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Introducing DZZ International

The DZZ is the largest scientific dental journal that is published in German. Topics and formats which are covered in this journal are clinical studies, case reports, dental material studies, experimental and clinical prevention papers, systematic reviews, etc.

A joint project between the German Society of Dental Medicine (DGZMK) and the Deutscher Ärzteverlag has prepared the way for the DZZ to enter the international stage, and to be listed on to important international data bases. The project is now completed by the launch of an English language Journal – the **DZZ International**. This new publication will be a scientific dental journal with a broad spectrum as mentioned above. It will be released online enabling worldwide access, but with a focus on readers within central Europe. This initiative fulfills the requirements necessary for inclusion into the PubMedCentral database with a proposed reinstatement on MEDLINE to follow.



Prof. Dr. Guido Heydecke

Below are listed the important features:

- A stringent **peer review** process will remain as the standard.
- All articles will be published in **English**. However, German manuscripts can also be submitted and the publishers will organize the translations. Quality assurance will be provided by translators whose mother tongue is English. Of course, English manuscripts will also be welcomed and their submission is encouraged.
- **Open Access Online:** Full access to the English version will be **free of charge**. The publication of all articles will be at **no cost** to the authors.
- **Speed:** All accepted manuscripts will be promptly made accessible.

The key strategic points for the DGZMK are to give increased incentives to authors and also to provide quality articles to the readership. It is our intention to **promote a flexible and easy entry** into the publishing World for the **next generation of young scientists in Europe and worldwide**.

The scientific management of DZZ International is in the hands of Guido Heydecke and Werner Geurtsen (Editors). The associate editors are Nico Creugers (Nijmegen), Henrik Dommisch (Berlin), Marco R. Kesting (Erlangen), Torsten Mundt (Greifswald), Falk Schwendicke (Berlin) and Michael Wolf (Aachen). Together they bring a broad technical expertise and experience to the project.

What can you do? We invite and welcome you as potential authors to immediately submit manuscripts for publication in the DZZ International. We do accept original papers, reviews, and case reports and more. For further details on the submission process, please see the guidelines for authors. And of course as a reader, you can participate and read. All articles are available online now at the **online-dzz.com** website.

Best regards

Editorial team, the DGZMK and Board of Management of the
Deutscher Ärzteverlag

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Online-Version of DZZ International: www.online-dzz.com

Hüsametlin Günay, Ingmar Staufenbiel, Werner Geurtsen, Knut Adam

The granulation tissue preservation technique in regenerative therapy of peri-implantitis – a treatment concept with case reports

Introduction:

In recent years, the indication for the placement of dental implants has expanded consistently. Therefore, more and more patients are treated with implant supported restorations resulting in increasing implant associated complications. Inflammatory peri-implant diseases represent the most frequent complications. For peri-implantitis, especially in advanced cases, a surgical approach is still the gold standard. However, to date no preferential surgical protocol has been established. Previous surgical techniques recommended the removal of the intralesional granulation tissue followed by grafting of the bony defect.

Material und Methods:

The present article demonstrates the systematic treatment protocol for inflammatory peri-implant diseases performed in our department at Hannover Medical School and a new surgical technique. The aim of this technique is to preserve as much intralesional granulation tissue as possible. The efficiency of the granulation tissue preservation technique has already been proven for regenerative periodontal therapy. Three case reports illustrate the practical application and the effectiveness of this new surgical technique in the regenerative treatment of peri-implantitis.

Results and Conclusion:

The present case series demonstrates a significant gain of clinical attachment level and a remarkable bone fill, proving the success of the new surgical therapy protocol. In addition to the preservation of multipotent mesenchymal stem cells and blood vessels, the enhanced soft tissue support with an endogenous matrix resulted in less postoperative mucosal recessions. This is the main advantage of the new surgical technique.

Keywords:

regenerative treatment of peri-implantitis; surgical protocol; granulation tissue preservation technique; decontamination protocol

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Introduction

Progress in the use of dental implants has extended the indication of their clinical application. In many cases they are now replacing traditional prosthetics. There is no scientific corroboration, but, estimates for Germany, based on dental trade sales in recent years, have indicated that approximately one million implants are being inserted annually. Previous meta-analyses demonstrate good survival rates for dental implants after 10 years of functional loading. Depending on the design of the prosthetic suprastructure these were reported to be between 93.1 % [20] and 95.2 % [15]. However, on the other hand dental implantology has high complication rates. Complications vary and include primary biological (e.g. no osseointegration immediately after implant insertion), aesthetic, technical (e.g. screw fractures, abutments becoming dislodged or loose) and secondary biological complications (e.g. peri-implant inflammation). These complications vary in frequency depending on the design of the prosthetic suprastructures [1]. Overall, the most common complication is peri-implant inflammation. This can be categorized into either peri-implant mucositis or peri-implantitis. Peri-implant mucositis is restricted just to the soft tissues around the implant whereas peri-implantitis is more extensive resulting in a progressive loss of peri-implant bone [11, 30]. The incidence of peri-implant inflammation in the scientific literature varies considerably due to differing definitions of the disease [26]. In a current meta-analysis, the patient based incidence of peri-implant mucositis was reported to be 43 % and that of peri-implantitis 22 % [8].

Preventive strategies have been widely described and comprise pre- and postimplantation measures. Pre-implantation measures include adequate planning of both the number and position of the proposed implants, a hygienic design of the suprastructure, rehabilitation of the remaining dentition (dental and periodontal), an evaluation and elimination of risk factors (e.g. smoking)

as well as securing a basic compliance (individual oral hygiene instruction to ensure self-reliant, and effective home maintenance) [32]. Postimplantation there should be risk-based follow-up intervals for prevention and maintenance necessitating full clinical examinations. These would encompass the recording of probing depths and inflammatory indices together with a radiographic diagnosis of any noticeable abnormalities to enable prompt therapeutic intervention [14]. It is crucial that during follow-ups, clinical and radiological findings are referred to a baseline to enable a meaningful comparison. With regard to the latest classification of peri-implant disease, the comparison of current clinical and radiological findings with their initial status, is the paramount diagnostic indicator of peri-implantitis. Therefore, peri-implantitis is present, when clinical signs of inflammation are evident and there is progressive bone loss after the initial healing phase. These changes are associated with bleeding on probing and increased probing depths when compared to the initial measurements [24]. This new definition of peri-implantitis results in the recommendation that after every prosthetic phase of treatment a basic examination should be undertaken. This should include not only radiographic controls but also the measurement of peri-implant probing depths.

Due to the fact that peri-implantitis is a biofilm-associated disease [3], the decontamination of the implant surface is the basis of any therapeutic regimen. Peri-implant mucositis can be successfully treated by professional removal of the biofilm using hand instruments, sonic-driven brushes, or an air abrasive device [14]. Antiseptics can also be utilized but the use of local or systemic antibiotics have not been shown to provide additional benefits [14]. An important prerequisite for therapeutic success is the establishment of an effective and self-reliant home care regime for adequate oral hygiene [25]. Successful therapy in many cases does not mean that there is no residual bleeding around the treated im-

plant, but rather that no bone loss results [29]. When there has been bone loss resulting in the exposure of implant threads due to an initial peri-implantitis, the use of hand instruments to remove biofilm is unsuitable. Here, a meta-analysis has shown that air polishing or an Er:YAG laser gave the best results for decontaminating the implant surfaces [28]. Controlled clinical trials have shown that the supplemental use of topical antibiotics or photodynamic therapy can also improve treatment outcomes [2, 21]. However, in many cases, especially when advanced peri-implantitis is present, non-surgical treatment is limited and ineffective due to the morphological characteristics of the implant surface [18]. In 2016, an S3-guideline regarding the treatment of inflammation around dental implants was published for the first time in Germany. Peri-implantitis cases presenting with probing depths > 7 mm are classified as prognostically unfavorable and the non-surgical treatment should be supplemented by surgical intervention at the earliest opportunity. However, up to the present time no preferred surgical protocol can be inferred from the literature [31]. Consensus among the authors of the guideline was that after decontamination of the implant surface, augmentation procedures (autologous bone or bone substitute materials) may result in radiologically detectable infill of intrabony defects. However, it has not yet been defined, which materials are suitable for grafting defects, and especially when referring to bone substitute materials what is meant by biological. Whether these defect fillers are resorbed, integrated into new bone, or encapsulated by connective tissue remains unclear. In addition, the authors of the guideline recommend the intraoperative removal of the granulation tissue and report that the surgical treatment of peri-implantitis is associated with a high risk for the development of postoperative recession. The present paper shows a case series in which a new periodontal surgical procedure has been successfully conducted. The aim of this procedure is to preserve as much as pos-

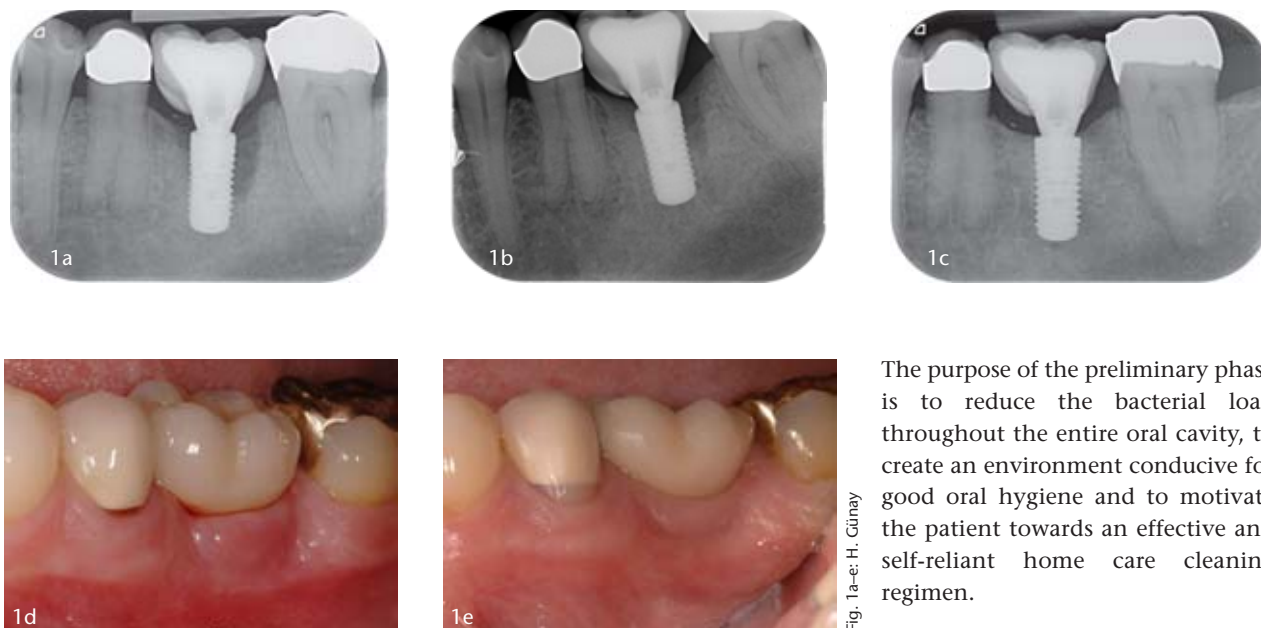


Fig. 1a-e: H. Günay

Figure 1a-e Clinical situation and radiographs before and after conservative therapy in a case of peri-implantitis regio 36; **Fig. 1a:** Radiograph before therapy; **Fig. 1b:** Radiograph one year after therapy; **Fig. 1c:** Radiograph 5.5 years after therapy; **Fig. 1d:** Clinical situation before therapy; **Fig. 1e:** Clinical situation 5.5 years after therapy

sible of the intralesional granulation tissue. By preserving this endogenous soft tissue support, postoperative recession can be significantly reduced. The effectiveness and safety of this procedure when used for regenerative periodontal surgery has already been demonstrated [10] and can be regarded as a part of the armamentarium for regenerative peri-implant treatment.

Systematic therapy of inflammatory peri-implant diseases

Successful treatment of peri-implant inflammation is never just limited to localized treatment of an affected implant, but must always include the whole mouth, which comprises all placed implants and any residual dentition. Therefore, there is a necessity for each patient presenting with peri-implant inflammation to undergo an appropriate preliminary phase as follows:

Preliminary phase

Since periodontal and peri-implant inflammations are always associated with a dysbiotic oral biofilm, it is important to eliminate this bacterial imbalance by employing a whole

mouth antibacterial strategy („Whole Mouth Therapy“). The preliminary phase includes the following treatment measures:

1. Establishment of an oral environment that permits good oral hygiene by rehabilitating any remaining dentition (such as extraction of any unsavable teeth, restoring carious lesions, recontouring and polishing overextended restoration margins, providing hygienic temporary restorations).
2. Professional prophylaxis with a thorough scaling and polishing. Recording of plaque and inflammation indices for individual information, motivation and instruction of patients (iIMI).
3. Evaluation and minimization of periodontal risk factors.
4. Evaluation of the implantological and peri-implantological history (see below).
5. Assessment of periodontal status and planning of the therapy regimen (see below).
6. Any non-surgical periodontal therapy for the residual dentition.
7. Assessing and if necessary modification of the implant suprastructure to enable adequate oral hygiene measures.

The purpose of the preliminary phase is to reduce the bacterial load throughout the entire oral cavity, to create an environment conducive for good oral hygiene and to motivate the patient towards an effective and self-reliant home care cleaning regimen.

Non-surgical peri-implantitis treatment

In contrast to non-surgical periodontitis therapy, non-surgical peri-implant therapy, especially in advanced cases, has low success rates due to the morphology of the implant surface (exposed threads, roughness, different surface modifications dependant on type of implant). This can hinder adequate mechanical removal of the biofilm without surgical access. The sufficient removal of mineralized biofilm (calculus) as part of non-surgical therapy is virtually impossible (Figure 3a).

The peri-implantological history, the defect morphology, and the accessibility to the implant surface should precisely be evaluated before initiation of the therapy. Peri-implantitis lesions at implants with a short history (functional loading < 1 year) do not show any mineralization of the submucosal biofilm in most cases. When there is adequate access to the peri-implant defect, regular closed decontamination of the implant surface without surgical intervention may result in remission of peri-implant bone loss. An appropriate case that demonstrates the potential of this conservative strategy are shown in Figures 1a–1e. The implant regio 36 had been under functional load for 11 months and presented with a 10 mm distal probing pocket depth at baseline. A pronounced vertical bone defect was visible radiographically (Fig. 1a).

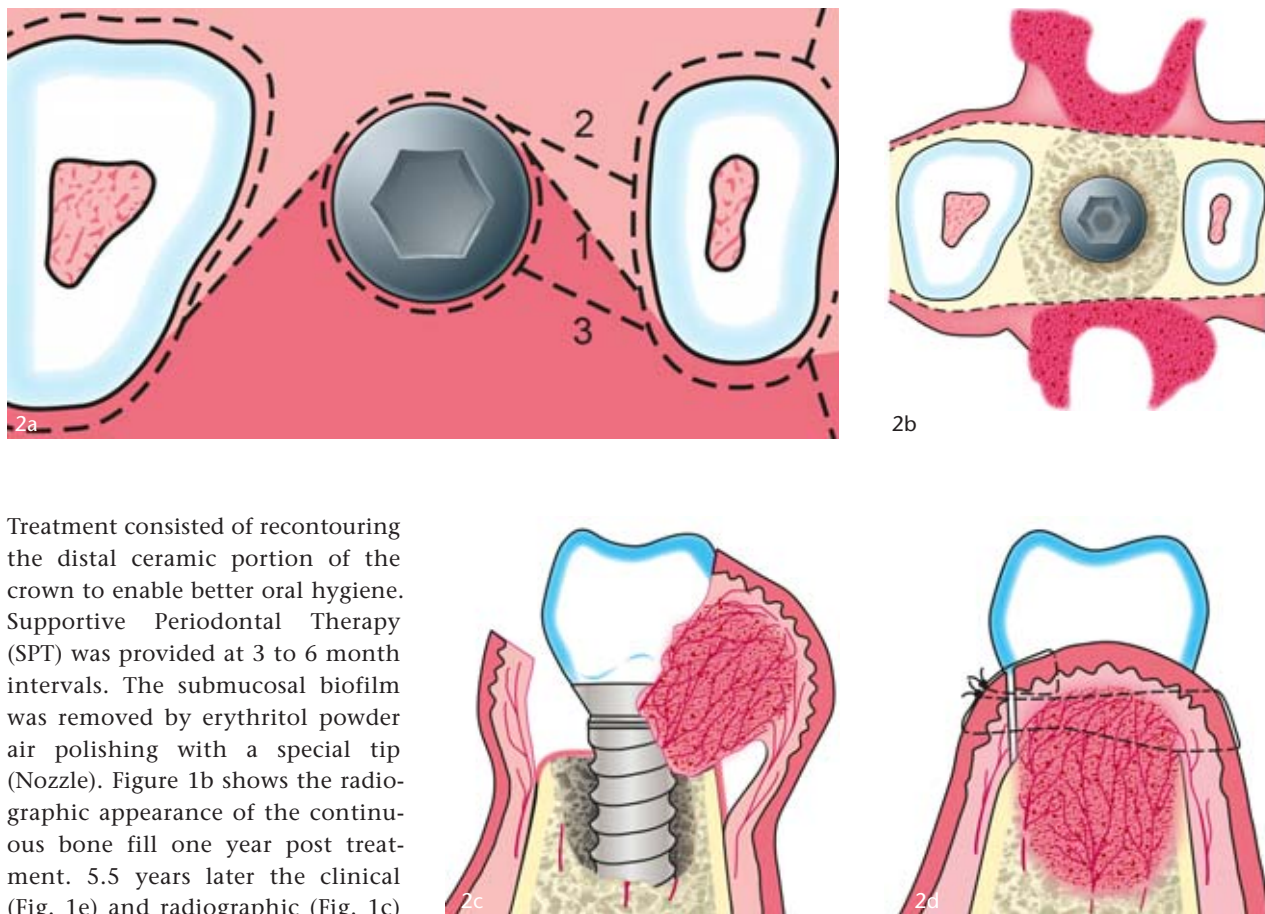


Figure 2a–d Schematic view of the granulation tissue preservation technique; **Fig. 2a:** Intrasulcular and z-shaped incisions; **Fig. 2b:** Mobilisation of the mucoperiosteal flap with adherent granulation tissue – occlusal view; **Fig. 2c:** Mobilisation of the mucoperiosteal flap with adherent granulation tissue – interproximal view; **Fig. 2d:** Reposition of the mucoperiosteal flap with adherent granulation tissue and wound closure by sutures

Fig. 2a–d: H. Günay, Digital Media/Graphics – Hannover Medical School

Treatment consisted of recontouring the distal ceramic portion of the crown to enable better oral hygiene. Supportive Periodontal Therapy (SPT) was provided at 3 to 6 month intervals. The submucosal biofilm was removed by erythritol powder air polishing with a special tip (Nozzle). Figure 1b shows the radiographic appearance of the continuous bone fill one year post treatment. 5.5 years later the clinical (Fig. 1e) and radiographic (Fig. 1c) follow-ups show stable, integrated bone replenishment with complete preservation of the marginal peri-implant soft tissue. Advanced peri-implantitis cases usually have a longer history and early surgical treatment is indicated. However, surgical intervention should also be preceded by a non-surgical therapy to eliminate or reduce inflammatory signs around implants. This is advantageous because it reduces intraoperative bleeding and the extent of postoperative mucosal recession, thereby contributing to the success of the surgical treatment. After non-surgical measures it has been shown to be worthwhile and it is recommended to wait for 2 to 3 weeks before commencing any surgery.

The protocol followed for non-surgical peri-implantitis treatment is shown in Table 1.

