UNIVERSIDAD COMPLUTENSE DE MADRID

FACULTAD DE ODONTOLOGÍA

DEPARTAMENTO DE ESTOMATOLOGÍA I

TESIS DOCTORAL

Estudio clínico para el desarrollo de un cuestionario específico, preciso y eficaz para evaluar la calidad de vida asociada al estado de salud oral en usuarios de implantoprótesis

Clinical trial for the development of a specific, precise and effective questionnaire to evaluate the OHRQoL of implant prosthesis wearers

MEMORIA PARA OPTAR AL GRADO DE DOCTOR

PRESENTADA POR

Arelis Preciado Uribe

Directores

Raquel Castillo de Oyagüe

Jaime del Río Highsmith

Madrid, 2014

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Tesis Doctoral

Presentada por **Arelis Preciado Uribe** para optar al título de Doctor por la U.C.M.

Directores:

Dra. Raquel Castillo de Oyagüe

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ARELIS PRECIADO URIBE

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Trabajo de investigación para optar al Grado de Doctor por la Universidad Complutense de Madrid presentado por

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CERTIFICA

Que el trabajo de investigación titulado: "**Estudio clínico para el desarrollo de un cuestionario específico, preciso y eficaz para evaluar la calidad de vida asociada al estado de salud oral en usuarios de implantoprótesis**". Del que es autora Dña. Arelis Preciado Uribe, ha sido realizado bajo mi dirección y supervisión, y reúne en su introducción, objetivos, antecedentes y justificación, artículos, discusión, conclusión y resumen, los requisitos requeridos para su defensa.

Y para que conste y surta los efectos oportunos, expido este certificado en Madrid a 29 de enero de 2014.

Fdo. Profa. Dra. Dña. Raquel Castillo de Oyagüe

D. Jaime Del Río Highsmith, Catedrático del Departamento de Estomatología I de la Facultad de Odontología de la Universidad Complutense de Madrid.

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Dedico esta Tesis a todos los que creyeron en mí, a toda la gente que me apoyó, a mis amigos y familiares; especialmente mi madre, mi esposo y mis adoradas hijas porque sin ellos, esto no hubiera sido posible.

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1. RESUMEN

1. RESUMEN

Es importante saber cómo las personas perciben el impacto de las enfermedades bucodentales en su calidad de vida. La OHRQoL (Calidad de Vida relacionada con la Salud Oral) es un concepto relativamente nuevo, pero en rápida progresión. La OHRQoL resulta particularmente significativa para tres áreas: la práctica clínica de la Odontología, la investigación y la educación dental. Por ello, la OHRQoL debería constituir la base para el desarrollo de cualquier programa de Salud Oral.

Existen diferentes enfoques para medir la calidad de vida relacionada con el estado de salud oral (OHRQoL) de los pacientes. El más popular utiliza cuestionarios para valorar la relación entre los tratamientos odontológicos y la calidad de vida. Por tanto, el objetivo de nuestro trabajo fue desarrollar y validar un cuestionario específico, preciso y eficaz para evaluar la autopercepción de satisfacción en usuarios de implantoprótesis.

La presente Tesis Doctoral está estructurada en tres artículos de impacto correlativos publicados en *Journal of Dentistry,* revista J.C.R. situada en el cuartil superior de la especialidad: 7/82).

En el primer artículo: "*Differences in impact of patient and prosthetic characteristics on oral health-related quality of life among implant-retained overdenture wearers"* evaluamos la calidad de vida relacionada con la salud oral (OHRQoL) en portadores de sobredentaduras implanto-retenidas mediante la aplicación del cuestionario genérico "OHIP–14sp" (Perfil de Impacto de Salud Oral validado en España). Se exploraron clínicamente 63 pacientes tratados con sobredentaduras implanto-retenidas, los cuales respondieron también al cuestionario OHIP–14sp. Las dimensiones con mayor impacto en la salud bucal fueron: dolor físico, malestar psicológico, incapacidad física e incapacidad psicológica.

Concluimos que el estado bucal de pacientes con sobredentaduras implanto-retenidas influye en la autopercepción de calidad de vida (QoL) de los adultos mayores y condiciona la sensación de dolor (dolor físico) y el estado de ánimo (malestar psicológico). A partir de los hallazgos de esta investigación obtuvimos información acerca de los dominios e ítems más relevantes para los pacientes con implantoprótesis de cara a desarrollar un cuestionario específico para rehabilitaciones implantológicas.

En el segundo artículo: *"A new, short, specific questionnaire (QoLIP–10) for evaluating the oral health-related quality of life of implant-retained overdenture and hybrid prosthesis wearers"* se desarrolló el primer cuestionario internacional para cuantificar la calidad de vida de pacientes rehabilitados con prótesis sobre implantes. Dicho instrumento, de 10 ítems, fue denominado "QoLIP–10" ("Calidad de vida con Implanto-prótesis"). El QoLIP–10 y el OHIP–20sp fueron aplicados en 150 portadores de sobredentaduras implanto-retenidas, prótesis híbridas o prótesis completas convencionales (grupo control). El análisis factorial del QoLIP–10 demostró que la calidad de vida tiene un carácter tridimensional (biopsicosocial, estética dento-facial y rendimiento funcional). Las pruebas de validez y fiabilidad confirmaron la capacidad psicométrica del QoLIP–10 para evaluar OHRQoL en usuarios de sobredentaduras implanto-retenidas o prótesis híbridas. Las prótesis híbridas mejoraban la QoL con respecto a la dimensión biopsicosocial. En general los resultados de QoL para las implantoprótesis analizadas fueron mejores que los obtenidos para las prótesis completas convencionales.

Finalmente en el tercer artículo: *"Impact of various screwed implant prostheses on oral health-related quality of life as measured with the QoLIP–10 and OHIP–14 scales: A cross-sectional study"* se validó el recién creado cuestionario QoLIP–10 para su aplicación en pacientes restaurados con prótesis atornilladas sobre implantes. 131 participantes con implantoprótesis atornilladas (completas y parciales) o híbridas (grupo control) respondieron las preguntas del QoLIP–10 y OHIP–14sp. El QoLIP–10 demostró fiabilidad y validez para evaluar OHRQoL asociada a implantoprótesis atornilladas. Ambos instrumentos registraron menor QoL para los

portadores de prótesis híbridas, no encontrando diferencias en función de la extensión de las prótesis atornilladas. En conclusión, hemos validado un cuestionario específico de calidad de vida para pacientes rehabilitados con prótesis sobre implantes, ya que hasta la fecha tan sólo disponíamos de cuestionarios genéricos de salud oral. Al cruzar los resultados de calidad de vida con variables sociodemográficas, clínicas y relacionadas con la prótesis, en los tres artículos encontramos que dichas características modulan el nivel de satisfacción personal. Esto contribuirá a predecir las probabilidades de éxito de los distintos tratamientos de prótesis implantológica y a tomar la decisión acerca de su diseño.

2. Introducción General

2. INTRODUCCIÓN GENERAL

La O.M.S. afirma que “la salud es un estado de completo bienestar físico, mental y social y no solamente la ausencia de afecciones o enfermedades”[1] (O.M.S., 1948)

En Odontología, este nuevo concepto de salud sugiere que el objetivo final de la atención dental no es solamente la ausencia de caries o enfermedades periodontales o cáncer oral, sino también el bienestar mental y social del paciente. El concepto de calidad de vida relacionada con la salud bucal (OHRQoL) capta la esencia de esta nueva perspectiva.

Entre las definiciones de OHRQoL, la más completa es la derivada de la comprensión de la salud relacionada con la calidad de vida. Consiste en la evaluación personal de cómo los siguientes factores afectan el bienestar de cada individuo: factores funcionales (ej.: masticación y pronunciación/habla); factores psicológicos (ej.: la apariencia de la persona y autoestima); factores sociales (ej.: interacción con los demás) y experiencia de dolor o malestar. La OHRQoL puede ser valorada, por tanto, cuando estos factores están en relación con preocupaciones oro-faciales.[2]

En las últimas décadas se ha dado un mayor reconocimiento de la incorporación de medidas de OHRQoL en la evaluación de la salud oral. Las medidas de OHRQoL se pueden utilizar para cuantificar el impacto de diversas enfermedades orales en la población general y en los grupos de alto riesgo con el fin de estudiar el éxito de diversos procedimientos preventivos y curativos en la mejora de la satisfacción de un individuo.[3]

Los investigadores, los clínicos y los profesionales de salud pública tienen la responsabilidad de documentar y evaluar la OHRQoL con instrumentos rigurosos, fiables y válidos, es decir una base sólida y científica para evaluarla.[3]

En definitiva, acorde al aumento de la demanda de instrumentos para calibrar el

estado de salud (en contraste con las clásicas medidas clínicas del estado de enfermedad), los investigadores se han centrado en el desarrollo de cuestionarios que podrían ser utilizados en entornos clínicos o en grandes estudios de población.

La medición de OHRQoL está dividida en tres categorías: indicadores sociales, autoevaluación global de OHRQoL (es decir, con un único ítem o pregunta) y cuestionarios de varios ítems o preguntas de OHRQoL.[3]

De esta forma los indicadores sociales evalúan mediante encuestas poblacionales el impacto social de las condiciones orales.[4-6]

La auto-evaluación global es un método para evaluar intuitivamente la OHRQoL con un solo ítem sobre la autopercepción de la salud oral. Por ejemplo una pregunta podría ser: ¿cómo calificaría la salud de sus dientes, encías y boca?. Las respuestas son proporcionadas en una escala ordinal de cinco puntos que van desde "excelente" a "muy pobre". Sin embargo, este proceso varía de un individuo a otro.[7] Algunas personas pueden considerar su salud oral excelente siempre y cuando no experimenten dolor dental, mientras que otros pueden considerarla aceptable a pesar de haber perdido varios dientes. Una característica de la evaluación global única es que ofrece respuesta positiva y no se limita a medir únicamente el impacto negativo de la salud oral. La escala visual analógica (VAS)[7] que se utiliza con frecuencia en la investigación del dolor es una escala de evaluación global única. La gran ventaja que ofrece este cuestionario es su facilidad de administración.

Por otra parte, los cuestionarios multi-ítem constituyen un método comúnmente aplicado para valorar dimensiones o dominios de OHRQoL formulando numerosas preguntas a los sujetos.[3] Algunas de estas cuestiones se centran en la función, otras en el dolor o molestia, mientras otras

evalúan la auto-imagen y la interacción social.[3] Este enfoque intenta delinear experiencias específicas que abarcan la definición de OHRQoL.[2,3]

Por lo general, los cuestionarios de varios ítems capturan más variación estadística que los de un solo ítem. Por lo tanto, la motivación para desarrollar cuestionarios multi-ítem es tanto filosófica (los investigadores se centran en una dimensión específica de OHRQoL utilizando un conjunto predeterminado de preguntas y categorías de respuesta) como metodológica (los investigadores intentan capturar la máxima variación en la OHRQoL).

Existe una heterogeneidad significativa en el enfoque, la longitud y el formato de los cuestionarios multi-ítem desarrollados para evaluar OHRQoL.[3] El formato de las preguntas y respuestas puede variar, desde preguntas con respuesta dicotómica ("sí" o "no"), por ejemplo, ¿Existe algún tipo de alimento que le dificulte masticar?; hasta cuestiones que indagan acerca de la frecuencia, gravedad e importancia de un problema específico (como el impacto oral sobre actuaciones diarias).[8] Una característica común de los cuestionarios multi-ítem de OHRQoL es que en ellos se pueden analizar las respuestas a preguntas individuales con puntuaciones numéricas.[9] En la mayoría de los cuestionarios las subescalas se pueden cuantificar. Por ejemplo, el Perfil de Impacto de Salud Oral (OHIP)[10] cuenta con siete dimensiones, cada una de las cuáles mide un dominio único de OHRQoL (por ejemplo, la limitación funcional). La versión original del OHIP contaba con 49 ítems, aunque actualmente se han validado versiones que constan de un menor número de preguntas (OHIP–14; OHIP–20).[11,12] Se ha encontrado que estas versiones más cortas son más convenientes en estudios poblacionales grandes.[13-15]

Las medidas de calidad de vida (QoL) no sólo están siendo utilizados en las encuestas de población, sino también en ensayos clínicos aleatorizados, en la evaluación de tecnologías sanitarias y en la evaluación de los sistemas de atención en salud.

3. REVISIÓN DE LA LITERATURA

3. REVISIÓN DE LA LITERATURA

En el contexto de la salud oral la cuestión de qué medida utilizar ha sido objeto de intenso esfuerzo de investigación en los últimos años. En la actualidad, tanto los cuestionarios genéricos como los específicos (medidas más sofisticadas) de OHRQoL son utilizados para evaluar las percepciones de los pacientes tanto de la salud como la presencia o ausencia de la enfermedad. Las medidas específicas sin embargo, aventajan a las medidas genéricas en que detectan cambios sutiles en determinadas condiciones. Por lo tanto, tienen una mejor capacidad de respuesta. Además, contienen afirmaciones y dominios que sólo son pertinentes a la condición clínica que se esté evaluando.[9] A pesar de esto, en los estudios de OHRQoL es recomendable utilizar medidas adecuadas, tanto específicas como genéricas.[16] Los datos obtenidos con dichas medidas sirven para diseñar programas de promoción de la salud y prevención de la enfermedad,[17] evaluar el resultado de la intervención clínica y asignar los recursos de salud.[18]

Una barrera importante para el empleo de medidas de OHRQoL en el ámbito clínico es el gran número de ítems en muchos de los instrumentos actualmente disponibles.[3] Algunos autores se han esforzado para reducir la extensión de las medidas existentes, pero conservando las propiedades psicométricas importantes como la fiabilidad y precisión.[11,19]

En esta línea, el presente trabajo se ha centrado en el desarrollo y validación de un cuestionario corto y específico para medir OHRQoL en usuarios de implantoprótesis. Esta revisión de la literatura se estructura en dos partes. La primera parte se enfoca en el cuestionario OHIP (Perfil de Impacto de Salud Oral/ Oral Health Impact Profile) que es una de las medidas multi-ítem más universalmente utilizada en estudios de OHRQoL,[20] y la segunda se centra en la metodología a seguir para el desarrollo y validación de medidas específicas de OHRQoL.

3.1. Primera parte: cuestionario OHIP (Perfil de Impacto de Salud Oral/ Oral Health Impact Profile)

3.1.1. Conceptos básicos

En 1991 la O.M.S. definió la calidad de vida como "la percepción de un individuo de su situación de vida, dentro del contexto cultural y del sistema de valores en que vive, en relación con sus objetivos, expectativas, estándares e intereses".[21] Se trata de un concepto muy amplio que afecta de un modo complejo la salud física, el estado psicológico, el nivel de independencia, las relaciones sociales y su conexión con las características más destacadas del entorno.[21]

Puesto que valorar la calidad de vida según el estado de salud bucal puede ser subjetivo, al estar directamente influenciada por el tipo de personalidad, así como por el entorno donde vive y se desarrolla cada individuo, se han creado instrumentos de medición que permiten evaluarla con un enfoque metodológico y más objetivo. Estos cuestionarios fueron desarrollados en el marco de un proyecto de colaboración entre varios centros en diferentes contextos culturales. Además, se demostraron las propiedades psicométricas de validez, fiabilidad y capacidad de respuesta que responda al entorno en el que se aplica, manteniendo así la comparabilidad de los resultados a través de diferentes contextos culturales.[21] Entre estos instrumentos encontramos el cuestionario OHIP (Perfil de impacto de salud oral/ The Oral Health Impact Profile), desarrollado por Slade y Spencer en Australia en 1994,[10] el cual se emplea como un índice de medición del impacto social de las patologías bucales en la calidad de vida. La base conceptual de este cuestionario se fundamenta en el modelo de salud oral adaptado para la Odontología por Locker en 1988[22] a partir de un modelo propuesto por la organización mundial de la salud (O.M.S.) para la salud general. Del modelo de Locker fueron identificadas las dimensiones conceptuales de la jerarquía del impacto social que pueden originarse de las enfermedades orales (Figura 1).[22]

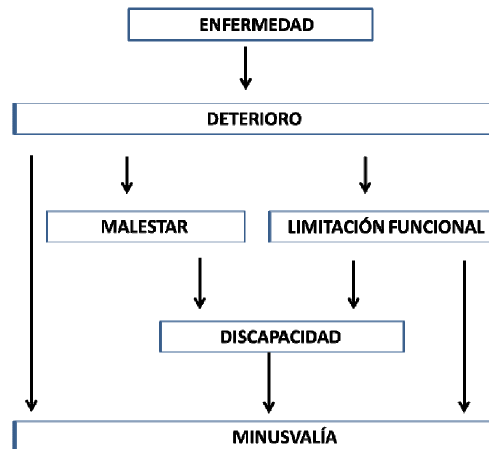

Figura 1: Modelo de Locker de salud oral. Tomado De Locker (1988).[22]

En este modelo, la enfermedad puede conducir al deterioro; definido como cualquier pérdida o anormalidad donde la pérdida de los dientes puede ser un ejemplo. El deterioro puede entonces llevar a la limitación funcional, descrita como la pérdida de la función de partes o sistemas del cuerpo. Por ejemplo, dificultad en la masticación. Otras consecuencias del deterioro pueden ser dolor y molestias, ya sean físicas o psicológicas. Cualquiera de ellas puede conducir a discapacidad física, psicológica o social, descrita por Locker como limitación o falta de capacidad para realizar actividades cotidianas. Un ejemplo podría ser la mala pronunciación, la cual puede hacer que una persona no sea comprendida durante una conversación. Una consecuencia final es la minusvalía, caracterizada por la experiencia de desventaja cuando una persona experimenta problemas con su empleo debido a una incapacidad para comunicarse claramente.[22]

3.1.2. Desarrollo del OHIP

Slade,[10] para desarrollar el cuestionario OHIP, realizó una adaptación del modelo de salud oral de Locker, según la cual una enfermedad oral puede llevar a la pérdida de dientes (deterioro). En algún momento esto puede conducir a dificultades en la masticación (limitación funcional) o a

dolor producto de las dentaduras (molestias). Eventualmente esto puede a su vez derivar en una limitación de la capacidad para comer o a la necesidad de evitar alimentos favoritos (discapacidad). En casos extremos esto puede impedir a las personas comer fuera de casa o incluso con su familia llevándolo a sentirse en aislamiento social (minusvalía) (Figura 2).[11]

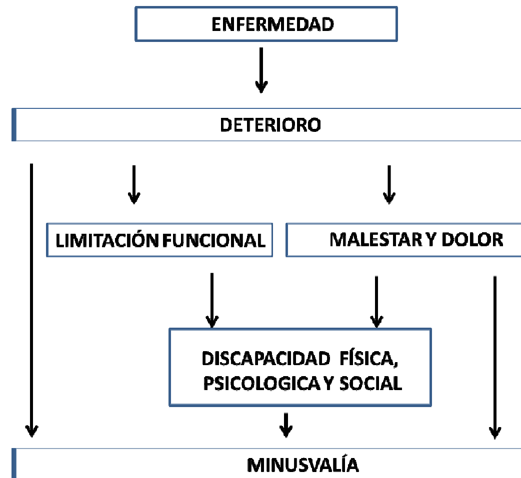

Figura 2. Adaptación de Slade del modelo de salud oral de Locker. Tomado de Slade (1997).[11]

El OHIP es un conjunto de preguntas que se derivaron de entrevistas en las que se indagó cómo la condición oral de las personas afectaba sus vidas. A raíz de esto, los autores del cuestionario analizaron los resultados para determinar qué factores eran los más importantes para la gente.[10] El OHIP original constaba de 49 preguntas organizadas en siete categorías o dimensiones, las cuales valoran la percepción psicosocial personal de cada individuo como herramientas de estimación adicional al tradicional enfoque de las evaluaciones físicas. Este cuestionario puede ser auto-cumplimentado o administrado por un entrevistador.[3,11] Esta forma larga del OHIP es muy empleada en la práctica clínica con adultos mayores, donde el profesional de la salud cuenta con una base objetiva para evaluar el impacto del estado de salud bucal en la calidad de vida.

A pesar de esto, el OHIP–49 desarrollado por Slade y Spencer,[10] presentaba limitaciones para su aplicación a la investigación debido a su extensión. Por ello Slade en 1997 validó una forma resumida y fácil de usar con 14 preguntas (OHIP–14) conformado, al igual que el anterior, por siete dimensiones (cada una de ellas con dos preguntas) denominadas: limitación funcional, dolor físico, malestar psicológico, incapacidad física, incapacidad psicológica, incapacidad social y minusvalía.[11] Del mismo modo, una forma corta del OHIP–49 para pacientes edéntulos llamada OHIP–20 (EDENT),[23] fue derivado y validado con veinte preguntas y siete dimensiones idénticas a las del OHIP–49 y el OHIP–14 (Figura 3).[24] Cada una de estas versiones mide la frecuencia y la gravedad de los problemas orales sobre el bienestar funcional y psicosocial de los pacientes.[20]

DIMENSIÓN	***TEMA DE LAS PREGUNTAS***
LIMITACIÓN FUNCIONAL	Dificultad para pronunciar palabras, cambio en el sabor de los alimentos.
DOLOR FÍSICO	Molestias doloras, incomodidad al comer algún alimento.
MALESTAR PSICOLÓGICO	Preocupación o estrés.
INCAPACIDAD FÍSICA	Dieta insatisfactoria, interrupción de comidas.
INCAPACIDAD PSICOLÓGICA	Dificultad para descansar, vergüenza.
INCAPACIDAD SOCIAL	Irritabilidad, dificultad para actividades cotidianas.
MINUSVALÍA	Vida insatisfactoria, incapacidad para actividades diarias.

Figura 3. Dimensiones y temas de las preguntas del OHIP–14. Tomado de Nuttall (2001).[24]

3.1.2.1. Cuantificación del OHIP

En las tres formas del OHIP, las respuestas se cuantifican con una escala tipo Likert,[10,11] codificada con valores que van de 0 a 4 que determinan la frecuencia de cada evento así; 4 = “muchas veces”, 3 = “algunas veces”, 2 = “ocasionalmente”, 1 = “rara vez” y 0 = “nunca”.

La puntuación del OHIP a partir de los valores antes citados puede ser calculada por tres métodos.[25] El primero, llamado método de conteo simple (OHIP–SC), que consiste en un conteo del número de preguntas para las cuales un sujeto responde “algunas veces” o “muchas veces”. Esto reduce las respuestas a una escala dicotómica y da una indicación del número de impactos funcionales y psicosociales experimentado sobre una base regular. El segundo, llamado método aditivo (OHIP–ADD), consiste en sumar los códigos de las todas las preguntas. Éste toma en cuenta todas las respuestas mediante la inclusión de todos los impactos independientemente de su frecuencia. El tercero, llamado método estandarizado-ponderado (OHIP–WS), los códigos de las respuestas son multiplicados por el peso de la pregunta y luego sumados para establecer subescalas de puntuación. Estas puntuaciones son estandarizadas a una media y desviación estándar de 1 y luego sumadas para proporcionar una puntuación total del OHIP. Los métodos OHIP–SC y OHIP–WS fueron descritos inicialmente por Slade y Spencer.[10] El método OHIP–WS muestra mejor sensibilidad y especificidad que el método OHIP–SC, pero la magnitud de la mejora es relativamente pequeña. Por otra parte, el método OHIP–ADD y el OHIP–WS son virtualmente idénticos con respecto a la sensibilidad y la especificidad.[25] Tanto la puntuación total del OHIP como la puntuación de cada ítem y de las subescalas (dimensiones) pueden ser calculadas por estos métodos.

En definitiva, una gran ventaja del cuestionario OHIP es que los ítems y dimensiones se obtuvieron de registros tomados en un grupo representativo de pacientes y no fueron preestablecidos por los investigadores. Esto aumenta la posibilidad del cuestionario para medir las consecuencias sociales de los trastornos orales considerados importantes por los pacientes, lo cual hizo del OHIP la medida de salud oral más sofisticada.[26]

El OHIP fue seleccionado para el presente estudio dado que es una de las medidas más empleadas en estudios clínicos de calidad de vida. Además, este cuestionario está validado en la población española en sus dos versiones cortas (OHIP–14; OHIP–20).[14,27]

3.2. Segunda parte: fases para el desarrollo de un instrumento de medición de OHRQoL

En esta segunda parte de la revisión se tratan los conceptos, principios y métodos de medición de OHRQoL. Este apartado está organizado en una secuencia cronológica que cubre los tópicos para desarrollar un nuevo instrumento de medición de OHRQoL.

3.2.1. Revisión de la literatura

Inicialmente es necesaria una búsqueda de la literatura de escalas de medición de variables específicas dependiendo de la aplicación (tal como: dolor, enfermedad, tratamiento o procedimientos, entre otros). Una vez localizadas varias escalas de interés potencial, se debe escoger una de esas escalas existentes o proceder al desarrollo de un nuevo instrumento. Esta decisión puede ser guiada por el juzgamiento de la idoneidad de los ítems de la escala, pero en cualquier caso ha de estar siempre soportado por una revisión crítica de la evidencia de los test existentes.[28]

3.2.2. Elaboración de los ítems del test

Cuando se opta por diseñar un nuevo test, el primer paso en la escritura de una escala o cuestionario será naturalmente la elaboración de los ítems. Lo primero es valorar los test existentes que están basados en lo que otras personas han considerado relevante, importante o exigente para un tema específico, teniendo en cuenta que muchos test han sido derivados de otros índices previos que son ampliamente usados en estudios clínicos de OHRQoL.[29]

3.2.2.1. Fuente de los ítems del test

En el desarrollo de una escala, una excelente fuente de ítems son los pacientes y los sujetos potenciales de investigación. Por su parte, los clínicos pueden ser los mejores observadores de las manifestaciones externas de un rasgo o trastorno, pues son los que pueden presentar un informe sobre los elementos más subjetivos del test.[30] Es conveniente formar dos o tres grupos de pacientes y/o sujetos potenciales y una vez diseñados los ítems, evaluar los ítems mediante entrevistas (indagando si son relevantes, claros, carentes de ambigüedades, si están escritos en términos que son comprendidos por futuros participantes y si los principales temas han sido cubiertos).[30]

Otra fuente de ítems es la observación clínica. Una manera de garantizar las observaciones clínicas es asegurarse de que todos los observadores persigan el mismo objetivo (calibración) y que todos los sujetos respondan los mismos ítems.[31]

Los hallazgos de investigación, junto con la revisión bibliográfica pueden ser una fructífera fuente de ítems.[31] Finalmente, la opinión de expertos puede ayudar a determinar cuáles son las características más importantes de la escala.[32] Debe tenerse en cuenta que estos métodos no son mutuamente excluyentes en la generación de ítems. Un cuestionario puede consistir de ítems derivados de algunas o todas de estas fuentes.[33]

3.2.2.2. Elección de la escala de respuestas y puntuación del test

Después de haber formulado los ítems que conformarán el índice, se debe escoger el método por el cual las respuestas del test serán obtenidas (escala de respuestas). La selección del método será dictada por la naturaleza de las preguntas o ítems y el tipo de variable de estudio. Como en la presente investigación la variable “puntuación del test” es continua, nos centraremos en las escalas aplicadas en este tipo de variables. Las variables continuas pueden evaluarse mediante tres métodos de respuestas: estimación directa (ej: escalas visuales analógicas, escalas

adjetivas, escalas tipo Likert, escalas aparentes, escalas uni o bipolares), métodos comparativos y econometría.[33]

Los métodos de estimación directa son diseñados para obtener de los sujetos una estimación cuantitativa directa de la magnitud de un atributo. La escala tipo Likert[34] es una escala psicométrica comúnmente utilizada en cuestionarios de amplio uso en encuestas de investigación. La escala tipo Likert es bipolar, donde el atributo más comúnmente medido es el grado de acuerdo del paciente con los diversos ítems, que va desde estar "totalmente de acuerdo" a estar "totalmente en desacuerdo", pasando por una posición medial que puede denominarse "neutral", que refleje una cantidad media del atributo y no la inhabilidad para responder la pregunta o ítem[34] (Figura 4). Por tanto, al responder a una pregunta de un cuestionario elaborado con la técnica de Likert se especifica el nivel de acuerdo o desacuerdo con una declaración (elemento, ítem, reactivo o pregunta).[34]

Totalmente de acuerdo	De acuerdo	Neutral	En desacuerdo	Totalmente en desacuerdo

Figura 4. Ejemplo de escala tipo Likert. Tomado de Likert (1952).[34]

Una vez elegida la escala de respuestas, se procede a la elección del método para calcular la puntuación del test. El seleccionado en este trabajo fue el método aditivo (ADD), el cual ya ha sido previamente descrito en la primera parte de esta revisión (consistente en sumar los códigos de las todas las preguntas). Este procedimiento toma en cuenta todas las respuestas, mediante la inclusión de todos los impactos, independientemente de su frecuencia.[25]

3.2.3. Métodos de administración del test

Una vez desarrollado el cuestionario, el siguiente paso es decidir cómo administrarlo. Esto depende del coste, la tasa de respuesta, el modo en que se pueden formular las preguntas y el formato a emplear.[33] Los tres métodos comúnmente manejados son la entrevista personal, la vía telefónica y el correo electrónico.[33] El sistema seleccionado en el presente estudio fue la entrevista personal que implica un entrevistador entrenado para administrar el test o cuestionario. Entre sus principales ventajas destacan que el entrevistador está seguro de quién está respondiendo (lo que puede dar lugar a equívocos cuando se realiza vía telefónica o electrónica) y que al responder verbalmente se reduce el número de ítems omitidos por el entrevistado. El entrevistador puede determinar si el sujeto está teniendo dificultades para entender los ítems, sea debido a una pobre comprensión del lenguaje, falta de entendimiento, problemas de concentración o tedio. Las únicas desventajas se asocian a los costes de tiempo y dinero que entraña una entrevista personal.[35]

3.2.4. Validez aparente y validez de contenido de un test

Mediante la validación aparente y la validación de contenido se seleccionarán los mejores ítems del test cubran todos los dominios que están en estudio.

