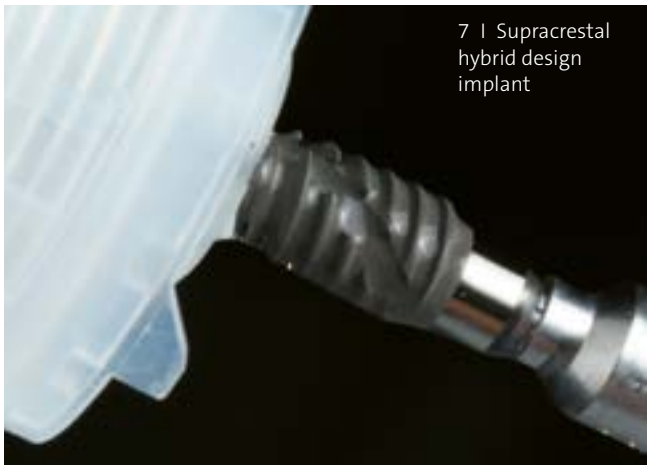
The case was planned for the static fully guided tooth-supported surgery (Fig. 3).

After the standard anesthetic procedure, a full-thickness sulcus flap was created and extended by one tooth anteriorly and posteriorly without making a vertical incision (Figs. 4a and b).

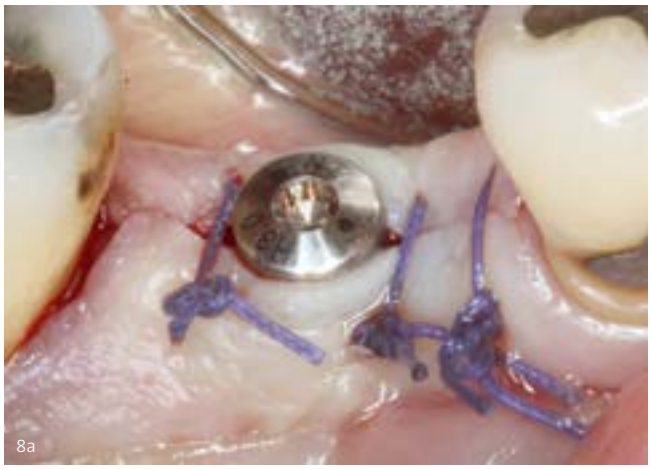
Following the crestal bone visualization, the implant preparation was performed according to manufacturer's instructions (TLX Drilling Protocol) for fully guided surgery. The drilling started with a pilot drill (2.2 mm of width) in full length, followed by 3.2 mm (full desired depth) and finishing with 3.5 mm allowing less tension to the cortical bone (Fig. 5).

The type II bone characteristics of the patient's lower jaw and the engaging implant behavior at the osteotomy site allowed a final torque over 50 N/cm^2 (Fig. 6).

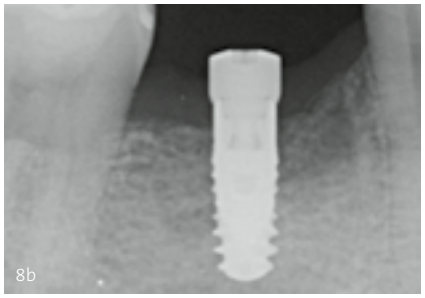
The hybrid macrogeometric placement of the implant allows the machined and polished collar to lie supracrestally and support proper tissue healing.



7 I Supracrestal hybrid design implant

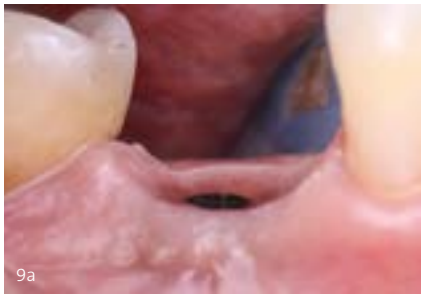


8a

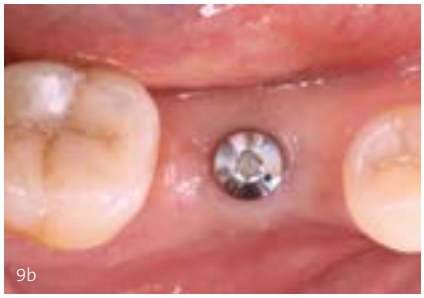


8b

8a and b I Healing abutment, suture and periapical radiograph

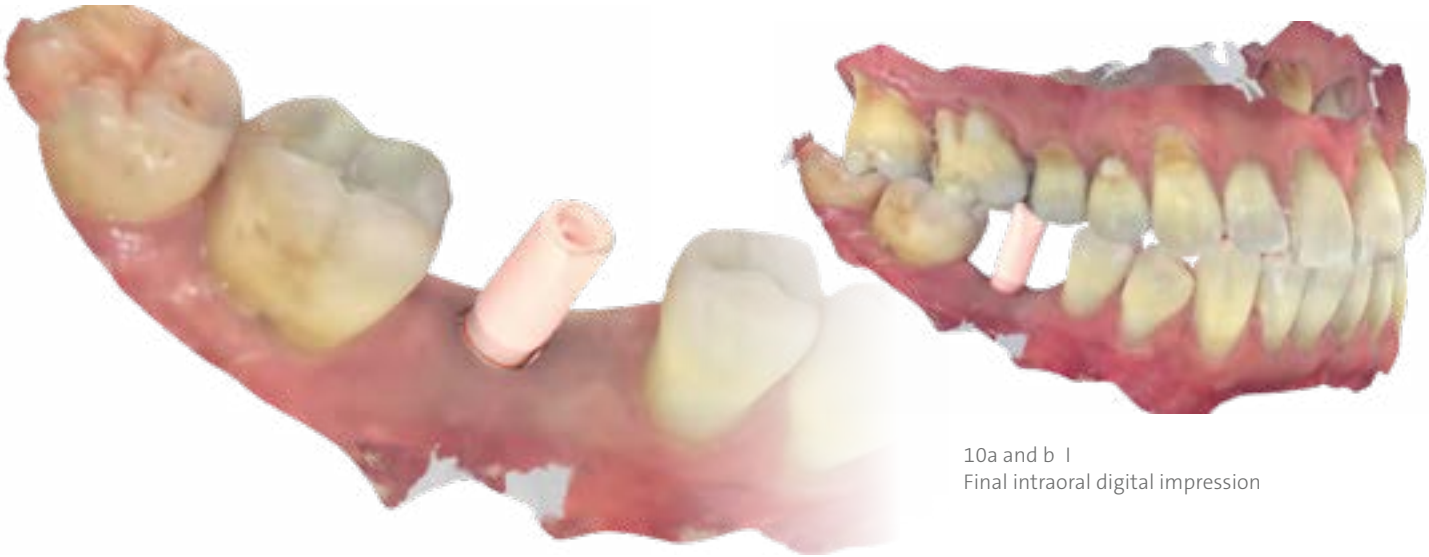


9a



9b

9a and b I Six weeks healing soft tissue stability



10a and b I
Final intraoral digital impression

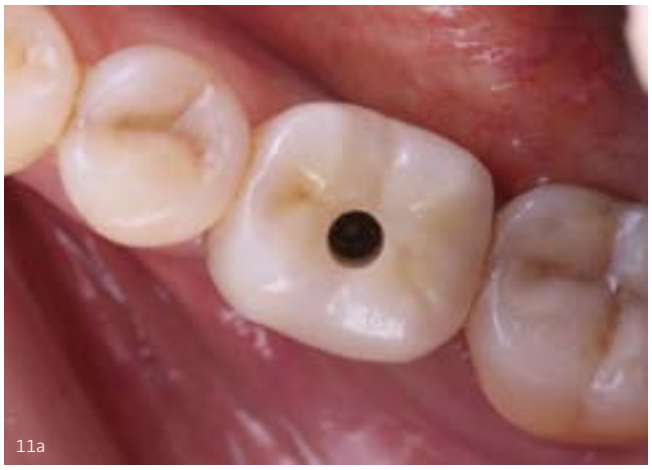
The TLX final depth was visually confirmed through the surgical template and by the horizontal marks in the Digital TLX implant driver (Fig. 7). The wound was closed and sutured, and a periapical radiography was initiated (Figs. 8 a and b).

