Community Dent Oral Epidemiol

Community Dentistry and Oral Epidemiology

Development of a specific indicator of the well-being of wearers of removable dentures

Javier Montero[1], Manuel Bravo[2] and Antonio López-Valverde[3]

[1]Faculty of Medicine, University of Salamanca, Campus Miguel de Unamuno, Salamanca, Spain, [2]Graduate in Medicine, Professor of Preventive and Community Dentistry, University of Granada, Faculty of Odontology, Campus de Cartuja, Granada, Spain, [3]Graduate in Medicine, Associate professor of Periodontology, University of Salamanca, Campus Miguel de Unamuno, Salamanca, Spain

Montero J, Bravo M, López-Valverde A. Development of a specific indicator of the well-being of wearers of removable dentures. Community Dent Oral Epidemiol 2011. © 2011 John Wiley & Sons A/S

Abstract – *Objectives:* Bearers of removable prostheses have certain particular characteristics that require the inclusion of items able to detect the specific effect on their oral functions (derived from the presence of such prostheses). We aimed to develop and validate a specific indicator for the assessment of oral health–related quality of life in bearers of dentures. *Methods:* A panel of experts compiled a questionnaire addressing oral health–related quality of life (11 items) to assess the degree of well-being afforded by removable dentures. After a pilot trial in patients bearing prostheses (n = 36), a consecutive sampling of denture wearers (n = 123) was conducted among patients not requesting odontological treatment and accompanying persons, attending their respective health centres in the City of Granada and its metropolitan area. The subjects were classified as RPP1 (removable partial prosthesis on one of the arches, RPP2 (on both) and complete prosthesis (CP on both arches). *Results:* The questionnaire was consistent (Cronbach alpha 0.814) and proved to have suitable validity. Factor analysis revealed three factors termed physical, psychological and social well-being, which coherently supported the interrelationship among the 11 items. The prevalence of impact was significantly higher in the CP individuals (97.1%) and in that of the RPP2 group (92.1%) than in the RPP1 subjects (80.7%). Prosthetic fit, aesthetics and self-confidence were significantly discrepant among the prosthetic groups, although the total prosthetic quality of life score was not able to differentiate them. The main prosthetic impact in all the prosthesis-wearing groups was attributed to 'food impaction', although all the groups were essentially satisfied with their mouth. *Conclusions:* The prosthetic quality of life (PQL) questionnaire is a valid and reliable indicator of the specific well-being of partial or complete denture wearers.

Key words: Oral health-related quality of life; dentures

Prof. Montero, Clínica Odontológica de la Facultad de Medicina de la Universidad de Salamanca, C/Alfonso X, el sabio S/N; Campus de Unamuno. 37007. Salamanca, Spain
Tel.: 619429971 0034
Fax: 923188716 0034
e-mail: javimont@usal.es

Submitted 31 May 2010;
accepted 18 April 2011

Traditionally, the criteria used in prosthodontics have been based on the success/failure of treatment according to standardized clinical parameters, both macro- (fit, attachment, retention, stability, occlusal plane, etc.) and microscopic (marginal discrepancy, occlusal fit, etc.), and even intangible criteria (centric relation, passive fit, distribution of forces, etc.). However, there have been few assessments of patient perceptions about chewing capacity, comfort, aesthetics, self-confidence or 'foreign body' sensation, which in the long run represent the benefits of treatment to health and quality of life.

Oral health–related quality of life (OHQL) has been described as a multidimensional concept that refers to the physical, psychological and social well-being afforded by people's mouths in their daily activities (1). Two decades ago, it was suggested that oral pathology had a greater impact on people's quality of life than had previously been suspected (2, 3). Several authors focused their attention on developing generic indicators that would be able to reveal the impact of oral status on daily life (4). However, bearers of removable prostheses have certain particular characteristics that require the inclusion of certain items able to

doi: 10.1111/j.1600-0528.2011.00620.x

detect the specific effect on their oral functions (derived from the presence of such prostheses). Recently, a specific questionnaire for the assessment of the oral health–related quality of life of edentate patients has been published (5), although this instrument mainly focuses on the impact reported by patients wearing complete dentures or implant overdentures, and has only been applied to partial edentate individuals rarely (6) Moreover, some researchers have found that the impact in partially edentulous subjects is significantly different from the situation in totally edentate people (7), mainly in the domains of functional limitation, pain and psychological discomfort. Thus, it seems necessary to have a specific questionnaire able to capture the general impact of removable prosthesis but also the specific impact to which partial dentures wearers are subject. In this sense, other workers have reported the results of a questionnaire for bearers of partial removable prostheses (8), although that questionnaire has not been evaluated in terms of validity and neither has the factor structure underlying the prosthetic quality of life (PQL) construct been described. The aim of the present study was thus to develop and validate a specific indicator for assessing the oral health–related quality of life in patients bearing totally or partially removable prostheses.

