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Clinical and Self-Reported Measurements to Be Included in the Core Elements of the World Dental Federation's Theoretical Framework of Oral Health

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ABSTRACT

Introduction: Oral health is part of general health, and oral diseases share risk factors with several non-communicable diseases. The World Dental Federation (FDI) has published a theoretical framework illustrating the complex interactions between the core elements of oral health (CEOHs): driving determinants, moderating factors, and general health and well-being. However, the framework does not specify which self-reported or clinical measurements to be included in the CEOHs.

Objectives: To explore oral health measurements relevant for a general adult population to be included in the CEOHs in the FDI's theoretical framework of oral health.

Materials and methods: A psychometric study was performed, using cross-sectional data from Sweden ($N = 630$, 54% women, mean age 49.7 years). The data set initially consisted of 186 self-reported and clinical measurements. To identify suitable measurements, the selection was discussed in different settings, including both experts and patients. Principal component analyses (PCAs) were performed to explore, reduce and evaluate measurements to be included in the three CEOHs. Internal consistency was estimated by Cronbach's Alpha.

Results: The validation process yielded 13 measurements (four clinical, nine self-reported) in concordance with the CEOHs. PCAs confirmed robust validity regarding the construction, predicting 60.85% of variance, representing psychosocial function (number of measurements = 5), disease and condition status (number of measurements = 4), and physiological function (number of measurements = 4). Cronbach's Alpha indicated good to sufficient internal consistency for each component in the constructs ($\alpha = 0.88, 0.68, 0.61$, respectively).

Conclusion: In a Swedish general adult population, 13 self-reported and clinical measurements can be relevant to include to operationalise CEOHs in the FDI's theoretical framework.

Introduction

According to the World Health Organisation (WHO), oral health is a key indicator of general health and well-being, and oral diseases share modifiable risk factors with several non-communicable diseases (NCDs) such as cancer, cardiovascular and chronic respiratory diseases[1]. Oral diseases, such as dental caries, periodontitis and oral cancer, may have an impact on an individual's life regarding discomfort, pain and death, and affect 3.9 billion people worldwide. For example, untreated dental caries is the most prevalent NCD globally[1,2]. Oral health has been defined by WHO as a state of being free from oral and facial

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pain, oral cancer, infection and lesions, periodontal disease, dental caries, tooth loss, and other diseases and conditions that may have an impact on an individual's psychosocial well-being and ability to function regarding chewing, smiling and speaking[1]. However, even though widely cited, the WHO's definition has been criticised as unrealistic and therefore unachievable, and has furthermore been interpreted differently by different dental professions[3]. The WHO has also identified the need for standardised indices to measure different components of oral health, including essential measurements that reflect the complex nature of oral health[4]. According to Figueiredo *et al.*[5], attempts have been made to create a multidimensional instrument, including several oral diseases or conditions, to measure clinical oral health. However, according to Locker[6], clinical oral health measurements can be directly related to both psychosocial and physiological functions, and subjective measurements should be included in a multidimensional instrument of oral health. To the best of our knowledge, a multidimensional valid instrument that includes both self-reported and clinical measurements of oral health has not yet been developed.

In 2017, the World Dental Federation (FDI) proposed a new definition of oral health, including a theoretical framework (*Figure 1*) that includes different domains that are essential for oral health[3].

> Oral health is multi-faceted, and includes the ability to speak, smile, smell, taste, touch, chew, swallow and convey a range of emotions through facial expressions with confidence, and without pain, discomfort and disease of the craniofacial complex.
>
> Further attributes of oral health:
>
> - is a fundamental component of health and physical and mental well-being. It exists along a continuum influenced by the values and attitudes of individuals and communities;
> - reflects the physiological, social and psychological attributes that are essential to the quality of life;
> - is influenced by the individual's changing experiences, perceptions, expectations and ability to adapt to circumstances[3]

This new definition and the accompanying framework are influenced by earlier theoretical models that have highlighted the importance of a wider perspective of determinants that affect oral health[7–9]. The definition and theoretical framework aim to create a common, acceptable and workable definition of oral health that can bring dental professionals and other stakeholders together as well as explain the interactions between different domains of oral health[3,10], whereas some of them cannot be detected by clinical examination alone. This new definition and theoretical framework also include patients' perceptions, experiences and expectations that previously have been overlooked when oral health was interpreted as absence of disease[3]. As stated by Glick *et al.*, this new definition and theoretical framework open up a possibility to further reflect on the complex nature of oral health and what it encompasses. The theoretical framework describes the interactions between several dimensions of oral health[3]. In order to promote oral health and tackle oral health inequalities by integrating oral healthcare with general healthcare systems, a common and acceptable definition and theoretical framework, useful both in research and clinical dental care, is essential[11]. Central parts of the framework are: disease and condition status; physiological function; and psychosocial function, described as the core elements of oral health (CEOHs). Together, the CEOHs refer to all diseases and conditions related to oral health and the craniofacial complex, including presence, severity and progression, abilities, capacities and functions[3,10]. The definition and theoretical framework emphasise the importance of bringing in different perspectives on oral health from both professional and patient perspectives, as oral health is influenced and affected by general health and well-being as well as the individual's perceptions and experiences[3].