Los términos de "validez aparente" y "validez de contenido" son descripciones técnicas del juicio de que la escala parece razonable. La validez aparente se refiere a cómo los entrevistados o encuestados y otros usuarios del test lo perciben; si puede ser juzgado por ellos y no por expertos en el campo.[28] Un test posee una validez aparente adecuada cuando así lo perciben los sujetos a los que se aplica.[33]

La validez de contenido consiste en juzgar si los dominios o todo el contenido del instrumento son relevantes o importantes. Se dice que un cuestionario o test cumple con las condiciones de validez de contenido si constituye una muestra adecuada y representativa de los contenidos y alcance del constructo o dimensión que se quiere evaluar.[36] En ambas formas de

validez la escala debe ser juzgada por expertos para definir si es pertinente para la intención propuesta.[36]

3.2.5. Fiabilidad de un test

Una vez aplicado el test producto de la validación aparente y de contenido a la población de interés, se debe probar su fiabilidad. El concepto de fiabilidad ha recibido diferentes nombres fuera de los campos de psicología y educación, tales como: exactitud, precisión, acuerdo, confiabilidad, reproducibilidad, repetitividad y consistencia. Sin embargo, en estudios de calidad de vida es preferible usar el de fiabilidad.[33] La fiabilidad evalúa que un test mida algo de una manera reproducible (cómo de reproducibles son los resultados de un test bajo diferentes condiciones).[33] Con la fiabilidad como medida de asociación, se examina el efecto de diferentes observadores en las puntuaciones de un test; la fiabilidad refleja la extensión de cómo un instrumento de medición puede diferenciar entre individuos (variabilidad inter-sujeto).[37] La fiabilidad es una propiedad psicométrica que hace referencia a la ausencia de errores de medida o al grado de consistencia y estabilidad de las puntuaciones obtenidas a lo largo de sucesivos procesos de medición con un mismo instrumento.[33] La fiabilidad puede oscilar entre 0 y 1. Así, el coeficiente de fiabilidad expresa la proporción de la varianza total en las mediciones, lo cual es debido a verdaderas diferencias entre sujetos. Entre los diferentes métodos para calcular la fiabilidad, el escogido en el presente trabajo fue el "coeficiente α" (también llamado "alpha de Cronbach")[38] el cual se utiliza cuando los ítems del test ofrecen más de dos alternativas de respuesta.

El incremento significativo del valor de α cuando un ítem específico es eliminado podría indicar que la exclusión de éste aumenta la homogeneidad del test, puesto que a mayor coeficiente mejor fiabilidad (mejor consistencia interna).[38] Esto hace que α no sólo sea dependiente de la magnitud de las correlaciones entre ítems, sino también del número de ítems del test y el tamaño de la muestra a la que fue aplicado.[39] Por lo tanto, numerosos autores dicen que un valor de α de al

menos 0.70 puede ser correcto (buena consistencia interna) para un test nuevo con menos de siete ítems y evaluado en menos de cien sujetos.[39] Sin embargo, si el test tiene más de once ítems y el tamaño de la muestra es mayor de trescientos individuos, el valor de α debe ser de 0.90 para ser aceptado.[39]

Como cada ítem mide distintos aspectos de un mismo atributo, la confiabilidad también se evaluó en el presente trabajo mediante el examen de la consistencia interna de las escalas, a través del uso de la "correlación inter-ítem" y la "correlación ítem-total". Para determinar la homogeneidad de los ítems, un ítem puede correlacionarse con cada uno de los otros ítem, y cada ítem correlacionarse con la puntuación total del test.[33] Cuando se mide una característica, comportamiento o síntoma es necesario que el test sea homogéneo, es decir, todos los ítems deben tocar diferentes aspectos de un mismo atributo y no diferentes partes de diferentes características. Un alto grado de homogeneidad es deseable en un test, porque esto indica directamente la habilidad del facultativo o el investigador para interpretar la puntuación total como un reflejo de los ítems del test.[40] En el desarrollo de un test debe existir una correlación moderada entre sus ítems. Si los ítems fueron elegidos sin tener en cuenta la homogeneidad, el test resultante podría llegar a tocar una serie de características o atributos diferentes. Si las correlaciones son demasiado altas habría mucha redundancia y una posible pérdida de validez de contenido.[41] Asimismo, mediante el "test de Pearson", las correlaciones inter-elementos, o de cada ítem con todos los demás, puede ser calculada.[41] Cuando los resultados obtenidos del test muestran que todos los coeficientes son de signo positivo o de relación directa, se deduce que miden a los constructos o atributos en una misma dirección, lo que confirma que la forma de redacción es correcta (validez aparente y de contenido). Además, la mayoría de las correlaciones pueden ser altamente significativas pero ninguna de ellas de tal intensidad que se pueda afirmar la existencia de redundancia entre los contenidos de los ítems.[41]

El otro método para probar la homogeneidad de un test es la "correlación ítem-total". En el análisis de la correlación entre cada ítem y la puntuación total del cuestionario todos los ítems presentarán índices de homogeneidad satisfactorios si al comprobar su efecto sobre la fiabilidad

del test completo se prueba que de proceder a la eliminación de un ítem especifico, no se produce una mejora sustancial de la fiabilidad del resto del test.[42] En este caso se deberá mantener junto al resto de ítems para la versión final del cuestionario. La regla de oro es que siempre un ítem debe correlacionarse con la puntuación total por encima de 0.20. Los ítems con correlaciones menores deben ser descartados.[42] En la mayoría de los casos el coeficiente más usado para calcular esta correlación es el test de Pearson.[41]

3.2.6. Validez de un test

Retomando la validez de un test (determinar si es posible extraer conclusiones precisas de la presencia y el grado del atributo para un individuo),[43] en esta sección se examinará como determinar si se pueden inferir conclusiones validas de un test.

3.2.6.1. Validez de criterio

La "validez de criterio" es el grado de eficacia con que se puede predecir o pronosticar una variable de interés (criterio) a partir de las puntuaciones en un test. Así pues, la validez de criterio es la correlación de un test con alguna otra medida del rasgo o trastorno en estudio, donde lo ideal sería un "gold standard" que se ha utilizado y aceptado en el campo del test que se está validando.[43] A mayor correlación, mayor capacidad predictiva del test. La evaluación de la validez está prácticamente restringida a responder a la pregunta de si las puntuaciones en un test concuerdan con el desempeño de una tarea que pretende predecir.[43] La validez de criterio se subdivide en dos tipos: "validez concurrente" y "validez predictiva". Con la validez concurrente se relaciona la nueva escala con la medida de criterio. Ambos son aplicados al mismo tiempo, es decir, el test y el criterio se miden simultánea o concurrentemente. A mayor correlación entre el test y el criterio, mayor capacidad predictiva del test. En la validez predictiva el criterio se mide pasado un periodo de tiempo tras la aplicación del test; los resultados de la medida del criterio

generalmente no se conocen durante algún tiempo, que puede ser de entre unos pocos días a unos años más tarde.[44]

3.2.6.2. Validez de constructo

La "validez de constructo" según Cronbach y Meehl,[45] consiste en un análisis de la significación de las puntuaciones de los instrumentos de medida expresada en términos de los conceptos psicológicos asumidos en su medición. La validación de un test abarca todas las cuestiones experimentales, estadísticas y filosóficas por medio de las cuales se evalúan las hipótesis y teorías científicas.[46] Entre los procedimientos o técnicas estadísticas utilizados para el contraste de la validez de constructo destaca en mayor medida el "análisis factorial" (en psicometría puede evaluar la validez de un instrumento o test estableciendo si el cuestionario mide exactamente los factores postulados).[46] Además, la validez de constructo puede dividirse en: validez convergente, validez discriminante y validez de rasgo o característica, entre otros.[44]

3.2.6.2.1. Análisis factorial

El análisis factorial de un cuestionario o instrumento de medición ayuda a establecer la validez de constructo de lo que estamos midiendo. En definitiva, el análisis factorial pretende hallar un nuevo conjunto de variables, en menor número que las variables originales, que exprese lo que es común a dichas variables.[46] Conceptualmente, el análisis factorial presenta dos tipos o modalidades diferentes: análisis factorial exploratorio y análisis factorial confirmatorio. Las diferencias entre ambos son numerosas, tanto desde una perspectiva teórica como matemática. La diferencia más importante está referida a que un análisis factorial confirmatorio se conduce principalmente por teorías sustantivas y por expectativas, mientras que un análisis factorial exploratorio implica principalmente una técnica que, basada en los datos, intenta descubrir la estructura subyacente que éstos poseen.[47] En general, podemos establecer que ambos tipos de

procedimientos se corresponden con las dos grandes aproximaciones que solemos llevar a cabo para la definición de los constructos: la aproximación inductiva o exploratoria y la deductiva o confirmatoria. La aproximación inductiva o exploratoria supone delimitar un número amplio de indicadores que miden el constructo. Seguidamente estos indicadores son analizados mediante el análisis factorial exploratorio para buscar patrones de relación entre los ítems y, finalmente, a posteriori, se pone nombre a dichos patrones de relación (dimensiones del test), definiendo de esta forma el constructo.[47]

El procedimiento que sucede al análisis factorial implica extraer automáticamente los factores estadísticamente, y, entonces, rotar la solución inicial para obtener la estructura factorial más simple desde el punto de vista de su interpretación más significativa, siguiendo los criterios de parsimonia establecidos por Thurstone.[48] Los cuales consisten en la aplicación de la técnica del análisis factorial para agrupar un número elevado de variables que se correlacionan fuertemente entre sí respecto a otros subconjuntos. Esto permite explicar un fenómeno complejo de manera más parsimoniosa.[48]

Para llevar a cabo un análisis factorial se deben seguir los siguientes pasos: el cálculo de una matriz capaz de expresar la variabilidad conjunta de todas las variables, la extracción del número óptimo de factores, la rotación de la solución para facilitar su interpretación y la estimación de las puntuaciones de los sujetos en las nuevas dimensiones.[33]

I. Paso: cálculo de la matriz:

Siguiendo el proceso previamente indicado, la primera fase sería el cálculo de una matriz capaz de expresar la variabilidad conjunta de todas las variables (para evaluar si el modelo factorial o la extracción de los factores en su conjunto es significativo).[49,50] Para analizar el modelo factorial se puede emplear el test KMO (Kaiser, Meyer y Olkin) que contrasta si las correlaciones parciales entre las variables son pequeñas.[49,50]

El test KMO toma valores entre 0 y 1. Cuanto más cerca de 1 se sitúe el valor obtenido del KMO, mayor será la relación entre las variables. De esta manera, si KMO ≥ 0.9, el test es excelente; para KMO ≥ 0.8, el test es notable; para KMO ≥ 0.7, el test es mediano; para KMO ≥ 0.6, es bajo; y muy bajo para KMO < 0.5. Por tanto, un valor de KMO < 0.5 no resultaría aceptable para efectuar un análisis factorial. Así, si se da que $0.5 <$ KMO < 0.6, el grado de correlación es medio, y habría una aceptación media; mientras que si KMO > 0.7, existiría una elevada correlación y, por tanto, sería oportuno realizar un análisis factorial.[49,50]

Con la prueba de esfericidad de Bartlett se evalúa la aplicabilidad del análisis factorial de las variables estudiadas. El modelo es significativo (lo que conlleva la aceptación de la hipótesis nula, H_0) cuando se puede completar el análisis factorial (es decir, si el *p* valor de la prueba de esfericidad de Bartlett es < 0.05). En caso contrario ($p > 0.05$) se rechazaría la H_0 y no podría aplicarse el análisis factorial.[49,50]

II. Paso: extracción de los factores:

Una vez determinado si es posible realizar el análisis factorial, el siguiente paso es extraer la estructura factorial o matriz de componentes (que contiene las correlaciones entre las variables originales o saturaciones y cada uno de los factores). El método más recomendado suele ser el del "análisis de componentes principales."[51]

El análisis de componentes principales se recomienda cuando las variables (o ítems) son unas veinte o incluso menos (como en el test diseñado en el presente estudio), siempre que se disponga de una estructura factorial clara.[51] Se considera que existe una estructura factorial clara cuando los ítems que definen un factor (o dimensión) tienen un peso de 0.50 o más en dicho factor y menor en los demás.[51] El método de componentes principales tiene como objetivo transformar un conjunto de variables originales en un nuevo conjunto de variables (sin perder información). En definitiva se trata de una combinación lineal de las variables originales, denominadas componentes

principales (o factores). El análisis de componentes principales trata de hallar estos componentes o factores, los cuales se caracterizan por estar inter-correlacionadas entre sí, de modo que expliquen sucesivamente la mayor parte de la varianza total. En el análisis de componentes principales, el primer factor o componente sería aquel que explica una mayor parte de la varianza total, el segundo factor sería aquel que explica la mayor parte de la varianza restante, es decir, la que no explicaba el primero y así sucesivamente.[52]

III. Paso: rotación de la solución:

Anteriormente se expuso que en el análisis de componentes principales se definen un nuevo conjunto de variables, combinación lineal de las originales, denominadas componentes (o factores). Mediante esta definición, y su formalismo matricial, estos componentes se pueden considerar como unos nuevos ejes que representan la nube de puntos que forman las variables originales. Así, la proyección de la nube de puntos sobre los componentes sirve para interpretar la relación entre las diferentes variables. Sin embargo, su explicación, a veces, puede llegar a ser muy compleja, por lo que se puede recurrir a la rotación de los componentes (ejes). Existen varias formas de rotar los ejes: Varimax, Quartimax, rotaciones oblicuas, Equamax, Promax, etc.[49,50] La más empleada es la rotación Varimax, la cual consigue que cada componente rotado presente correlaciones únicamente con unas cuantas variables.[49,50] Esta rotación es la más frecuentemente utilizada, y es adecuada cuando el número de componentes es reducido (como ocurre en el test diseñado en el presente estudio).[49-51]

Como procedimiento de extracción de los factores, el método Varimax, es un tipo de rotación ortogonal, es decir, que se mantiene la condición de perpendicularidad entre cada uno de los ejes rotados.[49,50] Con el análisis factorial y la rotación ortogonal se pretende simplificar la matriz para hacerla más fácilmente interpretable. Lo que suele suceder con este tipo de rotación es que los ítems o variables ejercen una carga o peso mucho mayor en un factor y mucho menor en todos los demás. La definición de la estructura es más simple y se descifra con más facilidad (lo

que se busca es una estructura simple).[51] En la construcción de escalas factoriales con subconstructos bien diferenciados y replicables con más probabilidad en otras muestras, suele recomendarse la rotación Varimax, que fue la utilizada en el presente proyecto.[51]

IV. Paso: estimación e interpretación de las puntuaciones:

Una vez estimados los factores comunes, es importante calcular las puntuaciones de los sujetos (individuos u objetos) investigados para saber cuánto puntúan en cada factor.[33,51] De este modo podremos: *(a)* Sustituir los valores de las variables originales para cada sujeto de la muestra por las puntuaciones factoriales obtenidas. En la medida en que el número de factores es menor que el número de variables iniciales, si el porcentaje de explicación de la varianza total fuese elevado, dichas puntuaciones factoriales podrían sustituir a las variables originales en muchos problemas de análisis o predicción. Además, muchas técnicas estadísticas se ven seriamente afectadas por la correlación entre las variables originales. En la medida en que las puntuaciones factoriales estén inter-correlacionadas podrán utilizarse en ulteriores análisis. *(b)* Colocar a cada sujeto en una determinada posición en el espacio factorial y conocer qué sujetos son los más raros o extremos (efecto de la puntuación del test en las variables del estudio), dónde se ubican ciertos grupos de la muestra (los más jóvenes frente a los mayores, los de clase alta frente a los de clase media o baja, los creyentes frente a los no creyentes, etc.), obteniendo en qué factores sobresalen unos y otros.[33,51]

Por último, la interpretación de los resultados del análisis factorial, se basa en el análisis de las correlaciones entre las variables y los factores que viene dado por las cargas factoriales.[33,51] Para que dicha interpretación sea factible, es recomendable que se cumplan las siguientes afirmaciones: *(a)* Las cargas factoriales de un factor con las variables estarán cerca de 0 ó de 1. Así, las variables con cargas próximas a 1 se explican en gran parte por el factor, mientras que las que tengan cargas próximas a 0 no se explican por el factor. *(b)* Una variable debe tener cargas factoriales elevadas con un solo factor. Es deseable que la mayor parte de la variabilidad de una

variable sea explicada por un factor único. *(c)* No debe haber factores con similares cargas factoriales.[33,51]

Dichos pasos anteriormente expuestos, pueden llevarse a cabo con el programa estadístico de análisis factorial del SPSS (Statistical Package for the Social Sciences / IBM Software v.20 - SPSS/PC+, Inc.; Chicago, IL, USA).[33]

3.2.6.2.2. Validez convergente

Retomando los demás subtipos de validez de constructo tenemos la validez convergente, que evalúa hasta qué punto el nuevo test se relaciona con otras variables y otras medidas del mismo constructo.[53] Existe validez convergente cuando las mediciones del mismo rasgo realizadas con distintos métodos son correlativas. El hecho de que un mismo rasgo sea detectado por igual con varias metodologías diferentes es un indicador fiable de la existencia real de ese rasgo.[53] La correlación debe ser alta, pero no demasiado alta, si se quiere que el nuevo test cubra los componentes del rasgo (o constructo) que no han sido cubiertos por los ya existentes.[53]

Cuando las puntuaciones de los tests que se están contrastando no se correlacionan, entonces el problema puede ser del nuevo test. Por otro lado, una correlación muy elevada revela que los tests están midiendo lo mismo y que el nuevo cuestionario no es más que una medida diferente del mismo constructo.[53]

3.2.6.2.3. Validez discriminante

Para terminar con el proceso de validación, la validez discriminante se refiere al grado de diferenciación entre distintos constructos a partir de un único sistema de medición.[54] Es decir, las medidas de distintos rasgos por el mismo método muestran una baja correlación en comparación con la que ofrecen las medidas del mismo rasgo con diferentes métodos, señal de que

los rasgos son independientes entre sí e independientes al sistema de medición empleado.[54] La validez discriminante ha sido utilizada para distinguir entre individuos o grupos clínicamente diferentes[54] Este tipo de validez está determinada no sólo por el atributo que se está midiendo, sino también por los aspectos del propio proceso de medición; lo que incluye el método por el cual se realiza el cálculo de la puntuación del test.[54] De esta manera utilizando tanto el método de conteo simple como el de ponderación, un test podría discriminar entre grupos clínicamente distintos involucrados en un estudio.[25]

4. JUSTIFICACIÓN

4. JUSTIFICACIÓN

En Odontología, generalmente, la información sobre la salud de los pacientes se obtiene a partir de la anamnesis, el examen físico y las pruebas de laboratorio. La anamnesis no contempla preguntas estandarizadas sobre aspectos cotidianos, físicos, sociales, personales, del bienestar mental o la percepción de salud por parte de los pacientes. Por ello, la información que se obtiene rara vez proporciona datos útiles para establecer conclusiones sobre la calidad de vida relacionada con la salud bucal.

Para obtener un cuadro más completo del paciente (con datos cuantificables y útiles para establecer el diagnóstico, elegir el tratamiento y evaluar su éxito), es conveniente complementar la información clínica (historia clínica y pruebas de laboratorio) con datos obtenidos de cuestionarios psicométricos que midan la calidad de vida relacionada con la salud bucal. El contraste que en ocasiones se obtiene entre las puntuaciones de estos cuestionarios y los datos biológicos objetivables del examen clínico puede sugerir la presencia de más de un trastorno o el fracaso de los tratamientos empleados.

El manejo de cuestionarios de OHRQoL en la práctica clínica odontológica puede facilitar la identificación precoz de los pacientes con síntomas no físicos, por ejemplo "cuando la disfunción psicosocial precede a la disfunción física". Las medidas de OHRQoL ofrecen al clínico información sobre cómo funcionan las diferentes formas de terapia odontológica (en el caso que nos compete, las implantoprótesis). Cuando una investigación rigurosa a través de estos cuestionarios muestra que la calidad de vida de los pacientes sometidos a un determinado tratamiento mejora, los clínicos pueden extrapolar cautelosamente los resultados para informar a sus pacientes de que dicha terapia es efectiva y viable.

La evaluación funcional que proporcionan las mediciones psicosociales, de calidad de vida y salud bucal, puede revelar alteraciones físicas, mentales o emocionales, que pasarían inadvertidas con la evaluación clínica.

El método utilizado actualmente para evaluar la calidad de vida relacionada con la salud bucal tiene las siguientes limitaciones:

1. Mientras que algunos cuestionarios se centran en los efectos adversos de OHRQoL, se requieren métodos adicionales para capturar dimensiones positivas de la salud. Esto es particularmente importante para el seguimiento de la mejora entre las personas que inicialmente carecen de síntomas adversos.

2. Los estudios anteriores se han centrado en factores limitados asociados con OHRQoL. Existe una necesidad de identificar determinantes adicionales de OHRQoL, incluyendo elementos psicológicos, variables sociales y los que describen la organización del sistema de salud.

3. Existen escasos estudios de cuestionarios o test específicos de OHRQoL sobre el impacto de tratamientos odontológicos en la calidad de vida. Se necesita investigación adicional para evaluar el tratamiento de la enfermedad existente, su prevención, y mejora de la salud. Además, se precisan más estudios sobre las últimas técnicas tales como los implantes y los tipos de prótesis asociadas a estos, para evaluar su efecto en la medición de OHRQoL.

4. La falta de consideración de los resultados obtenidos en los estudios de calidad de vida sobre las decisiones clínicas no permite integrar sistemáticamente datos de OHRQoL con otros resultados clínicos relevantes de los pacientes.

Por lo tanto, la atención en salud deberá tener por objetivo aumentar la capacidad funcional y el bienestar de las personas, integrando los datos registrados a partir de las mediciones de OHRQoL en las historias clínicas de los pacientes.

La investigación actual está comenzando a ofrecer resultados que correlacionan el estado funcional y el bienestar general con el funcionamiento psicológico.

Los creadores de instrumentos para medir OHRQoL continúan perfeccionando y estandarizando las puntuaciones, así como también entregando nuevas medidas de salud que relacionan los resultados y los procesos; es decir, la prevención, el diagnóstico, el tratamiento y la rehabilitación.

Existen diferentes cuestionarios que evalúan la calidad de vida relacionada con la salud bucal, tales como: Impacto social de la enfermedad dental (SIDD); Índice geriátrico de evaluación de la salud oral (GOHAI); Perfil de impacto de salud oral (OHIP); Impacto dental en la vida diaria (DIDL); Calidad de vida relacionada con la salud oral (OHRQoL); Impactos orales en la vida diaria (OIDP), entre otros.[3] Algunos de ellos resultan muy extensos. Únicamente dos están validados en España (OHIP–14 y OHIP–20). Sin embargo, ninguno de estos índices es específico para pacientes portadores de implantoprótesis.

En base a lo expuesto, en esta Tesis nos propusimos diseñar y validar un cuestionario específico, corto, eficaz y fácil de puntuar que contemple tanto los efectos positivos como los negativos de la OHRQoL en pacientes portadores de implantoprótesis en España. El uso de este cuestionario ayudará al clínico a identificar qué tipo de tratamiento prostodóntico sobre implantes es el más adecuado y satisfactorio para cada paciente dependiendo de sus características.

Para terminar, el cuestionario diseñado permitirá estimar el impacto social y funcional de las implantoprótesis en la calidad de vida. De este modo, los hallazgos registrados se traducirán en medidas clínicas objetivas para evaluar la efectividad de estos tratamientos en la mejora de la calidad de los servicios de salud bucal, y, por consiguiente, de la calidad de vida de los pacientes.

5. OBJETIVOS

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- Recabar información sobre: *(a)* manejo y aplicación de cuestionarios de OHRQoL y *(b)* ítems y dimensiones relevantes de dichos índices en el caso de usuarios de implantoprótesis.

- Diseñar un cuestionario corto, específico y eficaz que permita a los clínicos evaluar la calidad de vida asociada al estado de salud oral en portadores de implantoprótesis.

- Validar el cuestionario diseñado en diferentes tipos de implantoprótesis: sobredentaduras, prótesis hibridas y prótesis atornilladas sobre implantes.

- Evaluar el efecto modulador de variables como factores sociodemográficos, aspectos clínicos y características de las restauraciones sobre el nivel de autopercepción de bienestar de pacientes rehabilitados con prótesis implantológicas.

6. METODOLOGÍA

VALIDACIÓN DE UN CUESTIONARIO DE CALIDAD DE VIDA ASOCIADA AL ESTADO DE SALUD ORAL EN USUARIOS DE IMPLANTOPRÓTESIS

6. METODOLOGÍA

6.1. ARTÍCULO I: Arelis Preciado, Jaime Del Río, María-Jesús Suárez-García, Javier Montero, Christopher D. Lynch, Raquel Castillo- Oyagüe. **Differences in impact of patient and prosthetic characteristics on oral health-related quality of life among implant-retained overdenture wearers**. Journal of Dentistry 2012; 40: 857–65.

(Diferencias en cuanto al impacto que ejercen las características de los pacientes y sus prótesis sobre la calidad de vida relacionada con la salud oral en portadores de sobredentaduras implanto-retenidas).

TRADUCCIÓN DEL RESUMEN

Objetivos: *Evaluar la calidad de vida relacionada con la salud oral (OHRQoL) de usuarios de sobredentaduras implanto-retenidas.* ***Métodos:*** *63 pacientes entre 50 y 90 años, tratados con al menos una sobredentadura implanto-retenida en la Universidad Complutense de Madrid en el periodo 2000 a 2010 fueron incluidos en el estudio. 42 pacientes respondieron el cuestionario Perfil de Impacto de Salud Oral (OHIP–14sp). Para calcular la puntuación del OHIP se empleó el método aditivo. Los datos registrados fueron: sociodemográficos, características de la sobredentadura y factores clínicos. Los datos sociodemográficos y los relacionados con la sobredentadura de los pacientes perdidos (n = 21) se obtuvieron de las historias clínicas. Se aplicó estadística descriptiva, test de Kruskal-Wallis, test de Mann-Whitney y el coeficiente de correlación de Spearman ($p \leq 0.05$).* ***Resultados:*** *El perfil predominante de los participantes fue ser mujer entre 71- 80 años; con una sobredentadura mandibular retenida por una barra y con una prótesis completa en el maxilar superior. El 71,4 % de los encuestados habían sufrido algún tipo de*

impacto en su OHRQoL con una puntuación media de 2,7 ± 3,0 (rango: 0-13). El 100 % de los participantes no reportaron impacto en las dimensiones "discapacidad social" y "minusvalía". Las dimensiones más afectadas fueron "dolor físico" seguido de "limitaciones funcionales" y "malestar psicológico". Las variables: ubicación de la sobredentadura y sistema de retención afectaron las subescalas del OHIP con p ≤ 0.05. El mayor impacto en la OHRQoL, se registró en los participantes con una dentadura completa como prótesis antagonista (p < 0,01). ***Conclusiones:*** *Las sobredentaduras implanto-retenidas proporcionan una calidad de vida aparentemente aceptable en la población anciana estudiada, independientemente de la influencia de la ubicación, el sistema de retención y el tipo de prótesis antagonista.*

Importancia clínica: *Aunque se requieren más investigaciones, las sobredentaduras implanto-retenidas mandibulares se muestran más cómodas que las maxilares. Las prótesis retenidas por bolas fueron las que más facilitaban la masticación, mientras que la presencia de úlceras orales y/o candidiasis sólo se detectó en los casos de retención con barras, lo que disminuyó la calidad de vida. Una dentadura completa como prótesis antagonista reduce la satisfacción general del paciente.*

Title: Differences in impact of patient and prosthetic characteristics on oral health-related quality of life among implant-retained overdenture wearers.

