Abstract

Problem description: Edentulism fulfills the ICF/WHO[15] (ICF: International Classification of Function Disability and Health/ WHO: World Health Organization) definition for impairment, disability and dysfunction. However, due to the lack of an updated operational definition and epidemiologic, diagnostic and clinical resources for defining and characterizing edentulism, dentistry struggles to translate and bring to clinical practice recent scientific advances. New technology remains out of reach at the lab bench, for identifying, characterizing, diagnosing, treating, modulating, protecting and reaching all affected population and sectors of society at risk or suffering the burden of this common multidimensional condition. The ACP (American College of Prosthodontics) has proposed a diagnostic system to address this need. This study will test and observe the properties of this index. **Study purpose**: to observe, measure and describe the psychometric and epidemiological properties of the diagnostic system PDI-CE (Prosthodontic Diagnostic Index for Complete Edentulism) and its operational definition for identifying, quantifying and measuring complete edentulism. **Research question:** Does PDI-CE as applied by calibrated users under different testing conditions, accurately identify measure and quantify matching parameters provided by the ACP/PDI-CE validation task force as gold standard diagnostic outcomes for this test? **Materials and methods:** 3 calibrated groups of clinicians, from different sites, backgrounds and demographics were tested with the PDI-CE instrument. The groups applied this tool to a set of 11 standardized vignettes displaying a broad selection of clinical presentations of the condition ranging from class I, the mildest form, to class IV the most debilitating and advanced form of complete edentulism. A gold standard key containing the diagnostic outcomes for this test was provided by the ACP/PDI-CE validation task force. Tests and observations were conducted for: 1.validity, 2.reliability, 3. Clarity, simplicity and objectivity, 4. Quantifiability, 5. Sensitivity and specificity, and 6. Acceptability. **Definitions:** Validity was defined for this study, as the ability of the PDI-CE index to measure what it is intended to measure, so diagnosis by each test should correspond with the gold standard keys provided for each vignette, matching the disease under testing at each degree of compromise and complexity. Reliability will be regarded as the ability of the PDI-CE to consistently, at different times, under a variety of conditions and by the same or different examiners to interpret and use the index in the same way. For all items 1 to 6, data for descriptive statistics reporting such as counts, percentages, and averages was collected. Specific tests were conducted for: #1 the Kaiser-Meyer-Olkin measure of sampling adequacy (MAS), #2 Inter-rater reliability Kappa statistic analysis, Factor analysis (FA) and the Principal Component Analysis (PCA) using the ICF/MDDx (International Classification of Functioning Disability and Health / Multidimensional Diagnostic model) parameters for individual factor characterization, hypothesis development and testing. **Results:** It is expected that the present study will identify and quantify, measurable factors that consistently appeared in tests failing to diagnose the condition, when compared to the Gold-standard, whether they were missed or mistakenly used during each test, within providers and/or within field test site's groups. Thus, if observations, differences or recognizable patterns, in failure/success rates, are found for a specific site or group, they will be useful to preserve, simplify, modify, eliminate or add items, criterions or parameters to control, modulate and correct the potential confounders. Perhaps at last, consider a new study for validating an upgraded version of the PDI-CE.

Evaluating Epidemiological Properties of the American College of Prosthodontists (ACP) Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE)

[PDI-Study]

by

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I. Abstract

Problem description: Edentulism fulfills the ICF/WHO [15] (ICF: International Classification of Functioning Disability and Health/ WHO: World Health Organization) definition for impairment, disability and dysfunction. However, due to the lack of an updated operational definition and epidemiological, diagnostic and clinical resources for defining and characterizing edentulism, dentistry struggles to translate and bring to clinical practice recent scientific advances. New technology for identifying, characterizing, diagnosing, treating, and modulating edentulism remains out of reach at the lab bench. Protecting and reaching all affected population and sectors of society who are either at risk or afflicted by this common multidimensional condition remains elusive The ACP (American College of Prosthodontics) has proposed a diagnostic system to address this need. This study will test and observe the properties of this index. **Study purpose**: to observe, measure and describe the psychometric and epidemiological properties of the diagnostic system PDI-CE (Prosthodontic Diagnostic Index for Complete Edentulism) and its operational definition for identifying, quantifying and measuring complete edentulism. **Research questions:** When applied by calibrated users under different testing conditions, does the PDI-CE identify, measure, and quantify the parameters, generating results which consistently match the gold standard diagnostic outcomes provided by the ACP/PDI-CE validation task force? Does the use of ICF/MDDx characterization for factor analysis criteria facilitate the observation, documentation, organization and structure necessary to provide evidence that explains the data distribution within the proposed multiaxial factorial arrangement (success or failure)? **Materials and methods:** Three calibrated groups of clinicians from different sites, backgrounds and demographics were tested with the PDI-CE instrument. The groups applied this tool to a set of 11 standardized vignettes displaying a broad selection of clinical presentations of the condition ranging from class I, the mildest form, to class IV, the most debilitating and advanced form of complete edentulism. A gold standard key containing the diagnostic outcomes for this test was provided by the ACP/PDI-CE validation task force. Tests and observations were conducted for PDI-CE construct validity, and quantifiability. For all items, data for descriptive statistics reporting, such as counts, percentages, and averages, was collected. Specific tests were conducted with ANOVA, Bonferroni, Logistic regressions, and Kruska-Wallis, using the ICF/MDDx (International Classification of Functioning Disability and Health / Multidimensional Diagnostic model) parameters for individual factor characterization, hypothesis development, and testing. **Definitions:** *Validity* was defined for this study as the ability of the PDI-CE index to measure what it is intended to measure, i.e. diagnosis in each test should correspond with the gold standard keys provided. For each vignette. There is a key matching the disease under testing at each degree of compromise and complexity. *Construct Validity* was regarded as the ability of the conceptual definition to match the operational definition, at different times, within different users, under a variety of conditions. **Results:** The PDI-CE was able to identify, quantify and measure different types and degrees of compromise in edentulism as defined by this study, consistently and across all calibrated groups. For the analysis of all criteria as a construct, a total average of 65% of test takers agreed in the global diagnosis when compared with the gold standard. Criteria from axis 3 displayed the poorest agreement, followed by axis 2 and lastly by axis 1 respectively Among the 127 GPR/AEGD Resident, 75.59% provided the correct response to the Axis I measures. For general dentists (N = 111) and prosthodontists (N = 72), the proportions of individuals providing correct responses were 83.19% and 83.56%, respectively. When measuring parameters axis 2 and 3 a total of 64.5% and 56.8% of test takers agreed in the listed diagnosis respectively. Conclusion: edentulism, can be accurately, consistently, and reliably identified, measured, and quantified by current PDI-CE parameters.

Introduction

The 2007 Annual Review of Public Health Report in Harvard University[1] provides a framework for translational research in public health, addressing the gap between scientific advances and their application in clinical care. This document summarizes key factors which either facilitate or impair translation of research into clinical practice, and identifies a remarkable barrier: lack of standardized research diagnostic criteria and well-designed epidemiological instruments for characterizing and communicating evolving parameters in standards of care, scientific knowledge, and technical information. Accurate and efficient means of communication between researchers and practitioners are therefore lacking. The paper highlights the need to foster studies in epidemiology aimed at developing generic means of measuring health, disease, and dysfunction, useful in both laboratories and clinical settings.

The current lack of well designed studies, experimental tools and evidence-based diagnostic systems for identification, quantification and measurement of common conditions, incorporating evolving scientific parameters and knowledge, hinders the quality of available care. Traditional diagnostic systems in dentistry for diagnosing edentulism are deficient in measuring intensity of disease, impairment, and dysfunction; they lack valid parameters useful for measuring outcomes, safety, and efficacy of management. Research in current dental settings has not developed the capacity to estimate the impact that evolving concepts, knowledge, or technology available in laboratories will have when applied to clinical care.

This generic deficiency, according to the paper, also impairs resource allocation, strategic planning, and preventive program development by public health care and policy-making task forces. The present study addresses this lack in the context of dentistry by evaluating the epidemiological properties of the Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE) and its potential use in diagnosis and translational research in oral epidemiology, research, and clinical rehabilitation.

II. Problem description

The PDI-CE is the first multidimensional diagnostic index for rehabilitative dentistry. In an empiric development process lasting almost a decade to date, the American College of Prosthodontists (ACP) constructed this system to standardize complete edentulism diagnostic criteria. The index is intended to quantify the severity of compromise among edentulous patients. If the index's value as an indicator is proven, then it will standardize data analysis and outcome assessment for this condition and enable a stratified approach to edentulism's management. The triage effect of the index has potential epidemiological use and applications in health and non-health care diagnosis.

The problem is that the PDI-CE has not been scientifically tested and properly validated, although the new millennium brought development and validation of other multidimensional resources such as the ICF (International Classification of Functioning, Disability and Health)[14], and the MDDx (Multidimensional Diagnostic Model)[15]. This study addresses the problem by observing and measuring the epidemiological properties of the PDI-CE in a multicentered experimental trial. Joint use of the ICF/MDDX and the PDI-CE may prove valuable and useful in enhanced data characterization and multidimensional diagnosis of edentulism.

The concepts of the PDI-CE should evolve on a continuous basis, as the experiences and knowledge gained from its testing are incorporated back into the index's criteria[13]. The index's format has not as yet been changed. Ideally, an upgraded PDI-CE model would provide a framework for translational research, and for novel application of new parameters and methods that may contribute to advancements in the diagnosis and management of complete edentulism. The model would contain the latest diagnostic resources, standards, and concepts within the properties outlined in figure #1.

Fig. 1. Properties of an Ideal Index	
Validity: The index must measure what is intended to measure, so it should correspond with the clinical stages of the disease	**Reliability**: The index should be able to measure consistently at different times and under a variety of conditions. The term reliability is virtually synonymous with reproducibility, repeatability, and consistency, meaning the ability of the same or different examiners to interpret and use the index in the same way.
Clarity, simplicity, and objectivity. The criteria should be clear and unambiguous, with mutually exclusive categories. Ideally, they should be able to be readily memorized by an examiner after some practice.	**Quantifiability.** The index must be amenable to statistical analysis, so that the status of a group can be expressed by a distribution, mean, median or other statistical measure.
Sensitivity. The index should be able to detect reasonably small shifts, in either direction, in the condition.	**Acceptability.** The use of the index should not be painful or demeaning to the subject.
Dentistry, Dental Practice and the Community. The Methods of Oral Epidemiology. Chapter 14. Pag. 189. (56)	

Figure#1- Properties of an Ideal Index

The Value of the Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE).

The potential use of the PDI-CE for characterizing data relevant to edentulism, in subtypes, intensity of disease, impairment, and dysfunction, is possible with its diagnostic classification.

Grading levels of compromise in complete edentulism could potentially improve epidemiological surveillance and current estimates of this multidimensional condition, its distribution and impact in existing and future populations and sources of data.