Therefore, identifying both clinical and self-reported measurements can be useful when designing oral health research projects, and can also be a means to operationalise the CEOHs in the clinical setting. In oral health research, identifying relevant measurements to reflect oral health in different populations and settings can, in the long run, assist in refining a single outcome measure of oral health, which

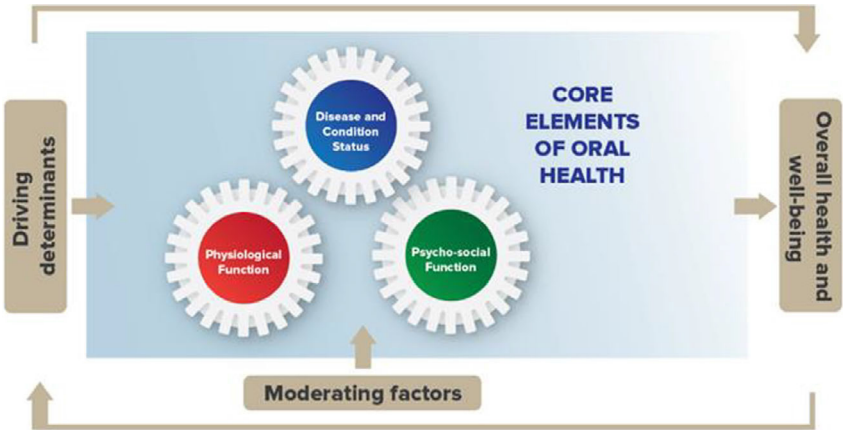

Fig. 1 – The theoretical framework developed by the World Dental Federation (FDI; adapted with permission from ©FDI World Dental Federation. All rights reserved).

can be an optimal goal[12]. By highlighting the importance of the CEOHs and with implementation of a wider perspective on oral health and its complex nature, additional questions can be asked in clinical dental care regarding the patients' perceptions, experiences and expectations. This approach can assist the dental practitioner to encourage personal-centred dental care, and towards a biopsychosocial view in providing support and thus promote oral health[10].

Even though it has several strengths, the FDI's theoretical framework does not yet specify which self-reported or clinical measurements could be included to illustrate the CEOHs[3,10]. The aim of the study was to explore oral health measurements relevant to a general adult population to be included in the CEOHs in the FDI's theoretical framework of oral health. Furthermore, the intention of this study was to propose a way to operationalise the CEOHs by testing self-reported and clinical measurements using an empirical data set. This could be a first step towards enabling the creation of a valid and reliable instrument to measure oral health based on the FDI's definition and theoretical framework.

Materials and methods

Design

A psychometric study was performed.

Description of data

Since 1973, an epidemiological research project with the main aim of describing and comparing oral health in a general population in the south of Sweden over time has been ongoing. Within the research project, a new data collection has been performed every 10 years. In each data collection wave, 130 participants in each of the following age groups, 5, 10, 15, 20, 30, 40, 50, 60, 70 and 80 years, have been randomly selected from the same region in the south of Sweden. Selected individuals have been invited to undergo clinical and radiographic examination, and asked to respond to a questionnaire. For this study, the study sample from 2013 was used, including only the adult age groups 20, 30, 40, 50, 60, 70 and 80 years of age ($N = 630$). The original data were collected by five specialised dentists from the Public Dental Health Service Departments of specialised dental care, and three general practitioners from the Public Dental Health Service. Before performing the clinical and radiographic examinations, the dentists were calibrated regarding diagnostic criteria and examination procedures according to the examination protocol. The clinical and radiographic examinations were carried out as complete dental examinations with modern equipment and optimal lightning. All parts of the data collection procedure were completed in one visit for each participant between autumn 2013 and autumn 2014. All of the measurements and indices that have been used in the present study can be considered praxis in both research and clinical dental care in a Swedish context in 2013–2014. Information regarding the examination procedure and diagnostic criteria has been thoroughly reported and published previously by Norderyd *et al.*[13,14] Some items were removed from further assessments in the present study, for example, identification number, date of examination and examiner. Thus, in this study, 186 clinical, radiographic and self-reported measurements were assessed for inclusion.

