

Patient's Informed Consent Prior to Implant-Prosthetic Treatment: A Retrospective Analysis of Expert Opinions

Frank Peter Strietzel, Dr Med¹

Purpose: The purpose of this retrospective analysis of expert opinions was to optimize the level of patient information prior to implant-prosthetic treatment. **Materials and Methods:** Twenty-eight expert opinion reports on implant treatment cases compiled between 1996 and August 2001 were analyzed. **Results:** Seventy-five percent of all cases subjected to expert opinion reports revealed generally inadequate patient information. Significant associations were found between diagnostic mistakes and a lack of or inadequate information about complications that occurred ($P = .04$). Inadequate prosthetic or periodontal pretreatment of the patient prior to implant treatment was associated with a lack of information concerning implant and periodontal maintenance ($P = .023$) as well as insufficient oral hygiene status ($P = .001$). **Discussion:** In addition to a general lack of patient information, a lack of information about possible complications and inadequate information about treatment risks, treatment costs, and treatment alternatives were also found. **Conclusion:** Optimization of pretreatment information for patients, as well as improvement of communication with patients throughout the whole treatment and maintenance period, seem to be necessary. (INT J ORAL MAXILLOFAC IMPLANTS 2003; 18:433–439)

Key words: dental implants, expert testimony, implant-supported dental prosthesis, informed consent

In light of growing numbers of requests for expert opinions from patients, courts, and liability insurance providers regarding the results of restorative dental implant treatment, a tendency toward legal conflict resolution has become apparent. This development has occurred despite numerous factors such as qualitatively high diagnostic standards, a broad spectrum of continuing education possibilities for treatment providers, certified training in the field of implant dentistry, more detailed information

for patients concerning the possibilities and limitations of implant-prosthetic rehabilitation, and high success rates and safety of the therapy.

Thorough diagnosis and treatment planning prior to implant treatment cannot prevent complications in every case. Complications can give rise to claims of mistakes in treatment. However, claims of incomplete information about the risks and complications of treatment are gaining importance as cause for legal claims seeking damages. Specifically, because of the elective character of implant-prosthetic rehabilitation, it is necessary to inform the patient optimally, giving attention to other treatment alternatives and allowing the patient to consider these, either to obtain effective informed consent or to have the patient decide against implant treatment.

The interdisciplinary nature of implant-prosthetic rehabilitation and achievement of long-term therapeutic success are complemented by patient cooperation, ie, the patient's understanding of the necessity for being an active partner and supporting

¹Researcher and Senior Staff Member, Department of Oral Surgery and Dental Radiology, School of Dentistry, Charité, Humboldt-University Berlin, Germany.

Reprint requests: Dr Frank Peter Strietzel, Universitätsklinikum Charité, Medizinische Fakultät der Humboldt-Universität zu Berlin, Zentrum für Zahnmedizin, Abteilung für Oralchirurgie und zahnärztliche Röntgenologie, Augustenburger Platz 1, 13353 Berlin, Germany. Fax: +49-30-450562901. E-mail: frank.strietzel@charite.de

- Age
- Gender
- Implant loss
- Impossible prosthetic loading of implants (implant malposition)
- Completed prosthetic as well as prophylactic pretreatment
- Injury to adjacent anatomic structures
- Diagnostic mistake
- Maltreatment
- Generally insufficient patient information
- Insufficient or total lack of patient information regarding risks
- Insufficient or total lack of patient information regarding costs of treatment
- Insufficient or total lack of patient information regarding possible complications
- Insufficient or total lack of patient information regarding necessity of follow-up treatment and prophylaxis
- Oral hygiene status
- Smoking status

Fig 1 Criteria for content analysis of expert evaluations.

the attempts to ensure success. The compliance necessary for such behavior is gained by the patient in a process of becoming thoroughly informed about the therapy's necessity, the foreseeable course of events involved, risks and possible complications, consequences arising from complications, alternative therapies, and measures necessary to maintain therapeutic success. At every stage of therapy, informed consent is a necessary prerequisite for the patient's cooperation.^{1,2} As such, it is required of the patient and treating dentist to work toward necessary compliance in situations where the results are unclear: before beginning with prosthetic rehabilitation, as well as at every stage of treatment. This, in turn, can have a positive effect on the further course of therapy, maintenance of the restoration, and identification of the patient with the outcome of therapy.³

If the patient is dissatisfied with results of the treatment because of excessive expectations that were not addressed in consultation and information prior to treatment, then the necessary willingness to cooperate in further stages of treatment will be lacking.⁴ In such cases, prognosis for the further course of therapy and for maintaining what was achieved in treatment is poor.

The aim of this retrospective study was to analyze patient information provided before and during the course of implant-prosthetic rehabilitation, drawing on conclusions reached in the content analysis of expert opinion appraisals of treatment.