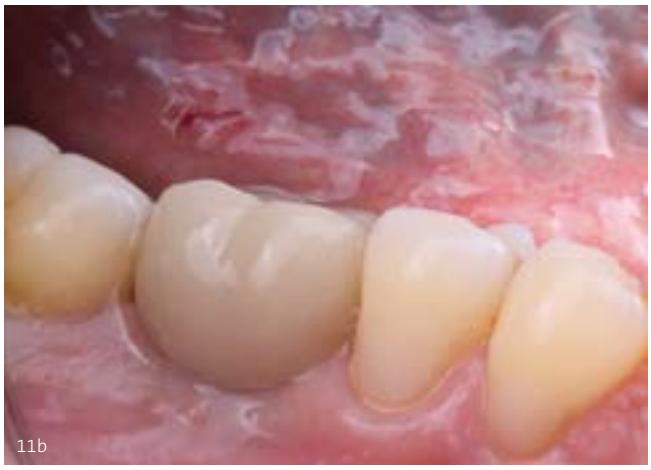
The patient was medicated with 2 g amoxicillin 1 hour prior to surgery and left with an analgesic regimen of Paracetamol 1 g each 8 hours. Radiograph (intra-oral periapical) confirmation was made.

The patient was checked 7 days after surgery and the bone level was assessed radiographically.

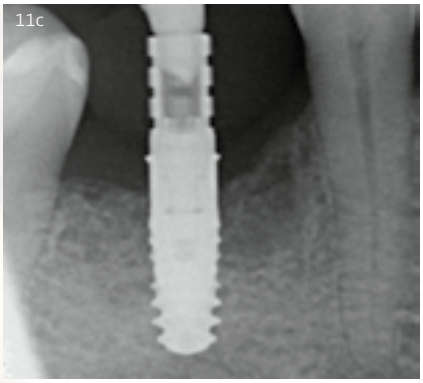
Prosthodontic procedure

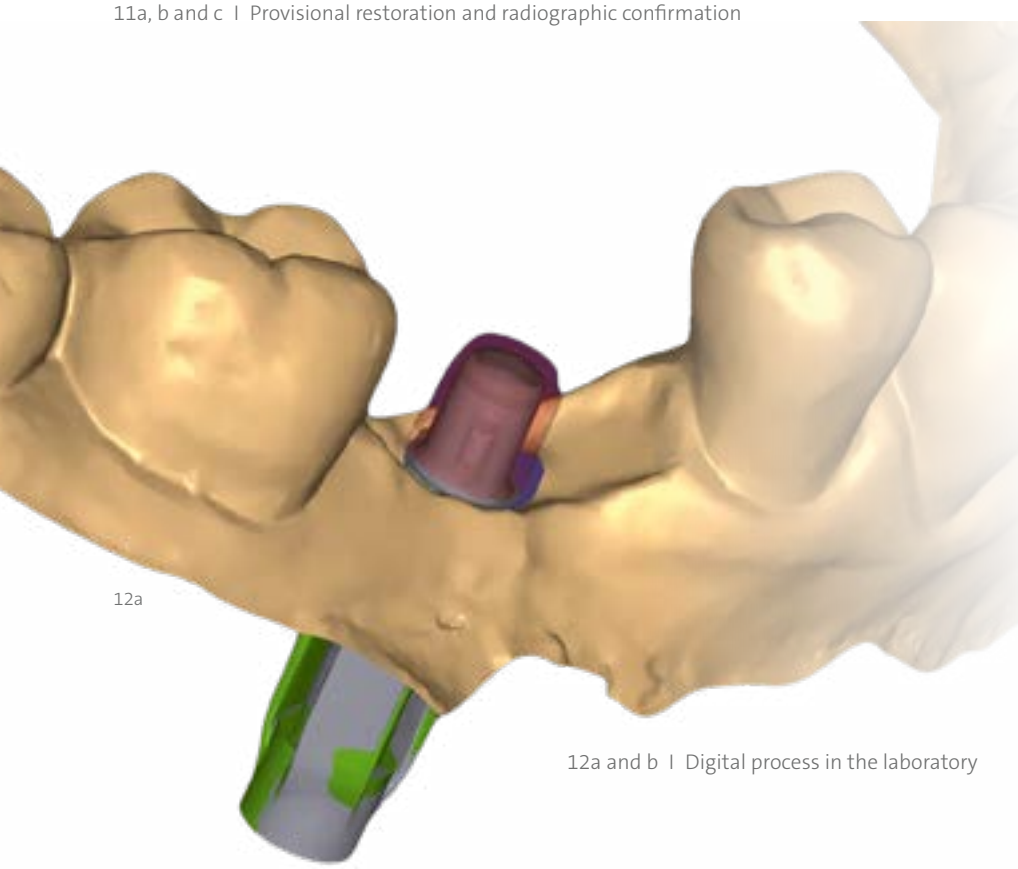
Six weeks after implant placement (osseointegration period), soft tissue and bone contours healed uneventfully (Figs. 9a and b). After confirming the healing and stabilization of the tissue and implant osseointegration, the prosthetic rehabilitation started with an intraoral impression made with an IOS (ITero) which was send to the 3D printer for the model fabrication and the abutment preparation (Figs. 10a and b).

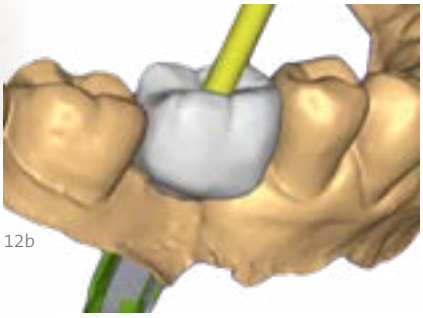

11a


11b

11a, b and c I Provisional restoration and radiographic confirmation


11c


12a


12b

12a and b I Digital process in the laboratory

The implant was digitally scanned and the abutment margin was located and individualized in the laboratory software (Cares Visual). The PMMA screw-retained temporary crown was relined and leveled to the implant platform, ensuring that no acrylic material overpassed the cylinder in the connection with the implant head (Figs. 11a to c).

Eight weeks postoperatively, a final digital double scan (Fig. 12) was performed with the iTero. Provisional crown volume and contour were copied, as well as the 3D positioning of the implant.

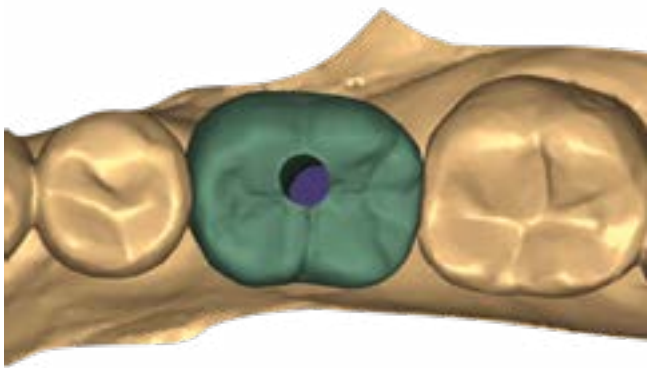
A monolithic zirconia CAD-CAM crown was cemented to a Variobase and screwed at a 35 N/cm final torque (Fig. 13a to e).