The PDI-CE may have additional value in assisting the science of epidemiology in characterizing and:

1. Describing normal and abnormal biological, functional and contextual processes of individuals and groups.
2. Enhancing understanding of the natural history of complete edentulism and its subtypes.
3. Revealing the distribution of disease and enabling comparison of traditional and non-traditional parameters and data distribution.
4. Identifying determinants of health, function, dysfunction, and disease.

5. Testing hypotheses for disease prevention and control.
6. Planning and evaluating health care services.

Epidemiological surveillance is fundamental to modern public health[2]. The Centers for Disease Control and Prevention (CDC) define epidemiological surveillance as:

> *"The ongoing systematic collection, analysis and interpretation of health data essential to the planning, implementation and evaluation of public health practice, as well as the timely dissemination of this data to those who need to know "*[3].

To understand and address possible patterns and trends in the epidemiology of common diseases and health conditions, it is critical to have valid, accurate, reliable, and comprehensive epidemiological data. Decision makers and strategy formulators require instruments and guidelines for developing and implementing disease prevention and control programs[2]. Standardized disease definitions and diagnostic criteria are essential to reporting, as they allow policy makers to collect uniformly meaningful and therefore useful data. Such data is crucial to organizing effective public health approaches at national and international levels, because a policy can only be as good as the data upon which it is based.

The *Health, United States* series of publications is a valuable epidemiological source that presents trends in health statistics. The latest document is the 29th report on the health status of the USA, submitted by the Secretary of The Department of Health and Human Services to the President and Congress in compliance with section 308 of the Public Health Service Act. The report was compiled by the National Center for Health Statistics (NCHS), the CDC, and the National Committee on Vital and Health Statistics[4]. In this extensive and detailed report there is a wealth of data for the most prevalent health conditions, however edentulism is not included.

Epidemiology of edentulism has been studied and reported by several authorities[5, 6, 7, 8, 9, 10, 11], reflecting concern about the prevalence and incidence of unmet health care needs in edentulous people within the rapidly growing segment of the population aged 55 years and above. However, the lack of standardized diagnostic systems with specific epidemiological profiles impairs both precise interventions and detailed observation over time or between populations. This lack also affects the identification, quantification and measurement of sub-

types of edentulism, impairing estimates of their distribution, assessment, comparison, and management.

Upgraded diagnostic systems are needed in developing characterized diagnostic-specific criteria, coding rules, service classifications, outcome assessments, and health care utilization parameters. Because of the multi-dimensional nature of edentulism, difficulty increases when analyzing the disease's naturally occurring rate, patterns, prevalence, and incidence distribution by subtype and degree of intensity; furthermore, by population group instead of in the population as a whole[4, 5].

The lack of specialized instruments may explain artifactual differences, constraints, and barriers in designing and developing specific preventive programs, and inconsistencies in allocation of public health resources. Poorly defined epidemiological data results in deficient programs aimed at compensating for changes in demographic distribution of populations by age and by condition.

Inconsistent reporting of distribution of populations by diagnosis, due to differences in diagnostic coding rules and lack of standardized diagnostic classifications, may induce misleading values and calculations. This is critical when accounting for percentages of population at risk of a given intensity or subtype of disease by geographic location and demographic characteristics such as age, gender, race, or socio-economic status. It may be possible to develop new strategies to characterize, identify, understand, prevent and modulate a condition's patterns of expression by non-traditional use and combinations of classic epidemiological diagnostic systems and parameters[1, 5], as well as by applying novel resources such as the PDI-CE and the ICF/MDDx[14,15].

The Prosthodontic Diagnostic Index (PDI) for Complete Edentulism (CE) may enhance further development, understanding, and use of existing knowledge for this condition. It also may improve the quality of both health care and non-health care related information, thus improving data management in epidemiological surveillance and outcome assessment of edentulism. Better data management would contribute to the effectiveness of current and future management of this condition.

III. Study Purpose

This study aims to evaluate the epidemiological and psychometric properties of PDI-CE in a longitudinal, prospective, double blind, randomized, multicentered field test by:

> Observing and describing the PDI-CE performance in measuring complete edentulism as rated by three different groups of health care providers when compared to a gold-standard set of parameters given by the PDI-CE developing agency.

Validity is defined as "the ability of the index to measure what is intended to measure, so it should correspond with the clinical stages of the disease under study at each point"[56].

Reliability is defined as "the ability of the index to measure consistently at different times and under a variety of conditions. The term reliability is virtually synonymous with reproducibility, repeatability, and consistency, meaning the ability of the same or different examiners to interpret and use the index in the same way"[56].

This study will determine whether the PDI-CE is a valid and reliable diagnostic classification system, useful to identify, quantify and measure complete edentulism parameters, criteria, and domains provided by the PDI-CE diagnostic check list.

This diagnostic system will be tested for effectiveness of construct and external validity in prescribing multidimensional diagnosis as reflected by matching the gold-standard test diagnoses and parameters to the diagnoses and parameters provided by three different groups of health care providers. These three groups measure the same condition across 11 vignettes provided by the testing agency, with different degrees of severity and clinical expression of the condition to be tested.

Validation will be regarded within this study as the process by which a psychometrician or test user collects evidence to support the type of inferences that are to be drawn from the test scores, i.e. the process by which "validity" is determined.

This study will be conducted to fulfill and document the formal process outlined in step 7, from the following generic methodology for validating instruments, in a progressive stepwise and milestones format proposed by Florida's Gulf Coast University Validity Task Force instrument validation protocol[16]:

1. Identify the purpose and population target for which this diagnostic test will be used.

2. Identify items to be included/excluded in this test.
3. Develop a set of test specifications, instructions, operational definitions, and aims to calibrate users.
4. Construct an initial pool of items to be included within the experimental diagnostic test.
5. Have items reviewed and preliminarily selected by the testing agency.
6. Hold preliminary pilot trials in a small sample of users to review, approve, or modify items 1 through 5.
7. Have the diagnostic test applied in a larger sample representative of the proposed examinee population (target).

Steps 1 through 6 from the list above were sequentially fulfilled by ACP Validation Task Force. This research project is specifically designed to fit step 7, so has its starting point at that step. If the findings of this experimental trial indicate the need for a new cycle of testing trials, then the next generation of tests could initiate at any of the above steps. The goal would remain the same: to confirm, preserve, eliminate, develop or upgrade items, criteria, domains, or properties statistically identified as useful, significant, and relevant.

The primary end point for this study will be to test the diagnostic system's ability to measure what it is intended to measure, and to determine the way that all users would consistently, reliably and reproducibly arrive at the same diagnosis (global diagnosis) when different providers observe the same condition. This experiment needs to be repeated several times across different degrees of compromise and expression. This will be accomplished by using varied testing vignettes and different target populations of providers.

A secondary endpoint will be the identification and measurement of the quantifiability, use, and value of individual items within the PDI-CE diagnostic system. This will be done by operationalizing the definition and accounting for the correct inclusion of the individual items used in constructing and prescribing the global diagnosis (the actual PDI-CE classification), as reported in the primary endpoint.

All tests will be compared to the gold-standard keys provided by the testing agency for primary and secondary endpoint evaluation.

Assumptions: All assumptions carry a risk, therefore the following assumptions and risks were considered in designing and controlling potential sources of error and limitations in this study.

Assumption #1.

Edentulism has patterns of causation, expression, and clinical presentation following naturally occurring pleiotropy and complex etiology. These can be reasonably standardized and are reflected within the clinical vignettes provided by the testing agency in the specific different degrees, criteria and domains designed to fit the test and its expected gold-standard scores.

Complex etiology and pleiotropy occur when multiple direct and indirect causes happen together. According to Brunette[17] and Spilker[18] a complex etiology operates in almost all clinical situations. They presented an example in a study with an antibiotic, which was tested to observe its effect against a given infection. They highlighted the importance of being able to establish a cause-effect relationship for a major entity, even if multiple minor or unknown factors may be involved. In their example, it was explained how it was considered appropriate to claim this property even when the immune system and other environmental factors may be active during the antibiotic's study, because the administration, measurement and effect of the antibiotic within the limits of the study were reproducible, reliable and measurable. These factors had greater control and influence than the effect of the immune system and other potential confounders. The key concept was to understand the phenomenon, and to adjust the study to control for the various factors that may operate within the same conditions.

In this study, the MDDx, the ICF, and the PDI-CE will be used to identify, characterize, capture, observe, display, and explain the items with measures of central tendency and variance by means of multiple statistical analyses. This is done in order to document the usefulness of the PDI-CE when applied by dentists from different levels of education, specialties, backgrounds, philosophies, and geographic origins, compared to a gold-standard key parameter provided by the ACP/PDI-CE Validation Task Force Committee.

Assumption #2

The establishment of diagnosis and cause-effect relationships are exercises of inductive reasoning that cannot ever be certain, but which are reasonably agreed, standardized, identified, measured and quantified[17, 19]. Different authorities, claims, processes and decisions in clinical diagnosis may require different degrees of certainty[18].

Brunette[17] proposed an example to illustrate Sackett's postulates[19] for diagnostic tests and their ability to relate potential causation. The example is based on the fact that even while remarkable epidemiological data and well designed sound studies found links between smoking and lung cancer, cigarette industries have not accepted these medical conclusions. Technically, these companies are correct; proof of causality would require true experiments in humans to demonstrate, in vivo, the effects of smoking on lung cancer. Controlling for confounding factors and all other aspects makes human experience of such tests unethical and unacceptably inhumane, thus rendering it impossible to provide desirable evidence for the given situation. Vignettes are an acceptable model frequently used by psychometricians and scientists to display and measure some standardized forms of diseases, trauma, and dysfunction when calibrating well developed diagnostic tests and instruments[23-51].

This study has assumed that edentulism, as other multidimensional chronic and acute conditions, is scientifically suitable for standardized modeling with vignettes[26, 27, 31, 40]. Vignettes may be well modeled with a calibrated set of parameters, standardizing a broad variety of degrees and expressions of the condition. Thus, it can be reasonably, consistently, and reproducibly identified, characterized, diagnosed, and represented by the vignettes provided for this exercise. The goal is to identify, quantify, and measure the different levels of disability, trauma, disease, and dysfunction rated within each edentulous vignette. The testing conditions depicted by the vignettes were set up to receive a global diagnostic score in each instance. The scores were then collected from the three testing groups, to be compared with the gold-standard (expected) scores from the developing agency.

This set of vignettes is designed to standardize the display and measurement of a broad spectrum of areas and domains. They include dimensions and levels of essential human life measured within the following three broad areas:

Biological (body parts, organs, constructs and systems), **functional** (body functions, mental, behavioral, and psycho-social processes) and **contextual** (impact of disease experience, management, measurement, and need for treatment) areas: These areas were

systematically arranged with different constructs on the PDI-CE and each clinical vignette.

In order to provide a standardized parameter to reflect and measure the efficacy, success and failure rates of PDI-CE based diagnoses, they will be compared by rating group and population, against the gold standard provided by the testing agency.

