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# A prospective clinical cohort study analyzing single-unit implant crowns after 3 years of loading: Introduction of a novel Functional Implant Prosthetic Score (FIPS)

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# A prospective clinical cohort study analyzing single-unit implant crowns after 3 years of loading: Introduction of a novel Functional Implant Prosthetic Score (FIPS)


## *ABSTRACT*

**Objectives**: The aim of this prospective clinical cohort study was to validate implant crowns with a novel Functional Implant Prosthetic Score (FIPS).

**Material and Methods**: Twenty patients were rehabilitated with cement-retained implant crowns in posterior sites and annually followed-up for 3 years. FIPS was applied for the objective outcome assessment including clinical and radiographic examinations. Five variables were defined for evaluation, resulting in a maximum score of ten per implant reconstruction. Patients' level of satisfaction was recorded and correlated to FIPS.

**Results**: All implants and connected crowns showed survival rates of 100 % without any biological or technical complications after 3 years of loading. The mean total FIPS score was 7.8 ± 1.5, ranged from 6 to 10. The variable 'bone' revealed the highest scores (2.0 ± 0.0; range: 2-2), followed by 'occlusion' (1.9 ± 0.1; range: 1-2). Mean scores for 'design' (1.2 ± 0.6; range: 0-2), 'mucosa' (1.3 ± 0.7; range: 0-2), and 'interproximal' (1.4 ± 0.4; range: 1-2) were more challenging to satisfy. The patients expressed a high level of functional satisfaction (84.1 ± 9.5; range: 68-100). A significant correlation was found between FIPS and the subjective patients' perception with a coefficient of 0.88 ($p < 0.0001$).

**Conclusions**: The findings of the clinical study indicated the potential of FIPS as an objective and reliable instrument in assessing implant success. FIPS can be considered as supportive tool to justify the patients' satisfactory outcome, to identify potential failure risks, and to compare follow-up observations.

# *INTRODUCTION*

Implant treatment concepts have become a standard therapy in dental medicine (Wismeijer, et al. 2014). An interdisciplinary approach considering a prosthetic backward planning is compellingly necessary for successful and predictable outcomes (Levine & Nack 2011). Today, implants and their reconstructions demonstrate high survival rates due to improved biological knowledge and enhanced practical skills, the use of three-dimensional imaging and virtual treatment planning including guided surgery techniques as well as computerized processing in the field of implant prosthodontics (Pjetursson, et al. 2014).

The presence of implant dental medicine in the public media and online society has pushed the expectations of the patients to a higher level and emphasizes on the imitation of a naturally look-alike appearance. Success criteria have been defined for long-term biological and technical stability, and especially, expanded by esthetic contemplation (Papaspyridakos, et al. 2012, Sadid-Zadeh, et al. 2015). Consequently, different clinical scores and indices have been developed to assess single-unit implant crowns in the esthetic zone (Belser, et al. 2009, Furhauser, et al. 2005, Juodzbalys & Wang 2010, Meijer, et al. 2005, Tettamanti, et al. 2015).

The reasons for tooth loss, and finally, the rehabilitation with an implant reconstruction can be categorized in traumatic cases located predominantly in the esthetic zone; and in contrast, in disease-associated factors, such as caries, endodontic failures and/or periodontitis for posterior sites (Le, et al. 2015). Even though the attention of implant therapy concepts is frequently shifted to esthetically challenging cases, the inner-arch distribution of implant-supported single-unit reconstructions is showing a ratio of 2:1 of restored implants in posterior sites rather than in the anterior region (http://www.aaid.com).

In this context, it is a paradox that no functionally based implant score has been established whereas various esthetic scores have been published yet. A selective assessment of the functional integration of fixed implant reconstructions with an objective, reliable, and quickly applicable score would help to justify the patient's satisfactory outcome, to identify potential failure risks at an early stage of the treatment and to compare follow-up maintenance.

Therefore, the aims of this prospective clinical cohort study were to validate single-unit implant crowns in posterior sites with a novel Functional Implant Prosthetic Score (FIPS) under standardized and objective criteria using clinical and radiographic outcomes after 3 years of loading; and secondary, to correlate these results to the subjective perception of the patients.