The occlusion was verified (200 µm articulating paper with contact and 80 µm without contact) and the contact points were rechecked. The stability of the implant and patient comfort were checked 2 months later, as was the bone level of the alveolar ridge (which was confirmed radiographically) (Fig. 14).

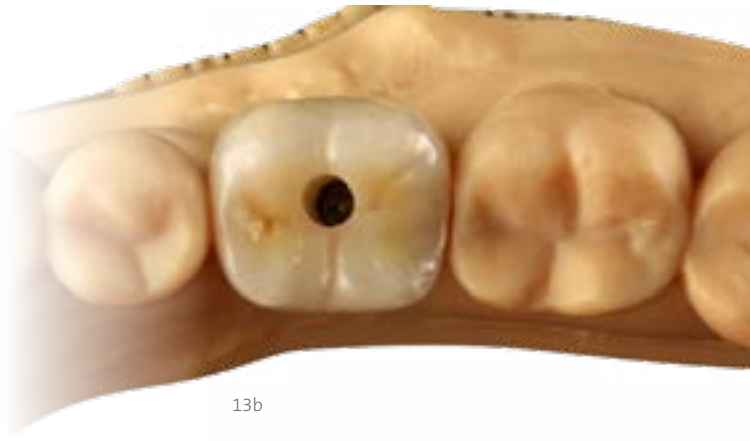
Discussion

The classical approach of the tissue level implants combined with the new implant macrogeometries allow a wide variety of new possible clinical outcomes.

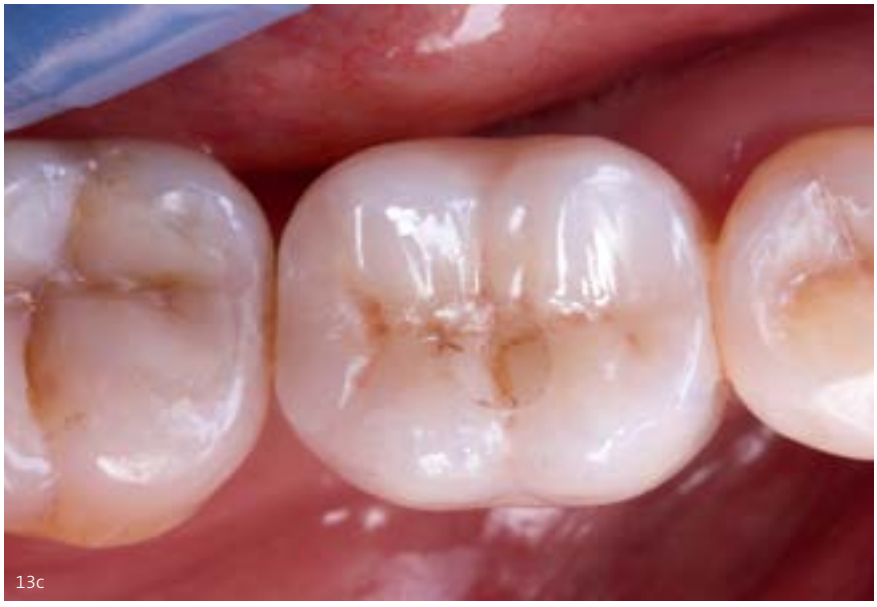
Implant performance and clinical outcomes are highly dependent on patient-related factors such as smoking, diabetes [25], as well as implant technology [16]. The prevalence of peri-implant disease favours the use of subtractive surface microgeometry [4]. The posterior areas may be more susceptible to marginal bone resorption [17] and therefore expose the implant surface to bacteria. They are the primary areas for these implants, but not exclusively, as the anterior maxilla may also bring some new advantages.



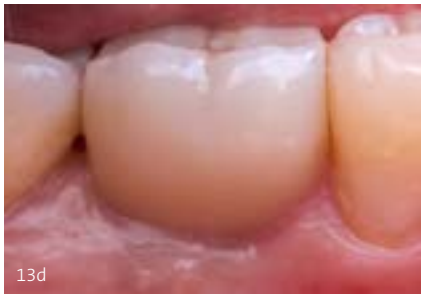
13a



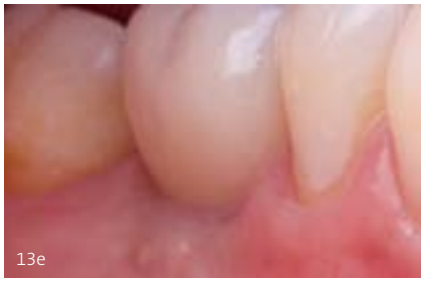
13b



13c



13d



13e

13a, b, c, d and e I Final design and insertion of the prosthesis

Proper understanding of the biology and confrontation with evidence-based literature led the science to move toward a less rough surface of the implant neck, allowing for greater soft tissue stability and better long-term prognosis [21].

In sites where the clinician predicts that bone remodeling may be a factor in exposing the implant neck, this hybrid implants may be an interesting solution.

The combination with a cutting tool technology displayed in the implant macrogeometry allows higher primary stabilities and therefore decreasing implant loss possibilities.

The use of digital technology came to aid in placing these implants in proper depth and control [24].

With a sealed biological implant complex, a supracrestal position (without microgap) represents the clinical situation with the higher survival rates.

Conclusion

This 6-month follow-up case demonstrates the good performance of a novel hybrid design implant in a healed ridge single tooth clinical situation.

Tissue-level implants are now a viable and alternative option for implant-based rehabilitation on an evidence-based and clinical level. The short-term data support this, but more clinical evidence is needed, especially the mid-term 5-year data.

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

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An evaluation of retrospective studies on flapless inserted implants

High survival rates even in the long term

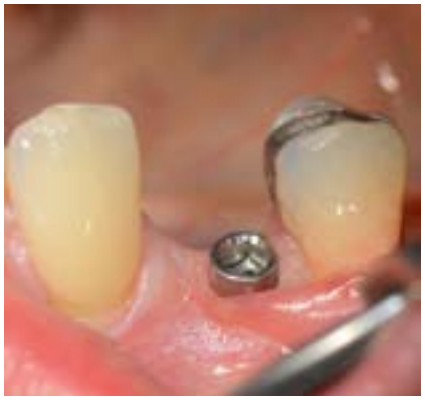
PROFESSOR RALF RÖSSLER, LUXEMBOURG

Less pain and less sensitivity, fewer and shorter treatment sessions – these are considered key advantages of flapless implants. But how reliable are the results obtained with this surgical technique? To start answering this question, this article takes a look at a selection of long-term studies and a systematic review, with a focus on statements about the success and survival rates of flapless implants.

Campelo and Camara took a long-term look at flapless implant placement in the early 2000s [1]. Their retrospective analysis evaluated 770 implants in 359 completely or partially edentulous patients over a ten-year period. Between 1990 and 2000, 126 men and 233 women had received either fixed or removable dentures supported by implants placed using a flapless technique. Only in exceptional cases – where implant placement had resulted in fenestration – a soft-tissue flap was elevated and the site covered with bone substitute and a resorbable membrane, a procedure required for just 21 implants. Another 15 implants were affected by dehiscence; where this occurred in a dentition to be restored with a removable prosthesis, a new implant position was selected. By contrast, if the prosthesis to be supported by the implant was fixed, a mucoperiosteal flap was elevated, and an implant was placed after a three-month healing period.

