The Burdens in Prosthetic Dentistry Questionnaire (BiPD-Q): Development and Validation of a Patient-Based Measure for Process-Related Quality of Care in Prosthetic Dentistry

Daniel R. Reissmann, DDS, Dr Med Dent[a]/Tim Hacker, DDS[b]/Daniel Farhan, DDS, Dr Med Dent[a]/Guido Heydecke, DDS, Dr Med Dent Habil[c]

Purpose: To develop and validate an instrument for the assessment of patient-based measures of process-related quality of care in prosthodontic patients. ***Materials and Methods:*** In this nonrandomized study, the new Burdens in Prosthetic Dentistry Questionnaire (BiPD-Q) was developed in two steps using a total of 128 prosthodontic patients in a mixed-method approach, combining quantitative-qualitative methodologies. First, the item pool for the instrument was created using semistructured interviews and a group of experts in prosthodontics. This resulted in a preliminary version of the questionnaire. Second, an assessment of redundancy, completion rates, face validity, difficulty, and distribution of the core set of the items was performed. The final version of the BiPD-Q had psychometric core properties (reliability and validity) evaluated. ***Results:*** The BiPD-Q consisted of 25 items. Reliability was satisfactory (Cronbach's alpha = .87). The mean score of all items of the BiPD-Q was significantly correlated with mean perceived burdens during treatment as rated by the clinician (r = 0.26; P < .01) and with overall satisfaction with the treatment procedures as rated by patients (r = .31; P < .01), indicating sufficient convergent validity. ***Conclusion:*** A reliable and valid instrument for the assessment of patient-based process-related quality of care in prosthodontics has been developed. The BiPD-Q allows comparisons of different dental procedures within a treatment course and of different treatment providers. The use of this type of questionnaire appears to be a valuable tool for dental health care research. The outcomes of research using the BiPD-Q may result in a more pleasant treatment experience for future patients. *Int J Prosthodont 2013;26:250–259. doi: 10.11607/ijp.3266*

Patient-based measures of quality of care in dental care have been of increasing scientific interest in the past three decades.[1–4] Such measures provide information regarding the patients' perspective of care and are considered an important component of the evaluation of treatment effects.[5,6] They are complementary subjective indicators for the impact of dental treatments to the traditional use of clinical oral health indicators and are important for the evaluation of dental treatments from a political, theoretical, and practical standpoint. Consequently, there is demand for including such measures in epidemiologic and clinical studies.

Quality of care can be defined in a widely accepted three-part model: outcomes-related, structure-related, and process-related.[7] A number of studies have investigated the effects of treatments on patient-based outcome measures in prosthodontics.[4,8] The impact of structural conditions and settings in which care is performed on patients' perceptions has also been investigated.[9,10] However, research on process-related quality of care in general is rare and has not yet been performed in the prosthodontic setting.[11,12]

Prosthodontic treatment requires multiple stages and is time consuming. Procedures such as anesthesia, tooth preparation, impressions, and the insertion

[a]*Assistant Professor, Department of Prosthetic Dentistry, University Medical Center Hamburg-Eppendorf, Hamburg, Germany.*
[b]*Postgraduate Student, Department of Prosthetic Dentistry, University Medical Center Hamburg-Eppendorf, Hamburg, Germany.*
[c]*Professor and Chair, Department of Prosthetic Dentistry, University Medical Center Hamburg-Eppendorf, Hamburg, Germany.*

Correspondence to: *Dr Daniel R. Reissmann, Department of Prosthetic Dentistry, University Medical Center Hamburg-Eppendorf, Martinistrasse 52, 20246 Hamburg, Germany. Fax: +49 7410 57077. Email: d.reissmann@uke.de*

of new restorations are likely to have a negative impact on patients' perception of their oral health and well-being. Therefore, it can be assumed that treatment process components are perceived as unpleasant by patients, even though treatment outcomes are beneficial for patients.[13–15] Since prosthodontic care covers a wide range of different treatment options, patients' perceived burdens due to the treatment process may vary. Measures of process-related quality of care would allow the assessment of the patients' perspective of the treatment procedures and may lead to a better understanding of individuals' perceptions of the various steps of treatment. Furthermore, different treatment options could be evaluated with respect to patients' burdens with the aim of providing the least unpleasant treatment procedures.

While measures for structure-related quality of care and outcomes of dental treatments are well established, the authors are not aware of validated instruments for patients' perception of the actual treatment procedures. Therefore, it was the aim of this study to develop and validate an instrument for the assessment of patient-based measures of process-related quality of care in prosthodontic patients.