# *MATERIAL AND METHODS*

**Definition of the novel implant score FIPS**

A functionally based implant score has to consider clinical and radiological issues for routine evaluation, risk assessment, and prognosis of long-term integrity. In addition, its performance has to be easy to use, simple and self-explaining, reliable and reproducible as well as quickly applicable.

The novel Functional Implant Prosthetic Score (FIPS) is defined by five variables: (1) interproximal, (2) occlusion, (3) design, (4) mucosa, and (5) bone. A scoring scheme of 0 – 1 – 2 is assigned for

each aforementioned variable, resulting in a maximum score of ten (5 x 2) per implant reconstruction [**Tab. 1**].

The variables 'interproximal', 'occlusions', and 'design' are scored in major discrepancy (score 0), minor discrepancy (score 1), and no discrepancy (score 2). The 'interproximal' variable is assessed for mesial and distal contact areas. The implant crown is clinically controlled for identical continuity with dental floss towards the adjacent dentition. In addition, the papillary conditions are inspected for presence and appearance as indicator for the cleanability and risk for food impaction. 'Occlusion' is evaluated for static and dynamic patterns with shimstock foil. Ideal conditions are defined by light occlusal contacts without dynamic interactions. The 'design' of the implant crown is analyzed for contour and color. Major discrepancies are defined by contour plus color deficiencies, and minor discrepancies for solely color deviations, whereas an optimal situation is a harmonious crown matching to the individual patient situation. The quality and quantity of peri-implant 'mucosa' is categorized in non-keratinized + non-attached (score 0), non-keratinized + attached (score 1), and keratinized + attached (score 2). 'Bone' is analyzed by the radiographic level of the alveolar crest mesially and distally: loss > ¼ of the implant length (score 0), loss < ¼ of the implant length (score 1), and no loss (score 2), respectively. In general, the lowest score within each single variable assessment is decisive in case of different observations for sub-variable evaluation; that means: e.g. papillae presence has a score of 0 and contacts a score of 1, the overall score for the variable 'interproximal' is 0, the lower value of this part of assessment [**Fig. 1; Fig. 2**].

**Clinical study setting**

A total of 20 patients with each one cement-retained single-unit implant crown in maxillary or mandibular premolar and molar sites were included for analysis after 3 years of prosthetic loading on soft tissue level implants (Straumann TL RN/WN, Institut Straumann AG, Basel, Switzerland).

All reconstructions were produced in a digital workflow including intraoral scanning (iTero Scanner, Align Tech Inc., San Jose, USA) and CAD/CAM-processing with individualized titanium abutments plus manually veneered zirconia-suprastructures (CARES X-Stream, Institut Straumann AG, Basel, Switzerland; ceramic veneering material Noritake CZR, Kuraray Noritake Dental Inc., Tokyo, Japan). The master casts were produced out of polyurethane (iTero modeling) in an off-house milling center (CAD/CAM-Center, Institut Straumann AG, Leipzig, Germany). Implant laboratory analogues were positioned according to the digital impressions with implant-specific scanbodies.

The individualized titanium abutments were screwed with a controlled torque of 35 Ncm according to the implant provider's recommendations; and then, the crowns were delivered with temporary cement (TempBond, Kerr Dental, Rastatt, Germany).

The described study protocol study is part of a previously published clinical trial (Joda & Bragger 2015, Joda & Bragger 2015). The research protocol is registered and approved by the Ethics Committee in Bern, Switzerland (KEK 053/12).

**Follow-up**

Finally, all patients were included for follow-up with annual examinations including enrollment in a dental hygienist recall program. Clinical assessments were made in order to record probing pocket depths (PPD), bleeding on probing (BoP), and a full-mouth plaque index (PI) during every follow-up

visit. Intraoral radiographic examinations were applied immediately after seating of the implant crowns (baseline) and after 3 years of loading (follow-up).

The FIPS evaluation was performed by an experienced prosthodontist for all patients at the time of the 3-year follow-up examination. In addition, patient satisfaction was supplementary analyzed with a shortcut questionnaire covering two central issues related to the implant reconstruction. Question 1 (Q1) focused on the treatment result whether the patients' general expectations have been fulfilled. The second question (Q2) addressed specifically the patients' satisfaction with the overall treatment outcome from a functional point of view. Both questions included a visual analogue scale (VAS) ranged from "unsatisfied" to "fully satisfied" (0-100). Here, the patients could separately mark on calibrated horizontal 0 – 10 cm lines to express their personal degree of satisfaction for Q1 and Q2.