The items within the PDI-CE will be evaluated and arranged by axes, with the MDDx/ICF[14, 15] criteria for factor analysis, as follows:

Axis 1: **Biological** factors (body parts, organs, constructs and systems)

Axis 2: **Functional** factors (body functions, mental, behavioral and psycho-social processes), and

Axis 3: **Contextual** factors (impact and disease experience, clinical management, measurement, and need for treatment)

This arrangement is provided in order to test the hypothesis that there are measurable differences among certain groups of factors that are better displayed and compiled by axes, and will have higher rates of failure/success depending on who is rating them[23]. They will be characterized, identified, quantified and measured using generic emerging concepts, methods, and parameters from the MDDx[14] and ICF[15] models, as well as current medical rehabilitation and other basic and applied health sciences resources designed for this purpose[14, 15, 34, 37].

Assumption #3

Edentulism is a multidimensional condition that can be identified, quantified, and measured using generic diagnostic and epidemiological methods and processes. These methods are commonly used within dentistry and medicine to develop guidelines, consensus in diagnosis, and measurement of common multifactorial conditions. Edentulism has a natural history of disease, pattern, occurrence, and impact, such as is found in caries[20] and periodontal disease[21], organ development and tissue engineering diagnosis, and failure analysis models[22].

Medical and dental literature systematic reviews[1-51] highlight common areas of weakness when considering studies to validate or propose diagnostic criteria. Within those problems, this study considered and adjusted for:

1. Variability of rater calibration.
2. Lack of standards and differences in criteria for clinical judgment.

3. Lack of an adequate number of clinical modalities and types of disease occurrence to test its sensitivity, specificity detection, and diagnosis of a given condition.

4. Lack of alternative parameters for confirmation of diagnosis.

In regard to the problems found in the literature review and summarized in this list[20], the following actions were taken:

#1. Calibration of all raters was provided in the same format, by the same team, with the same parameters, materials, guidelines, test formats, and vignettes across the three groups.

#2. Parameters for diagnostic classification were provided from the best evidence-based sources for diagnostic assessment currently recommended by organized dentistry in the U.S. and by educational centers for under- and post-graduate formal and informal education in accredited U.S. dental institutions. These criteria were developed and made available in 1999 for clinicians diagnosing and treating complete edentulism. Their purpose is clinical evaluation, measurement, diagnosis and research, and they are published within current medical and dental literature in English as the PDI-CE[13]. Evidence of standardized format was provided by the ACP (American College of Prosthodontists) for complete edentulism diagnosis and evaluation. The ACP's guidelines and training materials were requested from the ACP testing agency, and then used for evaluating the materials, training, and instructions given to all groups in this study, in order to establish uniform, standardized criteria and training to users.

#3. A total set of 11 vignettes was designed, tested, and provided by the ACP's PDI-CE validity task force committee. The design included multiple vignettes for each of the possible choices, displaying every degree of clinical condition considered within the relevant classification.

#4. The diagnostic development committee provided a gold standard key to the testing agency, which then provided it to this study for measuring and comparing observations between the groups tested. This gold-standard set will serve as the key to test control.

#5. A conceptual definition developed using the MDDx/ICF model will be used for this study.

"Edentulism is a multidimensional condition, with a cardinal sign [no teeth].

It is a chronic, progressive, irreversible, disabling and multifactorial condition, which requires comprehensive biological, functional and contextual analysis and evaluation.

Its diagnosis, management, rehabilitation and outcome assessment may involve processes within different levels and domains, depending upon the degree of stomatognatic and related systems compromise."

The elements contained in this definition were proposed and presented internationally[53] and within the U.S.[54] They were modified to fit this study, in order to provide an operational definition for joint use with the PDI-CE.

An operational definition provides objective parameters for clear measurement, describing precisely how each criterion is going to be measured[57]. The intent of an operational definition for edentulism is to enhance and facilitate understanding of the multidimensional nature and characteristics of complete edentulism in objective terms, as the PDI-CE describes. This operational definition is broad and inclusive, suitable for comparison with other forms of the condition (partial edentulism) as well as a broad variety of forms of stomatognatic system compromise, disease, impairment, trauma and dysfunction.

Edentulism fulfills the ICF/WHO[15] definition for impairment, disability, and dysfunction, however, due to the lack of an updated resource for defining and characterizing edentulism, dentistry struggles to protect and develop new technology reaching all affected population sectors of society. Therefore, the above definition is expected to document, facilitate, and reflect the validating process for the PDI-CE. When operationalized within this study, the definition is expected to evolve along with the PDI. It was developed for this purpose after taking into account other definitions. The development of a new definition is justified if one reviews the definition found within the Prosthodontic Glossary of Terms (PGT), the official reference authority for defining terms within the specialty of Prosthodontics:

Edentulism (1998)**:** the state of being edentulous; without natural teeth[55]

IV. Materials and Methods

Study design

This study was designed to measure the psychometric properties of the PDI-CE, in a longitudinal, prospective, double blind, randomized, multicentered field test. The study's purpose is to assess fundamental aspects for methodological construct and validity.

Three groups of calibrated users were randomly tested with the PDI-CE diagnostic instrument during classification of four types of completely edentulous clinical vignettes. These users were from different levels of education within the area of restorative dentistry, with diverse clinical and socio-cultural backgrounds, and from varying locations. The four vignettes ranged from class I, the mildest form of complete edentulism, to class IV, the most debilitating and advanced clinical form of this condition.

The users were provided standardized calibration, as outlined in the PDI-CE guidelines and syllabi **(See appendix #5)**, in an initial briefing. The briefing clarified the PDI-CE diagnostic criteria to be used and explained guidelines for the exercise prior taking the test. Assistance was given during the sessions to ensure proper testing protocol, avoiding any case-specific question, inducement, comment or clarification of any criterion. The users were not allowed to exchange information, and were randomly assigned starting points (case). They could then freely choose the number of tests to answer (from 1 to 11of the total number of vignettes) and the station for every vignette they provided with a diagnosis.

Study sequence:

Raw data will be collected, processed and analyzed using the SPSS graduate student statistical pack, for carrying out the following plan:

Specific aim #1 will address the taxonomy of PDI-CE analysis, and will be executed by using a taxonomic map developed with MDDx factorial group criteria, to characterize the PDI-CE and classify all of its variables into three main groups in a multi-axial factor classification arrangement.

Factors within the PDI-CE will be assigned to an axis according to the following classifications:

Axis 1= Biological factors. This level will include organic descriptors, objective observations, body parts, and physical traits. These factors are readily identifiable, quantifiable, and measurable by validated or empiric standard parameters, observations, currently accepted guidelines, general consensus, or best available means. Examples of biological factors are: bone height, ridge morphology, and muscle attachment; maxillo-mandibular relationships, inter-arch space, and tongue anatomy; local or systemic trauma; disease or dysfunction of any body part, organ, system, or construct of biological/organic structure.

Axis 2 = Functional/Psycho-social factors. This level will include body functions: organic, non-organic, behavioral, and socio-cultural local or systemic trauma, disease, or dysfunction of any bodily function, construct, or structural organization. These factors are subjective, but are generally agreed upon: validated or empiric standard parameters, observations, or currently accepted guidelines, general consensus or best available means. Examples of these factors are: tongue position, ataxia, paresthesia, dysesthesia, pain, TMD (temporomandibular disorder), MPD (myofacial disorder), local or systemic non-organic disease or dysfunction, such as anxiety, depression, mental, cognitive, personality, thought or psychosocial INDIVIDUAL readily identifiable, quantifiable, and measurable disorders and /or factors.

Axis 3 = Contextual and environmental factors. This level will include observations related to techniques, procedures, philosophies, experience, constraints, schools of thought, or subjective parameters not included within the other two groups, including contextual or environmentally influenced INDIVIDUAL and COLLECTIVE opinions, policies, rules, values, beliefs, guidelines, protocols, and parameters. E.g.: minor soft tissue or hard tissue surgical procedures, sequential, technical, or preprosthetic surgical corrections, bone grafts, implant choices, sites, requirements, and levels of complexity.

Since all variables classified within the proposed axes are spread across the different criteria, a number will be assigned for each variable as follows:

Bone height-mandible	(criterion #1)
21mm or greater	(variable #1)
16 – 20 mm	(variable #2)
11 – 15 mm	(variable #3)
10 mm or less	(variable #4)

Thus, taxonomy will be reported as follows:

> **Axis 1** (Biological factors), criterion 1 (bone height), variable 1 (parameter – 21mm or greater), etc.
>
> **Axis 2** (Functional/Psychosocial factors) criterion 8 (modifiers), variable 7 (parameter –psychosocial- major), etc.
>
> **Axis 3** (Contextual and environmental factors) criterion 5 (conditions requiring preprosthetic surgery), variable 4 (implants with bone graft – complex)

A matrix containing three groups of variables (factors), organized by axis as reported above, will be subject to further testing and analysis as explained in specific aim #2.

Specific aim #2 will address the construct validity of the PDI-CE, and will be executed by performing statistical analysis and employing observational epidemiology principles to test the structural integrity of the PDI-CE instrument at the following levels:

Construct level (Global diagnosis). This means the final prescription of diagnosis. i.e.: PDI-CE class I, II, III, or IV.

Criterion level (Individual diagnosis). This means at each of the 8 sections (Listed criteria) utilized to construct the global diagnosis, proposed by the PDI-CE system. Examples are: bone height mandibular, residual ridge morphology maxilla, muscle attachments mandible, etc.

Item level (Individual parameters). This means at each of the items composing each of the 8 sections (Listed criteria) proposed by the PDI-CE parameters (items).

Statistical tests will be performed to account for all the variance between all variables, and then determine whether it is useful to retain a given item or if it can be discarded, and which one. For example:

Bone height-mandible	(criterion #1)
21mm or greater	(item #1)
16 – 20 mm	(item #2)
11 – 15 mm	(item #3)
10 mm or less	(item #4)

The following statistical tests will be used for specific aim #2:

For all levels, descriptive statistics such as percentages and averages.

For construct level diagnosis, specificity, sensitivity, and positive and negative predictive value of the global diagnosis will be presented.

For criterion level diagnosis, measures of dispersion range, standard deviation, and variance, and central tendency parameters such as mean and median.

For factor (item) level diagnosis, measures of dispersion range, standard deviation and variance, and central tendency such as mean and median will be used. These data will derive from a correlation matrix and factor analysis that finds a linear combination of variables which are useful, by extracting factors according to odds ratio, use and correlation to accurate diagnosis.

Once specific aims #1 and #2 are carried out, data will be mapped and reorganized. The study will include a series of analysis and observations to answer the following research question(s) and test the following hypothesis (es).

Research questions

When applied by calibrated users in testing fields 1, 2, and 3, does the PDI-CE identify, measure, and quantify the parameters, generating results which consistently match the gold standard diagnostic outcomes provided by the ACP/PDI-CE validation task force?

Does the use of ICF/MDDx characterization for factor analysis criteria facilitate the observation, documentation, organization and structure necessary to provide evidence that explains the data distribution within the proposed multiaxial factorial arrangement (success or failure)?

Primary hypothesis:

Complete edentulism can be accurately, consistently, and reliably identified, measured, and quantified by current PDI-CE parameters across all groups of calibrated users in testing fields 1, 2 and 3.

