Evaluation of the implant disease risk assessment (IDRA) tool: A retrospective study in patients with treated periodontitis and implant-supported fixed dental prostheses (FDPs)

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Abstract
Aim: To evaluate the Implant Disease Risk Assessment (IDRA) tool for the prediction of peri-implantitis in treated periodontitis patients with implant-supported fixed dental prostheses (FDPs) after at least 5 years of function.

Material and methods: From the patient pool of implant patients enrolled in a regular supportive periodontal therapy programme (SPT) for at least 5 years, 239 patients were screened. Eighty patients met the inclusion criteria and underwent evaluation through the criteria of the IDRA tool. Areas under the curve (AUCs) for receiver operating characteristic (ROC) curves including 95% confidence intervals were estimated.

Results: Seventy-nine patients (43 males and 36 females, 8 smokers), aged on average 59.0 years (range: 40–79 years) at baseline (i.e. FDP delivery) were analysed. The calculated IDRA-risk was in 34 patients (42.5%) a moderate risk, while 45 patients (56.3%) were considered at high IDRA-risk. One patient categorized at low IDRA-risk was excluded from the analysis.

The AUC was 0.613 (95% CI: 0.464–0.762) if the IDRA-risk was associated with prevalence of peri-implantitis at the most recent follow-up. Peri-implantitis was diagnosed in 4 patients (12%) at moderate and in 12 patients (27%) at high IDRA-risk, respectively. The calculated odds ratio for developing peri-implantitis in patients with high IDRA-risk compared with patients with moderate IDRA-risk was 2.727 with no statistically significant difference between the two groups (95% CI: 0.793–9.376).

Conclusion: Within the limitations of the present retrospective study, the IDRA algorithm might represent a promising tool to assess patients at moderate or high risk of developing peri-implantitis.

KEYWORDS
assessment, implant, peri-implantitis, periodontitis, prosthesis, risk
1 | INTRODUCTION

It has been accepted worldwide that implant-supported fixed dental prostheses (FPDs) have dramatically changed the way to rehabilitate partially edentulous patients (Buser et al., 2017). Nevertheless, oral implants are not free from biological and technical complications when evaluated long-term (Heitz-Mayfield et al., 2020). Several longitudinal cohort studies (Buser et al., 2012; Chappuis et al., 2013; Kordbacheh Changi et al., 2019; Monje et al., 2014; Roccuzzo et al., 2010, 2012, 2014) and systematic reviews (Jung et al., 2018; Monje et al., 2016; Pereira et al., 2016; Sgolastra et al., 2015; Sousa et al., 2016) documented some specific risk indicators (i.e. history of periodontitis, lack of regular supportive periodontal/peri-implant therapy, tobacco use history) for the development of peri-implant diseases (Heitz-Mayfield, 2008; Renvert & Polyzois, 2015). Hence, the control of risk indicators to limit the chance for future complications has become a focus of interest in clinical implant dentistry (Heitz-Mayfield et al., 2014).

At the completion of active periodontal treatment, the use of a risk assessment tool has been advocated. This periodontal risk assessment (PRA) (Lang & Tonetti, 2013) has been validated in nine internationally performed studies and appears to help the clinicians to individualize supportive periodontal therapy (SPT) (Lang et al., 2015). In the oral implant field, a similar tool to predict the risk for a patient to develop peri-implantitis has recently been proposed (Heitz-Mayfield et al., 2020). The Implant Disease Risk Assessment (IDRA) identifies by means of an octagonal functional diagram patients at a low, moderate or high risk for peri-implant diseases (Heitz-Mayfield et al., 2020).