Short title: OHRQoL in overdenture wearers.

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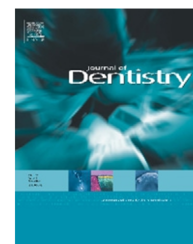

Differences in impact of patient and prosthetic characteristics on oral health-related quality of life among implant-retained overdenture wearers

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ABSTRACT

Objectives: To evaluate the oral health-related quality of life (OHRQoL) of implant-retained overdenture users.

Methods: 63 patients aged 50–90 years treated with at least one implant overdenture at the Complutense University (Madrid) in 2000–2010 were included. Of those, 42 answered the Oral Health Impact Profile (OHIP-14sp) questionnaire. The additive method was used in the OHIP analysis. Data regarding sociodemographic background, overdenture features, and clinical factors were recorded. Sociodemographic and overdenture-related variables for the lost patients ($n = 21$) were also gathered from their history files. Descriptive probes, Mann–Whitney and Kruskal–Wallis tests, and the Spearman correlation coefficient were applied ($p \leq 0.05$).

Results: The predominant participants' profile was that of a 71–80-year-old woman wearing a mandibular overdenture with a bar retention system and a complete denture in the opposite jaw. 71.4% of the respondents suffered from some kind of impact on OHRQoL, showing an average score of 2.7 ± 3.0 (range: 0–13). 100% of respondents reported no impact for the "social disability" and "handicap" dimensions. The most prevalently affected domain was "physical pain", followed by "functional limitation" and "psychological discomfort". Variables such as the overdenture location or the retention system affected specific OHIP subscales ($p \leq 0.05$). The greatest total score was achieved when the antagonist was a complete denture ($p < 0.01$).

Conclusions: Implant-retained overdentures provide a seemingly acceptable quality of life in the elderly population studied, irrespective of the influence of the location, retention system, and antagonist.

Clinical significance: Although further research is necessary, mandibular implant overdentures are more comfortable than maxillary ones. Ball-retained prostheses facilitate eating the most, whereas the presence of oral ulcers and/or candidiasis was only detected in the case of bars, thus impairing OHRQoL. A complete denture as antagonist decreases the patient overall satisfaction.

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1. Introduction

Oral health-related quality of life (OHRQoL) is a complex and multidimensional concept that focuses on the extent to which the well-being of individuals and society as a whole is affected by oral problems. Many variables influence the OHRQoL, including the patients' age, existing pathologies, dental diseases, tooth loss, prosthesis wear,[1] as well as socio-demographic, cultural, educational, psychological, dietary, and financial factors.[2] Even though most researchers agree in describing oral health in terms of both clinical and subjective aspects,[3] constructing a generally accepted definition of OHRQoL has proven elusive to date.

Despite recent advances in preventive dentistry, the burden of dental disease remains high in the elderly. Hence, it is likely that large numbers of older adults will continue to lose their natural teeth, mainly due to the population growth rates, together with the extended life expectancy.[4] Implant overdentures are economical and easy to fabricate osseointegrated prostheses that provide a significant improvement in stability, retention, bite force, chewing efficiency, and oral health compared to conventional dentures.[5] However, it remains unclear whether implant-retained rehabilitations restore the oral function perfectly taking into account the patients' subjectivity when they express their feelings.[4] This question can be answered only by using a valid and reliable subjective measurement scale of oral impacts[6] on a number of levels.[4]

During the last three decades, different questionnaires have been designed in an attempt to reflect the impact of oral diseases on the daily activities of dental patients. A recent European project[6] recommended focusing on three major OHRQoL indicators: (a) the Oral Health Quality of Life of United Kingdom (OHQoL-UK)[7]; (b) the Oral Impacts on Daily Performances (OIDP)[6] and (c) the Oral Health Impact Profile (OHIP-14), which is a shortened version of the OHIP-49 containing just 14 selected items to make it more practical to administer in the clinical setting.[8] The OIDP and OHIP-14 scales are the most widely used. Both instruments are based on Locker's conceptual model[9] and have verified satisfactory psychometric properties (reliability and validity) in a variety of cultural contexts, including Spain.[10,11] The OHIP has previously been used in clinical trials and cross-sectional studies to assess the effectiveness of treatments for edentulism,[12,13] resulting in better performance[14] and a 53% higher prevalence of impacts than the OIDP,[11] thus showing higher sensitivity in detecting dissatisfaction after prosthetic treatments.

This investigation is the first to assess the oral health-related quality of life of Spanish patients treated with implant-retained overdentures. The information achieved may be useful in predicting the level of satisfaction of patients from Spain and other countries treated with this type of rehabilitation, on the basis of the sociodemographic, cultural, and clinical features of the participants.

Therefore, the aim of this paper is to evaluate the differences in impact on oral health-related quality of life among elderly implant overdenture wearers, using the Oral Health Impact Profile (OHIP-14) instrument.

2. Materials and methods

2.1. *Study protocol*

The reference population was 133 patients aged 50–90 years treated with at least one implant-retained overdenture at the Department of Buccofacial Prostheses of the Complutense University of Madrid between 2000 and 2010. The exclusion criteria were: cognitive impairment, implant loss, motility disorders, and serious illness or death. 63 patients were included in the study and asked by telephone about changes in their aesthetic appearance and chewing ability (better, worse, or equal) since they began using the implant-retained overdenture. Patients were also invited for an interview and clinical examination free of charge. The 42 final volunteers were scheduled for appointments the next week. The study was conducted following the ethical principles of medical investigation involving human subjects under the Helsinki Declaration of the World Medical Association (http://www.wma.net) and the Spanish Law 14/2007 of July 3rd for Biomedical Research (http://www.boe.es). All of the participants were briefed about the purpose and process of the study. The Ethics Committee Approval (C.E.I.C., San Carlos University Hospital, Madrid; C.P. – C.I. 12/241-E) and the patients' approved written consent were obtained. Confidentiality was maintained.

The diagnosis of oral health conditions was performed by a single researcher through direct visual inspection. The study variables were grouped as follows: Group 1: sociodemographic variables (gender, age, marital status, and level of education); Group 2: variables related to the implant-retained overdenture (location, retention system, number of implants, and type of opposite prosthetic treatment); and Group 3: clinical variables (presence of oral candidiasis, ulcers, and need of dental treatment, which could involve medical management and control of oral lesions and/or repairing or changing the overdenture).[15] The sociodemographic (Group 1) and overdenture-related (Group 2) data of the lost patients were also gathered from their dental history files.

The OHIP-14sp (Spanish validated version of the OHIP-14 questionnaire)[10] was applied to investigate the oral health-related quality of life of the participants. Aided by a trained interviewer, the subjects filled out the OHIP-14sp, answering in terms of frequency the appearance of 14 situations of impact conceptually divided into seven domains or dimensions, *i.e.*, "functional limitation", "pain", "psychological discomfort", "physical disability", "psychological disability", "social disability", and "handicap". Frequency was codified using a Likert scale with 5 options.[8] The following were considered impact responses: "hardly ever" (score 1), "occasionally" (score 2), "fairly often" (score 3) and "very often" (score 4); whereas the "never" response (score 0) implied the absence of impact. The OHIP-14 outcome variable ranges from 0 to 56 such that the higher the total score was, the higher level of impact on oral well-being and quality of life was and, therefore, the lower the satisfaction of the patient was.

2.2. Data analysis

All data analyses were made by using the Statistical Package for the Social Sciences (software v.17.0) (SPSS/PC+, Inc.; Chicago, IL, USA) taking the cut-off level for statistical significance at $\alpha = 0.05$.[5,11]

The additive method (OHIP-ADD) was used in OHIP analysis by summing the item codes for the 14 questions of the test at whatever frequency.[16,17] Scores per dimension were also obtained.

Descriptive statistics were calculated for all of the sociodemographic, prosthetic, and clinical variables.[10,11] To investigate the possible selection bias, the Student *t*-test was used to compare the sociodemographic and prosthetic quantitative variables among participants and non-participants, and the Chi-Square test was applied to compare the frequency distributions concerning the aesthetic and functional improvements among the followed and lost patients.

As the Kolmogorov–Smirnov test confirmed that the OHIP-14sp outcome did not follow a normal distribution and because some groups involved relatively small cell sizes, non-parametric tests (Mann–Whitney for variables with two categories and Kruskal–Wallis for variables with three or more categories) were used to evaluate the impact scores of the participants depending on the study variables.[6]

3. Results

3.1. Analysis of sociodemographic, prosthetic, and clinical variables

91 (68.5%) patients were excluded from the reference population ($n = 133$), because of cognitive impairment ($n = 7$), implant loss ($n = 9$ patients), death ($n = 16$) or because they could not be contacted due to changes in their phone number and/or address details ($n = 38$ patients). A total of 21 patients refused to answer the questionnaire due to time constraints ($n = 21$; rejection rate = 15.8%) (Fig. 1). The study sample comprised 42 individuals. The most relevant statistical outcomes are shown in Tables 1–3.

Regarding the sociodemographic variables (Group 1), the study sample was drawn mainly from women (54.8%), with a predominant age range of 71–80 years (47.6%), married (78.6%), and with a secondary-level education (50%). Moreover, 81% of the lost patients were females, with a predominant age range of 61–70 years (52.4%) (Table 1).

Concerning the overdenture-related variables (Group 2), 69.9% of the participants wore mandibular overdentures, 92.9% of which were retained by two implants. 71.4% of the total prostheses had a bar retention system. 54.8% of the study patients and 100% of the lost subjects had complete dentures as antagonists. The location of the overdenture resulted in significant differences ($p = 0.01$) such that all of the lost patients had mandibular overdentures, whereas the study patients wore it in the mandible (69.9%), in the maxilla (7.1%), or in both (23.8%) (Table 1). The type of retention system (bars, balls, or locators) yielded no significant differences between the followed and lost patients (Table 1).

As regards the clinical variables (Group 3), oral candidiasis and ulcers were found in 14.3% and 7.1% of the cases, respectively. 42.9% of patients needed some type of dental treatment, such as medical management (14.3%), filling the prosthesis and/or changing the retention system (16.7%), or even making a new overdenture (11.9%) (Table 1).

Besides, whereas all overdenture wearers recognized aesthetic improvements, 61.9% of the participants and 90.5% of the lost patients noticed positive changes in their chewing ability with the use of the implant-retained prosthesis, with significant differences occurring between the two groups ($p = 0.04$).

3.2. Analysis of the OHIP-14sp scores

No questionnaires had to be eliminated from this study since all of the items were properly filled out in each case. 71.4% of the respondents suffered from some kind of impact on their quality of life. The mean total OHIP-14sp score was 2.7 ± 3.0 points (Table 2), ranging from 0 (no impact) to 13 points.

100% of the participants reported the response "no impact" or "never" in questions 11–14 (Table 2, Fig. 2). This led to the "social disability" and "handicap" domains resulting in no impact on oral health. The dimensions showing impact on oral health sorted in descending order of OHIP scores were: "physical pain" (impact = 1.2 ± 1.6), "functional limitation" (impact = 0.5 ± 1.2), "psychological discomfort" (impact = 0.5 ± 0.9), "psychological disability" (impact = 0.3 ± 0.7), and "physical disability" (impact = 0.2 ± 0.5) (Table 2).

The following study variables registered the highest impact on quality of life:

Group 1: age range of 50–60 years (impact = 4.7 ± 2.9), single (impact = 3.5 ± 2.1) or divorced (impact = 3.5 ± 5.9), and illiterate patients (impact = 3.2 ± 2.5) (Table 3). Age was negatively correlated with the total score of OHIP-14sp ($r = -0.34$) and with the score of the "psychological discomfort" dimension ($r = -0.36$). The level of education was also negatively correlated with the total score of OHIP-14sp ($r = -0.11$), and with the score of the "functional limitation" dimension ($r = -0.33$). However, these correlations were not significant.

Group 2: maxillary overdenture (impact = 4.1 ± 3.8), locator retention system (impact = 4.0 ± 2.9), and a complete denture as the antagonist (impact = 3.6 ± 3.1) (Table 3). The score of the "physical pain" dimension was significantly higher in patients who wore the overdenture in the maxilla ($p = 0.04$) (Table 2).

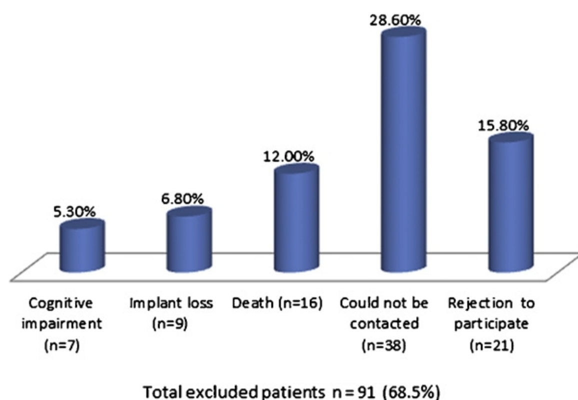

Fig. 1 – Distribution of patients excluded from the study.

Table 1 – Patient features.

Patients' features	*p*-Values	Patients followed (*N* = 42)		Patients lost (*N* = 21)	
		Frequency (*n*)	Percentage (%)	Frequency (*n*)	Percentage (%)
Group 1: social–demographic variables					
Gender					
Men	0.04	19	45.2	4	19.0
Women		23	54.8	17	81.0
Age group					
50–60	0.5	4	9.5	0	0.00
61–70		13	31.0	11	52.4
71–80		20	47.6	6	28.6
81–90		5	11.9	4	19.0
Marital status					
Married	NS	33	78.6	Not registered	Not registered
Single		2	4.8	Not registered	Not registered
Divorced		2	4.8	Not registered	Not registered
Widower		5	11.9	Not registered	Not registered
Level of education					
Illiterate	NS	4	9.5	Not registered	Not registered
Basic education		8	19.0	Not registered	Not registered
Secondary education		21	50.0	Not registered	Not registered
University education		8	19.0	Not registered	Not registered
Teaching special regime		1	2.4	Not registered	Not registered
Group 2: variables related to the implant-retained overdenture					
Location					
Maxillary	*0.01	3	7.1	0	0.0
Mandible		29	69.9	21	100
Bimaxillary		10	23.8	0	0.0
Superior retention system					
Bars	NS	11	26.2	0	0.0
Balls		2	4.8	0	0.0
Total		13	31.0	0	0.0
Lower retention system					
Bars	NS	30	71.4	Not registered	Not registered
Balls		2	4.8	Not registered	Not registered
Locator		7	16.7	Not registered	Not registered
Total		39	92.9	Not registered	Not registered
Number of implants					
Two lower	NS	39	92.9	21	100
Total		39	92.9	21	100
Four upper		13	31.0	0	0.0
Total		13	31.0	0	0.0
Opposite prosthetic treatment					
Complete denture	NS	23	54.8	21	100
Implant-retained overdenture		10	23.8	0	0.0
Removable partial denture		5	11.9	0	0.0
Fixed partial denture		4	9.5	0	0.0
Group 3: clinical variables					
Presence of oral candidiasis					
Yes	NS	6	14.3	Not registered	Not registered
No		36	85.7	Not registered	Not registered
Presence of oral ulcers					
Yes	NS	3	7.1	Not registered	Not registered
No		39	92.9	Not registered	Not registered
Need of dental treatment					
Yes	NS	18	42.9		
No		24	57.1	Not registered	Not registered
Type of dental treatment required					
Medical management	NS	6	14.3	Not registered	Not registered
Repairing the overdenture		7	16.7	Not registered	Not registered
Changing the overdenture		5	11.9	Not registered	Not registered
Total		18	42.9	Not registered	Not registered

* Significant differences between the study and lost to follow-up patients.
$p > 0.05$ indicates the absence of statistically significant outcomes among the participants and lost patients.
NS, no sense.

Table 2 – Response distribution of the OHIP-14. N (%) of respondents per question within the study sample (N = 42).

Question		Dimensions: N (%) of respondents					OHIP-14sp scores	
	Possible responses	Never	Hardly ever	Occasionally	Fairly often	Very often	Mean	(SD)
	Response code	0	1	2	3	4		
Functional limitation								
Q1	Trouble pronouncing words	41 (97.6)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.4)	0.5	1.2
Q2	Worse taste	33 (78.6)	5 (11.9)	1 (2.4)	2 (4.8)	1 (2.4)		
Physical pain (higher score for maxillary overdentures: *p = 0.04)								
Q3	Sore spots	25 (59.5)	12 (28.6)	2 (4.8)	2 (4.8)	1 (2.4)	1.2	1.6
Q4	Discomfort (with dentures)	27 (64.3)	9 (21.4)	5 (11.9)	0 (0.0)	1 (2.4)		
Psychological discomfort								
Q5	Worried	32 (76.2)	8 (19.0)	1 (2.4)	0 (0.0)	1 (2.4)	0.5	0.9
Q6	Tense	39 (92.9)	0 (0.0)	3 (7.1)	0 (0.0)	0 (0.0)		
Physical disability (higher score for bar-retained overdentures: *p = 0.05)								
Q7	Unsatisfactory diet	41 (97.6)	1 (2.4)	0 (0.0)	0 (0.0)	0 (0.0)	0.2	0.5
Q8	Interrupted meals	35 (83.3)	6 (14.3)	1 (2.4)	0 (0.0)	0 (0.0)		
Psychological disability								
Q9	Interrupted sleep	35 (83.3)	6 (14.3)	0 (0.0)	1 (2.4)	0 (0.0)	0.3	0.7
Q10	Been embarrassed	38 (90.5)	4 (9.5)	0 (0.0)	0 (0.0)	0 (0.0)		
Social disability								
Q11	Irritable with others	42 (100)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0.0	0.0
Q12	Having difficulty doing jobs	42 (100)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Handicap								
Q13	Unsatisfying life	42 (100)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0.0	0.0
Q14	Unable to function	42 (100)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)		
Total OHIP-14sp score							2.7	3.0

The score of the "physical disability" domain was significantly higher for bar overdentures compared to those retained by ball attachments ($p = 0.05$) (Table 2). Significant differences ($p < 0.01$) were found depending on the type of opposite prosthetic treatment, so that opposing complete dentures resulted in the greatest impact on quality of life (Table 3).

Group 3: patients requiring reparation of the overdenture (impact = 5.3 ± 4.3), having oral ulcers (impact = 4.7 ± 3.5), and/or candidiasis (impact = 3.2 ± 3.1). The presence of oral ulcers and/or candidiasis was identified only in the case of bar-retained prostheses, showing significant differences in the total OHIP-14sp scores ($p = 0.03$ and $p = 0.01$, respectively, for ulcers and candidiasis) (Table 3). Although no significant differences were recorded, patients needing repair of the overdenture showed a trend of attaining higher scores on the "physical pain" dimension than those who did not require any treatment (impact = 1.0 ± 0.7 *vs.* 0.6 ± 0.8).

4. Discussion

This cross-sectional study is an exploratory approach to provide the individuals' perspective on the outcome of oral disorders and to presume the possible effect of implant

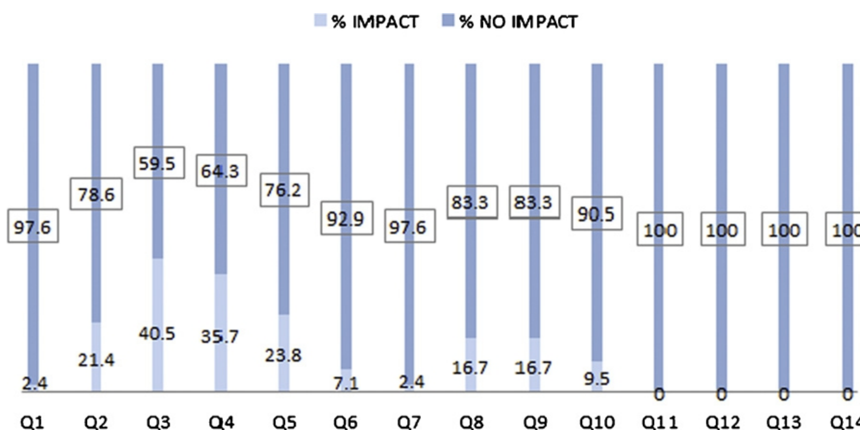

Fig. 2 – Impact percentages recorded for each question of the OHIP-14sp scale. The 14 questions of the questionnaire are grouped in the following dimensions or domains: Q1 and Q2: "functional limitation"; Q3 and Q4: "physical pain"; Q5 and Q6: "psychological discomfort"; Q7 and Q8: "physical disability"; Q9 and Q10: "psychological disability"; Q11 and Q12: "social disability"; Q13 and Q14: "handicap".

Table 3 – Oral health-related quality of life (OHRQoL): crossing variables.

Group of study variables	p-Values	Patients followed ($N = 42$)	
		Mean OHIP-14sp score	Standard deviation
Group 1: social–demographic variables			
Gender			
Men ($n = 19$)	0.5	3.05	3.42
Women ($n = 23$)		2.35	2.62
Age group			
50–60 ($n = 4$)	0.5	4.75	2.87
61–70 ($n = 13$)		3.54	3.80
71–80 ($n = 20$)		2.05	2.48
81–90 ($n = 5$)		1.20	1.30
Marital status			
Married ($n = 33$)	0.8	2.67	3.15
Single ($n = 2$)		3.50	2.12
Divorced ($n = 2$)		3.50	5.95
Widower ($n = 5$)		2.00	2.00
Level of education			
Illiterate ($n = 4$)	0.5	3.25	2.50
Basic education ($n = 8$)		2.87	3.36
Secondary education ($n = 21$)		2.43	3.36
University education ($n = 8$)		3.00	2.33
Teaching special regime ($n = 1$)		1.00	1.37
Group 2: variables related to the implant-retained overdenture			
Location			
Maxillary ($n = 3$)	0.2	4.10	3.81
Mandible ($n = 29$)		2.21	2.60
Bimaxillary ($n = 10$)		2.33	3.21
Superior retention system			
Bars ($n = 11$)	0.8	3.91	3.88
Balls ($n = 2$)		2.50	2.12
Lower retention system			
Bars ($n = 30$)	0.1	2.53	3.07
Balls ($n = 2$)		0.50	0.71
Locator ($n = 7$)		4.00	2.89
Number of implants			
Two lower ($n = 39$)	NS	3.69	3.64
Four upper ($n = 13$)		2.69	3.02
Opposite prosthetic treatment			
Complete denture ($n = 23$)	*0.01	3.63	3.13
Implant-retained overdenture ($n = 10$)		1.87	2.69
Removable partial denture ($n = 5$)		1.80	0.45
Fixed partial denture ($n = 4$)		1.17	0.98
Group 3: clinical variables			
Presence of oral candidiasis			
Yes ($n = 6$)	*0.03	3.17	3.13
No ($n = 36$)		2.58	3.01
Presence of oral ulcers			
Yes ($n = 3$)	*0.01	4.67	3.51
No ($n = 39$)		2.51	2.95
Need of dental treatment			
Yes ($n = 18$)	0.2	3.50	3.50
No ($n = 24$)		2.04	2.44
Type of dental treatment required			
Medical management ($n = 6$)	0.2	3.17	3.13
Repairing the implant overdenture ($n = 7$)		5.29	4.31
Changing the implant overdenture ($n = 5$)		1.40	0.89

* Significant differences in the total OHIP-14sp score depending on the study variable.
$p > 0.05$ indicates the absence of statistically significant differences.
NS, no sense.

overdentures in terms of the well-being of future patients. Even though specific questionnaires have been developed for removable denture bearers,[18,19] a generic health status scale was selected to facilitate the comparison of the results. The indicator of satisfaction utilized (OHIP-14sp) has been demonstrated to be a precise, consistent, and valid instrument for assessing OHRQoL among adults in Spain, thus confirming its psychometric capacity.[10]

One limitation of the research protocol is that the patients were recruited only from a university dental clinic. However, given the variability in the social class, level of education, age, gender, and other features of the volunteers (Table 1), our results might be extrapolated to patients from other countries having comparable sociodemographic and clinical profiles.

The sample size was small but similar to the cohorts of other studies with related aims and methods.[12,20] In this investigation the drop-outs were also analysed according to some potentially modulating factors of the OHRQoL (both sociodemographic and prosthetic variables) to exclude a possible selection bias. Most of the lost patients were elderly females who reported a remarkable improvement in their chewing ability after wearing their mandibular overdentures when they were contacted by phone. This concurs with the predominant gender of the participants and the low impact scores recorded by mandibular overdenture bearers (Tables 1 and 3). Furthermore, as chewing ability is one of the determinants of denture satisfaction best associated with OHRQoL,[21] comparable levels of impact might be expected if all of the eligible patients were examined and interviewed using the OHIP-14sp. Conversely, in the event that the lost patients refused to participate because of prosthetic-related problems, drawing conclusions based only on the participants' data could result in an under-estimation of the impact of implant-retained overdentures in the OHRQoL of the reference population.

Some reasons may be postulated to explain the refusal of lost patients to attend the dental clinic to participate in an observational study. First of all, most of the volunteers were retired (71–80 years), whereas the majority of the lost patients were working (61–70 years) (Table 1) and, therefore, had more difficulties scheduling an appointment. In addition, it seems that elderly females were less likely to enrol in the clinical research studies, as reported Covell et al.[22]

Similar to prior research findings,[10,19] most participants (71.4%) underwent some kind of impact. Given that the lower the impact score was, the lower the patient discomfort was, the mean overall impact on OHRQoL, as measured by the OHIP-14sp in the present study (2.7 ± 3.0) (Table 2), was notably lower than that published for a consecutive sample of 270 Spaniards aged 18–65 years (6.3 ± 1.2). Notwithstanding the known advantages of implant overdentures over complete removable prostheses,[5] such differences could be associated with the greater tolerance of pain and disability of mature patients.[7] This may also explain the negative relationship between age and level of impact on this research such that an enhanced quality of life was reported by the elderly (Table 3). Regarding the gender, no significant differences were encountered, although females tended to feel better with their overdentures (Table 3). Some authors stated the independence of this variable on the subjective perception of OHRQoL,[7,17] whereas others have reported opposite results.[3,6,10,12] Hence, the effect and magnitude of this factor should be addressed in future research.

Despite that the response distribution per question (Q) and domain was similar to that described in a previous research carried out in the general adult population of the same country[10] (Table 2, Fig. 2), the mean scores achieved in this study were much lower and situated from ''never'' to ''occasionally'' (Table 2, Fig. 2). Also the total OHIP-14 score was higher in other countries, such as China,[23] among others. This may be due to the fact that our study sample has not comprised a consecutive pool of individuals attending a dental clinic, but implant overdenture wearers who were not seeking any treatment.

The main subscales benefiting from the prosthetic rehabilitation assessed were ''social disability'' (Q11: irritable with others; Q12: having difficulty doing jobs) and ''handicap'' (Q13: unsatisfying life; Q14: unable to function), which unanimously received the response ''never'' (Table 2, Fig. 2). This indicates a positive perception for both domains, consistent with the trend observed by Slade et al.[24] when they used the original version of the questionnaire (OHIP-49) in a comparable population. An increased social confidence was also reported by Hyland et al.[25] for patients wearing implant-retained overdentures with respect to those bearing complete removable prostheses.

On the contrary, the mean overall satisfaction was affected by ''physical pain'' (Q3: sore spots; Q4: discomfort with dentures), ''functional limitation'' (Q1: trouble pronouncing words; Q2: worse taste), and ''psychological discomfort'' (Q5: worried; Q6: tense) (Table 2, Fig. 2). This was frequently observed in patients wearing conventional full opposite dentures, which significantly impaired OHRQoL (Table 3). Some studies have reported instability of the maxillary denture in antagonist implant-retained prostheses.[26]

Maxillary overdentures seem to be the least comfortable, thus providing significantly higher impact than mandibular overdentures concerning the ''physical pain'' subscale (Q3: sore spots; Q4: discomfort with dentures) (Table 2). This could be attributed to differences in the prosthesis design and/or in the characteristics of the support tissues. However, such result requires further validation, as, to date, no studies using the OHIP scale have been published on the effect of the overdenture location on OHRQoL.

The ''physical disability'' domain (Q7: unsatisfactory diet; Q8: interrupted meals) attained significantly lower impact scores in the case of ball-retained overdentures, which therefore seemed to facilitate eating the most (Table 2). MacEntee et al.[27] reported comparable levels of satisfaction with either ball or bar attachments, whereas Mumcu et al.[28] recorded the lowest OHIP-14 scores for mandibular implant-retained overdentures with bar attachments. In this investigation, the presence of oral ulcers and/or candidiasis was detected only in bar overdenture wearers, resulting in significantly higher levels of impact on quality of life, and thus, in lower satisfaction (Table 3). This finding had not been reported before. Karabuda et al.[29] claimed that one of the main complications of bar-retained overdentures was the difficulty of cleaning the periabutment zone due to the narrow space between the bar and the mucosa. This may somewhat explain the higher frequency of oral ulcers and candidiasis in patients with bars in our study.