H_0: PDI-CE diagnosis (Dx) [Gold-standard] for vignette "x"
"x" Dx [Gold-standard] = "x" Dx group1 = "x" Dx group2 = "x" Dx group3

Secondary hypothesis:

Analysis criteria from the MDDx/ICF arrangements can accurately and reliably capture explanatory evidence for data distribution interpretation (success or failure rates on diagnoses) because the more subjective, broad, and variable the parameter, the greater the likelihood of disagreement rate will be traced to it. In other words, factors included within MDDx parameters on axis 3 will have a higher failure to agree on listed diagnostic criteria rate than axis 2 factors, which in turn will have a higher rate than axis 1 factors.

H':
Failure to agree rate: axis 3> axis 2> axis 1
OR
Successful agreement rate: axis 1> axis 2> axis 3

Expectations

It is expected that the present study will identify, quantify and measure factors that have consistently failed to diagnose the condition, when compared to the gold-standard. The factors are expected to be identified across providers and across field test site's groups, regardless of whether they were missed or mistaken during each test. Thus, if we observe differences or patterns in axes 1, 2 or 3, along with the failure/success rates for a specific site or group, we can formulate inferences. These inferences can be used to preserve, simplify, modify, eliminate, or add items, criteria, or parameters to control, modulate, and correct the potential confounders. The inferences may also be useful in considering a new study for validating an upgraded version of the PDI-CE.

Sample size and power calculation

In analyzing tests there are no power calculation tables to tell exactly how many subjects are necessary to validate a given instrument. However, Gorsuch (1983)[54], an authority on factor analysis, proposes a minimum of five subject/variable ratios. He also suggests that this number could vary depending upon the relationship, which is affected by commonalities or differences among the variables, by whether the criteria are highly correlated or independent, and by acceptable or not acceptable ranges for confidence and reliability of results. The higher and more distant the relationship between the variables, the higher the ratio of subject to variable should be. Norman and Steiner (2000)[54] state that an average estimate over the number of analyses performed, ranges between two and ten subjects per variable, and they note the lower end about which almost 70% of current literature ranges.

For this study, the calculations will be made at three different levels, following Norman's and Steiner's suggested guidelines as outliers, and Gorsuch as a middle point, depending upon the anticipated relationship or independence between the variables.

For the construct level sample, since it is the global and higher level, this study will include broader and less related parameters. Thus, the highest guideline of 10 subjects per edentulous classification type will be used.

In order to have a 95% CI (Confidence Interval), all instruments, variables, and data with an ∂ (alpha) value of 0.05 will be regarded as statistically significant variables and will be kept within the model.

The sample size calculation is based on the ability to detect an influence and correlation between factors on axes 1, 2, and 3 within different levels and scopes of relationship. The calculation will be confirmed when compared to gold-standard parameters on successful diagnosis rates (or failure to diagnose rates) of 10.0% between variables that display a high level of correlation to success or failure to diagnose respectively. The calculation will use the standard parameters ∂ = 0.05 and β (beta) = 0.20.

$$n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 \sigma^2}{(\mu_0 - \mu_1)^2}$$

Thus:

For construct-related calculations:

> 4 Types of diagnoses: (class I to IV) X 10 (the highest parameters), requires 40 tests/cases.

For the criterion based analysis, due to the moderate range of relationship dispersion and variety between criteria, a moderate indicator will be used in total. Thus, five subjects will be indicated for such analysis(54).

> 8 criteria from bone height- to modifiers X 5, will require 40 cases in total.

For the item level sample calculation, since it is the least spread variable, the lowest estimate will be used, i.e. two subjects per variable. Therefore,

> 39 items within the 8 criteria X 2 will require 78 cases/tests in total.

In order to have a 95% CI in our result, all instruments, variables, and data with an ∂ value of 0.05 will be regarded as statistically significant and will be kept in the model.

The sample size calculation is based on the ability to detect an influence and correlation between factors on axes 1, 2, and 3 within different levels and scopes of relationship when compared to gold-standard parameters of successful diagnosis rates (or failure to diagnose rates) of 10.0%, between variables that display a high level of correlation to success or failure to diagnose respectively. The calculation will use the standard parameters of $\partial = 0.05$ and $\beta = 0.20$.

V. Results

Statistical Analyses - After the tests were collected, data was entered into a statistical database for analysis (SPSS, v.11.0, ©SPSS Inc., Chicago, IL). The three study populations were compared using a multiple comparisons procedure (Bonferroni procedure) to evaluate differences between the groups with regard to the percentage of correct diagnoses and the percentage of correct responses to the questionnaire. For all analyses, a p-value ≤ 0.05 was considered statistically significant, agreement of 60% to 70% marginally acceptable, 71% to 80% acceptable, 81% to 90% good, and above 90% excellent.

In accordance with specific aim #1 the existing format of the PDI-CE was characterized by using a taxonomic map developed using the ICF/MDDx [15] factorial group criteria. This characterization of the existing PDI-CE test anatomy was performed without modifying its current structure; this study distributed all of its variables into three main groups in a multi-axial factor classification arrangement.

Factors within the PDI-CE were assigned to an axis according to the following distribution by:

Criteria

Axis 1- Biological factors: criteria #1, 2, 3, 4, 6 and 8

Axis 2- Functional factors: criteria #7 and 8

Axis 3- Contextual factors: criteria #5 and 8

Item

Axis 1- Biological factors:

Item #1 to 16, 24, 25, 26, 28, 29, and 30

Axis 2- Functional factors:

Item# 27, 31, 32, 33, 34, 36 and 37.

Axis 3- Contextual factors:

Item# 17 to 23, 25, 33, and 37.

The characterization of PDI-CE criteria and items using the ICF/MDDx model (see appendix#2) facilitated the execution of specific aims #1 and #2 in answering the research questions.

For the first research question, the present study identified groups of test takers by training level. After the calibrating exercise, these groups consistently matched PDI-CE global diagnostic criteria (Table 1) when compared to the gold standard.

The groups observed and measured results at a global score level as well as criterion and item levels. The rationale for this analysis is that a test may have the right diagnosis with the wrong items, or vice versa. The global score is referred to as global diagnosis.

The global diagnosis is the overall appraisal given by the test to the condition displayed in the vignette. It assigns the highest value of compromise, rated as the global score, regardless of the item or criterion from which this rating. All factors are assumed to carry the same weight and value.

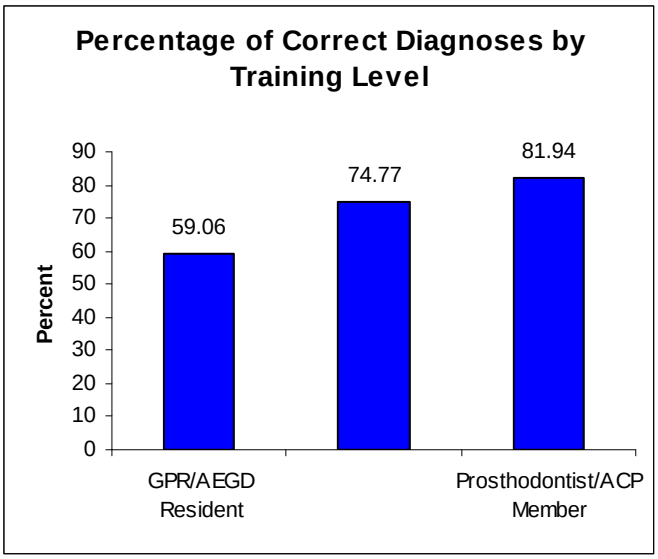
Table 1: Percentage of Correct Global Diagnosis, by Training Level

Level of Training	N	Percentage of Correct Global Diagnoses
GPR/AEGD Resident	127	59.06
General Dentist	111	74.77
Prosthodontist/ACP Member	72	81.94

ANOVA p = 0.001

	GPR/AEGD Resident	General Dentist
GPR/AEGD Resident	*	0.02
General Dentist	0.02	*
Prosthodontist/ ACP Member	< 0.01	0.88

Table 1b: Multiple Comparisons Procedure (Bonferroni)



Interpretation: Among the 127 GPR/AEGD Residents, 59.06% made correct diagnoses for the clinical cases provided. For general dentists (N = 111) and prosthodontists (N = 72), the number of individuals making correct diagnoses were 74.77% and 81.94%, respectively. Using the analysis of variance to compare the proportion of correct diagnoses by training level yielded an overall p-value of 0.001.

To identify where the differences between the groups actually existed, the Bonferroni multiple comparisons procedure was used (**Table 1b**). These data indicated that both general dentists and prosthodontists had statistically significant higher proportions of

correct diagnoses as compared to GPR/AEGD residents ($p \leq 0.02$). However, general dentists and prosthodontists were equivalent in terms of the proportion of correct diagnoses ($p = 0.88$).

A total average of 70% of test takers agreed in the global diagnosis when compared with the gold standard (Appendix 6 table 1).

Therefore, the primary hypothesis is accepted because the global diagnosis agreement with the gold-standard was statistically acceptable and consistent across all calibrated groups as proposed by this study. Thus, edentulism can be accurately, consistently, and reliably identified, measured, and quantified by current PDI-CE parameters across all groups of calibrated users in testing fields 1, 2, and 3.

In order to execute specific aim #2, and to measure the construct validity for PDI-CE, the criteria and items from the test format were labeled and grouped into axes, as proposed by the ICF/MDDx model. The criteria were quantified by groups of test takers and measured against the gold-standard. Descriptive statistics were used to summarize the results as displayed below, and acknowledged as "listed Criteria" (Table 2).