Three and six months after surgery, periodontal probing was performed, and the gingival index and implant mobility were determined. Subsequent follow-up examinations were performed at one-year intervals. Implants were considered successful if they met the criteria outlined by Albrektsson et al. [2]. It was not always possible to remove the prosthetic restorations to test implant mobility, so all the success criteria may not actually have been met in all cases, but the investigators nevertheless rated the respective implants as successful if it was free of pain in function and on percussion. Implant failure, on the other hand, was defined as any mobility or pain following treatment, implant removal due to pain, or annual bone loss of more than 0.5 mm for two consecutive years after the first year in function.

After an observation period of ten years, the flapless implants exhibited highly variable cumulative success rates, starting at 74.1 % for implants placed in 1990 but getting as high as 100 % for implants placed in 2000. In total, the researchers observed 37 implant failures, of which 45.94 % occurred after the first year in function, 37.83 % between insertion and loading, and 16.21 % during the first year in function. Many of the failures occurred in the early days of working with this technique, so investigators associated them with the learning curve and with patient selection. Failure rates, they pointed out, decreased with experience and more stringent patient selection, even with an increasing number of implants placed. Based on these findings, the authors considered flapless implants a predictable procedure, provided that the patient selection criteria and surgical techniques applied were adequate. In this context, choosing the correct drilling angle is crucial to avoid fenestrations or dehiscences.



High-risk patients in focus

The need for long-term evaluations of full-arch restorations on flapless implants was recognized by Lopes et al.[3]. Accordingly, in their retrospective clinical study, they observed 111 edentulous patients who received maxillary or mandibular fixed full-arch prostheses following guided flapless placement of four implants using surgical stents. The observation period was seven years. The patient population included 53 bruxers, 21 smokers, and 59 patients with comorbidities. The study included 133 full-arch prostheses on 532 implants.

Implant and restoration survival were the primary study parameters. Implant

survival was defined in terms of clinical stability, patient-reported function without discomfort, and absence of peri-implant radiolucency. To determine implant stability, the restorations were removed, and each implant was evaluated individually at the six-month follow-up visits. Secondary study parameters included marginal bone loss around the axial and tilted implants and the incidence of biological and mechanical complications. Periapical radiographs were taken at the five-year exam to determine bone loss.

At the seven-year follow-up exam, failure was recorded for 28 implants (17 in the maxilla and 11 in the mandible), for a cumulative survival rate of 94.5 % at seven years. The 14 patients who experienced implant failure were reported to exhibit a high prevalence of bruxism and smoking habits – eight patients were bruxers and six were smokers. Failure of the prosthetic components was observed in three cases, resulting in a survival rate of 97.8 % at the prosthetic level. The mean marginal bone loss at five years was 1.30 ± 1.06 mm. Complications affecting the provisional restoration were seen in 81.9 % of patients, and regarding the definitive prosthetic restoration, in 29.7 % of patients. Even considering the limiting factors of this study, its authors concluded that the treatment options studied could be considered suitable for edentulous patients and yielded high long-term survival rates.

Systematic review demonstrates high survival rates

The authors of a systematic review that included a meta-analysis of studies on the rehabilitation of completely edentulous patients with restorations on flapless implants found similarly high cumulative survival rates [4]. Parameters considered crucial included implant survival rates, changes in marginal bone levels, and complications associated with guided implantology. The work of two independent reviewers applying specific selection criteria, including a minimum study period of one year and a minimum case number of ten patients, yielded 13 studies dated 2005 to 2014, of which 10 prospective studies and 3 retrospective cohort studies.

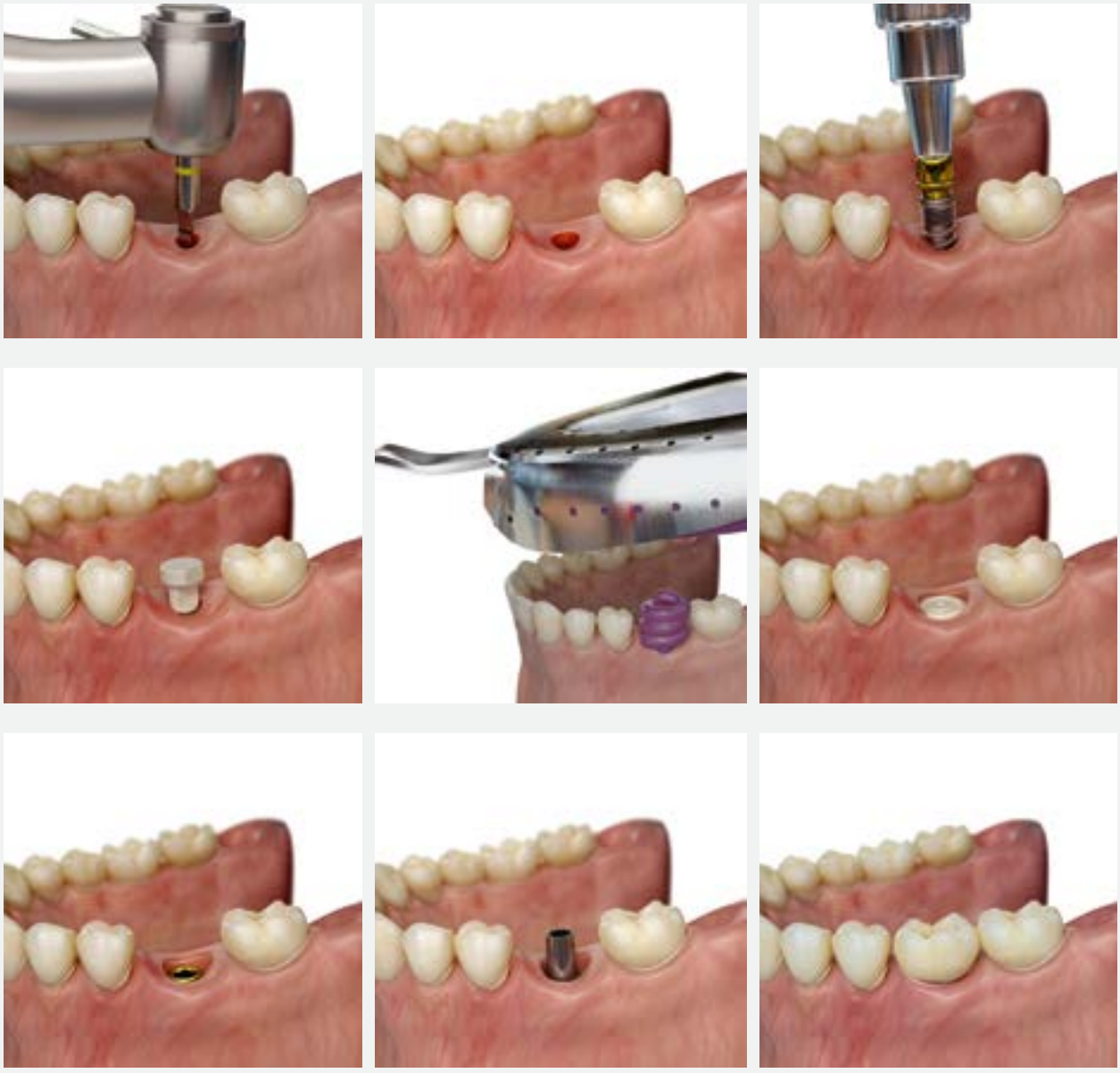
All told, this review included the results of 2,019 flapless implants placed in 329 patients. After reviewing the publications, the authors found a calculated cumulative implant survival rate of 97.2 % and a marginal bone loss of 1.45 mm over a study period of one to four years. In the discussion section of their paper, the authors rated this survival rate as high, but point out the frequency of surgical and prosthetic complications, which were at levels known from prospective and retrospective studies of freehand implant placement with flap elevation. Like Campelo and Camara [1], the authors of this review also mentioned the significant learning curve on the path to treatment success. Moreover, they held that to improve the technique and its success rates, additional comparative long-term studies would be desirable.