**Statistical Analysis**

Descriptive statistics of FIPS were calculated for mean scores including standard deviations (SD), minimum and maximum values. A linear regression analysis was performed for the detection of any significant correlations between the total FIPS scores and the subjective results of the patients' VAS responses to Q1 and Q2. A level of significance was set at $p < 0.05$. Statistic calculations were made with the open-source program "GraphPad Software" (http://www.graphpad.com).

## *RESULTS*

Demographic patient data revealed a mean age of 55 years at the time of baseline, and a gender ratio of 47 % females and 53 % males, respectively. All 20 study participants could be followed-up for a mean observational period of 36.2 ± 3.1 months (range: 30-43).

Survival rates for all implants and connected prosthetic reconstructions were 100 %. No technical or biological complications were observed during follow-up. Clinical examinations exhibited mean full-mouth scores for PI of 21.4 ± 2.1 (range: 17-24) at baseline and 20.4 ± 1.9 (range: 16-23) at 3-year follow-up, PPD of 3.7 ± 0.4 mm (range: 1-4) and 3.4 ± 0.3 mm (range: 1-5), and a mean score for BoP of 20.8 ± 2.3 (range: 16-24) and 19.6 ± 1.5 (range: 19-23), respectively.

Calculations of mean total FIPS scoring and for each of the five variables including standard deviations, minimum and maximum values are summarized in Table 2. The mean total FIPS score was 7.8 ± 1.5 (range: 6-10). In detail, all implants showed a stable level of the alveolar crest without any signs of bone loss in the radiographic analysis. Therefore, the variable 'bone' demonstrated the most consistent results and highest scores with a mean value of 2.0 ± 0.0 (range: 2-2). A slightly lower mean score was recorded for the variable 'occlusion' 1.9 ± 0.1 (range: 1-2). In contrast, mean scores for 'design' 1.2 ± 0.6 (range: 0-2), 'mucosa' 1.3 ± 0.7 (range: 0-2), and 'interproximal' 1.4 ± 0.4 (range: 1-2) were the most challenging to satisfy [**Tab. 2**].

The two questionnaires addressed the patients' satisfaction according to the treatment outcome. Q1 focused on the fulfillment of the patients' general expectations. Q2 asked explicitly for the overall patients' satisfaction according to the functionality of the implant crowns. In general, all patients marked their level of satisfaction above 65 % on the VAS for both questions. The mean score of Q1 was 81.6 ± 9.8 (range: 66-100), and 84.1 ± 9.5 for Q2 (range: 68-100).

The linear regression analysis showed a statistically significant correlation between the total FIPS score and the VAS response of Q1 and Q2. A moderately strong correlation was found between FIPS and Q1 with a coefficient of 0.85 ($p < 0.0001$). For linear regression analysis of Q2, the correlation was slightly pronounced revealing a coefficient of 0.88 ($p < 0.0001$) [**Fig. 3**].

## *DISCUSSION*

For the evaluation of implant reconstructions, survival as primary factor and additional surrogate parameters have been defined to estimate the treatment success (Wyatt & Zarb 1998). Numerous criteria were used in various clinical trials, starting with biological assessments of the bone level and peri-implant soft tissue, followed by technical complications of the prosthetic reconstruction (Chen & Buser 2009, Fuentealba & Jofre 2015, Le, Papia & Larsson 2015). Most frequently reported criteria of success mixed different parameters, such as mobility of the implant, radiolucency and substantial bone loss, bleeding and suppuration, the occurrence of technical failures, and esthetics (Papaspyridakos, Chen, Singh, Weber & Gallucci 2012).

Success in implant dentistry should ideally consider the long-term outcome of the entire implant-prosthetic complex as a whole. However, a generally accepted and well-established assessment tool estimating a reliable score merging clinical and radiographic findings in one approach is missing for the evaluation of implant reconstructions (in posterior sites).