Radiographic examination

In the age groups 20–50 years old, the radiographic examination was carried out by an orthopantomogram and six bite-wings, and in the age groups 60–80 years old with an orthopantomogram and a full-mouth, intra-oral radiographic examination including periapical and bite-wing radiographs. Additional periapical radiographs were performed when needed in all age groups. For edentulous individuals, the radiographic examination was carried out by orthopantomogram only.

Clinical examination

Dental caries was diagnosed (initial, manifest, secondary or root surface) by both clinical and radiographic examinations, and periodontal status was diagnosed and classified by alveolar bone level, probing depth > 4 mm, and presence of angular bony defects and/or furcation involvement. Dental status was recorded by number of missing teeth, fissure sealants, restorations, dental implants, crowns and bridges. The examination also included measurements of stimulated saliva (mL/min), buffer capacity, and clinical examinations of temporo mandible disorders (TMDs), gingival index, visible plaque index, periapical status, as well as presence of erosion, abrasion, abfractions and abrasions, supra- and subgingival calculus, endodontic treatment, and mucosal changes.

Questionnaire

After the clinical and radiographic examinations, the participants were asked to respond to a questionnaire including questions regarding, for example, medical history, socio-economy, dental care visits, dental hygiene habits, self-reported TMD-related problems measured with questions such as *How do you perceive your ability to chew?* and *Have you during the last month had any reductions in your ability to chew tough foods?*, the abbreviated version of Oral Health Impact Profile 14 (OHIP-14)[15] measuring oral health-related quality of life, and the short version of the Orientation to Life Questionnaire measuring the Sense of Coherence (SOC-13)[16]. For this population, validity aspects regarding SOC-13 have previously been reported by Lindmark *et al.*[17] and Einarson *et al.*[18], respectively.

Data selection procedure

The reduction procedure to identify self-reported and clinical measurements for inclusion in the CEOHs and assure face and content validity was carried out in several stages. The three CEOHs (disease and condition status; physiological function; and psychosocial function) derived from the FDI's theoretical framework were set as the basis for a three-component solution. Potential measurements were discussed several times within the multi-professional research group

consisting of dental hygienists, dentists, nurses and epidemiologists, as well as with expert and patient groups. To assure content validity, the expert group consisted of dental hygienists and dentists within the fields of general dentistry, public dental health, periodontology, cariology, oral prosthetics, orthodontists, paediatrics, oral pathology and orofacial pain/medicine (including TMD). Field notes were taken throughout discussions within the research group, and in discussions with expert and patient groups. In all discussions, both within the research group and with the expert and patient groups, the aim was to confirm the concordance of selected measurements with the theoretical framework, and to include both expert and patient perceptions (*Figures 1 and 2*).

First, the data selection procedure was initiated by a discussion within the research group to reduce the initial 186 measurements. Potential measurements that were regarded as theoretically more fitting in the FDI's theoretical framework related to driving determinants, moderating factors, and overall health and well-being were excluded, leaving 55 measurements for further discussion as CEOHs.

The next stage was to present the project and aim in the expert group to initiate an open discussion with open-ended questions, for example, *Is the initial selection of measurements relevant based on FDIs theoretical framework of oral health?* and *Which measurements could be included in the core elements of oral health and which are more fitting in for example driving determinants?* The selection of measurements was then presented and discussed. This step reduced the potential measurements to 31.

After performing a first principal component analysis (PCA), the selection was again discussed within the research group. Based on the statistical results derived from the PCA, the number of measurements was reduced to 16. The results from the PCA were then discussed within the research group before a second analysis with PCA was performed and 11 measurements remained.

After the second PCA, this result was then presented to the expert group to assure content validity. The expert group was asked regarding relevant changes or additions to reflect their knowledge and experience within their expert area, which added four potential measurements to be tested. After this, a third PCA was performed, which revealed a fairly robust component solution including 15 measurements.

To confirm face validity, a patient group was involved of this part in the data selection procedure. The patient group was recruited from the same region as the study sample and consisted of a purposeful convenience sample, with the main aim being to include adults with a representative demographic variation regarding age, education, sex and previous dental experiences. Patients with professional experience within dentistry were excluded. The patient group was introduced to the project with the theoretical framework, visualised by a projector during the discussion. The discussion started with an open-ended question: *What do you think is important to include in the core elements of oral health?* After this, a potential model derived from the third PCA was presented. The group was then asked to compare their thoughts and perceptions with the suggested model. The patient group suggested some changes that were implemented in the potential model before the final PCA was performed.