MATERIALS AND METHODS

A retrospective study was undertaken using the contents of 28 consecutive expert evaluations performed by 1 evaluator between 1996 and August 2001 on behalf of the Dental Board of Berlin, Germany. The evaluation criteria are listed in Fig 1. Inquiries into deficient patient information determined in the evaluations were supplemented with an analysis of documentation related to therapy, patient information (if available), and questions posed to the patient, including attempts to judge the reproducibility of patient statements.

In all, 2 evaluations from 1996, 4 from 1997, 6 from 1998 to 2000, and 4 from the period up to August 2001 were analyzed. Seventeen of the cases were instigated by the patients themselves in preparation for litigation with the treating dentist, 9 were called for by courts, and 2 were prompted by the liability insurance provider of the dentist.

Evaluation criteria were coded numerically, and a statistical analysis of the frequency distribution was performed. Since the sample size was small, and since for the most part only nominally scaled variables were analyzed, the structure and distribution of the data allowed the use of chi-square quotients to demonstrate possible correlations between the variables. The chi-square value was considered significant if $P < .05$. Statistical evaluation was performed using SPSS for Windows (Version 10.0, SPSS, Chicago, IL).

RESULTS

Data related to different criteria were drawn from 28 evaluations involving 18 female and 10 male patients with a median age of 49.5 years (range, 21 to 92) with a normal distribution. An overview of the frequency distribution of the evaluation criteria is presented in Table 1. In 14 cases, loss of the implant was the reason for patient dissatisfaction and thus was the main concern of the evaluation.

The levels of significance of correlations, represented in Table 2, were calculated from numerous combinations of individual parameters, which were reproducible in chi-square likelihood quotients.

In the analysis of the correlations between the criteria "generally insufficient patient information" and "insufficient or total lack of financial patient information" or "insufficient or total lack of patient information regarding therapy alternatives," a tendency (but insignificant correlation; $P = .053$) was determined. A possible association ($P = .078$) was suspected between the criteria "generally insufficient

Table 1 Frequency Distribution of Evaluation Criteria (n = 28; Multiple Counting)

Criteria	Frequency (%)	Frequency (n)
Maltreatment	75	21
No prosthetic as well as prophylactic pretreatment	64	18
Implant malposition (impossible prosthetic loading of implants)	57	16
Implant loss	50	14
Diagnostic mistake	43	12
Injury to adjacent anatomic structures	25	7
Nerve injury	18	5
Generally insufficient patient information	75	21
Insufficient or total lack of patient information regarding complications that occurred	71	20
Insufficient or total lack of patient information regarding risks	54	15
Insufficient or total lack of patient information regarding costs of treatment	29	8
Insufficient or total lack of patient information regarding therapy alternatives	29	8
Insufficient or total lack of patient information regarding necessity to follow-up treatment and prophylaxis	25	7

Table 2 Levels of Significance of Correlations Calculated Between Evaluation Criteria

First criteria	Second criteria	P value
Diagnostic mistake	Nerve injury	.004*
Diagnostic mistake	Injury to adjacent anatomic structures	.0005*
Diagnostic mistake	Insufficient or total lack of patient information regarding complications that occurred	.04
Bad oral hygiene status	Smoker	.006*
Bad oral hygiene status	Insufficient or total lack of patient information regarding necessity of follow-up treatment and prophylaxis	.001*
Prosthetic as well as prophylactic pretreatment was not completed	Insufficient or total lack of patient information regarding necessity of follow-up treatment and prophylaxis	.023
Generally insufficient patient information	Insufficient or total lack of patient information regarding complications that occurred	.0005*
Generally insufficient patient information	Insufficient or total lack of patient information regarding risks	.001*
Generally insufficient patient information	Insufficient or total lack of patient information regarding costs of treatment	.053
Generally insufficient patient information	Insufficient or total lack of patient information regarding therapy alternatives	.053
Generally insufficient patient information	Insufficient or total lack of patient information regarding necessity of follow-up treatment and prophylaxis	.078

*Highly significant differences concerning the distribution of frequencies confirmed by cross table analysis (see Table 3).

patient information” and “insufficient or total lack of patient information regarding the necessity of follow-up treatment as well as prophylaxis.”

Of 7 cases of injury involving adjacent anatomic structures, 1 noted dislocation of an implant into the maxillary sinus. Another of these cases described

maxillary sinusitis arising from an implant extending far into the sinus. In neither case was the patient informed about the possibility of such complications by the treating dentist. Five cases noted sensory deficits in the form of hypo- or paresthesias in the innervation of the mental nerve.