Materials and Methods

Subjects and Setting

In this nonrandomized study, the new Burdens in Prosthetic Dentistry Questionnaire (BiPD-Q) was developed in two steps using a total of 128 subjects in a mixed-method approach with combined quantitative-qualitative methodology. Dental patients (subjects) aged 18 years or older with a need or demand for prosthodontic treatment and proficient in the German language were included. First, the item pool for the instrument was created using semistructured interviews and expert groups.[16] This resulted in a preliminary version of the questionnaire. The second step involved the assessment of redundancy, completion rates, face validity (the extent to which an item seems to measure the previously defined construct, ie, process-related quality of care), difficulty, and distribution (used range of the complete response scale) of the core set of items. Subsequently, the final version of the BiPD-Q was developed and psychometric core properties (reliability and validity) calculated. The study was conducted in a private dental practice in Hamburg, Germany.

The study protocol was reviewed and approved by the Institutional Review Board of the Medical Association in Hamburg, Germany (PV3302). All study subjects gave signed informed consent.

Defining the Construct

The theoretic definition of process-related quality of care is mainly based on the model of Donabedian.[7] Process-related quality in a medical context describes the care itself in all aspects of patients' and practitioners' activities and has to be clearly distinguished from structure-related and outcomes-related quality of care. Structure-related quality of care describes aspects of material and human resources as well as organizational structure. Outcomes-related quality is the effect of care on patients' health status. Quality of care indicators can be broadly defined as impartial or subjective. Quality of care assessments using impartial criteria focus on structural indicators such as facilities and clinical training of the staff, on process indicators such as complication rates, and on outcomes such as survival rates or mortality. The patient perspective is the complementary subjective indicator for quality of care and includes patient-based measures (eg, satisfaction, quality of life, pain, perceived burdens) for the assessment of the components of quality of care.

For prosthodontic treatments, components of patient-based process-related quality of care were defined as patients' perceptions of all parts of the dental treatment performed by clinicians or medical staff during a dental appointment (eg, tooth preparation, taking impressions). Patients' perceptions related to the dental practice (setting or structure) or to the results of the treatment (outcomes) were not considered relevant for process-related quality of care and excluded from development of the questionnaire.

Defining the Items

Prosthodontic treatment was structured into three main groups: fixed dental prostheses (FDPs), removable dental prostheses (RDPs), and complete dentures (CDs). These three groups were further divided into subgroups according to attaching structures. The expert group (TH, DR) subdivided the prosthodontic treatments into seven main steps.

To generate an item pool, semistructured qualitative face-to-face interviews were conducted in a consecutive sample of 19 subjects (mean age: 52 ± 3 years; 53% female) regarding perception of burdens, pain, discomfort, or satisfaction with respect to actual treatment procedures. Subjects were interviewed immediately after each preliminarily defined treatment step. To reduce the probability of response bias, qualitative information was collected independently from the treating clinician. The gathering process was stopped after 19 subjects, as no new topics or answers were retrieved.

Answers from the semistructured interviews were grouped according to the corresponding treatment steps. Consequently, the reduction of the item pool and definition of the core set of items for the preliminary version of the BiPD-Q was performed based on the equally weighted criteria redundancy and reference to prosthodontic treatment based on the ratings of an expert group.

Testing the Preliminary Version of the BiPD-Q

The preliminary version of the BiPD-Q was then applied in a sample of 109 consecutively recruited subjects (mean age: 52 ± 14 years; range: 20 to 86 years; 51% female) between August 2009 and June 2010. In five cases, the treatment could not be finished within the survey period. The corresponding data sets have been omitted from further analysis, resulting in 104 (95%) complete sets.

Responses for each item were assessed using a visual analog scale (VAS) ranging from 0 = no expression of the attribute (eg, no pain at all, not at all unpleasant, not at all burdensome) to 100 = maximum expression (eg, severe pain, very unpleasant, very burdensome).

The items of the BiPD-Q were grouped according to the treatment procedures within each dental appointment. The complete instrument consisted of several item subsets and was therefore modular. Patients received only the item subset that was designed for their performed treatment procedures. If there was more than one appointment for the same procedure, the identical item subset was administered again.

After each dental appointment, the treating clinician rated the self-perceived burdens during the treatment using an ordinal five-point response scale. Additionally, time of treatment was recorded. At the end of the complete treatment, patients were asked to rate their satisfaction with the treatment using a global question with a VAS ranging from 0 to 100.

The analyses of psychometric properties of the preliminary version of the BiPD-Q utilized data from different occasions of the same treatment procedures, which were aggregated. If treatment stages were repeated, corresponding data were collapsed using means of each item.

The preliminary version of the BiPD-Q involved the use of the classical test theory. The decision was based on the assumption that different treatment steps are additive components of the complete treatment rather than homogeneous and equivalent aspects. For example, a patient might perceive substantial burdens during one treatment step (eg, taking impressions) but not in others (eg, tooth preparation) that are not directly related to the burdening procedure.

