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'Role of the modulating factors on the self-perceived OHRQoL of fully dentate subjects and wearers of screw-retained and cement-retained implant-supported FPDs: A cross-sectional study'

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ABSTRACT

Objectives: This research aimed to compare the oral health-related quality of life (OHRQoL) between fully dentate subjects and edentulous patients wearing implant-supported fixed partial dentures (i-FPDs). The clinical conditions of both types of restorations were evaluated.

Methods: Participants were assigned to: Group-1 (SR, $n = 50$): screw-retained i-FPD wearers; Group-2 (CR, $n = 50$): cement-retained i-FPD wearers; and Group-3 (ND, $n = 50$): dentate subjects with a healthy natural dentition *(controls)*. Patients answered the OHIP-14sp and QoLIP-10 questionnaires. Data related to sociodemographics, prosthesis features, peri-implant *status,* complications, and subjective evaluations, were compiled. Potential modulators of the OHRQoL and the i-FPDs' clinical conditions were assessed using non-parametric tests ($\alpha = 0.05$).

Results: ND individuals were the least satisfied (OHIP-14sp; $p < 0.001$). Both prosthodontic groups reported similar levels of wellbeing, excluding the speaking difficulties, which were lower for SR wearers as shown by both scales ($p = 0.001$). The most discontented patients (OHIP-14sp) were: women ($p = 0.022$), under 65 years ($p = 0.03$), without partner ($p < 0.001$) and having a crown ($p = 0.033$). The *level of education/schooling* also affected the OHIP-14sp scores ($p < 0.001$). *Implant mobility* and *peri-implantitis* were more frequent among CR wearers (p-values$= 0.008$ and 0.05, respectively).

Conclusions: The OHRQoL of both prosthodontic groups was comparably higher than that of the dentate subjects, who were the most nonconformist. The self-perceived satisfaction was mainly modulated by sociodemographic factors.

Clinical significance: Overall, the retention system did not impact the OHRQoL, prosthetic problems, and subjective evaluations of i-FPD wearers. However, the cementation may increase the risk of peri-implant diseases.

1. Introduction

Nowadays, the awareness of the importance of oral health and dental care, together with the gradual aging of our society, may explain the large numbers of partially edentate patients requesting prosthodontic treatment [1–3]. In the European countries, the annual incidence of subjects losing ≥ 1 teeth ranges from 1% to 14% [4]. Apart from removable and tooth-supported partial prostheses, implant-supported fixed partial dentures (i-FPDs) are increasingly more demanded because of their high survival rates and proper fixation without requiring tooth preparation [1-3,5]. The i-FPDs' superstructures may be screwed (SR) or cemented (CR); or even cemented with lingual/palatal fastening screws. Such retention systems make the prostheses substantially different about their construction, biomechanics, and aesthetics; which may impact the patients' satisfaction depending, as well, on other factors [2,6-10].

Undoubtedly, the achievement of optimal technical results and improved wellbeing of our patients is still a challenge. On the one hand,

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SR i-FPDs provide retention in reduced prosthetic spaces and are retrievable, which facilitates the peri-implant maintenance and the solution of biological and/or technical complications, including the modification of the prosthesis in case of adjacent tooth loss [8,11,12]. However, given that the screw channels interrupt the structural integrity of the restorations, the aesthetics, implants' axial load, occlusal stability, and ceramic strength may be negatively affected. Moreover, the screw loosening or fracture may occur as a consequence of an incorrect design, an inadequate occlusion, or an insufficient pre-load, among others [6,7,13-16].

On the other hand, the main advantages of CR i-FPDs are: the easy for obtaining a passive fit with simplified clinical and laboratory procedures, the lower fabrication costs, and the functional and esthetic benefits derived from the use of luting materials instead of screws [17–19]. Nevertheless, SR i-FPDs are the first option in the presence of subgingival margins, because the peri-implant health may be seriously compromised by inaccessible cement residuals left in the gingival sulcus [20–22]. In a CR i-FPD, the loads are axially transmitted thanks to the absence of chimneys, which preserves the implant/bone interface [7,17,18]. The greater seal and retention exerted by the cement seems to protect the abutment from loosening, in contrast with the gaps formed in a screwed union [23].

The decision as to which retention system best suits each patient is difficult to take, because, overall, the pros of the SRs coincide with the cons of the CRs, and vice versa [3,6,11,24]. The choice will depend on the individual case, the dentist preferences, and the realistic expectations that should be reached regarding the patient's happiness [8,25]. Thus, our research aimed to analyze and compare the OHRQoL between wearers of SR and CR i-FPDs and subjects with a fully and healthy natural dentition (who reflected the best oral situation possible). Differences in the clinical conditions of both types of rehabilitations were also evaluated. Pertinent OHRQoL indices were used and potential conditioning variables were explored. Given the lack of this type of evidence, and always seeking the best for our patients, we consider essential to delve into these methodological issues [26–31].

The null hypotheses tested were that: (a) there are no significant differences in OHRQoL between wearers of SR i-FPDs, CR i-FPDs, and dentate subjects, while both prosthodontic groups will show similar clinical conditions; and that (b) the patient satisfaction is not influenced by sociodemographic data, prosthesis-related features, peri-implant health *status*, prosthetic problems, peri-implant diseases, and subjective evaluations, despite the type of retention of the i-FPD.

2. Methods

2.1. Study protocol

This is an observational cross-sectional study in which the patients did not receive any intervention. They were clinically evaluated, and freely answered a series of QoL-related questions.