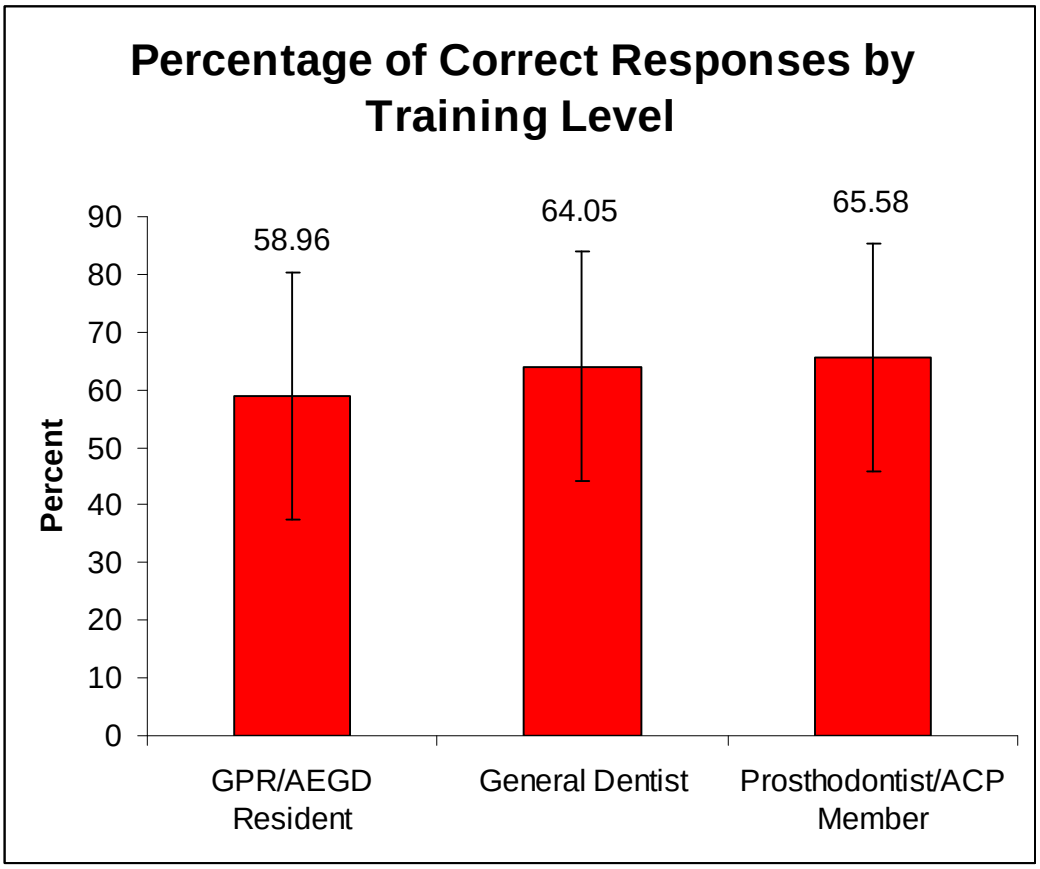
Table 2: Percentage of Correct Responses to Listed Diagnostic Criteria, by Training Level

Group	N	Mean Percentage of Correct Listed Criteria	Range
GPR/AEGD Resident	127	58.96 ± 21.47	0 - 100
General Dentist	111	64.05 ± 19.84	0 - 100
Prosthodontist/ ACP Member	72	65.58 ± 19.85	0 - 100

ANOVA p = 0.05

Table 2b: Multiple Comparisons Procedure (Bonferroni)

	GPR/AEGD Resident	General Dentist
GPR/AEGD Resident	*	0.17
General Dentist	0.17	*
Prosthodontist/ ACP Member	0.09	1.00



Interpretation: Among the 127 GPR/AEGD Resident, the average number of correct responses to questions pertaining to eight diagnostic criteria was approximately 60%. For general dentists (N = 111) and prosthodontists (N = 72), these means were 64.05% and 65.58%, respectively. Using the analysis of variance test to compare the mean percentages of correct responses by training level yielded an overall p-value of 0.05. To identify where the differences between the groups existed, the Bonferroni multiple comparisons procedure was used (Table 2b).

The data from the multiple comparisons procedure indicated that there were no statistically significant differences between the three groups with regard to percentage of correct responses to listed diagnostic criteria ($p \geq 0.09$).

Therefore the primary hypothesis is accepted because the global diagnosis agreement, even if it was marginally acceptable, was consistent across all calibrated groups as proposed by this study.

The discrepancy between the overall p-value and the multiple comparisons p-value may be due to the conservative nature of the Bonferroni correction and the borderline significance of the ANOVA ($p = 0.05$).

In summary, for the analysis of all criteria as a construct, there is room for improvement since a total average of 65% of test takers agreed with listed criteria when compared with the gold standard (Appendix 6 table 2). The sources of disagreement or failure to match the global diagnosis were observed and tested with the secondary hypothesis.

In order to tests the secondary hypothesis (page 20), observations were made through analysis of criteria and items by axes. The axis containing the criteria and items displaying the worst agreement was axis 3. A total average of 56.8% of test takers agreed in the listed diagnosis from criteria on axis 3 when compared with the gold standard (Table 3).

Table 3: Percentage of Correct Responses to Axis III Measure (Criterion 5), by Training Level

Level of Training	N	Percentage of Correct Responses
GPR/AEGD Resident	127	43.31
General Dentist	111	59.29
Prosthodontist/ ACP Member	72	76.71

ANOVA p < 0.001

Table 3b: Multiple Comparisons Procedure (Bonferroni)

	GPR/AEGD Resident	General Dentist
GPR/AEGD Resident	*	0.032
General Dentist	0.032	*
Prosthodontist/ACP Member	< 0.001	0.049

Interpretation: Among the 127 GPR/AEGD Residents, 43.31% provided correct responses to the tested Axis III criteria. For general dentists (N = 111) and prosthodontists (N = 72), the proportions of individuals providing correct responses were 59.29% and 76.71% respectively. Using the analysis of variance to compare the proportion of correct diagnoses by training level yielded an overall p-value < 0.001. To identify where the differences between the groups existed, the Bonferroni multiple comparisons procedure was used (**Table 3b**). These data indicated that prosthodontists were statistically significantly more likely to provide a correct response to the Axis III measure than general dentists (p = 0.049) and GPR/AEGD residents (p < 0.001) and that general dentists were more likely to provide a correct response than GPR/AEGD residents (p = 0.032).

Conversely and in accordance with the null hypothesis, the axis containing the criteria and items displaying the best agreement was axis 1. A total average of 80.1% of test takers agreed in the listed diagnosis from criteria on axis 1 when compared with the gold standard (Table 10).

Table 4: Percentage of Correct Responses to Axis I Measure (Criterion 1), by Training Level

Level of Training	N	Percentage of Correct Responses
GPR/AEGD Resident	127	75.59
General Dentist	111	83.19
Prosthodontist/ ACP Member	72	83.56

ANOVA p = 0.242

Interpretation: Among the 127 GPR/AEGD Resident, 75.59% provided the correct response to the Axis I measure. For general dentists (N = 111) and prosthodontists (N = 72), the proportions of individuals providing correct responses were 83.19% and 83.56% respectively. Using the analysis of variance to compare the proportion of correct diagnoses by training level yielded an overall p-value of 0.242. These results indicate that, for the Axis I measure, all training levels were statistically equivalent in terms of the proportion of correct responses provided.

To test the secondary hypothesis in further detail, criteria and items from axis 2 were observed displaying moderate agreement with the gold standard. A total average of 64.5% of test takers agreed in the listed diagnosis from criteria on axis 2 when compared with the gold standard (Table 5).

Table 5: Proportion of Correct Responses to Axis II (Criterion 8), by Training Level

Level of Training	N	Percentage of Correct Responses
GPR/AEGD Resident	127	58.27
General Dentist	111	69.03
Prosthodontist/ACP Member	72	68.49

ANOVA p = 0.160

Interpretation: Among the 127 GPR/AEGD Residents, 58.27% provided the correct response to the Axis II measure. For general dentists (N = 111) and prosthodontists (N = 72), the proportions of individuals providing correct responses were 69.03% and 68.49% respectively. Using the analysis of variance to compare the proportion of correct diagnoses by training level yielded an overall p-value of 0.160. These results indicate that, for the Axis II measure, all training levels were statistically equivalent in terms of the proportion of correct responses provided.

Therefore, the secondary hypothesis is accepted because criteria from axis 3 displayed the poorest agreement, followed by axis 2 and lastly by axis 1, as proposed by this study.

Observing the role of "level of complexity" in the test's diagnostic performance, cases that have consistently failed to match diagnostic criteria by level of compromised condition when compared to the gold-standard (by criterion) are summarized in Table 6:

Table 6: Agreement with Gold Standard, by Case Complexity and Training Level (see appendix 5 for diagnostic classification details)

Diagnostic Classification	Training Level	Proportion of Agreement	p-value (ANOVA)
Class I			0.001
	GPR/AEGD Resident	32.14	
	General Dentist	53.85	
	Prosthodontist/ ACP Member	100	
Class II			0.68
	GPR/AEGD Resident	33.33	
	General Dentist	50	
	Prosthodontist/ ACP Member	42.86	
Class III			0.119
	GPR/AEGD Resident	67.21	
	General Dentist	81.03	
	Prosthodontist/ ACP Member	82.86	
Class IV			0.974
	GPR/AEGD Resident	86.96	
	General Dentist	84.62	
	Prosthodontist/ ACP Member	85.71	

Interpretation: When evaluated by case complexity, there were no statistically significant differences in the proportions of correct diagnoses between the three groups for Class II, Class III or Class IV cases (ANOVA $p \geq 0.119$). For Class I cases, 32.14% of GPR/AEGD residents, 53.85% of general dentists and 100.0% of prosthodontists provided correct diagnoses (ANOVA $p = 0.001$).

Table 6b: Multiple Comparisons Procedure (Bonferroni) for Class I Diagnosis

	GPR/AEGD Resident	General Dentist
GPR/AEGD Resident	*	0.46
General Dentist	0.46	*
Prosthodontist/ ACP Member	0.001	0.063

Multiple comparisons testing (**Table 6b**) showed that, for Class I cases, prosthodontists were statistically significantly more likely to arrive at the correct diagnoses, compared to GPR/AEGD residents ($p = 0.001$), but were statistically equivalent to general dentists ($p = 0.063$). For Class I diagnoses, GPR/AEGD residents and general dentists performed equivalently ($p = 0.46$).

To trace items associated with disagreement, and to provide useful data to simplify, modify, retain, eliminate, or add items, criteria, or parameters in a upgraded version of the PDI-CE to control, modulate, and correct the potential confounders identified by this study, multiple logistic regressions were performed.

Table 7: Multiple Logistic Regression Model for Correct Diagnosis

	OR	p-value
Criterion 1	1.941	0.035
Criterion 2	1.200	0.545
Criterion 3	1.262	0.433
Criterion 4	0.488	0.012
Criterion 5	1.312	0.325
Criterion 6	2.313	0.062
Criterion 7	1.193	0.530
Criterion 8	1.181	0.545
Training Level	1.449	0.048
Constant	0.377484	0.062697

Interpretation: The multiple logistic regression model, containing responses to all 8 criteria against the binary outcome "Agreement with the Gold Standard Diagnosis" (0 = No, 1 = Yes), shows that, among the eight criteria, only one was statistically significantly associated with increased odds of obtaining the correct diagnosis, given a correct response to that criterion. Individuals who provided a correct response to Criterion 1 were 1.941 times more likely to obtain the correct diagnosis than those who provided an

incorrect response to Criterion 1, even after controlling for responses to the other seven criteria and training level.

Interestingly, a correct response to the Criterion 4 question is associated with a 50% lower likelihood of obtaining the correct global diagnosis (p = 0.012).