Any diagnostic assessment tool will be only helpful if its performance is easy to use, quickly and reproducibly applicable, and implies a clinical relevance for the dentist and the patient. The present trial proofed the applicability of FIPS. This novel functional score is defined by only five variables. In contrast, esthetic indices use much more complex scoring schemes with ten, up to 15 different sub-categories of assessment (Belser, Grutter, Vailati, Bornstein, Weber & Buser 2009, Furhauser, Florescu, Benesch, Haas, Mailath & Watzek 2005, Gehrke, et al. 2009, Juodzbalys & Wang 2010, Meijer, Stellingsma, Meijndert & Raghoebar 2005, Tettamanti, Millen, Gavric, Buser, Belser, Bragger & Wittneben 2015, Vaidya, et al. 2015).

These esthetic indices may confuse the dental practitioner due to its complexity, and consecutively, to deter applying a scoring tool in daily routine. Moreover, the use of esthetically based implant indices is predominantly intended as assessment instrument in clinical trials and research (Annibali, et al. 2012). Therefore, FIPS aimed to be as simple as possible; nevertheless, to cover all clinically and radiographically relevant aspects for the evaluation of fixed implant reconstructions in just one single assessment approach. The simple application combined with the clinical relevance and its derived impact is a prerequisite to implement FIPS regularly, both in a university setting and in common dental business.

The prospective clinical cohort study investigated the functional outcomes of digitally fabricated single-unit implant crowns after 3 years of loading using FIPS. The summarized analysis of the variables ‘interproximal’, ‘occlusion’, ‘design’, ‘mucosa’, and ‘bone’ revealed a high mean total score of 7.8 / 10 with a relatively narrow range (SD: ± 1.5) indicating a precise and reliable assessment of FIPS. The definition of variables and their distinctive weight is enormously important for the calculation of the scoring. Under optimal conditions, the defined variables of FIPS result in a top score of ten. It is well-

known that the number ‘ten’ is traditionally a synonym for an excellent performance, is easy to be recognized, and ensures an arbitrary estimation of a defined threshold of clinical acceptability at the level of 6, covering 60 % of the maximum conceivable score (Belser, Grutter, Vailati, Bornstein, Weber & Buser 2009). All examined implant crowns reached a mean score of ≥ 6 that can be interpreted as a successful (functional) treatment outcome.

The patients’ satisfaction was subjectively high-rated according to the expected treatment outcome, in general. Focusing particularly on functional aspects of the implant crowns, the level of satisfaction revealed even superior values. These results were confirmed by the linear regression analysis correlating of the patients’ perception to the objective assessments of the dental professional using FIPS.

Nevertheless, upcoming clinical studies are necessary to re-evaluate and ideally to confirm the use of FIPS. In addition, a trial setting analyzing the reproducibility among differently specialized dental professionals would be imperative to identify the strengths and possible limitations of FIPS.

Overall, the findings of the present prospective clinical cohort study indicate the potential of FIPS as a functional evaluation tool for fixed implant reconstructions in dental routine maintenance and as essential part of clinical studies assessing implant success. The reliable and quickly application of FIPS can be considered as additional assessment tool to justify the patients’ satisfactory outcome, to identify potential failure risks at an early stage of the treatment, and to compare follow-up observations. The variables of FIPS and the defined threshold of ≥ 6 help to classify objectively fixed implant reconstructions in posterior sites according to functional aspects during long-term follow-up.

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## *FIGURES*

**(a)** **(b)** **(c)**

| | | | |
|---|---|---|---|
| **Interproximal** | | **1** | |
| **Occlusion** | | | **2** |
| **Design** | | **1** | |
| **Mucosa** | | **1** | |
| **Bone** | | | **2** |
| **Total Score** | | | **7** |