Revision of the preliminary version of the BiPD-Q involved two steps. First, redundancy was assessed (Pearson correlation coefficients) for the pairwise correlation of the items. Items correlating higher than .70 were removed due to redundancy.

Second, psychometric properties of the resulting preliminary set of items were assessed, and a final item set selected based on these properties. The members of the expert group determined face validity of the preliminary item set. The rating of face validity, ie, to what extent does the item measure process-related quality of care in prosthodontic treatments, involved one of three judgments: optimal, fair, and poor. Consensus between raters was achieved by discussion. Acceptance was assessed by computing completion rates for each single item and by evaluating the comments of the patients regarding the wording and understanding of the items. Measures of discrimination (item-rest correlation), difficulty (mean), and distribution (range) were computed.

Items for the final version of the BiPD-Q were selected by three authors (TH, DR, DF) using the above-defined equally weighted criteria (face validity, acceptance, difficulty, discrimination, and distribution).

Assessment of Psychometric Properties of the Final Version

Measures of reliability and validity of the final version of the BiPD-Q were assessed using the data of the initial sample of 104 prosthodontic patients.

Reliability was assessed using Cronbach's alpha as a measure of internal consistency of the complete item set of the final version of the BiPD-Q.[17] Reliability coefficient has been compared and judged according to guidelines.[18]

Validity was assessed using analyses of convergent validity. Pearson correlation coefficients were calculated for the correlation of the mean scores of the questionnaire with the clinician's perceived burdens and the global questions regarding patients' satisfaction with the complete treatment. It was hypothesized that patients' ratings of burdens during treatment should be substantially correlated to *(1)* clinicians' perceived burdens and to *(2)* the global satisfaction score.

An additional sensitivity analysis was performed determining reliability and validity in a more homogeneous subgroup of the prosthodontic patients receiving only an FDP (n = 90) and comparing these values with the findings in the complete study population.

All statistical analyses were performed using STATA 12 software (StataCorp) with a probability of a type-1-error set at a .05 level.

Table 1 Treatment Characteristics for All Patients Stratified by Sex and Age*

		Sex (according to age)		Age	
	Total (n = 104)	Men (n = 52)	Women (n = 52)	20 to 52 y (n = 55)	> 52 y (n = 49)
Location					
Maxilla only	56 (53.8%)	27 (51.9%)	29 (55.8%)	31 (56.4%)	25 (51.0%)
Mandible only	32 (30.8%)	16 (30.8%)	16 (30.8%)	17 (30.9%)	15 (30.6%)
Both arches	16 (15.4%)	9 (17.3%)	7 (13.5%)	7 (12.7%)	9 (18.4%)
Type of treatment					
FDP	90 (86.5%)	46 (88.5%)	44 (84.6%)	52 (94.5%)	38 (77.6%)
RDP	10 (9.6%)	5 (9.6%)	5 (9.6%)	2 (3.6%)	8 (16.3%)
CD	4 (3.8%)	1 (1.9%)	3 (5.8%)	1 (1.8%)	3 (6.1%)
Abutments (mean ± SD)	3.1 ± 3.4	3.2 ± 3.8	2.9 ± 2.9	2.8 ± 3.0	3.3 ± 3.8

FDP = fixed dental prosthesis; RDP = removable dental prosthesis; CD = complete denture.
*Values do not add up to 100% due to rounding.

Language Adaption

The final version of the BiPD-Q has been translated using a forward-backward approach. A German native speaker (GH) with excellent English language skills, who was blinded to the development process, performed the translation of the BiPD-Q from German to English. Afterwards, a backward translation of an English native speaker (SS) was performed. The authors compared both German-language versions of the BiPD-Q. The English-language version was adapted until both German-language versions were congruent; therefore, the accuracy of the translation process could be confirmed. However, only the German language version has been tested in our sample of prosthodontic patients.

Results

Treatment characteristics

Fifty-six subjects were treated only in the maxilla (54%; Table 1), while 32 received new prosthodontic restorations only in the mandible (31%) and 16 patients (15%) were treated in both arches with neither substantial nor statistically significant differences with respect to sex or age (all chi-square: $P > .05$; Table 1). The majority of subjects received an FDP (n = 90, 87%). Only 4 subjects (4%) were provided with a CD. While patterns of types of prosthodontic restorations were not significantly different between sexes (Fisher exact: $P > .05$), age groups differed statistically significantly (Fisher exact: $P < .05$), with more subjects receiving an RDP or CD that were older than 52 years of age (Table 1).