2.1.1. Study sample

To avoid potential biases, objective selection criteria were firstly established, which made it possible to configure the reference population without involving subjective variables. The inclusion criteria consisted of: patients who had been prosthetically rehabilitated at the Specialist Postgraduate Course in Implant Prosthodontics of the Complutense University of Madrid, U.C.M. (Spain) over a fifteen year period (starting in 2002), with at least one screw-retained (SR) or one cement-retained (CR) metal-ceramic i-FPD, restoring 1 to 3 spaces and fitting onto 1 to 3 implants (either being crowns or bridges). In compliance with the inclusion criteria, the patients were recruited following a non-probabilistic consecutive sampling procedure from the authorised revision of the medical records of our institution's database. This methodology avoided probable cognitive biases, derived from subjective judgments that might have affected the researchers' perceptions during the selection process. As a result, the reference population included 140 partially edentulous patients, aged from 43 to 80 years, and restored with either a SR or a CR that had been in operation between 1 and 15 years. To avoid misinterpretations of the findings, and following the protocol of preceding related studies [29-31,33], these series of exclusion criteria were then applied: *(a)* patients with cognitive impairments to understand the study and/or answer the questions, as well as patients with serious systemic diseases and/or movement disorders; *(b)* patients whose implants had failed before or after loading; *(c)* patients seeking dental treatment; *(d)* patients rehabilitated with the combination of two different types of prostheses belonging to the experimental groups (SR + CR i-FPDs); and *(e)* patients who, after being informed about the

Table 1
Balance of the exclusion criteria applied to the reference population.

Patients excluded from the reference population (n = 40/140)			
Exclusion criteria	**SR**		**CR**
		***n* (%)**	
a) Patients with cognitive impairment, serious illness, and/or movement disorders	1 (0.71%)		2 (1.43%)
b) Patients who had lost implants	3 (2.14%)		1 (0.71%)
c) Patients who were demanding dental treatment	9 (6.43%)		5 (3.57%)
d) Patients restored with the combination of SR + CR		8 (5.71%)	
e) Patients who refused to participate (rejection rate)	4 (2.86%)		7 (5%)
Total of patients excluded separately in each group	17 (12.14%)		15 (10.71%)
Total of patients excluded jointly in both groups		8 (5.71%)	
Total of patients excluded from the reference population	**40 (28.57 %) =** 17 (12.14%) + 15 (10.71%) + 8 (5.71%)		

Footnote: SR = Wearers of screw-retained implant-supported fixed partial dentures (i-FPDs). CR = Wearers of cemented-retained i-FPDs.

study, refused to participate. The numbers and percentages of subjects who were discarded based on each of the listed *(a)-(d)* points are detailed in the Table 1. With this selection method, 40 patients were excluded from the reference population of 140 subjects.

Hence, the final sample was composed of 100 volunteers who satisfied the set of inclusion principles and did not meet any exclusion criteria (Table 1). Two study groups were configured (depending on the retention system of the implant prostheses worn by the patients), whose acronyms have already been defined: Group 1 (SR, $n = 50$): screw-retained i-FPD wearers; and Group 2 (CR, $n = 50$): cement-retained i-FPD wearers. In addition, a control group of young voluntary students of our University, with a complete and healthy natural dentition (i.e., with no oral pathologies and not seeking dental treatment), was included (ND, $n = 50$). The participation of the ND group allowed the comparison of the OHRQoL between healthy subjects and partially edentate patients rehabilitated with i-FPDs [33]. After being contacted by phone or by e-mail, the 150 participants were scheduled for an appointment free of charge.

The sample size was estimated to detect a clinically significant difference of 4.5 [32], considering a power of 95% and an alpha significance level of 0.05. With these parameters, each group should include 31 individuals (i.e., 93 in total). Upon over-sampling, we achieved a larger effective sample size.

All prosthodontic rehabilitations were carried out by postgraduate students, who conducted the treatments based on the protocols established in our Faculty under the professors' supervision. Hence, the prostheses' fabrication was step-by-step evaluated by expert prosthodontists, who gave their final approval to discharge the patient once the i-FPD attained the standards requested.

This work was conducted in full accordance with the ethical principles of medical investigation involving human subjects under the World Medical Association Declaration of Helsinki (http://www.wma.net) and the Spanish Law 14/2007, for Biomedical Research (https://www.boe.es/eli/es/l/2007/07/03/14). The volunteers were briefed about the study. Written informed consents were acquired from all of the participants. The approval of the Ethics Committee of the San Carlos University Hospital of Madrid, Spain (C.I. 12/242-E) was obtained. Following the the Spanish Organic Law 3/2018, on the Protection of Personal Data and Guarantee of Digital Rights (https://www.boe.es/eli/es/lo/2018/12/05/3), the subjects' anonymity was preserved, and their privileges were always protected [29-31,33].

2.1.2. Data gathering

Aided by a qualified interviewer who asked the questions, SR and CR i-FPD wearers were administered two OHRQoL scales: the OHIP-14sp [27], and the QoLIP-10 [29]. Both indices had been previously validated in the Spanish populatio and have been described in detail [27, 29-31]. The OHIP-14sp generic questionnaire was applied in the three groups, while the QoLIP-10 was not used in dentate patients, because this specific test was conceived for wearers of implant restorations.

When answering the OHIP-14sp ('Oral Health Impact Profile'), the patients scored the frequency of appearance of 14 situations of impact throughout 14 items or questions (Q), which were related to the i-FPDs in the case of SR and CR wearers. Such items are conceptually assigned to seven 'subscales', 'dimensions' or 'domains' (D), as follows: D1: 'Functional limitation' (Q1: You have trouble pronouncing words & Q2: You have worse taste); D2: 'Physical pain' (Q3: You have detected the presence of sore spots & Q4: You have discomfort with the restoration); D3: 'Psychological discomfort' (Q5: You are worried & Q6: You are tense); 'D4: Physical disability' (Q7: You have an unsatisfactory diet & Q8: You have interrupted meals); D5: 'Psychological disability' (Q9: You have disturbed sleep & Q10: You feel embarrassed); D6: 'Social disability' (Q11: You are irritable with others & Q12: You have difficulties doing jobs); and D7: 'Handicap' (Q13: You live an unsatisfying life & Q14: You are unable to function). As the dimensions of this index have self-explanatory names, we decided to report the OHIP-14 subscales' scores (instead of the items' ones) in order to simplify the interpretation of the results without loosing relevant information.

The frequency was codified using a classic Likert-type scale with five options [34,35]. The impact responses per item may be: 'hardly ever' (score: +1), 'occasionally' (score: +2), 'fairly often' (score: +3), and 'very often' (score: +4). The 'never' response (score: 0) represents the absence of impact. The OHIP-14sp outcome variable ranges from 0 to 56. With this scale, the higher the total score is, the higher the negative impact on the patient's OHRQoL is, and, therefore, the lower the satisfaction and wellbeing of the patient is [27].