Diagnostic properties of PDI-CE (Sensitivity and Specificity)

MDDx/ICF PDI	Axis 1 Criterion 1	Axis 1 Criterion 2	Axis 1 Criterion 3	Axis 1 Criterion 4	Axis 3 Criterion 5	Axis 1 Criterion 6	Axis 2 Criterion 7	All Criterion 8
Sensitivity	0.84	0.55	0.53	0.31	0.62	0.94	0.68	0.67
Specificity	0.28	0.47	0.52	0.54	0.53	0.16	0.4	0.41
PPV	0.73	0.71	0.72	0.61	0.75	0.72	0.73	0.73
NPV	0.43	0.31	0.32	0.25	0.37	0.56	0.35	0.35

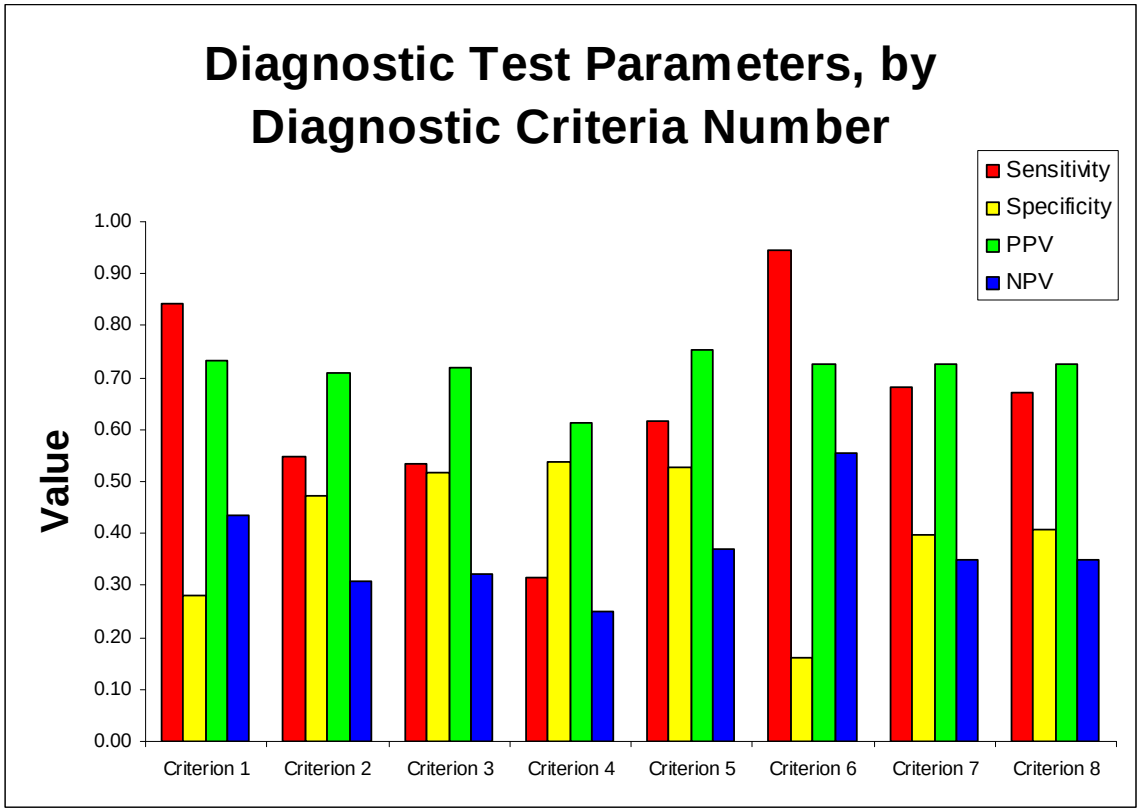
Interpretation: The sensitivity represents the probability that the correct diagnosis was selected, given a correct response to the listed criterion. The range of sensitivity values was 0.31 (Criterion 4) to 0.94 (Criterion 6).

The specificity represents the probability that the incorrect diagnosis was selected, given an incorrect response to the listed criterion. The range of specificity values was 0.16 (criterion 6) to 0.54 (Criterion 4).

The positive predictive value represents the probability that, given the correct diagnosis, the correct response was selected for the listed criterion. The range of positive predictive values was 0.61 (Criterion 4) to 0.75 (Criterion 5).

The negative predictive value represents the probability that, given an incorrect diagnosis, the incorrect response was selected for the listed criterion. The range of negative predictive values was 0.25 (Criterion 4) to 0.56 (Criterion 6).

Based on these results, it would appear the Criteria 4 and 6 offer the most information from the diagnostic tests. Individuals who provided a correct response to criterion 6 had a 94% chance of obtaining the correct global diagnosis. Individuals who provided an incorrect response to criterion 4 had a 54% chance of making a misdiagnosis.

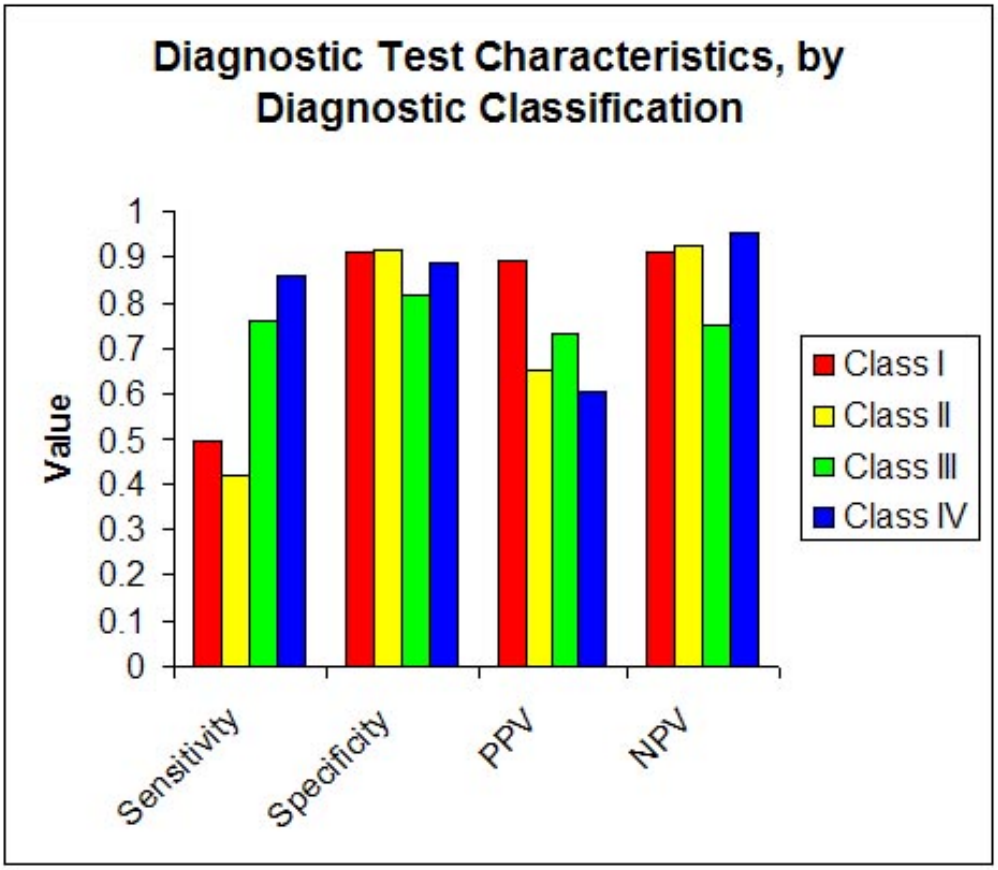


Interpretation: The diagnostic test is most sensitive for diagnosing Class III or Class IV cases, i.e. given a class III or class IV case, the diagnostic test will correctly provide the diagnosis 75 – 86% of the time.

	Class I	Class II	Class III	Class IV
TP	25	15	117	60
FP	3	8	43	39
FN	25	21	37	10
TN	257	266	113	201
Sensitivity	0.5	0.416667	0.75974	0.857143
Specificity	0.911348	0.914089	0.818841	0.889381
PPV	0.892857	0.652174	0.73125	0.606061
NPV	0.911348	0.926829	0.753333	0.952607

The test has good specificity across all diagnostic classes, i.e. if the diagnostic test suggests that one or more classes can be effectively ruled out, these classes will be correctly ruled out 81 – 91% of the time.

The positive predictive value is the greatest for Class I cases and the lowest for Class IV cases, suggesting that, for Class I cases, if the diagnostic test leads to a diagnosis of Class I, this will be the correct diagnosis 89% of the time. The test has uniformly high negative predictive values, suggesting that, given a test result rules out a diagnosis, this will be correct at least 75% of the time.



VI. Conclusion

As expected, the present study identified, quantified and measured factors that either diagnosed or failed to diagnose under the testing conditions, when compared to the gold-standard.

The factors were consistently identified across providers and across field test sites' groups, regardless of whether they were missed or mistaken during each test. Thus, this study observed measurable differences in criteria and items from axes 1, 2 and 3. However, due to limitations inherent in the study design, detailed characterization of test-takers was not achieved. A specific study designed for intra- and inter- rater reliability may be necessary.

Data reported and displayed in this study may serve in upgrading the PDI-CE test, prior to a new study. This information may also serve to elicit other researchers' observations, questions and inferences that can be used to simplify, modify, retain, eliminate, or add items, criteria, or parameters to control, modulate, and correct the potential confounders when measuring edentulism with the PDI-CE global and listed criteria and items.

Discussion

The PDI is the first multidimensional diagnostic instrument in oral rehabilitation. It is an important advance in dentistry that contains more than 20 years of expert observations synthesized in sophisticated diagnostic descriptors, parameters, and constructs. It is suitable for measurement, standardization and broad application across different levels of trained providers, however it can be improved.

During data collection at different sites, the moderator(s) in the debriefing sessions at all testing sites gathered feedback. The feedback contains facilitators and barriers which are summarized in the following observations:

1. PDI-CE is too complex.
2. It has important aspects useful to classify patients.
3. It requires adjustments in its morphology and modifications by sections, to facilitate the classification of patients.

4. It may provide quantifying and objective data for approaching different types of compromises, treatments, scopes, and users (such as general practitioners, researchers, and insurance companies).

5. This study should be used to raise awareness of the ACP's role in further developing the instrument.

6. The ACP should provide certification and standardize prosthodontists in use of the PDI-CE at every meeting.

7. Prosthodontists should be the experts in the system first, and then approach other users.

This feedback is consistent with previous findings. The Validation Task Force committee reports that, in a PDI Survey conducted during 2004 and 2005 among the program directors and chairmen of several schools in the US, the PDI-CE was rated by 63% of respondents as too complex, by 63% as lacking perceived benefits or incentives to use it, and it was not known or not used by almost 40% of surveyed academicians. A more simplified system with evidence based research, demonstrating the diagnostic reliability, validity and effectiveness was suggested.

This study was designed to meet that need, with the purpose of supporting and assisting the validation process at different levels of scientific method. First level construct validity was documented and reported in this stage.

The following table summarizes the properties observed in this study (construct validity and quantifiability), as well as the need to observe other properties for improving the PDI CE (reliability, sensitivity, clarity, simplicity, acceptability and objectivity).

