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Legal Risk Dossier 1

A Legal Review on Peri-Implantitis and Implant Health in 2020

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Her dual qualification means she primarily represents doctors and dentists throughout Germany on all issues relating to practice-based work, particularly allegations of malpractice or fee disputes.

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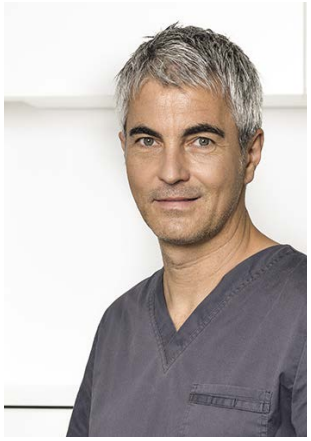
THE SUCCESS STORY THAT IS DENTAL IMPLANTOLOGY – OPPORTUNITIES AND RISKS



GUEST EDITORIAL
DR PETER RANDELZHOFER

Dental implantology is a success story that goes back over 30 years and is now an indispensable component of modern dental care. But implantologists are also facing increasing demands: implant patients are younger and live longer, so patient expectations of long-term implant success are steadily increasing.

However, with the prevalence of peri-implantitis also increasing, this is a risk that poses a major challenge to implantologists and prosthodontists.

The 95% success rate often cited in patient communications is fading now with the prevalence of peri-implantitis reaching 41% over a nine-year period (Derks et al.). It must now be included in ANY advice given to the patient, since the avoidance of inflammation is just as important as functionality.

Courts are increasingly finding in favour of patients and prioritising their protection.
This means that the demands for advice and documentation, as well as long-term sustainability through appropriate monitoring, documentation and prevention measures to be addressed at the patient consultation stage are increasing, particularly since an increasing number of studies point to the collateral effects of leaving periodontitis untreated.

The same applies to peri-implantitis, with one key difference: this risk is a result of an elective procedure performed by the implantologist, raising his or her risk of liability. This applies even if a patient's periodontal situation was unremarkable on the day of the procedure.

In fact, however, the role of patients and their joint responsibility are also increasingly important since ultimately the patients' immune system, lifestyle decisions and their dietary regimes or hygiene routines are decisive in determining long-term success.

Demands, then, are increasing on all sides and offering new opportunities for an implant health offensive that prioritises long-term success, care and recall. With over 100m implants worldwide, more attention and professional hygiene planning is required.

In Germany alone 8m implant patients will have to step up their recall and monitoring frequency considerably in future to keep their implants healthy.

In fact, that's no problem, especially in these days of "Personalised Medicine". New immunological diagnostic procedures such as the aMMP-8 ImplantSafe® technology identify peri-implant progression in minutes and alert patients to collagenolytic progression on the implant, displaying the preventative action required by the individual in a fully digital, quantitative and documentable form.

This opens up a bright new future with a genuine sustainable solution for long-term implantological success that strikes the right balance between risks and opportunities to create a new world of implant health.

The legal dossier offers us dentists both in-depth insights and specific solutions for our practice.

Join us and support the alliance for sustainable implantology: IMPLANTHEALTH 2020!

Kind regards,
Dr Peter Randelzhofer
ICC Implant Competence Center, Munich

LIABILITY FOR PRIOR PERIODONTAL DISEASE IN DENTAL IMPLANTOLOGY

LEGAL SITUATION

Over the past 20 years courts have increasingly dealt with patients' claims of malpractice due to failure to provide, or providing inadequate periodontal diagnostics and treatment.

20 years ago, on 30.09.1999, Düsseldorf Higher Regional Court ruled that any periodontal treatment required must be implemented prior to implantation. The court expert used a comparative evaluation of OPG images to demonstrate that progressive post-operative bone loss had occurred, and hence that pre-treatment had been required to permanently remove the pathogenic bacteria present. The practitioner's claim for compensation was rejected.

A few years later Oldenburg Higher Regional Court in a judgement dated 28.07.2004 sentenced the practitioner to reimburse the fee charged for the implant which amounted to approximately €25,000.00. The court found the implantation to be unlawful due to a lack of proper advice being given to the patient regarding the intervention, on the grounds that the practitioner was unable to demonstrate that he had considered the patient's particular risk situation when providing the advice. Prior to implantation, the patient had suffered from recurring gingivitis and severe calculus. The expert witness viewed poor oral hygiene as a contraindication for implantation.