The QoLIP-10 ('Quality of Life with Implant Prostheses') includes 10 items that are referred to the i-FPD worn by the patient in all cases. Such questions (Q) were initially divided into three dimensions (D) for SR wearers in this way: D1: 'Biopsychosocial' (Q1: You have never had oral pain, Q2: You have never been worried/concerned, Q3: You have never been angry with others because of problems with the prosthesis & Q4: You have never had difficulties in doing daily living activities); D2: 'Dental-facial aesthetics' (Q5: You are satisfied with the prosthesis appearance, Q6: You are satisfied with the realism of the i-FPD & Q7: You are satisfied with your smile); and D3: 'Performance' (Q8: You have a satisfactory chewing function, Q9: You have never had speaking difficulties or restrictions & Q10: You have never had oral hygiene difficulties) [29-31,33]. The QoLIP-10 questionnaire was validated for SR wearers in the reference population with the described item distribution [30]. However, the validation of this index for CR wearers in our country resulted in a re-organization of the items per domain by virtue of the required mathematic procedures [31]: D1: 'Biopsychosocial' (Q1, Q3, Q4 & Q9); D2: 'Dental-facial aesthetics' (Q6, Q7 & Q8); and D3: 'Performance' (Q2, Q5 & Q10). Therefore, the items of the QoLIP-10 are equally formulated for both prosthodontic groups, but they are differently assigned to the subscales depending on the retention system (screws or cement). As this study includes both types of i-FPDs, we have reported the QoLIP-10 scores per item instead of per domain, as it would not make sense to compare dimensions having the same name but containing different questions.

The responses of the QoLIP-10 are intuitive and expressed on a Likert-type scale [34,35] with proportional codes for the degrees of impact. The items evaluated as < 0 are considered to have a negative effect, while the values registered as +1 and +2 represent the positive side of each item (or at least, the absence of a negative impact). The possible responses are: 'strongly disagree' (score: −2), 'disagree' (score: −1), 'indecisive, indifferent, or neutral' (score: 0), 'agree' (score: +1), and 'strongly agree' (score: +2). The total QoLIP-10 score was the sum of all item scores, so that both negative and positive impacts contributed to the final punctuation. The total or summary score of the QoLIP-10 may range from −20 to +20 in such a way that the higher the score is, the higher the satisfaction of the patient is (meaning that negative or low positive scores indicate poorer OHRQoL) [29-31,33].

The completed forms of the questionnaires were placed in sealed envelopes and/or stored in a computer folder protected by a password. All of the evaluations made were linked by a unique identification code for each participant. No names, surnames, or other official ID identifications were consigned in any case to ensure the anonymity of the study subjects [36].

To explore the potential modulators of the patients' self-perceptions concerning their OHRQoL (groups: SR, CR and ND) and the clinical conditions of the prostheses of SR and CR wearers, a trained operator applied the diagnostic methodology published by the World Health Organization (WHO) for buccodental examinations [37]. The groups of study variables are explained below.

Group 1 of variables: 'Sociodemographic characteristics' [31,33,36]. Within this category, two *age* ranges were established both in the ND and in the prosthodontic groups to statistically balance the subgroups' sizes [38]. Concerning the *partnership status*, divorced, single, and widower patients were grouped as 'without partner'; while those patients who were married or who lived with their girlfriend/boyfriend were pooled

Table 2
Description of the sample and impact of the variables of Groups 1 and 2 on the OHRQoL.

Study variables	**Descriptive statistics ($n = 150$) % (n)**			**OHIP-14sp total score: crossing variables** Mean (SD)	*p*-values ($n = 150$) **SR + CR + ND**	**QoLIP-10 total score: crossing variables** Mean (SD)	*p*-values ($n = 100$) **SR + CR**
Sociodemographic characteristics (Group 1 of variables)							
	SR ($n = 50$)	**CR** ($n = 50$)	**ND** ($n = 50$)				
Gender							
Men (M)	34% (17)	64% (32)	26% (13)	2.44 (3.92)	0.022 * [b]	17.86 (2.75)	
Women (W)	66% (33)	36% (18)	74% (37)	5.7 (7.66)	*QoL: W* < M	15.98 (4.77)	0.08 NS [b]
Age (ND; n = 50)							
< 25 years old	N/A	N/A	56% (28)	8.93 (7.06)		N/A	N/A
≥ 25 years old	N/A	N/A	44% (22)	10.55 (8.91)	0.604 NS [b]	N/A	
Age (SR + CR; n = 100)							
< 65 years old (Y)	56% (28)	44% (22)	N/A	2.16 (3.45)	*0.03* * [b]	16.58 (3.55)	
≥ 65 years old (O)	44% (22)	56% (28)	N/A	1.26 (3.73)	*QoL: Y < O*	17.22 (4.43)	0.276 NS [b]
Employment status							
With job (WJ)	34% (17)	40% (20)	32% (16)	5.19 (7.72)		16.86 (3.41)	
Without job (WoJ)	66% (33)	60% (30)	68% (34)	3.9 (5.83)	0.499 NS [b]	16.92 (4.35)	0.794 NS [b]
Level of education/schooling							
Basic education (B)	32% (16)	42% (21)	0% (0.0)	0.59 (1.32)		17.73 (2.45)	
Secondary education (S)	20% (10)	22% (11)	58% (29)	7.36 (8.34)	< 0.001** [a]	15.57 (6.48)	0.167 NS [a]
Professional training (P)	6% (3)	10% (5)	28% (14)	6.14 (6.1)	*QoL* (M-*W* + BF):	14.25 (4.5)	
University education (U)	42% (21)	26% (13)	14% (7)	3.12 (5.17)	*S* < B ($p < 0.001$) **	17.44 (2.83)	
					P < B ($p < 0.001$)**		
					S < U ($p = 0.022$) *		
Partnership status							
With partner (WP)	58% (29)	78% (39)	10% (5)	1.84 (4.7)	< 0.001 ** [b]	17.44 (2.94)	
Without partner (WoP)	42% (21)	22% (11)	90% (45)	6.74 (7.2)	*QoL*: WoP < WP	15.75 (5.53)	0.213 NS [b]
Prosthesis-related features (Group 2 of variables)							
	SR ($n = 50$)	**CR** ($n = 50$)					
Date of installation of the i-FPD							
1 - 4 years before	50% (21)	44.2% (19)	N/A	1.92 (3.43)		16.88 (3.17)	
5 - 8 years before	45.2% (19)	34.9% (15)	N/A	1.69 (4.34)	0.417 NS [a]	16.61 (5.4)	0.69 NS [a]
≥ 9 years before	4.8% (2)	20.9% (9)	N/A	1.07 (1.98)		17.67 (2.35)	
Prosthesis span length							
Single crown (C)	42% (21)	46% (23)	N/A	2.34 (3.66)	0.033 * [b]	16.68 (3.47)	
Multiple unit (M)	58% (29)	54% (27)	N/A	1.21 (3.52)	*QoL*: C < M	17.07 (4.41)	0.422 NS [b]