Fig. 3. Properties of an Ideal Index. Observed*/To be observed**	
Validity*: "*The index must measure what is intended to measure, so it should correspond with the clinical stages of the disease"*. There are at least 7 types of validity; this study was designed to test for construct validity (how well an operational definition relates to a conceptual definition); in that regard **the PDI- CE is a valid** instrument. Specific aim # 1, research question #1. (Table 1)	**Reliability****: The index should be able to measure consistently at different times and under a variety of conditions. The term reliability is virtually synonymous with reproducibility, repeatability, and consistency, meaning the ability of the same or different examiners to interpret and use the index in the same way.
Clarity, simplicity, and objectivity**. The criteria should be clear and unambiguous, with mutually exclusive categories. Ideally, they should be able to be readily memorized by an examiner after some practice.	**Quantifiability*.** "The index must be amenable to statistical analysis, so that the status of a group can be expressed by a distribution, mean, median or other statistical measure". This study was able to test and validate this property.
Sensitivity.** The index should be able to detect reasonably small shifts, in either direction, in the condition.	**Acceptability**.** The use of the index should not be painful or demeaning to the subject.
Dentistry, Dental Practice and the Community. The Methods of Oral Epidemiology. Chapter 14. Pag. 189. (56)	

VII. References

1. Russell E. Glasgow and Karen M. Emmons. Dana-Farber Cancer Institute and Harvard School of Public Health, Boston MA, 02115. Ann. Rev. Public Health 2007. 28 – Downloaded from ajournals.annualreviews.org. by Harvard University on 01/03/07.
2. Epidemiology. Leon Gordis MD.,MPH., DrPH. John Hopkins School of Medicine, Baltimore Maryland. W.B. Saunders, second edition 2000.
3. Thacker S, Berkelman RL: Public health surveillance in the United States, Epidemiologic Rev. 10:164, 1988.
4. *Health, United States, 2005* – 29th report U.S. National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC). The National Committee on Vital and Health Statistics, Department of Health and Human Services -Michael O. Leavitt, Secretary. Centers for Disease Control and Prevention, Julie Louise Gerberding, M.D., M.P.H. Director. National Center for Health Statistics, Edward J. Sondik, Ph.D. Director.
5. Jamieson LM, Thomson WM. Adult oral health inequalities described using area-based and household-based socioeconomic status measures. J Public Health Dent. 2006 Spring;66(2):104-9. PMID: 16711629.
6. Carlsson GE, Omar R. Trends in Prosthodontics. Med Princ Pract. 2006;15(3):167-79. Review. PMID: 16651831.
7. Avlund K, Holm-Pedersen P, Morse DE, Viitanen M, Winblad B. The strength of two indicators of social position on oral health among persons over the age of 80 years. J Public Health Dent. 2005 Fall;65(4):231-9. PMID: 16468465.
8. Mojon P, Thomason JM, Walls AW. The impact of falling rates of edentulism. Int J Prosthodont. 2004 Jul-Aug;17(4):434-40. PMID: 15382779.
9. Waldman HB, Perlman SP, Goldstein SL. Oral health. Massachusetts versus the United States. J Mass Dent Soc. 2003 Fall;52(3):8-10. PMID: 14705577.
10. Vargas CM, Dye BA, Hayes KL. Oral health status of rural adults in the United States. J Am Dent Assoc. 2002 Dec;133(12):1672-81. PMID: 12512669.
11. Douglass CW, Shih A, Ostry L. Will there be a need for complete dentures in the United States in 2020? J Prosthet Dent. 2002 Jan;87(1):5-8. PMID: 11807476 .
12. Zarb, Bolender, CD text book for international stats, trends and references.
13. Classification system for complete edentulism. T. McGarry DDS., A. Nimo DDS., James F. Skiba DDS., Robert H. Ahlstrom DDS., MS., Christopher R. Smith DDS., Jack H. Koumjian DDS., MSD.
14. International Classification of Functioning, Disability and Health. World Health Organization Family of Diagnostic Instruments in Health. Geneva 2001.
15. The Harvard Multidimensional Diagnostic Model for Oral health, disease, trauma and dysfunction. O. Suarez-Sanchez DDS., MSD., Journal of Disability and Oral Health Volume 7 Number 2 August 2006.
16. The Validity Task Force - Report on the validation of the student evaluation of instruction instrument. C. Hewitt-Gervais, College of Education, T. Bevins, College of Health Professions, Volety, College of Arts and Sciences., G Mayfield, School of Social and Public Policy. Florida, USA April 2007.
17. Understanding Dental Research – Critical thinking. D. M. Brunette PhD., Scientific method, logic, measurement, statistical inferences, interpretation and research strategies. Department of Oral Biology, Faculty of Dentistry, University of British Columbia, Vancouver, Canada. Quintessence books 1996.

18. Spilker B. Guide to the clinical interpretation of data. New York: Raven Press 1986:19-26.
19. Sackett DL., Evaluation: requirements of clinical applications. In Warren KS(ed): coping with the biomedical literature. New York: Praeger, 1981:123-140.
20. NIH Consensus Development Conference Report and State of the Science Statements. NIH Consensus Development Program. Diagnosis and management of dental caries throughout life. NIH, website report 2004.
21. Translating findings of systematic reviews into consensus statements on periodontal therapy. J Am Dent Assoc. 2004 Aug;135(8):1099-107. Review. PMID: 15387048
22. Mendelson K, Schoen FJ. Heart valve tissue engineering: concepts, approaches, progress, and challenges. Ann Biomed Eng. 2006 Dec;34(12):1799-819. Epub 2006 Oct 12. PMID: 17053986.
23. Alcott D, Dixon K, et al: The reliability of the scales of the Functional Assessment Measure (FAM): Differences in abstractness between FAM scales. *Disability Rehabilitation* 19(9):355-358, 1997.
24. Donaghy S, Wass PJ: Interrater reliability of the Functional Assessment Measure in a brain injury rehabilitation program. *Arch Phys Med Rehabil* 79: 1231-6,1998.
25. Gurka JA, Fekmingham KL, Baguley IJ, Schotte DE, Crooks J, Marosszeky JE. Utility of the Functional Assessment Measure after discharge from inpatient rehabilitation. *J Head Trauma Rehabil* 14(3):247-256, 1999.
26. Hall KM: Overview of functional assessment scales in brain injury rehabilitation. *NeuroRehabilitation* 2(4):97-112, 1992.
27. Hall KM, Hamilton B, Gordon WA, Zasler ND: Characteristics and comparisons of functional assessment indices: Disability Rating Scale, Functional Independence Measure and Functional Assessment Measure. *J Head Trauma Rehabil* 8(2):60-74, 1993.
28. Hall KM, Johnston MV. Outcomes evaluation in traumatic brain injury rehabilitation: Part II. Measurement tools for a nationwide data system *Archives of Physical Medicine and Rehabilitation*; 75(12-S):SC-10-18, 1994.
29. Hall KM, Mann N, High WM, Wright JM, Kreutzer JS, Wood D: Functional measures after traumatic brain injury: ceiling effects of FIM, FIM+FAM, DRS, and CIQ. *J Head Trauma Rehabil* 11(5):27-39, 1996.
30. Hall KM: The Functional Assessment Measure (FAM). *J Rehabil Outcomes* 1(3):63-65,1997.
31. Hawley CA, Taylor R, Hellawell DJ, Pentland B. FIM+FAM in head injury rehabilitation: A psychometric analysis. J*ournal of Neurology, Neurosurgery, and Psychiatry* 67: 749-754, 1999.
32. Ditunno JF, Cohen ME, Formal CS, Whiteneck GG. Functional outcomes in spinal cord injury. In Stover SL, Whiteneck GG and DeLisa J (eds). *Spinal Cord Injury: Clinical Outcomes from the Model Systems.* Gaithersburg, MD: Aspen Publications, 1995.
33. Dodds TA, Matrin DP, Stolov WC, Deyo, RA. A validation of the Functional Independence Measurement and its performance among rehabilitation inpatients. *Arch Phys Med Rehabil* 1993;74(5):531-6.
34. Granger CV. The emerging science of functional assessment: our tool for outcomes analysis. *Arch Phys Med Rehabil* 1998;79(3):235-240
35. Granger CV, Cotter AS, Hamilton BB, Fiedler RC, Hens MM. Functional assessment scales: A study of persons with multiple sclerosis. *Arch Phys Rehabil* 1990;71:870-875.

36. Granger CV, Hamilton BB, Linacre JM, Heinemann AW, Wright BD. Performance profiles of the Functional Independence Measure. *Arch Phys Rehabil* 1993;72:84-89.
37. Granger CV, Hamilton BB, Keith RA, Zielesny M, Sherwin, FS. Advances in functional assessment for medical rehabilitation. *Top Geriatr Rehabil* 1986;1:59-74.
38. Grey N, Kennedy P. The Functional Independence Measure: a comparative study of clinician and self rating. *Paraplegia* 1993;31:457-461.
39. Guide for the Uniform Data Set for Medical Rehabilitation (including the FIM(TM) instrument), Version 5.1. Buffalo, NY 14214-3007: State University of New York at Buffalo; 1997.
40. Hall KM, Hamilton B, Gordon WA, Zasler ND: Characteristics and comparisons of functional assessment indices: Disability Rating Scale, Functional Independence Measure and Functional Assessment Measure. *J Head Trauma Rehabil* 1993;8(2):60-74.
41. Hall KM, Mann N, High W, Wright J, Kreutzer J, Wood, D. Functional measures after traumatic brain injury: ceiling effects of FIM, FIM+FAM, DRS and CIQ. *J Head Trauma Rehabil* 1996;11(5):27-39.
42. Hamilton BB, Granger CV, Sherwin FS, Zielezny M, Tashman JS. A uniform national data system for medical rehabilitation. In: Fuhrer M, ed. *Rehabilitation outcomes: analysis and measurement*. Baltimore: Brookes, 1987:137-147.
43. Hamilton BB, Laughlin JA, Granger CV, Kayton RM. Interrater agreement of the seven-level Functional Independence Measure (FIM). *Arch Phys Med Rehabil* 1991;72:790 (abstract).
44. Heinemann AW, Linacre JM, Hamilton BB: Prediction of rehabilitation outcomes with disability measures. *Arch Phys Med Rehabil* 1994;75:133-143.
45. Heinemann AW, Linacre JM, Wright BD, Granger CV. Relationships between impairment and physical disability as measured by the Functional Independence Measure. *Arch Phys Rehabil* 1993; 74:566-573.
46. Heinemann AW, Kirk P, Hastie BA, Semik P, Hamilton BB, Linacre JM, Wright BD, Granger CV. Relationships between disability measures and nursing effort during medical rehabilitation for patients with traumatic brain injury and spinal cord injury. *Arch Phys Rehabil* 1997;78(2):143-149.
47. Karamehmetoglu SS, Karacan I, Elbasi N, Demirel G, Koyuncu H, Dosoglu M. The Functional Independence Measure in spinal cord injured patients: comparison of questioning with observational rating. *Spinal Cord* 1997;35(1):22-25.
48. Linacre JM, Heinemann AW, Wright BD, Granger CV, Hamilton BB. The structure and stability of the Functional Independence Measure. *Arch Phys Rehabil* 1994;75:127-132.
49. Long WB, LSacco WJ, Coombes SS et al. Determining normative standards for Functional Independence Measure transitions in rehabilitation. *Arch Phys Med Rehabil* 1994;75:144-148.
50. Segal ME, Ditunno JF, Staas WE. Institutional agreement of individual Functional Independence Measure (FIM) items measured at two sites on one sample of SCI patients. *Paraplegia* 1993;31:622-631.
51. Whiteneck GG. A Functional Independence Measure trail in the SCI Models Systems. Abstract Digest, ASIA 14th Annual Scientific Meeting, 1998;48.
52. International Association of Disability and Oral Health (IADH) Biannual congress. Sweden, Gothenburg. Award scholarship for poster presentation. “The Harvard Multidimensional Diagnostic Model for Disease, trauma, and dysfunction” August 23 – 26, 2006.