On average, 3.1 (standard deviation [SD] ± 3.4) teeth or implants per patient were incorporated into the prosthodontic treatment. Complete treatment lasted an average of 135 (SD ± 108) minutes. Number of consultations for complete treatments ranged from three to eight (mean ± SD, 3.9 ± 1.2). Mean costs for treatments according to the private scale of fees for clinicians in Germany (GOZ 1988) with an identical factor (2.3) for all patients and treatment steps (minus laboratory costs) were 897 EUR (SD ± 894 EUR; range: 220 to 6512 EUR).

Item Pool

Subjects were asked about their experiences during the previous treatment procedures, which elicited 188 answers (the complete dataset is available from the corresponding author). Most frequently mentioned were: pain during placement of cords for impressions followed by discomfort during tooth preparation and discomfort due to taste, smell, and consistency of the impression material. This resulted in the operationalization of patient-based process-related quality of care using patients' reports of perceived burdens and unpleasantness. According to this operationalization, low ratings for perceived burdens and unpleasantness correspond to high quality of care.

Answers that were not directly related to the prosthodontic treatment (eg, implant treatment in an oral surgery practice) or those that were redundant were eliminated. All but seven of the remaining items could be allocated to one of the seven previously defined treatment steps. The seven remaining items captured the treatment as a whole. Therefore, an eighth part of the questionnaire was designed based on the seven items for a global assessment of the perception of the treatment (Table 2).

Table 2 Characteristics of Core Item Set and Final Subset* of the BiPD-Q

No.	Item	Face validity	Acceptance (%)	Difficulty (mean)	Distribution (range)	Discrimination (item–rest correlation)
Information						
1.1	Consultation time	C	98.1	9.8	0–58	0.43
1.2	Explanation of treatment	C	98.1	8.9	0–64	0.44
1.3	Explanation of alternatives†					
1.4	Provision of complete and thorough information	C	98.1	8.4	0–62	0.34
1.5	All questions answered	C	98.1	8.1	0–60	0.29
1.6	Burden consultation/information	A	97.1	12.7	0–100	0.21
Anesthesia						
2.1	Fear of anesthesia	C	86.5	22.7	0–100	0.45
2.2	Painful injection†					
2.3	Painful anesthesia	A	86.5	26.6	0–100	0.58
2.4	Absence of pain	B	86.5	15.0	0–100	0.19
2.5	Level of anesthesia	B	86.5	15.5	0–79	0.33
2.6	Unpleasant numbness	A	86.5	41.5	0–95	0.57
Tooth preparation						
3.1	Preparatory process	A	86.5	30.4	0–100	0.50
3.2	Length of time mouth was opened	A	86.5	40.1	0–99	0.55
3.3	Gagging feeling due to water	A	85.6	23.9	0–93	0.56
3.4	Comfort of the corner of the mouth	A	86.5	26.8	0–98	0.41
3.5	Feeling of the aspirator	A	86.5	15.5	0–86	0.45
Impression						
4.1	Placement of retraction cord	A	86.5	24.3	0–100	0.41
4.2	Pressure from the impression	A	100.0	27.3	0–100	0.51
4.3	Consistency of the impression material	B	100.0	24.7	0–100	0.47
4.4	Smell of the impression material†					
4.5	Taste of the impression material	A	100.0	23.4	0–99	0.53
4.6	Duration of the impression	B	100.0	31.9	0–100	0.16
4.7	Pain during the impression	A	100.0	6.7	0–50	0.36
4.8	Urge to gag during the impression	A	100.0	16.8	0–100	0.34
4.9	Mouth opening during the impression	A	100.0	33.4	0–100	0.47
4.10	Removal of the impression	A	99.0	25.9	0–96	0.49
4.11	Comfort of facebow in the ear	B	94.2	31.9	0–100	0.25
4.12	Comfort of facebow at the glabella	B	93.3	22.0	0–100	0.26
4.13	Duration of facebow measurement	B	93.3	15.4	0–83	0.38
4.14	Burden of facebow measurement	A	94.2	15.1	0–100	0.20
Provisional care						
5.1	Construction of provisional	A	90.4	21.6	0–100	0.25
5.2	Handling of provisional	C	90.4	17.8	0–100	0.06
5.3	Functional limitation due to provisional†					
5.4	Ability to chew with provisional	C	90.4	26.7	0–100	0.22
5.5	Fear during use of provisional	C	90.4	29.2	0–100	0.24
Try-in						
6.1	Removal of provisional	A	96.2	20.6	0–95	0.23
6.2	Try-in of definitive prosthesis	A	99.0	20.6	0–84	0.46
Cementation						
7.1	Drying before placement of definitive prosthesis	A	91.3	24.0	0–100	0.38
7.2	Placement of definitive prosthesis	A	100.0	22.3	0–100	0.43
7.3	Pain during placement†					
7.4	Removal of excess cement	B	94.2	18.3	0–95	0.48
Global treatment						
8.1	Information during treatment	B	100.0	12.8	0–98	0.17
8.2	Total time needed for treatment	B	100.0	35.6	0–100	0.37
8.3	Time spent in dental chair	A	100.0	12.7	0–92	0.36
8.4	Swelling of cheek	B	98.1	10.9	0–100	0.27
8.5	Functional limitation due to swelling of cheek†					
8.6	Adherence to announced treatment time	C	97.1	12.9	0–91	0.32
8.7	Burden of treatment	A	99.0	16.1	0–89	0.31

A = optimal; B = fair; C = poor.
*Shaded background indicates final subset.
†Omitted due to redundancy ($r > .70$).