(*continued on next page*)

Table 2 (*continued*)

Study variables	Descriptive statistics ($n = 150$) % (n)			OHIP-14sp total score: crossing variables Mean (SD)	*p*-values ($n = 150$) SR + CR + ND	QoLIP-10 total score: crossing variables Mean (SD)	*p*-values ($n = 100$) SR + CR
Type of antagonist							
Natural dentition	40% (20)	46% (23)	N/A	2.23 (4.2)		16.49 (5.02)	
Fixed prostheses	26% (13)	24% (12)	N/A	0.8 (1.85)	0.257 NS [a]	17.4 (2.74)	0.266 NS [a]
Natural dentition & fixed restorations	28% (14)	30% (15)	N/A	1.83 (3.89)		17.38 (3.3)	
Removable partial dentures	6% (3)	0% (0.0)	N/A	0.67 (1.16)		14 (0.0)	
Location							
Anterior	12% (6)	18% (9)	N/A	0.8 (1.37)		17.47 (2.82)	
Posterior	88% (44)	82% (41)	N/A	1.87 (3.85)	0.666 NS [b]	16.8 (4.19)	0.572 NS [b]
Presence of pontics (only in the case of multiple unit restorations, n = 56)							
Yes	31% (9)	44.4% (12)	N/A	1.67 (5.06)		16.86 (6.15)	
No	69% (20)	55.6% (15)	N/A	0.94 (2.17)	0.828 NS [b]	17.2 (3.02)	0.473 NS [b]

SR = Wearers of screw-retained implant-supported fixed partial dentures (i-FPDs). CR = Wearers of cemented-retained i-FPDs. ND = Fully dentate subjects with a healthy natural dentition. SD = Standard deviation. N/A: Not applicable. (*) = Significant at $\alpha = 0.05$. (**) = Significant at $\alpha = 0.001$. NS = Not significant. ([a]) = Kruskal-Wallis test. ([b]) = Mann-Whitney U test. (M-W + BF) = Mann-Whitney U test + Bonferroni correction. *QoL* = Quality of Life.

in the group 'with partner' (Table 2). Group 2 of variables: 'Prosthesis-related features' [31,38] (Table 2). Group 3 of variables: 'Peri-implant health *status*' [38–40] (Table 3). Group 4 of variables: 'Prosthetic complications & peri-implant diseases' [38–42] (Table 3). Within this sort of factors, the *implant mobility* was explored by exerting a labial-lingual force of approximately 500 g using two rigid instruments, and was then classified according to the Misch's Clinical Implant Mobility Scale [40]. Such classification differentiates the next grades: '0′: absence of clinical mobility in any direction; '1′: slight detectable horizontal movement; '2′: moderate visible horizontal mobility up to 0.5 mm; '3′: severe horizontal movement greater than 0.5 mm; and '4′: visible moderate to severe horizontal mobility and any visible vertical movement. In our study, each i-FPD was scored with the highest grade obtained after evaluating all of its implants. Continuing with the Group 4 of variables, the existence of *peri-implantitis* was annotated when the gum inflammation was accompanied by loss and deterioration of the supporting bone around any of the implants. This was confirmed by radiographs and by the probing depth ($\geq$ 5 mm at any location) [40]. Peri-implant mucositis was registered when the gum inflammation only affected the soft tissues with no signs of bone loss. In that case, the peri-implant mucositis (which is usually a precursor to peri-implantitis that may be reversible if caught early) [40], was classified as: 'Absent' (healthy peri-implant mucosa); 'Moderate' (slight swelling and redness, slight bleeding on gentle probing, but no spontaneous bleeding); or 'Intense' (severe swelling and marked redness, intense bleeding on gentle probing, spontaneous bleeding, and suppuration). Group 5 of variables: 'Functional & esthetic subjective evaluations' [33,38] reported by the patients together with the esthetic assessments made by the dentist. For these scoring, the scale of Weber et al. [21] with values from 1 to 4 was used, where '1′ means 'excellent' and '4′ means 'poor' (Table 3).

The variables of Groups 1–5 (Tables 2 and 3) were recorded for all i-FPD wearers. Conversely, in the ND group, only the sociodemographic data and the OHIP-14sp responses were gathered (Tables 2 and 4). Periodontal and peri-implant parameters were not compared due to the large differences between the union of the tooth and the implant to the surrounding bone.

2.2. Data analysis

Well-established statistical methods for research on OHRQoL were applied [27,30,31,43] using the SPSS software (Statistical Package for the Social Sciences, v. 26.0, IBM, IL, US). The statistical significance was set at α= 0.05. For the both the OHIP-14sp and QoLIP-10 indicators, the additive method (-ADD) [29-31,33,38,43,44] was utilized by adding the item codes at the appropriate frequency to calculate their total scores, as well as the OHIP-14sp dimensional scores.