Material and methods

Development of the prosthetic quality of life questionnaire (PQL)

A panel of University experts formed by three specialists in dental prosthodontics and two investigators of OHQL selected the relevant domains of the OHQL in patients bearing removable prostheses, on one hand based on studies assessing the OHQL of patients with prostheses (8–11) and on the other on the dimensions referred to by 44 patients treated at the School of Dentistry of the University of Granada, who participated in an in-depth face-to-face interviews about the areas of oral well-being affected by the presence of a prosthesis. The panel of experts selected and summarized the most prevalent or severe issues regarding PQL, finally deciding on an 11-item questionnaire (See Annexe to consult the answering options of the different PQL questions). This instrument was primarily formatted to have descriptive properties because its primary validation was to be carried out on nondental patients. However, the instrument could be easily adaptable to a global transition scale format (i.e. patients may be asked: do you think that the following activities/functions have improved, worsened or remained the same after the prosthetic treatment?) to assess the evaluative properties in future research.

Before the start of the main study, a pilot trial was conducted on 36 individuals bearing dental prostheses from the same reference population (patients treated at the School of Dentistry) to empirically check the face and content validity. The comprehensiveness of the pilot PQL was tested by detecting and asking specific questions on difficulties in understanding items, scales or the content of the dimensions to improve the intelligibility of the instrument when necessary and optimize the face and content validity for the main study.

The resulting 11 items were designated thus: prosthetic fit, chewing, sensation of foreign body in mouth, aesthetics, communication, realism of the prosthesis, unnoticeability of the prosthesis, hygiene, food impaction, functional comfort and self-confidence (see annexe). The 11-item PQL questionnaire was designed to be self-completed intuitively as the responses to the items were expressed in a Likert-scale format (from −2 to +2), with a coding proportional to the degree of impact. The items evaluated as <0 on the Likert scale were considered as having impact, while values of +1 and +2 represented the positive side of each item. The total score was the sum of the different item scores; hence, negative and positive impacts contributed to the total score in the opposite way. This additive scoring methods seem to be conceptually feasible.

Data acquisition

As well as the PQL, the subjects evaluated their oral satisfaction on an analogical scale from 0 to 10 [oral satisfaction scale (OSS)] and completed two generic questionnaires about their OHQL, the OIDP and the OHIP-14, which had been validated previously in the same reference population and described in-depth elsewhere (12, 13). The OIDP and OHIP assess the impact of oral conditions on the quality of life using either a severity or a frequency estimation of the disruption in daily activities, respectively. From the clinical point of view, the subjects were examined by a single investigator (JM) calibrated with the diagnostic methodology published by the World Health Organization (14) to capture the clinical modulat-

ing factors of prosthetic well-being. Social class was categorized as high (=5), medium-high (=4), medium (=3), medium-low (=2) or low (=1), based on the last occupation of the head of household.

Study sample

A total of 123 subjects bearing dentures were included in the main study, which was conducted in Granada (Spain) in 2005. The subjects were selected consecutively from patients and accompanying persons attending four randomly selected health centres within the Health District of the City of Granada and its metropolitan area. In order not to contaminate the impact on the PQL, the inclusion criteria were being older than 18 years, bearing a removable prosthesis and not requesting any type of odontological treatment. All subjects received detailed information about the nature of the study and filled in a written consent form for clinical exploration and for the questionnaires, which were performed at the health centres themselves. The subjects were classified as follows: RPP1 (removable partial prosthesis on one of the arches; RPP2 (RPP on both) and complete prosthesis (CP on both arches).

Data analysis

To probe the psychometric properties of the PQL questionnaire, the methodological guidelines reported by Streiner and Norman (15) were followed. Reliability was assessed using the Cronbach alpha value and inter-item and item-total correlation analyses.

