Validation of a new, specific, complete, and short OHRQoL scale (QoLFAST-10) for wearers of implant overdentures and fixed-detachable hybrid prostheses

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ABSTRACT

Objectives: To validate a new index for assessing the whole concept of oral health-related quality of life (OHRQoL) of implant-prosthesis wearers.
Methods: 113 patients who were not requesting dental treatment were assigned to: Group 1 (CD; $n = 38$): complete denture users (control); Group 2 (IO; $n = 38$): implant overdenture wearers; and Group 3 (HP; $n = 37$): hybrid implant prosthesis users. Patients answered the newly-designed 'Quality of Life related to Function, Aesthetics, Socialization, and Thoughts about health-behavioural habits' (QoLFAST-10) and the Oral Health Impact Profile (OHIP-20sp) questionnaires. Information on global oral satisfaction, socio-demographic, clinical, and prosthetic-related data were gathered. The QoLFAST-10 was investigated for reliability and validity. The Spearman's test determined the correlations between both indices' scores. Descriptive and non-parametric probes were run to assess the influence of the study variables on the OHRQoL ($\alpha = 0.05$).
Results: The QoLFAST-10 confirmed its psychometric capacity. HP wearers reported significantly better global and functional satisfaction than did IO wearers. The latter revealed significantly less consciousness about the importance of health-behavioural habits than did CD and HP groups. The *level of education, complaints about the mouth,* and the *global oral satisfaction measures* significantly modulated the QoL FAST-10 scores.
Conclusions: Implant overdentures supplied lower functional and global satisfaction than did hybrid prostheses, and represent the least predictable option concerning the maintenance of the restoration.
Clinical significance: The QoLFAST-10 may help in estimating the impact of implant restorations on patients' well-being. In this regard, hybrid prostheses seem to be the implant treatment of choice when compared with overdentures.

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1. Introduction

Different scales using a variety of methodological approaches have been designed in previous years to assess the personal self-perception of the oral status [1–5]. The effect of 'function' and 'comfort' of total rehabilitations on OHRQoL may be objectified, among others, with the Oral Health Impact Profile (OHIP-20), which is the most widely used instrument in case of edentulism [1,4,6,7]. The recently-introduced Quality of Life with Implant-Prostheses (QoLIP-10) questionnaire has specifically demonstrated its psychometric adequacy for all types of dental implant restorations, and includes items about 'function', 'comfort' and 'aesthetics' [8–10]. Nevertheless, to date, there is no questionnaire with items related to 'health-behavioural habits', which might be relevant for motivating the patients to shift practice toward preventive care [1], health promotion, and conservation of the oral tissues [11], and may also depend on the prosthesis design [10].

On the one hand, implant overdentures have demonstrated significantly higher retention, stability, and functional efficiency, than muco-supported complete dentures [12]. As the latter stay in place with natural suction without implant retention, their mobility may be considered inconvenient [4,12]. However, the

use of conventional complete dentures avoids surgical risks and other difficulties and costs that are inherent in implant therapy [13].

On the other hand, fixed-detachable hybrid implant prostheses are cantilevered restorations that are screwed onto premaxillary or interforaminal implants (or abutments). They are recommended in absence of osteomucosal support, and are composed of a metallic CAD/CAM framework covered with heat-polymerised resin and prosthetic teeth [8,14]. Despite being fixed for the patients, which provides many functional and psychological advantages [15], they are not exempt from other drawbacks such as plaque accumulation, *peri*-implant inflammatory problems, and/or fracture of the acrylic supraestructure [9,16].

This cross-sectional investigation is the first to compare the OHRQoL of patients rehabilitated with implant overdentures and hybrid implant prostheses through the use of a new customised index ('QoLFAST-10') that includes all of the possible areas through which the QoL (Quality of Life) concept may be defined [17]. These areas of evaluation are represented in the name of the scale (function, aesthetics, socialization, and thoughts about health behavioural habits). The initials of these key words form the acronym 'FAST', remarking that it is a short, and, then, a more applicable and effective questionnaire [18].

Given the lack of complete indicators for measuring the impact of implant prostheses on daily life, the aim of this paper is to develop and validate an effective, short, and specific scale for assessing the OHRQoL of implant overdenture and hybrid prosthesis wearers considering the possible influence of different variables, and to analyse the factorial construct of the well-being associated to these types of implant restorations. A control group of subjects with muco-supported complete dentures allowed estimation of the benefits of using implants for supporting the abovementioned removable and semi-removable acrylic oral rehabilitations.

In addition to the design and validation of the new index, the null hypothesis tested was that conventional complete dentures, implant overdentures, and fixed-detachable hybrid implant prostheses provide comparable levels of OHRQoL regardless of the socio-demographic, clinical, and/or prosthetic-related characteristics of the patients.

2. Materials and methods

2.1. Development of the Quality of life related to function, aesthetics, socialization, and thoughts about health-behavioural habits (QoLFAST-10) *questionnaire*

Following the EUROHIS [19] guidelines for the development of a universal quality of life (QoL) indicator, an extensive literature review was accomplished [1–10,20,21] in order to establish a theoretical framework about the preliminary structure and content of the scale. A team of five specialists in prosthodontics and an oral and maxillofacial surgeon (each with demonstrated research experience in QoL), selected the most relevant items in OHRQoL for consideration in patients wearing implant overdentures and hybrid prostheses. The development of the new questionnaire was therefore supported by previously published papers and based on existing instruments in the areas of patient satisfaction, oral symptoms, oral function, self-image/aesthetics, self-esteem, and socialization [8,12,17]. As a novelty, the authors decided to include items asking about the patients' thoughts about health behavioural habits, given their importance on the maintenance of the OHRQoL.

The research group interviewed 28 subjects who were rehabilitated at the Department of Buccofacial Prostheses (Stomatology I) of the Faculty of Dentistry of the Complutense

University of Madrid (U.C.M., Spain). Patients attended an in-depth, face-to-face interview in order to explore the areas of OHRQoL that might be affected by the presence of implant restorations. The volunteers were also distributed in group discussions (focus discussions). The purpose was to identify what they regarded as most important requirements related to OHRQoL. The experts selected and summarised the most prevalent issues. At this stage, redundant or inappropriate items were deleted [19,21].