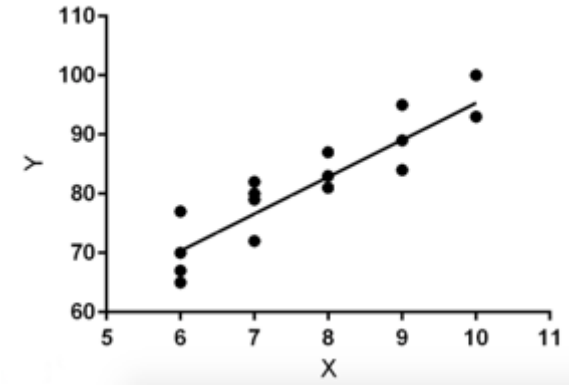
**Figure 1.** Study participant #01 showing an implant-supported single crown for the replacement of the first left maxillary molar (FDI 26) after 3 years of loading: (**a**) lateral and (**b**) occlusal views as well as (**c**) 2D radiographic imaging. Application of the Functional Implant Prosthetic Score (FIPS) revealed a total score of 7.

**(a)** **(b)** **(c)**

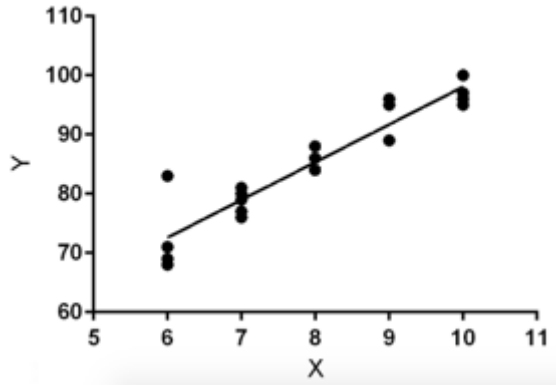
| | | | |
|---|---|---|---|
| **Interproximal** | | | **2** |
| **Occlusion** | | | **2** |
| **Design** | | | **2** |
| **Mucosa** | | | **2** |
| **Bone** | | | **2** |
| **Total Score** | | | **10** |

**Figure 2.** Study participant #02 showing an implant-supported single crown for the replacement of the first left maxillary molar (FDI 26) after 3 years of loading: (**a**) lateral and (**b**) occlusal views as well as (**c**) 2D radiographic imaging. Application of the Functional Implant Prosthetic Score (FIPS) revealed a total score of 10.

## *FIGURES*




**3a.** Linear regression: FIPS – Q1




**3b.** Linear regression: FIPS – Q2

**Figure 3.** Correlation between total FIPS scores and VAS responses of the 20 patients to the questions Q1 and Q2.

## *TABLES*

| Variables | 0 | 1 | 2 |
|---|---|---|---|
| **Interproximal** | | | |
| **Contacts & Papillae** | major discrepancy (2x incomplete) | minor discrepancy (1x complete) | no discrepancy (2x complete) |
| **Occlusion** | | | |
| **Static & Dynamic** | major discrepancy (supra-contact) | minor discrepancy (infra-occlusion) | no discrepancy |
| **Design** | | | |
| **Contour & Color** | major discrepancy (contour/color deficiencies) | minor discrepancy (color deficiencies) | no discrepancy |
| **Mucosa** | | | |
| **Quality & Quantity** | non-keratinized non-attached | non-keratinized attached | keratinized attached |
| **Bone** | | | |
| **X-Ray** | radiographic bone loss > ¼ of implant length | radiographic bone loss < ¼ of implant length | no radiographic bone loss |
| **Maximum Score** | | | **10** |

**Table 1.** Definition of the novel Functional Implant Prosthetic Score (FIPS). Five variables evaluating interproximal, occlusion, design, mucosa, and bone including corresponding sub-categories.

| | Mean | SD | Minimum | Maximum |
|---|---|---|---|---|
| **Interproximal** | | | | |
| **Contacts & Papillae** | 1.4 | 0.4 | 1 | 2 |
| **Occlusion** | | | | |
| **Static & Dynamic** | 1.9 | 0.1 | 1 | 2 |
| **Design** | | | | |
| **Contour & Color** | 1.2 | 0.6 | 0 | 2 |
| **Mucosa** | | | | |
| **Quality & Quantity** | 1.3 | 0.7 | 0 | 2 |
| **Bone** | | | | |
| **X-Ray** | 2.0 | 0.0 | 2 | 2 |
| **Maximum Score** | **7.8** | **1.5** | **6** | **10** |

**Table 2.** Summarized mean FIPS scores, standard deviations (SD), minimum and maximum values for each variable.