In a recent judgment by Münster Regional Court dated 26.04.2018 the expert confirmed a diagnosis of periodontal disease based on the X-ray findings. The expert stated that screening should therefore have been provided prior to implantation. The scope of the periodontitis should have been identified in detail by measuring pocket depths, checking for haemorrhagic diathesis and examining for calculus. The practitioner should have taken into account the tooth loss that had already occurred in the past due to the patient's poor oral hygiene and the considerable risk this entailed of the implants failing to heal and causing peri-implantitis due to bacterial colonisation.
The court further held that the failure to conduct a diagnostic assessment and the failure to advise on oral hygiene measures prior to implantation were entirely inexplicable and constituted gross malpractice. The practitioner's claim for compensation was rejected.

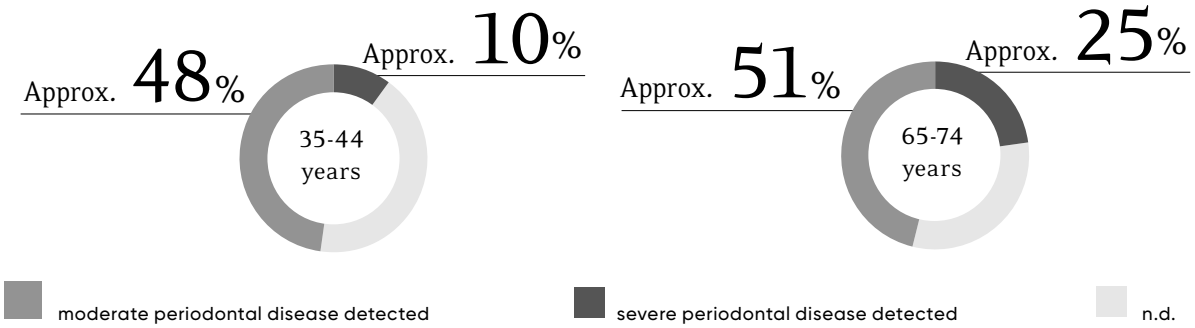
Personal liability insurance policies normally only cover liability for damages and compensation for suffering, not repayment of fees. Liability insurers will only assume the costs of proceedings that fall within that scope. Some liability insurers includes a provision in the insurance policy requiring the policyholder to accept a significant excess (deductible) of up to €5,000.00 in the event of a court finding that appropriate advice was not provided. A conviction based on a proven failure to provide appropriate advice or malpractice could therefore entail considerable financial losses.

RISK OF PERI-IMPLANTITIS

In the Münster Regional Court judgement cited above, it was asserted based on the expert witness's statements that the failure to perform the required periodontitis treatment had led to an eightfold increase in the risk of implant loss. If an individual's risk is so high as to jeopardise the success of implantation, the practitioner is under an even greater obligation to provide detailed advice to the patient.

The fifth German Oral Health Study published by the Institute of German Dentists (Deutscher Zahnärzte Verlag DÄV Cologne 2016) found that severe periodontitis is the world's sixth most prevalent disease, affecting approximately 10.8% of the entire population or 743 million people.

The disease has been classified here using the "Community Periodontal Index" (CPI), with moderate periodontal disease defined as CPI grade 3, probing depths of 4-5 mm and severe periodontal disease as CPI grade 4, probing depths ≥ 6 mm.



In the study year (2014) in Germany,
in younger adults (35-44 years) in
- 48% of cases moderate periodontal disease and in
- 10% of cases severe periodontal disease

was detected.

in younger elderly (65-74 years) in
- 51% of cases moderate periodontal disease and in
- 25% of cases severe periodontal disease

Additional aggravating individual risk factors include for example diabetes, smoker status or other underlying diseases. Finally, periodontitis is one of the causes of the loss of natural teeth.

In the Swedish study by Derks et al., "Effectiveness of Implant Therapy Analyzed in a Swedish Population: Prevalence of Peri-implantitis", Journal of Dental Research 95 (1): 43-49 peri-implantitis was diagnosed in 45% of patients given implant-supported treatment 9 years previously based on clinical and X-ray examinations. Moderate/severe peri-implantitis with bone loss greater than 2 mm was identified in 14.5% of this patient group.

According to case law implant loss is intrinsic to treatment and is therefore a risk that must be included in advice to patients. If no evidence can be produced to show that advice on this was provided, the treatment is not covered by the patient's consent form. Cologne Higher Regional Court has already awarded compensation for suffering of €7,500.00 in an older ruling dated 06.05.2002, 5 U 60/99. The level of compensation for suffering awarded by the courts has steadily increased in recent years.

The onset of peri-implantitis with possible implant loss or the possible necessity of peri-implantitis treatment is also a risk that needs to be addressed in patient consultation. It is absolutely necessary to include the risk of peri-implantitis in the advice to patients in view of the scientific findings on the prevalence of peri-implant diseases.