Conclusion

Despite differences in study designs and, in some cases, widely divergent publication dates, the cited publications present comparably high survival or success rates, sometimes over extended periods. In this context, the learning curve mentioned in two publications appears interesting, as clearly reflected by the varying cumulative success rates in Campelo and Camara [1]. However, in order to correctly assess the lower initial success rates in particular, it would seem appropriate to consider that the study was initiated over thirty years ago. In addition, the high survival rates reported by Lopes et al. [3] certainly also deserve mention; after all, they were achieved when treating patients with relevant risk factors such as bruxism or smoking habits. ■

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

The MIMI insertion protocol – a minimally invasive flapless implant technique



One particular flapless implant procedure is called MIMI (Champions Implants, Flonheim, Germany). Its special feature is that it combines the flapless approach in the surgical phase with an important supplementary aspect in the restorative phase: the so-called Shuttle makes re-entry through the gingiva unnecessary. The Shuttle doubles as a surgical cover screw and a healing cap, avoiding the risk of soft- and hard-tissue degradation associated with re-entry. Thus, the MIMI procedure combines the advantages of flapless placement and a relevant advantage in the prosthetic phase.

The surgical procedure is performed using a low-speed method, starting with long conical triangular drills. In the cortical bone, the MIMI drilling protocol calls for speeds of 250 rpm, and in the cancellous bone, 50 to 70 rpm. This is made possible by the so-called CNIP navigation (Cortical Navigated Implantation Procedure), in which the drill is guided by the cortical layer of the jawbone, which ensure it always stays in the cancellous bone. In addition, the final drill used has a diameter approximately 0.5 mm larger than the implant diameter, ensuring a measure of crestal relief.

If the anatomy permits, the implant is placed 1 to 2 mm subcrestally, fully harnessing the benefits of the "platform-switching effect." In the narrow ridge, implants can be placed using the MIMI II procedure described by Fuchs-Schaller, which is also based on CNIP navigation. Additionally, if needed, an internal direct maxillary sinus lift can be performed as a minimally invasive procedure. Future studies will focus on this.

IDS 2021: particularly exciting for implantologists

It's time for a lively trade fair discussion!

From 22 to 25 September 2021, the International Dental Show provides an overview of developments, procedures and products – particularly in implantology. Mark Stephen Pace, Chairman of the VDDI (Association of German Dental Manufacturers) gives an up-to-date assessment in our interview.

Mr Pace, what do you hope from the IDS 2021?

Further development of the dental industry is very important to us all. Industry, trade, dentists, dental technicians, and their teams have developed many good ideas in the past few months for ensuring progress. It is now time for personal discussion to shape the future together. As the world's leading trade fair, IDS 2021 offers our industry the right forum for shaping the future.

Many big players are not participating at the IDS. Will the trade fair retain its significance for modern dentistry?

It's true: The IDS 2021 will be smaller in size than its predecessors. But when I go through the list of those committed to participate, I come to the conclusion that at the trade fair we will see a complete picture of current trends as well as proven and innovative products from all areas of dentistry. This ensures that visitors, as usual, will gain a complete overview.

How do you envisage the future of the IDS?

I'm convinced that the IDS, as a classic trade fair with a presence, is exactly right for our industry. This is because dentists and dental technicians have haptic and kinaesthetic perception. They must take control of innovations, understand procedures in the truest sense of the word and visually appraise prosthetic restorations and treatment results.


Photo: Dentaurum/Andreas Fabry

Mark Stephen Pace, Chairman of the Association of German Dental Manufacturers (VDDI)

How is this at all possible at IDS 2021?

By and large we will see and comprehend a great deal, albeit with pandemic-related restrictions. To give an example: Anything that can be safely disinfected, we can probably also take hold of. In contrast, we can only look at equipment with surfaces that are not intended for continual disinfection. However, an informative, lively discussion will always be possible.

Where do you anticipate the biggest advances in implantology?

Implantology is a mature sub-discipline of dentistry, especially as far as the use of digital tools is concerned. There are in the meantime functioning workflows, with which it is now possible to achieve the best results economically. Nevertheless, we also regularly find that some intelligent solutions do not yet effectively intermesh for the implantological daily routine. We therefore need a whole range of additional interfaces. They are the lubricants that allow the large gears of the digital implantological workflow to run really smoothly. I anticipate different advances in this area at the upcoming IDS, which noticeably make the daily routine of implantologists easier.

Could artificial intelligence also contribute to this?

Partly – artificial intelligence can now simplify or at least accelerate, and sometimes even improve, evaluation of X-ray images. Systematic integration in backward-planning software could allow the entire pre-planning of implantological treatment to be performed more quickly and reliably.

Furthermore, I also expect further alternatives to today's established procedures and products in the fixation of implantological restorations and bone augmentation materials.

In short: The IDS from 22 to 25 September ought to be particularly exciting, especially for implantologists.

Thank you for your time, Mr Pace.

New solutions at the IDS 2021 and two events for 2022 in Europe

Back to live events

Osstem Implant is looking forward to exhibiting at the first major trade fair since the outbreak of the pandemic and is planning to show more commitment to the European market. On an area of 546 m^2, Osstem will present new products and solutions for the European market on the second floor of Hall 2 at booth number A010. As Osstem invests more than 7 % of its annual sales revenue into R&D to ensure that dentists can offer their patients better treatment, there will surely be new products for everyone to discover.

Three main zones on the IDS 2021

This year, the booth will be divided into three main areas. The product portfolio is presented in the "Display Zone" to present solutions for all the different areas of the dental industry. Visitors will get an overview and can dive deeper into each topic depending on their interests.

The "Experience Zone" focuses on practical experience. Visitors can try out the products at numerous demo stations and gain their own experience. There are always trained employees beside, who can demonstrate the correct application on the one hand and answer questions on the other. There will also be a so-called "Lecture Zone". There will be two lectures a day. The speakers are from Italy, Albania and Poland and will share their expertise and know-how from their various clinical cases.

For those who do not come to IDS in person this year, a virtual exhibition experience is available in addition to the regular event. There, interested parties can follow highlights and find out about news from the Osstem Implant product family.

Osstem is planning two big events for 2022 in Europe

The 13th "Osstem World Meeting" will take place in Istanbul from 25 to 26 June 2022. The topic of the event will be the future of the digital dentistry. Four different hands-on courses by renowned course directors are planned for Saturday with a joint gala dinner in the evening. The symposium follows on Sunday with seven lectures and two live surgeries.

Furthermore, the Osstem-Hiossen-Meeting is planned from 28 to 29 October 2022 in beautiful Rome. 700 participants from all over Europe are expected at the event. 29 speakers from Europe have already been confirmed, and two guest speakers from South Korea and the USA are also expected. At the symposium, six lectures will be given on each day. In addition, there will be a table discussion on the first day and a live surgery on the second day.

More information

on future events will be announced via social media, the AIC homepage (aic-europe.eu) and the Osstem website www.osstem.de.

The Bego Clinical Case Award is in its 4th round

The competition honors implantology cases that were restored using Bego Implant Systems products. Cases can be submitted from the specialties of implant surgery, navigated surgery, soft tissue regeneration, prosthetic rehabilitation or a combination of these topics.

Implantologists and dental students from around the world are invited to participate in the competition. Multiple patient cases may be submitted per entrant. An independent jury of experts consisting of Dr Mia Buljan (Croatia), Dr Francisco Delille (Portugal) and D. Sebastian Beetke (Germany) will award prizes to the six best case documentations from areas of dental implantology. There are prizes worth up to EUR 1,000 to be won.The deadline for entries is March 31, 2022.