Finally, the committee of experts decided on a 10-item questionnaire. The items on the designed index: 'Quality of Life related to Function, Aesthetics, Social, and Thoughts about health-behavioural habits', hereafter called QoLFAST-10, were the following: Item 1 (Social repercussion of oral pain), Item 2 (Social repercussion of eating well), Item 3 (Speaking well), Item 4 (Satisfaction with the size, shape, and colour of the prosthetic teeth), Item 5 (Self-confidence when smiling), Item 6 (Development of daily activities), Item 7 (Feeling socially comfortable), Item 8 (Importance of dental revisions), Item 9 (Importance of daily habits of oral hygiene), and Item 10 (Oral hygiene difficulties). Ten items tried to cover four important areas of OHRQoL that may be assessed when the patient is wearing an implant restoration: function, aesthetics, socialization, and thoughts about health behavioural habits. This reason explains the name of the questionnaire, and the names of the dimensions obtained after the correspondent statistical analysis.

The questionnaire may be easily adapted to a global scale format to be applied in future assessments (*i.e.*, patients could be asked: '*Do you think that the following aspects have improved, worsened or remained the same after the prosthetic treatment*?') [22].

The 10-item QoLFAST-10 indicator was designed to be intuitively self-completed as the items' responses were expressed in a Likert-type scale [23] with proportional codes for the impact degrees. The items evaluated as '<0' on the Likert scale were considered as having negative impact, while values of '+1' and '+2' represented the positive side of each item (absence of negative effect). The possible responses to the items were the following: 'strongly disagree' (score −2), 'disagree' (score −1), 'indecisive'/'indifferent'/'neutral' (score 0), 'agree' (score +1), and 'strongly agree' (score +2).

The total score of the questionnaire was calculated by means of the additive scoring method (ADD) by adding the different item scores [24]. Both negative and positive impacts contributed to the total score in such way that the higher the total score is, the higher the satisfaction of the patient is (meaning that negative or low positive scores indicate poorer self-perceived OHRQoL). Hence, the total score of the QoLFAST-10 ranges between '−2 × no. of items' (−20) and '+2 × no. of items' (+20). Similarly, the dimensional scores are the sum of the item scores that are included in each domain (ADD method) [8,24].

Following the recommendations of Streiner and Norman [22], the face and content validity of the QoLFAST-10 scale was empirically checked in a pilot trial that was conducted on a representative sample of patients ($n = 28$) from the same source population, which constituted 23.33% of the main study sample ($n = 120$). Although ten (or even fewer) patients have proven to be sufficient to assess the clarity of instructions, item wording, acceptability of formatting, and ease of administration of a questionnaire; [25] given the population variability in this study [22,25], approximately 10 patients per treatment group were selected for the pilot trial. Thus, they wore complete dentures ($n = 10$; 35.8% of the sample for the pilot trial), implant overdentures ($n = 9$, 32.1%), and hybrid implant prostheses ($n = 9$; 32.1%), and met selection criteria that were similar to those of the patients in the main study [10,21,22]. The comprehensiveness of the QoLFAST-10 index was evaluated by asking the participants specific questions about possible difficulties in understanding the

items in order to make the instrument more clear. This allowed optimising its face and content validity for the main cross-sectional research [22,25].

2.2. Study protocol

2.2.1. Study sample

The reference population included 120 subjects from 40 to 90 years-old and who were treated with at least one conventional complete denture, one implant overdenture, or one hybrid implant prosthesis; at the Department of Buccofacial Prostheses of the Complutense University of Madrid between 2000 and 2014. The patients were recruited by chronology of past treatment.

To standardise the inclusion criteria, patients with complete dentures, implant overdentures fitted over 4 implants in the maxilla and/or over 2–4 implants in the mandible, and hybrid implant prostheses screwed to 4–6 maxillary and/or interforaminally implants defined the reference population. The subjects were invited to take part in the study between January and March of 2014. The exclusion criteria were: patients rehabilitated with an implant overdenture and a hybrid implant prosthesis (to avoid misinterpretation of the findings), patients seeking dental treatment, and patients with cognitive impairment, motility disorders, implant loss, and/or serious illness [4].

The 113 final volunteers were scheduled for appointments that were to take place in April 2014. The subjects were assigned to three groups, depending on the type of implant restoration worn by each patient: Group 1 (CD; $n = 38$): muco-supported complete denture wearers (control); Group 2 (IO; $n = 38$): patients wearing implant overdentures and Group 3 (HP; $n = 37$): subjects with hybrid implant prosthesis.

This work was conducted in full accordance with the World Medical Association Declaration of Helsinki (http://www.wma.net) and the Spanish Law 14/2007 of July 3rd for Biomedical Research (http://www.boe.es) [4,7]. All of the participants were briefed about the purpose and process of the study. The experiment was undertaken with the written consent of each subject and according to the abovementioned principles. The approval of the Ethics Committee of the San Carlos University Hospital of Madrid (C.I. 12/240-E, and 12/241-E) was obtained after the ethical board of the Spanish Hospital completed an independent review of the study protocol. The subjects' anonymity was preserved, and their rights were protected in all cases.

2.2.2. Data gathering

Patients completed the QoLFAST-10 questionnaire aided by a trained interviewer, who formulated the questions. Participants also completed the 20-item Oral Health Impact Profile (OHIP-20sp) form, which had been previously validated in the Spanish population and has been described in detail elsewhere [6]. Answering the OHIP-20sp, patients scored in terms of the frequency of appearance, 20 situations of impact that were conceptually divided into seven 'domains' or 'dimensions' (i.e., Functional limitation, Physical pain, Psychological discomfort, Physical disability, Psychological disability, Social disability and Handicap). Frequency in the OHIP was codified using a classic Likert-type scale [23] with five options [26]. The possible impact responses were: 'hardly ever' (score +1), 'occasionally' (score +2), 'fairly often' (score +3), and 'very often' (score +4). The 'never' response (score 0) revealed the absence of impact. The OHIP-20sp outcome variable ranged from 0 to 80. With this index, the higher the total score is, the higher the level of negative impact on oral well-being and quality of life is, and, therefore, the lower the satisfaction of the patient is [6].