Based on the field notes, comparisons were done between expert and patient groups with the aim to confirm face validity, and concordance with the theoretical framework. This step revealed some minor differences that were adjusted before the final selection of measurements was concluded. The final adjustments after the discussion with the patient group assured both content and face validity, as the changes did not include removing measurements but to merge some of them to enhance understanding and readability.

Final adjustments were made based on the discussions with expert and patient groups, before a final three-component construction with satisfactory statistical properties could be derived. This final construction constitutes the result presented below (*Figure 2*).

Description of statistical processing and analysis

Principal component analysis was used to reduce the number of possible measurements and create subsets of measurements based on their intercorrelations. PCA was regarded as suitable as no prior assumptions of the final construct were made except general specifications regarding the theoretical framework[19]. Data were examined for suitability for PCA by inspection of the correlation matrix for coefficients of 0.3 or above. Factorability of the correlation matrix was also tested for support by performing Bartlett's test for sphericity regarding redundancy between measurements (statistical significance $P < 0.001$) and Kaiser–Meier–Olkin (KMO) test of sampling adequacy regarding the proportion of variance in the sample (value > 0.6)[20,21]. PCA was performed to cluster the measurements using Varimax rotation with Kaiser normalisation and the PCA extraction method with a fixed number of components to represent the three CEOHs (disease and condition status; physiological function; and psychosocial function). Kaiser's criteria[22] and Cattell's Scree plot[23] were used to find eigenvalues > 1[24]. Kaiser's criteria were regarded

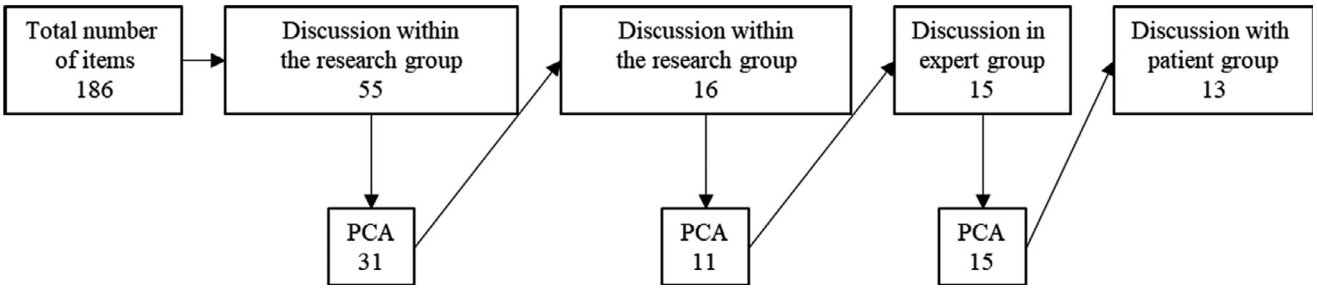

Fig. 2 – Description of reduction and validation process. PCA, principal component analysis.

as suitable, as the number of measurements included were < 40, the number of cases was large ($N = 630$), and the component solution was fixed ($n = 3$), thus lying within the calculated range between 2.6 and 4.3 (number of measurements/5 and number of measurements/3)[25]. Communalities were inspected for low values (< 0.3), which could indicate that a measurement did not fit well with the other measurements in the component[19,24,26].

Reliability of the three-component solution measured as internal consistency was analysed by Cronbach's Alpha for each component in the final three-component solution to estimate the average degree of correlation between the included measurements[25]. To test the stability of the three-component solution, an additional PCA was performed by using a split-file technique. The sample was split in half by a computer-generated random selection of 50% of all cases, then the statistical analyses, PCAs and calculations of Cronbach's Alpha coefficients were repeated. The results were then compared with the results from the analyses in which all cases were included. All statistical analyses were performed in IBM Statistical Package for the Social Sciences (SPSS) version 25[27].

Ethical considerations

The study, from which data were derived, was approved by the Regional Ethical Board in Linköping, Sweden[13,14] prior to data collection (ref. no. 2012/191-31). Before, during and after data collection, the rules of the Declaration of Helsinki[28] were applied, and informed consent was obtained from all participants.

RESULTS

Sample description

A total of 630 adults (20–80 years old) were included in the original study, although some participants did not respond to all the questions or undergo all assessments. In total, the sample comprised 343 (54.4%) women and 278 (44.1%) men, with missing data on sex for nine (1.5%) participants. The mean age of the whole sample was 49.7 years (Table 1).