Using an air abrasive device submucosally involves the risk of emphysema particularly when there is a limited amount of keratinized tissue or a thin soft tissue. In such cases, the peri-implant soft tissue should be compressed with a wet

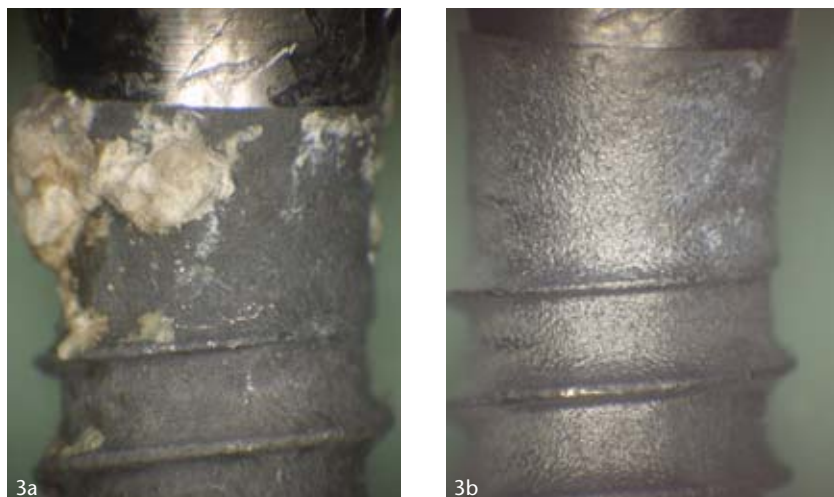
swab held parallel to the nozzle of the instrument, whilst decontaminating the implant surface. This will prevent any mixture of water, air and powder from penetrating the tissues.

Surgical treatment of peri-implantitis

In order to create optimal conditions for successful surgery, the preliminary phase and non-surgical therapy must have already been accomplished. In essence, there are two competing surgical strategies; using resective techniques or alternatively a regenerative approach. Resective procedures are limited to cases where regenerative methods are contraindicated. These include primarily patients with a high periodontal risk (heavy smokers, non-compliant patients, poor diabetic

control), but also local implant specific factors (poor design, oral hygiene measures hindered by the suprastructure). In addition, the morphology of the peri-implant bone defect and the implantological history are critical for the choice and predictability of the treatment regimen [27]. In particular, prior surgical augmentations must be enquired about. In cases of a single or two walled bony defect with no buccal plate and a history of pre-implantation augmentation it is likely that the current peri-implantitis derives from the base of a failed augmentation. In such cases, regenerative therapy has a poor prognosis and conservative or resective procedures are preferable.

Peri-implant surgical regenerative therapy by means of the Granulation Tissue Preservation Technique (GTPT)



Figures 3a–b Surface of a removed implant before and after decontamination with a titanium brush; **Fig. 3a:** Implant surface with mineralized bacterial deposits; **Fig. 3b:** Cleaned implant surface after decontamination with a (sonic) titanium brush

Fig. 3a–b: H. Günay

is performed in the following chronological order:

An antibacterial mouth rinse is applied 24 h and immediately before the operation, e.g. with a 0.2 % chlorhexidine digluconate solution (CHX). Local analgesia with an adrenalin containing local anesthetic is given followed by rinsing of the peri-implant pockets with CHX. Next an intrasulcular incision is made around the affected implant together with any neighboring teeth or implants using a microsurgical scalpel (Micro Miniature Blade 6962, Surgistar, Knoxville, USA). Interproximally the incision is contoured in an oblique z-shaped design (Fig. 2a). During mobilization of the mucoperiosteal flap, care must be taken to preserve the intralesional granulation tissue, so far as it is possible, by separating it distinctly from the underlying bony surface (Fig. 2b, 2c).

The mobilization of the mucoperiosteal flap should be made with a minimally invasive technique using a microsurgical raspatorium (Hamacher, Solingen, Germany) until the edge of the defect becomes visible. This ensures that there is a safe access for the decontamination of the implant surface. For the removal of soft, non-mineralized biofilm air polishing is sufficient. If mineralized bacterial deposits (calculus) are present (Fig. 3a), the additional use of a sonic-driven polymer pin

(e.g. Komet Dental, Lemgo, Germany) and/or a titanium brush (e.g. TiBrush, Straumann GmbH, Freiburg, Germany) is recommended to ensure their complete removal (Fig. 3b).

The mechanical decontamination of the implant surface can be chemically reinforced by the subsequent application of a saturated tetracycline hydrochloride solution or an EDTA gel (PrefGel, Straumann GmbH, Freiburg, Germany). After intensive rinsing with a sterile, isotonic saline solution, the implant surfaces are dried by means of aspirating using the surgical suction. Next follows the application of enamel matrix derivatives (Emdogain, Straumann GmbH, Freiburg, Germany) with care being exercised so that the exposed implant surfaces are not contaminated with blood or saliva. In cases where the application of enamel matrix derivatives is not possible (e.g., for religious or financial reasons), the decontaminated implant surface should be kept saliva free until a stable fibrin clot has had time to form. The mucoperiosteal flap is then replaced together with its adherent granulation tissue and fixed with sutures (e.g., GORE-TEX Suture CV-6, W.L. Gore & Associates, Putzbrunn, Germany and /or Prolene 6-0, Ethicon GmbH, Norderstedt, Germany; Figure 2d). A recommended suturing technique would

be to place either a modified mattress suture or a horizontal internal mattress suture in combination with a single interrupted suture. The surgery is completed by applying gentle pressure to the wound by means of moistened, sterile swabs for 1 min. Postoperative antibiotics should only be prescribed in extremely advanced cases of peri-implantitis (peri-implant bone loss > 50 %) or in unfavorable locations (e.g., deep lingual defect in the proximity of the sublingual space). In such cases, clindamycin (2x 600 mg daily over 7 days) has been effective. In regard to „Antibiotic Awareness“ antibiotics should in principle only be used judiciously. They are rarely indicated and should preferably be used as an adjunct to non-surgical treatment.

The protocol followed for surgical peri-implantitis treatment is shown in Table 2.

Postoperative care

In order to achieve the best possible treatment outcome, patients must comply with the postoperative instructions that they are given. In addition to a verbal explanation, it has been shown to be beneficial to hand out a written instruction leaflet prior to the surgery (possibly during the informed consent process) which the patient can take home and study. To ensure optimal wound healing, the patient should not perform any home based oral hygiene at the surgical site for at least 14 days after the procedure. During this time, a twice daily use of a CHX containing mouth wash to rinse the area is recommended except the first 24 h postoperatively. In this period a gentle mouth bath of isotonic saline solution at 2 hourly intervals should be employed and has been shown to be adequate for initial home care. Vigorous rinsing, at any time, should definitely be avoided to prevent dehiscences and wound breakdown. In most cases, normal oral hygiene measures can be resumed after 14 days with a soft manual toothbrush. However, it is recommended that interdental hygiene measures be discontinued for another 2 weeks in order to ensure a safe healing of the interdental papil-

lae. Just as important as the patient's compliance with postoperative instructions are frequent professional follow-up appointments in order to supervise the healing process. The postoperative follow-up regimen should include controls at 1, 2, 3 and 6 weeks postoperatively. At each appointment, careful debridement and biofilm removal is performed in the region of the surgical site. The sutures should be removed 2 weeks postoperatively.

Supportive peri-implant therapy

Analogous to supportive periodontal therapy [7, 16], follow-up intervals every 3 months are recommended for the first postoperative year following peri-implant treatment. This is followed by a recall frequency adapted to the individual risk profile. However, follow-up intervals of 6 months should not be exceeded. As a part of supportive peri-implant therapy, in addition to professional cleaning and maintenance of any remaining teeth, it is always advisable to use an air abrasive device (powder based on glycine or erythritol) on any treated implants. Bone regeneration around an implant is slower when compared to that seen around natural teeth and consequently radiographs should be taken at least 1 year postoperatively for diagnostic purposes. A radiograph 6 months after surgery may demonstrate healing tendency but is probably too early to show any regenerative effects.

Case reports

Case report 1

The patient was 47 years old when she was referred to the Department of Conservative Dentistry, Periodontology and Preventive Dentistry of the Hannover Medical School due to an advanced peri-implantitis regio 46. She revealed no periodontal risk factors and her periodontal and dental status was adequate. As part of her initial evaluation, a radiograph of the implant regio 46 was made (Fig. 4a) and the probing depths around the implant were measured (maximum probing depth distoves-

Chronological decontamination protocol	
1	1 minute use of a chlorhexidine digluconate (0.2%) (CHX) or octenidine dihydrochloride (0.1%) (OCT) mouthwash
2	Local analgesia
3	Remove (if possible) and clean the suprastructure
4	Antibacterial irrigation of the peri-implant pockets with CHX (0.2%) or OCT (0.1%)
5	Supramucosal removal of the biofilm with a sonic-driven brush, polymer pin and air abrasive device
6	Glycine or erythritol powder air polishing with a special tip (Nozzle) to remove submucosal biofilm
7	Antibacterial irrigation of the peri-implant pockets with CHX (0.2 %) or OCT (0.1 %)
8	Application of a local antibiotic (e.g., Ligosan® Kulzer GmbH, Hanau, Germany) or systemic antibiotic (e.g., clindamycin) in exceptional cases

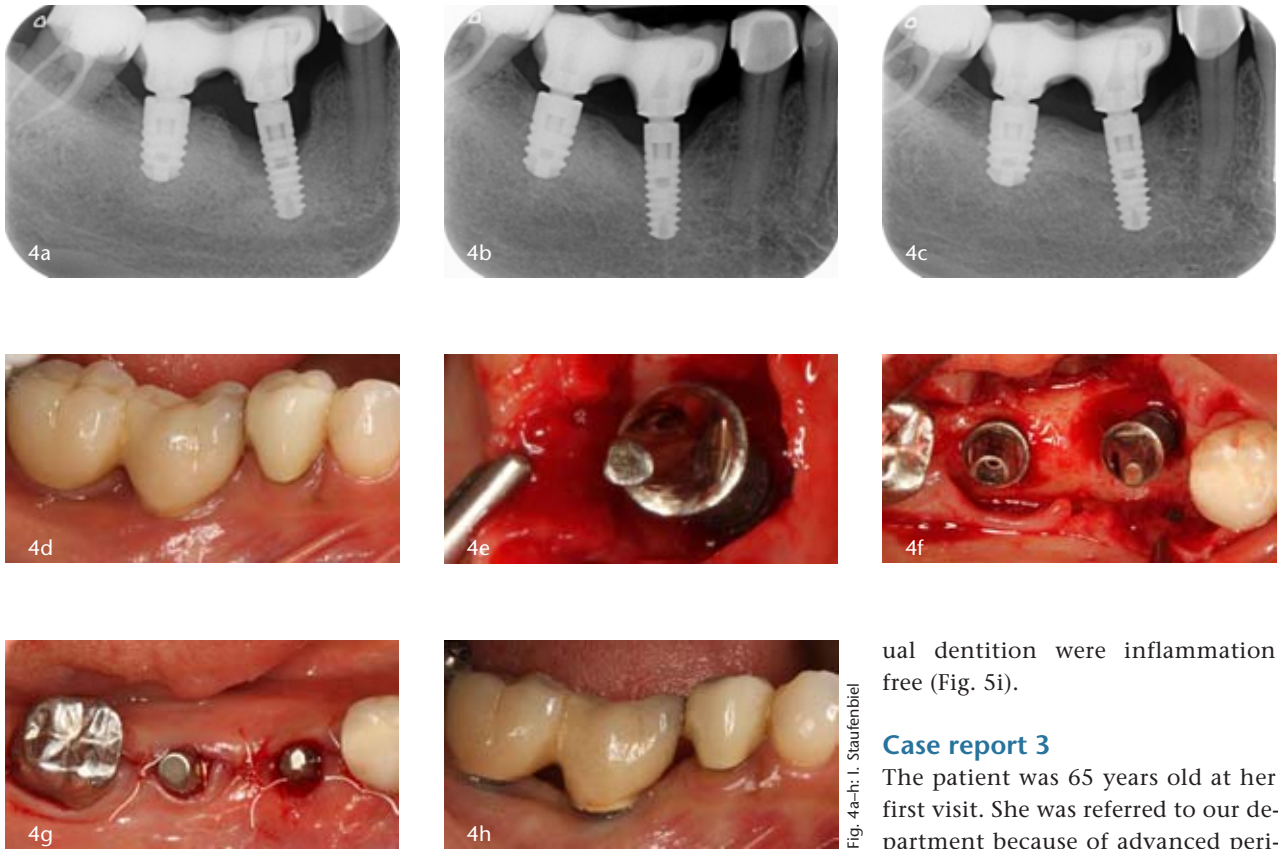
Table 1 Decontamination protocol in non-surgical periimplantitis therapy (Tab. 1 and 2: I. Staufienbiel and H. Günay)

tibular: 9 mm). The patient was informed about the diagnosis and treatment options and underwent professional oral hygiene at the same session. In a second session, a non-surgical peri-implant treatment was carried out at the implant regio 46 under local analgesia. There was a slight mobility of the crown block 46/47. After removal of this crown block it became obvious that the luting cement of the crown 46 had been completely lost. In addition, its screw channel was exposed, resulting in a massive plaque accumulation in this conduit. This was identified as a potential etiological factor. The splinted crowns and abutment were professionally cleaned. The decontamination of the implant surface was carried out according to the decontamination protocol (Table 1). After 2 weeks, surgical intervention was performed according to the surgical protocol (Table 2). The patient returned for all immediate postoperative follow-up appointments and attended to supportive peri-implant therapy at 3-monthly

intervals. The clinical situation before surgery, intraoperatively and after suture closure is shown in Figure 4d–4g. Radiographs taken after 1 and 2.5 years following the surgery document the resolution of the osseous defect (Fig. 4b, 4c). The clinical picture 2.5 years postoperatively (Fig. 4h) reveals the development of a 1 mm mucosal recession. The periodontal parameters after surgery show a significant reduction in probing depths (Δ PD 7 mm) and marked clinical attachment gain (Δ CAG 6 mm) compared to the baseline findings.

Case report 2

The patient was 71 years old when first seen in our department. He had been referred due to generalized periodontal and localized peri-implant problems around the implant regio 45. The patient had chronic generalized periodontitis but no lifestyle associated periodontal risk factors. As part of his initial diagnosis, a radiograph was taken of the implant regio 45 (Fig. 5a). The initial



Figures 4a–h Case 1 – regenerative therapy in a case of peri-implantitis regio 46; **Fig. 4a:** Radiograph before therapy; **Fig. 4b:** Radiograph one year after therapy; **Fig. 4c:** Radiograph 2.5 years after therapy; **Fig. 4d:** Clinical situation before therapy; **Fig. 4e:** Intraoperative view after mobilisation of the mucoperiosteal flap with adherent granulation tissue; **Fig. 4f:** Intraoperative view of the bony defect (three-wall defect) after decontamination of the implant surface; **Fig. 4g:** Clinical situation after reposition of the mucoperiosteal flap and wound closure by sutures; **Fig. 4h:** Clinical situation 2.5 years after therapy

probing depths around this implant revealed a maximum probing depth of 8 mm. The patient was informed about the diagnostic and therapeutic options and underwent systematic periodontal therapy. As part of his non-surgical periodontal therapy, decontamination of the implant surface was carried out under local analgesia according to the decontamination protocol (Table 1). To do this, the screw retained bridge regio 45, 46, 47 was removed (Fig. 5d) and healing abutments were inserted in its place. As an etiological factor, noticeable plaque accumulation on the bottom side of the bridge (Figure 5e) was identified. This indicated insufficient home care and poor oral hygiene. The patient was instructed accordingly and the bridge was professionally cleaned in the dental laboratory. After 3

weeks surgical peri-implant therapy was carried out according to the surgical protocol (Table 2) (Fig. 5f, 5g). The patient attended to the postoperative follow-ups and was recalled subsequently every 3 months for supportive peri-implant therapy. The bridge was refastened on its abutments 6 weeks after surgery. Figure 5h shows the clinical situation after suture closure. The radiographs at 1 and 3 years postoperatively (Fig. 5b, 5c) show the resolution of the bony defect. The periodontal measurements 3 years after surgery (maximum probing depth 3.5 mm) demonstrate a significant reduction in probing depths (Δ PD 4.5 mm) compared to the baseline findings. Since no mucosal recession occurred, 4.5 mm of clinical attachment was re-established. Clinically, the implant regio 45 and the resid-

ual dentition were inflammation free (Fig. 5i).

Case report 3

The patient was 65 years old at her first visit. She was referred to our department because of advanced peri-implantitis regio 43. As part of the initial diagnosis, a radiograph was made of the implant regio 43 (Fig. 6a) and the initial probing depths were recorded around the implant (maximum probing depth buccal: 9 mm). The patient underwent professional tooth cleaning. At the same session non-surgical peri-implant therapy on the implant regio 43 was conducted under local analgesia. The suprastructure was cement retained and showed no marginal leakage. The implant angulation was unfavorable for adequate oral hygiene measures and this seemed to be the crucial etiological factor in this case. Through individual instruction, the patient was able to achieve satisfactory plaque control at home despite the challenging unhygienic design limitations. Therefore, the suprastructure was left in position. The decontamination of the implant surface was carried out according to the decontamination protocol (Table 1). After 2 weeks surgical peri-implant therapy was performed according to the surgical protocol (Table 2). However, in this case no enamel matrix derivatives were used. The patient returned for all immediate postoperative follow-

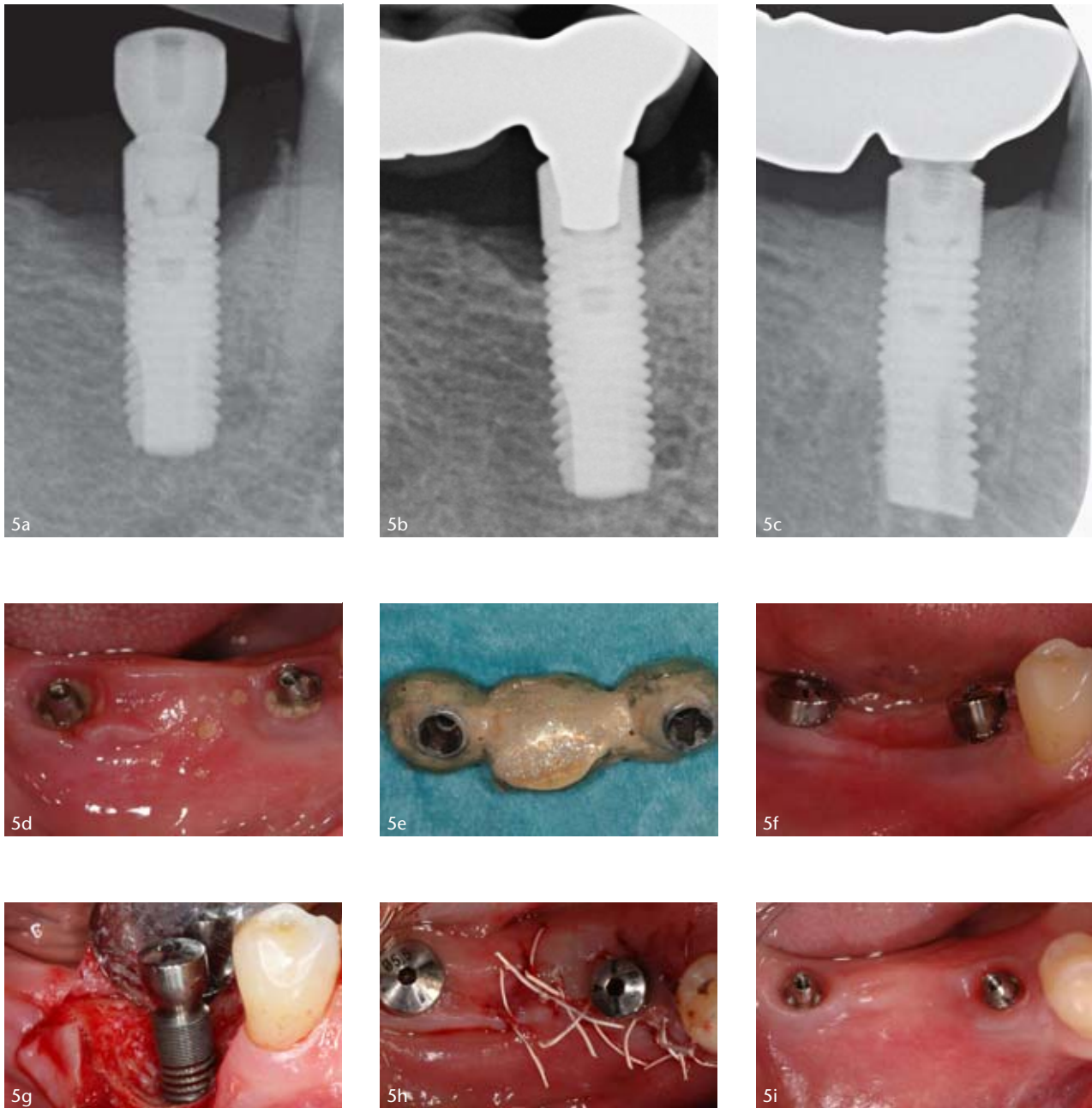


Fig. 5a-i: H. Günay

Figures 5a-i Case 2 – regenerative therapy in a case of peri-implantitis regio 45; **Fig. 5a:** Radiograph before therapy; **Fig. 5b:** Radiograph 1 year after therapy; **Fig. 5c:** Radiograph 3 years after therapy; **Fig. 5d:** Clinical situation after removal of the bridge; **Fig. 5e:** Bridge with matured biofilm – basal view; **Fig. 5f:** Clinical situation before surgery with inserted healing abutments; **Fig. 5g:** Intraoperative view of the bony defect (three-wall defect) after decontamination of the implant surface; **Fig. 5h:** Clinical situation after reposition of the mucoperiosteal flap and wound closure by sutures; **Fig. 5i:** Clinical situation 3 years after therapy

up appointments and then began supportive peri-implant therapy at 3-monthly intervals. The clinical situation before surgery, intraoperatively and after suture closure are shown in Figures 6d–6f. The dental film 30 months postoperatively shows an infilling of the bony defect (Fig. 6b). After 6 years the condition remained stable (Fig. 6c). In comparison to the baseline findings,

the probing depths were significantly reduced (Δ PD 6 mm), resulting in a clinical attachment gain of 6 mm. The corresponding clinical picture shows the most important advantage of the granulation tissue preserving technique: soft tissue conditions remained stable over the observation period and no mucosal recession occurred (Fig 6g).