The volunteers were also asked about their overall satisfaction with their mouths, which comprised individual assessments of the satisfaction with their oral aesthetics, functionality, and comfort with their prostheses [9,10,20]. A visual analogue scale (VAS) was used for each of the abovementioned areas, so that these perceptions were quantified in a continuous range from 0 to 10 [27]. Subjects could thereby declare themselves to be 'dissatisfied', 'neutral', or 'satisfied', offering values situated left to the midpoint of a 100-mm long line, on the midpoint, or to the right of the midpoint, respectively [8–10,27].

A different researcher conducted each questionnaire. To ensure that the clinic staff had no access to the patients' responses, the completed forms were placed in sealed envelopes. The QoLIP-10 (original version) [8], the OHIP-20sp, and the VAS evaluations were then linked by means of a unique identification code for each participant [20,21].

To capture the clinical modulating factors, subjects were examined by a single investigator using the diagnostic methodology published by the World Health Organization [28].

The study variables were grouped as follows: Group 1: Socio-demographic variables (gender, age, marital status, and level of education/schooling); Group 2: Clinical variables (presence of oral candidiasis, and mucosal lesions); Group 3: Variables related to the prosthetic rehabilitation [9,10,29] (location, type of antagonist, status of the prosthesis, and retention system in case of overdentures); and Group 4: Self-perceived satisfaction with the mouth (complaints about the mouth, and perception of needing dental treatment).

2.3. Data analysis

The additive method (-ADD) [6,9,21] was used for both the QoLFAST-10 and the OHIP-20sp analyses by adding the item codes at the appropriate frequency [4,24]. The dimensional scores of each questionnaire were obtained in a similar fashion. All of the data collected were processed according to well-established statistical methods used in related research [4,8–10].

Descriptive statistics and percentages for qualitative and categorical variables were calculated [4,8–10,21].

The main psychometric characteristics of the QoLFAST-10 questionnaire (reliability and validity) were investigated. On the one hand, as each item measured different aspects of the same attribute, the reliability was assessed by examining the internal consistency of the scales through the use of the Cronbach's α value, the α value if an item was deleted, the inter-item correlation, and the item-total correlation [30,31]. On the other hand, different types of validity were tested:

(a) The face and content validity (which refers to the extent to which a measure represents all facets of a given construct) were verified in the pilot trial because the patients reported no difficulties in understanding the items and did not mention any situation of impact that had not been included in the questionnaire [6].

(b) The construct validity of the QoLFAST-10 (or the extent to which the OHRQoL was actually recorded with this scale) [6,30] was examined using the factor analysis (a data reduction technique that allows homogeneous subgroups of variables to be found), and the convergent validity of the scale (which measures how closely the new scale is related to other variables and measures of the same construct to which it should be associated) [22].

Concerning the factor analysis, the principal components' analysis (PCA) was applied together with the rotation method: the Varimax plus Kaiser normalization was selected to extract the underlying domains of the prosthetic construct [32]. Afterwards, the Bartlett's Sphericity and the Kaiser-Meyer-Olkin (KMO) tests,

which are measures of sampling adequacy, were run to detect the factorial structure of the QoLFAST-10. [4,20] Factors with an eigenvalue of less than one were disregarded to avoid distortion [9,10,20]. The items were assigned to the rotated factors (or dimensions) when they had a loading of 0.5 or greater in a single factor [8,33].

To establish the degree of convergent validity, the QoLFAST-10 total and sub-scale scores were correlated to the total score of the OHIP-20sp with the Spearman's rank test [33].

(c) The criterion validity of the QoLFAST-10 indicator (which measures how well the test predicts the OHRQoL based on information obtained from other variables) [6,30] was

Table 1
Impact of the study variables on the OHRQoL (N = 113).

Patients' features (%, n)	Statistical significance			
	QoLFAST-10 total score		OHIP-20sp total score	
	Mean (SD)	p-values	Mean (SD)	p-values
Group 1: Socio demographic variables **Gender**				
Male (31.9%, n = 36)	9.50 (5.2)	0.27 NS (a)	4.6 (3.8)	0.37 NS (a)
Female (68.1%, n = 77)	10.10 (6.6)		7.0 (7.3)	
Age				
≤60 years (23.0%, n = 26)	8.3 (7.0)	0.13 NS (a)	6.3 (6.1)	0.90 NS (a)
>60 years (77.0%, n = 87)	10.4 (5.8)		6.2 (6.6)	
Being partnered				
Without partner (23.9%, n = 27)	10.78 (4.7)	0.57 NS (a)	5.6 (5.0)	0.98 NS (a)
With partner (76.1%, n = 86)	9.6 (6.5)		6.5 (6.9)	
Level of education/schooling				
Illiterate (17.7%, n = 20)	10.2 (5.7)	0.004 ** (b)	7.5 (8.8)	0.86 NS (b)
Non-university education (56.6%, n = 64)	11.4 (6.0)		6.1 (6.6)	
University education (25.7%, n = 29)	7.6 (6.1)		5.9 (4.8)	
Group 2: Clinical variables **Presence of oral candidiasis**				
Yes (17.7%, n = 20)	9.8 (5.9)	0.34 NS (a)	6.4 (6.8)	0.87 NS (a)
No (82.3%, n = 93)	10.5 (7.3)		5.6 (5.1)	
Presence of mucosal lesions				
Yes (23.9%, n = 27)	9.1 (8.0)	0.87 NS (a)	6.6 (6.7)	0.71 NS (a)
No (76.1%, n = 86)	10.1 (5.5)		6.1 (6.5)	
Group 3: Variables related to the prosthetic rehabilitation **Location**				
Maxillary (36.3%, n = 41)	10.9 (5.2)	0.16 NS (b)	5.6 (6.0)	0.48 NS (b)
Mandibular (27.4%, n = 31)	8.0 (7.2)		7.3 (6.8)	
Bimaxillary (36.3%, n = 41)	10.4 (6.0)		6.1 (6.8)	
Type of antagonist				
Complete denture (CD) (21.2%, n = 24)	8.4 (7.5)	0.43 NS (b)	6.3 (6.0)	0.36 NS (b)
Implant-supported FDP (49.6 %, n = 56)	10.4 (5.1)		6.7 (6.4)	
Tooth-supported FDP (25.7%, n = 29)	10.5 (6.6)		5.3 (7.4)	
Removable partial denture (RPD) (3.5%, n = 4)	9.7 (7.5)		6.3 (6.5)	
Status of the prosthesis				
Good condition (GC) (70.8%, n = 80)	10.0 (5.6)	0.27 NS (b)	5.4 (5.9)	0.17 NS (b)
Needs reparation (R) (16.8%, n = 19)	11.6 (5.3)		8.7 (8.3)	
Requires to be replaced (CH) (12.4%, n = 14)	6.8 (9.0)		7.6 (6.7)	
Retention system (overdentures)				
Bar (84.21%, n = 32)	9.2 (7.4)	0.20 NS (b)	7.4 (5.7)	0.15 NS (b)
Balls (2.63%, n =1)	11.0 (-)		0.0 (-)	
Locators (13.16%, n = 5)	3.8 (7.0)		11.6 (8.5)	
Group 4: Self-perceived satisfaction with the mouth **Complaints about the mouth**				
Yes (18.6%, n = 21)	5.8 (8.5)	0.001** (a) QoL: Complaint < No complaint	11.3 (7.8)	0.001** (a) QoL: Complaint < No complaint
No (81.4%, n = 92)	10.8 (5.1)		5.1 (5.6)	
Perception of needing dental treatment				
Yes (29.2%, n = 33)	8.7 (7.6)	0.29 NS (a)	8.7 (7.5)	0.02* (a)
No (70.8%, n = 80)	10.4 (5.4)		5.2 (5.8)	QoL: Perception of needing dental treatment < No perception