Descriptive statistics and percentages were calculated for each qualitative and categorical variable, using frequencies and means with standard deviations (SD) [31,35,45]. To analyze the quantitative variables, arithmetic means with SD were given as representative measures of the sample. However, as the Kolmogorov-Smirnov test revealed that the data was not normally distributed, non-parametric probes (based on the comparisons of medians) were selected [29,30,33]. The Chi-Square test was used to cross the percentages of qualitative variables in pairs. The Kruskal-Wallis probe was run for quantitative variables with three or more categories. The Mann-Whitney U test was conducted for quantitative variables with two categories and for pair-wise *post hoc* comparisons. To avoid the risk of a type I error, the *p*-values of the Mann-Whitney U test were adjusted by the Bonferroni correction when multicategorical variables were crossed in pairs [33]. The questionnaires' scores were compared among the study groups using the Kruskal-Wallis test for the OHIP-14sp, and the Mann-Whitney U test for the QoLIP-10. The effect of the Groups 1–5 of variables on the patients' OHRQoL was assessed with the same non-parametric probes [29,30,33,43].

Table 3
Clinical conditions of the i-FPDs (Groups 3–5 of variables) ($n = 100$).

Study variables	Prosthodontic groups evaluated			Mann-Whitney U test, *p-values* ($n = 100$)
	SR ($n = 50$)	CR ($n = 50$)	SR + CR ($n = 100$)	
Peri-implant health *status* (Group 3 of variables)	**Mean (SD)**			
Plaque index (PI)	1.02 (0.820)	0.96 (0.856)	0.99 (0.835)	0.653 NS
Gingival index (GI)	0.96 (0.755)	1.28 (0.858)	1.12 (0.82)	0.055 NS
Keratinized mucosa width (KM)	2.22 (1.799)	2.72 (1.938)	2.47 (1.877)	0.171 NS
Probing depth				
Mesiobuccal probing depth (MB)	3.06 (0.956)	3.48 (1.951)	3.27 (1.543)	0.469 NS
Center-buccal probing depth (CB)	3.06 (1.114)	3.32 (1.932)	3.19 (1.574)	0.971 NS
Distobuccal probing depth (DB)	3.56 (1.643)	3.8 (2.222)	3.68 (1.948)	0.81 NS
Center lingual probing depth (CL)	3.16 (1.330)	3.72 (1.896)	3.44 (1.653)	0.074 NS
Prosthetic complications & peri-implant diseases (Group 4 of variables)	***n* (%)**			**Chi-Square test, *p-values* ($n = 100$)**
Ceramic fracture	14 (28%)	16 (32%)	30 (30%)	0.663 NS
Loosening of the retentive mechanism	5 (10%)	1 (2%)	6 (6%)	0.092 NS
Fracture of the retentive mechanism	0 (0%)	0 (0%)	0 (0%)	N/A
Unsatisfactory occlusion	10 (20%)	7 (14%)	17 (17%)	0.424 NS
Implant mobility	1 (2%)	9 (18%)	10 (10%)	0.008 * (SR < CR)
Peri-implantitis	1 (2%)	6 (12%)	7 (7%)	0.050 NS ^{ms} (SR < CR)
Peri-implant mucositis				
Absent	33 (66%)	28 (56%)	61 (61%)	0.178 NS
Moderate	14 (28%)	13 (26%)	27 (27%)	
Intense	3 (6%)	9 (18%)	12 (12%)	
Functional & esthetic subjective evaluations (Group 5 of variables)	**Mean (SD)**			
				Mann-Whitney U test, p-values ($n = 100$)
Functionality (scored by the patient)	1.26 (0.599)	1.24 (0.555)	1.25 (0.575)	0.836 NS
Aesthetics				
Aesthetics (scored by the dentist)	2.2 (0.699)	2.14 (0.808)	2.17 (0.753)	0.592 NS
Aesthetics (scored by the patient)	1.32 (0.713)	1.16 (0.370)	1.24 (0.571)	0.379 NS
Global evaluation: functionality & aesthetics (scored by the patient)	1.3 (0.647)	1.26 (0.565)	1.28 (0.604)	0.808 NS

SR = Wearers of screw-retained implant-supported fixed partial dentures (i-FPDs). CR = Wearers of cemented-retained i-FPDs. SD = Standard deviation. (*) Significant at $\alpha = 0.05$. NS = Not significant. (^{ms}) This *p*-value of 0.050 was also corroborated by the Fisher's exact test. Some authors consider this outcome as "marginally significant" [46]. N/*A* = not applicable.

3. Results

3.1. Description of the sample

Based on the selection criteria, 40 (28.57%) potential participants were excluded from the reference population ($N = 140$). A total rejection rate of 7.86% was registered, mainly due to time constrains (Table 1). Hence, adding the control group of fully dentate subjects (ND, $n = 50$) the final study sample comprised 150 individuals.

As for the 'Sociodemographic characteristics' (Group 1 of variables; Table 2), which were the only factors assessed in the ND group, the predominant participants' profile was that of a woman (58.67%, $n = 88/150$); younger than 65 years in the SR group (56%, $n = 28/50$), older than or equal to 65 years in the CR group (56%, $n = 28/50$), and younger than 25 years in the ND group (56%, $n = 28/50$); unemployed (64.67%, $n = 97/150$), with secondary education (33.34%, $n = 50/150$), and without partner (51.34%, $n = 77/150$).

With respect to the 'Prosthesis-related features' (Group 2 of variables; Table 2), most of the prosthetic rehabilitations had been *installed* 1–4 years before (40%). There were more multiple unit prostheses (56%) than crowns (44%). This was reflected within each prosthodontic group. The most common *type of antagonist* was natural dentition (43%); situation that was repeated within each i-FPD group. The general *location* was posterior (85%). Only 21 multiple restorations had pontics (37.5%, $n = 21/56$), which were more frequent in the CR than in the SR group (44.4% vs. 31%).

About the 'Peri-implant condition' (Group 3 of variables; Table 3), the *plaque index, the gingival index, the keratinized mucosa width,* and *the probing depth* (measured at three vestibular and one lingual locations) yielded no significant differences between SR and CR i-FPD wearers. Both the *gingival index* and the *keratinized mucosa width* were slightly higher in the CR group. The *probing depth* was deeper in the distobuccal and lingual locations of both groups.