The Kolmogorov–Smirnov test assumed a normal distribution of PQL total scores ($P = 0.12$). Thus, the criterion validity of the PQL was evaluated using Pearson correlation coefficients with the score obtained on the generic questionnaires (OIDP and OHIP-14), because both these instruments are designed to quantify oral well-being. Construct validity was studied using subjective criteria potentially related to oral well-being (perceived need of treatment, complaints about the mouth, self-reported oral satisfaction) to create groups in which the total scores of the PQL questionnaire were compared using parametric tests (Student's t test and ANOVA test). The factors modulating prosthetic well-being were evaluated using Pearson correlation coefficients. The ANOVA test was used to compare the scores of the items between the prosthodontic groups, and the chi-squared test was employed to compare the proportion of patients with impact. For the factor analysis, the sphericity test of Bartlett and that Kaiser–Meyer–Olkin (KMO) test were used as a preliminary method for the detection of a factor structure. Following this, a principal component analysis (PCA) with varimax rotation was undertaken to extract the underlying dimensions of the prosthetic construct. Items were assigned to the rotated factors when they had a loading of 0.4 or greater on a single factor.

All analyses were performed with the SPSS (v15) (Statistical Package for the Social Sciences; SPSS. Inc., Chicago, IL, USA).

Results

Description of sample

From the sociodemographic point of view, the study sampled comprised 57% women of middle-to-low class (82.1%) residing in the urban area (68%), with a mean age (mean ± SD) of 60.8 ± 11.7 years. Of the 123 subjects, 51 (41.5%) belonged to the PPR1 group; 38 (30.9%) to PPR2 and 34 (27.6%) to PC. In 79.9% of the cases, the subjects had been wearing the prostheses for more than 5 years.

Validation

The inter-item correlation analysis revealed a distribution of positive correlations within a range of 0.06 between 'hygiene' and 'comfort' to 0.69 between 'functional comfort' and 'foreign body'. However, none of the intercorrelations was negative or sufficiently high to be considered redundant. The item-total correlation analysis obtained values ranging from 0.25 ('Hygiene') to 0.72 ('functional comfort'). From this analysis, a Cronbach alpha value of 0.814 was obtained with the standardized items. This value was not increased by deleting any of the items.

The face and content validities were evaluated as satisfactory after the pilot trial upon checking – through a cognitive interview – that the questions had been understood perfectly by the participants, no unanswered item or lack of relevant content of prosthetic well-being being found. Additionally, the Likert-type responses with a symmetric format that allowed intuitive understanding by the participants were checked, because the range was well demarcated by the most extreme positive or negative options. Construct validity (Table 1) was based on the following findings: the individuals who did not perceive the need for treatment or did not have complaints about their mouth scored significantly lower on the PQL than those who did.

Table 1. Construct validity of the PQL

	[(n (%)]	PQL total score (mean ± standard deviation)	*P*-value
Perceived need of treatment			
No	76 (61.6%)	16.3 ± 4.0	0.020[a]
Yes	47 (38.4%)	12.0 ± 4.7	
Complaints about mouth			
No complaints	30 (24.4%)	14.5 ± 4.4	0.001[a]
Complaints	93 (75.6%)	10.7 ± 6.6	
Oral satisfaction			
Dissatisfied	22 (17.9%)	8.1 ± 6.3	0.002[b]
Neutral	17 (13.8%)	9.5 ± 8.5	
Satisfied	84 (68.3%)	13.0 ± 5.4	

[a]Results from Student's *t* tests.
[b]Results from ANOVA tests.
PQL, prosthetic quality of life.

Also, those who were unsatisfied with their mouth scored significantly higher on the PQL than those who were satisfied.

Criterion validity (Table 2) was corroborated upon observing a strong correlation between the total score of the PQL and the other generic indicators of oral well-being (OIDP, OHIP-14 and OSS). The modulating factors of prosthetic well-being (Table 2) were clinical (periodontal health and caries meriting pulp treatment) and sociodemographic (the higher social class, the higher PQL).

Impact on prosthetic quality of life

Once it had been ascertained that the PQL was a consistent and valid indicator, the data on the prevalence of impact between the groups with removable prostheses were compared (Table 3).

Table 2. Criterion validity of the PQL and factors modulating prosthetic well-being using correlation coefficients

	Total PQL score
Generic indicators of OHQL	
OHIP-14 (Oral health impact profile)	$r = -0.61$**
OIDP (Oral impacts on daily performances)	$r = -0.51$**
OSS (Oral satisfaction scale in a 0–10 visual range)	$r = 0.46$**
Clinical factors	
Number of teeth with caries requiring endodoncy	$r = -0.22$*
Numbers of sextants with CPI = 0	$r = 0.24$**
Number of sextants with Mov = 0	$r = 0.23$**
Sociodemographic factors	
Social class[a]	$r_s = 0.22$*

r = Pearson correlation; *$P < 0.05$; **$P < 0.01$; [a]Social class: the higher the social class, the higher the ordinal category.