Table 3 German- and English-Language Versions of the BiPD-Q

	German		English	
No.	Item	Response	Item	Response
1	Wie belastend empfanden Sie die Aufklärung?	Überhaupt nicht belastend–sehr belastend	How burdensome did you perceive the explanation of the procedures?	Not at all burdensome–very burdensome
2	Wie empfanden Sie den Einstich der Spritze?	Überhaupt nicht unangenehm–sehr unangenehm	How did you feel about the injection of local anesthetic?	Not at all unpleasant–very unpleasant
3	Hatten Sie nach der Betäubung ein unangenehmes Taubheitsgefühl?	Überhaupt nicht unangenehm–sehr unangenehm	Did you have an unpleasant numbness after anesthesia?	Not at all unpleasant–very unpleasant
4	Hat sich das Beschleifen des/r Zahnes/Zähne unangenehm angefühlt?	Überhaupt nicht unangenehm–sehr unangenehm	Did the drilling of your teeth/tooth feel unpleasant?	Not at all unpleasant–very unpleasant
5	Empfanden Sie das lange Offenhalten des Mundes als anstrengend?	Überhaupt nicht anstrengend–sehr anstrengend	Did you find keeping your mouth open tiring?	Not at all tiring–very tiring
6	Hatten Sie das Gefühl, sich am Kühlwasser und/oder Speichel zu verschlucken?	Überhaupt nicht unangenehm–sehr unangenehm	Did you feel you needed to swallow because of the amount of water spray and saliva in your mouth during the procedure?	Not at all unpleasant–very unpleasant
7	Empfanden Sie während oder nach der Behandlung ein unangenehmes Gefühl im Mundwinkel?	Überhaupt nicht unangenehm–sehr unangenehm	Did you experience an unpleasant feeling in the corner of your mouth during or after treatment?	Not at all unpleasant–very unpleasant
8	Empfanden Sie durch den Sauger ein unangenehmes Gefühl im Mund?	Überhaupt nicht unangenehm–sehr unangenehm	Did you experience an unpleasant feeling with the aspirator in your mouth?	Not at all unpleasant–very unpleasant
9	Wie empfanden Sie das Einlegen des Fadens um die beschliffenen Zähne?	Überhaupt nicht unangenehm–sehr unangenehm	How did you feel when the gingival retraction cord was placed around your teeth?	Not at all unpleasant–very unpleasant
10	Spürten Sie beim Einbringen der Abformung in den Mund einen unangenehmen Druck?	Überhaupt kein starker Druck–sehr starker Druck	Did you feel any unpleasant pressure as the impression trays were placed in your mouth?	Not at all unpleasant–very unpleasant
11	Wie empfanden Sie den Geschmack des Abformmaterials?	Überhaupt nicht unangenehm–sehr unangenehm	How did you feel the taste of the impression material?	Not at all unpleasant–very unpleasant
12	Hat die Abformung bei Ihnen Schmerzen verursacht?	Überhaupt keine Schmerzen–sehr starke Schmerzen	Was the impression painful?	No pain at all–severe pain
13	Hatten Sie einen Würgereiz während oder bei Entfernung der Abformung?	Überhaupt kein Würgereiz–sehr starker Würgereiz	Did you feel like gagging during or after the impression procedure?	No gag reflex at all–very strong gag reflex
14	Empfanden Sie das lange Offenhalten des Mundes als unangenehm?	Überhaupt nicht unangenehm–sehr unangenehm	Did you find keeping your mouth open unpleasant?	Not at all unpleasant–very unpleasant
15	Wie empfanden Sie die Entnahme des Abdrucks aus dem Mund?	Überhaupt nicht unangenehm–sehr unangenehm	How did you feel when the impression was removed from your mouth?	Not at all unpleasant–very unpleasant
16	Wie empfanden Sie das Einsetzen des Provisoriums?	Überhaupt nicht unangenehm–sehr unangenehm	How did you feel when the provisional/s was/were placed?	Not at all unpleasant–very unpleasant
17	Wie empfanden Sie das Entfernen des Provisoriums?	Überhaupt nicht unangenehm–sehr unangenehm	How did you feel when the provisional/s was/were removed?	Not at all unpleasant–very unpleasant
18	Wie empfanden Sie die Einprobe des (fertig gestellten) Zahnersatzes?	Überhaupt nicht unangenehm–sehr unangenehm	How did you feel when your final prosthesis was fitted?	Not at all unpleasant–very unpleasant
19	Wie haben Sie die Trocknung des Zahnes vor dem Einsetzen empfunden?	Überhaupt nicht unangenehm–sehr unangenehm	How did you feel when the tooth was dried before insertion of the final prostheses?	Not at all unpleasant–very unpleasant
20	Wie empfanden Sie das Einsetzen des fertig gestellten Zahnersatzes?	Überhaupt nicht unangenehm–sehr unangenehm	How did you feel when the final prostheses were inserted?	Not at all unpleasant–very unpleasant
21	Wie empfanden Sie das Entfernen von Zementresten nach dem Zementieren?	Überhaupt nicht unangenehm–sehr unangenehm	How did you feel when the excess cement was removed after cementation?	Not at all unpleasant–very unpleasant
22	Wie empfanden Sie den Zeitaufwand der Behandlung insgesamt?	Überhaupt kein hoher Zeitaufwand–sehr hoher Zeitaufwand	How did you feel about the amount of time involved with the treatment?	Not at all time consuming–very time consuming
23	Empfanden Sie das lange Liegen auf dem Behandlungsstuhl als unangenehm?	Überhaupt nicht unangenehm–sehr unangenehm	Did you feel the amount of time you were in the dental chair as unpleasant?	Not at all unpleasant–very unpleasant
24	War während oder nach Ihrer Behandlung Ihre Wange unangenehm geschwollen?	Überhaupt nicht unangenehm–sehr unangenehm	Did your cheeks swell or were in any discomfort during or after treatment?	Not at all unpleasant–very unpleasant
25	Wie belastend fanden Sie insgesamt die Behandlung?	Überhaupt nicht belastend–sehr belastend	How burdensome was the overall treatment?	Not at all burdensome–very burdensome