Regarding the 'Prosthetic complications & peri-implant diseases' (Group 4 of variables; Table 3), the most frequent prosthetic problem was the *ceramic fracture* or 'chipping', which was observed in 30% of the cases, with very similar percentages in both treatment groups. This complication was followed by *unsatisfactory occlusion* (17%), which was slightly higher in the SR than in the CR group (20% vs. 14%). The SR group showed more cases of *loosening of the retentive mechanism* than did the CR group (5/50 *vs.* 1/50). No *fracture of the retentive mechanism* was registered in the study.

Focusing on the peri-implant diseases (Group 4 of variables; Table 3), the only scores registered according to the Misch's scale for *implant mobility* were '0′ and '1′ [40]. The *implant mobility* was significantly more frequent in the CR than in the SR group (18% vs. 2%; $p = 0.008$). CR wearers were more prone to *peri-implantitis* than did SR wearers (12% vs. 2%; $p = 0.05$). Even though an exact *p*-value of 0.05 is not statistically significant at $\alpha = 0.05$, some authors consider this result as 'marginally significant' [46]. The peri-implant mucositis was 'Absent' in most cases (61%), with comparable 'Moderate' percentages between SR and CR groups, and higher percentages in the 'Abundant' category for CR than for SR wearers (18% vs. 6%).

Considering the 'Functional & esthetic subjective evaluations' (Group 5 of variables; Table 3), the *esthetic* scores assigned by the dentist and by the patients yielded no significant differences between the SR and CR groups. Patients gave slightly higher esthetic scores to SR than to CR i-FPDs, and assigned non-significantly lower esthetic scores compared to those of the dentist despite the retention system. The *functionality* and the *global evaluation* of SR and CR wearers were similar.

Table 4
Comparison of the OHRQoL among the three study groups (OHIP-14sp: dimensional and total scores).

OHIP-14sp domains	SR ($n = 50$) Mean (SD)	CR ($n = 50$)	ND ($n = 50$)	*p*-values Kruskal-Wallis test ($n = 150$) *Post-hoc: Mann-Whitney U test*
D1. Functional limitation	0.14 (0.606)	0.36 (0.663)	0.24 (0.476)	0.052 NS [a]
Q 1 (D1): Trouble pronouncing words	0.08 (0.566)	0.32 (0.587)	0.10 (0.364)	0.001 * [a] *QoL:* CR < SR ($p = 0.001$) * [b]; CR < ND ($p = 0.019$) * [b]
D2. Physical pain	0.58 (1.715)	0.8 (1.629)	2.58 (1.785)	< 0.001 ** [a] *QoL:* ND < SR ($p < 0.001$) ** [b]; ND < CR ($p < 0.001$) ** [b]
D3. Psychological discomfort	0.58 (1.617)	0.48 (1.015)	2.58 (2.524)	< 0.001 ** [a] *QoL:* ND < SR ($p < 0.001$) ** [b]; ND < CR ($p < 0.001$) ** [b]
D4. Physical disability	0.04 (0.283)	0.1 (0.416)	1.06 (1.743)	< 0.001 ** [a] *QoL:* ND < SR ($p < 0.001$) ** [b]; ND < CR ($p < 0.001$) ** [b]
D5. Psychological disability	0 (0.000)	0.16 (0.792)	1.56 (1.631)	< 0.001 ** [a] *QoL:* ND < SR ($p < 0.001$) ** [b]; ND < CR ($p < 0.001$) ** [b]
D6. Social disability	0.08 (0.566)	0 (0.000)	0.84 (1.405)	< 0.001 ** [a] *QoL:* ND < SR ($p < 0.001$) ** [b]; ND < CR ($p < 0.001$) ** [b]
D7. Handicap	0.1 (0.505)	0 (0.000)	0.78 (1.375)	< 0.001 ** [a] *QoL:* ND < SR ($p < 0.001$) ** [b]; ND < CR ($p < 0.001$) ** [b]
OHIP-14sp total score	1.52 (4.057)	1.9 (3.118)	9.64 (7.881)	< 0.001 ** [a] *QoL:* ND < SR ($p < 0.001$) ** [b] ND < CR ($p < 0.001$) ** [b] CR vs. SR ($p = 0.807$) NS [b]

SR = Wearers of screw-retained implant-supported fixed partial dentures (i-FPDs). CR = Wearers of cemented-retained i-FPDs. ND = Fully dentate subjects with a healthy natural dentition. SD = Standard deviation. (*) = Significant at $\alpha = 0.05$. (**) = Significant at $\alpha = 0.001$. NS = Not significant. ([a]) = Kruskal-Wallis test. ([b]) = Mann-Whitney U test. *QoL* = Quality of Life.

3.2. Comparison of the OHRQoL among the groups of patients

The groups evaluated were significantly differentiated by the OHIP-14sp total score ($p< 0.001$). The ND subjects reported a significantly lower OHRQoL with respect to SR and CR i-FPD wearers ($p< 0.001$). Both prosthodontic groups recorded similar OHIP total scores ($p = 0.807$) (Table 4).

The D2-D7 OHIP subscales depicted analogous outcomes. 'Physical pain', 'Psychological discomfort', 'Physical disability, 'Psychological disability', 'Social disability', and 'Handicap' disclosed a significantly worse QoL for the ND volunteers when compared with SR and CR wearers ($p< 0.001$). The i-FPDs' retention system did not affect the OHIP dimensional scores (Table 4).

'Functional limitation' was the only OHIP-14sp subscale that resulted in no significant differences between groups ($p = 0.052$). After analyzing the two items included in this domain, we found that only the Q1: 'Trouble pronouncing words', significantly discriminated among the three groups ($p< 0.001$). In this case, the CR group showed a significantly lower QoL than did both the SR and ND groups ($p = 0.001$ and 0.019, respectively) (Table 4). The results of the items Q2-Q14 coincided with those of their respective dimensions and, thus, with the OHIP-14sp total score.

Even though the OHIP-14sp subscales did not discerned between the SR and CR groups, CR wearers showed a trend to perceive lower OHRQoL than did SR wearers in the domains: 'Functional limitation', 'Physical pain', 'Physical disability' and 'Psychological disability'. The opposite occurred with the dimensions: 'Psychological discomfort', 'Social disability', and 'Handicap' (Table 4).