However, as recommended within the final paragraph of the original publication, the "IDRA-risk assessment tool will require validation through retrospective or prospective studies in multiple private practice and university settings" (Heitz-Mayfield et al., 2020). Therefore, the purpose of the present study was to evaluate the reliability of this tool in estimating the risk for development of peri-implantitis in a cohort of patients treated for periodontal disease and rehabilitated with implant-supported single unit crowns (SUCs) or fixed dental prostheses (FPDs) up to December 2015 were recruited. The following inclusion criteria had to be met:

- male and female patients aged ≥18 years
- patients in systemic health or with controlled medical conditions
- patients with healthy periodontal conditions or following completion of active periodontal therapy (i.e. non-surgical and surgical interventions)
- availability of patient charts with anamnestic records, including tobacco use history, diabetic status and complete dental treatment records
- patients treated with dental implants, rehabilitated with SUCs or FPDs and enrolled in supportive periodontal therapy (SPT) at the Department of Periodontology, University of Bern, Switzerland with full documentation of the SPT regime
- placement of at least 1 osseointegrated dental implant following transmucosal or submerged placement and a healing period of 3–6 months
- at least 5 years of functional loading
- availability of full-mouth intraoral radiographs or orthopantomogram (OPT) prior to periodontal treatment and implant placement.

The following exclusion criteria were applied:

- untreated or active periodontal diseases
- hollow-screw and hollow-cylinder implants (Straumann Dental Implant System, Institut Straumann AG, Basel, Switzerland)
- implants supporting removable dental prostheses (RDPs)
- patients not enrolled in a SPT programme at the Department of Periodontology, University of Bern, Switzerland

2 | MATERIAL AND METHODS

The study protocol was submitted to and approved by the Ethical Committee of the Canton of Bern (KEK), Switzerland (Nr.: 2018–01877). The investigation was conducted according to the revised principles of the Helsinki Declaration (2013), and signed informed consent was obtained from each patient before entering the study.

2.1 | Patient selection

From the patient pool of the Department of Periodontology, University of Bern, Switzerland, partially edentulous patients rehabilitated with implant-supported single unit crowns (SUCs) or fixed dental prostheses (FPDs) up to December 2015 were recruited. The following inclusion criteria had to be met:

- male and female patients aged ≥18 years
- patients in systemic health or with controlled medical conditions
- patients with healthy periodontal conditions or following completion of active periodontal therapy (i.e. non-surgical and surgical interventions)
- availability of patient charts with anamnestic records, including tobacco use history, diabetic status and complete dental treatment records
- patients treated with dental implants, rehabilitated with SUCs or FPDs and enrolled in supportive periodontal therapy (SPT) at the Department of Periodontology, University of Bern, Switzerland with full documentation of the SPT regime
- placement of at least 1 osseointegrated dental implant following transmucosal or submerged placement and a healing period of 3–6 months
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- patients not enrolled in a SPT programme at the Department of Periodontology, University of Bern, Switzerland

2.2 | Clinical parameters

The following clinical variables were obtained from the patients’ dental records at time of restoration delivery (i.e. baseline) and at the most recent SPT visit:

- Full-mouth bleeding on probing (BOP) (%) (Lang et al., 1986) at 4 sites of all teeth and implants using a graduated Michigan periodontal probe (Deppeler SA, Rolle, Switzerland)
- Full-mouth pocket probing depth (PPD) measurements (mm) at 4 sites per tooth and implant using a graduated Michigan periodontal probe (Deppeler SA, Rolle, Switzerland).

2.3 | Implant disease risk assessment (IDRA)

A patient-based implant disease risk assessment was calculated according to the criteria of the IDRA tool (Heitz-Mayfield et al., 2020).

In brief, the IDRA was calculated inserting the requested baseline parameters in the online software (http://www.ircohe.net/
IDRA). In patients with multiple implants, the implant with the highest calculated IDRA-risk was selected at baseline (i.e. FDP delivery) to determine the overall patient's risk for developing peri-implant diseases and the same implant was assessed at the most recent SPT visit whether or not it developed peri-implantitis. In case of multiple implants within a patient with the same highest IDRA-risk at baseline, the implant with the longest follow-up was considered.

2.3.1 | History of periodontitis

The evaluation of the history of periodontitis (i.e. dichotomous variable) was performed by assessing the presence of periodontal bone loss in the overall dentition on radiographs (i.e. periapical radiographs or OPT) prior to periodontal therapy according to the recommendations by Heitz-Mayfield et al. (2020).

2.3.2 | Percentage of sites with BOP

The evaluation of the percentage of BOP positive sites was performed calculating the overall full-mouth bleeding on probing score (BOP) (%) (Lang et al., 1986) assessed at the time of delivery of the implant-supported restoration (i.e. baseline) or at the first SPT recall appointment immediately thereafter.