Discussion

Presently, despite the high prevalence of peri-implant inflammation, there are no evidence-based treatment recommendations. Although the new S3-guideline for the treatment of peri-implant inflammation provides information on the effectiveness of various methods for decontaminating the implant surface, it also reveals the low success rate of non-surgical

Surgical protocol	
1	One minute use of a chlorhexidine digluconate (0.2 %) (CHX) or octenidine dihydrochloride (0.1 %) (OCT) mouthwash
2	Local analgesia
3	Remove (if possible) and clean the suprastructure
4	Antibacterial irrigation of the peri-implant pockets with CHX (0.2 %) or OCT (0.1 %)
5	Mobilization of a mucoperiosteal flap with adherent intraslesional granulation tissue (intrasulcular incision)
6	Removal of mineralized biofilm with a polymer pin and/or a titanium brush Removal of the biofilm with sonic-driven brush, titanium brush and/or air abrasive device (powder based on glycine or erythritol).
7	Irrigation of the peri-implant pockets with sterile isotonic saline
8	Chemical decontamination with an EDTA gel (PrefGel®)
9	Irrigation of the peri-implant pockets with sterile isotonic saline solution
10	Regenerative therapy preferred with enamel matrix derivatives (EMD – Emdogain®) (Note: Inform patients about non-indicated specific use of the EMD!)
11	Suture and compression of the surgical field
12	Systemic antibiotics (e.g., clindamycin) only in exceptional cases
13	Information on postoperative instructions (information sheet)

Table 2 Operation protocol for surgical periimplantitis therapy

approaches to pronounced peri-implantitis. The recommendation, therefore, is to treat cases of advanced peri-implantitis early with a surgical approach. However, the question of which surgical protocol is preferable is still unresolved [31]. Basically, the following different operative procedures compete:

1. Access flap surgery, decontamination of the implant surface [6, 23]
2. Access flap surgery, decontamination of the implant surface and defect filling with bone substitute materials with or without the use of a membrane [6, 23]
3. Access flap surgery, decontamination of the implant surface and defect grafting with autologous

bone with or without use of a membrane [6, 23]

4. Access flap surgery, decontamination of the implant surface and application of biological mediators, e.g. enamel matrix derivatives [12, 13].

All these procedures recommend the removal of intraslesional granulation tissue, although the subsequent increased risk of postoperative mucosal recession is well known [31]. The case reports shown in the present paper were invariably operated on using the granulation tissue preserving technique. The greatest possible preservation of the intraslesional granulation tissue provides the following advantages:

1. The greatest possible preservation of multipotent mesenchymal stem cells, which are essential for regeneration, especially when enamel matrix derivatives are used.
2. Preservation of the vascular network in the granulation tissue allows for faster and better wound healing.
3. The intraslesional granulation tissue represents the body's own matrix, serves as an optimal soft tissue support, prevents the development of postoperative mucosal recession and thus allows the greatest possible bony defect filling.

For regenerative periodontal therapy it has been shown that the presence of mesenchymal stem cells is an important prerequisite [17]. Previous *in vitro* studies have revealed that populations of multipotent mesenchymal stem cells are present in periodontal and peri-implant granulation tissue [9, 19]. The granulation tissue preservation technique also allows the implant to be in the proximity of the greatest possible number of multipotent mesenchymal stem cells, which are of crucial importance for regeneration, especially when biological mediators such as enamel matrix derivatives are used.

The goal of regenerative therapy of peri-implantitis is the reosseointegration of previously contaminated implant surfaces. There is general agreement in the literature that an open, surgical procedure and a closed healing phase give better results for reosseointegration than a non-surgical, closed procedure and an open, transgingival healing [22]. However, as yet no procedure has been identified that predictably leads to a reosseointegration of previously contaminated implant surfaces. The healing of peri-implant defects is frequently associated with the formation of a long junctional epithelium or a connective tissue attachment and can therefore not be regarded as regeneration but as repair [5]. In regenerative periodontal therapy, regeneration of the root cementum, the periodontal ligament and alveolar bone can be achieved by the use of enamel matrix derivatives. This effect from enamel matrix derivatives is based essentially

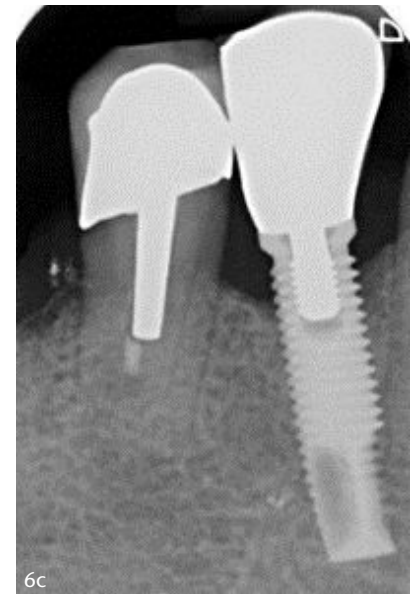


Fig. 6a-g: H. Gümay

Figures 6a–g Case 3 – regenerative therapy in a case of peri-implantitis regio 43; **Fig. 6a:** Radiograph before therapy; **Fig. 6b:** Radiograph 2.5 years after therapy; **Fig. 6c:** Radiograph 6 years after therapy; **Fig. 6d:** Clinical situation before therapy; **Fig. 6e:** Intraoperative view of the bony defect (three-wall defect) after decontamination of the implant surface; **Fig. 6f:** Clinical situation after repositioning of the mucoperiosteal flap and wound closure by sutures; **Fig. 6g:** Clinical situation 2.5 years after therapy

on an inhibition of the cells of the gingival epithelium and a stimulation of the cells of the periodontal ligament and alveolar bone. For a detailed description of the effects of

enamel matrix derivatives on the cells of the periodontium, reference should be made to the review by Bosshardt [4]. A regenerative effect from enamel matrix derivatives is also

more than likely in the healing of peri-implant defects. However, so far there is no histological evidence that enamel matrix derivatives, applied during regenerative therapy of peri-implantitis, prevent the formation of a long junctional epithelium or a connective tissue attachment and promote reosseointegration.

In the third case report, the application of enamel matrix derivatives was abandoned and yet a pronounced bone fill was achieved. This shows that the application of enamel matrix derivatives is not an absolute prerequisite but only one aspect of regenerative peri-implant therapy. Many factors contribute to predictable therapeutic success. In addition to adequate pre-treatment and post-operative care, this primarily includes the surgical technique. In the past, even in non-surgical peri-implantitis therapy, soft tissue curettage (exfoliation of the pocket epithelium and infected connective tissue) was recommended, but in most cases today, preservation of the soft tissue level is the primary focus. For this, the use of microsurgical instruments, a minimally invasive surgical procedure, an adequate decontamination of the implant surface, the stability of the fibrin clot and sufficient suture closure are of crucial importance. All of these components can be combined through the rationale of the granulation tissue-preserving technique. The use of enamel matrix derivatives

is in no way disadvantageous and in many cases can accelerate the healing time. Therefore, in most cases, the granulation tissue preservation technique should be supplemented with an application of enamel matrix derivatives.

Conclusion

The three case reports show the potential and demonstrate the effectiveness of the granulation tissue preservation technique, especially with regard to the prevention of postoperative mucosal recession and the achievement of the greatest possible infilling of bony defects. In addition, enamel matrix derivatives have been shown to be an important supplement in the surgical treatment of peri-implantitis.

Conflicts of interest:

The authors declare that there is no conflict of interest within the meaning of the guidelines of the International Committee of Medical Journal Editors.

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(Photos: Hannover Medical School)

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Indication and treatment strategies in antiresorptive risk patients

Summary:

Antiresorptive drug related osteonecrosis of the jaw (ARONJ) develops primarily in patients with bisphosphonate and/or denosumab therapy. The therapeutic indications of these drugs range from patients with osteoporosis to multi-morbid patients with osseous metastases of solid tumors. In addition to reduced bone remodeling, etiology also describes other factors such as changes to the soft tissues, vessels and the immune system. Here, trigger factors such as inflammatory changes in the oral cavity, periodontitis, peri-implantitis or even surgical procedures such as tooth extractions and prosthesis pressure points play a decisive role in the pathological process. If a full dental functional rehabilitation is to be realized, it is crucial to select a treatment regime that considers the least possible risk of developing osteonecrosis. Clearly general dental surgical procedural risks should also be considered. In individual cases functional rehabilitation may also include an implant-supported denture. The possible risk factor for the development of a drug-associated necrosis of the jaw by prosthetic pressure points caused by removable dentures can be reduced by using implant-supported restoration.

Keywords:

bisphosphonate; individual risk; antiresorptive drug related osteonecrosis of the jaw (ARONJ); DGI-evaluation chart; dental implant insertion; current state of the guidelines

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Introduction

Bisphosphonates have been used successfully in medicine for more than 25 years for the treatment of osteoporosis as well as for osseous metastases of solid tumors. The first description of bisphosphonate-associated osteonecrosis of the jaw [BP-ONJ] in 2003 [18] presented doctors and dentists with new challenges and new treatment issues. On the one hand bisphosphonates achieve positive bone balance and thus a reduction of bone resorption through effective inhibition of osteoclast activity. On the other hand, however, they lead to reduced rate of bone regeneration and remodeling, which can lead to osteonecrosis of the jaw under certain circumstances. Osteonecrosis of the jaw similar to that of bisphosphonate-associated osteonecrosis of the jaw, has subsequently been described following the use of other medications. The term bisphosphonate-associated osteonecrosis of the jaw was replaced by the term antiresorptive drug related osteonecrosis of the jaw because this old terminology was based on the commonality of the antiresorptive properties in bone metabolism or the osteoprotective properties factors involved. The terminology of medication-associated osteonecrosis of the jaw (MRONJ) describes the same entity and is used in particular to cover new medication groups, e.g. Bevacizumab (Avastin), whereby these are much more rarely associated with osteonecrosis of the jaw.

The occurrence of ARONJ is usually fostered by intraoral wounds, e.g. inflammatory changes to the oral mucous membrane, periodontal disease, surgical intervention or denture pressure points (Figure 1). An interdisciplinary approach with cooperation between dentists and medical doctors is best adopted to ensure a successful outcome in such cases. Implant support for the prevention of or sustained reduction of denture pressure points on the oral mucous membrane can reduce individual risk for the patient and lead to improved retention and stability of the prosthesis. As any surgical procedure on the jaw of an ARONJ patient entails the risk of later osteonecrosis of the jaw

the risk must be measured against benefit and an individual risk profile analysis carried out.

This article discusses current recommendations in the literature, the classification of risk profiles, and prevention strategies adopted in ARONJ patients undergoing dental implant regimes [33].

Bisphosphonates and antiresorptive drug related osteonecrosis of the jaw (BPONJ/ARONJ)

Physiological bone metabolism involves a coordinated system of bone resorption and formation processes. The osteoblasts that form the bone substance, the osteoclasts that break it down and the osteocytes that are created, are regulated by different regulatory systems both inside and outside the bone matrix. Stimulation of the osteoblasts leads to bone formation. Stimulation of the osteoclasts, on the other hand, has the opposite effect, leading to continually regulated resorption and formation. "In a steady state the resorption and formation are balanced, which leads to continual renewal of the existing bone tissue (bone remodeling)" [10]. Different pathological situations can substantially disrupt this balance. The most important diseases in this category are osteoporosis, in which generalized negative bone balance occurs, and oncological diseases associated with bone metastases (e.g. mammary and prostate carcinoma) or that occur primarily in the bone tissue (plasmocytom, multiple myeloma). The issue that all these diseases have in common is the progressive instability of the skeletal system with increasing risk of spontaneous fracture and consequences through to paraplegia. Bisphosphonates strive, as a group of medications, to intervene positively into this derailed regulation mechanism.

Bisphosphonates are synthetically manufactured analogs of pyrophosphates and inhibit an enzyme, mainly in osteoclasts. The suppressed enzyme in the osteoclasts then leads to reduced resorption of the bone. The intervention into this regulatory circuit of bone metabolism means that the physiological bone remodel-

ing no longer occurs and the bone-remodeling rate reduces. However the intervention into the regulatory circuit as described above is considered to be the main cause of antiresorptive drug related osteonecrosis of the jaw, in combination with other factors.

The leading symptom of antiresorptive drug associated osteonecrosis of the jaw is exposed bone which may be determined by inspection or palpation with a probe. Further classical symptoms are loose teeth, foeter ex ore, jaw ridge fistula with or without exudation, swelling or spontaneous sensitivity disorders of the lower lip (Vincent symptom). A patient's existing or intermittent pain should not be considered as a principal symptom. This is rather an expression of the (super) infection and frequently characterized by additional pus exudation.

The monoclonal IgG2-Anti-RANKL antibody denosumab (trade name: Prolia or X-Geva) is also associated with the formation of osteonecrosis [6]. Denosumab also intervenes in the bone metabolism by deactivating a protein that normally activates osteoclasts, precipitating osteoclast inhibition. Denosumab and bisphosphonate therapy produce a similar incidence of osteonecrosis in ARONJ, oncological and osteoporosis patients [22, 27].

Treatment of primary and secondary osteoporosis as well as supportive therapy for oncological diseases are the main indications for antiresorptive agents. These include:

- multiple myeloma (or plasmocytom),
- the osseous metastases of solid tumors, whereby mammary carcinoma and prostate carcinoma are the main indication here,
- primary (usually postmenopausal) osteoporosis,
- secondary (usually therapy-induced) osteoporosis,
- Paget's disease.

Probably the most frequent treatment with antiresorptive agents is for primary osteoporosis with oral bisphosphonate medication or intravenous dose just once a year. Cases of secondary osteoporosis or malign diseases without bone metastases usually indicate intravenous adminis-

tration 2 to 4 times a year [6]. Osseous metastases and multiple myeloma, however, require increased medication commonly with one intravenous therapy every 4 weeks [1, 30].

Besides the above antiresorptive agents several other medications are also now suspected of being able to trigger osteonecrosis of the jaw. The only secured data on the subject is on the prevalence of osteonecrosis of the jaw with the angiogenesis inhibitor bevacizumab, which (without accompanying bisphosphonate medication) is 0.3–0.4 % [11]. However the combination of an angiogenesis inhibitor such as bevacizumab or sinitinib with bisphosphonates reveals an ONJ risk elevation of 16 % [3].

Further case reports for triggered osteonecrosis of the jaw exist for the medications trastuzumab (trade name: Herceptin) and aflibercept (trade name: Zaltrap) [19, 20, 37]. It is not currently possible to make a statement on the prevalence for these medications.

Therefore, the group of antiresorptive agents and the individual medication Alvestin are important and must be included in the dentist's medical history record.

Definition and prevalence of the antiresorptive drug related osteonecrosis of the jaw

The special aspect of the patient group with using antiresorptive agents is not explained wholly on the basis of the prevalence rates but rather with the knowledge that there



Figure 1 Exposed bone around lower jaw. Typical clinical picture of antiresorptive drug related osteonecrosis.

is a half-life time that can last several years caused by the complex bond of the medication to the hydroxyapatite of the bone that is sometimes extremely long and individually very difficult to estimate. This means that osteonecrosis of the jaw can even develop after years without oral mucous membrane symptoms.

The currently recognized definition of antiresorptive drug related osteonecrosis of the jaw is a combination of 3 symptoms:

- exposed bone for more than 8 weeks (inspection or probe palpation),
 - bisphosphonate, denosumab medication or intake of another corresponding medication and
 - a lack of head/neck radiotherapy in the medical history [18, 24, 25].
- Patient risk susceptibility to ONJ is variable. In order to determine the individual risk of each person we must first differentiate the risk according to literature-based rates of osteonecrosis of the jaw for three typical groups of patients that are described in the guideline on bisphosphonate-associated osteonecrosis of the jaw (BP-ONJ) and other medication-associated osteonecrosis of the jaw [6]:

- Low risk profile: 0.1 %
 - With primary osteoporosis (usually oral alendronate, more rarely zoledronate 5 mg i.v. every 12 months or 60 mg denosumab every 6 months)
- Moderate risk profile: 1 %
 - With therapy-induced osteoporosis (e.g. zoledronate 4 mg every 6 months or denosumab) or with prophylactic administration without bone metastases
- High risk profile: 4 to 20 %
 - With oncological indications with bone metastases or with plasmocytom (e.g. zoledronate 4 mg or denosumab 120 mg every 4 weeks) [6].

This categorization of patients into a low, moderate or high-risk profile is very helpful but only represents an initial approach to the evaluation of the individual's risk profile. This comprises [23, 31, 32]:

- The selected bisphosphonate preparation (non-amino versus amino-BP),

- The method of application (i.v. versus oral intake),
- The dose and number of individual doses,
- The therapy duration,
- The underlying disease (oncological versus non-oncological),
- Further medication and therapies (e.g. chemo, cortisone, anti-angiogenic or radiation therapy),
- Other risk factors (e.g. diabetes mellitus, nicotine abuse, other underlying diseases etc.),
- Local infection entry sites (periodontitis, oral hygiene with any injury to the oral mucous membrane, surgical intervention, denture pressure points).

A so-called 'routing slip' has been developed in order to simplify this very complex evaluation of the individual's risk profile for the dentist and to improve the necessary, interdisciplinary communication between the doctors prescribing the antiresorptive agents. Use of this slip is also recommended in the S3 guideline [8]. It includes the patient's underlying disease, the type of medication and any other oncological therapies (chemotherapy, radiation therapy, immune or antibody therapy or cortisone therapy) and can be implemented individually.

Etiology and pathogenesis of antiresorptive drug-related osteonecrosis

Multiple factors are assumed in the development of ARONJ [12, 35]. Besides the reduced bone remodeling rate described above the medication that is used has a differing level of influence on the gingiva. This involves fibroblast, keratinocyte and vessel cell functions.

It has become apparent that infections in the jaw area are possible trigger factors. These include gingivitis, periodontitis and dentito difficilis. The literature also reveals that tooth extraction, injury to the oral mucous membrane from denture pressure points, sharp bone edges, defective cleaning or biting inter alia, have a strong influence on oral bacterial populations.

Several studies support the assumption that there is a direct correlation between having untreated or

exacerbated periodontitis and the development of osteonecrosis of the jaw [21, 26, 28, 29]. Thus patients with bisphosphonate-associated osteonecrosis of the jaw usually have fewer teeth than corresponding control groups and greater quantitative (more teeth) and qualitative attachment loss (more severe affliction) [28, 36]. The same evidence exists for the important triggers 'denture pressure point' and 'tooth extraction without safety provisos'. It is important that the infection is manifest in the soft tissue (including the parodontium) or that the bacterial population is in the bony embedding tissue at the 'integumental perforation' (pressure point) or open soft tissue bone wound (extraction alveolus). This does not then cause passing osteitis or osteomyelitis, in contrast to infected osteoradionecrosis or more rarely sequestration in chronic osteomyelitis, but rather to the bone directly entering necrosis (Figures 2–5).