The OHIP-14sp subscales that obtained the highest scores and, thus, the worst self-perceived QoL were: 'Physical pain' and 'Psychological discomfort'; ND subjects reporting a significantly lower QoL than both prosthodontic groups, which were comparable to each other. On the contrary, the D4-D7 dimensions registered the significantly highest patient satisfaction within both i-FPD groups (Table 4).

With respect to the QoLIP-10 scale, the total and item scores (except one item) did not discriminate between the SR and CR groups (Table 5). Nevertheless, the QoLIP-10 questionnaire appeared to attribute higher OHRQoL to SR wearers concerning the 'Oral pain' *(which conceptually coincided with the trend observed for the 'Physical pain' dimension of the OHIP-14sp),* 'Oral hygiene difficulty', and 'Speaking difficulty or restriction' (this last item being the unique with significant differences $p = 0.001$). In contrast, the QoL data for CR wearers were more favourably inclined for the items: 'Activities of daily living' *(in line with the observations for the 'Social disability' and 'Handicap' domains of the OHIP, which cover similar concepts)*, 'Satisfaction with the appearance', and 'Satisfaction with the realism' *(both having a correspondence with the 'Psychological discomfort' domain of the OHIP, which expressed the same tendency)* (Tables 4 and 5).

Therefore, 'Speaking difficulties' was the only QoLIP-10 item that discriminated between the prosthodontic groups. Its effect coincided with that of the OHIP item: 'Trouble pronouncing words', as in both cases SR wearers reached superior levels of QoL than did CR wearers (Tables 4 and 5). The best-scored QoLIP-10 items in both prosthodontic groups were: 'Worry/concern' and 'Communication/social relations', which supplied improvements in QoL for all patients (Table 5).

3.3. Analysis of the modulating effects of groups 1 and 2 of variables on the OHRQoL

When analyzing all groups (SR, CR, and ND), the *gender* ($p = 0.022$), the *level of education/schooling* ($p< 0.001$), and the *partnership status* ($p< 0.001$), significantly influenced the OHIP-14sp scores. Regarding the prosthodontic groups, both the *age* ($p = 0.03$) and the *prosthesis span length* ($p = 0.033$) significantly modulated the OHIP-14sp values of OHRQoL (Table 2).

Starting by the *gender*, the females reported the significantly highest OHIP-14sp scores (i.e., the worst QoL). With respect to the *level of education/schooling*, the subjects having basic education perceived a significantly better OHRQoL compared to those with secondary education ($p< 0.001$), and professional training ($p< 0.001$). The secondary education was associated to a significantly worse QoL when compared to the university education ($p = 0.022$). Relating to the *partnership status*, those patients who lived with a partner attained the significantly lowest OHIP-14sp scores (i.e., the highest QoL). About the *age,* the patients younger than 65 years reported a significantly worse QoL with respect to their older counterparts ($p = 0.03$). Concerning the *prosthesis span length*, crowns led to a significantly worse QoL when compared to multiple unit restorations ($p = 0.033$) (Table 2).

Table 5
Comparison of the OHRQoL among the prosthodontic groups (QoLIP-10: item and total scores).

QoLIP-10 items (*related to the SR or CR i-FPDs*)	**SR ($n = 50$) Mean (SD)**	**CR ($n = 50$)**	***p*-values Mann-Whitney U test ($n = 100$)**
Oral pain	1.74 (0.853)	1.6 (0.782)	0.062 NS
Chewing difficulty	1.62 (1.048)	1.7 (0.735)	0.691 NS
Worry/concern	1.92 (0.566)	1.96 (0.198)	0.576 NS
Communication/social relations	2.00 (0.000)	2.00 (0.000)	1.000 NS
Activities of daily living	1.32 (1.186)	1.68 (0.653)	0.215 NS
Satisfaction with the appearance	1.5 (0.886)	1.78 (0.418)	0.196 NS
Satisfaction with the realism	1.32 (1.019)	1.56 (0.787)	0.281 NS
Satisfaction with the smile	1.76 (0.687)	1.78 (0.418)	0.517 NS
Speaking difficulty or restriction	1.92 (0.566)	1.64 (0.663)	0.001 * *QoL:* CR < SR
Oral hygiene difficulty	1.66 (0.626)	1.34 (0.895)	0.058 NS
QoLIP- total score	16.76 (4.800)	17.04 (3.057)	0.487 NS

SR = Wearers of screw-retained implant-supported fixed partial dentures (i-FPDs). CR = Wearers of cemented-retained i-FPDs. SD = Standard deviation. (*) = Significant at $\alpha = 0.05$. NS = Not significant. *QoL* = Quality of Life.

The QoLIP-10 total scores were not significantly affected by the Groups 1 and 2 of variables (Table 2).

4. Discussion

This study aimed to evaluate the differences in OHRQoL between dentate subjects *(controls)* and wearers of SR and CR i-FPDs. Two indices with an excellent internal reliability (confirmed by their Cronbach's α values) were used: the OHIP-14sp (α= 0.89) [27], and the QoLIP-10 (α= 0.82) [29]. The control group represented a baseline situation with an almost perfect oral *status*. Potential modulators of both the patients' QoL and the clinical conditions of their prostheses were explored.

Our results require the rejection of the first null hypothesis, since the OHRQoL of SR and CR i-FPD wearers were comparably higher than that of fully dentate subjects. Moreover, the clinical conditions of both types of restorations were different concerning the peri-implant diseases.

The OHIP-14sp significantly discriminated between the tested groups with its total score, most of its dimensional scores (D2-D7), and even the score of its first item (Q1 of D1). In all cases, the SR and CR prosthetically restored patients reported comparably higher satisfaction than did the healthy dentate subjects (Table 4), who were the most nonconformist and revealed the highest concerns about their OHRQoL [33]. This could be due to a more consciousness of the importance of dental care in young people; which has been transmitted to them from their childhood.