2.3.3 | Prevalence of probing depths ≥5 mm

The assessment of the number of probing depths ≥5 mm both at tooth and implant sites was performed at the time of delivery of the restoration (i.e. baseline) or at the first SPT recall appointment immediately thereafter at four sites (i.e. mesial, buccal, distal, oral).

2.3.4 | Periodontal bone loss in relation to age

The percentage of the loss of alveolar bone was estimated in either periapical radiographs or dental panoramic radiographs calculating the ratio between the defect depth and the overall root length at the worst affected posterior tooth site. The calculated percentage was entered in the IDRA software tool where it was divided by the patients age resulting in a factor (Lang & Tonetti, 2003).

2.3.5 | Periodontitis susceptibility

The susceptibility of each patient to periodontal disease was scored according to the 2017 World Workshop on the Classification of Periodontal and Peri-implant Diseases which includes staging (i.e. I, II, III and IV) and grading (i.e. A, B and C) (Tonetti et al., 2018). This was determined using the clinical and radiographic data obtained at baseline.

2.3.6 | Supportive periodontal therapy (SPT)

The adherence of patients to the suggested SPT regime was defined according to the proposed recall interval (i.e. compliant (3–4 months), ≤5 months, 6 months, casual attender (>6 months), no SPT) according to Monje et al. (2016).

2.3.7 | Distance from the restorative margin (RM) of the implant-supported prosthesis to the alveolar bone level

The distance between the restoration margin and the level of the alveolar crest was measured mesially and distally at all implants from baseline radiographs. Analogue intraoral radiographs obtained with the long-cone technique at time of delivery of restoration (i.e. baseline) were analysed with a 2.1x magnification device (Directa AB) on a light table. The distance between threads reported by the manufacturer (i.e. 1.25 mm for tissue level implants and 0.8 mm for bone level implants), implant length and implant diameter were used to adjust for distortion on each radiograph. The restoration margin was identified as a landmark and the distance to the alveolar bone crest was measured at the mesial and distal aspects of each implant. The smallest value was considered for risk categorization.

Based on the outcomes of a study reporting the effectiveness of implant therapy in a Swedish population (Derks et al., 2016), a distance <1.5 mm from the restoration margin to the bone level was associated with an increased risk for peri-implantitis. Therefore, for the purpose of the present study, all tissue level implants with a polished neck of 1.8 or 2.8 mm were categorized at low risk, while bone level implants with a distance <1.5 mm were categorized at high risk. Whenever the linear measurement was ≥1.5 mm, the implant was categorized at moderate risk.

2.3.8 | Implant prosthesis-related factors

All reconstructions were defined at low risk whenever the prosthesis was well fitting (i.e. no marginal gap identified), cleanable, screw-retained or without radiographic evidence of excess cement. On the other hand, a prosthesis with a supramucosal marginal gap without cement excess was categorized as moderate risk. Finally, high risk was assigned if the prosthesis was uncleanable, poorly fitting, with submucosal excess cement and/or suboptimal submucosal fit (Serino & Ström, 2009).

2.4 | Clinical examinations at follow-up

A comprehensive clinical examination including an update of the medical history, soft tissue examination, assessment of dental (i.e.
caries control), periodontal and endodontic (i.e. tooth vitality) conditions was performed at every SPT appointment. Assessment of PPD and BOP was performed at 4 sites/tooth or implant (i.e. mesial, distal, oral and buccal) with a graduated Michigan periodontal probe (Deppeler SA). Whenever an increase in peri-implant PPD was detected, a periapical radiograph was taken to assess the peri-implant marginal bone level change. For the purpose of the present study, only the most recent radiographic documentation was analysed by the same author (S.D.R.) also performing the baseline radiographic measurements. Based on the fact that the follow-up of the present study extended up to 22 years, clinical assessments were performed by various members of the department of periodontology (i.e. clinicians and dental hygienists).

In case of patients diagnosed with peri-implantitis at the selected implant, treatment was provided and the implant was recorded as an implant with peri-implantitis.