Lower QoLFAST-10 scores and higher OHIP-20sp punctuations indicate poorer self-perceived quality of life. NS = not significant (p > 0.05). (*) significant at α = 0.05. (**) significant at α = 0.001. (a) Mann–Whitney U test. (b) Kruskal-Wallis test.

analysed by contrasting the total QoLFAST-10 and OHIP-20sp scores with the VAS punctuations using non-parametric probes, since the Kolmogorov-Smirnov test did not assume a normal distribution of the QoLFAST-10 outcome variable in the treatment groups. The Kruskal-Wallis test was applied for variables with three or more categories, while the Mann-Whitney *U* test was run for variables with two categories, and for pair-wise comparisons [8–10,31,34].

(d) In order to investigate the discriminant validity, the total and dimensional scores of the QoLFAST-10 were compared with the total score of the OHIP-20sp (and *vice versa*) among the prosthodontic groups. The Kruskal-Wallis test was used to assess the differences among the three prosthodontic groups, and the Mann-Whitney *U* test was chosen for *post-hoc* comparisons [6,9,10,20].

After evaluating the psychometric characteristics of the new questionnaire, the possible modulating effect of the study variables on the QoLFAST-10 impact scores were examined with the Kruskal-Wallis and the Mann-Whitney *U* tests [9,34].

Data were processed using the Statistical Package for the Social Sciences (software v.22) (SPSS/PC+, Inc.; Chicago, IL, USA) taking in advance the cut-off level for statistical significance at $\alpha = 0.05$ [4,7,32,34].

3. Results

The main findings of the study are outlined in Tables 1–5. The description of the study sample, the analysis of the reliability and validity of the QoLFAST-10 index, and the assessment of the prosthetic well-being construct are detailed below.

3.1. Description of the sample

A total of 7 (5.8%) patients were excluded from the reference population ($n = 120$), because they could not participate in the study due to medical reasons. Hence, the final study sample was composed of 113 individuals.

From a socio-demographic point of view (Group 1 of variables), the main profile was that of a woman (68.1%, $n = 77$), older than 60 years (77.0%, $n = 87$), with partner (76.1%, $n = 86$), and non-university education (56.6%, $n = 64$) (Table 1).

Within the group of clinical variables (Group 2 of variables), 82.3% ($n = 93$) of the participants did not suffer from oral candidiasis, and 76.1% ($n = 86$) of the volunteers had no mucosal lesions (Table 1).

Concerning the prosthesis-related variables (Group 3 of variables), the most frequent location of the prosthesis in this study was maxillary and bimaxillary (each 36.3%, $n = 41$). An implant-supported FDP (fixed dental prosthesis) was the most common type of antagonist (49.6%, $n = 56$). With respect to the status of the restoration, 70.8% ($n = 80$) of the prostheses were in good condition; 16.8% ($n = 19$) required to be repaired; and the remaining 12.4% ($n = 14$), needed to be changed. Most implant overdentures (84.21%, $n = 32$) had a bar retention system (Table 1).

Assessing the self-perceived satisfaction with the mouth (Group 4 of variables), most study patients did not complain (81.4%, $n = 92$) and did not perceive a need for dental treatment (70.8%; $n = 80$) (Table 1).

All of the described results were significant at $\alpha = 0.001$. The variable 'age' was distributed in two categories for statistical purposes in order to balance the groups' sizes. Similarly, concerning the variable 'being partnered', divorced, single, and widower patients were grouped together forming the group 'without partner'; while those patients who were married or who lived with their girlfriend/boyfriend were pooled in the group 'with partner' (Table 1).

Regarding the VAS analysis, most volunteers were 'satisfied' with their aesthetics (86.7%, $n = 98$; $p < 0.001$), function (82.3%, $n = 93$; $p < 0.001$), and prosthetic restoration (80.5%, $n = 91$; $p < 0.001$) (Table 2).

3.2. Analysis of the reliability and validity of the QoLFAST-10 index

The reliability (or internal consistency) of the QoLFAST-10 instrument was supported by Cronbach α values of 0.72 (direct values) and 0.75 (typical values) (Table 3). These results were significant ($p < 0.001$); therefore, the reliability of the index was estimated to be within the interval of 0.15–0.27 with a 95% degree of confidence. Alpha values were lower or equal when either item was deleted.

The inter-item correlation analysis displayed an overall distribution of positive items (ranging from 0.006 between Items 5 and 9, to 0.94 between Items 4 and 5). This fact revealed that the concept was measured in the same direction. Although most correlations were significant, none of them was intense enough to verify the existence of clear redundancy in content. In the item-total correlation matrix, all of the items surpass the threshold of 0.20, which is the minimum requirement for including an item on a scale [22]. Therefore, the ten items that were finally included in the test exhibited adequate homogeneity, with coefficients ranging from 0.32 to 0.56. As all of the items and their possible responses were presented together in a matrix (which facilitates self-completion by patients), the face and content validities of the index were considered adequate in the pilot trial. The participants did not mention any situation of impact that was not included in the questionnaire and declared that all of the items were comprehensible. Additionally, the symmetric format of the Likert-type [23] responses was very intuitive, as the range was demarcated by the most extreme positive and the most extreme negative options.