Table 1 – Description of the study sample

Measurement	Total ($n = 630$)
Age, m (SD)	49.7 (19.2)
Sex, *n* (%)	
Female	343 (54.4)
Male	278 (44.1)
Number of missing teeth, m (SD)	3.04 (5.26)
Ability to chew tough food, m (SD)	1.04 (2.01)
Perceived ability to chew, *n* (%)	
Good	471 (74.8)
Fairly good	107 (17.0)
Fairly poor	9 (1.4)
Poor	1 (0.2)
OHIP-14, m (SD)	
Social disability	3.44 (2.3)
Psychological disability	3.68 (2.5)
Handicap	3.12 (1.9)
Physical disability	3.29 (2.1)
Psychological discomfort	3.59 (2.5)
Physical pain	4.07 (2.6)
Functional limitation	2.92 (1.7)
Classification according to the severity of periodontal diseases experience, *n* (%)*	
Healthy or almost healthy	192 (30.5)
Gingivitis	176 (27.9)
Alveolar bone loss < 1/3	174 (27.6)
Alveolar bone loss 1/3–2/3	52 (8.3)
Alveolar bone loss > 2/3 and furcation involvement and/or angular bony defects	19 (3.0)
Total DFS score, m (SD)	29.3 (24.1)
Number of dental implants, crowns or bridges, m (SD)	2.15 (3.9)

DFS, decayed, filled surfaces; OHIP, Oral Health Impact Profile.

* Classification according to criteria by Hugoson and Jordan[39]: (1) healthy or almost healthy with no more than 12 bleeding gingival units around molars/premolars; (2) gingivitis with more than 12 bleeding units in molars/premolars with normal alveolar bone height; (3) alveolar bone loss not exceeding 1/3 of root length around most teeth; (4) alveolar bone loss between 1/3 and 2/3 of root length around most teeth; (5) alveolar bone loss exceeding 2/3 of root length around most teeth and presence of furcation involvement and/or angular bony defects.

Included measurements in the three CEOHs

Based on the results derived from the discussions within the research, expert and patient groups, the final result comprised 13 self-reported and clinical measurements, relevant to a general adult Swedish population. The field notes revealed that the patient group leaned more towards the perceived functional (social and personal), aesthetics and pain-free measurements than the expert group. The expert group discussed the clinical and radiographic measurements to a higher extent, but also emphasised that self-reported measurements were highly relevant to determine which measurements to include. The final selection of clinical and self-reported measurement relies on the joint experience, knowledge, recommendations and perceptions from all three groups.

The number of decayed teeth and restorations was merged into one measurement, decayed, filled surfaces (DFS), as well as number of dental implants, crowns and bridges. Chewing ability is represented with self-reported TMD-related problems measured with questions such as *How do you perceive your ability to chew?* and *Have you during the last month had any reductions in your ability to chew tough foods?* The Swedish version of OHIP-14[29,30] was used where the participants were asked; *How often in the last year have you experienced the following situations because of problems with your teeth, mouth or dentures?*

Measurements from OHIP-14 were then merged pairwise into seven dimensions representing: functional limitation (*Problems with pronouncing words* and *Felt that your sense of taste has worsened*); physical pain (*Had painful aching in your mouth* and *Had found it uncomfortable to eat any foods*); psychological discomfort (*Have been self-conscious* and *Felt tense*); physical disability (*Had unsatisfactory diet* and *Had to interrupt meals*); psychological disability (*Had found it difficult to relax* and *Have*

been embarrassed); social disability (*Have you been irritable with other people* and *Had difficulties doing usual jobs)*; and handicap (*Felt that your life in general was less satisfying* and *Have been totally unable to function*)[31].

The three components were named according to the CEOHs in the FDI's theoretical framework: psychosocial function (number of measurements = 5); disease and condition status (number of measurements = 4); and physiological function (number of measurements = 4). All the included measurements are or can be used in clinical dental care to operationalise the CEOHs.

The combination of the measurements in the three CEOHs is illustrated in *Figure 3*.

The first core element, psychosocial function, included five self-reported measurements. All were derived from OHIP-14 included in the questionnaire used in the original study. Included measurements were: social disability; psychosocial disability; handicap; physical disability; and psychological discomfort.

Regarding the second core element, diseases and condition status, all four included measurements were clinical measurements. The *Number of dental implants, crowns and bridges, Total DFS score, Number of missing teeth* and the *Severity of periodontal diseases experience*, were included.

The third core element, physiological function, included four self-reported measurements. One statement and one question regarding chewing ability were derived from the original questionnaire used in the study (*Ability to chew tough food* and *How do you perceive your ability to chew?*). From the OHIP-14 scale, two measurements were included: physical pain; and functional limitation.