The prevalence of impact in the PQL (some item evaluated as ≤0) was 80.7% in RPP1, 92.1% in RPP2 and 97.1% in CP, these proportions being significantly different ($\chi^2 = 6.281$ (2 gl), $P = 0.043$), although the mean range was not significantly different. Also, the total OIDP and OHIP scores among the prosthetic groups were not found to be statistically different according to the ANOVA test. The main prosthetic impact in all the prosthetic groups was attributed to 'food impaction'. The mean range of impact as regards 'prosthetic fit', 'aesthetics' and 'self-confidence' differed significantly among the prosthesis-bearing groups (Table 3). In terms of satisfaction, it was observed that all groups were essentially satisfied, the patients in the CP group being who felt significantly more satisfied.

Factor analysis

To reveal the underlying factor structure, the Bartlett sphericity test was implemented. The results ($\chi^2 = 416.371$ (55 gl), $P < 0.0001$) suggested that there were latent factors. The KMO test afforded a global value of 0.81 and values above 0.70 for the items (Table 4). The extraction of commonalities estimated the amount of variance accounted for by those items after the factor analysis and revealed that some items ('Aesthetics' and 'Food impaction') did not fit the factorial solution perfectly, values lower than the rest being obtained. Principal component analysis revealed the existence of three factors that explained 59.4% of the variance, designated here as 'physical well-being', 'psychological well-being' and 'social well-being' (Table 4). After orthogonal rotation (Varimax), the weight of each factor and the distribution of variance were seen to become equilibrated, simplifying the interpretation of the factor model. In the light of the weights of the items shown in Table 4, it may be seen that 'physical well-being' comprised 'prosthesis fit', 'chewing', 'foreign body sensation' and 'self-confidence'. 'Psychological well-being' comprised 'aesthetics' and 'hygiene'. 'Social well-being' comprised the variables 'communication', 'realism of prosthesis' and 'unnoticeability of prosthesis'. The food impaction variable was a complex variable that loaded in a similar way on 'physical well-being' and 'psychological well-being'.

Figure 1 shows the prevalence of impact on prosthetic well-being, grouping the items according to the factor model. In all the prosthesis-bearing groups, a greater prevalence of impact can be seen

Table 3. Prevalence of impacts and oral dissatisfaction within prosthetic groups, mean of each item and percentage of subjects responding ≤0 on the Likert scale

Items	PPR1 (n = 51)		PPR2 (n = 38)		CP (n = 34)		P value (from ANOVA tests)
	$\overline{\chi}$ ± SD	%	$\overline{\chi}$ ± SD	%	$\overline{\chi}$ ± SD	%	
PQL1: Prosthetic fit	0.8 ± 1.0*	31.4	0.3 ± 1.0*	52.6	0.4 ± 1.2	50	0.05
PQL 2: Chewing	1.0 ± 1.2	41.2	1.1 ± 1.2	36.8	0.7 ± 1.1	38.2	0.32
PQL 3: Foreign body	1.3 ± 0.8	17.6	1.1 ± 0.8	26.3	1.2 ± 0.9	23.5	0.47
PQL 4: Aesthetics	1.0 ± 1.1	25.5	1.1 ± 0.8*	23.7	0.5 ± 1.1*	50	0.03
PQL 5: Communication	1.9 ± 0.4	3.9	1.9 ± 0.5	5.3	1.8 ± 0.6	8.8	0.63
PQL 6: Realism of prosthesis	1.6 ± 1.2	13.7	1.4 ± 1.3	21.1	1.5 ± 1.2	20.6	0.74
PQL 7: Unnoticeability	2.0 ± 0.3	2.0	1.8 ± 0.7	5.3	1.7 ± 0.9	11.8	0.19
PQL 8: Hygiene	1.2 ± 0.9	7.8	1.2 ± 0.7	5.3	1.4 ± 0.5	0	0.15
PQL 9: Food impaction	−0.1 ± 1.5	74.5	−0.7 ± 1.4	86.8	−0.3 ± 1.5	79.4	0.12
PQL 10: Functional Comfort	−0.1 ± 1.5	23.5	0.4 ± 0.5	36.8	0.2 ± 0.4	17.6	0.40
PQL 11: self-confidence	1.0 ± 1.0*	9.8	0.7 ± 1.2*	31.6	1.0 ± 0.8	17.6	0.05
PQL total (some impact)	12.9 ± 5.8	80.4	10.6 ± 6.6	92.1	10.9 ± 6.8	97.1	0.19
Impact on satisfaction	6.0 ± 2.2*	35.3	5.8 ± 2.4*	39.5	7.7 ± 2.6*	17.6	0.009