As for the construct validity, the factor analysis showed average QoLFAST-10 scores ranging from −1.8 for Item 8, to 1.8 for Item 5 (Table 3). Hence, the responses were situated in both the non-impact and impact zones. Moreover, the communalities extracted for the PCA, and the results of the factor analysis support the conclusion that all of the items were well-represented in the factorisation, being required in the final version of the questionnaire, as detailed below (Table 3).

Table 2
Criterion validity of the QoLFAST-10 (N = 113).

Patients' features (%, n)	Statistical significance			
	QoLFAST-10 total score		OHIP-20sp total score	
	Mean (SD)	p-values	Mean (SD)	p-values
Global oral satisfaction (Visual analogue scale: VAS)				
Aesthetic satisfaction				
Satisfied (86.7%, n = 98)	10.9 (5.1)	0.001 ** (b)	5.8 (6.4)	0.04 * (b)
Neutral (0.9%, n = 1)	15 (-)		2.0 (-)	
Dissatisfied (12.4%, n = 14)	2.6 (7.8)		10.1 (6.5)	
Satisfaction with chewing				
Satisfied (82.3%, n = 93)	10.9 (5.1)	0.001 ** (a)	5.1 (5.7)	0.001 ** (a)
Neutral (0%, n =0)	–		–	
Dissatisfied (17.7%, n =20)	5.1 (7.5)		11.7 (7.4)	
Satisfaction with the prosthetic restoration				
Satisfied (80.5%, n = 91)	10.8 (5.0)	0.002 ** (a)	5.2 (5.6)	0.004 ** (a)
Neutral (0%, n = 0)	–		–	
Dissatisfied (19.5%, n = 22)	5.5 (8.2)		10.5 (8.1)	

Lower QoLFAST-10 scores and higher OHIP-20 punctuations indicate poorer self-perceived quality of life. NS = not significant (p > 0.05). (*) significant at $\alpha = 0.05$. (**) significant at $\alpha = 0.001$. (a) Mann-Whitney *U* test. (b) Kruskal-Wallis test.

Table 3
Factor analysis and reliability of the QoLFAST-10 index (N = 113).

Items' scores			Factor load matrix (factorial weight > 0.5)			
Items	Mean (SD)	Communalities (PCA)	QoLFAST-10 dimensions			
			Social	Aesthetic	Functional	Thoughts about health-behavioural habits
(1) Social repercussion of oral pain	0.5 (1.8)	0.7	0.7	–	–	–
(2) Social repercussion of eating well	0.7 (1.7)	0.7	0.8	–	–	–
(3) Speaking well	1.1 (1.4)	6	–	–	0.5	–
(4) Satisfaction with the size, shape and colour of the prosthetic teeth	1.7 (0.9)	0.9	–	0.9	–	–
(5) Self-confidence when smiling	1.8 (0.8)	0.9	–	0.9	–	–
(6) Development of daily activities	1.6 (0.8)	0.6	0.6	–	–	–
(7) Feeling socially comfortable	1.1 (1.5)	0.7	0.8	–	–	–
(8) Importance of dental revisions	−1.8 (0.7)	0.7	–	–	–	0.7
(9) Importance of daily habits of oral hygiene	1.6 (0.5)	0.7	–	–	–	0.8
(10) Oral hygiene difficulties	1.5 (1.1)	0.6	–	–	0.8	–
Percentage of variance explained			32.90%	16.53%	12.17%	10.14%
Items per dimension in this study (total = 10 items)			4 items (7, 2, 1, 6)	2 items (4, 5)	2 items (10, 3)	2 items (9, 8)
Dimensional Cronbach αvalues			0.69	0.7	0.67	0.74
Reliability of the QoLFAST-10/Cronbach α value of the index = 0.75			Percentage of total accumulated variance = 71.74%			

Low QoLFAST-10 scores indicate poor self-perceived quality of life. PCA = principal component analysis.

Table 4
Correlation among satisfaction variables and QoLFAST-10 and OHIP-20sp scores (N = 113).

	rho values	
	QoLFAST-10 total score	OHIP-20sp total score
Variables		
Aesthetic satisfaction	-0.33 **	0.21 *
Satisfaction with chewing	-0.32 **	0.37 **
Satisfaction with the prosthesis	-0.29 **	0.27 **

	Sub-scale and total scores	
	QoLFAST-10	OHIP-20sp
Questionnaires		
Social	0.73 **	−0.34 **
Aesthetic	0.49 **	−0.15 NS
Functional	0.91 **	−0.48 **
Thoughts about health-behavioural habits	0.51 **	−0.20 NS
QoLFAST-10 total score	N/A	−0.50 **
Functional limitation	−0.30 **	0.85 **
Physical pain	−0.55 **	0.80 **
Psychological discomfort	−0.36 **	0.51 **
Physical disability	−0.13 NS	0.50 **
Psychological disability	−0.30 **	0.33 **
Social disability	-0.09 NS	0.20 *
Handicap	0.12 NS	0.05 NS
OHIP-20sp total score	QoLFAST-10 Convergent validity: −0.50 **	N/A

NS = not significant (p > 0.05). (*) significant at α = 0.05. (**) significant at α = 0.001. rho: Spearman's rank correlation coefficients. N/A = not applicable.

Results from the Bartlett's Sphericity test (χ^2 = 446.5, 45gl; $p < 0.001$) suggested the existence of a high number of inter-significant correlations among the items and latent factors (or dimensions) of the QoLFAST-10. The KMO measure produced a global value of 0.67. Four components with eigenvalues above 1 emerged from the factor analysis of the QoLFAST-10 and were supported by the elbow in the corresponding scree plot of eigenvalues. These four factors explained 71.74% of the total variance and were named according to the items loading (Table 3). Most items consistently and coherently loaded on a single factor. The final validated questionnaire included ten items. Thus, the

name of the 'QoLFAST-10' index was maintained. According to the factorization, those items with factorial weights greater than 0.5 were re-ordered from higher to lower factorial weight within their respective dimensions in the definitive version of the scale (Table 3; Appendix A).