Results from the PCA

The results from the PCA based on the 13 measurements that were selected from the stepwise procedure described above are shown in *Table 2*.

The factorability of the correlation matrix was supported by Bartlett's test for sphericity (approx. $X^2 = 2871.\ 15$, $P < 0.001$) and the KMO test of sampling adequacy (value 0.78). After oblique rotation of the correlation matrix, the component correlation matrix showed weak correlations (−0.07, 0.07 and 0.29, respectively) between the components, indicating that PCA with Varimax rotation was suitable as a rotation method. As shown in *Table 2*, component loadings were fair to excellent (0.45−0.87). Inspection of the rotated pattern matrix revealed quite a solid component solution; however, two measurements loaded in two components. The physiological function component measurements (physical pain and functional limitation) showed cross-loadings on the psychosocial function component (0.47 and 0.41, respectively), but both showed higher loadings (0.48 and 0.45, respectively) on the physiological function factor. The communalities indicated that all retrieved measurements did fit the components (0.37−0.76). The lowest communality was found in functional limitation.

The three-component solution explained 60.85% of the variance in the data in total, and the components explained

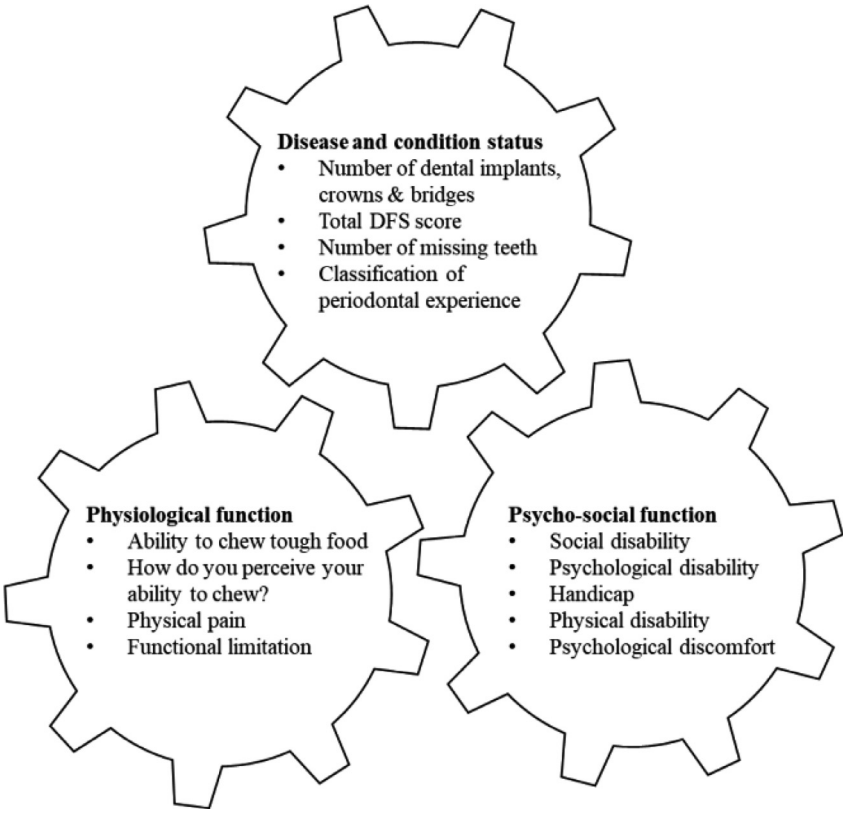

Fig. 3 – Illustration of the three-factor solution with distribution in each core element of the final selection of measurements in the core elements of oral health (CEOHs).

Table 2 – Mean scores, inter-item correlation coefficients, inter-total correlation, Cronbach's Alpha coefficients, component loadings and communalities for the three-component solution

CEOHs	Mean	IIC	ITC	Cronbach's Alpha	Component loadings			Communality
				α	1	2	3	
Psychosocial function ($n = 599$)								
Social disability	3.44	0.51–0.70	0.734		**0.862**			0.753
Psychological disability	3.68	0.58–0.69	0.664		**0.861**			0.753
Handicap	3.12	0.46–0.70	0.691		**0.817**			0.672
Physical disability	3.29	0.51–0.59	0.664		**0.743**			0.604
Psychological discomfort	3.59	0.46–0.64	0.657		**0.725**			0.609
Total	3.42	0.46–0.70		0.87				
Disease and condition status ($n = 613$)								
Number of dental implants, crowns and bridges	2.13	0.29–0.70	0.695			**0.871**		0.759
Total DFS score	4.39	0.24–0.70	0.538			**0.824**		0.705
Number of missing teeth	2.77	0.24–0.51	0.468			**0.656**		0.562
Classification of periodontal disease experience		0.29–0.38	0.425			**0.633**		0.413
Total		0.24–0.70		0.68				
Physiological function ($n = 575$)								
Ability to chew tough food	1.04	0.32–0.46	0.458				**0.775**	0.645
How do you perceive your ability to chew?		0.20–0.46	0.425				**0.748**	0.569
Physical pain	4.07	0.29–0.34	0.427		0.469		**0.484**	0.495
Functional limitation	2.92	0.20–0.34	0.400		0.408		**0.453**	0.372
Total		0.20–0.46		0.61				
Eigenvalue					4.110	2.414	1.386	
Variance explained (%)					31.614	18.571	10.665	