More information
www.bego.com.

Show and share your talent.

CleanImplant Foundation: On-site SEM analysis of implants for dentists at IDS 2021

Dental implant quality under scrutiny

"Sterile packaged" does not mean an implant is necessarily free of contaminants. This disturbing realization is slowly dawning on dentists not only in Europe and the US. Exceeding 100.000 subscriptions on Facebook's CleanImplant site, the number of dentists worldwide intrigued by this revelation increased tenfold over the past two years.

Transparent testing procedure

At the International Dental Show IDS in Cologne coming up in September, the non-profit CleanImplant Foundation based in Berlin, Germany, once again showcases the quality check of dental implants using a scanning electron microscope. Installed exclusively for this event in Hall 10.2 in collaboration with Thermo Fisher Scientific and the 'Medical Materials Research Institute', the set-up provides full transparency of the Foundation's quality assessments.

Dentists and manufacturers alike can witness the independent quality check of dental implants in detail. The open and public demonstration allows spectators to learn about the extent of factory-related contamination of sterile packaged implants, and most importantly, its direct consequences. The SEM unveils whether an implant meets the strict consensus-based CleanImplant Quality Guidelines, and dentists are encouraged to participate in finding out whether the implant system used in their practice is actually safe.

Clear the stage for high-quality manufacturers

The CleanImplant Foundation has been coordinating worldwide quality assessment studies of dental implants with renowned universities for many years. Following a strict peer-review process, the Trusted Quality Mark is awarded to particularly clean implant systems only. To date, recipients awarded the quality seal include selected implant systems by Biotech Dental, Bredent Medical, BTI Biotechnologies, Camlog, Global D, medentis medical, MegaGen, Nobel Biocare, NucleOSS, Straumann, Sweden & Martina, and Zircon Medical.

SEM testing station at the IDS

Dr Duddeck, dentist and founder of the CleanImplant Foundation, explains the dangers of contaminated medical devices.

However, before the coveted Trusted Quality Mark is awarded, each implant system is tested based on five randomly selected samples from multiple batches. With at least two of these samples purchased from anonymous blind-shopping or provided directly from dental practices as they would be used on patients, this procedure avoids a possible pre-selection of testing samples by the manufacturer. Samples must comply with the strict thresholds set in a consensus process by renowned scientists of the Foundation's Scientific Advisory Board, such as Tomas Albrektsson, Ann Wennerberg, Hugo De Bruyn, Michael Norton, Florian Beuer, and others. Simply technical cleanliness, however, does not suffice for the time-limited award. After additional proof of successful clinical documentation, the peer review process will determine if an implant system meets the quality criteria and thus receives the award. In order to remain relevant and up-to-date, this process must then be repeated every two years to refresh the quality seals lifecycle. As of this year, dentists can showcase their commitment to dental excellence and clean implantology as a so-called 'CleanImplant Certified Dentist', ultimately rewarding their patients' trust with added backed-up confidence in their chosen implant.

Dental trade show visitors and manufacturers are free to book appointments in advance for the live demo at the SEM: IDS Hall 10.2 | P032.

Full-size high-resolution SEM image mapping of two original-packaged implants, both samples with FDA clearance and ready to use for patients.

More information

www.cleanimplant.org or
www.facebook.com/cleanimplant

The Astra Tech Implant System

Optimal marginal bone preservation

In a recent meta-analysis comparing how three premium implant brands' surfaces influence marginal bone maintenance, the OsseoSpeed surface, used for Astra Tech Implant System, comes out on top. The difference, compared to the other two surfaces, is statistically significant.

The story, co-authored by Dr Michael R. Norton and statistician Mikael Åström, came about for two reasons. First, no meta-analysis existed to compare the marginal bone loss due to different surface modifications among currently marketed premium brands. Second, published articles by Dr Dirk Duddeck et al. suggest that premium implant surfaces are free of foreign materials. In contrast, cheaper implants may be riddled with both mechanical and organic impurities. Is this the case? And if so, was there any difference between premium brands too?

According to Dr Norton, the answer is essential as the surface affects osseointegration and marginal bone maintenance. In the case of cheaper clones, the research suggested that these may cause peri-implant infections and compromised function.

After establishing that premium surfaces are better, the study focused on performing a meta-analysis of the entire body of literature concerning OsseoSpeed (Dentsply Sirona), TiUnite (Nobel), and SLA/SLActive (Straumann).

Three good surfaces. OsseoSpeed is outstanding.

The meta-analysis included over 11,000 implants from 113 articles, and key takeaways include:

- OsseoSpeed has, on average, the least marginal bone loss in both 1-year (-0.29 mm) and 5-year (-0.35 mm) follow-ups.
- There is a statistically significant difference between OsseoSpeed and TiUnite and SLA/SLActive in both 1-year and 5-year follow-ups.
- OsseoSpeed offers more predictable outcomes with less variation around the mean and less spread.

In conclusion, the authors state that OsseoSpeed demonstrates superior marginal bone levels—which is vital to achieving the best possible functional, biologic and esthetic outcomes over the long term.

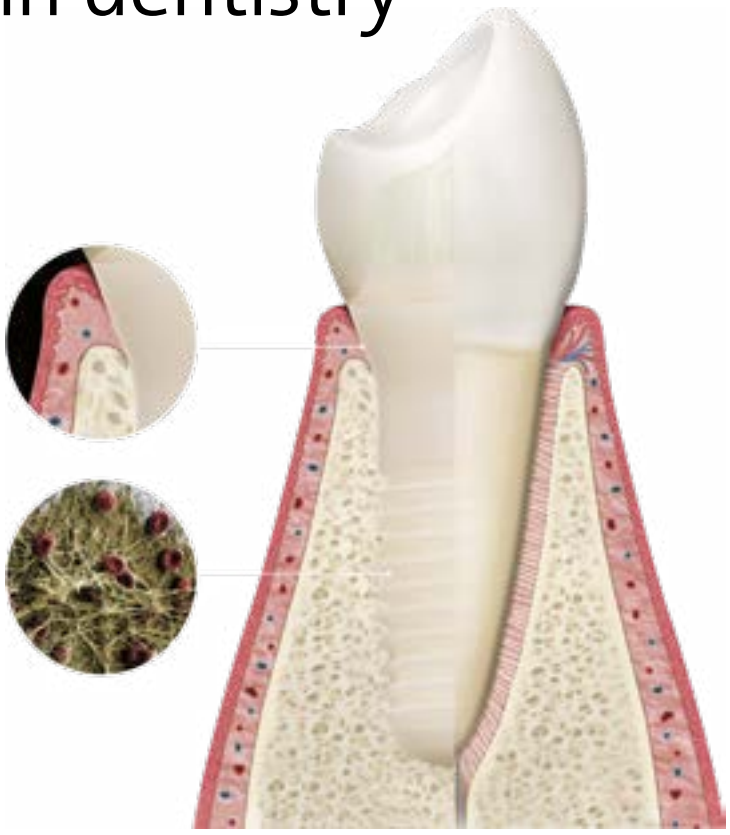
Astra Tech Implant System

This scientifically proven, highly versatile and flexible implant system enables successful outcomes for every case. It is great to grow with, and equally suited to handle even the most complex treatments. Astra Tech Implant System has a unique implant range - different sizes and lengths, straight, profiled and conical designs that supports early and immediate loading, as well as a flexible drilling protocol and a full set of restorative options, including patient-specific and prefabricated solutions.