DIAGNOSTIC ASSESSMENT

If implant loss does occur, a key question is whether such loss was avoidable and thus constitutes malpractice or whether it was unavoidable despite the greatest possible care being taken and thus unrelated to the treatment. This question is answered by expert evidence based on an evaluation of the patient documentation. A verbal statement from the practitioner or questioning of witnesses may be accepted as evidence of whether advice was provided in the absence of documented evidence that advice was provided. However, a practitioner cannot provide evidence by alternative means in the absence of documented evidence of medically necessary diagnostic or therapeutic measures. Failure to conduct a diagnostic assessment reverses the burden of proof. In the absence of documented findings for reviewing the periodontal situation pre- or post-implantation, therefore, the patient is not required to prove malpractice, whilst the practitioner must prove that the implant loss could not have been prevented. This proof can only be provided in very rare cases.

In a study by Al-Maijd et al. *"Matrix Metalloproteinase-8 as an Inflammatory and Prevention Biomarker in Periodontal and Peri-Implant Diseases"*, International Journal of Dentistry 2018: 7891323, the authors investigated whether an active matrix metalloproteinase (aMMP-8) acts a biomarker for prevention of periodontal and peri-implant diseases. It found that

> *"aMMP-8 in oral fluids reflects clinical periodontal parameters and findings and clinical disease activity in periodontitis and peri-implantitis together with the assessment of treatment outcomes, is correlated with the latter and is a good predictor for them"*

and are therefore *"tools for personalised medicine"*.

Allegations of malpractice are upheld if a deviation from medical or dental standard practice is identified. Treatment is defined as state of the art if it meets *"the generally recognised professional standards existing at the time of treatment"* as set out in § 630a (2) of the German Civil Code (BGB).

At the present time, failure to apply the aMMP-8 diagnostic procedure is not tantamount to a failure to conduct a proper diagnostic assessment. In future, however, the question will arise of whether the term *"standard"* should be replaced by the term *"personalised medicine"*. The German Wikipedia entry, accessed on 27.06.2019, states that:

> *"Personalised medicine entails treating each patient based on a comprehensive consideration of individual factors beyond the functional pathological diagnosis. This also includes continuously adjusting treatment to patient's response."*

The aMMP-8 diagnostic procedure is suitable for determining treatment based on a comprehensive consideration of individual factors and adjusting this treatment to the patient's response. Pharmacotherapy is currently adjusted using diagnostic biomarkers and determined on a personalised basis. If the opportunities presented by personalised medicine do assume greater prominence in future, the question of whether aMMP-8 diagnostics are required may arise. Even today, however, it can be used as evidence that an individual diagnostic assessment has been conducted. For high-risk patients with an elevated risk of peri-implantitis and/or implant loss in particular, it is helpful and advisable to use digital testing procedures to identify individual risk, discuss it with the patient and document the results.