Table 3a Cross Table for Diagnostic Mistake vs Nerve Injury

Diagnostic mistake	Nerve injury		Σ
	Yes	No	
Yes			
n	5	7	12
% of diagnostic mistake	41.7	58.3	100
% of nerve injury	100	30.4	42.9
No			
n	0	16	16
% of diagnostic mistake	0	100	100
% of nerve injury	0	69.6	57.1
Σ			
n	5	23	28
% of diagnostic mistake	17.9	82.1	100
% of nerve injury	100	100	100

Table 3b Cross Table for Diagnostic Mistake vs Injury to Adjacent Structures

Diagnostic mistake	Injury to adjacent structures		Σ
	Yes	No	
Yes			
n	7	5	12
% of diagnostic mistake	58.3	41.7	100
% of injury to adjacent structures	100	23.8	42.9
No			
n	0	16	16
% of diagnostic mistake	0	100	100
% of injury to adjacent structures	0	76.2	57.1
Σ			
n	7	21	28
% of diagnostic mistake	25.0	75.0	100
% of injury to adjacent structures	100	100	100

Table 3c Cross Table for Oral Hygiene vs Information About Follow-up

Oral hygiene status	Patient information regarding necessity of follow-up treatment and prophylaxis		Σ
	Insufficient or total lack of information	Adequate information	
Good			
n	17	1	18
% of oral hygiene status	94.4	5.6	100
% of patient information regarding necessity of follow-up treatment and prophylaxis	85.0	14.3	66.7
Bad			
n	3	6	9
% of oral hygiene status	33.3	66.7	100
% of patient information regarding necessity of follow-up treatment and prophylaxis	15.0	85.7	33.3
Σ			
n	20	7	27
% of oral hygiene status	74.1	25.9	100
% of patient information regarding necessity of follow-up treatment and prophylaxis	100	100	100

For highly significant differences between the distribution of frequencies with a level $P < .005$, the distributions are listed in cross tables (Tables 3a to 3f). In the analysis, a significant correlation was determined between “diagnostic mistakes” and “nerve damage” ($P = .004$) (Table 3a). The correlation was even stronger between the criteria “diag-

nostic mistakes” and “injury to adjacent anatomic structures” ($P = .0005$) (Table 3b). A correlation was found between “bad oral hygiene status” and a smoking habit of the patient ($P = .006$) (Table 3f). This was confirmed by analyzing the distribution of frequencies, which demonstrated significant differences (Table 3f).

Table 3d Cross Table for General Information vs Information About Complications

General information	Patient information regarding complications occurred		Σ
	Insufficient or total lack of information	No complications occurred	
Sufficient			
n	0	7	7
% of general information	0	100	100
% of patient information regarding complications occurred	0	87.5	25.0
Not sufficient			
n	20	1	21
% of general information	95.2	4.8	100
% of patient information regarding complications occurred	100	12.5	75.0
Σ			
n	20	8	28
% of general information	71.4	28.6	100
% of patient information regarding complications occurred	100	100	100

Table 3e Cross Table for General Information vs Information About Risks

General information	Patient information regarding risks		Σ
	Insufficient or total lack of information	Adequate information	
Sufficient			
n	7	0	7
% of general information	100	0	100
% of patient information regarding risks	53.8	0	25.0
Not sufficient			
n	6	15	21
% of general information	28.6	71.4	100
% of patient information regarding risks	46.2	100	75.0
Σ			
n	13	15	28
% of general information	46.4	53.6	100
% of patient information regarding risks	100	100	100

The results of implant-prosthetic rehabilitation taken under scrutiny were performed in a total of 22 offices. One of these offices was involved in 6 evaluations, and another involved 2. In the office with the most requests for evaluation, 5 patients claimed instances of insufficient information. Four made loss of the implant the subject of the evaluation,

whereas 2 other cases involved implants that remained in situ but did not fulfill their prosthetic aim. The necessary pretreatment, which consists of initial periodontal therapy and an effective check of oral hygiene, did not occur in any of these cases.

The main reasons cited for dissatisfaction among the patients were implant loss, the inability of the

Table 3f Cross Table for Oral Hygiene Status vs Smoking Status

Oral hygiene status	Smoking status		Σ
	Yes	No	
Good			
n	4	14	18
% of oral hygiene status	22.2	77.8	100
% of smoker	36.4	87.5	66.7
Bad			
n	7	2	9
% of oral hygiene status	77.8	22.2	100
% of smoker	63.6	12.5	33.3
Σ			
n	11	16	27
% of oral hygiene status	40.7	59.3	100
% of smoker	100	100	100

prosthesis to fulfill its purpose, and the consequences of injury to adjacent anatomic structures, as well as insufficient information.