Hence, the factor called *Social dimension* was the most explanatory (32.9% of variance). This factor was formed by the combination of the items: 7 (Feeling socially comfortable), 2 (Social repercussion of eating well), 1 (Social repercussion of oral pain), and 6 (Development of daily activities). The second factor, named *Aesthetic dimension* (which explained 16.53% of variance),

Table 5
Comparison of self-reported satisfaction among the prosthodontic groups tested.

Subscale and total scores	Muco-supported complete denture wearers (CD, n = 38) Mean (SD)	Implant overdenture wearers (IO, n = 38)	Hybrid implant prosthesis wearers (HP, n = 37)	p-values (Kruskal-Wallis) (N = 113) Discriminant validity
QoLFAST-10				
Social	5.1 (15.7)	5.3 (16.3)	5.6 (18.0)	0.87 NS
Aesthetic	7.1 (21.7)	7.2 (21.8)	6.1 (18.4)	0.64 NS
Functional	5.1 (15.8)	2.4 (8.2)	6.2 (19.3)	0.03*
Thoughts about health-behavioural habits	3.1 (9.6)	1.7 (5.3)	2.5 (7.6)	0.003*
QoLFAST-10 total score	10.5 (4.9)	8.5 (6.0)	10.7 (7.3)	0.05*
OHIP-20sp				
Functional limitation	4.8 (14.8)	6.5 (19.8)	5.0 (15.2)	0.30 NS
Physical pain	2.5 (7.8)	5.4 (16.7)	3.3 (10.4)	0.02*
Psychological discomfort	1.6 (2.2)	1.0 (3.1)	1.2 (3.7)	0.92 NS
Physical disability	1.0 (3.3)	1.5 (4.8)	0.4 (1.6)	0.12 NS
Psychological disability	0.9 (2.8)	0.6 (2.0)	0.4 (1.5)	0.32 NS
Social disability	0.1 (0.4)	0.2 (0.7)	0.0 (0.0)	0.18 NS
Handicap	0.1 (0.6)	0.05 (0.2)	0.0 (0.0)	0.37 NS
OHIP-20sp total score	5.7 (6.2)	7.8 (6.2)	5.3 (7.0)	0.04*

NS = not significant (p > 0.05). (*) significant at $\alpha = 0.05$.

comprised the items: 4 (Satisfaction with the size, shape, and colour of the prosthetic teeth), and 5 (Self-confidence when smiling). The third factor, which was designated as *Functional dimension* (explaining 12.17% of variance), incorporated the items: 10 (Oral hygiene difficulties), and 3 (Speaking well). Finally, the fourth factor, called *Thoughts about health-behavioural habits dimension*, was the less explanatory (10.14% of variance), and was composed of the items: 9 (Importance of daily habits of oral hygiene), and 8 (Importance of dental revisions) (Table 3; Appendix A).

The QoLFAST-10 total and dimensional scores exhibited inverse correlations with the total score of the OHIP-20sp, meaning that subjects with higher QoLFAST-10 scores (lower negative impact) tended to present lower OHIP-20sp scores. Given that the qualitative interpretation of both tests coincided, the convergent validity of the QoLFAST-10 was statistically confirmed. Among such correlations, those of the *Social*, *Functional* and total QoLFAST-10 scores with the OHIP-20sp total score, were significant ($p < 0.001$; Table 4: Convergent validity).

The total score of the QoLFAST-10 questionnaire showed direct significant correlations with all of its dimensions ($p < 0.001$), and significant inverse correlations ($p < 0.001$) with some dimensions of the OHIP-20sp indicator (i.e., *Functional limitation*, *Physical pain*, *Psychological discomfort*, and *Psychological disability*) (Table 4).

The OHIP-20sp scale demonstrated direct significant correlations ($p < 0.05$) with all of its dimensions except for the *Handicap* domain (Table 4).

The global oral satisfaction measures (VAS) showed significant correlations with both the QoLFAST-10 total score (lower QoLFAST-10 total scores implied higher *global oral dissatisfaction*); and with the OHIP-20sp total score (higher OHIP-20sp scores corresponded to higher *global oral dissatisfaction*) (Tables 2 and 4).

Therefore, all of the *global oral satisfaction* measures reported by the patients (Table 2: Criterion validity) were found to modulate the QoLFAST-10 impact scores ($p < 0.001$). This fact confirmed adequate criterion validity for the created index (Table 2). Actually, the three VAS self-rated *satisfaction measures* were factors that directly influenced the OHRQoL as evaluated with either the QoLFAST-10 or the OHIP-20sp questionnaires ($p < 0.05$) (Table 2: Criterion validity).

Concerning the analysis of the discriminant validity, the prosthodontic groups were significantly discriminated by the

QoLFAST-10 total score ($p = 0.05$); and by the scores of its *Functional* ($p = 0.03$), and *Thoughts about health-behavioural habits dimensions* ($p = 0.003$) (Table 5: Discriminant validity).

Hence, patients restored with HP showed significantly higher OHRQoL than did IO wearers as measured with the QoLFAST-10 index ($p = 0.03$). No significant differences were encountered between CD and IO wearers ($p = 0.09$), and between CD and HP users ($p = 0.3$).

Similarly, as regards the *Functional dimension* of this scale, HP users confirmed significantly higher functional satisfaction than did IO wearers ($p = 0.01$). No significant differences were found between CD and IO ($p = 0.12$), or between CD and HP groups ($p = 0.15$).

Patients wearing IO reported less adequate *Thoughts about health-behavioural habits* than did both CD and ($p < 0.001$) and HP groups ($p = 0.03$). CD and HP users showed statistically comparable results in this regard ($p = 0.51$).

On the other hand, the total score of the OHIP-20sp and its *Physical pain* dimension significantly discriminated among the prosthodontic groups ($p = 0.04$, and $p = 0.02$; respectively) (Table 5: Discriminant validity). Using this scale, IO wearers showed significantly lower OHRQoL than did HP users ($p = 0.02$). However, both IO and HP groups attained comparable values with respect to CD wearers ($p = 0.06$, and $p = 0.34$; respectively). Concerning *Physical pain*, subjects with IO demonstrated significantly lower satisfaction than did CD ($p = 0.02$), and HP users ($p = 0.02$); while CD and HP groups revealed no differences in this aspect ($p = 0.79$).