More information
www.dentsplysirona.com/science

Interview with Dr Sophia Karapataki on zirconia implants

Long-term clinical evaluation on materials used in dentistry



Dr Karapataki maintains a private practice in Athens, Greece and is specialized in implantology and periodontology. Besides being extensively published as well as lecturing internationally on the topics related to peri-implantitis, metal-free dentistry, and material intolerance/immune system involvement, she is a founding member of Leading Ladies in Dentistry. In collaboration with the University of Graz, Austria, Dr Karapataki is preparing to publish this fall a landmark retrospective study on her long-term results with soft tissue health around Patent zirconia implants. She has amassed data on over 90 implants with 5–12 years of follow-up. In this interview, she gives us insights into the topic of metal-free dentistry.

Dr Sofia Karapataki

Dr Karapataki, you have been an active proponent of metal-free dentistry for some time now, and your practice is specialized in this regard. Are most of the patients in your region interested in this type of dental treatment?

Typically, new patients who visit my practice, are not looking for metal-free solutions, they are looking for dental treatment to solve any number of oral health issues. This though starts to change with all information that exists in the internet and people that are interested in their health and consciously look for alternative solutions appear more and more. Unfortunately, according to the European Commission on Health, the adult Greek population has among the highest smoking rates in Europe and in addition, among the highest rates of obesity. These two significant health conditions make healing oral diseases like periodontitis and tooth loss very challenging to resolve. This is the main reason why I do my best to reduce each patient's toxicity profile and promote a healthier rehabilitation of their condition.

When you talk about a "healthier rehabilitation", how do you measure "healthier", isn't dental treatment in general "healthy"?

Well, of course, traditional periodontics and traditional dentistry is intended to heal and improve oral health. However, now that we have significant evidence on the long-term effect of certain metals and materials used in dentistry, we must be aware that long term exposure to some materials has an undesired negative impact on the immunological health of some our patients. As an example, according to the 2013 Jacobi-Gresser study, microparticles released by titanium implants on the immunological mechanism of the body could possibly initiate peri-implantitis. For our average patients who come to see us with lifestyle-related risk factors, we must achieve lower or even

eliminate their toxicity profile and bolster their overall health to overcome these long-term complications.

What makes a Zirconia Implant "healthy"?

Zirconia is a ceramic material devoid of any metal properties. It is electrochemically inert, causing no galvanizing nor electro current negative effects at an inter- and intracellular level. It is the most bioinert and biocompatible material currently available in the market, with no detected allergies or intolerances. The material as such exhibits lower surface free energy that leads to reduced biofilm accumulation which is the foundation for the formation of plaque. The lower levels of bacterial accumulation result in better soft and hard tissue adaptation, not only making the surrounding tissues healthier looking and more esthetic, but it also allows for long term healing stability, and predictability.

Can you give us a sneak preview about your next publication? We understand it is related to long term results regarding peri-implant health around zirconia implants?

I have been treating my patients for the last 8 or so years solely with the Patent Dental Implant system. It was formerly known as ZV3. The implant possesses several special production and design features which have been quite helpful to me in treating my patients. Nonetheless, beyond today's implants installed in my private practice, I have been following over 90 of these implants performed in collaboration with Dr Harald Fahrenholz in Vienna, ranging from 5–12 years in function, and meticulously tracking the soft-tissue performance around them. Besides their highly reliable osseointegration, I have discovered significant soft tissue benefits and stability over this period. I am excited about my collaboration with the University of Graz, who has been able to review my data, and conclude very compelling evidence to show how zirconia in the long term can have a "health benefit" for all types of patients when it comes to tooth replacement. Stay tuned for the published results, the paper is titled "Results of zirconia implants after 5 years of clinical performance – a retrospective study" and will be available this fall.

What would you advise a new dentist just starting in implantology regarding treatment philosophy?

I would advise any new dentist to pay attention to the integrity of the research that supports the clinical choices they make. They should scrutinize the material that product manufacturers provide them and use peer-reviewed long-term clinical evidence to give them an indicator of what they should expect as their patient base grows. Much too often, some of my colleagues are satisfied with word of mouth recommendations for the products they use. I prefer to challenge the claims being made and ensure the highest standards of quality and safety. In the end I must help my patients become healthier, and I can only do this with products that are not only proven, but also safe for the human body.

Patent Dental Implant System

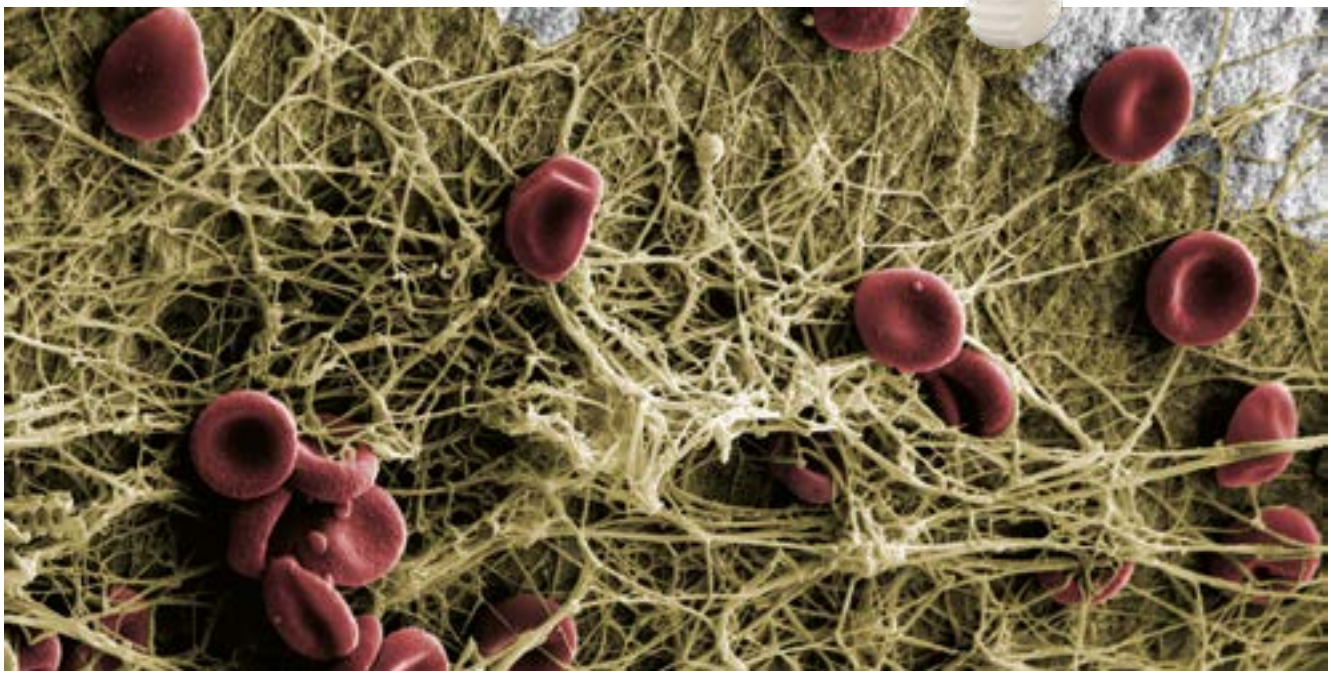


Photo: Dr Peter Schubpach

Human blood on Patent surface –within 10 minutes the fibrin network is attached to the surface. This attachment is a prerequisite for contact osteogenesis.

curasan bone regeneration scaffold technology now approved for use with antibiotics

A significant milestone in reducing the risk of reinfection

The β-TCP collagen matrix Cerasorb Foam, a resorbable, osteoconductive and cancellous bone-like bone regeneration material prepared from β-tricalcium phosphate and collagen, was recently recertified by curasan AG's notified body with the additional claim for use with antibiotics. The intraoperative combination of Cerasorb Foam with a wide range of commercially available antibiotics provides surgeons with a novel option in filling and bridging degenerative and traumatic bone defects.