Primary importance is placed on all measures to avoid an ONJ before beginning antiresorptive therapy (ONJ prophylaxis) or during or after AR therapy (ONJ prevention). The cooperation of dentist, doctor and patient are required for a successful outcome.

A 2016 study involving 192 inter-nists, orthopedists and pediatricians in Seoul were interviewed on ARONJ, the prophylaxis, prevention and therapy. 22 % of those questioned were not aware of osteonecrosis as a disease. Only less than 30 % refer for oral prophylaxis/prevention measures [14]. The central point is that 78 % of those questioned were aware of the ONJ problem but still only approximately 30 % initiated an ONJ prophylaxis! The aim was to alert this almost 50 % of those questioned so that they refer the patient to the relevant dentist before AR therapy. This study reveals the major issue that osteonecrosis cannot be prevented if the dentist is aware of the disease but the patient is still not provided with information by the doctor treating him or her.

ONJ Prophylaxis

This is why prophylaxis for osteonecrosis of the jaw is carried out prior to

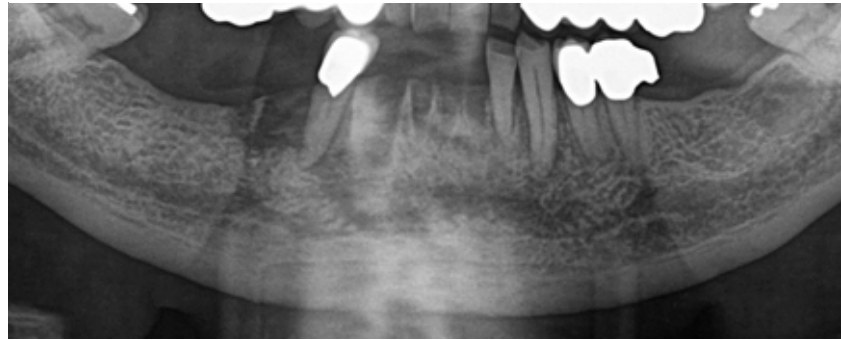


Figure 2 Part of an OPTG. The extraction sockets and osteolytic processes in the lower jaw front and region 45 are clearly visible.

therapy with antiresorptive agents. It should be noted that the measures listed correspond to standard dental prophylaxis and are not a special therapy for bisphosphonate patients [6]:

- Extraction of teeth and implants that cannot be saved or are not worth maintaining,
- Rehabilitation of infections in recesses by beginning systematic periodontal therapy on teeth with periodontal disease that are worth maintaining (this can also be continued in parallel to the beginning of the BP therapy),
- Beginning a systematic peri-implantitis therapy on implants that are worth maintaining (this can also be continued in parallel to the beginning of the BP therapy),
- Removal of partially retained teeth with chronic pericoronitis,
- Removal of cysts, foreign bodies and other enossal chronic sources of infection,
- Root tip re-sectioning only with clinically symptomatic apical periodontitis (caution: a radiological finding alone for apical osteolysis is not an indication of WSR because of the reduced rate of bone remodeling in these patients!),
- Root canal treatment on non-vital teeth without root treatment,
- Rehabilitation of existing and avoidance of future entry points for pathogens by treating existing pressure points (modification of dentures),
- Reduction of the risk of pressure points by adapting the prosthesis base, smoothing sharp bone edges, exostoses and tori with relevant

risk for future mucous membrane perforation,

- Motivation and instruction relating to above average oral hygiene,
- Classification of the patient in a risk-adapted recall program.

Achievable oral hygiene should be taken into account for all the recommendations to the patient. Of course optimum results in domestic oral hygiene should be exhausted and the patient re-motivated in the course of the treatment or at check up appointments. However, limitations of oral hygiene because of possible general disorders (e.g. rheumatoid arthritis, Parkinson's disease or a condition following a stroke) must also be considered in the approach to and assessment of the value of maintaining teeth with existing periodontal disease. If the patient is not capable of appropriate oral hygiene even after implementing all possibilities then he or she should be classified as a high-risk patient for the formation of osteonecrosis of the jaw.

Following the confirmation of any necessary surgical intervention in this group of patients, subsequent ONJ risk factors should be considered and balanced against the consequences of non-action. For example, degree of dental/periodontal pathology and their likely consequences versus risk of ARONJ.

Tegumental denture pressure points represent a further risk factor that could also trigger the occurrence of osteonecrosis [34]. The insertion of implants is a good way to reduce the risk of a denture pressure point by avoiding tegumental dentures. However, implants per se do represent a



Figure 3 The corresponding enoral clinical picture. Exposed bone at the alveoli with a putrid superinfection show the enoral status.

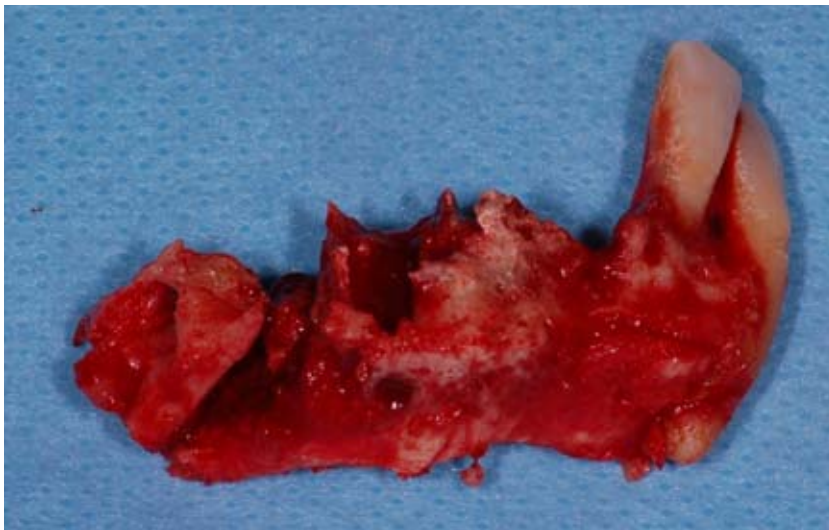


Figure 4 Resectate of the lower jaw with partial greyish-green bone necrosis.

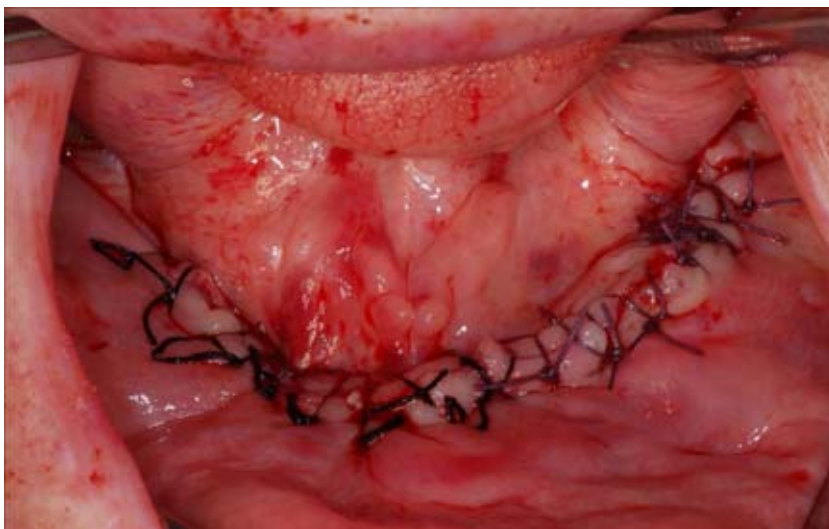


Figure 5 Condition after resection and smoothing of the sharp bone edges in the lower jaw with plastic covering.

risk for the development of osteonecrosis of the jaw [34] from possible periimplantitis or intervention following antiresorptive agent therapy.

Precautionary measures for tooth removal

As with other patients, a necessary tooth extraction should not be long delayed in risk patients. A number of defined safety measures exist in order for the intervention to take place with as few problems as possible:

- A prolonged, peri-operative, systemic antibiotic prophylaxis at least from the day before the operation and until the clinical signs of bacterial load abate. Here the antibiotic Amoxicillin, 1 g is recommended 3× daily, or (in the case of a penicillin allergy) Clindamycin 600 mg 3× daily.
- Minimally invasive operations and atraumatic procedures (avoiding thermal or mechanical lesions in the bony tissue),
- Careful removal of the sharp bone edges (modeling osteotomy), particularly in order to prevent secondary perforation of the mucosa. It should be noted here that a flap opening or formation of a flap is still necessary for ‘simple’ tooth extraction. Minimally invasive piezosurgery has established itself for the additional, atraumatic smoothing of the sharp bone edges.
- Primary, plastic cover of the defect with tension-free wound closure.

Antiresorptive agents and implants

A new guideline was published in 2016 entitled ‘Tooth implants during medical treatment with bone antiresorptive agents (including bisphosphonate) [33] in order to help both the patient and his or her doctor/dentist with this issue.

Risk evaluation is the primary factor to be considered in functional rehabilitation involving antiresorptive agent therapy as described above. A risk evaluation sheet with traffic light classification has been developed and commissioned by the German Association for Implantology. in order to simplify risk assessment for surgeons. The risk assessment consider underlying disease, antiresorptive medication

dosage dynamics, oncological considerations bone remodeling dynamics. The relevant ONJ risk is classified as 'low = green', 'moderate = yellow' or 'high = red' [5].

Particular significance is given to the radiological diagnosis of a 'persistent alveolus'. Radiological changes in the panoramic tomography that are induced by the antiresorptive agent therapy can mean that an unhealed alveolus in the x-ray can be taken as a very low level of bone regeneration [4]. The clinical and radiological healing process of alveolus should therefore be included in the evaluation of a possible implant procedure [33].

A difficult but necessary factor involving all patients with underlying oncological diseases is the prognosis *quoad vitam*. The participation of the patients oncologist should be sought in this respect [33].

The implant indication should also be checked with regard to whether the risk of osteonecrosis can be lowered through the insertion of implants by avoiding denture pressure points and therefore reducing the stress on the mucous membrane [33]. The degree to which the peri-implant embedding tissue needs to be improved with bone augmentation procedures will determine the risk of a wound healing disorder, of osteonecrosis and the possible failure of implants.

A table from the guidelines: 'Dental implants during medication with bone resorptive agents (including bisphosphonate)' [33] provides a good summary of implant indication (Table 1). The attending dentist or physician can also go through the algorithm to reach a decision for or against an implant together with the patient.

If the above aspects are observed and the patient is classified in the correct risk group then implantation in antiresorptive agent patients is promising. Past studies and meta-analyses and evaluation of the literature show implant survival rates of 95–100 % [7, 16] or 86 % [13]. While most studies were carried out with patients with primary and secondary osteoporosis and involved concurrent oral bisphosphonate medication, it

Arguments in favor of an implant	Arguments against an implant
Low risk of osteonecrosis	High risk of osteonecrosis
No osteonecrosis in personal medical history	Existing/prior osteonecrosis
Good oncological prognosis	Poor oncological prognosis
No source of infection	Existing source of infection
Clinically no sharp bone edges, radiologically no persistent alveoli	Clinically and radiologically poor bone remodeling and poor bone remodeling rate
Good compliance	Poor compliance
Good oral hygiene	Poor oral hygiene
Avoidance of denture pressure points	No avoidance of denture pressure points
High strength of indication	Questionable necessity of an implant or equivalent conventional prosthetic replacements possible
No augmentation necessary	Augmentation necessary

Table 1 Overview and summary of implant indication in antiresorptive agent patients. From S3 guideline: „Dental Implants in Medicinal Treatment with Bone Antiresorptive agents (Including Bisphosphonates)“ [33]

should be noted that subjects involved had a rather lower risk to develop osteonecrosis. Two systematic reviews from 2013 show no absolute contraindication for implant therapy in oral or intravenous bisphosphonate therapy [2, 9].

Patients must be informed at the end of the pre-operative phase. The patient should be informed of the individual risk of osteonecrosis prior to the planned implant insertion. This information should also include alternatives to the therapy, the advantages and disadvantage and the necessary structured aftercare, along with a note of these subsequent costs. Two central points should be discussed with patients: the risk of osteonecrosis from a dental operation, i.e. the implantation itself, and the possible future risk of periimplantitis. Studies currently show that the risk of periimplantitis, i.e. of bacterial population of the gingiva and the embedding tissue around the implant, is seen as a significant factor in

causing osteonecrosis of the jaw compared to the risk of the implantation itself. As several implants need to be inserted in order to avoid a removable denture the consequent prophylaxis and aftercare for the implants is one of the central points for the patient and the dentist [15, 17, 28, 34]. Regular aftercare is essential for dentures mounted on implants. The focus here is on correct fit, particularly of small denture saddles in the distal area. This could also lead to pressure point-associated necrosis with an imprecise fit.

Surgical procedure

Surgical intervention on antiresorptive agent patients requires an exact planning phase. There is no resilient data in current literature for a so-called 'drug holiday' around the time of the operation and this cannot be recommended [33].

Implant placement can take place safely if certain safety precautions are observed (including prolonged peri-

operative treatment with antibiotics, a strict diet of liquid or soft food, a minimally invasive operation). The peri-operative, systemic antibiotics prophylaxis should be carried on with all antiresorptive agent patients. However, no uniform regime of antibiotics can be recommended. Antibiotic indications must be assessed individually. Analogously to the endocarditis prophylaxis a single dose 30–60 min before the intervention could be sufficient, whereby antibiotic regimes are sometimes started earlier in the literature and given over a period of several days [33]. A prolonged, peri-operative, systemic antibiotic screen has proven effective in clinical practice until clinical signs of germ population have abated after the operation.

Overall conservative treatment regimes dominated with these patients, following assessment of a positive indication for implantation:

- No immediate implantation (together with tooth extractions!),
- No immediate restoration,
- No immediate loading,
- Preference for medium strength primary stability (e.g. thread tapping, avoidance of conicity),
- Preference for regimes to avoid periimplantitis (e.g. angulation, vertical biological width etc.).

There is no reliable data available concerning implant healing. Transgingival healing with initial, possibly lesser contamination of the bone via the larger wound is contrasted with a second intervention when exposing subgingival healing. Healing time following implantation is also based on conjecture. A longer healing time can be assumed, based on the reduced bone-remodeling rate, until the implant is integrated into the bone.

Conclusion

The new guideline ‘Dental implants in the medical treatment with bone antiresorptive agents (including bisphosphonate)’ provides the caregiver with a valuable decision reaching aid. The indication for implant care can be reviewed precisely in combination with a further risk evaluation using the ASORS routing slip and the DGI evaluation sheet. The insertion of im-

plants in antiresorptive agent patients may include functional rehabilitation in certain circumstances and thus probably reduce the risk of the development of osteonecrosis by avoiding denture pressure points. However, further long-term studies are necessary in order to evaluate the probability of success of the implant/denture solution for the patient.

Conflicts of Interest:

The authors declare that there is no conflict of interest as defined by the guidelines of the International Committee of Medical Journal Editors.

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In vitro wear of two bioactive composites and a glass ionomer cement

Objective of the study:

to measure the in vitro wear of two bioactive smart composite restorative materials and one glass ionomer cement.

Materials and methods:

The smart composites Activa (Pulpdent) and Cention N (Ivoclar Vivadent) and the glass ionomer cement Fuji IX (GC) were applied into aluminum sample holders, pressed against a glass plate and stored in water for 3 weeks after curing. The samples were subjected to 400,000 load cycles of 49 N in the CS-4 chewing simulator (Mechatronik) against steatite antagonists and subjected to 4,440 thermocycles from 5 °C to 55 °C. Samples were evaluated with replicas after 5,000, 10,000, 20,000, 40,000, 60,000, 80,000, 100,000, 120,000, 160,000, 200,000, 240,000, 280,000, 320,000, 360,000 and 400,000 cycles with a laser scanner (LAS-20, Mechatronik) and the Geomagic software (wear volume). The data was analyzed with ANOVA and Tukey test. Selected wear facets were analyzed with a scanning electron microscope (SEM).

Results:

The increase in wear was almost linear and after 60,000 cycles significantly different depending on the material (Activa < Cention N < Fuji IX). After 400,000 load cycles the following wear was measured: Activa 1.571 mm³, Cention N 2.455 mm³ and Fuji IX 5.622 mm³. The wear of the antagonist was slight and in the reverse order ($p < 0.001$): Fuji IX 0.021 mm³, Activa 0.091 mm³ and Cention N 0.126 mm³. SEM analysis showed pores in the powder-liquid systems. The composite and their antagonists had scratched surfaces, something that was not seen on the glass ionomer cement.

Discussion:

The bioactive composites that were tested had wear values comparable to the modern hybrid composites determined by the authors with the identical test method. The lesser wear of Activa in comparison to Cention N can be explained by the fact that the latter material is designed as a powder-liquid system with manual mixing.

Conclusion:

Based on their wear behavior the tested bioactive smart composites are suitable for posterior fillings (as an amalgam replacement) while the great wear to the glass ionomer cement confirms this indication (non load-bearing class I and II fillings).

Keywords:

smart composites; alcasites; glass ionomer cement; in-vitro-wear

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Name	Type	Manufacturer	Charge #
Activa	Smart composite	Pulpdent, Watertown MA 02472 USA	160615
Cention N	Smart composite	Ivoclar Vivadent Schaan FL-9494	U19921
Fuji IX GP	Radiopaker glass ionomer cement	GC Tokyo, Japan	1604121

Table 1 Materials used

Introduction

Composites have been improved continuously since their invention in the 1950s [1–3]. But this has happened without abandoning their fundamental concepts [12]. Most of the improvements took place in the filler technology. In parallel to the improvement of the milling technology it was realized that an optimal ‘smart’ distribution of the filler particle sizes caused a reduction of the share of the resin content, which had a positive effect on the polymerization shrinkage behavior [27].

Diacrylates continue to be used on the resin side, whereby many different monomers with widely differing molecular weights are used [27].

A new generation has been developed recently that is termed bioactive or ‘smart’ [20]. This name aims to communicate that these materials are capable of reacting to environmental conditions. If the pH drops then these materials release ions that can both neutralize the acids produced by the bacteria in the biofilm and are available for remineralization processes as well [29]. This is achieved through the use of acid-soluble glass in combination with new types of monomers that can be polymerized as diacrylates as before [30].

As only little data can be found in the literature on Activa (Pulpdent) [6, 24], we will provide a brief description of this new class of composite, named Alcasite [11, 30] based on the example of Cention N (Ivoclar Vivadent). The fillers in this composite comprises proven components (barium-aluminum glass, calcium-barium-aluminum-fluoride silicate glass, ytterbium trifluoride and isofillers [pre-polymerized particles]) [30]. A calcium-fluoride silicate glass is added as an active component that can release

Load	49 N
Upward movement	2 mm
Downward movement	1 mm
Horizontal movement	0,7 mm
Speed of upward movement	60 mm/sec
Speed of downward movement	60 mm/sec
Speed of horizontal movement	40 mm/sec
Frequency	1 HZ
Alternating temperature bath	5–55 °C; 30 sec holding time, transfer time 15 sec, total cycle length 90 sec
Direction	Forwards under load, backwards without load

Table 2 Settings on the chewing simulator

ions as a function of the acidity of the environment. This filler mixture powder, which also contains parts of the initiator system, is mixed with a diacrylate mixture consisting of urethane dimethacrylate, TMX urethane dimethacrylate [22], a short chain diluent monomer (tricyclodecane dimethanol dimethacrylate) and an hydrophilic dimethacrylate (polyethylene glycol dimethacrylate) for improved wetting of the tooth structure [30].

The cured material is capable of releasing Ca^{2+} , F^- and OH^- ions as a function of the acidity of the environment because of their composition. The OH^- ions neutralize the acid while forming water, the calcium and fluoride ions can form calcium fluoride and together with phosphate ions calcium phosphate can be pro-

vided for the remineralization of enamel. This effect was documented in vitro up to 100 μm from the filling-enamel-interface [30].