53. American College of Prosthodontics (ACP) Annual meeting. Clinical table presentation. “The Harvard Multidimensional Diagnostic Model” -Defining rehabilitation one word at a time- Poster presentation applying The Prosthodontic Diagnostic Index, and the Multidimensional Diagnostic Model in a case presentation at the Prosthodontic Advanced Graduate Program, Harvard School of Dental Medicine. Miami, Florida, November 1 to 4, 2006.
54. Biostatistics. The Bare Essentials. Second ed. G. Norman, D. Streiner. B.C. Decker Inc. 2000. Pag. 166-197.
55. The Glossary of Prosthodontic Terms (GPT) J. Prosthetic Dentistry. 2005 Jul;94(1):10-92.
56. Dentistry, Dental Practice and the Community. Chapter 14. Measurement of Oral Disease. Pag. 183-193. Sixth Edition, Brian A. Burt, Stephen A. Eklund. Elsevier Saunders 2005.
57. Biostats. Data Analysis for Dental Health Care Professionals. Weintraub, Douglass and Gillings. Pag. 247. Second edition 1994. CAVCO, Publishing Division of Quintiles, Inc., Research Triangle Park, NC.

VIII. Appendices

The following additional supportive material is enclosed with this proposal:

Appendix 1. Research project process outline **(flow charts)**

Appendix 2. The Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE) **original format**.

Appendix 3. The Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE) **Anatomic format (taxonomy).**

Appendix 4. The Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE) **Functional analysis (proposed observation)**

Appendix 5. The Prosthodontic Diagnostic Index for Complete Edentulism (PDI-CE) **Syllabi (ACP Diagnostic Classification Systems)**

Appendix 1

Anatomy *PDI CE- by Existing Organization

*PDI CE=Prosthodontic Diagnostic Index for Complete Edentulism

Diagnostic classification (Global score): Class I / Class II / Class III / Class IV

Bone Height-Mandibular

Criterion 1

1. 21 mm or greater
2. 16-20 mm
3. 11-15 mm
4. 10 mm or less

Criterion 1: items 1 to4

Residual Ridge Morphology-Maxilla

Criterion 2

5. Type A-resists vertical & horizontal, hamular notch, no tori
6. Type B-no buccal vestibule, poor hamular notch, no tori
7. Type C-no ant vestibule, minimal support, mobile anterior ridge
8. Type D-no ant/post vestibule, tori, redundant tissue

Criterion 2: items 5 to 8

Muscle Attachments-Mandibular

Criterion 3

9. Type A-adequate attached mucosa
10. Type B-no buccal attach mucosa (22-27), +mentalis m
11. Type C-no ant buccal & lingual vest (22-27), +genio & mentalis m
12. Type D-attached mucosa in posterior only
13. Type E-no attached mucosa, cheek/lip moves tongue

Criterion 3: items 9 to 13

Maxillo mandibular Relationships

Criterion 4

14. Class I
15. Class II
16. Class III

Criterion 4: items 14 to 16

Conditions Requiring Preprosthetic Surgery

Criterion 5

17. Minor soft tissue procedures
18. Minor hard tissue procedures
19. Implants - simple
20. Implants with bone graft - complex
21. Correction of dentofacial deformities
22. Hard tissue augmentation
23. Major soft tissue revisions

Criterion 5: items 17 to 23

Limited Interarch Space

Criterion 6

24. 18-20 mm
25. Surgical correction needed

Criterion 6: items 24 to 25

Tongue Anatomy

Criterion 7

26. Large (occludes interdental space)
27. Hyperactive- with retracted position

Criterion 7: items 26 to 27

Modifiers

Criterion 8

Oral manifestation of systemic disease

28. mild
29. moderate
30. severe

Psychosocial

31. moderate
32. major
33. TMD Symptoms
34. Hx of paresthesia or dysesthesia
35. Maxillofacial defects
36. Ataxia
37. Refractory Patient

Criterion 8: items 28 to 37

Appendix 2

Anatomy *PDI CE- by **MDDx/***ICF Characterization

*PDI CE=Prosthodontic Diagnostic Index for Complete Edentulism
**MDDX= Multi-Dimensional Diagnostic Model
***ICF= International Classification of Functioning, Disability and Health

Diagnostic classification (Global score): **Class I / Class II / Class III / Class IV**

Item distribution by Axes
Axis1 (biologic), *Axis 2* (Physiologic, Psychosocial), Axis 3 (Environmental & Contextual)

Bone Height-Mandibular

Criterion 1

1. 21 mm or greater
2. 16-20 mm
3. 11-15 mm
4. 10 mm or less

Criterion 1: axis1: 1 to4, *axis 2: 0*, axis 3:0

Residual Ridge Morphology-Maxilla

Criterion 2

5. Type A-resists vertical & horizontal, hamular notch, no tori
6. Type B-no buccal vestibule, poor hamular notch, no tori
7. Type C-no ant vestibule, minimal support, mobile anterior ridge
8. Type D-no ant/post vestibule, tori, redundant tissue

Criterion 2: axis 1: 5 to 8, *axis 2*:0, axis 3:0

Muscle Attachments-Mandibular

Criterion 3

9. Type A-adequate attached mucosa
10. Type B-no buccal attach mucosa (22-27), +mentalis m
11. Type C-no ant buccal & lingual vest (22-27), +genio & mentalis m
12. Type D-attached mucosa in posterior only
13. Type E-no attached mucosa, cheek/lip moves tongue

Criterion 3: axis 1: 9 to 13, *axis 2*:0, axis 3:0

Maxillo mandibular Relationships

Criterion 4

14. Class I
15. Class II
16. Class III

Criterion 4: axis 1: 14 to 16, *axis 2*:0, axis 3:0

Conditions Requiring Preprosthetic Surgery

Criterion 5

17. Minor soft tissue procedures
18. Minor hard tissue procedures
19. Implants - simple
20. Implants with bone graft - complex
21. Correction of dentofacial deformities
22. Hard tissue augmentation
23. Major soft tissue revisions

Criterion 5: axis 1: 0, axis 2:0, axis 3:17 to 23

Limited Interarch Space

Criterion 6

24. 18-20 mm
25. Surgical correction needed

Criterion 6: axis 1: 24 & 25, axis 2:0, axis 3:0

Tongue Anatomy

Criterion 7

26. Large (occludes interdental space)
27. Hyperactive- with retracted position

Criterion 7: axis 1: 26, axis 2:27, axis 3:0

Modifiers

Criterion 8

Oral manifestation of systemic disease

28. mild
29. moderate
30. severe

Psychosocial

31. moderate
32. major
33. TMD Symptoms
34. Hx of paresthesia or dysesthesia
35. Maxillofacial defects
36. Ataxia
37. Refractory Patient

Criterion 8: axis 1: 28, 29, 30, 33*, 35, 37*
axis 2:31, 32, 33*, 34, 36, 37*, axis 3:33*, 37*

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5. Type A-resists vertical & horizontal, hamular notch, no tori
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7. Type C-no ant vestibule, minimal support, mobile anterior ridge
8. Type D-no ant/post vestibule, tori, redundant tissue

Criterion 2: items 5 to 8

Muscle Attachments-Mandibular

Criterion 3

9. Type A-adequate attached mucosa
10. Type B-no buccal attach mucosa (22-27), +mentalis m
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Criterion 3: items 9 to 13

Maxillo mandibular Relationships

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15. Class II
16. Class III

Criterion 4: items 14 to 16

Conditions Requiring Preprosthetic Surgery

Criterion 5

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18. Minor hard tissue procedures
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22. Hard tissue augmentation
23. Major soft tissue revisions

Criterion 5: items 17 to 23

Limited Interarch Space

Criterion 6

24. 18-20 mm
25. Surgical correction needed

Criterion 6: items 24 to 25

Tongue Anatomy

Criterion 7

26. Large (occludes interdental space)
27. Hyperactive- with retracted position

Criterion 7: items 26 to 27

Modifiers

Criterion 8

Oral manifestation of systemic disease

28. mild
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Psychosocial

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37. Refractory Patient

Criterion 8: items 28 to 37

Appendix 4

Anatomy *PDI CE- by **MDDx/***ICF Characterization

*PDI CE=Prosthodontic Diagnostic Index for Complete Edentulism
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3. 11-15 mm
4. 10 mm or less

Criterion 1: axis1: 1 to4, *axis 2: 0*, axis 3:0

Residual Ridge Morphology-Maxilla

Criterion 2

5. Type A-resists vertical & horizontal, hamular notch, no tori
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7. Type C-no ant vestibule, minimal support, mobile anterior ridge
8. Type D-no ant/post vestibule, tori, redundant tissue

Criterion 2: axis 1: 5 to 8, *axis 2*:0, axis 3:0

Muscle Attachments-Mandibular

Criterion 3

9. Type A-adequate attached mucosa
10. Type B-no buccal attach mucosa (22-27), +mentalis m
11. Type C-no ant buccal & lingual vest (22-27), +genio & mentalis m
12. Type D-attached mucosa in posterior only
13. Type E-no attached mucosa, cheek/lip moves tongue

Criterion 3: axis 1: 9 to 13, *axis 2*:0, axis 3:0

Maxillo mandibular Relationships

Criterion 4

14. Class I
15. Class II
16. Class III

Criterion 4: axis 1: 14 to 16, *axis 2*:0, axis 3:0

Conditions Requiring Preprosthetic Surgery

Criterion 5

17. Minor soft tissue procedures
18. Minor hard tissue procedures
19. Implants - simple
20. Implants with bone graft - complex
21. Correction of dentofacial deformities
22. Hard tissue augmentation
23. Major soft tissue revisions

Criterion 5: axis 1: 0, axis 2:0, axis 3:17 to 23

Limited Interarch Space

Criterion 6

24. 18-20 mm
25. Surgical correction needed

Criterion 6: axis 1: 24 & 25, axis 2:0, axis 3:0

Tongue Anatomy

Criterion 7

26. Large (occludes interdental space)
27. Hyperactive- with retracted position

Criterion 7: axis 1: 26, axis 2:27, axis 3:0

Modifiers

Criterion 8

Oral manifestation of systemic disease

28. mild
29. moderate
30. severe

Psychosocial

31. moderate
32. major
33. TMD Symptoms
34. Hx of paresthesia or dysesthesia
35. Maxillofacial defects
36. Ataxia
37. Refractory Patient

Criterion 8: axis 1: 28, 29, 30, 33*, 35, 37*
axis 2:31, 32, 33*, 34, 36, 37*, axis 3:33*, 37*