*Bonferroni *post hoc* comparisons tests detected significant difference between these groups at $P \leq 0.05$.
PPR1, removable partial prosthesis on one of the arches; PPR2, removable partial prosthesis on both arches; PQL, prosthetic quality of life; CP, complete prosthesis on both arches.

Table 4. Factor load matrix of the PQL items

Items	Factors			Quality criteria	
	Physical well-being	Psychological well-being	Social well-being	KMO value	Commonalities
Prosthetic fit	**0.634**	0.272	0.179	0.852	0.508
Chewing	**0.747**	0.225	0.072	0.904	0.614
Foreign body	**0.726**	0.045	0.171	0.778	0.558
Functional comfort	**0.862**	0.052	0.235	0.776	0.800
Self-confidence	**0.788**	−0.037	0.109	0.861	0.634
Food impaction	**0.475**	**0.495**	−0.005	0.856	0.471
Aesthetics	0.108	**0.569**	0.205	0.873	0.377
Hygiene	0.018	**0.780**	0.082	0.812	0.616
Communication	0.110	0.141	**0.801**	0.707	0.674
Realism of prosthesis	0.209	0.057	**0.695**	0.853	0.530
Unnoticeability	0.139	0.154	**0.840**	0.714	0.748
Eigenvalue	4.02	1.02	1.50		
% variance explained	36.5	9.3	13.6		
Cronbach α	0.84	0.73	0.39		

PQL, prosthetic quality of life; OHQL, Oral health–related quality of life. Significant loadings in bold.

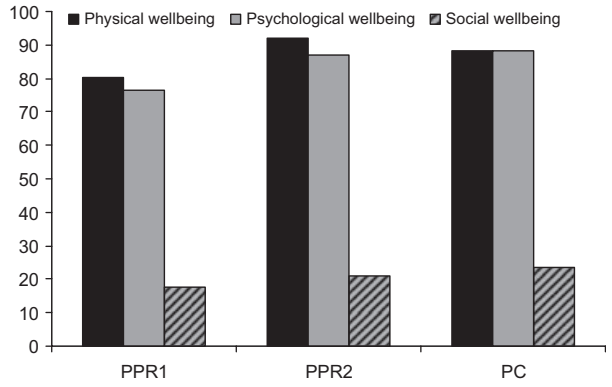

Fig. 1. Prevalence of impact on physical, psychological and social wellbeing.

on physical and psychological well-being; more so than on social well-being.

Discussion

In this study, the impact of removable prostheses on oral well-being was evaluated in three clinically different prosthodontic groups (RPP1, RPP2 and CP) using a specially designated new indicator. The type of probabilistic sampling of a population bearing prostheses not demanding odontological treatment seems to offer an optimum scenario for the validation of a specific indicator of prosthetic

well-being. To achieve this aim, a sample size of between 100 and 200 is adequate (16). As the items were mainly derived from a preliminary questionnaire given to the same reference population, the content of the questionnaire faithfully matches the perceptions of specific oral well-being of this particular clinical profile. The method raises the descriptive capacity of the indicator as it is based on impacts previously referred to by the patients and hence prevalent in the reference population. If we had based our efforts only on the judgements of the panel of experts, we would have included items that point to severe but not very prevalent impacts, increasing the discriminatory power among qualitatively different groups but decreasing the capacity to detect positive changes in those items (17). Another specific instrument for edentate patients (OHIP-EDEN) (5) comprises a subset of questions derived from the original 49-item OHIP (oral health impact profile) (18), which has proved to have measuring properties equivalent to the extended version and is appropriate for use in fully edentulous patients. However, we believe that denture-related impacts could be qualitatively different among partially edentulous patients, and indeed, only three of the 49 items of the extended version of the OHIP specifically refer to denture-related disorders (Q9, Q18, Q30). Moreover, both instruments [OHIP-49 (18) and OHIP-EDEN (5)] are designed to capture only negative impacts, whereas dentures can actually afford positive impacts on the quality of life that should be measured by offering a bidirectional range of responses on the Likert-type scale, as with other generic OHQoL instruments (19). In fact, most of the PQL items are perceived as positive events (See Table 3).