Preliminary Version of the BiPD-Q

The preliminary questionnaire comprised a set of 49 items (Table 2). Due to inter-item correlation coefficients higher than 0.70, six items were dropped. Completion rates of the remaining 43 items of the preliminary questionnaire were high and ranged from 79.8% to 100% (Table 2). Response ranges were distributed between 0 to 50 and 0 to 100, and means ranged from 6.7 to 41.5. Item-rest correlation differed substantially between items (.06 to .58). More than half of the items were rated as having optimal (A) face validity, while 11 items showed fair (B), and 9 items poor (C) face validity (Table 2). Based on the findings of these equally weighted criteria, the final set of items was selected.

Final Version of the BiPD-Q

The final BiPD-Q consisted of 25 items with at least one item of each predefined treatment step (shaded background in Table 2). The complete items of the German- and the English-language version can be seen in Table 3.

Reliability of the BiPD-Q assembled from the selected items was satisfactory (Cronbach's alpha = .87). The mean score of all items of the BiPD-Q was significantly correlated with mean perceived burdens during treatment rated by the clinician (r = .26; P < .01) and with overall satisfaction with the treatment procedures rated by the patients (r = .31; P < .01), indicating sufficient convergent validity.

Results of sensitivity analysis of reliability (Cronbach's alpha = .88) and validity (clinician's burdens: r = .23, P < .05; patients' global satisfaction: r = .29, P < .01) in the subgroup of patients with only an FDP were comparable with the findings in the complete study population.

Discussion

A reliable and valid instrument for the assessment of patients' perspectives of prosthodontic treatment procedures was developed. The BiPD-Q includes the relevant aspects of patient perceptions during all stages of several kinds of treatments. Applying the BiPD-Q will allow for a deeper insight into how patients perceive treatment procedures and will result in a patient-based measure of process-related quality of care in prosthodontics.

The creation of the BiPD-Q was performed in several steps in accordance with recommendations for the development and use of health measurement scales.[16] Since the authors were interested in aspects of prosthodontic treatment that are relevant and perceived as a burden by patients, the target population (prosthodontic patients) was included in the creation of the initial item pool for the instrument.

The Scientific Advisory Committee of the Medical Outcome Trust has defined eight criteria for patient-reported outcome measures.[19] These criteria (conceptual and measurement model, reliability, validity, responsiveness, interpretability, respondent and administrative burden, alternative forms, cultural and language adaptions/translations) can also be applied to the newly developed BiPD-Q assessing patients' perceptions of prosthodontic treatment procedures. As no definition of process-related quality of care in prosthodontics was available in the literature, a conceptual framework and a measurement model were initially established. The construct of interest that provided the theoretic basis for the selection of the content of the BiPD-Q was predefined.