With regard to the mechanical properties Cention behaves for the most part in the same way as a nano hybrid composite [30]. Its bending strength remains stable within the range between 100–120 MPa when stored in water (measured for up to 3 months). The same is true for the modulus of elasticity which is in the range of around 5 GPa [11]. Thus, Cention N fits into the range of known and clinically proven hybrid and nano hybrid composites [12]. The mechanical data for Cention N are also comparable with those of Bulkfil composites [11]. But Cention N can be applied more easily. The material is offered as a powder-liquid system for

Material	120,000 cycles	400,000 cycles
Activa	0.54875 ± 0.06151	1.57125 ± 0.22787
Cention N	0.95000 ± 0.15946	2.45500 ± 0.24202±
Fuji IX	3.05000 ± 0.31491	5.62250 ± 0.54706

Table 3 Wear in mm³ after 120,000 and 400,000 load cycles (mean ± standard deviation); ($p < 0.0001$)

manual mixing. It is intentionally positioned by the manufacturer (Ivoclar Vivadent) as an amalgam replacement material on permanent teeth as well as a replacement for glass ionomer cement on deciduous teeth, particularly in countries where simple dentistry is required. The alternative to amalgam in these countries is glass ionomer cement.

The conceptual structure of Activa is similar to that of Cention N. It is provided as a 2-paste system in a static mixer, displays a bending strength of 105 MPa [6] and is comparable to Cention/N with regard to its mechanical properties. Both materials are auto-curing (amine peroxide 2-component system), but can also be photo-polymerized [24, 30]. As the material Cention N is relatively new, comparatively little is known about its wear behavior. Thus the objective of this study was to measure the wear of Cention N in vitro in comparison to a competitor product with similar composition and a classic glass ionomer cement (control).

Material and methods

The materials that were used are summarized in table 1. The production of samples took place at room temperature (approx. 21 °C) in accordance with the manufacturer's recommendations for each product. Activa (Pulpdent, Watertown MA 02427 USA) was applied with the Activa-Spenser and static 5 ml automix syringe (Pulpdent) in aluminum sample holders that were sand-blasted and pretreated with Adhese Universal (Ivoclar Vivadent, FL 9494 Schaan Liechtenstein). Then a mylar matrix was laid on the material and the surface pressed flat with a glass

plate. The material was cured for 10 minutes (autocuring, no light curing!). Then polishing was carried out with Soflex discs (3M Espe, St. Paul, MN 55144 USA).

Two measuring spoons of powder and 2 drops of resin of Cention N (Ivoclar Vivadent) were applied to a mixing pad and mixed manually to a smooth consistency. First the liquid was mixed with half of the powder until it was well wetted and then the remaining powder was added in small quantities. The mixing time did not exceed 60 seconds. Then the paste was placed in the sand blasted and pretreated aluminum sample holder with a spatula, covered with a mylar matrix and pressed to a flat surface. The material was left for 10 minutes from the start of mixing (no light curing!). Then it was polished using Soflex discs (3M Espe, St. Paul, MN 55144 USA).

Two measuring spoons of powder and 2 drops of liquid of Fuji IX (GC, Tokyo, Japan) were applied to a mixing pad and mixed manually to a smooth consistency. First the liquid was mixed with half of the powder until it was well wetted and then the remaining powder added in small quantities. The mixing time did not exceed 30 seconds. Then the paste was applied as described above in the pretreated aluminum sample holder. After 10 minutes the mylar matrix was removed and the surface polished with Soflex discs (3M Espe). Finally a layer of GC Fuji Varnish (GC) was applied to the surface. All samples were stored for at least 3 weeks in water at 37 °C before being subjected to wear.

Steatite antagonists (ø 6 mm, SD Mechatronik, D-83620 Feldkirchen-Westerham, Germany) were mounted

with a light-cured composite in a pretreated aluminum antagonist holder as described above. New antagonists were used for each sample. The pairs of samples and antagonists were distributed on the chewing simulator chambers (CS-4, Mechatronik) using random numbers [25].

The chewing simulator was programmed in accordance with the parameters listed in table 2. The samples were simultaneously subjected to 4440 thermocycles of 5–55 °C.

After 5000, 10,000, 20,000, 40,000, 60,000, 80,000, 100,000, 120,000, 160,000, 200,000, 240,000, 280,000, 320,000, 360,000 and 400,000 load cycles impressions of the samples were taken with a hydrophilic polyvinylsiloxane (Virtual Light Body Wash Material, Ivoclar Vivadent) and standard small trays (ø 18 mm). They were poured with stone (Microstone, Premium Dental Stone, Golden, Whip Mix, Louisville, KY 40209, USA) and scanned with a laser scanner (LAS-20, Mechatronik). Impressions were taken on the antagonists at the start and after 60,000, 120,000, 200,000, 280,000 and 400,000 load cycles. They were poured with stone as described above and scanned with a laser scanner (LAS-20, Mechatronik).

The wear measurement (volume) was carried out using Geomagic software as described by Matias et al. [18]. The same principle was used in order to measure the wear on the antagonists. The wear data was determined by 2 evaluators independently of one another (HH and NA).

The data was analyzed with the SAS program using the ANOVA and Tukey test (SAS® 9.4, Cary NC 27513, USA).

Scanning electron microscope (SEM) images were produced of selected samples in order to perform a qualitative assessment of the wear facets and their surface structure. The samples and antagonists were coated in gold-platinum in a Technic Hummer 22020 Sputter (Technics Inc, Alexandria VA 22310) for this purpose.

Results

The results of the material wear are shown in Figure 1 and Table 3. It is

clear that the wear of the glass ionomer cement was much greater at 400,000 load cycles ($5.622 \pm 0.547 \text{ mm}^3$) than the one of the resin based materials (Cention N $2.455 \pm 0.242 \text{ mm}^3$; Activa $1.571 \pm 0.228 \text{ mm}^3$). These differences were statistically significant (see table 3). No significant difference was determined between Cention N and Activa up to 60,000 load cycles (see Figure 1).

The antagonist wear is shown in Figure 2. It should be noted that Fuji IX had caused the least abrasion of the antagonists ($0.065 \pm 0.0185 \text{ mm}^3$). Both composite materials abraded the antagonists significantly more severely (Activa $0.156 \pm 0.0239 \text{ mm}^3$; Cention N $0.192 \pm 0.013 \text{ mm}^3$). This difference was statistically significant ($p < 0.0001$).

SEM images of the wear facets and the corresponding antagonists of the different materials are shown in Figures 3–5. It should be noted that both powder-liquid formulations (Cention N and Fuji IX) ended with pores in the structure (Figures 4 and 5) that were not found with Activa (static mixer in the paste-paste system) (Figure 3). The minimal wear of the antagonists by Fuji IX is confirmed by the surface structure of the antagonists. Hardly any damage is visible. Fuji IX only displayed small scratches on its surface. On the other side the composite materials displayed clear scratches on their wear facets and created similar scratches in the antagonists.

Discussion

If we look at the mechanical properties of composites then it is important to ensure that the composite is well cured and stable. The tested composite materials are auto-curing with light curing option [24, 30], in order to accelerate the application process. Light curing was purposely omitted in order to avoid a further variable that could distort the results, especially as Cention N was positioned for use in the markets with simple dentistry, where it can be assumed that light curing cannot be presupposed as standard.

Wear is a very complex process. That is why there is no specific stan-

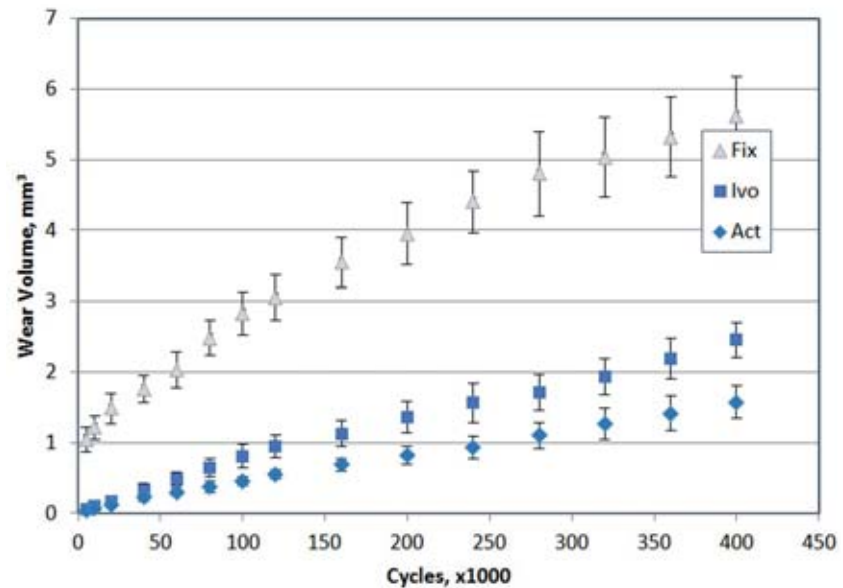


Figure 1 Wear of the investigated materials in mm^3 (Fix = Fuji IX, Ivo = Cention N, Act = Activa); ($p < 0.0001$)

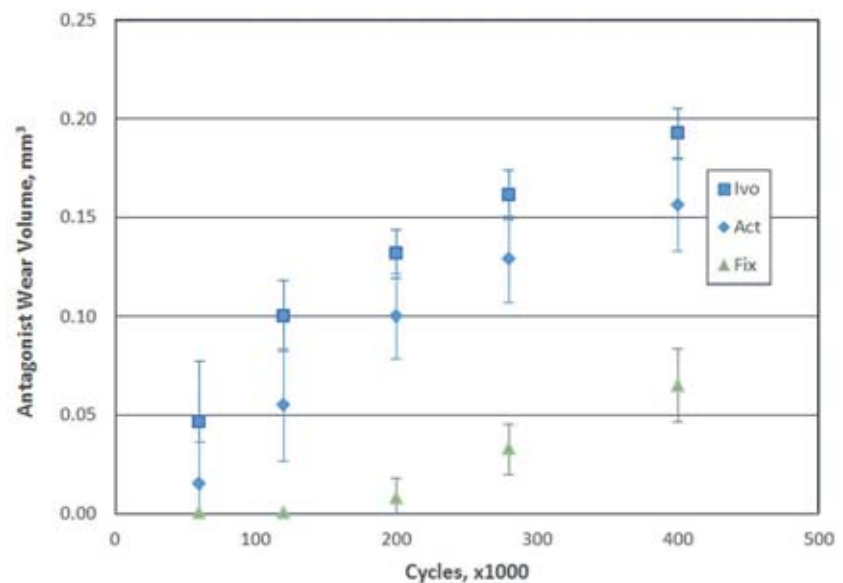


Figure 2 Wear of antagonists in mm^3 against the materials tested (Fix = Fuji IX, Ivo = Cention N, Act = Activa); ($p < 0.0001$)

dard for wear testing. It is particularly difficult to completely reproduce the clinical situation in vitro. The different in-vitro wear machines use different approaches; however machines with two-body wear and sliding component and preferably computer-controlled forces and movements have been preferred recently [13]. As every wear tester has a different approach to the work [13] different antagonists are used with regard to material, form and dimensions [4, 8, 14, 15, 18, 21].

In this study spherical steatite antagonists were used ($\varnothing 6 \text{ mm}$) because of their hardness, reproducibility, the standard form similar to a tooth cusp and easy availability. In addition to this most Mechatronik chewing simulator users use this antagonist, which allows comparisons with other studies. Standard parameters were used for the operation of the chewing simulator. This makes our data easy to compare with those of the Ivoclar Vivadent Group in Schaan [16]. The

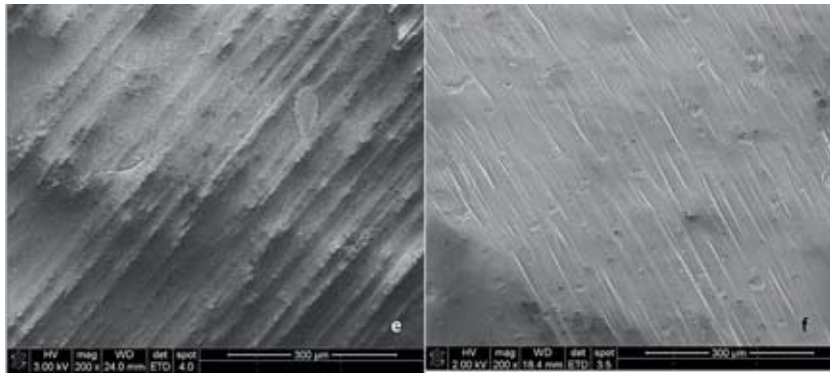


Figure 3 Activa wear facet after 400,000 load cycles (left) and corresponding antagonist (right). SEM 160x.

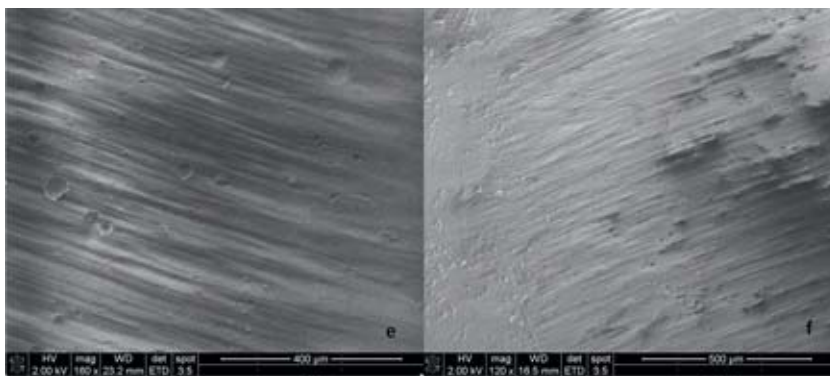


Figure 4 Cention N wear facet after 400,000 load cycles (left) and corresponding antagonist (right). Note the air bubbles in the material. REM, 160x (left); 120x (right)

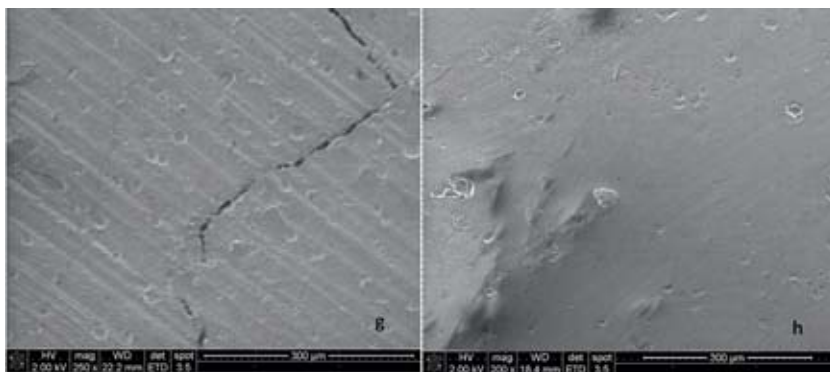


Figure 5 Fuji IX wear facet after 400,000 load cycles (left) and corresponding antagonist (right). Note the air bubbles in the material. Cracks are artifacts due to dehydration of the glass ionomer cement for sample preparation. SEM, 250x (left); 200x (right).

slight difference can be explained by the different antagonists. Spherical steatite antagonists were used in this experiment while Ivoclar Vivadent used standardized Empress (leucite-ceramic) antagonists that are in the form of a molar cusp. The wear values that resulted from this experiment were only half of those achieved with similar composite materials in an earlier experiment [19] using

the same chewing simulator. This difference can be explained by the different settings of the chewing simulator [19]. A load of 49 N was used in this experiment while the previous experiment used 59 N, which appears to be too much as fractures appeared in the samples. It is difficult to determine the actual chewing force in vivo. The data in the literature reveals great variations (20–120 N). The

decision to use 49 N is based on a study by Gibbs et al. [7] that reported that 49 N is the average chewing force in normal functions.

A laser scanner was used to measure wear facets. Heintze et al. [9] showed that there is no significant difference between a mechanical or optical profilometer and a laser scanner.

This study was performed using almost the same study as earlier studies [10, 19, 28]. The difference was that the samples and antagonists that were used together in the Matias study were scanned directly while we decided to use hard plastic replicas. The reason for this was that we found distortions in the flat surface at the transition to the facet during the direct observation of facet in polished, flat composite or ceramic surfaces in the Geomagic software [5]. We also had 2 assessors who measured the wear based on the LAS 20 scans, which displayed identical data. This resulted in slight standard discrepancies overall, so that we were able to differentiate between the material wear in the different materials at an early stage (from 80,000 load cycles between Cention N and Activa).

However, the total number of cycles was increased to 400,000 in this study because the linear course of the wear changed at approx. 350,000 cycles in a pilot study with glass ionomer cement (unpublished data).

The smart composites Activa and Cention N both offer a light curing option. However, Cention N is directed towards emerging economies where it is generally unlikely that light-curing equipment will be available. Therefore, it was decided to only use these materials in auto-curing mode.

The wear behavior in the first 5,000 cycles was inconsistent and had greater variability, as in an earlier experiment [19]. This is a known effect known as ‘running in’. The analysis of the data therefore began at 5,000 cycles. From this point the wear development was linear with excellent correlation ($R^2 > 0.98$; see Figure 2), which confirms the results of Heintze et al. [8, 9], Wang et al. [31] and Matias et al. [19].

(Tables 1–3, Fig. 1–5; Roulet et al.)

When the wear volume was compared the smart composites with the bioactive properties had approximately the same values as Tetric N Ceram Bulkfil and X-tra fil, as tested in an earlier study [28]. At 120,000 load cycles Tetric N-Ceram had $0.66 \pm 0.27 \text{ mm}^3$ and X-tra fil $0.64 \pm 0.32 \text{ mm}^3$ wear. This compares well with this study, also at 120,000 load cycles, at $0.5487 \pm 0.061 \text{ mm}^3$ (Activa) and $0.950 \pm 0.159 \text{ mm}^3$ (Cention N). The data presented in this study is of the same order as the wear values (volume) submitted by Lendenmann and Wanner [16] for composites. The slight differences could be explained by the fact that different antagonists were used. Thus study used steatite spheres with a diameter of 6 mm while the Ivoclar-Vivadent method used Empress antagonists in the form of a natural cusp. The wear values of Cention N and Activa at 120,000 load cycles (table 3) correspond well to those of nanohybrid composites that had positioned themselves between $0.428 \pm 0.083 \text{ mm}^3$ und $1.578 \pm 0.37 \text{ mm}^3$ under identical conditions [10]. The mechanical data (bending strength and modulus of elasticity of the tested composite are over 100 MPa and around 5 GPa respectively [6, 11, 12], which corresponds to the values for the hybrid composites that are used routinely these days for posterior tooth fillings. The values are also substantially higher than required by the ISO norm (bending strength > 80 MPa).

Composites have shown excellent survival rates in use as posterior tooth fillings in long-term clinical studies. Lempel et al. [17] tested 4 composite materials in a well-controlled patient population in a retrospective study. After 10 years this showed a 0.1 % annual failure rate for Filtek Z250 and Herculite XR. For the products Gradia direkt and Renew this annual failure rate was 0.8 %. After 22 years of observation Da Rosa Rodolpho et al. [26] reported annual failure rates of 1.5 % for P-50 APC and 2.2 % for Herculite XR. Pallesen and van Dijken [23] tested P10, P30 and Miradapt as posterior fillings in a prospective study and found after 30 years an annual failure rate of

1.1 %. These experiments showed that composite materials with a bending strength of at least 100 MPa [12] function well in clinical application.

The very high wear rate of the glass ionomer Fuji IX confirms the limitation of the indication of this material for posterior tooth fillings in deciduous teeth and non load-bearing posterior fillings in permanent teeth. The low wear rate of the smart composites tested in this study makes them suitable for load-bearing posterior fillings given the bending strength of > 100 MPa. The simple method of application seems to make them very well suited to use as an alternative to amalgam fillings. The somewhat greater wear of Cention N can be explained by the smaller size of the glass filler, as can be seen in the scratch pattern on the SEM images (Figure 4). The differences in resin chemistry could also be responsible [24].

The clear difference between the glass ionomer and the smart composite materials can also be seen both in the surfaces and the materials themselves and in the corresponding antagonists (Figures 3–5). The composite materials and their antagonists display clear scratch marks that can be explained by the fact that filler particles (glass) are released under load and these could have served as an abrasive medium at times. The surface of the antagonist that wore the glass ionomer cement and that was only slightly changed suggests that the glass used in the glass ionomer cement seems to be substantially softer than the glass in the composite materials.

The powder-liquid systems displayed air bubbles in the SEM images that were probably incorporated during mixing. It seems that the manual mixing of Cention N resulted in larger pores than the capsule mixing of the glass ionomer cement.