Patients who required repair of their prostheses tended to express less satisfaction (Table 3), especially concerning the ''physical pain'' domain (Q3: sore spots; Q4: discomfort). Similar results have been reported for conventional dentures.[19] Nonetheless, Zani et al.[30] concluded that the technical requirements of implant overdentures did not necessarily influence satisfaction in terms of rehabilitation.

Both the aesthetic appearance and chewing ability improved in most patients wearing implant overdentures (100% and 71.3%, respectively; $n = 63$). Such results coincided with those of Ellis et al.,[31] who described a comparable enhancement in the chewing function (74.9%) in patients rehabilitated with two implant-retained mandibular overdentures. Harder et al.[32] found improvements in both OHRQoL and chewing ability in single implant-supported mandibular overdenture wearers. However, the denture base was frequently fractured in the midline area.[32] Consistent with recent research,[33] an extended review of the literature stated that the two-implant overdenture (which was the most common in the present investigation, as shown in Table 1) is the minimum standard of implant therapy that should be sufficient for most people, considering performance, patient satisfaction, cost and clinical time.[34]

The findings of this study should be interpreted with some caution and require further confirmation with a larger sample. The Oral Health Impact Profile has supplied sufficient evidence to demonstrate that implant-retained overdentures provide better OHRQoL than do complete removable prostheses.[19,20,35–37] However, the factors involved in this improvement still remain to be ascertained. Thus, apart from clinical and technical considerations, implant-based prosthetic treatments should be always investigated in terms of OHRQoL and level of patient satisfaction.

Further research should be conducted concerning possible differences in quality of life and patient satisfaction comparing different loading protocols in rehabilitations with implant-retained overdentures. In this regard, mandibular bone height does not seem to influence patients' satisfaction with the function, chewing ability and comfort of their prostheses.[38] Nevertheless, other factors such as bone density and quality, implant shape, design and surface characteristics and surgical technique[39] should be taken into consideration.

5. Conclusions

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

1. Implant-retained overdentures provide a proper OHRQoL in edentate elderly population.
2. The overall patient satisfaction as regards OHRQoL is enhanced by having an opposite fixed dentition.
3. Mandibular implant overdentures are rated as more comfortable than maxillary ones.
4. Ball-retained prostheses facilitate eating the most. Moreover, the presence of oral ulcers and/or candidiasis was only detected in bar-retained overdenture wearers, resulting in lower patient satisfaction.

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6.2. ARTÍCULO II: Arelis Preciado, Jaime Del Río, Christopher D. Lynch, Raquel Castillo-Oyagüe. **A new, short, specific questionnaire (QoLIP-10) for evaluating the oral health-related quality of life of implant-retained overdenture and hybrid prosthesis wearers** Journal of Dentistry 2013; 41 (9): 753 – 63.

(Un cuestionario nuevo, corto y específico (QoLIP–10) para la evaluación de la calidad de vida relacionada con la salud oral de usuarios de sobredentaduras implanto-retenidas y de prótesis híbridas sobre implantes).

TRADUCCIÓN DEL RESUMEN

Objetivos: *Este estudio tuvo como objetivo validar un nuevo cuestionario para evaluar la calidad de vida relacionada con la salud oral (OHRQoL) en portadores de implantoprótesis.* ***Métodos:*** *Un grupo de especialistas diseñó un test de 10 ítems, llamado "Calidad de vida con Implanto-prótesis" (QoLIP-10). Se realizó un estudio piloto. En la investigación principal participaron 150 pacientes que no solicitaban tratamiento dental, y portaban una implantoprótesis o una dentadura completa. Se crearon tres grupos (n = 50 cada uno) en función del tipo de restauración dental; así: Grupo 1 (DC): portadores de dentadura completa (control); Grupo 2 (SD): portadores de sobredentadura implanto- retenidas, y Grupo 3 (PH): sujetos con prótesis híbridas. Los participantes respondieron los cuestionarios QoLIP-10 y el Perfil de Impacto de Salud Oral (OHIP-20sp). Se recogieron datos: sociodemográficos, comportamientos en salud, clínicos y relacionados con la prótesis (además información sobre la satisfacción oral global). Las propiedades psicométricas del QoLIP-10 fueron investigadas. El test de correlación de Spearman se utilizó para determinar la asociación entre las puntuaciones totales del QoLIP-10 y el OHIP-20sp. Estadística descriptiva y test no paramétricos se llevaron a cabo para evaluar el impacto de los valores obtenidos, en función de las variables del estudio.* ***Resultados:*** *El análisis factorial confirmó la existencia de tres dimensiones e inter-correlaciones significativas entre los 10 ítems, por lo tanto, el cuestionario QoLIP-10 demostró ser confiable y válido. Los portadores de HP manifestaron una mejor calidad de vida biopsicosocial, como se indicó en sus respuestas al ítem 1 (dolor bucal) e ítem 3 (dificultad para masticar).*

Conclusiones: *El test QoLIP-10 confirmó su capacidad psicométrica para evaluar la OHRQoL de portadores de sobredentadura implanto-retenida y de prótesis híbrida. En general, los participantes se mostraron satisfechos con la boca y las implanto-prótesis.*

Importancia clínica: *El QoLIP-10 se puede recomendar para determinar la influencia de sobredentaduras implanto-retenidas y prótesis híbridas en el bienestar de futuros pacientes. Las prótesis híbridas son la opción de tratamiento más predecible para mejorar la satisfacción del paciente en términos de dolor bucal y función masticatoria en comparación con las sobredentaduras implanto-retenidas y las dentaduras completas.*

Title: A new, short, specific questionnaire (QoLIP-10) for evaluating the oral health-related quality of life of implant-retained overdenture and hybrid prosthesis wearers.

Short title: New questionnaire on OHRQoL for implant-prosthesis wearers.

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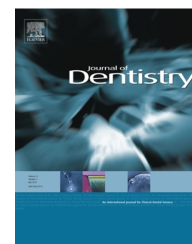

A new, short, specific questionnaire (QoLIP-10) for evaluating the oral health-related quality of life of implant-retained overdenture and hybrid prosthesis wearers

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ABSTRACT

Objectives: This study aimed to validate a new questionnaire for assessing the oral health-related quality of life (OHRQoL) of implant-prosthesis wearers. *Methods*: A group of specialists designed the 10-item scale: 'Quality of Life with Implant-Prostheses' (QoLIP-10). After completing a pilot trial, 150 subjects wearing implant-prostheses or complete dentures who were not requesting dental treatment participated in the main investigation. They were divided into three groups ($n = 50$ each) depending on the type of dental restoration. Group 1 (CD): complete denture wearers (control); Group 2 (IO): implant-retained overdenture wearers and Group 3 (HP): subjects with fixed implant hybrid prostheses. Participants answered the QoLIP-10 and the Oral Health Impact Profile (OHIP-20sp) questionnaires. Information on global oral satisfaction, socio-demographic, health-behavioural, clinical and prosthetic-related data were gathered. The psychometric characteristics of the QoLIP-10 were investigated. The Spearman's rank correlation test was used to determine the association between the total scores of the QoLIP-10 and OHIP-20sp. Descriptive and non-parametric probes were run to evaluate the impact scores obtained depending on the study variables. *Results*: The QoLIP-10 scale is reliable and valid. The factor analysis confirmed the existence of three dimensions and meaningful inter-correlations among the 10 items. HP wearers demonstrated better biopsychosocial QoL, as indicated by their answers to Item 1 (oral pain) and Item 3 (chewing difficulty). *Conclusions*: The QoLIP-10 index confirmed its psychometric capacity for assessing the OHRQoL of implant overdenture and hybrid prosthesis wearers. Overall, the participants were satisfied with their mouth and implant-restorations. *Clinical significance*: The QoLIP-10 may be recommended for determining the influence of implant-retained overdentures and hybrid prostheses on the well-being of future patients. Hybrid prostheses are the most predictable treatment option for improving patient satisfaction in terms of oral pain and chewing functionality when compared to implant overdentures and complete dentures.

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1. Introduction

Several questionnaires employing a variety of methodological approaches have been designed in the last few decades to assess the personal outcomes of oral disorders.[1,2] Among others, the Oral Health Impact Profile (OHIP),[3] Oral Health Quality of Life (United Kingdom)[4] and Oral Impacts on Daily Performances health scales[5] are the most often used in longitudinal and cross-sectional studies.[6,7]

Fixed implant prostheses are similar to natural dentition in terms of functionality and quality of life and any generic index could be used to assess their effect on OHRQoL. However, implant overdentures and fixed implant hybrid prostheses substantially differ in their shape, construction principles and biomechanics, which may impinge the patients' well-being to some extent, requiring specific indicators of quality of life (QoL). The more precise the questionnaire is, the more reliable the comparison of the results will be, bearing in mind that the real effectiveness of the implant prostheses in recovering oral function, aesthetics and social life will depend on the supporting tissues, the design of the prosthesis, the connection system and the patients' subjectivity.[8,9]

Implant overdentures offer significantly improved stability, retention, bite force, chewing efficiency and oral health compared to conventional complete dentures.[10] However, their removability may be considered disadvantageous by some patients. Conversely, fixed implant hybrid prostheses (also called fixed-detachable prostheses) consist of a metallic CAD/CAM framework covered with complete denture components (heatpolymerized resin and denture teeth), which is screwed onto the implants or the abutments. This supplies functional and psychological advantages, as hybrid prostheses are fixed for the patients.[11] Nevertheless, mucositis, periimplantitis and fracture of the acrylic may occur.[12]

This study is the first to compare the OHRQoL of patients rehabilitated with implant overdentures and hybrid prostheses using a customized measure for both types of rehabilitations. A control group of individuals with complete dentures allowed estimation of the benefits of using implants for supporting such removable (implant overdentures) and semi-removable (hybrid) acrylic restorations. The information acquired may be helpful in predicting the satisfaction of patients in Spain and in other countries on the basis of the sample variability.

Furthermore, given the lack of specific scales for measuring the impact of implant restorations on daily life, the aim of this paper is to develop and validate a specific, short and effective questionnaire for assessing the OHRQoL of patients wearing implant overdentures and hybrid prostheses and to analyse the factorial construct of the prosthetic well-being.

2. Materials and methods

2.1. *Development of the Quality of Life with Implant-Prostheses (QoLIP-10) questionnaire*

After an extensive review of the existing literature,[5,13–15] a team of three specialists in prosthodontics and an oral and maxillofacial surgeon (each with demonstrated research experience in OHRQoL) selected the most relevant domains in OHRQoL for consideration in patients wearing implant overdentures and hybrid prostheses. Thus, the development of the new questionnaire was supported by previously published works and based on existing instruments in the areas of oral functional status, patient satisfaction, oral symptoms, self-image/aesthetics, self-esteem and socialization.[5]

The research group interviewed 43 patients who were rehabilitated at the Faculty of Dentistry of the University of the Complutense University of Madrid (UCM). Participants attended an in-depth, face-to-face interview in order to explore the areas of oral well-being that might be affected by the presence of implant-supported prostheses. After this, the committee of experts decided on a 10-item questionnaire. The dimensions and items of the designed 'Quality of Life with Implant-Prostheses' index, hereafter called QoLIP-10, were the following: *biopsychosocial dimension* (composed of: Item 1: oral pain; Item 3: chewing difficulty; Item 5: worry/concern; Item 6: communication/social relations and Item 7: activities of daily living); *dental–facial aesthetics dimension* (containing: Item 8: satisfaction with the prosthesis' appearance; Item 9: satisfaction with the realism of the prosthesis and Item 10: satisfaction with the smile) and *performance dimension* (consisting of: Item 2: speaking difficulty or restriction and Item 4: oral hygiene difficulty). The questionnaire may be easily adapted to a global scale format to be applied in future evaluations (*i.e.*, patients could be asked: '*Do you think that the following activities or functions have improved, worsened or remained the same after the prosthetic treatment?*').[16]

The 10-item QoLIP-10 indicator was designed to be intuitively self-completed as the items' responses were expressed in a Likert scale with proportional codes for the impact degrees. The items evaluated as <0 were considered as having negative impact, while values of +1 and +2 represented the positive side of each item (absence of negative effect). The possible responses were: strongly disagree (−2), disagree (−1), indecisive, indifferent or neutral (0), agree (+1) and strongly agree (+2). The total score was the sum of the different item scores, so that negative and positive impacts contributed to the total score (*i.e.*, the additive scoring method: ADD).[17] The total score of the QoLIP-10 questionnaire could range from −20 to +20 in such a way that the higher the total score, the higher the satisfaction of the patient (meaning that negative or low positive scores indicate poorer self-perceived quality of life).

Following the recommendations of Streiner and Norman,[16] the face and content validity of the QoLIP-10 scale was empirically checked in a pilot trial conducted on a representative sample of patients ($n = 32$) from the same source population, which constituted about 20% of the main study sample ($n = 167$). Although ten (or even fewer) patients have proven to be sufficient to assess the clarity of instructions, item wording, acceptability of formatting and ease of administration of a questionnaire[18]; given the population variability,[16,18] 32 patients were selected for the pilot trial (*i.e.*, approximately 10 patients per treatment group). Thus, they wore complete dentures ($n = 12$; 37.5%), implant-retained overdentures ($n = 11$; 34.38%) and hybrid prostheses ($n = 9$; 28.12%) and met selection criteria that were similar to those of

the main study.[16] The comprehensiveness of the index was evaluated by asking the volunteers specific questions about possible difficulties in understanding the items in order to make the instrument more comprehensible, which optimized its face and content validity for the main cross-sectional investigation.[16,18]

2.2. *Study protocol*

2.2.1. *Study sample*

The reference population included 167 subjects aged from 40 to 90 years who were treated with at least one conventional complete denture, one implant-retained overdenture, or one hybrid implant-prosthesis at the Department of Buccofacial Prostheses of the Complutense University of Madrid between 1996 and 2011. To standardize the inclusion criteria, patients with complete dentures, implant-retained overdentures fitted over 4 implants in the maxilla and/or over 2–4 implants in the mandible, and fixed implant hybrid prostheses screwed to 4–6 maxillary and/or interforaminally implants defined the reference population. The subjects were invited to take part in the study when they attended the clinic for a routine yearly review between January and March of 2012. The exclusion criteria were: patients rehabilitated with both implant-retained overdenture and fixed implant hybrid prosthesis (to avoid misinterpretation of the findings), implant loss, patients seeking dental treatment, cognitive impairment, motility disorders, and serious illness.[8]

The 150 final volunteers were scheduled for appointments that were to take place in April 2012. The subjects were assigned to the groups (each containing 33.3% of the subjects; $n = 50$ per group), depending on the type of implant-restoration worn by the patient: Group 1 (CD): complete denture wearers (control); Group 2 (IO): subjects with implant-retained overdentures and Group 3 (HP): patients wearing hybrid implant-prostheses.

The study was conducted following the ethical principles of medical investigation involving human subjects under the Helsinki Declaration of the World Medical Association (http://www.wma.net) and the Spanish Law 14/2007 of July 3rd for Biomedical Research (http://www.boe.es). All of the participants were briefed about the purpose and process of the study. The Ethics Committee Approval (C.E.I.C., San Carlos University Hospital, Madrid; C.P. – C.I. 12/241-E) and the patients' approved written consent were obtained. Confidentiality was maintained.

2.2.2. *Data gathering*

Aided by a trained interviewer, the patients completed the QoLIP-10 questionnaire. Participants also completed the 20-item Oral Health Impact Profile (OHIP-20sp) form, which had been previously validated in the Spanish population and has been described in detail elsewhere.[19] Therefore, subjects filled out the OHIP-20sp answering in terms of frequency the appearance of 20 situations of impact conceptually divided into seven domains or dimensions (*i.e.*, *functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability and handicap*). Frequency was codified using a Likert scale with five options.[7,8] The possible impact responses were: 'hardly ever' (score 1), 'occasionally' (score 2), 'fairly often' (score 3) and 'very often' (score 4); whereas the 'never' response (score 0) disclosed the absence of impact. The OHIP-20sp outcome variable ranged from 0 to 80. On this scale, the higher the total score is, the higher level of negative impact on oral well-being and quality of life is and, therefore, the lower the satisfaction of the patient is.

Moreover, the participants were asked about their overall satisfaction with their mouth, which comprised individual evaluations of the satisfaction with their oral aesthetics, functionality and prosthetic treatment.[20] A visual analogue scale (VAS)[21] was used for each area, as these perceptions can be assumed to vary in a continuous range from 0 to 10. Subjects could thereby declare themselves to be 'dissatisfied', 'neutral', or 'satisfied', offering values situated left to the midpoint of a 100-mm long line, on the midpoint, or to the right of the midpoint, respectively.[21]

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

To capture the clinical modulating factors, subjects were examined by a single researcher using the diagnostic methodology published by the World Health Organization.[22]

The study variables were grouped as follows: Group 1: socio-demographic variables (gender, age, marital status and level of education); Group 2: health behavioural variables (daily rate of tooth-brushing and number of dental visits per year); Group 3: clinical variables (presence of oral candidiasis and mucosal lesions); Group 4: variables related to the prosthetic rehabilitation (location, status of the prosthesis,[23–27] type of antagonist and retention system in case of overdentures) and Group 5: self-perceived satisfaction with the mouth (complaints about the mouth and perception of needing dental treatment).

2.3. *Data analysis*

The additive method (-ADD) was used for both the QoLIP-10 and OHIP-20sp analyses by adding the item codes at the appropriate frequency.[8,17] The scores per dimension of the QoLIP-10 were obtained in a similar fashion.

Descriptive statistics[7,8,28] and percentages for qualitative and categorical variables were calculated. The main psychometric characteristics of the QoLIP-10 questionnaire were evaluated. As each item measured different aspects of the same attribute, the reliability was assessed by examining the internal consistency of the scales through the use of an inter-item correlation, item-total correlation, Cronbach's α and the α value if an item was deleted.[29,30]

The Kolmogorov–Smirnov test[8] did not assume a normal distribution of the QoLIP-10 outcome variable. Therefore, the criteria validity of the QoLIP-10 indicator (which measures how well the test predicts the QoL based on information obtained from other variables)[19,30] was analysed by contrasting the total scores achieved in each of the QoLIP-10 and OHIP-20sp questionnaires with the VAS punctuations using non-parametric probes (*i.e.*, Kruskal–Wallis test for variables with

three or more categories and Mann–Whitney *U* test for variables with two categories).[6,28]

The construct validity of the QoLIP-10 (or the extent to which the OHRQoL was actually recorded with this questionnaire)[19,30] was investigated using factor analysis (a data reduction technique that allows homogeneous subgroups of variables to be found) and the convergent validity of the scale (which measures how closely the new questionnaire is related to other variables and measures of the same construct to which it should be related).[16]

Regarding factor analysis, the Bartlett's Sphericity and the Kaiser–Meyer–Olkin (KMO) tests, which are measures of sampling adequacy, were run to make evident the underlying factor structure of the QoLIP-10 index.[20] Additionally, the principal components' analysis (PCA) was performed along with the rotation method: the Varimax plus Kaiser normalization was used to extract the underlying dimensions of the prosthetic construct.[31] The items were assigned to the rotated factors when they had a loading of 0.5 or greater in a single factor.

Factors with an eigenvalue of less than one were disregarded to avoid distortion.[20] To establish the degree of convergent validity, the QoLIP-10 total and dimensional scores were correlated to those of the OHIP-20sp questionnaire. The Spearman's rank correlation test[28] was applied to estimate the magnitude of association between these outcome variables.[32]

After evaluating the psychometric properties of the QoLIP-10 questionnaire, the modulating factors of prosthetic well-being were assessed using non-parametric probes. The Kruskal–Wallis and the Mann–Whitney *U* tests[28] were run to evaluate the participants' impact scores depending on the study variables.[8,20] The total scores obtained with the QoLIP-10 and OHIP-20sp questionnaires and the scores per item and dimension registered with the QoLIP-10 were compared among the prosthodontic groups. The possible correlations between the QoLIP-10 and OHIP-20sp total scores and the clinical data recorded for the study variables were also explored using the same non-parametric tests.[20,28]

Data were processed using the Statistical Package for the Social Sciences (software v.20) (SPSS/PC+, Inc.; Chicago, IL, USA) taking the cut-off level for statistical significance at $\alpha = 0.05$.[8,10,28]

3. Results

3.1. Description of the sample

A total of 17 (10.18%) patients were excluded from the reference population ($n = 167$). Among them, three subjects were seeking endodontic treatments, four patients could not be contacted due to changes in their phone number and/or address details and 10 patients refused to participate due to time constraints ($n = 10$; rejection rate = 5.99%). Thus, the study sample was composed of 150 individuals.

From a socio-demographic point of view (Group 1), the main profile of the participants ($p < 0.001$) was a woman (64%), between 61 and 80 years-old, married (79.3%), with a basic education (52.7%). As regards the health behavioural variables (Group 2), 65.3% of the volunteers performed tooth-brushings three times a day while 95.3% of the study subjects did not visit the dentist every year. Within the group of clinical variables (Group 3), 86% of the participants did not suffer from oral candidiasis and 77.3% of them had no mucosal lesions.

Concerning the prosthesis-related variables (Group 4), 71.3% of the prostheses were in good condition, 17.3% required repair and the remaining 11.3% needed to be changed. A conventional complete denture was the most common type of antagonist (52.66%) and the majority of the implant-retained overdentures (88%) had a bar retention system. Assessing the self-perceived satisfaction with the mouth (Group 5), most study patients did not complain (80%) and did not perceive a need for dental treatment (76%) (Table 1).

Regarding the overall oral satisfaction, most volunteers were satisfied with their aesthetics (87.3%), chewing function (84%) and prosthesis (81.3%) (Table 2).

All of the described results proved to be significant at $\alpha = 0.001$. Some contiguous categories of the variables have been grouped together for statistical purposes, thus balancing the groups' sizes (Table 1).

The impact on the OHRQoL was not significantly modulated by social-demographic, health behavioural or clinical variables. However, the QoLIP-10 total score was significantly lower (meaning a lower QoL) in those participants who were required to *change their prosthesis* and who had *locators* ($p < 0.05$). Within the Group 5 of variables, *complaints about the mouth* were found to be a direct modulator (revealing a lower QoL) ($p < 0.001$), whereas the *perception of needing dental treatment* did not significantly affect the patients' satisfaction (Table 1).

3.2. Analysis of the reliability and validity of the QoLIP-10 questionnaire

The reliability (or internal consistency) of the QoLIP-10 instrument was supported by α values of 0.80–0.81 (direct values) and 0.82 (typical values). These results were significant ($p < 0.001$); therefore, the reliability of the index was estimated to be within the interval of 0.76–0.85 with a 95% degree of confidence. An overall distribution of positive inter-item correlations was confirmed and α values were lower or equal when either item was deleted.

The inter-item correlation analysis showed that all of the coefficients were positive (ranging from 0.01 between Items 1 and 8, to 0.96 between Items 9 and 10). This revealed that the concept was measured in the same direction. Although most correlations were significant, none of them was intense enough to confirm the existence of clear redundancy between types of content. All of the items showed satisfactory homogeneity with coefficients ranging from 0.47 to 0.67 except Item 4, which had a lower rate (coefficient = 0.26). Nevertheless, the removal of Item 4 did not cause a substantial improvement in the reliability of the remaining scale, given that the usual rule of thumb is that an item should correlate with the total score above 0.20. Consequently, it was included in the final version of the questionnaire.

As all of the items and their possible responses were presented together in a matrix (which facilitates self-completion by patients), the face validity of the index was considered adequate in the pilot trial. Moreover, the participants declared

Table 1 – Features of the participants (*N* = 150).

Study variables	Descriptive statistics		QoLIP-10 total score: crossing variables	
	% (*n*)	*p*-Value (Chi² test)	Mean (SD)	*p*-Value
Group 1: Social-demographic variables				
Gender				
Men	36.0% (54)	0.00[**]	12.15 (7.61)	0.79 NS[a]
Women	64.0% (96)		12.34 (8.12)	
Age range				
40–50	2.0% (3)	0.00[**]	11.82 (7.28)	0.75 NS[b]
50–60	20.0% (30)			
61–70	36.7% (55)		11.62 (9.24)	
71–80	32.0% (48)		12.79 (7.01)	
81–90	9.3% (14)		14.14 (6.90)	
Marital status				
Married	79.3% (119)	0.00[**]	11.96 (8.26)	0.60 NS[b]
Single	6.0% (9)		13.48 (6.38)	
Divorced	1.4% (2)			
Widower	13.3% (20)			
Level of education				
Illiterate	14.7% (22)	0.00[**]	13.32 (7.80)	0.07 NS[b]
Basic education	52.7% (79)		13.15 (7.67)	
Secondary education	21.3% (32)		11.09 (8.67)	
University education	5.3% (8)		12.00 (7.69)	
Special regime of teaching (*i.e.*, language, art, dance or sport teaching)	6.0% (9)		6.33 (5.85)	
Group 2: Health behavioural variables				
Tooth brushing/daily rate				
None	0.7% (1)	0.00[**]	10.94 (–)	0.86 NS[b]
Once a day	11.3% (17)		10.94 (9.06)	
Twice a day	21.3% (32)		12.38 (7.88)	
Three times	65.3% (98)		12.69 (7.50)	
More than three times	1.3% (2)			
Number of dental visits per year				
None	95.3% (143)	0.00[**]	9.86 (14.19)	0.99 NS[b]
One	1.3% (2)		12.39 (7.54)	
Two	2.7% (4)			
More than two	0.7% (1)		12.41 (–)	
Group 3: Clinical variables				
Presence of oral candidiasis				
Yes	14.0% (21)	0.00[**]	13.76 (9.67)	0.11 NS[a]
No	86.0% (129)		12.03 (7.60)	
Presence of mucosal lesions				
Yes	22.7% (34)	0.00[**]	12.32 (10.48)	0.23 NS[a]
No	77.3% (116)		12.26 (7.04)	
Group 4: Variables related to the prosthetic rehabilitation				
Location				
Maxilla	34.7% (52)	0.19 NS	12.37 (7.61)	0.33 NS[b]
Mandible	26.7% (40)		10.73 (8.86)	
Maxilla and mandible	38.7% (58)		13.26 (7.45)	
Status of the prosthesis				
Good condition (GC)	71.3% (107)	0.00[**]	12.78 (7.09)	0.03[*,b]
Needs being repaired (R)	17.3% (26)		13.42 (7.91)	*QoL:*
Requires to be changed (CH)	11.3% (17)		7.35 (11.07)	CH < GC[*]
				CH < R[*]
Type of antagonist				
Complete denture	52.66% (79)	0.00[**]	11.16 (8.80)	0.74 NS[b]
Implant-supported FDP	17.34% (26)		14.25 (6.70)	
Tooth-supported FDP	6.67% (10)		14.25 (6.70)	
RPD	23.33% (35)		13.55 (5.80)	
Retention system of the overdenture (*n* = 50)				
Bars	88.0% (44)	0.00[**]	12.77 (6.74)	0.03[*,a]
Locators	10.0% (5)		5.20 (8.56)	
Balls	2.0% (1)	Not registered	15 (–)	Not registered
Group 5: Self-perceived satisfaction with the mouth				
Complaints about the mouth				

Table 1 (*Continued*)

Study variables	Descriptive statistics		QoLIP-10 total score: crossing variables	
	% (*n*)	*p*-Value (Chi^2 test)	Mean (SD)	*p*-Value
Yes	20.0% (30)	0.00**	6.73 (9.83)	0.00**,a
No	80.0% (120)		13.66 (6.72)	
Perception of needing dental treatment				
Yes	24.0% (36)	0.00**	10.31 (10.01)	0.14 NS[a]
No	76.0% (114)		12.89 (7.06)	

Lower scores indicate poorer self-perceived quality of life. NS = not significant ($p > 0.05$).
FDP = fixed dental prosthesis; RPD = removable partial denture; QoL = quality of life.
[a] Mann–Whitney *U* test.
[b] Kruskal–Wallis test.
* Significant at $\alpha = 0.05$.
** Significant at $\alpha = 0.001$.

that they understood all of the items. Additionally, the Likert responses had a symmetric format that allowed intuitive understanding because the range was demarcated by the most extreme positive or negative options. The QoLIP-10 also demonstrated satisfactory content validity in the pilot study, as the patients did not mention any situation that was not included in the questionnaire.

Among the psychological variables tested, *complaints about the mouth* (Table 1) and the three *global oral satisfaction* (Table 2) measurements were found to modulate the QoLIP-10 scores in the expected direction ($p < 0.001$). This fact confirmed suitable criterion validity for the created index.