ADVICE TO PATIENTS

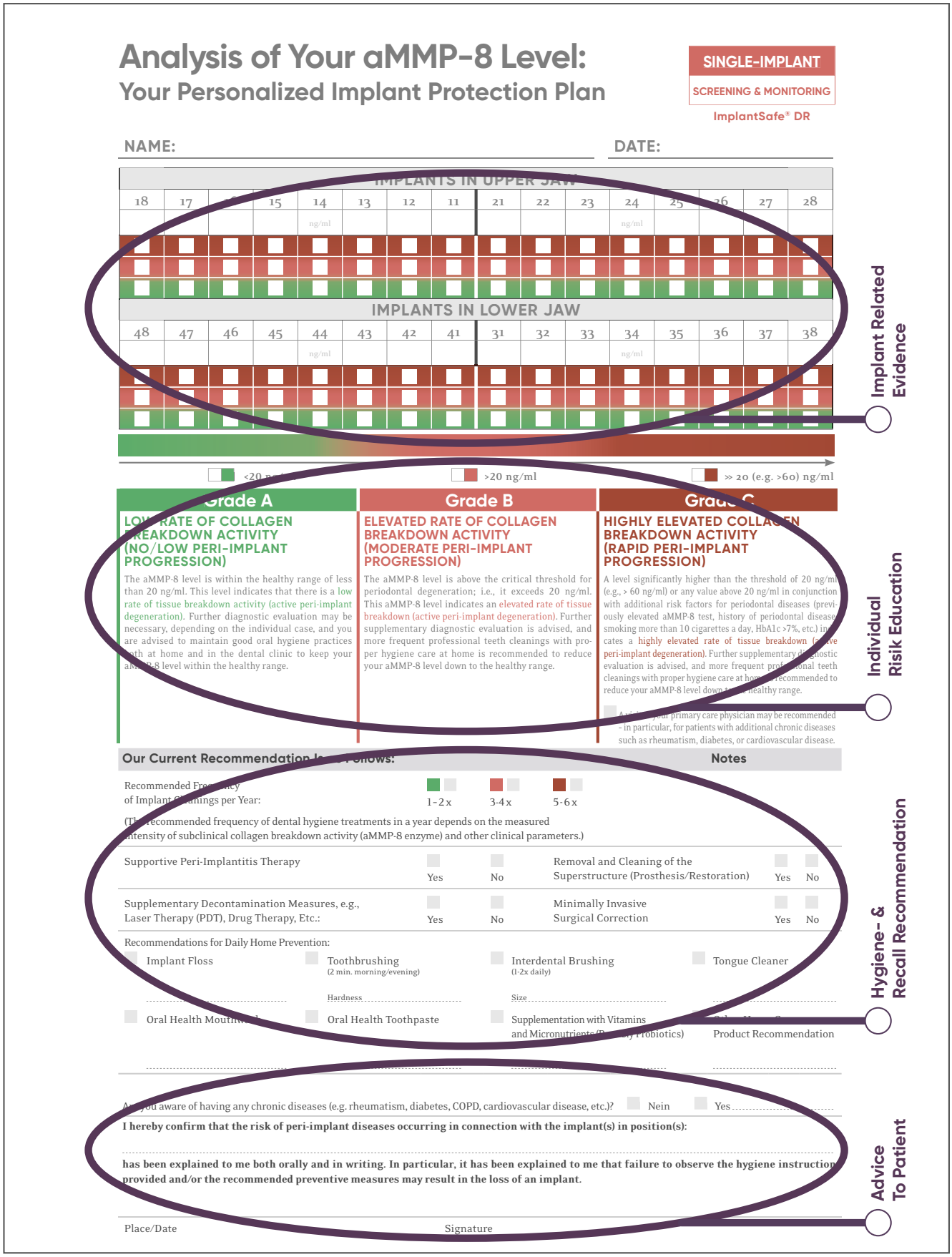
A practitioner is obliged not only to provide advice on the risks of treatment but also on how to ensure that the treatment is successful. If close monitoring is needed to ensure the treatment is successful, this should be communicated clearly and unambiguously to the patient.

Case law is generally reluctant to hold patients jointly responsible and sets low requirements on their duty to cooperate. The Federal Civil Court (Bundesgerichtshof, BGH) found in its judgement of 16.06.2009, VI ZR 157/08 that:

> *"The patient's failure to cooperate with a medically necessary treatment does not exclude the possibility of malpractice where the patient was not given adequate advice on the risks of failing to undergo treatment."*

The court held that a general reference to the fact that the patient should re-attend if problems occur or the condition deteriorates is not adequate. However if a practitioner has demonstrably and clearly issued instructions on treatment and monitoring, a patient would be expected to follow the doctor's instructions.

The practitioner must provide evidence to show that the individual advice was provided, including information on the patient's duties to cooperate during follow-up. A practitioner should use individualised patient advice forms as evidence that the patient was advised on what to do to ensure success of the treatment. The advice forms form part of the patient records and are thus official documents as defined in the Code of Civil Procedure. If, for example, a patient confirmed that he or she has received written and verbal advice that failing to adhere to the hygiene instructions issued or the suggested prevention measures could run the risk of implant loss, the practitioner can provide evidence to show that the advice provided was complete and the patient's failure to cooperate despite the advice given could not be construed as malpractice on his or her part.



Analysis of Your aMMP-8 Level:
Your Personalized Implant Protection Plan

SINGLE-IMPLANT
SCREENING & MONITORING
ImplantSafe® DR

NAME: DATE:

IMPLANTS IN UPPER JAW

18	17	16	15	14	13	12	11	21	22	23	24	25	26	27	28
				ng/ml							ng/ml				

IMPLANTS IN LOWER JAW

48	47	46	45	44	43	42	41	31	32	33	34	35	36	37	38
				ng/ml							ng/ml				

<20 ng/ml >20 ng/ml >> 20 (e.g. >60) ng/ml

Implant Related Evidence

Grade A

LOW RATE OF COLLAGEN BREAKDOWN ACTIVITY (NO/LOW PERI-IMPLANT PROGRESSION)

The aMMP-8 level is within the healthy range of less than 20 ng/ml. This level indicates that there is a low rate of tissue breakdown activity (active peri-implant degeneration). Further diagnostic evaluation may be necessary, depending on the individual case, and you are advised to maintain good oral hygiene practices with at home and in the dental clinic to keep your aMMP-8 level within the healthy range.