The SEM images of Fuji IX all displayed cracks (Figure 5) that must be classified as artefacts. It is known that glass ionomer cement displays severe cracks in the surface during drying.

Conclusion

The wear behavior of Cention N is in the same range for composites with the same chewing simulator. The wear rate was almost linear up to

400,000 load cycles. The wear of glass ionomer cement was 2.3 times greater than that of Cention N and 3.6 times greater than that of Activa.

From the point of view of wear behavior the positioning of Cention N as a filling material for posterior teeth is correct without limitations. Both tested composite materials have bending strengths above 100 MPa, which supports the above assessment. A capsulated material has somewhat better wear behavior because of its better and more homogeneous mixtures and smaller air bubbles and would therefore be desirable.

However, this data from one in-vitro experiment should be interpreted with caution and this should be validated with in-vivo studies!

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Conflicts of Interest:

Ivoclar Vivadent financed the study (contract ROULETARG50 dated 15.09.2016). The authors have no conflict of interest. The sponsor had no influence on the study design or the data collection and analysis. The decision to publish the study and the produce the manuscript were also taken independently of the sponsor.

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German dentists' management of non-cavitated proximal caries lesions: A qualitative interview study

Understanding German dentists' management of proximal caries

Background:

For managing non-cavitated proximal caries lesions, non- or micro-invasive strategies (NI/MI) are currently recommended over invasive (restorative) approaches. However, survey data indicate that dentists may not have adopted these strategies. This qualitative study aimed to identify barriers and facilitators for using NI/MI in Germany.

Methods:

A diverse sample of 12 dentists was recruited. Semi-structured interviews were conducted by telephone, using an interview schedule based on the Theoretical Domains Framework.

Results:

Limited financial reimbursement and an organizational framework centering around placing restorations, patients' lacking adherence to advice and oral hygiene (and associated high caries risk) as well as the fear of lesion progression (anticipated regret) were identified as relevant barriers for NI/MI. Facilitators were found to be working in a team where NI/MI is promoted, having knowledge of the disadvantages of restorations and the evidence supporting NI/MI, regularly attending ongoing professional development courses and professional satisfaction when doing "the right thing" for the patient.

Conclusions:

A number of aspects at individual, practice and healthcare level could be targeted to enhance dentists' uptake of NI/MI for managing non-cavitated proximal caries lesions.

Keywords:

attitudes; dental; decision-making; enamel caries; evidence-based practice; qualitative studies; theoretical domains framework

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Background

Dental caries is the most prevalent disease worldwide, burdening billions of people and generating substantial direct and indirect costs [16, 17]. In Germany, the caries experience in children has been decreasing, but remains high for adults and seniors [15]. The traditional approach towards managing caries lesions has been the removal of all this tissue and the placement of a restoration. This was grounded on an understanding of caries as an infectious disease. This understanding has been superseded by caries being seen as a bacterially-mediated, behavioral disease: Only when sufficient dietary carbohydrates are supplied, the physiologic dental biofilm is altered, with selection of cariogenic species, and eventually becomes highly cariogenic [18]. Thus, caries and also caries lesions can be controlled without removing hard tissue, especially for early caries lesions, where the surface is non-cavitated [29].

Such control can be performed using different strategies. Non-invasive strategies do not breach the surface of the tooth and include, for example, reducing the intake of cariogenic sugars (dietary control), avoiding biofilm maturation (oral hygiene control) and providing remineralizing agents like fluoride (remineralization control) [23, 32]. Micro-invasive strategies remove a few micrometers of tooth tissue during an acid-conditioning step; they involve, for example, sealing or infiltrating lesions using resins. The installed diffusion barrier (on or within the lesion) impedes acid diffusion into the tooth tissues and mineral loss from it, thereby arresting the lesion [29]. Both non- and micro-invasive techniques (NI/MI) are successful in controlling caries lesions [8, 32] and are currently recommended over invasive (restorative) treatments when managing early, non-cavitated lesions [29]. This recommendation is based on the understanding that (1) during invasive (restorative) treatments, significant amounts of sound or remineralizable tissues are lost during preparation; this is the more true for proximal surfaces, where the marginal ridge will usually be intact if an

early non-cavitated lesion is present proximally, and (2) the fact that restorations have limited lifespans and need to be replaced at some point, leading to more tooth tissue loss, repeated treatment costs and, in some instances, tooth loss [1, 31, 33].

International data indicate that not all dentists have adopted NI/MI [14]. To change the underlying attitude and the resulting behavior of dentists, it is necessary to understand factors driving these attitudes and behaviors; that is, the underlying barriers and enablers. To gain such understanding, qualitative studies are needed; these should, if possible, employ a theoretical framework to understand the behavior processes that could be tackled later on by interventions [29]. In the present study, we used the Theoretical Domains Framework (TDF), which is a common framework in implementation research [12, 20, 35], but has only sparsely been used in dentistry so far [10, 12, 30]. The aim of this study was to identify barriers and enablers for dentists managing non-cavitated proximal caries lesions using NI/MI. Interviews were conducted in 3 countries; the US, New Zealand and Germany. Results of this cross-country analysis have been published elsewhere [28]. Here, we report in-depth on the findings from Germany.

Method

This study used semi-structured interviews (see appendix for the interview schedule, p. 41-42). The TDF was utilized to develop the interview schedule and analyze the data. The reporting of this study follows the COREQ (Consolidated criteria for Reporting Qualitative research) checklist [36]. Ethical approval was obtained (Charité – Universitätsmedizin Berlin EA2/137/14).

The research team involved an experienced psychologist and qualitative researcher (SB), who focused on the design of the interview schedule and the analysis, as well as clinicians, cariologists and epidemiologists (FS, LAS, LFP, MF, WMT). The interviews were conducted by one independent interviewer in 2016. Pilot interviews were conducted prior to full data collection in order to train

the interviewer, and to adapt the interview schedule where necessary. A dental researcher with previous experience in qualitative research (LAS) coded the interviews; 10 % were additionally and independently coded by SB to check if different coders would lead to relevant differences in findings; this was not the case. The interviewees did not have any relationship to the interviewers.

A sample size calculation, as required for quantitative studies, is usually not performed in qualitative research [9]. However, we aimed to collect sufficiently broad data to allow some generalization as to the identified barriers and facilitators. Hence, dentists of different gender, age, and practice location and type were sampled from registration lists or by convenience, as detailed in the results. Non-responders were not separately analyzed and reasons for non-response not followed up.

As described, the interview schedule was designed based on the TDF, with some modifications to allow ease of administration. A mix of open- and closed interview questions were used. The interviews were conducted by telephone and audio-recorded and lasted between approximately 20 minutes and one hour.

The data were analyzed by LS by grouping the responses under the TDF domains and constructs, this was double-checked by SB. A simple count of the excerpts grouped under the different constructs was taken to provide an overall picture of the pervasiveness of a domain (these are shown and explained in Table 1).

Results

The 12 dentists (7 female, 5 male) had an average of 17.8 years of clinical practice (ranging from 10 months to 41 years). Eight participants worked in urban practices; 4 in rural practices, with diversity as to the practice model (single-practitioner or group practice). All worked predominantly within the statutory health insurance, as would be expected in Germany.

When analyzing the interview data, some domains were more common than others with regards to the number of excerpts grouped within them (Figure 1).

Domain	Construct	Definition
Knowledge	Knowledge	Knowledge of a condition or scientific rationale
	Procedural knowledge	Knowing how to do something
	Knowledge of task environment	Knowledge of the social and material context in which a task is undertaken
Skills	Skills	An ability or proficiency acquired through practice
	Skills development	The gradual acquisition or advancement through progressive stages of an ability or proficiency acquired through training and practice
	Competence	One's repertoire of skills, and ability especially as it is applied to a task or set of tasks
	Ability	Competence or capacity to perform a physical or mental act. Ability may be either learned or unlearned
	Interpersonal skills	An aptitude enabling a person to carry on effective relationships with others, such as ability to cooperate, to assume appropriate relationships with others or to exhibit adequate flexibility
	Practice	Repetition of an act, behaviour or series of activities, often to improve performance or acquire a skill
	Social influences	Social pressure
	Social norms	Socially determined consensual standards that indicate what behaviours are considered typical in a given context and what behaviours are considered proper in the context
	Group conformity	The act of consciously maintaining a certain degree of similarity to those in your general social circle
	Social comparisons	The process by which people evaluate their attitudes, abilities, or performance relative to others
	Group norms	Any behaviour, belief, attitude or emotion reaction held to be correct by any given group in society
	Social support	The apperception or provision of assistance or comfort to others, typically in order to help them to cope with a variety of biological, psychological or social stressors. Support may arise from interpersonal relationships in an individual's social network, involving friends, neighbours, religious institutions, colleagues, caregivers or support groups
	Power	The capacity to influence others, even when they try to resist this influence
	Intergroup conflict	Disagreement or confrontation between two or more groups and their members. This may involve physical violence, interpersonal discord, or psychological tension
	Alienation	Estrangement from one's social group; a deep seated sense of dissatisfaction with one's personal experiences that can be a source of lack of trust in one's social or physical environment or in oneself; the feeling of separation between one's thoughts and feelings

	Group identity	The set of behaviour or personal characteristics by which an individual is recognizable (and portrays) as a member of a group
	Modelling	In developmental psychology, the process by which one or more individuals or other entities serve as examples (models) that a child will copy
Social/ professional role and identity	Professional identity	The characteristics by which an individual is recognised relating to, or connected with, or benefitting, a particular profession
	Professional role	The behaviour considered appropriate for a particular kind of work or social position
	Social identity	The set of behaviours or personal characteristics by which an individual is recognizable [and portrays] as a member of a social group, relating to, or connected with or benefitting a particular profession
	Identity	An individual's sense of self defined by a) a set of physical and psychological characteristics that is not wholly shared with any other person and b) a range of social and interpersonal affiliations (e.g. social roles)
	Professional boundaries	The bounds or limits relating to, or connected with, a particular profession or calling
	Professional confidence	An individual's beliefs in his or her repertoire of skills, and ability as it is applied to tasks or set of tasks
	Group identity	The set of behaviours or personal characteristics by which an individual is recognisable [and portrays] as a member of a group
	Leadership	The process involved in leading others, including organising directing, coordinating and motivating their efforts toward achievement of certain group or organisational goals
Beliefs about consequences	Beliefs	The thing believed, the proposition or set of propositions held true
	Outcome expectancies	Cognitive, emotional, behavioural, and affective outcomes that are assumed to be associated with future or intended behaviours. These assumed outcomes can either promote or inhibit future behaviour
	Characteristics of outcome expectancies	Characteristics of the cognitive, emotional, behavioural outcomes that individuals believe are associated with future or intended behaviours and that are either believed to promote or inhibit these behaviours. These include whether they are sanctions/rewards, proximal/distal, valued/not valued, probable/improbable, salient/not salient, perceived risks or threats
Reinforcement	Anticipated regret	A sense of the negative consequences of a decision that influences the choice made; for example an individual may decide not to make an investment because of the feelings associated with an imagined loss
	Consequence	An outcome of behaviour in a given situation
	Rewards	Return or recompense, made to or received by a person contingent on some purpose
	Incentives	An external stimulus, such as a condition or object that enhances or serves as a motive for behaviour

	Punishment	The process in which a relationship between a response and some stimulus or circumstance results in the response becoming less probable; a painful, unwanted or undesired event or circumstance imposed on a wrong doer
	Consequents	An outcome of behaviour in a given situation
	Reinforcement	A process in which the frequency of a response is increased by a dependent relationship or contingency with a stimulus
	Contingencies	A conditional probabilistic relation between two events. Contingencies may be arranged via dependencies or they emerge by accident
	Sanctions	A punishment or other coercive measure, usually administered by a recognised authority, that is used to penalise and deter inappropriate or unauthorised actions
Intentions	Stability of intentions	Ability of one's resolve to remain in spite of disturbing influences
	Stages of change model	A model that proposes that behaviour change is accomplished through five specific stages: pre-contemplation, contemplation, preparation, action and maintenance
	Trans-theoretical model and stages of change	A five-stage theory to explain changes in people's health behaviour. It suggests that change takes time, that different interventions are effective at different stages, and that there are multiple outcomes occurring across different stages
Goals	Goals (distal/proximal)	Desired state of affairs of a person or system; these may be closer (proximal) or further away (distal)
	Goal priority	Order of importance or urgency of end states toward which one is striving
	Goal/target setting	A process that establishes specific time based behaviour targets that are measurable, achievable and realistic
	Goals (autonomous/controlled)	The end state towards which one is striving: the purpose of an activity or endeavour. It can be observed by observing that a person ceases or changes its behaviour upon attaining this state; proficiency in a task to be achieved within a set period of time
	Action planning	The action or process of forming a plan regarding a thing to be done or a deed
	Implementation intention	The plan that creates in advance of when, where and how one will enact a behaviour
Environmental context and resources	Environmental stressors	External factors in the environment that cause stress
	Resources material resources	Commodities and human resources used in enacting behaviour
	Organisational culture/ climate	A distinctive pattern of thought and behaviour shared by members of the same organisation and reflected in their language, values, attitudes, beliefs and customs
	Salient events/critical incidents	Occurrences that one judges to be distinctive, prominent or otherwise significant

	Person – environment interaction	Interplay between an individual and their surroundings
	Barriers and facilitators	In psychological contexts barriers/facilitators are mental, emotional or behavioural limitations/strengths in individuals or groups
Behaviour regulation	Self-monitoring	A method used in behaviour management in which individuals keep a record of their behaviour, especially in connection with efforts to change or regulate the self; a personality trait reflecting an ability to modify one's behaviour in response to a situation
	Breaking habit	To discontinue a behaviour or sequence of behaviours that is automatically activated by relevant situational cues
	Action planning	The action or forming of a plan regarding a thing to be done or a deed

Table 1 Domains of the Theoretical Domains Framework (TDF) (mod. to [10])

Environmental context and resources

(TDF definition: Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence, and adaptive behavior)

The overwhelming majority of participants mentioned that the lack of financial reimbursement for NI/MI under the statutory health insurance was a barrier for implementing NI/MI in their practice. Moreover, 3 participants stated that they were pressured by their bosses to make money from providing restorations instead of NI/MI. Some explained that other dentists performed restorations because they wanted their practice to be profitable, while they themselves did not do that. Consequently, an organizational culture where restorations were favored over NI/MI, due to more favorable reimbursement rates, was a barrier. These comments are typified by the following:

G2: Well most colleagues think that invasive measures generate more income than non-invasive measures. That's why most (colleagues) wouldn't consider non-invasive treatments.

G3: In short, our boss wants to make money (laughs). Non-invasive procedures are desirable for the patient and of course are very good, but in reality [one] has to place some fillings.

G4: [NI and MI methods] ... requires more work that is not paid. Hence it isn't really worth it for me, maybe for

the patient but sadly not for me. It just isn't paid well.

G7: Well it's a bit iffy financially. It is dependent on the area one is in.

At the same time, G10 said being her/his own boss meant that s/he could choose to implement NI/MI:

G10: Well firstly of course, that I am under no pressure or obligation from my employer to practice a certain way. Yes. And that I have access to all the resources and I can pretty much use the treatment approach/concept I want.

Another identified barrier was a lack of patients' oral hygiene. For instance, when G4 asked whether there had been instances when s/he had chosen to place restorations rather than using NI/MI, she answered:

G4: That has probably happened to a patient with lots of decay and poor oral hygiene. And maybe [also had] a certain pain sensibility.

Social influences

(TDF definition: Those interpersonal processes that can cause individuals to change their thoughts, feelings and behaviors)

Practicing or socializing with colleagues who shared similar philosophies was another identified enabler for the implementation of NI/MI. For instance, G1 explained:

G1: When I do see [colleagues] then I do notice an amazing knowledge in that area. There are a lot of colleagues that are pretty careful.

On the other hand, comparison with colleagues but also fear of being

judged negatively were factors determining behavior:

G2: I see colleagues that have got themselves financially into a difficult situation and seal everything that is possible and change fillings that don't even need to be changed. Black sheep are here and there and everywhere. But generally I believe the greater part of my colleagues think like I.

G7: When the patient goes to a different practice, because this one is closed, then the colleague says: "Oh what is this, look, there is more decay and what not." And that is wrong and terrible. One would have to be able to understand that dentistry isn't all about a burr and filling materials, but also how you would act in respect to the patient. And one does not drill a hole into everything. However, this understanding is still lacking.

Patients who had a good oral hygiene and were judged as being likely to cooperate were more likely to be selected for NI/MI. Consequently, patient factors such as the ability to comply was an enabler:

G2: I think [treatment] would be depending on the overall oral hygiene of the patient. If the patient has great oral hygiene, apart from, for example, 1–2 interproximal lesions that extend up to the inner enamel part ... if he has otherwise a great oral hygiene, then I would not consider invasive treatments. We would observe it. However, the patient will need to cooperate.

Knowledge

(TDF definition: An awareness of the existence of something)

An extensive knowledge of NI/MI methods and how to perform them was an enabler. For instance, G7 explained:

G7: Well I would take a holistic approach. That's what we normally do here. The patient comes in for an appointment, visual report, what needs doing, followed by periodontal screening index, [and] then we talk about his/her oral hygiene. I ask him/her what he/she uses to maintain his/her oral hygiene. Most of the time the answer is, just the toothbrush. Then I would draw his/her attention to dental floss and the interdental brushes. Then there is of course the diagnostic analysis based on the X-rays and from all this I come up with a diagnostic analysis and, sadly I, as a practitioner, have to say that only very few are able to optimize their [dental] situation to largely avoid the use of a drill ... However, then the requirement also is to regularly have the teeth professionally cleaned and have regular checkups. If I then notice that it is working I lengthen the appointment intervals to a year, under the condition that the patient has his teeth professionally cleaned twice a year.

Some participants also reported that they knew particular NI/MI methods worked because this is what they were taught during their training. Nevertheless, when the participants were asked if they based their practice on scientific research, 4 participants stated that they had not participated in any on-going professional or knowledge development since they graduated from dental school. Not practicing with up-to-date knowledge was a barrier to the implementation of NI/MI:

G1: I really can't tell you. I haven't looked at any studies for 20 years.

G2: I believe so because this is what I was told at university.

G10: I can't think of the name of the study, but this is what I had learnt back in the day.

G12: Can I answer that with I do think it is scientifically proven ... during my studies [is where I learned it

and] everything you learn there you apply in your practice.

Having knowledge of specific patient (risk) factors, such as age, impacted on decision-making:

G11: Well to be honest. I am a bit hesitant with elderly patients, [but] with younger ones I tend to check their general oral hygiene first and then I would check the papillary bleeding, well the papillary bleeding index. And if they have heaps of plaque everywhere, then ... I will ask the patient to have a prophylaxis appointment. And I would decide afterwards and again will ask for them to come more frequently to see whether or not the situation has improved and then I would be more conservative and wouldn't drill ... [I am a bit hesitant with elderly people] because it takes longer ... I speak from experience.

Beliefs about consequences

(TDF definition: Acceptance of the truth, reality or validity about an ability, talent or facility that a person can put to constructive use)

Almost all of the participants stated that restorations served to weaken the tooth structure, and began a cycle of continually needing to replace the restoration. Consequently, a belief that restorations might cause damage to healthy tooth structure served as an enabler:

G2: The advantage is the preservation of the tooth structure. We will preserve the tooth without a filling because even the best filling isn't the greatest compared to an untouched enamel layer.

G6: I would say it is always possible for people who look after their teeth well. One can definitely remineralize these things.

G9: It's encouraging when you notice that there hasn't been any change to the worse after 1, 2, 3 years.

At the same time, some participants were hesitant to implement NI/MI with some patients who were unlikely to return for regular follow-up appointments, fearing lesion progression. The sense of anticipated regret about not restoring earlier and protecting patients from cavitation, pain, or the need for an extraction was a barrier:

G9: If I know that I can't motivate the patient to have better oral hygiene, then I know that interproximal decay in its early stages can progress to quite deep decay within a quarter of a year. Often that is too late. And often the patients don't come back. That's why I rather treat an early decay in the dentine right away. Those patients tend to only come when they are in pain. I am less invasive with people that come regularly to the recalls.

G1: The disadvantage is that if one cannot see the patient for a follow up then it can turn to custard, rather quickly and 2 years down the track the next dentist would say: "This dentist had used micro-invasive treatments and now the tooth needs to be taken out, because no one removed the decay". That is why I would be careful.