DISCUSSION

Because of the increase in dental implant–prosthetic rehabilitation and the broadening of its indication, even in situations where the patient's anatomy is disadvantageous, a greater number of complications can be expected. Severe complications in such cases are often the consequence of inadequate treatment planning, inappropriate diagnosis and treatment, and poor preconditions for the treatment.⁵

Parameters that contribute to success in implant–prosthetic treatment, in addition to factors predominantly associated with the qualitative and quantitative characteristics of the implant bed, surgical techniques, an undisturbed phase of initial healing, and adequate prosthetic loading,⁶ should include the proper recognition of whether the therapy is actually indicated.

The loss of an implant is not only considered the strongest criterion for the failure of implant–prosthetic rehabilitation⁷; it is also an obvious reason for the patient to view the course of therapy critically, despite the fact that implant loss can occur as a result of complications about which the patient was informed prior to treatment. In over half of the evaluations examined in this study, implant loss was the main reason for patient claims of incorrect treatment. Complete and detailed documentation from which the course of diagnosis, treatment planning, and the operation can be ascertained retrospectively, along with the course of follow-up ther-

apy, prosthesis maintenance, the content of administered patient information, and a copy of the cost estimates, should be kept.

Significant findings correlated injury to adjacent anatomic structures to proof of mistakes in preimplantation diagnosis, as well as to incomplete or an absence of patient information about such complications. In such cases, incompetence in the field on the part of the treating dentist was often combined with an uncritical view of the dentist's own therapeutic capacity. This was exemplified in one case in which an implant became dislocated in the maxillary sinus, and in another in which the implant projected into the maxillary sinus, leading to sinusitis. In neither case was the patient informed about such possible complications. The dislocation of an implant in the maxillary sinus has been described as a rare complication.⁸ In such a situation where disadvantageous preconditions included atrophic maxillary bone and pronounced spongy bone quality, the patient should still have been informed beforehand about possible complications arising from such treatment and the necessity of frequent recall intervals.

Sensory deficits in the region of the inferior alveolar nerve are seen in 6% to 10% of implantation cases involving mandibular atrophy.⁹ An explanation citing violation of a 1-mm safety margin between the implant and the border of the mandibular canal as the reason for the frequency of such deficits was supported by the association, which was determined by diagnostic mistakes and the likelihood of occurrence of this sensory deficit. Incorrect measurements, insufficient ability to recognize the mandibular canal on radiographs because of incorrect settings, intraoperative mistakes in estimation of the height of the mandibular ridge above the canal following previous reduction of a pointed ridge, and excessive implantation depth in cases of spongy bone conditions were named as reasons for exceeding the mandibular canal level. The bases for measurement in all evaluated cases involving injury to adjacent anatomic structures were panoramic radiographs without the use of a radiopaque marker. In some patients, the course of the mandibular canal was not clearly distinguishable. To minimize the risk of nerve damage in the case of mandibular implants, the mandibular canal can be examined with a special panoramic radiography technique involving changing Frankfort horizontal by -5 degrees from the horizontal¹⁰ or by computed tomographic scans in exceptional cases.¹¹

A further significant correlation existed between neglect of the necessary preoperative treatment (eg, periodontal prophylaxis or prosthetic pretreatment prior to implant–prosthetic rehabilitation) and both

insufficient patient information regarding necessary follow-up treatment and poor oral hygiene status at the time of examination called for by the evaluation. These findings were significantly more frequent in smokers. This underscores the importance of the preventative aspect of patient information. At the time, patients must also be informed about their responsibility for oral hygiene and prophylaxis as measures necessary to maintain therapeutic success. This must also include the link between smoking and a poor prognosis for the implant. It is apparent that damage to microcirculation caused by nicotine abuse is a negative prognostic factor.¹²

The group of patients represented in this investigation may be highly selective; therefore a selection bias may not be excluded. Nonetheless, it is important to analyze those failures in patient selection, diagnosis, and treatment documented by expert opinions to draw the following conclusions. The results of this study underscore the importance of patient information before treatment begins and during the course of treatment. If complications arise, the patient should have been informed about their possibility and about further treatment options or changes in the planned treatment; such information may be essential for further cooperation of the patient. Today, despite progress in implant dentistry and various treatment options for implant placement in patients with anatomically disadvantageous preconditions, defensive behavior is called for—particularly in the critical estimation of one's own diagnostic and therapeutic abilities as a treatment provider, and of the infrastructure of the dental office.

Difficulties arise in the determination of the indication for treatment, as this requires compliance of the patient. At times, this cannot be judged until the patient has been involved in preparation for some time. Willingness of the patient to cooperate and the patient's effective informed consent to the planned treatment, which consists of knowledge and understanding of the necessary treatment, its possibilities and limitations, the possible complications

and risks involved, costs, and alternatives, form an important basis for the treatment relationship and require good communication between the doctor and patient. With respect to thorough patient information, compromise—for reasons of time or cost-effectiveness—should not be made.

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