Overall, SR and CR i-FPD wearers demonstrated similar levels of wellbeing (Tables 4 and 5) and clinical conditions of their prostheses (Table 3) [26,36]. Both retention systems were only differentiated in terms of QoL by two equivalent items: 'Trouble pronouncing words' (OHIP-14sp), and 'Speaking difficulty or restriction'(QoLIP-10), which attributed the significantly best speaking ability to SR wearers (Tables 4 and 5). The reason for this particular finding deserves further research. Several authors attributed better outcomes to SR than to CR i-FPDs [7, 11-13,16,20-22,38], while CR wearers manifested higher OHRQoL than did SR wearers in other study [31]. The causes of such disparities may rely on the patients' features and on the QoL predictors in each case [47].

Actually, the Groups 3–5 of variables define the clinical conditions approached in the second part of the first null hypothesis (Table 3). The SR and CR groups showed comparable *probing depth* values (Table 3), probably thanks to our oral hygiene program, which emphasizes on the continuous positive reinforcement. The *ceramic fracture* became the most frequent prosthetic failure with similar percentages in both groups (Table 3). The intensity of the chewing loads (most prostheses were posterior; Table 2), may have contributed to this fact [48]. In our investigation, 17% of the prosthetically restored patients had an *unsatisfactory occlusion* (Table 3), which may be related to the wear of the occlusal surfaces over time [41,42].

The *implant mobility* was significantly more frequent in the CR group than in the SR group (Table 3). Accordingly, Sherif et al. [49] concluded that cemented i-FPDs were more prone to be lost than screwed restorations. Among the possible causes, we could cite the presence of undetected cement residuals [20–22], their irretrievability for maintenance, and/or the higher percentages of older patients in our CR group (Table 2), who usually have more difficulties to keep up a good hygiene routine [39]. In view of our statistical analysis, the incidence of *peri-implantitis* was not significantly different between both prosthodontic groups (Table 3). However, as we have an exact *p*-value of 0.050, we could, at most, talk about a 'marginal significance'. This term implies that the result is close to the limit of being considered statistically significant, so that some kind of clinical significance should be taken into account [46]. In summary, CR i-FPD wearers would have an increased propensity to suffer some peri-implant diseases.

The *functionality* and *global evaluation* made by the SR and CR wearers yielded statistically similar values. The patients' *esthetic* scores were statistically comparable between the SR and CR groups and did not differ to those of the dentist within each group [33]. This confirmed a positive concordance between patients and dentists, and stated that both retention systems are well accepted.

The second null hypothesis was partly rejected, because some sociodemographic characteristics *(gender, level of education/schooling, partnership status, and age)* together with the *prosthesis span length,* significantly affected the OHRQoL as measured by the OHIP-14sp scale (Table 2).

Women reported a significantly lower self-perceived satisfaction. This have been related to a greater concern with their health *status* when compared to men, but this question remains unclear [30,50]. Our volunteers with basic education demonstrated a significantly higher QoL than did those with secondary and training education, which agrees, in the first part, with a former study [33]. Patients with university education had exhibited a greater wellbeing when compared to illiterate [30], while other research stated the independence of the *level of education* variable [31]. In our case, university-educated patients reported a significantly better QoL than did those with secondary education. The sociodemographic features diverge in different populations. So, the contextualization plays a key role in QoL-related studies. Patients living alone perceived a worse OHRQoL. Some authors reported contrary results [38,47], while others did not identify the *partnership* variable as a QoL modulator [29-31,51]. The quality of the coexistence is difficult to assess, which may support such differences. Within the prosthodontic groups, the oldest patients notified the best QoL. Actually, the elderly use to have more serious health problems, which makes them more tolerant [29,33,52].

The *prosthesis length* resulted in significant differences in favor of the multiple unit subgroups. Although single crowns are simpler and easier to clean, 85% of our i-FPDs were posterior (with most multiunit

restorations having no pontics) (Table 2). This may somehow justify that these findings are not-so-surprising. About the *date of installation of the prosthesis*, a curious trend of a progressive increase in QoL was observed, possibly due to the patient adaptation over time [38] (Table 2).

All of the participants were treated at the same institution with trustworthy prosthodontic protocols. This enabled keeping many variables under control. Moreover, the sociodemographic heterogeneity of our cosmopolitan sample reinforces the repercussion of our results [29-31,33,38,51,52]. Nevertheless, multicentre prospective longitudinal studies would supply higher levels of evidence to facilitate the data comparisons and to prevent unwise extrapolations. Some uncontrolled confounding variables that are present in all clinical trials [53–55], including the laboratory work [56–60], may have affected our findings in an unpredictable manner. However, the selection bias was reduced in this research by: *(a)* verifying that all of the participants met the selection criteria (correct selection of the sample) [29], and *(b)* assigning them to each study group by element availability [32]. Due to the cross-sectional nature of the investigation, there were no study drop-outs, as all the required information was collected in a unique appointment [61,62].

The retention system of an i-FPD does not seem to affect the patients' overall OHRQoL and the clinical conditions of their prostheses. Nonetheless, CR i-FPD wearers may have a major susceptibility to developing peri-implant diseases (Table 3). Decision-making is a complex process influenced by the clinical and technical feasibility [3,8,25] and by the knowledge of the QoL modulators, which may help predict which type of restoration will be the best option for each individual from a holistic perspective [30,31,36,63].

5. Conclusion

Within the limitations of the present study, the next conclusions may be drawn:

1 The OHRQoL of partially edentulous patients restored with SR and CR i-FPDs was comparably higher than that of the subjects with a fully and healthy natural dentition, who expressed the highest concerns about their oral *status* (OHIP-14sp).
2 The conceptually-equivalent items 'Trouble pronouncing words' (OHIP-14sp) and 'Speaking difficulty' (QoLIP-10) were the only discriminant factors between both prosthodontic groups, showing significantly better outcomes for SR than for CR i-FPD wearers.
3 Overall, the choice of the retention system does not affect the patients' QoL and the prosthesis' clinical condition. However, the cementation would increase the risk of peri-implant diseases.
4 Some sociodemographic characteristics *(*i.e., *gender, level of schooling, partnership status, age)* and the *prosthesis span length* were identified as OHRQoL modulators (OHIP-14sp).

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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