The factor analysis showed average QoLIP-10 scores ranging from 0.48 for Item 1 to 1.77 for Item 8 (Table 3). Therefore, almost every response was situated in the non-impact zone. Items 1, 3 and 5 were located at the points that were closest to the neutral position. Both the communalities extracted and the standard deviations obtained for the principal components' analysis support the conclusion that all items were well-represented in the factorization, making all of them necessary in the final version of the questionnaire.

Results from the Bartlett's Sphericity test ($\chi^2 = 941.54$; 45 gl; $p < 0.0001$) suggested the existence of a high number of inter-significant correlations between items and latent factors (or dimensions) in the QoLIP-10 index. The KMO produced a global value of 0.683. Three components with eigenvalues above 1 emerged from the factor analysis of the QoLIP-10 and were supported by the elbow in the corresponding scree plot of eigenvalues. These three factors explained 70% of the total variance and were named according to the items loading. This factor structure revealed that most items consistently and coherently loaded on a single factor.

Table 3 presents the items with factorial weights greater than 0.5, ordered on three dimensions. The first factor, named

Table 2 – Criterion validity of the QoLIP-10 index: comparison with the VAS results.

Patients' satisfaction ($N = 150$)	% (*n*)	*p*-Value (Chi^2 test)	VAS scores		
			Mean (SD)	QoL scales: crossing variables	
				QoLIP-10	OHIP-20sp
Aesthetic satisfaction					
Satisfied	87.3% (131)	0.00**	13.56 (6.72)	0.00**,b	0.00**,b
Neutral	0.7% (1)		13.00 (–)		
Dissatisfied	12.0% (18)		2.44 (9.20)		
Satisfaction with chewing					
Satisfied	84.0% (126)	0.00**	13.60 (6.78)	0.00**,a	0.00**,a
Neutral	0% (0)		–		
Dissatisfied	16.0% (24)		5.33 (9.80)		
Satisfaction with the prosthesis					
Satisfied	81.3% (122)	0.00**	13.76 (6.50)	0.00**,a	0.00**,a
Neutral	0% (0)		–		
Dissatisfied	18.7% (28)		5.79 (10.14)		

Lower scores indicate poorer self-perceived quality of life. NS = not significant ($p > 0.05$).
VAS = visual analogue scale; QoL = quality of life.
[a] Mann–Whitney *U* test.
[b] Kruskal–Wallis test.
** Significant at $\alpha = 0.001$.

Table 3 – Factor analysis and reliability of the QoLIP-10 questionnaire (N = 150).

Items’ scores			Factor load matrix (factorial weight > 0.5)		
			QoLIP-10 dimensions		
Items	Mean (SD)	Communalities (PCA)	Biopsychosocial	Dental–facial aesthetics	Performance
(1) Oral pain	0.48 (1.76)	0.59	0.68	_	_
(2) Speaking difficulty or restriction	1.07 (1.43)	0.58	_	_	0.64
(3) Chewing difficulty	0.62 (1.70)	0.59	0.73	_	_
(4) Oral hygiene difficulty	1.57 (0.99)	0.70	_	_	0.83
(5) Worry/concern	0.79 (1.68)	0.81	0.83	_	_
(6) Communication/social relations	1.09 (1.48)	0.76	0.87	_	_
(7) Activities of daily living	1.62 (0.85)	0.39	0.50	_	_
(8) Satisfaction with the prosthesis’ appearance	1.77 (0.79)	0.80	_	0.87	_
(9) Satisfaction with the realism of the prosthesis	1.69 (0.95)	0.95	_	0.96	_
(10) Satisfaction with the smile	1.70 (0.90)	0.90	_	0.94	_
Percentage of variance explained	N/A	N/A	28.21%	28.11%	14.28%
Cronbach α value	N/A	N/A	0.80	0.94	0.44
Items per dimension (total = 10 items)			5 items (1, 3, 5, 6,7)	3 items (8, 9, 10)	2 items (2, 4)
Reliability of the QoLIP-10 scale/Cronbach α value = 0.806			*Percentage of total accumulated variance = 70.60%*		

Lower scores indicate poorer self-perceived quality of life. N/A = not applicable; PCA = principal component analysis.

biopsychosocial dimension, was the most explanatory (28.21% of variance). This factor was formed by the combination of Items 1, 3, 5, 6 and 7 (oral pain, chewing difficulty, worry/concern, communication/social relations and activities of daily living, respectively). The second factor, called *dental–facial aesthetics dimension* comprised Items 8, 9 and 10 (satisfaction with the prosthesis’ appearance, satisfaction with the realism of the prosthesis and satisfaction with the smile, respectively). Finally, the third factor, which was designated as *performance dimension*, included Items 2 and 4 (speaking difficulty or restriction and oral hygiene difficulty, respectively).

The QoLIP-10 total and dimensional scores showed significant inverse correlations with those of the OHIP-20sp ($p < 0.001$). Therefore, subjects with higher scores (lower negative impact) in the QoLIP-10 scale and its three dimensions tended to present lower scores, as measured with the OHIP-20sp. As the qualitative interpretation of both tests coincided, the convergent validity of the QoLIP-10 index was confirmed (Table 4: convergent validity).

To finish with the construct validity, the QoLIP-10 questionnaire satisfactorily proved to be reliable and valid because of its psychometric capacity (Table 3). For this reason, the ten items analysed were included in the final version of the index.

3.3. *Analysis of the prosthetic well-being construct*

Concerning the impact of the prosthesis on the OHRQoL, the QoLIP-10 outcome variable and the effect of possible modulating factors were analysed. HP wearers demonstrated the greatest QoL (corresponding to the greatest QoLIP-10 score) in the *biopsychosocial dimension* ($p < 0.05$) as indicated by their answers to Item 1 and Item 3 (oral pain and chewing difficulty, respectively), which attained the highest significant scores in the HP group ($p < 0.001$) (Table 4: impact of the prosthesis on the OHRQoL).

The total scores of the QoLIP-10 and the OHIP-20sp were compared among the three prosthetic groups to evaluate the discriminant validity of the QoLIP-10 index. Although no significant differences were found depending on the prosthesis design, both indexes consistently attributed a better quality of life to HP wearers (Table 4: discriminant validity).

4. Discussion

In this cross-sectional study, a 10-item survey, containing specific measures of OHRQoL and named ‘Quality of Life with Implant-Prostheses’ (QoLIP-10), was developed to determine the perception of oral well-being of current and future patients wearing implant-retained overdentures and hybrid prostheses. Short questionnaires have been rated as more efficiently administered and have received a higher response rate, which makes this instrument beneficial.[3]

The pilot trial confirmed the content and face validity of the QoLIP-10, given that it faithfully matches the perceptions of implant-treated patients that are prevalent in the reference population.[18,32,33] Therefore, the face and content validities were evaluated as satisfactory upon checking that the questions had been understood perfectly by the participants so that no unanswered items and/or lack of relevant content of prosthetic well-being were found.[32]

In the main study, the reliability of the index was supported by high Cronbach’s α values that pointed to a satisfactory internal consistency[30] (Table 3). The bipolar measure configured by the matrix of items’ responses was more complete than those scales limited to evaluating the presence of negative effects[5] in which important data on positive feelings were lost.[32,34] This is essential, as most of the QoLIP-10 items were perceived as positive events in this study (Table 3).

As for the construct validity, the exploratory factor analysis showed the multidimensionality of the QoLIP-10 instrument,

Table 4 – Comparison of self-reported satisfaction among groups; and convergent and discriminant validity of the QoLIP-10 index ($N = 150$).

	Impact of the prosthesis on the OHRQoL			Convergent validity (correlation among OHIP-20sp and QoLIP-10 total scores)	
	Mean (SD)	Difference between means	p-Value	rho	p-Value
QoLIP-10 dimensional scores					
Biopsychosocial					
Group 1: CD (control) ($n = 50$)	3.68 (5.74)	**QoL:**	0.02[*,a]	−0.59	0.00[**]
Group 2: IO ($n = 50$)	3.88 (5.83)	HP > CD[*]			
Group 3: HP ($n = 50$)	6.16 (5.30)	HP > IO[*]			
Dental–facial aesthetics					
Group 1: CD (control) ($n = 50$)	5.26 (2.34)	NS	0.63 NS[a]	−0.19	0.00[**]
Group 2: IO ($n = 50$)	5.52 (1.53)				
Group 3: HP ($n = 50$)	4.74 (3.27)				
Performance					
Group 1: CD (control) ($n = 50$)	2.82 (1.80)	NS	0.84 NS[a]	−0.37	0.00[**]
Group 2: IO ($n = 50$)	2.66 (1.90)				
Group 3: HP ($n = 50$)	2.44 (2.28)				
QoLIP-10 significant-items' scores					
Item 1: Oral pain					
Group 1: CD (control) ($n = 50$)	0.18 (1.84)	**QoL:**	0.00[**,a]	N/A	N/A
Group 2: IO ($n = 50$)	0.18 (1.70)	HP > CD[*]			
Group 3: HP ($n = 50$)	1.02 (1.65)	HP > IO[*]			
Item 3: Chewing difficulty					
Group 1: CD (control) ($n = 50$)	0.50 (1.78)	**QoL:**	0.00[**,a]	N/A	N/A
Group 2: IO ($n = 50$)	0.12 (1.76)	HP > CD[*]			
Group 3: HP ($n = 50$)	1.18 (1.41)	HP > IO[**]			
Discriminant validity					
QoLIP-10 total score					
Group 1: CD (control) ($n = 50$)	11.34 (7.72)	NS	0.14 NS[a]	−0.60	0.00[**]
Group 2: IO ($n = 50$)	12.06 (7.16)				
Group 3: HP ($n = 50$)	13.42 (8.79)				
OHIP-20sp total score					
Group 1: CD (control) ($n = 50$)	6.92 (6.82)	NS	0.06 NS[a]	N/A	N/A
Group 2: IO ($n = 50$)	6.76 (6.01)				
Group 3: HP ($n = 50$)	4.98 (6.73)				

Low scores indicate poor self-perceived quality of life. CD = complete dentures; IO = implant-retained overdentures; HP = implant-retained hybrid prostheses; NS = not significant ($p > 0.05$); N/A = not applicable.
Rho: Spearman's rank correlation coefficient.
[*] Significant at $\alpha = 0.05$.
[**] Significant at $\alpha = 0.001$.
[a] Kruskal–Wallis test.

which has three independent emerging subscales that are clearly differentiated in statistical terms (Table 3). A simple structure was achieved, because each of the items was weighted heavily and exclusively on only one particular dimension, as occurred in previous related research[5,31] (Table 3). The logical convergence between the total scores of the QoLIP-10 and the OHIP-20sp demonstrated that both instruments measured the same constructs[6,16,32] (Table 4: convergent validity). This is relevant, as the OHIP-20sp had recently been validated in the same reference population.[19]

Moreover, the criterion validity of the QoLIP-10 was confirmed because those participants who reported being satisfied with their aesthetics, chewing function and prosthesis obtained significantly higher QoLIP-10 scores and, therefore, had a better QoL (Table 2), which is in agreement with previous investigations.[19,32,35] *Complaints about the mouth* significantly hampered the level of QoL (Table 1). This supports the ability of the created questionnaire to discriminate subjects who were discontent with the major areas of oral-related well-being.[13] Our patients provided more complex feedback than that expressed by a global transition judgement, as they reported positive impacts in some QoLIP-10 domains, negative impacts in others, and no change in yet others.

Concerning the discriminant validity, the fact that the QoLIP-10 did not significantly differentiate among the rehabilitations tested should be attributed not only to the lack of statistical significance, but also to the narrow differences in the mean scores among the prosthetic groups[28] (Table 4). Several authors who used other questionnaires have not detected significant differences in the total scores registered with different types of prosthetic restorations.[13,36,37] Other possible explanation is that the participants did not demand dental care during the study, and, thus, most of them had no

complaints about their mouth and did not perceive a need for dental treatment (Table 1). Nonetheless, the prosthodontic groups were definitely distinguished by both Items 1 and 3 of the *biopsychosocial dimension* (oral pain and chewing difficulty, respectively) (Table 4: impact of the prosthesis on the OHRQoL). This characteristic may allow for an expansion of the clinical applications of the QoLIP-10 scale and facilitate comparisons among different patient populations or dental treatments, given that chewing ability is one of the determinants of denture satisfaction that is best associated with OHRQoL.[26,32] Fixed implant hybrid prostheses showed significantly better biopsychosocial QoL than did implant-retained overdentures and complete dentures regarding the above-mentioned issues (Table 4: impact of the prosthesis on the OHRQoL). Notwithstanding the absence of significant differences, the highest QoL as measured with both the QoLIP-10 and OHIP-20sp scales also corresponded to fixed implant hybrid prostheses (Table 4: discriminant validity), which agrees with previous studies that attributed better stability and facility for eating hard food to fixed implant restorations than to removable ones.[11,26,38] However, disparities among the study protocols make comparisons difficult.

The modulating effect of the study variables on the OHRQoL was also analysed. Significant differences were found when the scores of the QoLIP-10 scale were crossed with variables related to the prosthesis and satisfaction with the mouth (Groups 4 and 5, respectively). As in previous research,[8,9,39] patients who required a *change of their prosthesis* or *complained about their mouth* reported a significantly lower QoL and, therefore, obtained lower QoLIP-10 scores. The retention system was an additional factor affecting patient satisfaction in case of overdentures, as locators supplied a significantly lower QoL than did bars (Table 1). Bars had previously been found to provide higher comfort, stability and ability to chew than other appliances.[32,40]

Other clinically relevant results have been inferred. Even though not all study variables demonstrated significant correlations with the total punctuation of the QoLIP-10 index, several close, non-significant associations were identified. Patients who perceived a need for dental treatment tended to obtain lower scores on the questionnaire.[6,32] However, no significant differences were found in this study (Table 1). It is generally accepted that the technical complications of implant prostheses do not necessarily affect the prosthetic-related satisfaction of patients.[41] Elderly edentate patients who have not received information on how to avoid oral problems seem to feel the need for dental treatment less frequently and report higher levels of QoL. Such results reinforce the requirement of enabling individuals in identifying non-painful signs and symptoms of oral disease or problems related to the prosthesis at an early stage.[42] In this regard, a trend to perceive a greater QoL was associated with more visits to the dentist per year and higher tooth brushing frequencies (Table 1), which emphasizes the importance of practicing healthy habits when patients are prosthetically restored.[6]

Patients tended to express more satisfaction when they wore the tested prosthetic restorations both in the upper and lower jaw. Particularly, mandibular prostheses seemed to supply lower comfort (a lesser QoL) than maxillary ones (Table 1). This could be attributed to differences in the support tissues and resorption patterns of the maxillary and mandibular ridges.

Those subjects who were married and had received a special regime of teaching showed higher dissatisfaction (Table 1). Nevertheless, such results require further validation because, to date, no research has been published on the effect of these variables on patients' self-perceived satisfaction.

Finally, the profile of the subjects reporting the lowest psychological discomfort in this investigation was that of 81- to 90-year-old women with candidiasis and mucosal lesions (Table 1). This may be due to a greater tolerance of pain and to the disability of mature patients,[4,8] which may also explain the inverse relation between age and level of negative impact. Regarding gender, although females tended to feel better with their prosthesis, no significant differences existed (Table 1). Some authors stated the independence of this variable on the subjective perception of QoL,[4,7,8] whereas others have reported opposite findings.[6,13,20,43] In addition, self-perceived discomfort with dentures faded into the background for patients with candidiasis and mucosal lesions, who always suffered from other severe illnesses in the present study and were medicated daily with painkillers. Related findings have been published.[9]

One limitation of the study protocol is that the patients were recruited only from a university dental clinic. However, given the variability in gender, age, marital status, level of education and other features (Table 1), our results might be extrapolated to patients from other countries that have comparable socio-demographic and clinical profiles.[8] The results of this investigation should be interpreted with some caution and require confirmation in other broader settings.

5. Conclusions

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

1. The QoLIP-10 index has suitable psychometric properties for measuring the impact of implant-retained overdentures and hybrid prostheses on oral-related well-being.
2. Fixed implant hybrid prostheses seem to be the most predictable treatment option for improving patient satisfaction in terms of oral pain and chewing when compared to implant overdentures and conventional complete dentures.
3. The status of the prosthesis, the type of retention system (in case of overdentures), the complaints about the mouth and the existence of oral pain and chewing difficulties are the main factors that may influence patient satisfaction.
4. The QoLIP-10 has potential benefits for decision-making in subjects demanding implant therapy. This information will be relevant in order to target resources and to measure the results of the clinical intervention.

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6.3. ARTÍCULO III: Arelis Preciado, Jaime Del Río, Christopher D. Lynch, Raquel Castillo-Oyagüe. **Impact of various screwed implant prostheses on oral health-related quality of life as measured with the QoLIP–10 and OHIP–14 scales: A cross-sectional study.** Journal of Dentistry 2013; 41:1196–207

(Impacto de diversas prótesis atornilladas sobre la calidad de vida relacionada con la salud bucal, medido con los cuestionarios QoLIP–10 y OHIP–14: Estudio transversal)

TRADUCCIÓN DEL RESUMEN

Objetivos: *El objetivo del estudio fue validar el cuestionario "Calidad de vida con Implanto-prótesis" (QoLIP–10) para evaluar la OHRQoL (calidad de vida relacionada con la salud oral) de portadores de restauraciones atornilladas sobre implantes.* ***Métodos:*** *En el estudio participaron 131 pacientes desdentados totales o parciales rehabilitados con una prótesis implanto-retenida atornillada o una prótesis híbrida desmontable que no solicitaban tratamiento dental. Se establecieron tres grupos. Grupo 1 (PH, n = 50): portadores de prótesis híbrida fija-desmontable (control), Grupo 2 (S-DP, n = 43): sujetos con prótesis parciales atornilladas sobre 2-3 implantes y Grupo 3 (S-DC, n = 38): sujetos con dentaduras completas atornilladas sobre 6-8 implantes. El impacto de la OHRQoL se midió con los cuestionarios QoLIP–10 y "Perfil de Impacto de Salud Oral" (OHIP–14sp). Se recogió información sobre la satisfacción oral global, características sociodemográficas, comportamientos de salud y datos relacionados con la prótesis. La fiabilidad y la validez del QoLIP–10 fueron investigadas en pacientes portadores de prótesis atornilladas. El test de correlación de Spearman se aplicó para determinar la asociación entre las puntuaciones totales de ambos cuestionarios. Se utilizaron pruebas estadísticas descriptivas y tests no paramétricos para evaluar el impacto de los resultados obtenidos en función de las variables de estudio.* ***Resultados:*** *El QoLIP–10 mostró capacidades psicométricas adecuadas en sujetos restaurados con prótesis atornilladas. Los cuestionarios empleados mostraron una correlación inversa. Los usuarios de PH referían los peores resultados de calidad de vida con respecto a las dimensiones de estética dento-facial y rendimiento funcional del QoLIP–10, como también, con respecto a la dimensión*

limitación funcional del OHIP–14. El género, el nivel de educación, las quejas sobre la boca, la percepción de necesidad de tratamiento dental y el estado de las prótesis modularon la OHRQoL. ***Conclusiones:*** *Una restauración atornillada convencional sobre implantes proporciona una mayor calidad de vida que una prótesis híbrida desmontable.*

Significación clínica: *el cuestionario QoLIP–10 puede recomendarse para estimar el efecto de varios tipos de prótesis atornilladas sobre implantes en el bienestar de futuros pacientes, lo que puede resultar relevante en la toma de decisiones y en el campo de la investigación. Cuando las comparamos con prótesis híbridas, las prótesis convencionales atornilladas sobre implantes conllevan una mayor mejora de la autopercepción de la estética y funcionalidad por parte de los pacientes.*

Title: 'Impact of various screwed implant prostheses on oral health-related quality of life as measured with the QoLIP–10 and OHIP–14 scales: A cross-sectional study'.

Short title: OHRQoL of screwed implant-supported prosthesis wearers.

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Key words: Quality of Life with Implant-Prostheses (QoLIP–10); Oral Health Impact Profile (OHIP); Oral health-related quality of life (OHRQoL); patient satisfaction; screwed implant-supported denture; fixed-detachable hybrid prosthesis.

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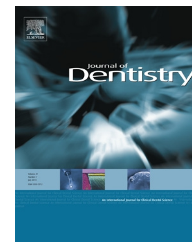

Impact of various screwed implant prostheses on oral health-related quality of life as measured with the QoLIP–10 and OHIP–14 scales: A cross-sectional study

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ABSTRACT

Objectives: This study aimed to validate the Quality of Life with Implant-Prostheses (QoLIP–10) questionnaire for assessing the impact of screwed implant-supported rehabilitations on oral health-related quality of life (OHRQoL).
Methods: 131 patients wearing screw-retained implant restorations were assigned to the following groups: Group 1 (HP; $n = 50$): fixed-detachable hybrid prostheses (control), Group 2 (S-PD; $n = 43$): metal–ceramic screwed partial dentures, and Group 3 (S-CD; $n = 38$): metal–ceramic screwed complete dentures. Impacts on OHRQoL were evaluated using the QoLIP–10 and Oral Health Impact Profile (OHIP–14sp) scales. Data on global oral satisfaction, socio-demographics, health-behaviours, and prosthetics were gathered. Reliability and validity of the QoLIP–10 were investigated for screwed prosthesis wearers. The Spearman's rank test was applied to determine the correlation between both indices. Descriptive and non-parametric probes were run to evaluate the influence of the study variables on OHRQoL.
Results: The QoLIP–10 confirmed its psychometric capacity for screwed prosthesis wearers. Both tests were inversely correlated. HP wearers reported the worst dental–facial aesthetics, performance, and functional limitation outcomes. Gender, education level, complaints about the mouth, perception of treatment needs, and prosthetic status modulated the OHRQoL.
Conclusions: Screwed implants restorations provide better OHRQoL than do fixed-detachable hybrid prostheses.

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1. Introduction

In recent years there has been a growing interest in measuring the effects of oral conditions and therapeutic alternatives on oral health-related quality of life (OHRQoL).[1–4] In the field of Prosthodontics, this vein of research has mainly focused on totally edentate patients restored with implant-retained overdentures and muco-supported complete dentures.[3–6]

Several quality of life (QoL) indicators may be utilised for assessing patient satisfaction.[1,7,8] Nevertheless, customised or 'focal' indices have proven higher reliability than general

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questions.[9] This cross-sectional study is the first to validate a specific scale for screwed implant-supported denture wearers. A control group of subjects with fixed-detachable hybrid prostheses has been used due to their similar screw-based retention system. The index has been adapted upon the recently created QoLIP–10, which demonstrated adequacy for implant-retained overdenture wearers in the same reference population.[10] A generic questionnaire with high sensitivity for detecting dissatisfaction with prosthetic rehabilitations (the short validated version of the Oral Health Impact Profile: OHIP–14sp)[1,11] has also been applied in a retrospective fashion.

Overall, metal–ceramic fixed implant restorations are recommended when no replacement of the support tissues is required and a sufficient number of implants may be distributed along the edentulous arch.[12] In the case of screwed implant-supported prostheses, while screws offer the benefits of providing retention in compromised prosthetic spaces and enabling retrievability, they may negatively affect the aesthetics, implants' axial load, occlusal stability, and resistance of the veneering material around the screw access holes.[12,13] Fixed-detachable hybrid prostheses represent the treatment of choice in the absence of osteomucosal support. They consist of a metallic framework covered with complete denture components (heat-polymerized resin and denture teeth) that is screwed onto premaxillary or interforaminal implants (or abutments) and thus incorporates cantilever extensions.[12,14] Although fixed-detachable hybrid prostheses offer functional and psychological advantages over removable dentures (as they are fixed for the patients),[15] potential problems such as plaque accumulation, mucositis, periimplantitis, and/or fracture of acrylic may affect the OHRQoL.[16]

Even though fixed implant-supported prostheses are in great demand and have resulted in more satisfactory oral function than removable prosthetic treatments,[2,17–19] possible aesthetic deficiencies and/or biomechanical failures may impair patients' satisfaction.[4] Individuals may also feel frustrated when their high (and sometimes unrealistic) expectations are not met. Therefore, the aim of this paper is to analyse the psychometric capacity of the QoLIP–10 questionnaire for assessing the OHRQoL of screwed implant prosthesis wearers and to determine the factorial construct of the well-being associated to this type of implant restoration.

The results of this study may help to predict the satisfaction of candidates for screwed implant therapy worldwide on the basis of the sample variability and type of rehabilitation to be performed. The null hypothesis tested was that the type of screwed implant restoration does not affect the level of patient satisfaction and that the QoL of screwed prosthesis wearers does not depend on socio-demographic, health-behavioural, and/or prosthetic related variables.

2. Materials and methods

2.1. Study protocol

2.1.1. Pilot trial and sampling procedure

Before beginning the main investigation, a pilot trial was conducted on a representative sample of patients ($n = 34$) recruited from the same source population, which numerically represented 23.8% of the main study sample ($n = 143$).

It has been shown that ten patients (or even fewer) are sufficient to evaluate a questionnaire for precision, wording, formatting, and ease of administration.[20] Given the population variability in this study,[20,21] 34 volunteers (*i.e.*, around 10 patients per treatment group) were selected for the pilot trial. The participants met selection criteria that were similar to those of the patients in the main investigation. Thus, they wore fixed-detachable hybrid prostheses (32.4%, $n = 11$), screwed partial dentures supported by two or three implants (38.2%, $n = 13$), and screwed complete dentures supported by six to eight implants (29.4%, $n = 10$).

This trial allowed the researchers to empirically check the face and content validities of the QoLIP–10 scale[10,21,22] in screwed implant prosthesis wearers. The index was evaluated by asking the volunteers about the clarity of the questionnaire; this guaranteed the scale's validity for the main cross-sectional research.[20,21]

The main study was initially composed of 143 subjects over 18 years old, all of whom had been treated with one fixed-detachable hybrid prosthesis, one screwed partial restoration (supported by two or three implants), or one screwed complete denture (supported by six to eight implants), at the Department of Buccofacial Prostheses of the Complutense University of Madrid (Spain). The subjects were invited to take part in the study when they attended the clinic for a yearly routine exam between September and December 2012. Patients who agreed to be interviewed for the study were offered a clinical examination free of charge.

The study included several exclusion criteria. Patients were excluded based on serious illness, motility disorders, cognitive impairment, implant loss, implants received less than 12 months ago, demand for dental treatment, and/or removable antagonists (implant-retained overdentures, muco-supported complete dentures, or removable dental prostheses), to avoid misinterpretation of the findings. Mainly due to the inclusion of a partially dentate group, the presence of an opposing occlusal plane of natural teeth, fixed tooth-supported prostheses or cement-retained implant-supported restorations was required.

The 131 final volunteers were scheduled for appointments in January 2013. The subjects were assigned to the following groups depending on the type of implant restoration worn by the patient: Group 1 (HP; $n = 50$): fixed-detachable hybrid prosthesis wearers (control) (Fig. 1), Group 2 (S-PD; $n = 43$): patients with screwed partial dentures supported by two or three implants (Fig. 2), and Group 3 (S-CD; $n = 38$): participants wearing screwed complete dentures supported by six to eight implants (Fig. 3).

The study was conducted following the ethical principles of medical investigation involving human subjects under the Helsinki Declaration of the World Medical Association (http://www.wma.net) and the Spanish Law 14/2007 of July 3rd for Biomedical Research (http://www.boe.es). All of the participants were briefed about the purpose and process of the study. The Ethics Committee Approval (C.E.I.C., San Carlos University Hospital, Madrid; C.P. – C.I. 12/280-E) and the patients' approved written consent were obtained. Confidentiality was maintained.

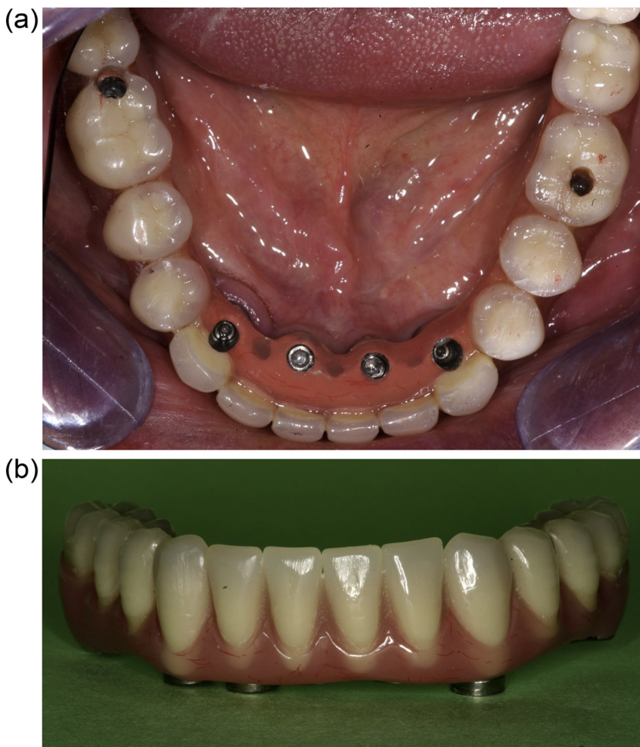

Fig. 1 – Acrylic fixed-detachable hybrid prosthesis fitted onto six implants located in the mandible. Pink acrylic replaces missing hard and soft tissues. (a) Horizontal view. (b) Frontal view.