Grade B

ELEVATED RATE OF COLLAGEN BREAKDOWN ACTIVITY (MODERATE PERI-IMPLANT PROGRESSION)

The aMMP-8 level is above the critical threshold for periodontal degeneration; i.e., it exceeds 20 ng/ml. This aMMP-8 level indicates an elevated rate of tissue breakdown (active peri-implant degeneration). Further supplementary diagnostic evaluation is advised, and more frequent professional teeth cleanings with proper hygiene care at home is recommended to reduce your aMMP-8 level down to the healthy range.

Grade C

HIGHLY ELEVATED COLLAGEN BREAKDOWN ACTIVITY (RAPID PERI-IMPLANT PROGRESSION)

A level significantly higher than the threshold of 20 ng/ml (e.g., > 60 ng/ml) or any value above 20 ng/ml in conjunction with additional risk factors for periodontal diseases (previously elevated aMMP-8 test, history of periodontal disease, smoking more than 10 cigarettes a day, HbA1c >7%, etc.) indicates a highly elevated rate of tissue breakdown (active peri-implant degeneration). Further supplementary diagnostic evaluation is advised, and more frequent professional teeth cleanings with proper hygiene care at home is recommended to reduce your aMMP-8 level down to the healthy range.

Individual Risik Education

Action: your primary care physician may be recommended – in particular, for patients with additional chronic diseases such as rheumatism, diabetes, or cardiovascular disease.

Our Current Recommendation is as follows: **Notes**

Recommended Frequency of Implant Cleanings per Year: 1-2x 3-4x 5-6x

(The recommended frequency of dental hygiene treatments in a year depends on the measured intensity of subclinical collagen breakdown activity (aMMP-8 enzyme) and other clinical parameters.)

Supportive Peri-Implantitis Therapy	Yes	No	Removal and Cleaning of the Superstructure (Prosthesis/Restoration)	Yes	No
Supplementary Decontamination Measures, e.g., Laser Therapy (PDT), Drug Therapy, Etc.:	Yes	No	Minimally Invasive Surgical Correction	Yes	No

Recommendations for Daily Home Prevention:

- Implant Floss
- Toothbrushing (2 min. morning/evening) — Hardness .....
- Interdental Brushing (1-2x daily) — Size .....
- Tongue Cleaner
- Oral Health Mouthwash
- Oral Health Toothpaste
- Supplementation with Vitamins and Micronutrients (Prebiotics, Probiotics) — Product Recommendation .....

Hygiene- & Recall Recommendation

Are you aware of having any chronic diseases (e.g. rheumatism, diabetes, COPD, cardiovascular disease, etc.)? Nein Yes .....

I hereby confirm that the risk of peri-implant diseases occurring in connection with the implant(s) in position(s):

.....

has been explained to me both orally and in writing. In particular, it has been explained to me that failure to observe the hygiene instruction provided and/or the recommended preventive measures may result in the loss of an implant.

Place/Date Signature

Advice To Patient

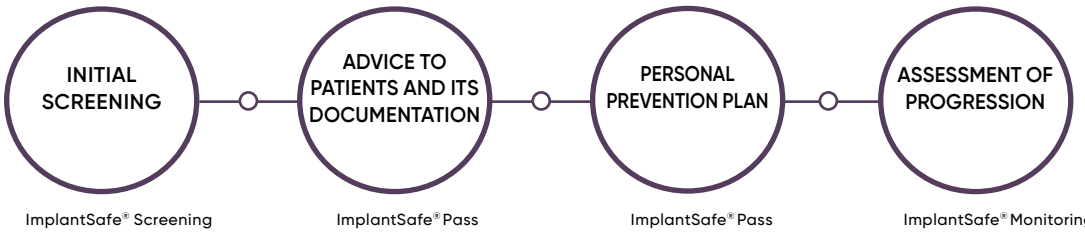
Example of advice to patients

SUMMARY

Assuming that implantation is state of the art in terms of implant type, implant position, number of implants, X-ray diagnosis, analysis of model etc.,

A PRACTITIONER'S LIABILITY RISK IS GREATLY MINIMISED IF THE FOLLOWING ARE DOCUMENTED:

- an analysis of aMMP-8 readings as implant-related findings,
- an assessment of the progression of peri-implant collagen degradation as individual advice on risks,
- hygiene and recall instructions based on this and
- a signed declaration by the patient stating that the advice has been issued.



Conventionally measured pocket depths or haemorrhaging may be queried by an expert. However, an expert is very unlikely to be able to express doubts around objectively verifiable and logged findings.

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