3.3. Analysis of the prosthetic well-being construct

From a socio-demographic point of view (Group 1 of variables), the OHRQoL of the study patients was not significantly affected by gender, age, and/or being partnered or not; regardless of the QoL scale utilized (Table 1). However, the *level of education* was identified as a modulator of patients' satisfaction ($p = 0.004$) (Table 1). Those subjects having non-university education recorded significantly higher QoLFAST-10 scores and, thus, better oral-related well-being than did patients with university education ($p = 0.002$). Illiterate patients showed intermediate QoL values, with no significant differences concerning non-university and university-educated participants ($p = 0.18$, and $p = 0.08$; respectively).

The clinical variables: *presence of oral candidiasis* and *mucosal lesions* (Group 2 of variables) did not modify the OHRQoL of the volunteers as scored with the QoLFAST-10 or the OHIP-20sp indices (Table 1). Nor did the *location, type of antagonist, status of the prosthesis,* and *retention system (in the case of overdentures)* (Group 3 of variables) (Table 1).

With regard to the self-perceived satisfaction with the mouth (Group 4 of variables), both scales confirmed the influence of the *complaints about the mouth* on patients' satisfaction ($p = 0.001$) so that patients who did not complain reported higher QoL. Finally, the *perception of needing dental treatment* modulated the patients' well-being as shown by the OHIP-20sp scale ($p = 0.02$). Hence, patients who did not perceive the need for dental treatment showed higher satisfaction (Table 1).

The profile of the subjects obtaining lower QoLFAST-10 scores (*i.e.,* poorer OHRQoL) was that of a man with 60 years or less, with partner, and university education ($p = 0.004$) (Group 1 of variables); who had oral candidiasis and mucosal lesions (Group 2 of variables), worn the prosthesis in the mandible (with locators in case of bearing an implant overdenture), had a complete denture as antagonist, required his/her prosthesis to be replaced (Group 3 of variables); complained about the mouth, and perceived the need for dental treatment (Group 4 of variables) (Table 1). Nevertheless, except for the level of education and the variables of Group 4, these factors did not significantly affect the OHRQoL.

4. Discussion

For the first time, items related to aesthetics and health-behavioural habits have been combined with other functional and social aspects in a new, complete, short, and effective OHRQoL questionnaire, named 'QoLFAST-10'. This scale was validated for IO and fixed-detachable HP wearers in this clinical trial. The null hypothesis was rejected because the type of prosthetic restoration affected the oral well-being, and various study variables modulated the QoL of the tested groups. One limitation of this study was that the patients were recruited from a unique university dental clinic. However, the diverse precedence of the participants makes our results extrapolable [4,7,24]. The presence of uncontrolled confounding factors that are inherent in clinical investigations may have also affected the results to some extent [35].

The content and face validities of the QoLFAST-10 index were confirmed in the pilot trial: subjects understood the questionnaire and the items precisely capture the perceptions about OHRQoL of implant-treated patients, without lacking any relevant content [1,8–10,25,33].

The Cronbach's α value confirmed the reliability of the new scale [30,31,36] (Table 3). The strong correlation between the total and dimensional QoLFAST-10 scores remarked the internal consistency [22,30] (Table 4). Also the bidirectional items' responses resulted more complete than the traditional negative-oriented QoL measures of the OHIP indices (among others) [33,37]. This is crucial, as most of the QoLFAST-10 items were perceived as positive events (Table 3).

As for the construct validity, the multidimensionality of the QoLFAST-10 index was confirmed by the statistical emergence of four differentiated dimensions. According to previous studies [9,10,17,21,32], a simple structure was obtained because each item was weighted heavily and exclusively on one dimension (Table 3).

The convergent validity of the QoLFAST-10 was supported by the significant inverse correlations between: *a)* the total scores of both scales; and *b)* the total score of the OHIP-20sp with the *Social* and *Functional* dimensional scores of the QoLFAST-10; and between the QoLFAST-10 total score with the scores of four dimensions of the OHIP-20sp (Table 4). These associations confirmed that both indices assessed the same construct [23], which is important, as the OHIP-20sp had recently been validated in the same reference population [6].

Moreover, the criterion validity of the QoLFAST-10 was proven because those participants who reported being unsatisfied with their aesthetics, chewing function, and prosthesis, obtained significantly lower QoFAST-10 scores, demonstrating poorer QoL (Table 2), which is in line with the literature [6,8–10,21].

However, the main achievement of this study is that the implant prosthetic groups were discriminated by the total score of the new questionnaire (Table 5); which, consistently with the OHIP-20sp, attributed greater discontent to those patients restored with IO when compared to subjects rehabilitated with HP. Both the QoLFAST-10 dimensions: *Functional* and *Thoughts about health-behavioural habits,* significantly discriminated among the tested groups (Table 5). In terms of *Function*, HP wearers showed significantly better self-perceived satisfaction when compared to IO wearers. Previous studies attributed improvements in stability, comfort, and ability to chew to fixed implant restorations when compared to removable ones [15,38]. Although several clinical trials have found a better QoL in implant therapy [4,5,39], CD users reported significantly comparable *Functional* satisfaction than did subjects rehabilitated with IO and HP, as measured with the QoLFAST-10 index. Similar results were found when considering the total scores of the new scale. CD wearers (who just formed a control group to validate the new index for implant-restored patients), use to select low-stress and low-costs interventions because of their socio-economic and/or clinical conditions. This probably lead them to have lower expectations and to accept the limitations of conventional dentures [40,41]. Moreover, our participants were not demanding dental care during the study, suggesting that most patients were pleased with their functional and overall oral-related well-being [8]. Nonetheless, the effect and magnitude of socio-economic status, expectations, ease of adaptation, and anxiety towards dental rehabilitation on the final patient satisfaction should be addressed to validate these results. Consistent with previous research [16], IO wearers reported significantly more inadequate *Thoughts about heath-behavioural habits* than did CD and HP groups. Patients rehabilitated with IO normally require more dental check-ups than do CD and HP users (*e.g.,* for activating/replacing attachment components)[42–44]. The narrow space between the bar and the mucosa complicates the cleaning process of the *peri*-abutment zone of bar-retained overdentures [45]. However, the idea of having implant retention could make IO wearers more unconcerned about prosthetic maintenance with respect to CD users. Regular dental check-ups have been associated with a better OHRQoL [46]. In this regard, HP wearers use to be more aware of the relevance of dental revisions and daily care because of their fixed design. Finally, CD wearers (who showed similar levels of consciousness with the importance of health-behavioural habits than did HP users), are specially advised to maintain correct hygiene in order to prevent the occurrence of stomatitis [5,39,47]. These reasons may somewhat explain our findings. The OHIP-20sp scale attributed the significantly highest *Physical pain* to IO wearers. Although the presence of implants increases the stability of overdentures, their characteristic mobility and its effect onto the mucosa probably cause a greater pain in this group [48].