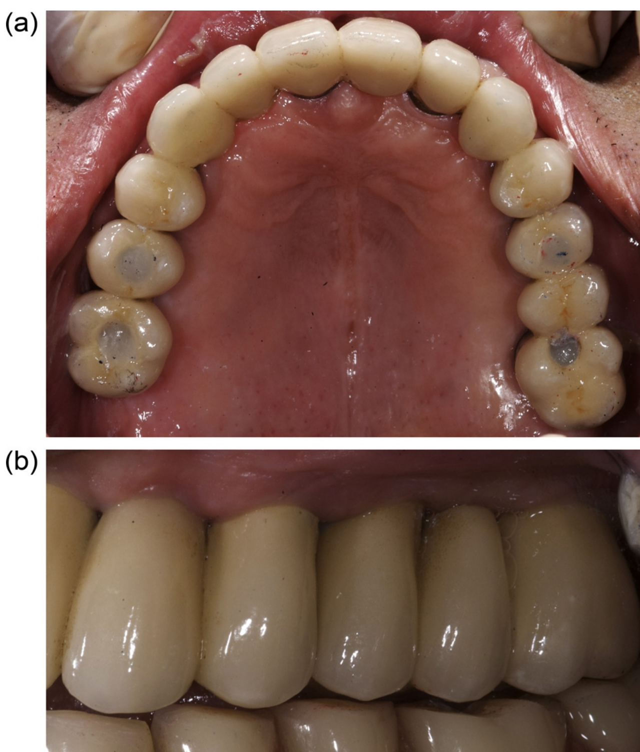

Fig. 2 – Metal-ceramic screwed implant dentures fitted onto two implants located in the maxilla. The screwholes are filled with composite resin. (a) Horizontal view. (b) Lateral view.

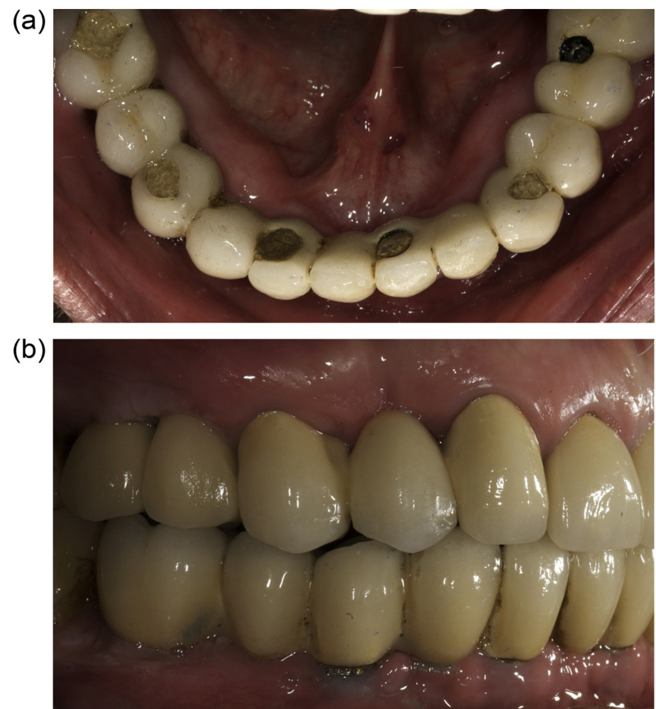

Fig. 3 – Metal-ceramic screwed complete denture fitted onto six implants located in the mandible. The screwholes are filled with temporary cement. (a) Horizontal view. (b) Lateral view.

2.2. Data gathering

Aided by a trained interviewer, the volunteers completed the QoLIP–10 and OHIP–14 forms, which had previously been validated in the source population.[10,11]

The QoLIP–10 scale[10] has recently been developed for evaluating the OHRQoL of implant-retained overdenture wearers. This scale originally included the following dimensions (also called 'sub-scales' or 'domains') and distribution of the items: *biopsychosocial dimension* (composed of: Item 1: oral pain, Item 2: chewing difficulty, Item 3: worry/concern, Item 4: communication/social relations, and Item 5: activities of daily living); *dental–facial aesthetics dimension* (containing: Item 6: satisfaction with the prosthesis' appearance, Item 7: satisfaction with the realism of the prosthesis, and Item 8: satisfaction with the smile); and *performance dimension* (consisting of: Item 9: speaking difficulty or restriction and Item 10: oral hygiene difficulty).[10] As explained later in the Results, an adapted version of the QoLIP–10 for screwed prosthesis wearers was the one used in this study (Appendix A). In such version of the scale, the original Item 2 (chewing difficulty) was moved from the *biopsychosocial domain* to the *performance dimension* as a consequence of the factor analysis. In any case, this 10-item indicator is intuitive; responses are expressed on a Likert scale[23] with proportional codes for the degrees of impact. Items evaluated as <0 are considered to have a negative effect, while values evaluated as +1 and +2 represent the positive side of each item (or at least the absence of a negative effect). The possible responses were: 'strongly disagree' (score -2),

'disagree' (score −1), 'indecisive, indifferent, or neutral' (score 0), 'agree' (score +1), and 'strongly agree' (score +2). The total or summary score was the sum of the different item scores, so that negative and positive impacts contributed to the total net score (*i.e.*, the additive scoring method: ADD).[24] The total score of the QoLIP–10 questionnaire can range from −20 to +20 in such a way that the higher the summary score is, the higher the satisfaction of the patient is (meaning that negative or low positive scores indicate poorer self-perceived quality of life).[10]

Participants also completed the 14-item Oral Health Impact Profile (OHIP–14sp), which has been described in detail elsewhere.[1,11] Subjects filled out the OHIP–14sp answering in terms of frequency the appearance of 14 situations of impact conceptually divided into seven dimensions (*i.e.*, *functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap*). Frequency was codified using a classic Likert scale[23] with five options. The possible impact responses were: 'hardly ever' (score 1), 'occasionally' (score 2), 'fairly often' (score 3), and 'very often' (score 4). The 'never' response (score 0) revealed the absence of impact. The OHIP–14sp outcome variable ranged from 0 to 56. On this scale, the higher the total score is, the higher the level of negative impact on patients' well-being is, so that higher scores imply lower QoL and patient satisfaction.[11]

Participants reported their overall satisfaction with their mouths, including aesthetics, chewing, and prosthetic restorations.[25] A visual analogue scale (VAS)[26] was used for each of the abovementioned areas, evaluating these perceptions in a continuous range from 0 to 10. Subjects could thereby declare themselves to be 'dissatisfied', 'neutral', or 'satisfied', offering values situated left to the midpoint of a 100-mm long line, on the midpoint, or to the right of the midpoint, respectively.[26]

A different investigator conducted each questionnaire. To ensure that the clinic staff had no access to the patients' responses, the completed forms were placed in sealed envelopes. The QoLIP–10, OHIP–14p, and VAS evaluations were then linked by means of a unique identification code for each study patient.[10,25]

To capture the clinical modulating factors, subjects were examined by a single researcher using the diagnostic methodology published by the World Health Organisation (WHO).[27] The study variables were grouped as follows: Group 1: Social-demographic variables (gender, age, marital status, and level of education); Group 2: Health behavioural variables (daily rate of tooth-brushing and number of dental visits per year); and Group 3: Self-perceived satisfaction with the mouth and prosthetic-related data (complaints about the mouth, perception of the need for dental treatment, and status of the prosthesis).

2.3. Data analysis

The additive method (–ADD)[11,24] was used for both the QoLIP–10 and OHIP–14sp analyses by adding the item codes at the appropriate frequency. The dimensional scores of each index were obtained in a similar fashion. All of the data collected in the study were processed according to well-established statistical methods used in related research.[10,25]

Descriptive statistics[5,25,28] and percentages for qualitative and categorical variables were calculated.[10] The main psychometric capacity (reliability and validity)[25] of the QoLIP–10 questionnaire was tested in screwed implant prosthesis wearers. As each item measured different aspects of the same attribute, the reliability was assessed by examining the internal consistency of the scale through the use of an inter-item correlation, item-total correlation, Cronbach's alpha, and alpha value if an item was deleted.[10,29]

The Kolmogorov–Smirnov test[5] did not assume a normal distribution of the QoLIP–10 outcome variable in the groups tested ($p = 0.0001$). Hence, the criteria validity of the QoLIP–10 indicator (which measures how well the test predicts the QoL based on information obtained from other variables)[29,30] was analysed by contrasting the total scores achieved in each of the QoLIP–10 and OHIP–14sp questionnaires with the VAS scores, using non-parametric probes (*i.e.*, Kruskal–Wallis test for variables with three or more categories and Mann–Whitney *U* test for variables with two categories).[8,10,28]

The construct validity of the QoLIP–10 (or the extent to which the OHRQoL was actually recorded with this questionnaire)[29,30] was investigated using factor analysis (a data reduction technique that allows homogeneous subgroups of variables to be found) and the convergent validity of the scale (which measures how closely the new questionnaire is related to other variables and measures of the same construct to which it should be related).[21]

Regarding factor analysis, the Bartlett's Sphericity and the Kaiser–Meyer–Olkin (KMO) tests, which are measures of sampling adequacy, were run to make evident the underlying factor structure of the QoLIP–10 index in screwed implant prosthesis wearers.[25] Additionally, the principal components' analysis (PCA) was performed along with the rotation method: the Varimax plus Kaiser normalisation was used to extract the underlying dimensions of the prosthetic construct.[31] The items were assigned to the rotated factors when they had a loading of 0.5 or greater in a single factor.

Factors with an eigenvalue of less than one were disregarded to avoid distortion.[25] To establish the degree of convergent validity, the QoLIP–10 total and sub-scale scores obtained were correlated to those of the OHIP–14sp questionnaire using the Spearman's rank correlation test.[32]

To investigate the discriminant validity, the total and dimensional scores of both indices were compared among the prosthodontic groups using non-parametric tests (*i.e.*, Kruskal–Wallis test for variables with three or more categories and Mann–Whitney *U* test for variables with two categories).[8,10,28]

After evaluating the psychometric properties of the QoLIP–10 for implant prosthesis wearers, the modulating factors of prosthetic well-being were explored. The Kruskal–Wallis and Mann–Whitney *U* tests[28] were run to evaluate the influence of the study variables on the impact scores of the QoLIP–10 and OHIP–14sp.[5,25]

Data were processed using the Statistical Package for the Social Sciences (software v.20) (SPSS/PC+, Inc., Chicago, IL, USA) taking the cut-off level for statistical significance at $\alpha = 0.05$.[28,32]

3. Results

3.1. *Description of the sample*

A total of 12 (8.4%) patients were excluded from the reference population ($n = 143$), five of whom were seeking periodontal treatment and seven of whom refused to participate due to time constraints (rejection rate = 4.9%). The final study sample comprised 131 individuals.

Socio-demographically, (Group 1), most participants were female (57.3%, $n = 75$), over 60 years old (51.1%, $n = 67$), married (78.7%, $n = 103$), and had a basic education (42.7%, $n = 56$) (Table 1). In regards to health behaviour variables (Group 2), 61.1% ($n = 80$) of the subjects brushed their teeth three times a day, while 84% ($n = 110$) of the patients did not visit the dentist every year (Table 1).

Most participants did not complain about their mouths (77.9%, $n = 102$), and did not perceive a need for dental treatment (86.3%, $n = 113$) (Group 3) (Table 1). Prosthetic-related data (Group 3) revealed that 87.1% ($n = 114$) of the implant restorations were in good condition, while 9.9% ($n = 13$) required repair, and 3% ($n = 4$) needed to be replaced (Table 1). Overall, most participants were satisfied with their dental aesthetics (91.6%, $n = 120$), chewing functionality (91.6%, $n = 120$), and implant prostheses (90.1%, $n = 118$) (Table 1).

3.2. *Analysis of the reliability and validity of the QoLIP–10 questionnaire adapted for screwed implant prosthesis wearers*

The reliability (or internal consistency) of the QoLIP–10 for screwed implant prosthesis wearers was supported by alpha values of 0.80 (direct values) and 0.83 (typical values) (Table 2). These results were significant ($p < 0.0001$); therefore, the reliability of the index was estimated to be within the interval of 0.22 to 0.35 with a 95% degree of confidence. Furthermore, the QoLIP–10 total score was strongly correlated ($p < 0.001$) with all of its sub-scale scores (Table 3), whereas the OHIP–14sp total score was not significantly correlated with the scores of its *social disability* and *handicap dimensions* ($p > 0.05$) (Table 3).

An overall distribution of positive inter-item correlations was confirmed for the QoLIP–10 scale and alpha values were lower or equal when either item was deleted. The inter-item correlation analysis showed that all of the coefficients were positive (ranging from 0.13 between Items 1 and 8, to 0.95 between Items 9 and 10). This revealed that the concept was measured in the same direction. Although most correlations were significant, none of them was intense enough to confirm the existence of clear redundancy between types of content. All of the items showed satisfactory homogeneity with coefficients ranging from 0.45 to 0.63, except Item 4, which had a lower rate (coefficient = 0.25). Nevertheless, the removal of Item 4 did not cause a substantial improvement in the reliability of the remaining scale, given that the usual rule of thumb is that an item should correlate with the total score above 0.20. Consequently, it was included in the final version of the questionnaire for screwed implant prosthesis wearers.

As all of the items and their possible responses were presented together in a matrix (which facilitates self-completion by patients), the face validity of the index was considered adequate in the pilot trial. Moreover, the participants declared that they understood all of the items. Additionally, the Likert responses[23] had a symmetric format that allowed intuitive understanding because the range was demarcated by the most extreme positive or negative options. The QoLIP–10 also demonstrated satisfactory content validity for screwed implant prosthesis wearers. This questionnaire focuses on physical, psychological, and social activities that might be impaired by oral conditions, and the study subjects did not mention any situation of impact that was not included in the index.

The QoLIP–10 questionnaire demonstrated adequate criterion validity, as its total score was significantly correlated with patients' satisfaction with aesthetics ($rho = 0.24$, $p < 0.001$), chewing function ($rho = 0.22$, $p < 0.001$), and prosthesis ($rho = 0.33$, $p < 0.001$) (Table 3). Concerning the relationship between the OHIP–14sp total score and the satisfaction-related variables, the only inversely correlated variables ($p < 0.001$) were satisfaction with chewing ($rho = -0.29$) and satisfaction with the prosthesis ($rho = -0.35$) (Table 3).

As for the construct validity, the factor analysis showed average QoLIP–10 scores ranging from 1.1 for Item 1 to 1.9 for Item 6. Hence, every response was situated in the non-impact zone (Table 2). Both the communalities extracted and the standard deviations obtained for the principal components' analysis support the conclusion that all items were well-represented in the factorisation, making all of them necessary in the questionnaire for screwed implant prosthesis wearers (Table 2).

Results from the Bartlett's Sphericity test ($\chi^2 = 766.759$, 45gl, $p < 0.0001$) suggested the existence of a high number of inter-significant correlations among items and latent factors (or dimensions) in the QoLIP–10. The KMO measure produced a global value of 0.70. Three components with eigenvalues above 1 emerged from the factor analysis of the QoLIP–10 and were supported by the elbow in the corresponding scree plot of eigenvalues. These three factors explained 69.44% of the total variance (Table 2). Most items consistently and coherently loaded on a single factor. Table 2 presents the items with factorial weights greater than 0.5 ordered on three dimensions.

An adapted form of the QoLIP–10 scale has been validated and applied for screwed implant prosthesis wearers in this trial (Appendix A). In this version of the index 'chewing difficulty' has been moved from Item 2 to Item 8 as a result of the factor analysis. Then, the first factor of the QoLIP–10 for screwed prosthesis wearers, named *biopsychosocial dimension*, was formed by the combination of the Items 1, 3, 4, and 5 of the original QoLIP–10 index (oral pain, worry/concern, communication/social relations, and activities of daily living, respectively). This factor was the most explanatory (29.85% of variance). The second factor, called *dental–facial aesthetics dimension* comprised the original Items 6, 7, and 8 (satisfaction with the prosthesis' appearance, satisfaction with the realism of the prosthesis, and satisfaction with the smile, respectively). The third factor, designated as *performance dimension*, included the Items 2, 9, and 10 of the original questionnaire

Table 1 – Impact of the study variables on the OHRQoL ($N = 131$).

Patients' features (%, n)	Statistical significance			
	QoLIP–10 total score		OHIP–14sp total score	
	Mean (SD)	p values	Mean (SD)	p values
Group 1: Social-demographic variables				
Gender				
Male (42.7%, n = 56)	17.4 (4.3)	0.03 * (a)	1.1 (2.2)	0.02 * (a)
Female (57.3%, n = 75)	12.2 (7.8)		4.9 (4.5)	
Age				
≤60 years (48.9%, n = 64)	16.1 (5.5)	0.62 NS (a)	1.5 (3.0)	0.12 NS (a)
>60 years (51.1%, n = 67)	13.9 (7.6)		2.8 (4.3)	
Marital status				
Single (11.4%, n = 15)	13.7 (8.2)	0.64 NS (b)	2.7 (3.9)	0.84 NS (b)
Married (78.7%, n = 103)	15.8 (6.7)		2.0 (3.3)	
Divorced (3.8%, n = 5)	14.4 (4.6)		3.2 (5.0)	
Widower (6.1%, n = 8)	14.2 (5.0)		2.6 (2.6)	
Level of education/schooling				
Illiterate (3%, n = 4)	13.0 (6.9)	0.04* (b)	4.8 (2.1)	0.04* (b) QoL:
Basic education (42.7%, n = 56)	15.7 (5.4)		3.1 (4.1)	Illiterate < University
Secondary education (31.4%, n = 41)	17.0 (7.6)		2.6 (3.4)	
Special teaching (language/art/dance/sport teaching) (10.7%, n = 14)	16.1 (6.3)		2.0 (4.5)	
University education (12.2%, n = 16)	18.0 (6.6)		1.1 (2.3)	
Group 2: Health behavioural variables				
Tooth brushing/daily rate				
Once a day (10.7%, n = 14)	14.0 (5.6)	0.08 NS (b)	3.8 (2.7)	0.52 NS (b)
Twice a day (25.2%, n = 33)	15.1 (7.1)		2.0 (3.7)	
Three times a day (61.1%, n = 80)	15.8 (6.5)		2.3 (4.0)	
More than three times/day (3%, n = 4)	16.4 (6.3)		1.8 (2.9)	
Number of dental visits per year				
None (84%, n = 110)	14.1 (6.2)	0.42 NS (b)	2.2 (4.0)	0.90 NS (b)
One (8.4%, n = 11)	15.9 (5.4)		1.7 (2.4)	
Two (6.1%, n = 8)	16.3 (3.7)		1.3 (1.4)	
More than two (1.5%, n = 2)	17.7 (12.5)		1.5 (5.8)	
Group 3: Self-perceived satisfaction with the mouth, and prosthetic-related data				
Complaints about the mouth				
Yes (22.1%, n = 29)	10.7 (9.9)	0.001** (a)	5.6 (5.5)	0.001** (a)
No (77.9%, n = 102)	16.8 (4.6)		1.2 (2.4)	
Perception of the need for dental treatment				
Yes (13.7%, n = 18)	9.8 (7.6)	0.001** (a)	5.8 (4.5)	0.001** (a)
No (86.3%, n = 113)	15.9 (4.2)		1.1 (1.9)	
Status of the prosthesis				
Good condition (GC) (87.1%, n = 114)	17.1 (6.4)	0.001** (b)	1.3 (4.2)	0.001** (b) QoL:
Needs reparation (R) (9.9%, n = 13)	15.8 (5.2)		2.1 (2.8)	CH < GC*
Requires to be replaced (CH) (3%, n = 4)	7.2 (4.3)		6.1 (5.7)	CH < R*
Global oral satisfaction (Visual analogue scale: VAS): Criterion validity of the QoLIP–10				
Aesthetic satisfaction				
Satisfied (91.6%, n = 120)	16.3 (5.2)	0.001** (b)	1.9 (3.6)	0.001** (b)
Neutral (5.4%, n = 7)	4.6 (11.9)		2.5 (2.6)	
Dissatisfied (3%, n = 4)	5.2 (3.9)		6.6 (4.4)	
Satisfaction with chewing				
Satisfied (91.6%, n = 120)	16.3 (5.3)	0.001** (b)	1.4 (2.5)	0.001** (b)
Neutral (1.5%, n = 2)	4.8 (12.8)		7.0 (1.4)	
Dissatisfied (6.9%, n = 9)	10.0 (2.8)		11.0 (5.6)	
Satisfaction with the prosthesis/implant restoration				
Satisfied (90.1%, n = 118)	16.6 (4.7)	0.001** (b)	1.4 (2.6)	0.001** (b)
Neutral (9.2%, n = 12)	4.2 (11.6)		6.0 (6.2)	
Dissatisfied (0.7%, n = 1)	11.0 (–)		9.0 (–)	

Lower QoLIP–10 scores and higher OHIP–14 punctuations indicate poorer self-perceived quality of life. NS = not significant ($p > 0.05$). *Significant at $\alpha = 0.05$. **Significant at $\alpha = 0.001$. (a) Mann–Whitney U test. (b) Kruskal–Wallis test.

Table 2 – Factor analysis and reliability of the QoLIP–10 index for screwed implant-supported denture wearers ($N = 131$).

Items' scores			Factor load matrix (factorial weight > 0.5)		
Items (ordered as in the original version of the index)	Mean (SD)	Communalities (PCA)	QoLIP–10 dimensions		
			Biopsychosocial	Dental-facial aesthetics	Performance
(1) Oral pain	1.1 (1.6)	2.52	1.42	–	–
(2) Chewing difficulty	1.3 (1.3)	1.80	–	–	0.75
(3) Worry/concern	1.2 (1.5)	2.25	0.92	–	–
(4) Communication/social relations	1.6 (1.0)	1.08	0.53	–	–
(5) Activities of daily living	1.8 (0.6)	0.34	0.50	–	–
(6) Satisfaction with the prosthesis' appearance	1.9 (0.7)	0.49	–	0.51	–
(7) Satisfaction with the realism of the prosthesis	1.8 (0.8)	0.72	–	0.62	–
(8) Satisfaction with the smile	1.8 (0.8)	0.62	–	0.56	–
(9) Speaking difficulty or restriction	1.5 (1.3)	1.59	–	–	0.65
(10) Oral hygiene difficulty	1.5 (1.2)	1.45	–	–	0.86
Percentage of variance explained			29.85%	24.03%	15.56%
Items per dimension in this study (total = 10 items)			4 items (1, 3, 4,5)	3 items (6, 7, 8)	3 items (2, 9, 10)
Dimensional Cronbach α values			0.67	0.65	0.78
Reliability of the QoLIP–10/Cronbach α value of the index = 0.80			Percentage of total accumulated variance = 69.44%		

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

(chewing difficulty, speaking difficulty or restriction, and oral hygiene difficulty, respectively) (Appendix A).

The total QoLIP–10 and OHIP–14sp scores were inversely correlated ($p < 0.001$). Moreover, the total score of the QoLIP–10 questionnaire showed significant inverse correlations ($p < 0.001$) with the *functional limitation, pain, psychological discomfort*, and *physical disability* dimensions of the OHIP–14sp (Table 3). In turn, the OHIP–14sp total score was inversely correlated ($p < 0.001$) with the *biopsychosocial* and *performance* sub-scales of the QoLIP–10 (Table 3). Therefore, subjects with higher scores (lower negative impact) in the QoLIP–10 scale, tended to present lower scores with the OHIP–14sp. The identical qualitative interpretations of both tests confirmed the convergent validity of the QoLIP–10 among screwed implant prosthesis wearers (Table 3).

To finish with the construct validity, the QoLIP–10 questionnaire satisfactorily proved to be reliable and valid for screwed implant prosthesis wearers because of its psychometric properties (Table 2). This implied that the ten items measured by the index were appropriate.

Table 3 – Correlation among satisfaction variables and QoLIP–10 and OHIP–14sp scores ($N = 131$).

			rho values	
			QoLIP–10 total score	OHIP–14sp total score
Variables				
Aesthetic satisfaction			0.24**	−0.16 NS
Satisfaction with chewing			0.22**	−0.29**
Satisfaction with the prosthesis			0.33**	−0.35**
Questionnaires				
QoLIP–10	Sub-scale and total scores	Biopsychosocial	0.88**	−0.65**
		Dental-facial aesthetics	0.43**	−0.11 NS
		Performance	0.78**	−0.51**
		QoLIP–10 total score	N/A	−0.70**
OHIP–14sp		Functional limitation	−0.39**	0.60**
		Pain	−0.62**	0.85**
		Psychological discomfort	−0.56**	0.74**
		Physical disability	−0.24**	0.38**
		Psychological disability	−0.17 NS	0.22*
		Social disability	−0.16 NS	0.16 NS
		Handicap	−0.14 NS	0.14 NS
		OHIP–14sp total score	Convergent validity of the QoLIP–10: −0.70**	N/A

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

Table 4 – Comparison of self-reported satisfaction among the prosthodontic groups tested.

Subscale and total scores	Hybrid prosthesis wearers ($n = 50$)	Screwed partial denture wearers ($n = 43$)	Screwed complete denture wearers ($n = 38$)	p values (Kruskal–Wallis) ($N = 131$) Discriminant validity
	Mean (SD)			
QoLIP–10				
Biopsychosocial	5.0 (4.2)	6.0 (3.3)	6.1 (3.1)	0.42 NS
Dental-facial aesthetics	3.7 (3.3)	6.0 (0.0)	5.9 (1.5)	0.02*
Performance	3.2 (3.3)	5.1 (2.0)	5.6 (2.4)	0.02*
QoLIP–10 total score	13.4 (8.8)	16.9 (4.3)	16.3 (5.1)	0.24 NS
OHIP–14sp				
Functional limitation	1.4 (2.4)	0.1 (0.5)	0.3 (0.9)	0.04*
Pain	1.0 (1.9)	1.0 (2.0)	0.6 (1.0)	1.00 NS
Psychological discomfort	0.6 (1.2)	0.6 (1.3)	0.4 (0.9)	0.83 NS
Physical disability	0.1 (0.4)	0.1 (0.4)	0.1 (0.4)	0.67 NS
Psychological disability	0.0 (0.0)	0.1 (0.4)	0.1 (0.8)	0.39 NS
Social disability	0.0 (0.0)	0.0 (0.0)	0.1 (0.4)	0.32 NS
Handicap	0.0 (0.0)	0.0 (0.0)	0.0 (0.2)	0.16 NS
OHIP–14sp total score	2.8 (4.8)	1.6 (3.0)	1.7 (2.7)	0.94 NS

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

3.3. *Analysis of the prosthetic well-being construct*

The total scores of the QoLIP–10 and the OHIP–14sp were compared among the three prosthodontic groups to evaluate the discriminant validity of the QoLIP–10 index. Although the two scales pointed to lower levels of satisfaction among HP wearers (QoLIP–10 = 13.4 ± 8.8 and OHIP–14sp = 2.8 ± 4.8), no statistical significance was achieved (Table 4).

Conversely, some dimensions of the questionnaires demonstrated to have discriminative capacity among the prosthodontic groups. HP wearers attained the lowest quality of life outcomes in both the *dental–facial aesthetics* and *performance* domains of the QoLIP–10 ($p = 0.02$), and the *functional limitation* dimension of the OHIP–14sp ($p = 0.04$) (Table 4).

Concerning the impact of the prostheses on OHRQoL, the effect of possible modulating factors was also examined. The QoLIP–10 total score was significantly lower (indicating a lower QoL) in subjects who were female ($p = 0.03$), illiterate (compared to patients having university education) ($p < 0.05$), complained about their mouth ($p < 0.001$), perceived the need for dental treatment ($p < 0.001$), and/or were required to change their prostheses ($p < 0.001$). Therefore, *gender*, *level of education, complaints about the mouth, perception of the need for dental treatment*, and *status of the prosthesis* were direct modulators or 'predictors' of patients' satisfaction (Table 1). In addition, the *three global oral satisfaction* measures (*i.e.*, satisfaction with the aesthetics, chewing, and prosthesis) (Table 1) were found to influence the QoLIP–10 impact scores in the expected direction ($p < 0.001$), which confirmed the suitability of this scale for assessing the OHRQoL of screwed implant prosthesis wearers and moreover remarks its adequate criterion validity. The same QoL modulators were consistently detected by the OHIP–14sp. Age and marital status were not found to modulate patient satisfaction (Group 1), and nor did any of the health-behavioural variables tested (*i.e.*, frequency of tooth-brushings and dental visits per year) (Group 2) (Table 1).