"This is a major milestone in minimizing the risk of a reinfection at the defect site. We have been evaluating various antibiotics in combination with our industry- leading synthetic bone regeneration materials under laboratory conditions for years and collected important insights and data on the commercially available composite materials in comparison to our products*", marks Dirk Dembski, CEO at curasan AG. "With the approval of the claim we have found a consensus for the patients and surgeons", he continues.

"Our in-vitro studies have proven that Cerasorb Foam can be soaked to saturation with antibiotic solutions that have been prepared according to the manufacturer's instructions. Vancomycin, Gentamicin, Tobramycin, Refobacin, Imipenem/Cilastatin and Meropenem solutions were tested in the investigations. Our studies have shown, that antibiotically loaded Cerasorb Foam shows an excellent initial burst release of the antibiotics into the environment, followed by a long-term elution of the substrates. Furthermore, our investigations underline, that in comparison to competitive products, the antibiotic elution from Cerasorb Foam has shown to be above the necessary MIC (minimal inhibitor concentration), but below the cytotoxic level in order not to interfere with the cell activity during osteogenesis. In addition, Cerasorb Foam has clearly shown to have a higher loading and release capacity than other commercially available products", states Florian Früh, Head of Global Product Management at curasan AG.

First successful revision surgeries of infected hip prosthesis and treatment of infected bone areas have been carried out with very promising results. Further clinical investigations are ongoing.

Thus, the major problem of implant and bone defect infections was addressed, and a consensus created, so that after detailed patient education and full debridement of the infected bone defect, surgeons, under their responsibility, may prophylactically use Cerasorb Foam in combination with above mentioned antibiotics in the bone defect to minimize the risk of a renewed infection.

Besides many other regions, Cerasorb Foam for the use in Orthopedic surgery is CE-marked, FDA and ANVISA approved. Further regulatory approval processes, e.g. in China, are currently ongoing and approvals are expected soon.

* Data on file at curasan AG

More information
www.curasan.de

Osstem Implant SOI Implant surface

Product
New superhydrophilic implant surface

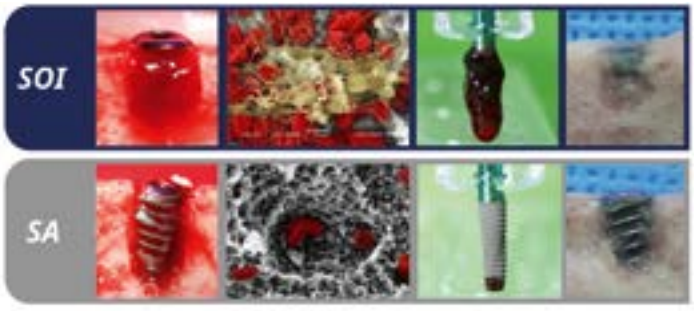
Indication
Dental implantology

Distribution
Deutsche Osstem GmbH
Mergenthalerallee 35–37
65760 Eschborn
Germany
www.osstem.de

Osstem Implant is expanding its own product portfolio for implant surfaces. The new surface is called SOI and is characterized by particular bioactive properties. By adding a pH-buffering agent as coating to the surface after vacuum-UV treatment, the hydrophobic titanium surface is converted into a superhydrophilic surface.

Improvement of the initial bone formation

Thanks to faster blood wettability, the initial bone formation ability improves. By activating the blood to form clots, protein adhesion is many times higher than with conventional surfaces. This not only creates an excellent accumulation of proteins for bone growth, but it also promotes the formation of fibrin clots. Compared to the SA implants, the initial bone formation has improved by 65%.



Shorter treatment time and easier handling

Thanks to the improved osseointegration, the SOI surface also offers a significantly shorter treatment time. The healing time compared to conventional surfaces has been reduced by 35 %. Furthermore, the SOI implants are very user-friendly. No post-treatment, such as UV radiation, is necessary for the implants.

More information is available through Osstem's local sales representatives, at the IDS 2021 and online on www.osstem.de.

Zimmer Biomet Dental RealGuide Software Suite

Product
Cloud-based software

Indication
Digital workflow/ implant planning

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

The ability to place a dental implant in the intended position is priceless; it often allows for a less invasive surgical procedure and supports a more aesthetic design of the definitive prosthesis. Zimmer Biomet is now bringing access to restoratively driven guided surgery collaboration to select markets in Europe and the United States through the launch of the RealGuide Software Suite. A universal open platform, RealGuide is a flexible and intuitive cloud-based software that provides everything clinicians might need for precise implant planning, design and production of a user-friendly surgical guide, aimed at providing a secure, accurate and minimally invasive guided surgery. Placing implants in the intended position becomes easy.

The new software consists of several software modules that may be combined as desired for a thorough diagnosis, intended implant positioning, and advanced surgical guide design. Its many features include a vast implant library, powerful Artificial Intelligence (AI) tools, a built-in communication and file-sharing platform, open architecture for maximum flexibility, and interconnected modules to ensure seamless workflows. RealGuide is compatible with Mac, PC or iOS mobile.

Zimmer Biomet is currently offering a complimentary 30-day trial of the Guide module, which enables users to seamlessly import their implant planning data, design complex guides supported by bone, teeth or soft tissue, and then export STL files optimized for 3D printing or milling. After the 30-day free trial, customers will continue to have free access to the planning features if they don't subscribe.

MEMBERSHIP REGISTRATION FORM

I hereby apply for a membership in the BDIZ EDI
(European Association of Dental Implantologists)

Name: .....

First Name: .....

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Homepage: .....

Date of Birth: .....

Practicing implantology since: .....

Member of other Societies:

☐ ICOI ☐ BDO ☐ DGI ☐ DGZI ☐ DGMKG ☐ EAO

Continuing education Courses: .....

.....

Fellowship status / diplomate status in implantology

☐ Yes ☐ No ☐ Organization .....

Entry in BDIZ EDI Directory: ☐ Yes ☐ No
(For information on BDIZ EDI Directory of Implant Dentists see overleaf)

The annual membership fee for:

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☐	Full member - clinical	345,00	Euro
☐	Assistant dentist / young professional (up to 5 years after graduation)	172,50	Euro
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Calendar of Events

	Event	Location	Date	Details/Registration
9/2021	**International Dental Show IDS**	Cologne, Germany	22–25 September 2021	ids-cologne.de
10/2021	**Straumann Symposium 2021 – Dental Implant Convention**	Scottsdale, USA	7–8 October 2021	straumann.com
	Ivoclar Vivadent Live experience Tour 2021	• Copenhagen, Denmark • Hannover, Germany • Rom, Italy • Seville, Spain • Zurich, Switzerland • Cuijk, Netherlands	Please check the registration site for details	ivoclarvivadent.com/live-experience
	European Association for Osseo-integration EAO Digital Days 2021	Digital event	12–14 October 2021	digitaldays.eao.org

EDI Journal – Information for authors

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

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

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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.
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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 to 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.
Captions should be brief one or two-line descriptions of each illustration, typed on a separate page following the references. Captions must be numbered in the same numerical order as the illustrations.Tables should be typed on a separate page and numbered consecutively, according to citation in the text. The title of the table and its caption must be on the same page as the table itself.

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

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

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References

[1] Conserva E. Initial stability after placement of a new buttress threaded implant. A case series study. implants. 2019(3):24-28.

[2] Ruppin J. One-year clinical experience with Progressive-Line implants. EDI journal. 2020(4):54-63.

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