Internal consistency was chosen as a measure for reliability of the instrument. Although internal consistency (Cronbach's alpha = .87) was satisfactory, supporting the assumption of a single construct, it was lower compared to other patient-reported measures in the target population, eg, the 49-item Oral Health Impact Profile for the assessment for oral health–related quality of life (Cronbach's alpha = .95),[20] or in other clinical populations, such as the 9-item Shared Decision Making Questionnaire for the assessment of patient involvement in medical decision making (Cronbach's alpha = .94).[21] Item-rest correlations of the selected items ranged from .21 to .58 in the preliminary version of the BiPD-Q. This indicates that the measured construct of process-related quality of care is rather broad. This is not surprising since the BiPD-Q included different aspects of treatment procedures and perceptions (eg, pain, numbness, mouth opening, urge to gag). The possibility that the construct of process-related quality of care in prosthodontics is multidimensional cannot be excluded since a factor analysis was not performed due to limited sample size. Furthermore, test-retest reliability was not assessed. Patients were asked to complete the part of the questionnaire corresponding to the actual performed treatment procedures immediately after the treatment was finished. This approach ensured that patients could directly report their perceptions and limited the effect of memory bias. However, future research is necessary to study whether retest effects in the assessment of process-related quality of care in prosthodontics exist.

Third, validity of the single items and the complete scale of the BiPD-Q was assessed. Three investigators rated each item of the preliminary version of

the BiPD-Q regarding face validity. Only items with fair or optimal face validity were chosen for the final version. Items with poor face validity were removed. Convergent validity of the complete scales has been assessed as the correlation of the instrument's mean score with two external criteria: the patients' general satisfaction with the treatment and the clinicians' mean burdens during treatment. Both correlation coefficients were substantial and of comparable magnitude (r = .26 and r = .31). This translates to less than 10% explained variance of patients' global ratings of satisfaction and clinicians' ratings of perceived burdens by the instrument's score (or vice versa, respectively). Higher correlations were not expected since general satisfaction with the treatment procedures might be affected by satisfaction with treatment outcomes and clinicians' burdens do not have to be strongly related to patients' burdens and perceptions. It has to be assumed that a patient's global satisfaction rating not only referred to the content of the authors' definition of process-related quality of care but also to the setting and the structure of the dental practice, the social interaction with the clinician and staff, and to the result of the treatment. Furthermore, it is not very likely that burdens perceived by the clinician are highly correlated with the patients' perception. A patient's pain will probably not result in high burdens for the clinician but will be perceived by the patient as (highly) unpleasant. However, patient's pain might increase treatment time and result in slightly more difficulties for the clinician during treatment and thus, a small but significant correlation is plausible. Therefore, the relationship of the BiPD-Q's means with global measures of the patient's and the clinician's perspective is a strong indicator for the validity of the instrument. Limited sample size in some treatment subgroups (eg, only four subjects received new CDs) prevented analyses from being performed in those subgroups.

Responsiveness of the BiPD-Q could not be investigated since treatment procedures were not changed or compared due to a very heterogeneous study population. This warrants further studies into the responsiveness of the instrument for competing treatment options. The authors believe that several competing options are available and testable in specific clinical situations (eg, FDP vs RDP in shortened dental arches or single implant-supported FDP vs conventional tooth-supported FDP), and more options may be relevant in the future.

Another criterion, interpretability, was fulfilled. Negative emotions (eg, pain, unpleasantness) were consistently applied for responses to the perception of the different treatment procedures. All of these perceptions can be summarized as burdening for patients. Therefore, the BiPD-Q's mean can be easily interpreted as patients' reports of burdens during prosthodontic treatments.

As the final BiPD-Q is quite short, respondent and administrative burdens are low, and as alternative forms do not exist yet, it is not clear whether mode of administration (paper based, face-to-face interview) may affect results. However, in accordance with research results of the effect of administration mode on quality of life measures, the authors believe that different methods of administration will not substantially change results.[22] During development, the instrument consisted of several parts, each for a single particular treatment procedure that is usually combined in a dental appointment. These parts were administered immediately after the particular appointment. While the authors are satisfied that this approach was reasonable during instrument development, it might have some practical limitations in studies applying the final BiPD-Q. Although administration of the complete scale of the BiPD-Q has not been tested as a whole yet, application of the complete BiPD-Q is recommended once prosthodontic treatment has been completed.

A language adaption was performed by translating the German-language version into English. Although the chosen forward-backward approach could confirm the accuracy of the translation process and, therefore, the English-language version of the BiPD-Q, the translated version was not administered. However, the authors believe that the content of the BiPD-Q is neither sensitive to cultural impacts nor to the wording of the items. Hence, it can be assumed that application of the English-language version would result in similar results as the German version applied in this study.