The challenge in developing an index reflecting the impact of dentures is the identification of a range of relevant events and domains and a means of combining the positive or negative effect of prostheses within an ordinal index. We considered that it was appropriate to add a new indicator, conceptually different and at the same time methodologically rigorous, to the existing set of measures of oral health–related quality of life.

All the items of the PQL surpassed a threshold of 0.2 in the item-total correlation matrix, this being a basic requirement for including an item on a scale, and as a synthesis, the Cronbach alpha ($\alpha = 0.814$) supports its excellent internal consistency (16).

The capacity of the PQL to discriminate subjects who perceive a need for treatment or refer to some complaint about their mouth endows it with desirable attributes in any descriptive instrument that aims to reliably measure perceptions of prosthetic well-being. Also, the simultaneous use of generic indicators of oral health status (OIDP and OHIP-14) and the OSS revealed that there was a logical convergence with PQL scores (Table 2). However, it should be openly acknowledged that the total PQL score was not able to discriminate among the prosthetic groups (the results in Table 3 show that there were no differences among the three prosthetic groups as regards the total PQL score and for eight of 11 items). However, none of the OIDP or OHIP items was seen to discriminate among prosthetic groups, *P*-values far from the significant threshold being obtained (results not shown). These unsatisfactory results were not only because of the lack of statistical significance but also were owing to the narrow differences in the mean scores among the prosthetic groups (Table 3). A possible explanation for these negative results is that not all participants were dental patients, and thus, most of them were not dissatisfied with their mouth, had no complaints and did not perceived treatment needs (Table 1). This reduces the cell size and the power for assessing differences in impacts among groups. Moreover, prosthetic variables (for instance, the number of standing teeth, the number of missing teeth or teeth replaced, etc.) were not seen to be significantly correlated with the total PQL (Table 2), hampering the discrimination of prosthetic groups. Several authors have also reported the absence of significant differences in the total well-being score among prosthetic groups after distinct prosthetic treatments. (6, 7, 9, 11).

Nevertheless, some item scores were seen to be statistically different among the prosthetic groups (i.e. prosthetic fit, aesthetics and self-confidence), and the prevalence of impact was also found to be statistically discrepant, the CP group being the most affected in general (97.1%), and the PPR2 group perceiving lower prosthetic fit and self-confidence than the PPR1 group. Thus, it could be argued that, as hypothesized, prosthetic well-being is qualitatively different between totally and partially edentulous patients in some functional aspects, as reported elsewhere (7). Further research should test the discriminant validity of the PQL in experimental studies.

On the other hand, the opinion of experts may be valid for a preliminary assignation of items to conceptual dimensions. The statistical explanation by factor analysis allows the construct and the

interaction between variables to be confirmed (20). We consider that the factor analysis fulfilled certain quality criteria. First, the global KMO value of 0.81 suggests that the sample was suitable for the search for underlying factors and that all the items could be involved in this search with considerable statistical weight, as most of them had KMO values above 0.80, which is considered excellent, and the rest above 0.7, considered adequate (21) (Table 4). Furthermore, the factor structure achieved is coherent with the underlying theory on which the questionnaire was based (1); the factor solution accounted for more than 50% of the variance (21); each factor was valued by more than two items, reducing the pernicious effect of an individual value (22), and the weights of the items on the factors were in general excellent (>0.71) (23), with the exception of food impaction, which behaved as a mixed-load variable. However, we decided not to remove it in view of the prevalence found within this prosthetic population. Despite this, it is noticeable that some items were not clearly linked conceptually to the expected specific factor (Table 4). For example, the 'self-confidence' item was highly loaded on the 'physical well-being' factor, when it would be expected that such an item would be loaded on the 'psychological well-being' factor. This could perhaps be explained in the sense that principal component analyses are based on the intercorrelations of items, and hence, self-confidence has been found to be highly correlated with functional items such as chewing, prosthetic fit, functional comfort, etc. (all of them already belonging to the 'physical well-being' factor). We should interpret this finding in the sense that people wearing dentures perceive their self-confidence to be affected when functional items are also affected too, although this is a speculation that should be backed by further research. The same rationale could be applied to explain why the 'food impaction' item belongs to both 'physical' and 'psychological well-being'. People wearing dentures would perceive 'food impaction' as an entity that disturbs their physical function (when they are eating) but also produces psychological discomfort once they have finished the meal, mainly if they are in circumstances in which prompt oral hygiene cannot be guaranteed. Thus, 'food impaction' seems to be able to affect both the physical and psychological performances in denture wearers.