Concerning the effect of the study variables, the *level of education* significantly influenced the patients' well-being as scored with the QoLFAST-10 index (Table 1). Subjects not educated at university expressed significantly higher satisfaction with their prostheses; while those who had graduated from university were more likely to exhibit concerns and anxieties about oral treatments [21,49]. However, the absence of significant differences between illiterate patients with the two other groups deserves further investigation. Patients who *complained about their mouths* reported

significantly lower QoL and, thus, obtained lower QoLFAST-10 scores. [4,7,10,24] This expected effect was even detected by the generic OHIP-20sp index [8–10] (Table 1).

The remaining study variables did not significantly affect the patients' satisfaction as shown by the QoLFAST-10 index (Table 1). Nevertheless; several close, non-significant associations were identified, considering that a larger sample could reveal statistical significance in some of them. The profile of the least satisfied patients was that of a man under 60 years of age, with partner, university education, and candidiasis and mucosal lesions. Psychological differences between men and women would help explain the absence of significant effect of *gender* on the QoL, as the perception of individuals is more strongly influenced by self-evaluation than by objective parameters [50]. *Age* was not a modulating factor of oral-related well-being, as previously reported [4,7,10]. Nevertheless, satisfaction and tolerance of complications seem to increase with age [44]. Although more studies are necessary, subjects who lived with their partner expressed higher dissatisfaction, which is consistent with previous research [8]. In addition, candidiasis and mucosal lesions tended to hamper the self-perception of QoL. [51] Full, lower-jaw prostheses seem to provide lower satisfaction [7,8], probably due to the centrifugal resorption pattern of the mandible that affects the osteomucosal support of the residual ridge; which frequently results in flat ridges [7,8,52]. The OHRQoL lowered by having a complete denture as antagonist, as reported in related investigations [7,10]. This may be explained by the poorer stability and retention of muco-supported complete restorations [4,7] when compared with RPDs (removable partial dentures) or implant-supported or tooth-supported FDPs (fixed dental prostheses). As in previous studies [7,53], patients who required their prosthesis to be replaced reported minor satisfaction. Locators supplied the lowest QoL among the attachments tested in the case of IO. [8,54] In contrast, balls and bars have been described to provide higher satisfaction regarding comfort, stability, and ability to chew [8,15,54]. Patients who *perceived the need for dental treatment* obtained lower levels of OHRQoL [10]. However, unlike what happened with the OHIP-20sp, the new index' scores were not significantly affected by this variable [8]. Actually, the technical complications of implant prostheses do not necessarily affect the prosthetic-related satisfaction of patients [55], which may also depend on personality traits [56].

Patient motivation and improvements of strategies for oral rehabilitation are essential to promote oral health worldwide [46,57]. The QoLFAST-10 index may help in predicting the satisfaction of candidates for implant therapy on the basis of their socio-demographic, clinical, and prosthesis-related features. When compared with IO, HP restorations seem to provide better OHRQoL.

5. Conclusions

Within the limitations of the current investigation, the following conclusions may be drawn:

1. The QoLFAST-10 questionnaire has suitable psychometric characteristics for measuring the impact of implant over-dentures and hybrid implant prostheses on oral-related well-being.
2. The total punctuation and the dimensional scores of both the *Function* and *Thoughts about health behavioural habits domains* of the QoLFAST-10 significantly discriminated among the prosthodontic groups.
3. Implant overdentures supplied lower functional and overall satisfaction than did hybrid implant restorations, and represent

the least predictable treatment option concerning the long-term maintenance of the prosthesis.
4. The *level of education, complaints about the mouth,* and the three *global oral satisfaction measures of the VAS analysis* significantly modulated the OHRQoL as measured with the QoLFAST-10 index.
5. The QoLFAST-10 scale may help estimating the impact of implant restorations on patients well-being. In this regard, hybrid prostheses seem to be the implant treatment of choice when compared with overdentures. Hence, the information provided by the QoLFAST-10 shows potential benefits for decision-making; since the thoughts about health-behavioural habits included in this questionnaire play a key role in the patient satisfaction with the restoration.

Appendix A.

Validated questionnaire QoLFAST-10

*Please indicate your level of agreement with the following statements and give the appropriate score in each case:

Quality of Life related to Function, Aesthetics, Socialization and Trends of health-behavioural habits (QoFAST-10)	Strongly disagree (−2)	Disagree (−1)	Indecisive, indifferent or neutral (0)	Agree (+1)	Strongly agree (+2)

Item and dimensional scores*
D1. SOCIAL
1. You feel comfortable in social situations with your implant prosthesis
2. You can eat well with your implant prosthesis, which has a positive social repercussion
3. If you suffer oral pain due to your implant prosthesis, such pain has no social impact
4. Your implant prosthesis helps you developing your daily activities
D2. AESTHETIC
5. You are satisfied with the size, shape and colour of your prosthetic teeth
6. You smile confidently with your implant prosthesis
D3. FUNCTIONAL
7. You clean your mouth and implant

(Continued)

Quality of Life related to Function, Aesthetics, Socialization and Trends of health-behavioural habits (QoFAST-10)	Strongly disagree (−2)	Disagree (−1)	Indecisive, indifferent or neutral (0)	Agree (+1)	Strongly agree (+2)
prosthesis without difficulties					
8. You can speak well with your implant prosthesis					
D4. *THOUGHTS ABOUT HEALTH-BEHAVIOURAL HABITS*					
9. You consider that your daily habits of oral hygiene are decisive for the maintenance of your implant prosthesis					
10. You consider that oral revisions are essential to improve your QoL and the durability of your implant prosthesis					
Total score of the QoLFAST-10 scale*					

*The dimensional and total scores can be obtained by adding the respective item scores (the negative and positive signs must be considered).

The higher the resultant score is, the higher the satisfaction of the patient is (meaning that negative or low positive scores indicate poorer self-perceived QoL).

D1, D2, D3, and D4: dimensions of the QoLFAST-10 index.

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