To the authors' knowledge, there is no other measure for process-related quality of care in dentistry available. However, measures for patient perceptions have already been developed for other medical settings, eg, a measure of patients' perception of rational empathy in general clinical settings[23] or a measure of patients' experience of cancer care coordination.[24] Both measures have been developed in a similar manner compared to the approach applied here. However, the number of items of the BiPD-Q (n = 25) is slightly higher than measure for cancer care coordination (n = 20) and substantially higher than the measure for empathy in primary care (n = 10). This is not surprising since definitions of the constructs of interest vary substantially between the measures. Patient-based quality of care in prosthodontics is a wide construct, whereas rational empathy in consultation is a rather narrow one. Corresponding to that, internal

consistency of the BiPD-Q (Cronach's alpha = .87) was comparable to the measure of cancer care coordination (Cronach's alpha = .88) and lower compared to the measure of empathy (Cronbach's alpha = .92).

Due to limited sample size, the study's patients could not be divided into a development and a test sample. Therefore, the assessment of reliability (internal consistency) and convergent validity (correlation with external criterion) of the BiPD-Q has been performed in the same sample as the development of the questionnaire. However, since the selection of the items was not based on the measure of internal consistency and correlation with the external criterion, the present approach was appropriate to develop and to test the BiPD-Q. The authors believe that two different samples for development and testing of the questionnaire would not have yielded a different set of items or substantially different measures of psychometric properties.

The study was conducted in a private practice and not in a university setting. Creating a measurement tool in a scientific treatment area might create extensive bias because treatment time is often longer and the socioeconomic status of patients is not as broadly distributed as in a private practice. Hence, the results might be slightly different if the BiPD-Q had been developed in a university setting.

Interaction between patients and treatment provider or staff might be important for the perceptions and ratings of the patients. It was previously reported that satisfaction with treatment outcome is related to the communication behavior of clinicians.[25] Although it is not known whether and how patient-clinician communication affects patients' perceptions during dental treatments, this source of variance was reduced by having only one treating dentist in the study.

Although semistructured interviews were performed with prosthodontic patients until no new information could be gathered, some aspects of prosthodontic treatment may have been missed. Patients enrolled in testing the preliminary instrument were also given the option to point out missing aspects of treatment or problems in understanding questions at the end of each questionnaire. This option did not result in any new information from the larger sample of 109 patients. It should be noted that during the course of the study, not a single patient was provided with a cast clasp-retained RDP. However, as treatment procedures are quite similar for different kinds of prosthodontic devices, the BiPD-Q captures perceptions most relevant for patients.

Considering all strengths and limitations of this study, it can be concluded that a reliable and valid instrument for the assessment of patient-based process-related quality of care in prosthodontics has been developed. The BiPD-Q not only provides a deeper insight into patients' perceptions during several steps of prosthodontic treatments, but also allows comparisons of different dental procedures within treatments and of different treatment providers. Thus, it represents a valuable tool for dental health care research and may result in a more positive dental experience for patients in the future.

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Literature Abstract

Effect of treatment with fixed and removable dental prostheses. An oral health–related quality of life study

This study aims to evaluate the effects of fixed dental prostheses (FDP) treatment compared with removable dental prostheses (RDP) treatment as reported by patients. This study also relates the change in Oral Health–Related Quality of Life (OHRQoL) to the treatment type and objective dental variables (esthetics and mastication) as well as identifies aspects of impairment and improvement that the treatments bring about. Details such as sex, age, region of replacement, and number of teeth present and replaced were noted and the participants completed the Oral Health Impact Profile 49 (OHIP-49) before and after treatment. There were 200 patients who received FDP treatment and 107 who received RDP treatment. A control group, which had no need for dental treatment, also completed the OHIP-49. Although all participants had a significant improvement in OHRQoL, the improvement was higher for the RDP group than the FDP group. There was no significant improvement of the OHRQoL for RDP that replaced only masticatory teeth. The improvement in OHRQoL for both the treatment groups was not at the level of the control group. Increased age was associated with lower improvement in OHRQoL. Decline in OHRQoL was related to factors such as increased age, being a woman, and teeth replacement in the esthetic zone. RDP treatment was associated with new problems caused by the treatment. Although both FDP and RDP treatments improved OHRQoL and reduced the number of problems, the RDP participants showed more marked improvement.

Özhayat EB, Gotfredsen K. *J Oral Rehabil* 2012;39:28–36. **Reprints:** Esben Boeskov Ozhayat, Department of Oral Rehabilitation, Institute of Odontology, Faculty of Health Science, University of Copenhagen, Nørre Alle 20, 2200 Copenhagen N, Denmark. Email: eboz@sund.ku.dk—*Sapphire Gan, Singapore*