G3: Well the disadvantages are that one would risk the decay to go deeper and that the patient, the decay would advance further resulting in the inflammation of the pulp and in extreme cases the need for a root canal.

Reinforcement

(TDF definition: Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus)

The personal and/or professional rewards that participants experienced as a result of the implementation of NI/MI methods was an enabler:

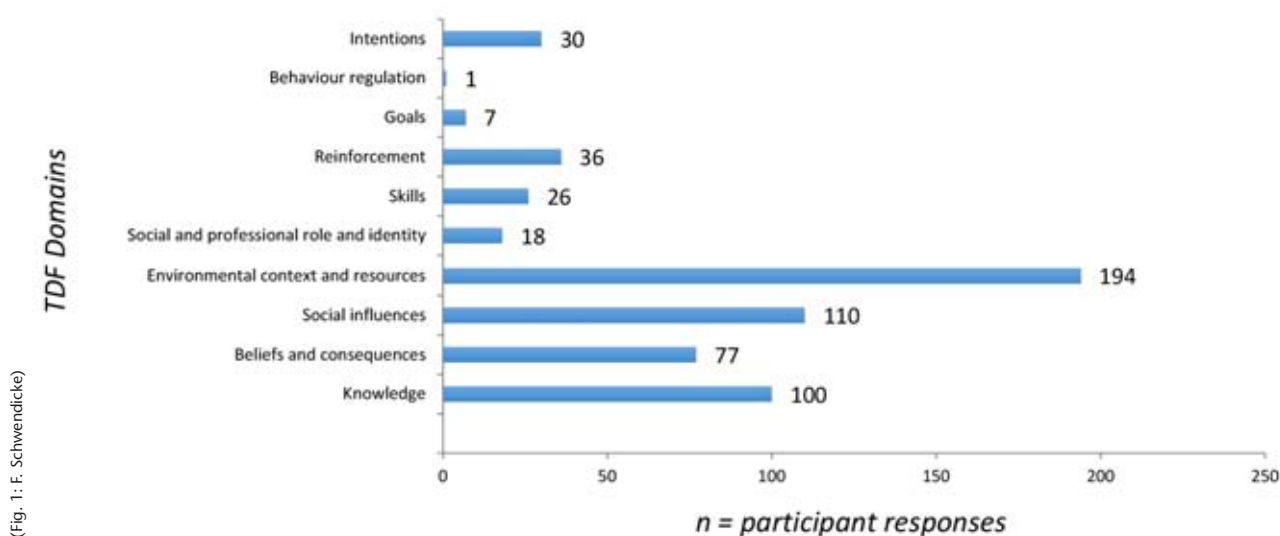
G1: Certainly for the patient, preserving tooth enamel. I tend to have a better feeling with it and sleep better at night.

G9: In the end it is also good for the dentist-patient-relationship when the patient knows that one is doing everything they can to preserve their teeth with the least invasive approach.

G8: Respectively this would delay or eliminate the point at which one would really need ... to use invasive measures, which ultimately results in the delay of losing that tooth.

Intentions

(TDF definition: A conscious decision to perform a behavior or a resolve to act in a particular way)



(Fig. 1: F. Schwendicke)

Figure 1 Total number of participant responses grouped per the domains of the TDF (mod. to [10])

The desire to implement NI/MI, whenever possible now and in the future was a further facilitator:

G2: I always try to, when one does have a filling then it will need to be renewed at some point, and if one is somehow able to keep the surface area intact and to allow it to remineralize, then it is better in the long term.

G10: I would take the same approach [if the decay is extending into the enamel-dentine-junction] ... In general, we can say that I would be conservative, even when it is already extending up to the enamel-dentine-junction. We do have a very good prophylaxis program at the practice. Firstly, I would inform the patients about it all and would try to find out whether they are interested in maintaining the situation or improving it. I tend to be conservative.

G11: I would take non-invasive approaches in the same way, whether the compliance is good or not.

Skills

(TDF definition: An ability or proficiency acquired through practice)

Greater clinical competence in and knowledge of NI/MI, as a result of years of practice experience or education, was another enabler. Moreover, specific knowledge of tooth morphology and how this changes over time was mentioned by G3. This comment was grouped under the

skills domain because it highlights his/her diagnostic skills and the ability to cater treatment methods to patients' needs.

G5: Well I have been working as a dentist for ages and am increasingly treating my patient using that concept. Well not in the beginning, seen as I had learnt about this in a very different way, however, due to the regular courses I attend and due to my personal experience I have learnt [a lot] and observe my patients and it was worth it ... I am doing the same with my patients and over the years my assumption had been proven correct, that ... if one uses fluoridation treatment and if one has a good compliance and regularly attends prophylaxis appointments, then one can prevent micro-lesions from demineralization any further.

G3: Yes, there are definitely differences. Regarding the youth, for example, it's very possible to educate them. One would probably be able to manage the oral hygiene habits. However, if the patient is 70 years of age, then if you tell him to use floss, after 50 years of never doing so then he would most likely not do it. There are definitely differences. One would also have to think about the technical aspect, for youth the pulp is bigger, meaning it can become hypersensitiv[e] if one drills too extensively.

Social and professional role and identity

(TDF definition: A coherent set of behaviors and displayed personal qualities of an individual in a social or work setting)

The comments grouped under social and professional role and identity generally centered on the participants' role as dentists in offering patients advice on their oral health care and treatment. Consequently, the participants' role as a dental expert in helping to shape patients' oral hygiene practices was a facilitator. One participant also mentioned his/her role as a practice leader to implement NI/MI.

Goals and behavior regulation

(TDF definition "goals": Anything aimed at managing or changing objectively observed or measured actions; TDF definition "behavior regulation": Anything aimed at managing or changing objectively observed or measured actions)

Few comments were grouped here, and most had already been categorized under other domains. The goal of implementing NI/MI was a facilitator:

G2: Well the biggest benefit is to the patient directly to avoid having restorative work done on their teeth and preserving the natural tooth structure ... maintaining ... existing tooth structure should be of paramount priority.

Only one comment was grouped under behavior regulation. This comment highlighted how patient consultation and decisions by the patient determined the course of action:

G4: I would definitely prefer a minimal invasive filling, however, in individual cases I may leave the decision up to the patient, yes ... if the patient is willing to wait then I would also wait.

Discussion

For decades, dental caries has been seen as an infectious disease, and dentists had been trained accordingly to remove all carious tissue from a tooth to “cure” the disease. Numerous studies have shown that a large part, in some countries even the majority, of dentists continue to follow that path, which involves significant overtreatment and induces unnecessary tooth tissue loss and costs [14]. The present study aimed to understand barriers and facilitators determining dentists' behavior towards non-cavitated proximal lesions. Based on such understanding, we will develop interventions to change this behavior and increase the uptake of evidence-based management of early lesions. We found a number of factors that acted as barriers or facilitators. These can be structured according to the level to which potential interventions can be directed; that is, the individual, practice and healthcare levels.

On an individual level, the dentists' knowledge, their professional role, but also the individual patient and his/her adherence and risk profile have been found to significantly impact on the management of non-cavitated proximal lesions. Dentists basing their decision on outdated knowledge as to the pathogenesis of caries – and those not attending continuous professional development in the field of cariology – seem to adhere to “traditional” management options more frequently. There are a number of ways for tackling this. First, undergraduate education should follow current standards in cariology, as outlined for example in the European Core Curriculum for Cariology [26]. This might not be the case for all universities at present [27]. Second, con-

tinuous professional development should not be only mandatory in fields like first aid and radiology, as is currently the case, but also in cariology (with caries being the most frequently found disease in dentistry).

Dentists also decide their interventions based on patients' characteristics, like caries risk. High-risk patients are managed more invasively, as has been found in numerous other studies [14]. We showed that such behavior is grounded in anticipated regret, assuming that the efficacy of NI/MI, for example, is lower in such high-risk individuals and the risk of needing to place a (then larger) restoration soon after. However, as demonstrated by abundant evidence, the lifetime of restorations is lower in high-risk patients [5–7, 22], and risk-group adjusted analyses showed that especially in these patients, efforts should be undertaken to holistically manage them (and not restoratively mask their symptoms) [34]. Thus, especially high-risk patients should be provided with the needed non-invasive care to modify their risk (patient-level interventions such as dietary control or biofilm control can be used, for example). In addition, and given that these patients usually also come with a less favourable utilization pattern [25], adherence-independent therapies should be used as well (dentists seem to perceive restorations as such therapy). Sealing and infiltration may be such therapies.

On the practice level, having a team focused on a holistic and multi-professional management of oral health seems beneficial. It is likely that being able to interact with other oral health care professionals with differing undergraduate and continuous professional education, regulation, culture etc. may provide new perspectives on and confidence in NI/MI, as well as on the changing dentists professional role and view of themselves. The current trend to practices with more than one practitioner, relying on a team of care providers, may be beneficial in that sense [2, 11].

Finally, on a system's level, the remuneration model for dental care should be re-thought. While there is an ongoing debate over the mode of

dental remuneration (fee-per-item versus capitation) [24], it is clear that regulators should incentivize preventing disease and avoiding invasive re-interventions and tooth loss. The current focus on restorative and/or prosthetic dentistry is unlikely to be suitable to facilitate NI/MI [3, 4, 37].

In conclusion, and within the limitations of this qualitative study, a range of factors on individual, practice and healthcare level were identified as barriers and facilitators. These could be targeted to enhance dentists' uptake of NI/MI for managing non-cavitated proximal caries lesions [19, 21].

Conflicts of Interest:

The authors declare that there is no conflict of interest as defined by the guidelines of the International Committee of Medical Journal Editors.

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(Photo: private)

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Appendix 1: Interview Guide

Welcome and establishment of ground rules

Participants will be thanked for agreeing to take part in the study and sparing time for the interview. They will be reassured there are no right or wrong answers. It will be explained that the use of a tape recorder by the researcher is to help them remember what is said without them having to take notes. Participants will be assured that the researcher will treat the information given as confidential.

The interviewer will then inform the participant about the focus of the study which is on gaining more information about the barriers and enablers for dentists in using non- or micro-invasive measures for managing proximal lesions confined to the outer half of enamel and at the enamel-dentine junction. Non- or micro-invasive measures include applying remineralizing agents (fluoride varnish, CPP-ACP etc.), proximal sealing or caries infiltration, flossing and/or demonstrating oral hygiene maintenance.

Thinking generally in relation to these recommendations, please explore the following. There are no right or wrong answers!

The interviewer will be open to the participants' narratives and flexible in switching between the interview topics. The following is therefore a guide based on the domains from the revised theoretical domains framework. Although all domains need to be covered, the interview can be flexible in their approach to the interview structure.

Background: To begin, participants will be asked:

- Job title, years of experience since qualification
- Brief synopsis of place of work (solo/group practice; private-insurance/public mix; rural/urban; number of patients registered; number of dentists/hygienists in practice; remuneration system e.g. fee-for-service, capitation)

Current Practice/Skills:

- Ask the participant to describe the routine care they'd provide to manage proximal lesions confined to the (1) outer half of enamel and (2) at the enamel-dentine junction in the permanent teeth of an adolescent or adult.

Prompt: What were the circumstances? Why was the decision made? Is this situation common?

1. Knowledge and Skills

Are you aware of any guidelines in relation to non- or micro-invasive measures for the management of proximal lesions confined to the outer half of enamel (or at the enamel-dentine junction)?

- If yes, what is your understanding of the recommendation for management of permanent teeth?
- How strong do you think the evidence is for the recommendations? Is there anything that would give you more confidence in the guidance?
- Does the guidance help you give non- or micro-invasive management to patients? Why or why not?

2. Intentions/ Social/Professional Role and Identity

Do you view it as your responsibility to ensure non- or micro-invasive management is carried out in every situation possible? Is it a priority for you in your professional role?

Is management with non- or micro-invasive measures rather than restoration something that you intend to do wherever possible in the future? If yes, explore whether this maps to current practice. If no, explore why their intentions aren't in line with guidelines.

3. Goals/Behavioural Regulation

Are non- or micro-invasive measures part of a routine you have for managing all patients with proximal lesions confined to the outer half of enamel (or at the enamel-dentine junction)?

Are there procedures or ways of working that would make it easier using non- or micro-invasive measures as a 'first step' rather than restoring proximal lesions confined to the outer half of enamel (or at the enamel-dentine junction) (prompts: training needs, courses; guidelines)?

4. Beliefs about Consequences/Reinforcement

What are the benefits/advantages of using non- or micro-invasive measures as a 'first step' instead of restoring lesions at the (1) outer half of enamel and (2) enamel-dentine junction lesions? (prompt: To you? Your patients? Time? Staff resources? Financial incentives/disincentives? Prevent caries?)

Are there any disadvantages/downsides of using non- or micro-invasive measures instead of restoring proximal lesions confined to the outer half of enamel (or at the enamel-dentine junction)?

Do you think the benefits of non- or micro-invasive measures outweigh the costs?

5. Environmental Context and Resources

To what extent do factors within your practice influence your ability to use non- or micro-invasive measures?

- physical resources (e.g. access to equipment; more staff/space)
- finances (e.g. time available; remuneration)
- colleague's expectations, beliefs, attitudes etc.

(prompt: which factors act as barriers and which as facilitators?)

What factors related to your patients may influence your decision?

- co-operation, expectations, beliefs, attendance record, oral hygiene etc.

(prompt: which factors act as barriers and which as facilitators?)

What about factors outside your practice influence your decision whether you use non- or micro-invasive measures?

(e.g. dental association, health policy, performance targets)

(prompt: which factors act as barriers and which as facilitators?)

6. Social Influences

Is non- or micro-invasive management something that your patients want?

Is managing proximal lesions confined to the (1) outer half of enamel and (2) enamel-dentine junction by non- or micro-invasive actively supported by colleagues in your practice?

In what way does the wider dental profession influence your decision about preventive management?

7. Other

Is there anything else about the non- or micro-invasive management of caries that you would like to mention that we haven't already covered?

Is there anything that you have found the most helpful in assisting you in adopting non- or micro-invasive caries management? (if haven't adopted – what would be the most helpful in assisting you?)

Who would you trust/consider to be an expert/leader in the non- or micro-invasive management of caries?

Closing

Participants will be asked if they would like to add any further information and thanked for the discussion. Participants will be de-briefed on the next steps of the research process. To include giving participants product voucher and recommendations on non-invasive management of lesions.

Till Dammaschke, Kerstin Galler, Gabriel Krastl (in alphabetical order)

Current recommendations for vital pulp treatment

Scientific Communication

Status: 01.01.2019



Leading professional association:

German Society of Endodontology and Dental Traumatology

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Introduction

1.1. Definition and objectives of vital pulp treatment

In the last few years, clinicians and scientists in the dental field have become more aware of the importance of preserving pulp vitality. While excavating deep caries lesions (caries profunda), special attention should be given to the remaining dentin layer covering the pulp. While it has been taught over the years to excavate caries until reaching healthy, hard dentin (cri dentinaire), meanwhile it appears justifiable to selectively leave infected dentin close to the pulp in order to avoid exposure of the pulp tissue [19]. The traditional methods aiming to preserve the pulp, such as indirect or direct pulp capping and pulpotomies are also addressed. The standardized classification of reversible and irreversible pulpitis and the respective associated therapy decision of pulp preservation versus vital extirpation is being questioned and it appears that the indications of pulpotomies are expanding. The present scientific work highlights the current state of knowledge on vital pulp treatment strategies and provides recommendations on how to proceed clinically. The collective term maintaining vitality sums up conservative treatments that protect exposed dentin and pulp areas from external stimuli, which prevents the progression of microorganisms (and components of filling materials). After a pulp capping material is applied, a bacteria-proof restoration follows. Key factors are the pulp status at the time of the procedure and the extent of the lesion or degree of dentin infection. Vital pulp treatment methods include the treatment of deep caries lesions (indirect pulp capping), direct pulp capping, partial and full pulpotomy.

The objective of all vital pulp treatment strategies is to create a state that enables the formation of a hard tissue barrier and the recovery of tissue, preserving the functionality and therefore ensuring that a vital tooth remains in the oral cavity long-term.

1.2. Function and loss of function of pulp tissue

The main functions of the dental pulp include dentin formation during tooth development and life span of the tooth, signal transmission through proprioceptors and pain receptors, immune function towards invading bacteria and their metabolites, the formation of tertiary dentin as a defense mechanism towards external stimuli, and in the particular case of juvenile teeth, the completion of root formation.

If vital pulp therapies are not indicated, root canal treatment should be performed, where remaining pulp tissue is ideally completely removed, the root canals are enlarged, disinfected and finally obturated with a root canal filling material. Although success rates of over 90 % after 5 years could be achieved following a thorough approach after vital extirpation [42], this procedure goes along with the complete loss of function of pulp tissue and can carry disadvantages. The proprioceptive safeguard mechanism is partially lost. It has been described that a root canal treated tooth allows a occlusal load 2.5 times higher than a vital tooth before a proprioceptive reaction occurs [89]. Even though there is no evidence of this resulting in a higher risk of fracture, this may be the case. Furthermore, changes in root canal geometry (weakening of the root canal wall dentin through preparation), that are inevitable during root canal treatment, can lead to increased incidence of fractures [45, 67]. Additional problems that can possibly occur during treatment are tooth discolorations [62] and higher susceptibility to caries due to increased plaque formation and an altered microflora [77], or due to missing immune response of the pulp-dentin-complex and the lack of pain perception as a warning system. A root canal procedure can present itself as more complex than initially thought. Vital pulp therapies are conservative and cost effective measures [57, 98].

2. Indication for vital pulp treatment

The invasion of microorganisms and their metabolites initiates a stimulus

that results in the development of an inflammatory reaction of the pulp. The immune response is mediated through cell receptors on odontoblasts, dendritic cells and pulp fibroblasts. Initially, this results in hyperemia and the developing inflammatory reaction is characterized by reduction in cell count, flattening of the odontoblasts as well as the immigration of lymphocytes and plasma cells [92]. This correlates clinically with the development of a reversible pulpitis, where it is assumed that the healing of the tissue could be enabled by therapeutic intervention. There are bacteria detectable in the pulp cavity following persisting stimulus, which results in micro abscesses and tissue necrosis that are lined with polymorphonuclear neutrophil granulocytes and inflammatory infiltrates in the peripheral region [92]. This stage is referred to as irreversible pulpitis.

Reversible pulpitis is characterized by a positive sensibility test and pain linked to a stimulus.

Irreversible pulpitis is diagnosed by (increased) positive sensibility, radiating pain that outlasts the stimulus or constant pain, pain after heat and possibly the patient's insufficient localizability of the tooth causing the pain.

Irreversible pulpitis can also progress asymptotically [1]. Vital pulp treatment is indicated only when the clinical diagnosis of a reversible pulpitis is made. According to current scientific opinion, in case of an irreversible pulpitis, a healing of the tissue cannot be predictably achieved after removing the triggering stimulus. In this case, the diagnosis "irreversible pulpitis" requires the initiation of root canal treatment. Although there is some evidence that the histological observations described above correlate with the clinical diagnosis [92], it should be mentioned that the clinical classification of the symptoms yields little information about the regenerative capacity of the tissue. It solely eases decision-making of the practitioner in terms of therapeutic approach because a schematic approach is possible. The diagnosis and therapy regimen regarding the state

of the pulp and the resulting therapy are increasingly questioned. Because of this, the indication for a pulpotomy treatment of irreversible pulpitis is currently in flux and is investigated in clinical studies. According to current state of knowledge, measures maintaining vitality can only be conducted on teeth that do not exhibit a pronounced pain symptomatology (reversible pulpitis). Vital pulp treatment can not and should not be carried out when the tooth shows no reaction to a sensitivity test (here the pulp status must be verified after exposure of the pulp chamber), if the tooth is tender to percussion or occlusal load, exhibits spontaneous or persistent pain, as well as radiographic signs of a periapical osteolysis.

Further exclusion criteria after exposure of the pulp chamber include bleeding that cannot be stopped, a leakage of serous or purulent exudates, or necrotic tissue that is no longer supplied with blood. Teeth should be excluded if bacteria-proof sealing cannot be assured due to limited restorability. To avoid an infection of exposed pulp tissue during or after pulp capping, further conditions must be met. This includes the usage of sterile instruments, using rubber dam, full caries excavation as well as the possibility of immediate and definite bacteria-proof seal. If these conditions are not met unequivocally, root canal treatment (or extraction) is preferred.