4. Discussion

Notwithstanding the progressive development of more predictable implant prostheses,[33] the use of patient-centred outcome measurement techniques may be helpful in facilitating a more appropriate patient-oriented implant-prosthetic solution.[4,18] In this paper, the QoLIP–10 scale was adapted and validated for screwed implant-supported prosthesis wearers. The impact of screwed restorations on patient satisfaction was also evaluated on the basis of cross-sectional survey-based data and clinical examination. The study results require rejection of the null hypothesis because the type of screwed implant restoration influenced the level of patient satisfaction and various study variables modulated the OHRQoL of screwed prosthesis wearers.

The content and face validities of the QoLIP–10 for screwed implant denture wearers were confirmed in the pilot trial; subjects understood the questionnaire, and the instrument was not shown to lack any important content relating to prosthetics.[20,32,34]

In the main study, the high Cronbach's alpha value confirmed the reliability[29] of the QoLIP–10 in the groups tested (Table 2). A strong correlation between the total and dimensional QoLIP–10 scores demonstrated internal consistency[21,29] (Table 3). In addition, the ten items of the index surpassed a threshold of 0.2 in the item-total correlation matrix, which is the basic requirement for including an item on a scale.[21] The bidirectional measurement of responses of the QoLIP–10 is more complete than the exclusive evaluation of negative effects made by other instruments.[7,32] This is relevant, as most of the QoLIP–10 items have been rated as positive events in this investigation.

Consistent with previous research,[10,30,32] the criterion validity of the QoLIP–10 was proven by the fact that its total score was positively correlated with all of the satisfaction variables (Tables 1 and 3). Those patients who reacted positively to the aesthetic results and comfort with eating,

and were overall satisfied with their implant restorations,[17] achieved significantly higher QoLIP–10 scores, meaning a higher QoL (Table 1). In-depth information about patients' experiences of eating with dentures is necessary to fully assess the impact of the prosthesis and to formulate dietary advice.[35–37] However, the opposing occlusal plane, among other factors, may have influenced the patients' satisfaction with their prostheses and chewing functionality.[38] Even though an effort was made to reduce the likelihood of the antagonistic occlusal plane through the exclusion criteria, the influence of occlusion on OHRQoL may require further assessment in future studies. Nonetheless, the occlusal schemes of the tested restorations were standardised following criteria of the university dental clinic (*i.e.*, fixed-detachable hybrid prostheses were restored with a bilateral balanced occlusion whereas screwed dentures had a mutually protected occlusion, always using semi adjustable articulators).

Regarding construct validity, the multidimensionality of the QoLIP–10 was evidenced by the exploratory factor analysis, which showed three statistically differentiated emerging dimensions (Table 2). According to previous related studies,[10,22,31] a simple structure was obtained because each item was weighted heavily and solely on one sub-scale (Table 2). The convergent validity of the QoLIP–10 was supported by: (a) the logical inverse convergence ($rho = -0.70$, $p < 0.001$) between the total scores of the QoLIP–10 and OHIP–14sp,[8,10,21,32] (b) significant inverse correlations among the total score of each questionnaire and some dimensional scores of both indices (Table 3) These associations confirmed that the questionnaires assessed the same constructs.[21] This is important because the OHIP-14sp had recently been validated in the same reference population.[11]

As for discriminant validity, both the *dental–facial aesthetics* and *performance* dimensions of the QoLIP–10 significantly discriminated among the tested groups (Table 4), attributing the worst self-perceived satisfaction to HP wearers (Table 4). This may allow for an expansion of the clinical applications of the index, as chewing ability (which is an item included in the *performance* sub-scale) is one of the determinants of denture satisfaction most closely related to patient well-being.[39] The OHIP–14sp consistently detected significantly higher levels of self-rated *functional limitation* among HP users (Table 4). Although clinical experience suggests that fewer numbers of replaced teeth should be associated to higher levels of OHRQoL,[40] no significant differences were identified among partially and totally edentate patients restored with metal–ceramic screwed dentures (Table 4). A partially dentate group was thus included in the study design to assess the possible effect of the prosthesis' extension on patient satisfaction. However, in light of the results and their clinical utility, the present validation resulted primarily for application in screw-retained complete prostheses, be they metal–ceramic or hybrid.

According to that published in previous studies that used OHRQoL questionnaires[10,41] the prosthodontic groups were not discriminated by the total scores of the scales. This may be attributed to the narrow differences in means[28] (Table 4). Moreover, the volunteers did not demand dental care during the study, implying that most of them had no complaints about their mouths and were satisfied with their treatments[10] (Table 1). This could be expected as all of the study subjects (including the control group) were wearers of fixed implant prostheses, which offer more stability and greater facility for eating than do removable dentures[15,35,39] Nevertheless, despite the lack of significant differences, HP wearers expressed lower levels of satisfaction than did the other patients as measured with both questionnaires (Table 4). When implants are angled or placed labially to the planned tooth position as a result of severe bone resorption or maxillomandibular malocclusion (which are indications for treatment with fixed-detachable hybrid prostheses), the access holes of hybrid dentures may compromise aesthetics and occlusion more than screwed restorations would.[12,14]

The modulating influence of the study variables on the OHRQoL was also analysed. The socio-demographic profile of the volunteers reporting the highest psychological discomfort was an illiterate woman, which was consistently detected by both the QoLIP–10 and OHIP–14sp questionnaires (Table 1). Patients with university education reported significantly higher levels of satisfaction than did illiterate subjects (Table 1). This finding is in line with public health research on the correlation between lower socioeconomic status and poor health.[42] In accordance with previous investigations,[25,43] men showed significantly better satisfaction than did women. Psychological differences between men and women would help explain the possible effect of *gender* on patient satisfaction, as the perception of individuals is more strongly influenced by self-evaluation than by objective parameters.[44] Age was not a modulating factor of well-being, which agrees with the results of a study on conventional complete denture wearers conducted in the same reference population.[45] Elderly patients, however, tended to be more dissatisfied than their younger counterparts (Table 1). This is in keeping with evidence that oral health worsens with age, mainly due to natural and inevitable tooth loss.[46] Participants without partners tended to have a poorer self-perception of oral health than did married patients. Although further research is needed, Perea *et al.*[45] observed the same tendency, whereas Preciado *et al.*[10] reported the opposite.

Despite the lack of significant differences, a better QoL was associated with more frequent tooth brushings and more visits to the dentist per year (Table 1), which emphasizes the importance of teaching patients to practice healthy habits[8] and identify early, non-painful symptoms of oral problems.[47] Logically, patients who *complained about their mouths, perceived the need for dental treatment*, and *were required to change their prostheses* reported a significantly lower QoL, which is in agreement with the literature[5,45,48] (Table 1).

The continuous evaluation of the satisfaction of dental patients allow verifying that the needs of society are being met.[49] This study was limited by the fact that participants were recruited from a single university dental clinic. Nonetheless, the use of a heterogeneous sample (Table 1) facilitates the extrapolation of our findings to other countries.[5,45,48] Validation of this study's results in other settings would offer interesting feedback[50] on this index. Also, it would seem prudent to increase the teaching of dental implants to best prepare graduating students for independent clinical practice.[51]

5. Conclusions

Within the limitations of the present research, the following conclusions may be drawn:

1. The QoLIP–10 index has proven its adequacy for evaluating the OHRQoL of future patients wearing screwed implant dentures, which may be relevant for decision-making, measuring clinical outcomes, and research purposes.
2. As indicated by participants' answers to various QoLIP–10 and OHIP–14sp sub-scales, screwed implant restorations are superior to fixed-detachable hybrid prostheses in terms of patients' self-perceived aesthetics and functionality.
3. Overall, the extension of screwed implant restorations (partial or full-arch) did not affect the well-being of patients.
4. Gender, level of education, complaints about the mouth, perception of the need for dental treatment, and status of the prosthesis were modulating factors of patient satisfaction among screwed and fixed-detachable hybrid implant prosthesis wearers.

Clinical significance

The QoLIP–10 may be recommended for estimating the effect of various screwed implant prostheses on the well-being of future patients, which may be relevant to decision-makers and researchers. When compared to fixed-detachable hybrid prostheses, screwed restorations lead to greater improvements in patients' self-perceived aesthetics and functionality.

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Appendix A. Appendix A

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

QoLIP–10 questionnaire for screwed implant-supported denture wearers.

Quality of Life with Implant Prostheses (QoLIP–10) for screwed implant-supported denture wearers		Strongly disagree (−2)	Disagree (−1)	Indecisive, indifferent or neutral (0)	Agree (+1)	Strongly agree (+2)
Item and dimensional scores*						
D1	**Biopsychosocial**					
Item 1	You have never had oral pain related to wearing implant prostheses					
Item 2	You have never been worried/concerned because of problems with your implant prosthesis					
Item 3	You have never been angry with others because of problems with your implant prosthesis					
Item 4	You have never had difficulties in doing daily living activities because of problems with your implant prosthesis					
D2	**Dental-facial aesthetics**					
Item 5	You are satisfied with the appearance of your implant prosthesis					
Item 6	You are satisfied with the realism of your implant prosthesis					
Item 7	You are satisfied with your smile					
D3	**Performance**					

(Continued)

Quality of Life with Implant Prostheses (QoLIP–10) for screwed implant-supported denture wearers		Strongly disagree (−2)	Disagree (−1)	Indecisive, indifferent or neutral (0)	Agree (+1)	Strongly agree (+2)
Item 8	You have a satisfactory chewing function with your implant prosthesis					
Item 9	You have never had speech difficulties or restrictions related to wearing implant prostheses					
Item 10	You have never had oral hygiene difficulties due to the implant prosthesis					
Total score of the QoLIP–10 scale*						

*The dimensional and total scores can be obtained by adding the respective item scores (their negative or positive signs must be considered). The higher the summary score is, the higher the satisfaction of the patient is (meaning that negative or low positive scores indicate poorer self-perceived quality of life).
D1, D2, and D3: dimensions of the index.

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7. DISCUSIÓN

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La presente investigación consiste en un estudio transversal en el que se diseñó y validó un cuestionario para evaluar la calidad de vida relacionada con la salud bucal (OHRQoL) en usuarios de distintos tipos de implantoprótesis. Esta investigación se desarrolló en tres etapas, cada una de las cuales corresponde a un artículo.

7.1. Discusión de los resultados del primer artículo

Esta primera etapa o artículo es un acercamiento exploratorio en el uso de medidas de OHRQoL para ofrecer una perspectiva sobre el impacto de los trastornos orales y analizar el efecto de las sobredentaduras implanto-retenidas en la autopercepción de bienestar de los pacientes.

A pesar de que se han desarrollado cuestionarios específicos para portadores de dentaduras removibles,[55,56] en este trabajo se seleccionó una medida genérica del estado de salud oral para facilitar la comparación de los resultados. El test de satisfacción utilizado (OHIP–14sp) ha demostrado ser un instrumento preciso, consistente y válido para evaluar OHRQoL en los adultos en España, lo que confirma su capacidad psicométrica.[15]

Una de las limitaciones del protocolo de investigación es que los pacientes fueron reclutados únicamente de una clínica odontológica universitaria. Sin embargo, dada la variabilidad en el estatus social, nivel de educación, edad, sexo y otras características de los voluntarios (Tabla 1), nuestros resultados podrían extrapolarse a pacientes de otros países con rasgos sociodemográficos y clínicos parecidos.

El tamaño de la muestra se asemejaba a las cohortes de otros estudios con objetivos y metodología comparables.[57,58] Como originalidad del protocolo, en esta investigación los casos perdidos también se estudiaron de acuerdo con algunos posibles factores de modulación de OHRQoL (tanto variables sociodemográficas como asociadas a la prótesis). De este modo tratamos de controlar un posible sesgo de selección. La mayoría de los pacientes perdidos fueron mujeres mayores que reportaron telefónicamente una notable mejoría en su capacidad de masticación tras usar sobredentaduras mandibulares. Este hallazgo coincide con el género predominante de los participantes y las puntuaciones de bajo impacto registradas en el caso de los portadores de sobredentaduras mandibulares (Tablas 1 y 3). Por otra parte, dado que la habilidad masticatoria es uno de los determinantes de satisfacción protésica más vinculados con OHRQoL,[59] si los pacientes perdidos hubiesen sido examinados y encuestados con el OHIP–14sp podrían haberse esperado niveles comparables de impacto a los encontrados en los participantes. Por el contrario, en el supuesto de que los pacientes perdidos se hubiesen negado a participar debido a problemas relacionados con sus prótesis, podría subestimarse el impacto de las sobredentaduras implanto-retenidas en la OHRQoL de la población de referencia en el caso de que las conclusiones se obtuvieran únicamente a partir del grupo de estudio.

Se pueden apuntar algunas razones para explicar la negativa de los pacientes perdidos a participar en un estudio observacional. En primer lugar, la mayoría de los voluntarios eran jubilados (71-80 años), mientras que la mayor parte de los pacientes perdidos estaban en edad laboral (61-70 años) (Tabla 1) y, por lo tanto, encontraban más dificultades para programar una cita. Además, según Covell y cols.[60] parece que las mujeres mayores son menos propensas a inscribirse en estudios de investigación clínica.

Al igual que en estudios previos,[15,56] la mayoría de los participantes (71.4%) resultaron estar sometidos a algún tipo de impacto. El impacto medio general en OHRQoL calculado mediante el OHIP–14sp en el presente estudio (2.7 ± 3.0) (Tabla 2) fue notablemente inferior al publicado para una muestra consecutiva de 270 españoles de entre 18 y 65 años (6.3 ± 1.2);[56]

teniendo en cuenta que cuanto menor sea la puntuación de impacto menor será la incomodidad del paciente.

A pesar de las ventajas de las sobredentaduras implantosoportadas sobre las prótesis completas convencionales,[61] las diferencias existentes podrían explicarse en virtud de la mayor tolerancia al dolor y a la discapacidad que muestran los pacientes ancianos.[62] Este mismo hecho permite explicar la relación negativa entre la edad y el nivel de impacto obtenido en nuestra investigación, observándose mayor calidad de vida en el caso de los ancianos (Tabla 3). En cuanto al género, no se encontraron diferencias significativas, aunque las mujeres tienden a sentirse mejor con su sobredentadura (Tabla 3). Algunos autores declararon la independencia de esta variable sobre la auto-percepción de OHRQoL,[62,63] mientras que otros han encontrado resultados contradictorios.[15,58,64,65] Por lo tanto, el efecto y la magnitud de este factor deben abordarse en futuras investigaciones.

Pese a que la distribución de impactos por pregunta (Q) y por dimensión fue similar a la descrita en una investigación previa llevada a cabo en población adulta general del mismo país[15] (Tabla 2, Figura 2), las puntuaciones medias registradas en este estudio fueron mucho menores y ubicadas entre las frecuencias de "nunca" a "ocasionalmente" (Tabla 2, Figura 2). También la puntuación total del OHIP–14sp fue superior en otros países, tales como China,[66] entre otros. Esto puede ser debido al hecho de que nuestra muestra estaba compuesta de pacientes que no buscaban tratamiento dental y que portaban una sobredentadura implanto-retenida, en lugar de ser una muestra consecutiva de pacientes que acudían a la clínica dental.

Las principales subescalas o dimensiones del OHIP–14sp que se beneficiaron de la rehabilitación protésica evaluada en el presente estudio fueron "discapacidad social" (Q11: irritabilidad con los demás; Q12: dificultades para realizar actividades diarias), y "minusvalía" (Q13: vida insatisfactoria; Q14: incapacidad total de llevar una vida normal), que recibieron por unanimidad la respuesta (o frecuencia) "nunca" (Tabla 2, Figura 2). Esto indica una percepción

positiva de ambas dimensiones, consistente con la tendencia observada por Slade y cols.[10] cuando utilizaron la versión original del cuestionario (OHIP–49) en una población comparable. Un aumento de la "confianza social" fue también reportado por Hyland y cols.[67] para pacientes que portaban sobredentadura implanto-retenida en comparación con los que llevaban prótesis completas removibles.

Por el contrario, la media de la satisfacción global fue afectada por las dimensiones "dolor físico" (Q3: puntos de dolor; Q4: malestar con las prótesis), "limitación funcional" (Q1: problemas para pronunciar las palabras; Q2: mal sabor de los alimentos), y "malestar psicológico" (Q5: preocupación; Q6: estrés) (Tabla 2, Figura 2). Este hecho se observó con frecuencia en pacientes que portaban una dentadura completa como tratamiento antagonista, lo cual afectaba significativamente su percepción de satisfacción (Tabla 3). Estudios previos han confirmado la inestabilidad de una dentadura completa superior cuando es antagonista de una prótesis retenida por implantes.[68]

Las sobredentaduras maxilares parecen ser menos cómodas que las mandibulares, proporcionando significativamente mayor impacto en las dimensiones de "dolor físico" (Q3: puntos de dolor; Q4: malestar con las prótesis) (Tabla 2). Esto podría atribuirse a diferencias en el diseño de la prótesis y/o a las características de los tejidos de soporte. Sin embargo, este aspecto requiere futuras validaciones, ya que, hasta la fecha, no hay estudios publicados que hayan empleado el cuestionario OHIP para evaluar el efecto de la localización de una sobredentadura sobre la OHRQoL.

La dimensión "discapacidad física" (Q7: dieta insatisfactoria; Q8: comidas interrumpidas tuvo significativamente menor impacto en los portadores de sobredentadura retenida por bolas, ya que la mayoría manifestó que este sistema de retención parecía facilitar la masticación (Tabla 2). MacEntee y cols.[69] informaron niveles similares de satisfacción, tanto con sistema de retención de bola como de barra, mientras que Mumcu y cols.[70] registraron menores

puntuaciones del OHIP–14 para sobredentaduras implanto-retenidas mandibulares sobre barras. En este trabajo se detectó la presencia de úlceras orales y/o candidiasis únicamente en portadores de sobredentaduras retenidas por barras, lo que resulta en niveles significativamente más altos de impacto en la calidad de vida, y, por lo tanto, en una menor satisfacción (Tabla 3). Este hallazgo no se había informado antes. Karabuda y cols.[71] afirmaron que una de las principales complicaciones de las sobredentaduras retenidas por barra era la dificultad de higienización debido al estrecho espacio entre la barra y la mucosa, lo que contribuye a explicar la mayor frecuencia de úlceras orales y candidiasis en pacientes con barras en nuestro estudio.

Los pacientes que requirieron reparación de sus prótesis tienden a expresar menos satisfacción (Tabla 3), especialmente en relación con la dimensión "dolor físico" (Q3: puntos de dolor; Q4: malestar con las prótesis). Resultados similares han sido reportados por usuarios de dentaduras convencionales.[56] Sin embargo, Zani y cols.[72] concluyeron que los requisitos técnicos de una sobredentadura implantológica no tienen por qué influir en la satisfacción del paciente en términos de rehabilitación.

Tanto el aspecto estético como la habilidad masticatoria mejoraron en la mayoría de los pacientes portadores de sobredentaduras sobre implantes (100% y 71.3%, respectivamente, n = 63). Estos resultados coincidieron con los de Ellis y cols.,[73] que encontraron una mejoría comparable en la habilidad masticatoria (74.9%) de pacientes rehabilitados con sobredentaduras retenidas por implantes en ambos maxilares. Harder y cols.[74] hallaron mejorías tanto en la OHRQoL como en la habilidad masticatoria de portadores de sobredentaduras implanto-retenidas en un solo maxilar. Sin embargo, la base de la prótesis se fracturó con frecuencia en la zona de la línea media.[74] De acuerdo con investigaciones recientes,[75] en una extensa revisión bibliográfica se indicó que las sobredentaduras implanto-retenidas bimaxilares (caso más común en la presente investigación, tal como se muestra en la Tabla 1) son el estándar mínimo del tratamiento implantológico que debería ser suficiente para la mayoría de las personas, teniendo en cuenta el rendimiento funcional, la satisfacción del paciente, el coste y el tiempo clínico.[76]

Los resultados de este estudio deben interpretarse con cierta cautela y requieren confirmación ulterior con una muestra mayor. El Perfil de Impacto de Salud Oral ha aportado pruebas suficientes para demostrar que las sobredentaduras implanto-retenidas proporcionan una mejor OHRQoL que las dentaduras completas removibles convencionales.[56,57,77-79] Sin embargo, los factores que intervienen en esta mejoría aún quedan por determinar. Entre otros, la altura del hueso mandibular no parece influir en la satisfacción de los pacientes con la función, la habilidad masticatoria y la comodidad de las prótesis.[80] Para terminar este primer artículo, se debe tener en cuenta que, aparte de las consideraciones clínicas y técnicas, los tratamientos protésicos con implantes deberían ser siempre investigados en términos de OHRQoL y nivel de satisfacción de los pacientes.

7.2. Discusión de los resultados del segundo artículo

Siguiendo con la línea de investigación propuesta en el presente estudio se proseguirá a discutir los resultados obtenidos en el segundo artículo.

En este segundo estudio transversal se desarrolló un cuestionario específico (test) que contiene 10 ítems para medir OHRQoL, al que se denominó "Calidad de Vida con Implanto-Prótesis" (QoLIP–10); para determinar la percepción de bienestar oral tanto de los pacientes actuales como futuros restaurados con sobredentaduras retenidas por implantes y prótesis híbridas. Los cuestionarios cortos han sido considerados más eficientes en cuanto a su administración y obtienen una mayor tasa de respuesta, lo que hace del QoLIP–10 un instrumento beneficioso.[11]

La prueba piloto realizada en este segundo estudio confirmó la validez de contenido y la validez aparente del QoLIP–10, dado que coincide fielmente con las percepciones más frecuentes de los pacientes tratados con implantes en la población referencia.[10,81,82] Por lo tanto, la validez aparente y de contenido se evaluaron como satisfactorias al verificar que las preguntas se habían

comprendido a la perfección por los participantes dado que no se encontraron ítems sin respuesta y que no faltaban contenidos relevantes acerca del bienestar protésico.[81,82]

En el estudio principal, la fiabilidad del índice fue apoyada por los valores de alpha de Cronbach que indican una consistencia interna satisfactoria[38] (Tabla 3). La medición bipolar configurada por la matriz de respuestas de los ítems fue más completa que las escalas de medición que se limitan a valorar la presencia de efectos negativos[3] y por tanto pierden datos importantes sobre percepciones positivas.[82,83] Esto es esencial, ya que la mayoría de los ítems del QoLIP–10 fueron percibidos como eventos positivos en este estudio (Tabla 3).

En cuanto a la validez de constructo, el análisis factorial exploratorio mostró la multidimensionalidad del instrumento QoLIP–10, que consta de tres subescalas independientes claramente diferenciadas en términos estadísticos (Tabla 3). Se logró una estructura simple, donde cada uno de los ítems se ponderó exclusivamente en una sola dimensión, como ocurrió en investigaciones anteriores relacionadas[3,84] (Tabla 3). La convergencia lógica entre puntuaciones totales del QoLIP–10 y el OHIP–20sp mostró que ambos instrumentos miden el mismo constructo[10,33,65] (Tabla 4: Validez convergente), lo cual es relevante, ya que el OHIP–20sp había sido validado recientemente en la misma población referencia.[14]

Por otra parte, se confirmó la validez de criterio del QoLIP–10, ya que aquellos participantes que manifestaron estar satisfechos con su estética, función masticatoria, y prótesis obtuvieron significativamente mayores puntuaciones en el QoLIP–10, y, por tanto, una mejor calidad de vida de acuerdo con investigaciones precedentes[14,56,82] (Tabla 2). Las quejas sobre la boca afectaron de manera significativa el nivel de calidad de vida (Tabla 1). Esto apoya la capacidad del cuestionario creado para discriminar sujetos disconformes con las áreas principales del bienestar oral.[85] Nuestros pacientes proporcionaron una información más completa que la expresada en juicios globales (como la escala analógica visual o VAS), ya que informaron efectos

positivos en algunos ítems del QoLIP –10, impactos negativos en otros, y ausencia de cambios en otros.

En cuanto a la validez discriminante, el hecho de que el QoLIP–10 no diferenciara significativamente entre las rehabilitaciones testadas no debe atribuirse sólo a la falta de significación estadística, sino también a las estrechas diferencias entre las puntuaciones medias de los grupos protésicos[86] (Tabla 4). Varios autores que usaron otros cuestionarios tampoco han detectado diferencias significativas en las puntuaciones totales registradas en diferentes tipos de restauraciones protésicas.[86-88] Otra posible explicación es que los participantes no eran demandantes de atención dental durante el estudio, y, como consecuencia, la mayoría de ellos no tenía ninguna queja sobre su boca y no percibían necesidad de tratamiento dental. (Tabla 1). No obstante, los grupos protésicos fueron sin duda diferenciados por los ítems 1 y 3 de la dimensión biopsicosocial (es decir, dolor en la boca y dificultad para masticar, respectivamente) (Tabla 4: Impacto de la prótesis en la OHRQoL). Esta característica puede permitir la expansión de las aplicaciones clínicas de la escala QoLIP–10 y facilitar las comparaciones entre las diferentes poblaciones de pacientes o tratamientos dentales mediante la evaluación de la influencia de la habilidad masticatoria en la auto-percepción de la OHRQoL.[59,82] Los portadores de prótesis híbridas mostraron significativamente mejor calidad de vida biopsicosocial que los portadores de sobredentaduras implanto-retenidas y dentaduras completas convencionales con referencia a los ítems mencionados anteriormente (Tabla 4: Impacto de la prótesis en la OHRQoL). A pesar de la ausencia de diferencias significativas, la calidad de vida más alta, medida tanto con el QoLIP–10 como con el OHIP–20sp también se dio en portadores de prótesis híbrida (Tabla 4: Validez discriminante), lo cual concuerda con estudios previos que atribuyen mejor estabilidad y facilidad para comer alimentos duros a las restauraciones fijas sobre implantes que a las removibles.[59,89,90] No obstante, las diferencias entre los protocolos de estudio dificultan las comparaciones.

También se analizó el efecto modulador de las variables de estudio en la calidad de vida relacionada con la salud bucal. Se encontraron diferencias significativas cuando las puntuaciones

del QoLIP–10 se cruzaron con las variables relacionadas con la prótesis y la satisfacción con las condiciones bucales (Grupos 4 y 5, respectivamente). Al igual que en investigaciones previas,[9,91,92] los pacientes que requirieron un cambio de su prótesis o se quejaron de su boca reportaron una calidad de vida significativamente menor y, por tanto, obtuvieron puntuaciones bajas en el QoLIP–10. El sistema de retención fue un factor adicional que afectó a la satisfacción del paciente en el caso de sobredentaduras. Los "locator" proporcionaron una calidad de vida significativamente menor que las barras (Tabla 1). En otros estudios se había encontrado que las barras proporcionan una mayor comodidad, estabilidad, y habilidad masticatoria que otros dispositivos.[82,93]

Otros resultados clínicamente relevantes también han sido evaluados. A pesar de que no todas las variables de estudio mostraron correlaciones significativas con la puntuación total del QoLIP–10, se identificaron varias asociaciones cercanas no significativas. Los pacientes que percibían necesidad de tratamiento dental obtuvieron puntuaciones más bajas en el cuestionario.[65,82] Sin embargo, no se encontraron diferencias significativas en este estudio (Tabla 1). Tal y como ha sido expuesto anteriormente, la satisfacción protésica de los pacientes no parece depender de las complicaciones técnicas de las implantoprótesis.[72] Los pacientes desdentados de edad avanzada que no habían recibido información sobre cómo evitar problemas orales precisaron tratamiento dental con menos frecuencia y a la vez manifestaron niveles más altos de calidad de vida. Estos resultados refuerzan la necesidad de los individuos para identificar en etapas tempranas, los signos y síntomas no dolorosos de las enfermedades orales o problemas relacionados con las prótesis.[94] A este respecto, un número mayor de visitas al dentista por año, así como una mayor frecuencia de cepillado dental (Tabla 1) se asociaron a una mayor calidad de vida; lo que hace hincapié en la importancia de practicar hábitos saludables cuando los pacientes están restaurados protésicamente.[65]

Los pacientes que portaban las prótesis en ambos maxilares expresaron mayor satisfacción. En particular, una prótesis localizada en la mandíbula se mostraba menos confortable (menor calidad de vida) que una localizada en el maxilar superior (Tabla 1). Esto podría atribuirse

a las diferencias en los tejidos de soporte y los patrones de reabsorción de las crestas maxilares y mandibulares.

Los sujetos que estaban casados y habían recibido un régimen especial de enseñanza reportaron mayor insatisfacción (Tabla 1). Sin embargo, estos resultados requieren ser confirmados, ya que el efecto de estas variables sobre la calidad de vida no ha sido evaluado hasta la fecha en pacientes similares a los del presente estudio.