CEOH, core elements of oral health; DFS, decayed, filled surfaces; IIC, inter-item correlations; ITC, item-total correlations. The bold values show the highest factor loading above .4, as there are crossloadings in factor 3.

31.61% (psychosocial function), 18.57% (disease and condition status) and 10.67% (psychological function) of the variance, respectively. Internal consistency, estimated by Cronbach's Alpha, was α = 0.87, 0.68 and 0.61, respectively (*Table 2*). The homogeneity of the measurements was controlled by mean inter-item correlations (0.59, 0.42 and 0.32, respectively) and item-total correlations (range 0.40–0.73). No additional component showed an eigenvalue > 1 (Kaiser's criterion), and Cattell's scree plot also showed a break after three components.

After the sample had been split in half by a computer-generated random selection of 50% of the cases, the statistical analyses were repeated. No major differences could be seen compared with the total sample when repeating the PCA in the split-half data set. Data were checked for suitability using Bartlett's test for sphericity (approx. $X^2 = 1{,}388.83$, $P < 0.001$) and KMO test of sampling adequacy (0.76). Internal consistency remained stable (α = 0.87, 0.68 and 0.61, respectively). This three-component solution explained 60.50% of the total variance in the data, with no alterations in the highest component loadings.

Discussion

This study aimed to explore self-reported and clinical measurements to be included in the CEOHs: psychosocial function; disease and condition status; and physiological function; and to propose a way to operationalise the CEOHs in clinical dental care. In this explorative research process, several decisions were made to confirm results were valid and reliable, including both self-reported and clinical oral measurements. All decisions aimed to validate that all included measurements were in concordance with the theoretical framework from both experts' and patients' perspectives. The results revealed satisfactory validity as well as reliability in terms of internal consistency estimated by Cronbach's Alpha regarding the three-component solution (number of measurements = 13). The final construction remained stable after cross-validation by repeating the statistical procedures in 50% of the cases. Thus, this study suggests that the CEOHs can be operationalised in a Swedish context using empirical data from a general population, and supports further research regarding validation of the theoretical framework and development of a single outcome measurement for oral health based on the theoretical framework developed by the FDI.

Reliability

Based on the distribution of demographic factors, this study sample has previously been assumed to be representative of a Swedish adult population regarding age, sex and ethnicity[13]. Sample size in factor analysis is important as the component solution can be regarded as more stable and therefore more reliable in large-scale analyses[32]. However, the criterion of adequate sample size is dependent on high values of communalities and well-determined components, and not just the number of cases[26]. Both sample size and communalities in this study were considered to adequately meet the criteria[21,26], indicating a solid three-component solution.

The internal consistency estimated by Cronbach's Alpha was regarded as sufficient for all three components in the factorial construct. Psychosocial function showed the highest

estimated alpha coefficient. The other two core elements: disease and condition status; and physiological function; had alpha values just below a common threshold of $\alpha = 0.7$[33]. As the α-values were somewhat low, the mean inter-item correlation was also controlled (between 0.15 and 0.50 or above)[34], and the item-total correlations were above 0.3[24]. Adding additional measurements to increase avalues did not improve the three-component solution. Reducing the number of measurements could have raised the α-values, but with a risk of reducing content validity[35]. Altogether, α-values, inter-item and item-total correlations indicated sufficient internal consistency for the three components identified in the study.

Validation

Validation can be regarded as an ongoing process, where there is an interaction between measurements, study population, and the context the study was performed in. The validity of a construct concerns how much meaningful information that can be derived from the results, and can also guide the reader into which conclusions to be made[35]. To enhance the validity of the three-component solution, included measurements were derived from several sources, including theory, clinical and self-reported measurements, as well as perspectives from both experts and patients[15]. In this study, both experts and patients confirmed the selection of measurements regarding concordance with the CEOHs. The combination of discussions with experts within and outside dentistry, and patients enhanced the content and face validity. The main aim with the discussions with expert and patients was not to obtain total agreement, but to ensure perceptions from a wide set of individuals regarding readability, understanding, experiences and knowledge were recovered. As somewhat expected, the patient group leaned more towards subjective measurements than the expert group. However, when reviewing the field notes from all discussion, the degree of agreement between the groups was regarded as satisfactory, making the selection of measurements plausible.