Another controversial issue is that aesthetics was not loaded on the social well-being factor, although this may have been because of the actual meaning of dental aesthetics for this age range sample, in which the social impact of dental appearance may be minimized precisely because of their age. This finding is in agreement with other authors (24). Future research should check whether this factorial structure is stable and replicable.

Our factorial solution supports the notion that the PQL is multidimensional, three dimensions emerging (physical, psychological and social well-being) that are clearly differentiated in statistical terms, because an analysis performed after the transformation of the components revealed that the rotation was only slight and that the factors found were almost independent with respect to one another, such that an oblique rotation would not have improved our understanding of the factorial structure.

The literature reveals consensus as regards the multidimensional nature of the oral quality of life, but there is some discrepancy concerning the factorial solutions. Some generic questionnaires addressing the OHQL have identified factorially a set of dimensions that could readily be included in the proposals offered in the present work (20, 25).

Recently, the presence of physical, psychological and social factors in the construct of the well-being of edentate individuals has been ratified (26). However, other authors believe that there is a main component that has so much capacity to explain the variance that they consider the oral quality of life construct as a single-dimensional construct (19, 27). In the present study, a dominant factor was also striking, but after orthogonal rotation, the presence of another two explanatory factors was observed, with a fairly equal share of the eigenvalues and the variance.

In the light of the sample size studied here, the data on prevalence should be interpreted with caution. The main prosthetic impact detected in all the groups involved physical and psychological well-being, the most prevalent event being food impaction, as reported by other authors using the same threshold on the Likert scale (17). In agreement with other authors (28), in the present study, we found that prosthetic well-being was poorer in the CP than in the RPP groups, suggesting that the step from RPP to CP is a transition that limits oral function and psychological well-being. Nevertheless, in terms of satisfaction, this study shows that bearers of complete dentures are globally more satisfied than bearers of RPP, as reported by others (29). This is possibly because the former individuals

value the absence of teeth positively because they suffered painful events in the past or because the transitional adaptation from RRP to CP had already occurred and they were already adapted (7). Moreover, they may have been more satisfied with their prostheses because without them they would have been functionally more challenged than bearers of RPPs, in which some teeth persist. The prevalence of dissatisfied individuals is comparable to what has been published in other studies carried out on bearers of RPPs (8, 9, 11) and CPs (30).

This apparent contradiction satisfied patients but suffering from different types of impact is a common finding in studies assessing quality of life and oral health, because people are used to becoming adapted to minor bearable problems, which are unable to reduce the global satisfaction with mouth. Satisfaction could variously be impinged by some nonimpact-related factors, such as personal traits, life values, expectations, beliefs, self-comparisons with previous status (12), etc. that were been addressed in this study. We believe that evaluating the impact on OHQoL or perceived oral satisfaction is two opposite but complementary approaches to measuring oral well-being, but why people affected by oral conditions are, nonetheless, satisfied with their mouths needs to be further investigated.

To summarize, the PQL is a valid and reliable indicator of prosthetic well-being as it discriminates in the expected direction between denture wearers who perceive dental treatment needs, report complaints about the mouth and self-report oral satisfaction (See Table 1). However, the major concern lies in the inability of the new indicator to discriminate among the different prosthetic groups, except for three of the 11 items. The new instrument was designed to be a descriptive tool of prosthetic well-being and to discriminate between comfortable removable prosthesis against uncomfortable ones. In fact, according to our results, we should not, as clinicians, presume that complete dentures are less comfortable than partial ones, and indeed, in this sense in our study, it was observed that wearers of full dentures were significantly more satisfied than their counterparts. In fact, we believe that the PQL has desirable attributes that would presumably allow it to perform well in any evaluative study (17) because it proved capable of recording a high level of prosthetic impacts in a population not requesting dental treatment (ranging from 80.4% to 97.1%). Thus, the prevalence and average number of impacts would presumably increase in the population demanding treatment or enrolled in intervention studies, minimizing the so-called floor effect or basal effect that occurs when a measurement affords extreme values that cannot be improved after an intervention. There are some prosthetic intervention studies in which a single-dimensional indicator has proved to be sensitive to changes (31) in well-being, but the use of a multidimensional indicator such as the PQL would allow the most discriminating domains or those sensitive to a given treatment to be recognized. Nevertheless, this promising aspect should be properly investigated in further interventional research and in different settings by looking at sensitivity to change and the minimal important differences.