Favorable conditions for maintaining vitality are given in a juvenile pulp without damage [109]. With increasing age, a reduced regenerative capacity is expected due to changes in terms of a reduced cell number and increased content of fibrous tissue [48, 80]. Nevertheless, the patient age plays a subordinate role with regard to treatment success [6, 30, 33, 37, 44, 59, 65, 70, 75, 107]. The same applies to factors such as the tooth position, size or location of pulp exposure [35].

In general, it must be noted that success rates of vital pulp treatment described in the literature vary significantly, especially for direct pulp capping after carious exposure. Prior

clinical setbacks (within days or weeks) are multifactorial, but certainly correlate with improper diagnosis of the state of the pulp. This can result in underestimating the level of inflammation of the pulp, from which irreversible pulpitis and pulp necrosis can develop that can lead to postoperative pain.

3. Indirect pulp capping

In the German dental literature, indirect pulp capping refers to the treatment of a thin, caries-free layer of dentine close to the pulp [96]. Because this situation generally arises when a deep caries is excavated, indirect pulp capping is also referred to as treatment of profound caries. In English language literature the term "indirect pulp capping" is defined differently; it refers to the permanent capping of a thin layer of affected or infected dentin, where complete excavation during a second appointment is omitted [9, 40]. Since only a minimal dentin layer remains above the pulp tissue, there is a risk of irreversible inflammation of the pulp through the dentinal tubules: on one hand, this can occur through microorganisms remaining in or having penetrated the tissue, or through cytotoxic components of filling materials that diffuse through the remaining dentin. The capping material is expected to disinfect dentin close to the pulp, seal the pulp tissue and stimulate the formation of tertiary dentin [91]. This form of tertiary dentin is also referred to as reactionary dentin, which by definition is formed by surviving postmitotic primary odontoblasts [101]. Therefore, indirect pulp capping protects the vital pulp, particularly after caries excavation. In the case of a reversible pulpitis, indirect pulp capping should create conditions for pulp healing. Despite comprehensive reasons that favor a separate treatment of dentin close to the pulp in the sense of direct pulp capping, it has to be noted that there is no evidence in favor of this therapy from clinical studies [19].

An indirect pulp capping should be performed under controlled isolation using rubber dam. To avoid cross-contamination, it is recom-

mended to disinfect the clinical crown before excavation using sodium hypochlorite (NaOCl; 1–5 %) or chlorhexidine-gluconate (CHX; 2 %).

Microorganisms and spreading carious processes pose a threat to the pulp [93]. Therefore, the number of microorganisms in the cavity and close to the pulp should be reduced to a minimum. The issue of how much infected dentin can remain in order to enable healing of the pulp is not entirely resolved [19].

After successful excavation, the cavity is to be cleaned with NaOCl or CHX and water spray [18, 22]. There is no need to fear damage of the pulp tissue when applying NaOCl [95]. Materials used for indirect pulp capping are supposed to kill microorganisms close to the pulp, neutralize acidic tissue resulting from the carious defect, remineralize dentin and stimulate the pulp to form tertiary dentin [72]. Traditionally, calcium hydroxide has been recommended since the 1930s [55]. Because of the disadvantages of soluble calcium hydroxide suspensions, the usage of hydraulic calcium silicate-based cements today is possibly a better alternative for indirect pulp capping [3]. A definitive adhesive restoration is supposed to follow any kind of pulp capping material in the same session. After indirect pulp capping the formation of reactionary dentin can follow, however, depending on the odontoblasts' degree of damage the repair and deposition of an atubular hard tissue is more likely. Reactionary and reparative dentin can be found located right next to each other histologically [91].

4. Direct pulp capping

Direct pulp capping is defined as the treatment of an exposed pulp, which can be caused by caries, preparation measures or dental trauma. The indication is given when "reversible pulpitis" is diagnosed.

After clinical and radiological assessment, the tooth is isolated using rubber dam and the clinical crown is disinfected. It is important to use sterile instruments. The complete excavation of caries is carried out

with slowly rotating round burs and hand instruments from the peripheral to the central region, ideally using magnification (dental loupe, microscope). To reach hemostasis and disinfection, it is advised to use pellets soaked in sodium hypochlorite. This is followed by the application of a calcium hydroxide suspension or a hydraulic calcium silicate-based cement on the exposed pulp and the surrounding dentin, where a sufficiently broad seam must remain available for the adhesive restoration. To avoid unintentional removal of pulp capping material when sealing the cavity, it is advised to layer a hard-setting material. Subsequently, the dentin should be sprayed with water thoroughly to minimize negative impacts of disinfecting solution on the adhesive bond. The definitive adhesive restoration should follow in the same session. Because pulp exposure is associated with demise of the local odontoblasts, the hard tissue formation induced by the pulp capping procedure is regarded as a repair process in which a mineralization tissue develops, usually formed by fibroblasts [91].

5. Pulpotomy

Pulpotomy (pulp amputation) is a method to maintain vitality of the pulp after artificial exposure of the coronal pulp (iatrogenic, traumatic). The coronal pulp is partially amputated (partial pulpotomy) or amputated at the level of the root canal orifices (full or cervical pulpotomy) and treated similar to direct pulp capping after successful hemostasis [1, 63].

5.1. Partial pulpotomy

During a partial pulpotomy the coronal pulp is reduced by 2 mm from the area of exposure to remove potentially inflamed irreversibly damaged parts of pulp tissue and maintain vitality of the remaining pulp [15]. Partial pulpotomy is preferably conducted using a small diamond bur [51] that removes the coronal 2 mm of the pulp in a high-speed manner, ideally with continuous rinsing using saline solution [40]. For practical reasons, pulp am-

putation is often conducted under water cooling using a handpiece [41]. There is no evidence that the use of cooling water from an accurately reconditioned and prepared handpiece will lead to lower success rates.

Similar to direct pulp capping, during partial pulpotomy the rinsing of the site of amputation with NaOCl is recommended until the bleeding is suspended. Provided that the formation of a blood clot is prevented, the same pulp repair mechanisms of direct pulp capping are to be expected [24, 33]. If the remaining pulp is healthy, the bleeding is expected to suspend within 5 minutes. If hemostasis has not taken place within this time, it may be concluded the pulp has not been reduced to a healthy level. In this case, the removal of the entire coronal pulp, a full pulpotomy, can be considered as the last possible measure to maintain vitality [63].

A calcium hydroxide suspension or hydraulic calcium silicate-based cement is applied to the artificially exposed pulp surface and covered with a thin layer of curing material [24].

Because more pulp capping material is used in partial pulpotomies than direct pulp capping, there would be a greater risk of tooth discoloration when using hydraulic calcium silicate-based cements [63]. The bacteria-proof restoration follows.

5.2. Full pulpotomy

Full pulpotomy is defined as the removal of the entire coronal pulp, whereas the radicular pulp that is to be preserved is capped at the height of the root canal orifices. Further steps take place according to a partial pulpotomy, followed by a definitive bacteria-proof restoration [63].

6. Pulp capping materials

6.1. Preparations containing calcium hydroxide

Calcium hydroxide is still commonly used as a pulp capping material today. In aqueous suspensions it has a high pH value, a bactericide effect, can neutralize bacterial acids

and lipopolysaccharides in dentin and results in the release of dentin-bound growth factors [50]. Calcium hydroxide therefore supports formation of hard tissues and healing of the pulp [39, 102]. Disadvantages are the mechanical instability and the absorption of the material over time [10, 49]. After applying calcium hydroxide, porosities (“tunnel defects”) in the reparative dentin are observed, which can act as an entry point for microorganisms [28]. The high pH value of aqueous calcium hydroxide suspensions results in liquefactive (or colliquative) necrosis if in direct tissue contact [103]. Calcium hydroxide is supposed to be applied sparingly in the area of exposed pulp and adjacent dentin [10, 103, 104]. Calcium hydroxide in aqueous suspensions would be preferable to other calcium hydroxide combinations (calcium salicylate cements, liners or putties). These exhibit a significantly lower release of hydroxyl ions [105], a continuous disintegration beneath the main filling [10], they induce a slower and less dense hard tissue formation [86] and a few additives, that cause the setting of the materials and possibly have a toxic effect on the pulp [69].

New light-curing liners and cements with calcium hydroxide or MTA-additives (product examples: Ultrablend Plus, Ultradent, South Jordan, USA; Calcimol LC, VOCO, Cuxhaven, Germany or TheraCal LC, Bisco, Schaumburg, USA) should be regarded as critical. These products are missing the specific calcium hydroxide effect that triggers bioactivity [21,106].

A cytotoxicity of these products is clearly verified and can be traced back to the monomer content [52]. According to current data, it is not advisable to perform pulp capping with light-curing materials containing calcium hydroxide or calcium silicates.

6.2. Dentin adhesives and composite resins

Two decades ago, the use of dentin adhesives has been propagated for pulp capping procedures [26, 27, 29], based on the idea that the bacte-

ria-proof seal is key for the success of maintaining vitality [3, 97]. However, dentin adhesives contain monomers that result in moisture-related incomplete polymerization and therefore have a toxic effect that largely remains close to the pulp [25, 36, 78]. It was proven that components of dentin adhesives inhibit the ability of pulp cells to form hard tissue [47]. Dentin adhesives and composite resins are not biocompatible [25] and therefore cannot be recommended as pulp capping materials [3].

6.3. Calcium silicate-based hydraulic cements

With the introduction of hydraulic calcium silicate-based cements, such as mineral trioxide aggregate (MTA), aqueous calcium hydroxide suspensions are not seen as the first choice material for vital pulp treatment [3, 22]. Hydraulic calcium silicate-based cements are similar to Portland cement, which is well known in the construction industry. They are known as “hydraulic”, because they set and are resistant in contact to air as well as under water [14]. Calcium silicate-based cements consist mainly of dicalcium or tricalcium silicates and are mixed with water. During the reaction and subsequent setting, calcium hydroxide is released over a longer period of time [14], which may explain the prolonged antibacterial properties [84].

Hydraulic calcium silicate-based cements are biocompatible and promote pulp cells to form hard tissue [111]. Mineral contents of the cement interact with the dentin [8], which results in a dentin adhesion similar to glass ionomer cements [60]. The advantage compared to calcium hydroxide products is the increased mechanical strength [34]. Even though more long-term clinical studies on vital pulp therapy with hydraulic calcium silicate-based cements would be preferable, they seem to be better suited for pulp capping than calcium hydroxide [3, 56, 64, 76].

Hydraulic calcium silicate-based cements may lead to tooth discoloration, which can be especially problematic in anterior teeth, for

example after trauma [79]. This can be caused by the heavy metals included like bismuth oxide as radiopacifier [13, 38] or iron [99]. Oxidation of these metals after contact with sodium hypochlorite or the absorption of blood components play an important role [20, 66, 99]. In hydraulic calcium silicate-based cements that contain less or few heavy metals, the risk of discoloration is reduced. Calcium silicate-based cements, that contain zirconium oxide or tantalum oxide appear to be especially color-stable [79]. Lipski et al. (2018) did not detect any grayish discoloration in any case with such a cement 18 months after direct pulp capping. However, tooth discoloration has been proven in vitro for these materials in the presence of blood [99]. In vital pulp therapy after pulp exposure, contact between these capping materials and blood is inevitable. However, this seems unproblematic from an aesthetic viewpoint at least in posterior teeth [79].

7. Vital pulp treatment after trauma-induced pulp exposure

In most cases, pulp exposure caused by dental trauma offers an ideal setting for vital pulp treatment, particularly in sound teeth without any predamage of the pulp and provided that the procedures are carried out accurately. In order to simulate the conditions after dental trauma, coronal pulp exposure was induced in an earlier animal study in monkeys. Dental pulps were directly exposed to the oral cavity for 3 hours, 2 days and 7 days, and histologically examined afterwards. Inflammatory pulp changes were found depending on the duration of exposition, however, even after 7 days of exposure these were limited to the coronal 2 mm [32]. Heide und Mjör confirmed these results in 1983 and stated that a partial pulpotomy with removing 2 mm of coronal pulp tissue can be successful after several days of contact of the pulpal tissue with the oral cavity [54]. It must be taken into account that additional luxation injuries compromises the circulation and thus the healing capacity of the pulp [94].

8. Vital pulp treatment after carious pulp exposure

In comparison to teeth with trauma-induced pulp exposure, teeth with a carious exposure have inflamed pulps due to longer term contact with bacterial toxins or even bacterial invasion. Lesion size, bacterial spectrum and speed of progression impact pulpal status. When treating dentin in deep lesions in the sense of indirect pulp capping, the transition to direct pulp capping is fluent. Even the remaining dentin layer is affected by the cutting of odontoblast processes close to the pulp. When pulp tissue is exposed punctiform, it can go clinically unnoticed and a thorough inspection of the cavity using a dental loupe is advised.

Even after full caries excavation and thorough disinfection, microorganisms can still be left behind. It is therefore recommended to apply capping material not only to the area of the pulp exposure, but also the surrounding dentin to treat bacteria effectively. This increases the success rate of pulp capping especially in teeth with deep caries [18]. For calcium hydroxide, it should be noted that extensive application can lead to disintegration and mechanic instability [10, 49]. Furthermore, after pulp exposure in carious dentin a contamination of tissue with infected dentin chips is possible. When the exposure of the pulp can be anticipated, it is recommended to use a new, sterile round bur. Because the capping of pulp tissue is only indicated after full caries excavation, a pulpotomy can be considered when pulp tissue is exposed to cariously infected dentin after excavation. Infected dentin chips that have already been transported into the pulp and damaged tissue parts can be removed and the conditions for pulp healing can be improved.

9. Follow-up and success rates

The failure of vital pulp treatment may be caused by an infection that can be attributed to remaining microorganisms or the intrusion of new bacteria along a gap between tooth and filling material in defective restorations [82]. In the process, pulp ne-

crois and formation of periapical inflammation can occur unnoticed. This is why the sensibility after vital pulp treatment should be tested regularly, after 3, 6, and 12 months and annually thereafter. A thermal sensibility test is suitable using refrigerant spray or CO₂ dry ice. A reduced reaction is to be expected after partial and especially cervical pulpotomy, and is not to be seen as a criteria for failure. A radiographic examination is only recommended in the case of a negative sensibility test [61]. It should be noted that a possible formation of new hard tissue around the point of exposure, or rather the site of amputation, cannot be clearly judged radiologically. Also a minor widening of the periodontal ligament space must not necessarily have any pathological meaning [2].

A clinical treatment success after vital pulp treatment is when the teeth can be classified as “asymptomatic”, which means when they react to a sensibility test, there is no spontaneous pain, no pain on palpation or percussion, and no swelling present. Radiographic changes such as a periapical lesion must not be visible. If a tooth does not react to a sensibility test, or is tender to percussion and/or palpation, or presents a periapical radiolucency it can be assumed that the treatment was a failure. Teeth, where a root canal treatment or an extraction is indicated after pulp capping, represent a failure of treatment [35].

The studies available suggest, that after partial pulpotomy there is no increased risk for pulp canal obliteration [11, 59, 74, 88]. In comparison, the long-term risk for obliterations is higher after a full pulpotomy. While the risk is considered very low during the first 2 years [5, 46, 100], partial obliterations occur in 30 % of the cases after a mean observation period of 3 years [70] and occur in nearly 40 % of the cases after a mean observation period of 4,8 years.

Vital pulp treatment after trauma offers high success rates if the pulp was not previously damaged or the circulation compromised due to luxation injury. The prognosis for direct pulp capping using calcium hydroxide is 54 %–90 % [43, 53, 90].

Partial pulpotomy using the same material exhibits higher success rates of 86 %–100 % [4, 30, 31, 33, 37, 53, 109] and is therefore favored. It remains to be seen if the success rates achieved with calcium hydroxide suspensions in partial pulpotomies after trauma-induced pulp exposure can be increased by a clinically relevant amount when hydraulic calcium silicate-based cements are used instead [63].

Although the conditions for vital pulp therapies after carious pulp exposure appear unfavorable compared to trauma-induced exposure, decent success rates are still possible. These rates lie at 62 % and 98 % after 3 to 10 years in indirect pulp capping using calcium hydroxide preparations [3, 58]. There are only few studies in the literature regarding hydraulic calcium silicate-based cements and indirect pulp capping, so that further investigations concerning this appear necessary [85]. Clinically and radiographically, teeth treated with indirect pulp capping using MTA show higher success rates after 3 months compared to using a setting calcium salicylate cement (Dycal, Dentsply Sirona, Konstanz, Germany). After 6 months, this result is put into perspective [68].

The listed success rates in the literature for direct pulp capping during caries excavation vary substantially [12, 56, 76]. Under the premise of correct indication and technical implementation, direct pulp capping using calcium hydroxide can reach success rates of nearly 60 % after 10 years [76, 110]. Success rates after using hydraulic calcium silicate-based cements such as mineral trioxide aggregate (MTA) are even higher at 80 % [56, 64, 71, 76].

For partial pulpotomy after carious pulp exposure using hydraulic calcium silicate-based cements the success rates are 85 %–97 % after 2 years and 94 % after 4 years [74].

Success rates of full pulpotomies using hydraulic calcium silicate-based cements are at 74 %–100 % after 1 to 5 years [5–7, 46, 70, 81, 87, 100, 107]. It is worth mentioning that the cited studies concerning full pulpotomies also included

teeth that were diagnosed with irreversible pulpitis. If further studies confirm the data over a longer period of time, the indications for vital pulp treatment could be extended to teeth diagnosed with irreversibly damaged pulp areas (irreversible pulpitis). During a partial or full pulpotomy, these areas can be targeted and removed selectively, in order to preserve vitality of the remaining pulp.

Despite the overall favorable success rates for vital pulp treatment after carious exposure, the selective or step-wise excavation method is another treatment alternative with comparable success rates. These approaches have demonstrated 5-year success rates ranging between 56 % (step-wise excavation) and 80 % (selective excavation) [73]. A clinically relevant difference regarding the success rates of a pulp capping or pulpotomy compared to the selective or step-wise caries excavation cannot be verified.

Only one clinical investigation exists that compares both treatment strategies directly and published data after 1 and 5 years [16, 17]. In this study, the prognoses of the step-wise excavation and full excavation with subsequent direct capping were compared. After stepwise caries excavation, preservation of pulp vitality after 5 years was possible in 60 % of the cases. In contrast, the prognosis after direct pulp capping and partial pulpotomy during the same observation period was 6 % and 11 %, respectively [16]. These success rates are considerably lower than those of other clinical trials. The highly unfavorable results in that study may be attributed to the fact that the cavity was restored only with a temporary filling for 8–10 weeks after pulp capping or partial pulpotomy instead of an immediate definite restoration [16]. Furthermore, the lack of disinfection after pulp exposure, as well as the choice of pulp capping material (Dycal), are considered unfavorable. These factors might have contributed to the low success rates in the study. The data does not match the remaining literature, which attests a favorable prognosis for vital pulp treatment after carious pulp exposure if properly performed.

10. Final evaluation of vital pulp treatment strategies

The improved understanding of the interaction between microorganisms and tissue response led to increased use of minimally invasive, tissue conserving treatment concepts in conservative dentistry in the last few years. With this in mind, vital pulp treatment strategies can preserve functional endogenous pulp tissue and avoid its replacement with synthetic materials.

Maintaining pulp vitality should always be aspired to when the indication is given.

According to the current state of knowledge, the evaluation that measures maintaining vitality are considered uncertain is obsolete. Provided that a careful assessment and adequate implementation of all required treatment steps took place, the prognosis of vital pulp treatment can be considered to be very good, thus improving conditions for long-term tooth conservation.

It is not possible to prove higher success rates for the currently propagated selective or stepwise caries excavation methods as opposed to vital pulp treatment after complete excavation and pulp exposure.

It is the responsibility of well-designed, future clinical studies to find out which approach offers better long-term conditions for maintaining pulp vitality. For teeth diagnosed with irreversible pulpitis, future trials need to evaluate whether pulp vitality can be maintained on long-term if irreversibly damaged pulp areas are removed.

Conflict of interest:

Till Dammaschke has received fees from Septodont for lectures.

Kerstin Galler and Gabriel Krastl declare that there is no conflict of interest within the meaning of the guidelines of the International Committee of Medical Journal Editors.

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