Por último, el perfil de los sujetos que informaron el menor malestar psicológico en esta investigación fue: mujeres entre 81-90 años de edad, con candidiasis y lesiones de la mucosa bucal (Tabla 1). Esto puede ser debido a una mayor tolerancia de los pacientes maduros tanto al dolor como a la discapacidad (tal y como se ha indicado anteriormente);[62,91] lo cual pone de manifiesto la relación inversa entre la edad y el nivel de impacto negativo. En cuanto al género, aunque las mujeres mostraron una mayor tendencia a sentirse mejor con sus prótesis, los resultados no fueron estadísticamente significativos (Tabla 1). Ciertos estudios hablan de la falta de asociación entre el género y la auto-percepción de la QoL,[62,63,91] mientras otros autores sí que encuentran vinculación entre género y satisfacción con la salud bucal.[64,65,85,95] Además, en el presente trabajo, la percepción de malestar con las dentaduras parecía ocupar un segundo plano en el caso de los pacientes con candidiasis y lesiones mucosas puesto que sufrían de otras enfermedades severas y estaban medicados con analgésicos diariamente. Otros autores han reportado hallazgos similares.[92]

Los pacientes fueron reclutados en una sola clínica odontológica universitaria, lo que *a priori* podría representar una limitación en el estudio realizado. Sin embargo, dada la variabilidad en las características de los participantes (Tabla 1), nuestros resultados podrían extrapolarse a pacientes de otros países con características sociodemográficas y clínicas comparables.[91] Los hallazgos de esta investigación deben interpretarse con cierta cautela y requieren confirmación en otros contextos más amplios.

7.3. Discusión de los resultados del tercer artículo

Finalmente se discutirá el tercer artículo; en el cual la hipótesis probada fue que el tipo de restauración implantosoportada atornillada no condiciona el nivel de satisfacción de los pacientes; y que la satisfacción de usuarios de prótesis atornillada no depende de las variables sociodemográficas, comportamientos de salud, y / o hábitos relacionadas con las prótesis. En este caso, los resultados del estudio confirmaron el rechazo de dicha hipótesis nula, puesto que las implantoprótesis atornilladas influenciaron el nivel de satisfacción de los pacientes. Además, algunas variables de estudio modularon la OHRQoL de los portadores de prótesis atornilladas.

A pesar del progresivo desarrollo de prótesis implantológicas más predecibles,[96] el uso de técnicas de medición de resultados centrados en el paciente pueden ser útiles para facilitar una solución rehabilitadora más adecuada.[97,98] En este artículo, el cuestionario QoLIP–10, diseñado para portadores de implantoprótesis, fue adaptado y validado para usuarios de prótesis implantosoportadas atornilladas.

Mediante un estudio de corte transversal se evaluó el impacto de las restauraciones atornilladas en la satisfacción del paciente mediante el uso de cuestionarios y examinen clínico. La validez de contenido y la validez aparente del QoLIP–10 fueron confirmados en la prueba piloto, puesto que todos los ítems fueron perfectamente entendidos por los participantes ya que no se encontraron preguntas sin respuesta y / o falta de contenido importante de las percepciones relacionadas con la prótesis, como ocurría en el caso del segundo artículo.[81,82,90]

En el estudio principal, la fiabilidad del QoLIP–10 fue confirmada por un alto valor alpha de Cronbach[38] en los grupos evaluados (Tabla 2). La consistencia interna del índice fue demostrada por una fuerte correlación entre la puntuación total y las puntuaciones por dimensión del QoLIP–10[33,38] (Tabla 3). Además, los diez ítems del QoLIP–10 superaron un umbral de 0.2 en la matriz de correlación ítem-total, que es un requisito básico para la inclusión de un ítem en un test.[33]

Consistentemente con previas investigaciones,[14,82,99] se probó la validez de criterio del QoLIP–10, ya que su puntuación total se correlacionó positivamente con todas las variables de satisfacción (Tablas 1 y 3). Aquellos pacientes que estaban satisfechos con su estética, masticación y restauraciones implantosoportadas[100] alcanzaron significativamente las mayores puntuaciones en el QoLIP–10, lo que significa que tenían mayor QoL (Tabla 1). Con el fin de evaluar plenamente el impacto de las prótesis y formular asesoramiento dietético apropiado, fue necesario recabar información en profundidad de las experiencias de los pacientes al comer con dentaduras,[90,101] aunque otros factores, tales como el plano de oclusión antagonista pueden haber afectado la satisfacción de los pacientes con la masticación y las restauraciones implanto-retenidas.[102] A pesar de que se trató de reducir el posible efecto del plano oclusal antagonista a través de los criterios de exclusión, la influencia de la oclusión en la calidad de vida relacionada con la salud bucal requiere ser reevaluada en futuros estudios. No obstante, los esquemas oclusales de las restauraciones seguían los criterios estandarizados de la clínica odontológica universitaria (es decir, las prótesis híbridas fijas-desmontables tenían oclusión balanceada bilateral, mientras que las prótesis atornilladas tenían una oclusión mutuamente protegida; utilizando siempre articulador semi-ajustable).

En cuanto a la validez de constructo, la multidimensionalidad del QoLIP–10 se puso de manifiesto con el análisis factorial exploratorio, que mostró tres dimensiones emergentes estadísticamente diferenciadas (Tabla 2). De acuerdo con estudios anteriores,[3,99,84] se obtuvo una estructura simple, ya que cada ítem fue ponderado en gran medida sobre una sola dimensión (Tabla 2).

La validez convergente del QoLIP–10 fue soportada por: *(a)* la convergencia inversa lógica ($rho = -0.70$, $p < 0.001$) entre las puntuaciones totales del QoLIP–10 y el OHIP–14sp;[33,65,82,99] *(b)* las correlaciones inversas significativas entre la puntuación total de cada cuestionario y algunas puntuaciones dimensionales de ambas pruebas (Tabla 3). Estas asociaciones confirmaron que los cuestionarios probados evaluaron el mismo constructo.[33]

En cuanto a la validez discriminante, tanto la dimensión de estética dento-facial como la dimensión de rendimiento funcional del QoLIP–10 discriminaron significativamente entre los grupos de estudio (Tabla 4), atribuyendo a los usuarios de prótesis híbridas la peor auto-percepción de satisfacción de modo significativo (Tabla 4). Esto podría permitir una ampliación de las aplicaciones clínicas del índice, puesto que la habilidad masticatoria (ítem de la dimensión de rendimiento funcional) como ya se mencionó en el estudio previo, ayuda a determinar la satisfacción protésica en términos de OHRQoL.[59] El OHIP–14sp detectó consistentemente mayores niveles (mayor puntuación) de auto-percepción de limitación funcional en usuarios de prótesis híbridas (Tabla 4).

Aunque la experiencia clínica sugiere que un menor número dientes reemplazados puede estar asociado a niveles más altos de OHRQoL,[103] no hubo diferencias significativas entre los pacientes parcial y totalmente desdentados restaurados con prótesis metal-cerámicas atornilladas (Tabla 4).Se incluyó un grupo de restauraciones parciales atornilladas en el estudio para evaluar el posible efecto de la extensión de la prótesis en la satisfacción del paciente. Sin embargo, a la luz de los resultados y su utilidad clínica, la presente validación resulta principalmente práctica para su aplicación en prótesis completa atornillada, ya sea metal-cerámica o híbrida.

De acuerdo con lo publicado en estudios previos que utilizaron cuestionarios de calidad de vida,[87,99] los grupos evaluados no fueron discriminados por las puntuaciones totales de los tests. Esto podría atribuirse a los hallazgos del segundo artículo de esta Tesis, que fue desarrollado en la misma población de referencia (Tabla 4);[86,99] (donde la mayoría se mostraron satisfechos con su tratamiento protésico[99] (Tabla 1). Dichos resultados eran esperables ya que todos los sujetos del estudio (incluido el grupo control) eran portadores de implantoprótesis fijas, con mejor estabilidad y facilidad para masticar que una prótesis removible.[59,89,90] Sin embargo, a pesar de la ausencia de diferencias significativas en los resultados arrojados por ambos cuestionarios, los usuarios de prótesis híbridas mostraron una tendencia a expresar una menor satisfacción que los otros pacientes (Tabla 4). De hecho, cuando los implantes son angulados o colocados labialmente con

respecto a la posición dental prevista como resultado de reabsorción ósea severa o maloclusión maxilo-mandibular (indicaciones para el tratamiento con prótesis híbridas), los orificios de acceso pueden comprometer la estética y la oclusión más que en el caso de las restauraciones atornilladas.[104,105]

También se analizó la influencia moduladora de las variables de estudio en la calidad de vida. El perfil sociodemográfico de los voluntarios que informaron mayor malestar psicológico fue el de mujeres no escolarizadas, lo que fue detectado consistentemente con ambos cuestionarios (QoLIP–10 y OHIP–14sp) (Tabla 1). Los pacientes con estudios universitarios reportaron significativamente mayores niveles de satisfacción que los no escolarizados (Tabla 1). Estos hallazgos están en línea con la investigación en salud pública que correlaciona un nivel socioeconómico más bajo con menor salud.[106] Al igual que en investigaciones previas,[95,107] los hombres mostraron significativamente mejor satisfacción que las mujeres.

Las diferencias psicológicas entre hombres y mujeres podrían ayudar a explicar el posible efecto del género en la percepción de satisfacción por parte del paciente.[108] La edad no fue un factor modulador del bienestar, lo que concuerda con los resultados de un estudio sobre portadores de prótesis completas convencionales llevado a cabo en la misma población de referencia.[92] Los pacientes ancianos, sin embargo, tienden a mostrarse más insatisfechos que los más jóvenes (Tabla 1). Esto concuerda con la evidencia de que la salud bucal empeora con el envejecimiento, debido principalmente a la natural e inevitable pérdida de dientes.[109] Los participantes sin pareja tienden a considerar que el estado de su salud bucal es peor que el de los pacientes casados. Aunque son necesarios más estudios sobre la capacidad moduladora del estado civil en la auto-percepción de OHRQoL, Perea y cols.[92] encontraron la misma tendencia, mientras que Preciado y cols.[99] observaron mayor insatisfacción en los participantes casados que habían cursado un régimen especial de enseñanza.

A pesar de la ausencia de diferencias significativas, una tendencia a percibir una mayor QoL se asoció con mayores frecuencias de cepillado dental y más visitas anuales al dentista (Tabla

1), lo que hace hincapié en la importancia de enseñar a los pacientes prácticas de hábitos saludables,[65] y a identificar los primeros síntomas, no dolorosos de problemas bucales.[94] De acuerdo con la literatura, lógicamente, los pacientes que se quejaron de su boca, percibieron necesidad de tratamiento dental y requirieron cambiar la prótesis reportaron una menor QoL, siendo estas diferencias significativas[9,91,92] (Tabla 1).

La evaluación continua de la satisfacción de los pacientes dentales permite verificar que las necesidades de la sociedad están siendo satisfechas.[110] Pese al origen único de los pacientes (clínica odontológica universitaria), el uso de una muestra heterogénea (Tabla 1) facilita la extrapolación de nuestros resultados a otros países.[9,91,92] La validación de los resultados de este estudio en otros contextos ofrecería retroalimentación interesante sobre la administración de este nuevo índice.[111]

8. CONCLUSIONES

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Dentro de las limitaciones de la investigación desarrollada se pueden extraer las siguientes conclusiones:

- A partir de la aplicación del OHIP–14 en usuarios de implantoprótesis, se encontró que los principales factores que pueden influenciar la satisfacción y auto-percepción de calidad de vida son aquellos que están relacionados con la salud bucal, la habilidad o función masticatoria, y el diseño y estado de la prótesis. Estos factores han de tenerse en cuenta para la elaboración de índices de medición de OHRQoL.

- En el presente estudio se diseñó y validó un cuestionario corto y específico para usuarios de prótesis sobre implantes, llamado QoLIP–10 (Calidad de vida con Implanto-prótesis), el cual demostró tener propiedades psicométricas adecuadas para medir el impacto de las implantoprótesis (grupos testados: prótesis híbridas, sobredentaduras implanto-retenidas e implantoprótesis atornilladas) en la calidad de vida asociada al estado de salud oral.

- Las principales variables que modularon el nivel de autopercepción de bienestar de pacientes rehabilitados con prótesis implantológicas fueron: el género, el nivel de educación, las quejas sobre la boca, la percepción de la necesidad de tratamiento dental, el estado de la prótesis, el tipo de retención (en el caso de las sobredentaduras) y la existencia de dolor bucal y de dificultades en la masticación.

- La aplicación del QoLIP–10 en portadores de implantoprótesis permitió concluir: *(a)* Las prótesis híbridas son la opción de tratamiento más predecible para mejorar la satisfacción

del paciente en términos de dolor bucal y masticación en comparación con las sobredentaduras implanto-retenidas y las prótesis completas convencionales. *(b)* La extensión (parcial o total) de las restauraciones atornilladas sobre implantes no afectó a la medición del bienestar de los pacientes, aunque éstas se mostraron superiores a las prótesis híbridas en términos de autopercepción de estética y funcionalidad.

- Los resultados obtenidos de la medición de calidad de vida relacionada con el estado de salud oral en portadores de implantoprótesis mediante cuestionarios y registro de variables clínicas, pueden ayudar al odontólogo a anticipar qué tipo de tratamiento protético será con mayor probabilidad el que obtendrá una mejor autopercepción subjetiva según los casos.

9. REFERENCIAS

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10. ANEXOS

10.1. ANEXO 1. Cuestionario QoLIP–10 validado para usuarios de sobredentaduras y prótesis híbridas implantológicas (en español).

** Por favor indique su grado de acuerdo con las siguientes afirmaciones y proporcione la puntuación adecuada en cada caso:*

Calidad de vida con implantoprótesis (QoLIP–10) *para usuarios de sobredentaduras y prótesis híbridas implantológicas*		**Totalmente en desacuerdo** **(- 2)**	**En desacuerdo** **(- 1)**	**Indeciso, indiferente, neutro** **(0)**	**De acuerdo** **(+ 1)**	**Totalmente de acuerdo** **(+ 2)**
Puntuación por ítem y por dimensión*						
D1.	***BIOPSICOSOCIAL***					
1.	Vd. nunca ha sentido molestias dolorosas relacionadas con su implantoprótesis.					
2.	Vd. mastica satisfactoriamente con su implantoprótesis.					
3.	Vd. nunca ha estado preocupado o estresado debido a problemas con su implantoprótesis.					
4.	Vd. nunca ha estado malhumorado con los demás por problemas con su implantoprótesis.					
5.	Vd. nunca ha tenido dificultad para realizar sus actividades diarias por problemas con su implantoprótesis.					
D2.	***ESTÉTICA DENTO-FACIAL***					
6.	Vd. está satisfecho con la apariencia estética de su implantoprótesis.					
7.	Vd. está satisfecho con la naturalidad (realismo) de su implantoprótesis.					
8.	Vd. está satisfecho con su sonrisa.					
D3.	***RENDIMIENTO FUNCIONAL***					
9.	Vd. nunca ha tenido dificultades o limitaciones para hablar, debido al uso de su implantoprótesis.					
10.	Vd. nunca ha tenido dificultad para realizar su higiene oral debido a su implantoprótesis.					
Puntuación total delQoLIP–10*						

* La puntuación total y la puntuación de cada dimensión será la suma de los marcajes de todos los ítems (los signos negativos o positivos deben considerarse). Cuanto mayor sea la puntuación total, mayor será la satisfacción del paciente (es decir, que los resultados negativos o bajos positivos indican pobre auto-percepción de QoL).

D1, D2, y D3: dimensiones del índice QoLIP–10.

10.1. ANEXO 1. Cuestionario QoLIP–10 validado para usuarios de sobredentaduras y prótesis híbridas implantológicas (en inglés: *QoLIP–10 index validated for implant-retained overdenture and hybrid prosthesis wearers).*

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

Quality of Life with Implant-Prostheses (QoLIP–10) ***for implant-retained overdenture and hybrid prosthesis wearers***		**Strongly disagree** **(- 2)**	**Disagree** **(- 1)**	**Indecisive, indifferent or neutral** **(0)**	**Agree** **(+ 1)**	**Strongly agree** **(+ 2)**
Item and dimensional scores*						
D1.	***BIOPSYCHOSOCIAL***					
1.	You have never had oral pain related to wearing implant prostheses.					
2.	You have a satisfactory chewing function with your implant prosthesis.					
3.	You have never been worried/concerned because of problems with your implant prosthesis.					
4.	You have never been angry with others because of problems with your implant prosthesis.					
5.	You have never had difficulties in doing daily living activities because of problems with your implant prosthesis.					
D2.	***DENTAL-FACIAL AESTHETICS***					
6.	You are satisfied with the appearance of your implant prosthesis.					
7.	You are satisfied with the realism of your implant prosthesis.					
8.	You are satisfied with your smile.					
D3.	***PERFORMANCE***					
9.	You have never had speech difficulties or restrictions related to wearing implant prostheses					
10.	You have never had oral hygiene difficulties due to the implant prosthesis					
Total score of the QoLIP–10 scale*						

*The dimensional and total scores can be obtained by adding the respective item scores (their negative or positive signs must be considered). The higher the summary score is, the higher the satisfaction of the patient is (meaning that negative or low positive scores indicate poorer self-perceived QoL).

D1, D2, and D3: dimensions of the QoLIP–10 index.

10.2. ANEXO 2. Cuestionario QoLIP–10 validado para usuarios de implantoprótesis atornilladas (en español).

** Por favor indique su grado de acuerdo con las siguientes afirmaciones y proporcione la puntuación adecuada en cada caso:*

	Calidad de vida con implanto-prótesis (QoLIP–10). ***para usuarios de implanto-prótesis atornilladas***	**Totalmente en Desacuerdo (- 2)**	**En desacuerdo (- 1)**	**Indeciso, indiferente, neutro (0)**	**De acuerdo (+ 1)**	**Totalmente de acuerdo (+ 2)**
Puntuación por ítem y por dimensión*						
D1.	***BIOPSICOSOCIAL***					
1.	Vd. nunca ha sentido molestias dolorosas relacionadas con su implantoprótesis.					
2.	Vd. nunca ha estado preocupado o estresado debido a problemas con su implantoprótesis.					
3.	Vd. nunca ha estado malhumorado con los demás por problemas con su implantoprótesis.					
4.	Vd. nunca ha tenido dificultad para realizar sus actividades diarias por problemas con su implantoprótesis.					
D2.	***ESTÉTICA DENTO-FACIAL.***					
5.	Vd. está satisfecho con la apariencia estética de su implantoprótesis.					
6.	Vd. está satisfecho con la naturalidad (realismo) de su implantoprótesis.					
7.	Vd. está satisfecho con su sonrisa.					
D3.	***RENDIMIENTO FUNCIONAL***					
8.	Vd. mastica satisfactoriamente con su implantoprótesis.					
9.	Vd. nunca ha tenido dificultades o limitaciones para hablar, debido al uso de su implantoprótesis.					
10.	Vd. nunca ha tenido dificultades para realizar su higiene oral debido a su implantoprótesis.					
Puntuación total del QoLIP–10*						

* La puntuación total y la puntuación de cada dimensión será la suma de los marcajes de todos los ítems (los signos negativos o positivos deben considerarse). Cuanto mayor sea la puntuación total, mayor será la satisfacción del paciente (es decir, que los resultados negativos o bajos positivos indican pobre auto-percepción de QoL).

D1, D2, y D3: dimensiones del índice QoLIP–10.

10.2. ANEXO 2. Cuestionario QoLIP–10 validado para usuarios de implantoprótesis atornilladas (en inglés: QoLIP–10 index validated for screwed implant prosthesis wearers).

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

	Quality of Life with Implant-Prostheses (QoLIP–10). ***for screwed implant-supported denture wearers***	**Strongly disagree** **(- 2)**	**Disagree** **(- 1)**	**Indecisive, indifferent or neutral** **(0)**	**Agree** **(+ 1)**	**Strongly agree** **(+ 2)**
	Item and dimensional scores*					
D1.	***BIOPSYCHOSOCIAL***					
1.	You have never had oral pain related to wearing implant prostheses					
2.	You have never been worried/concerned because of problems with your implant prosthesis					
3.	You have never been angry with others because of problems with your implant prosthesis					
4.	You have never had difficulties in doing daily living activities because of problems with your implant prosthesis					
D2.	***DENTAL-FACIAL AESTHETICS***					
5.	You are satisfied with the appearance of your implant prosthesis.					
6.	You are satisfied with the realism of your implant prosthesis					
7.	You are satisfied with your smile					
D3.	***PERFORMANCE***					
8.	You have a satisfactory chewing function with your implant prosthesis					
9.	You have never had speech difficulties or restrictions related to wearing implant prostheses					
10.	You have never had oral hygiene difficulties due to the implant prosthesis					
Total score of the QoLIP–10 scale*						

*The dimensional and total scores can be obtained by adding the respective item scores (their negative or positive signs must be considered). The higher the summary score is, the higher the satisfaction of the patient is (meaning that negative or low positive scores indicate poorer self-perceived QoL).

D1, D2, and D3: dimensions of the QoLIP–10 index.

10.3. ANEXO 3.

Abstract:

The assessment of OHRQoL of a community is necessary to formulate a patient-centered and culturally accepted oral health policy. Dental education also requires to be refocused to incorporate the concept of OHRQoL in the curriculum. Various measures for the assessment of OHRQoL are available in the literature. This paper discusses the development of a short questionnaire to accurately and efficiently assess the OHRQoL of implant-prosthesis users.

Accordingly, this Thesis has been divided into three successive articles published in Journal of Dentistry, which is a JCR journal situated in the upper quartile of the specialty (7/82).

The first article was entitled: ***"Differences in impact of patient and prosthetic characteristics on oral health-related quality of life among implant-retained overdenture wearers"*** The aim of the study was to evaluate the oral health-related quality of life (OHRQoL) of implant-retained overdenture users.

63 patients aged 50-90 years treated with at least one implant overdenture at the Complutense University (Madrid) in 2000-2010 were included. Of those, 42 answered the Oral Health Impact Profile (OHIP–14sp) questionnaire. The additive method was used in OHIP analysis. Data regarding sociodemographic background, overdenture features, and clinical factors were recorded. Sociodemographic and overdenture-related variables for the lost patients (n = 21) were also gathered from their history files. Descriptive probes, Mann-Whitney and Kruskal-Wallis tests, and the Spearman correlation coefficient were applied ($p \leq 0.05$).

The predominant participants' profile was that of a 71- to 80-year old woman wearing a mandibular overdenture with a bar retention system and a complete denture in the opposite jaw. 71.4% of the respondents suffered from some kind of impact on OHRQoL, showing an average score of 2.7 ± 3.0 (range: 0 – 3). 100% of respondents reported no impact for the "social disability" and "handicap" dimensions. The most prevalently affected domain was "physical pain", followed by "functional limitation" and "psychological discomfort". Variables such as the overdenture location or the retention system affected specific OHIP subscales ($p \leq 0.05$). The greatest total score was achieved when the antagonist was a complete denture ($p < 0.01$).

The study concluded that implant-retained overdentures provide a seemingly acceptable quality of life in the elderly population studied irrespective of the influence of the location, retention system, and antagonist.

The clinical significance of this study was that mandibular implant overdentures are more comfortable than maxillary ones. Ball-retained prostheses facilitate eating the most, whereas the presence of oral ulcers and/or candidiasis was only detected in the case of bars, thus impairing OHRQoL. A complete denture as antagonist decreases the patient overall satisfaction.

The second article, entitled: ***"A new, short, specific questionnaire (QoLIP-10) for evaluating the oral health-related quality of life of implant-retained overdenture and hybrid prosthesis wearers";*** aimed to validate a new questionnaire for assessing the oral health-related quality of life (OHRQoL) of implant-prosthesis wearers.

A group of specialists designed the 10-item scale, "Quality of Life with Implant-Prostheses" (QoLIP–10). After completing a pilot trial, 150 subjects wearing implant-prostheses or complete dentures who were not requesting dental treatment participated in the main investigation. They were divided into three groups (n = 50 each) depending on the type of dental restoration. Group 1 (CD): complete denture wearers (control); Group 2 (IO): implant-retained overdenture wearers and Group 3 (HP): subjects with fixed implant hybrid prostheses.

Participants answered the QoLIP–10 and the Oral Health Impact Profile (OHIP–20sp) questionnaires. Information on global oral satisfaction, socio-demographic, health-behavioural, clinical and prosthetic-related data were gathered. The psychometric characteristics of the QoLIP–10 were investigated. The Spearman's rank correlation test was used to determine the association between the total scores of the QoLIP–10 and OHIP–20sp.

Descriptive and non-parametric probes were run to evaluate the impact scores obtained depending on the study variables.

The QoLIP–10 scale resulted reliable and valid. The factor analysis confirmed the existence of three dimensions and meaningful inter-correlations among the 10 items.

The first factor, named biopsychosocial dimension, was the most explanatory (28.21% of variance). This factor was formed by the combination of Items 1, 3, 5, 6 and 7 (oral pain, chewing difficulty, worry/concern, communication/social relations and activities of daily living, respectively). The second factor, called dental-facial aesthetics dimension comprised Items 8, 9 and 10 (satisfaction with the prosthesis' appearance, satisfaction with the realism of the prosthesis and satisfaction with the smile, respectively). Finally, the third factor, which was designated as performance dimension, included Items 2 and 4 (speaking difficulty or restriction and oral hygiene difficulty, respectively).

HP wearers demonstrated better biopsychosocial QoL, as indicated by their answers to Item 1 (oral pain) and Item 3 (chewing difficulty).

In conclusion, the QoLIP–10 index confirmed its psychometric capacity for assessing the OHRQoL of implant overdenture and hybrid prosthesis wearers. Overall, the participants were satisfied with their mouth and implant-restorations.

The clinical significance of this study was that the QoLIP–10 may be recommended for determining the influence of implant-retained overdentures and hybrid prostheses on the

well-being of future patients. Hybrid prostheses are the most predictable treatment option for improving patient satisfaction in terms of oral pain and chewing functionality when compared to implant overdentures and complete dentures.

Finally, in the third article, entitled: ***"Impact of various screwed implant prostheses on oral health-related quality of life as measured with the QoLIP–10 and OHIP–14 scales: A cross-sectional study";*** aimed to validate the Quality of Life with Implant-Prostheses (QoLIP–10) questionnaire for assessing the impact of screwed implant-supported rehabilitations on oral health-related quality of life (OHRQoL).

131 patients wearing screw-retained implant restorations were assigned to the following groups: Group 1 (HP; *n* = 50): fixed-detachable hybrid prostheses (control), Group 2 (S-PD; *n* = 43): metal-ceramic screwed partial dentures, and Group 3 (S-CD; *n* = 38): metal-ceramic screwed complete dentures. Impacts on OHRQoL were evaluated using the QoLIP–10 and Oral Health Impact Profile (OHIP–14sp) scales. Data on global oral satisfaction, socio-demographics, health-behaviours, and prosthetics were gathered. Reliability and validity of the QoLIP–10 were investigated for screwed prosthesis wearers.

The Spearman's rank test was applied to determine the correlation between both indices. Descriptive and non-parametric probes were run to evaluate the influence of the study variables on OHRQoL.

The study results confirmed the psychometric capacity of the QoLIP–10 for measuring the OHRQoL in screwed prosthesis wearers.

The factor analysis resulted in the following distribution of the items: biopsychosocial dimension (composed of: Item 1: oral pain, Item 3: worry/concern, Item 4: communication/social relations, and Item 5: activities of daily living); dental-facial aesthetics dimension (containing: Item 6: satisfaction with the prosthesis' appearance, Item 7: satisfaction with the realism of the prosthesis, and Item 8: satisfaction with the smile); and performance dimension (consisting of:

Item 2: chewing difficulty, Item 9: speaking difficulty or restriction and Item 10: oral hygiene difficulty).

Both tests were inversely correlated. HP wearers reported the worst dental-facial aesthetics, performance, and functional limitation outcomes. Gender, education level, complaints about the mouth, perception of treatment needs, and prosthetic status modulated the OHRQoL.

This study concluded that screwed implants restorations provide better OHRQoL than do fixed-detachable hybrid prostheses.

The clinical significance of this study showed that the QoLIP–10 may be recommended for estimating the effect of various screwed implant prostheses on the well-being of future patients, which may be relevant to decision-makers and researchers. When compared to fixed-detachable hybrid prostheses, screwed restorations lead to greater improvements in patients' self-perceived aesthetics and functionality.

GENERAL CONCLUSION OF THE ENTIRE INVESTIGATION

As a global conclusion of the three papers, a new specific OHRQoL questionnaire for implant prosthesis users has been validated. This is relevant, as, to date; only general scales on QoL were available. Crossing the OHRQoL results with sociodemographic, clinic and prosthesis-related data, the authors found that these features are modulators of the level of patient satisfaction. This may help to predict the success of different types of implant prosthesis treatments and may also contribute to choose the best prosthesis design.