Altogether, the process included several recommended steps in scale development[36], and PCAs were performed both in the selection and validation process. Regarding content validation, the presented construct in this study included 13 clinical and radiographic, and self-reported measurements. Even if numerous measurements could be included, the aim was to explore which measurements could be used to cover most of the important aspects of the three CEOHs. To increase the internal consistency, as mentioned above, some measurements could have been excluded but with the risk to decrease content validity. Creating a construct with both high internal consistency and content validity is a balance act, where the decision to not exclude more items was regarded as more important to reflect the complex nature of oral health.

Another important aspect, related to face and content validity, is utility of a construct in clinical dental care. A construct with too many measurements, or poor face or content validity, can reduce the practical use, even if it is valid and reliable[35]. A time-consuming construct or one that requires additional resources to administer may be too impractical to ever be used. Because this study focused on one part of the theoretical framework, additional measurements will be added when the whole framework is validated. Therefore, optimising just the central part of the theoretical framework is essential to minimise the number of measurements to be included.

Implications

To be able to operationalise the definition and theoretical framework of oral health, an instrument that includes both self-reported and clinical measurements with an emphasis on dental caries and periodontal status should be developed[12]. Hescot[12] argues that having a commonly accepted definition of oral health could be of great importance to raise awareness of oral health as an integral part of general health. A valid and reliable theoretical framework can be used both in research and clinical dentistry. Theoretically driven research, like this study, can aid the implementation of evidence-based practices as it relies on research evidence, professional experience and expert knowledge, as well as patients' perceptions, preferences, experiences and expectations[37]. The findings of this study show that the CEOHs can be operationalised within clinical dental care, for example, by adding specific questions addressed to the patient. It is also suggested that a study designed with the purpose of developing an instrument to measure oral health as a single outcome measurement can be aided by the results of this study. The complex nature of oral health needs to be thoroughly investigated in different settings to ensure global generalisability of the definition and the theoretical framework. Both the CEOHs and the whole FDI theoretical framework of oral health need to be assessed in different settings, both geographical and in specific populations, to make sure that all relevant issues in different populations can be addressed.

Limitations

As mentioned above, in construct validation, the process should be seen as ongoing as it reflects the interaction among selected measurements, participants and the conditions under which the process was carried out[35]. Therefore, in this study, there are some considerations that should be mentioned before interpreting the results. The measurement selection process was limited due to the composition of the data set used in the study[13,14], as the measurements were not specifically developed for this study. For example, inclusion of clinical assessment of the mucosal status, and oral cancer in particular, as well as the presence of dentures was thoroughly discussed, considering their relevance to the theoretical framework, and these factors were analysed statistically. However, due to the low prevalence of mucosal lesions or conditions in the data set and the relatively low prevalence in the population in general[34], the results were unsatisfactory. If mucosal diseases or conditions were painful or had other impacts, it is suggested that this is reflected by OHIP-14. Another limitation that needs to be addressed is the context where the original study was performed, whereas the Swedish context itself could be considered a limitation for the generalisability of this study. Dental care is in general easy accessible both regarding public dental health care and

private dental care clinics. Moreover, the National Dental Insurance (NDI) has also subsidised the cost of dental care for adults since 1974[38]. The higher prevalence of dental implants could be regarded as an example of this, as the high-cost protection system included in NDI subsidises more expensive dental treatments at 85%. In this study sample, the presence of dentures was very low, and the presence of dental implants had increased since the last wave of data collection in 2003[14]. Therefore, the presence of dentures was excluded, and dental implants were considered more relevant in this population. However, this might be relevant to reconsider to better represent the dental status in another population. Furthermore, due to the limited research within this area, no results were found to compare with our results. Altogether the limitations highlighted in this section could affect the generalisability of the study, which should be kept in mind when interpreting the results.

Conclusions

Our findings suggest 13 valid and reliable clinical and self-reported measurements to be considered relevant for inclusion in the three CEOHs in the FDI's theoretical framework of oral health. The results are significant as they highlight the importance of including several clinical and self-reported measurements to enhance awareness of an individual's oral health. Considering the complex nature of oral health and the limitations highlighted in this study, both the CEOHs and the entire framework should be further investigated in several different settings, including both general and specific populations, to ensure the global adaptability and workability of the definition and theoretical framework.

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