As the PQL is short (11 items), it can be applied in epidemiological studies or clinical trials with no special cost as regards the time required for exploration. The bipolar design of the responses of the items of the PQL allows both negative and positive impacts to be recorded, such that the assessment of the physical, psychological and social well-being deriving from the use of dental prostheses will be much more complete than questionnaires limited to evaluating the presence of negative impacts (5, 18), in which data concerning positive feelings will be lost. Traditional negative-oriented measures are unable to detect positive changes in patients with no negative impacts recorded at baseline. Few questionnaires designed with this formal bidirectionality have been reported (19, 25, 32).

The authors are well aware that in oral well-being, it is plausible that 'positive' impacts might rule out 'negative' impacts (i.e. nonaesthetic but comfortable dentures; or not well-fitting but comfortable dentures; no pain but poorly functional dentures…). It therefore seems reasonable it is plausible to gather the positive and negatives aspects of the construct to make a global assessment of well-being. However, we assumed that this is not an ideal way to summarize prosthetic well-being because the items should be weighted by subject according to their values or perceptions to obtain a global weighted score, although this would complicate the implementation of the instrument.

No tests addressing stability over time were conducted (test–retest) because the type of sampling in the Health Centres hindered subject follow-up. Future research should confirm the behaviour of the PQL in epidemiological or intervention studies.

Conclusions

The PQL is a useful indicator of oral well-being in subjects with removable prostheses.

Competing interests

The authors declare that they have no competing interests.

Authors contributions

MB conceived and coordinated the study from its design to the drafting of the manuscript. JM carried out the study and drafted the manuscript. ALV made substantial contributions to the conception, design, data analysis and interpretation. All authors also read and approved the final manuscript.

Acknowledgement

Data collection was funded by the corresponding author's fellowship from the Spanish Ministry of Culture and Education.

Annexe: prosthetic quality of life

Prosthetic fit
Item 1: What do you think about the fit of your upper/-lower prosthesis?
- Very good 1
- Good 2
- Acceptable 3
- Bad 4
- Very bad 5

Chewing
Item 2: Do you have to be careful about what you eat or drink owing to the quality of your prosthesis?
- No, never 1
- Yes, but only very occasionally 2
- Yes, sometimes 3
- Yes, nearly always when I drink or eat 4
- I can't eat with the prosthesis in my mouth 5

Foreign body
Item 3: Do you feel the prosthesis is some kind of foreign body in your mouth or does it seem to be integrated in it?
- Completely integrated, as though it were my own 1
- I have become adapted to it and do not notice it 2
- I don't seem able to adapt even though I wear it all the time 3
- I can't adapt to it and I hardly ever wear it 4
- I never wear it because I can stand the feeling 5

Aesthetics
Item 4. Do you think that the prosthesis has changed the aspect of your smile?
- Yes, a lot 1
- Yes, slightly 2
- It's more or less the same3
- I think it's worse 4
- It's much worse 5

Communication
Item 5: Do you avoid speaking to people because of the prosthesis?
- Never 1
- Rarely 2
- Sometimes 3
- Often 4
- Always 5

Realism of prosthesis
Item 6: Do you think people realise you are wearing a prosthesis?
- Never 1
- Rarely 2
- Sometimes 3
- Often 4
- Always 5

Unnoticeability
Item 7: Do you try to hide the fact that you are wearing a prosthesis?
- Never 1
- Rarely 2
- Sometimes 3
- Often 4
- Always 5

Hygiene
Item 8: Do you think taking hygienic care of your prosthesis is easy?
- Very easy 1
- Easy 2
- Neither easy nor difficult 3
- Difficult 4
- Very difficult 5

Food impaction
Item 9: Do you feel food getting impacted as a result of your prosthesis?
- Never 1
- Rarely 2
- Sometimes 3
- Often 4
- Always 5

Functional comfort
Item 10: Do you feel at ease with your prosthesis with respect to the usual functions of your mouth: eating, speaking, smiling…?
- I feel completely at ease 1
- I am fairly at ease 2
- I don't feel too bad 3
- I feel a bit uncomfortable 4
- I feel very uncomfortable 5

Self-confidence
Item 11: Does your prosthesis make you feel self-confident in your daily life?
- Yes I feel very confident 1

Yes, I feel fairly confident 2
Neither one nor the other 3
I don't always wear it because I don't feel very confident wearing it 4
I hardly ever use it because I never feel confident when I'm wearing it 5

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