### 2.5 Assessment of peri-implant health or disease

Peri-implant health or disease were assessed at follow-up examinations according to the definitions of the consensus report of the World Workshop on the classification of periodontal and peri-implant diseases and conditions (Berglundh et al., 2018).

Peri-implant health was characterized at the clinical level by the absence of signs of soft tissue inflammation, that is absence of bleeding on gentle probing (BOP) and suppuration (Araujo & Lindhe, 2018). Peri-implant mucositis was defined as presence of BOP and/or suppuration with or without increased probing depth compared to previous examinations in conjunction with the absence of bone loss beyond crestal bone level changes resulting from initial bone remodelling (Heitz-Mayfield & Salvi, 2018). Peri-implantitis was defined by the presence of BOP and/or suppuration, increased probing depths compared to previous examinations and presence of bone loss beyond

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**FIGURE 1** Flow-chart of the screened, analyzed and included patients
2.6 Statistical analysis

All statistical analyses were performed using IBM SPSS Statistics for Windows, version 26.0.0.0 (IBM Corp.). Means, percentages and standard errors were calculated by means of descriptive statistics. Student’s t tests and Mann–Whitney tests were used to test for statistical significance of differences between numerical variables within subgroups of patients categorized with moderate IDRA-risk or high IDRA-risk, respectively. Risk estimates were determined with odds ratios and relative risks including 95% confidence intervals for patients developing peri-implantitis or no peri-implantitis.

Areas under the curve (AUCs) for receiver operating characteristic (ROC) curves including 95% confidence intervals were estimated non-parametrically with all patients and a composite of all parameters included in the IDRA tool as described by Heitz-Mayfield et al. (2020). p values <0.05 were defined as statistically significant.

3 RESULTS

3.1 Patients’ flow chart

Two hundred and thirty-nine patients underwent implant placement up to January 2015 at the Department of Periodontology, University of Bern, Switzerland. After screening, 159 patients were excluded (i.e. 11 were deceased before reaching the 5-year post-loading SPT appointment and 148 received SPT in private practice).

The data of the remaining 80 patients available at baseline (i.e. delivery of restoration) and at the most recent SPT appointment were extracted from the charts in order to assess the IDRA-risk. When multiple implants were present in the oral cavity, the implant with the highest risk was used for the IDRA-risk profile. Out of 80 patients, 34 (42.5%) were categorized as moderate and 45 (56.3%) as high IDRA-risk at baseline. Only one patient (1.2%) exhibited a low IDRA-risk, and therefore, was excluded from the final analysis due to insufficient numbers in that group for statistical evaluation. Details of the patients’ flow chart are provided in Figure 1.

3.2 Patient’s characteristics

Seventy-nine patients (43 males and 36 females) with a mean age of 59.0 years (range: 40–79 years) at baseline (i.e. delivery of restoration) were included. Eight patients were categorized as smokers (i.e. ≥5 cigarettes/day), while 2 were former smokers (i.e. smoking cessation 10 years before implant placement) (Ramseier et al., 2020). The mean full-mouth BOP score at baseline was 10.9% (range: 0–39%).

3.3 Implant and reconstruction characteristics

Within the IDRA moderate-risk group (n = 34), none of the 14 (41%) patients with a follow-up between 5 and 9 years were diagnosed with peri-implantitis. On the other hand, when considering the two other time intervals (i.e. 10–13 and 14–22 years), peri-implantitis was diagnosed around the selected implants in four patients. Overall, peri-implant health was found in 29% of patients, peri-implant mucositis in 59% and peri-implantitis in 12%. (Table 2).

Of the 45 patients included in the high IDRA-risk, 12 (27%) developed peri-implantitis after a follow-up of at least 10 years. Overall, 15 (33%) patients were diagnosed with no signs of peri-implant infections, while 18 (40%) experienced peri-implant mucositis (Table 3).

3.5 Risk estimate

The calculated odds ratio (OR) of developing peri-implantitis for patients with high IDRA-risk compared with patients with moderate IDRA-risk was 2.727 with no statistically significant difference between the two groups (95% CI: 0.793–9.376). Moreover, the calculated relative risk (RR) of developing peri-implantitis for patients with high IDRA-risk compared with patients with moderate IDRA-risk was 2.267 with no statistically significant difference between the two groups (95% CI: 0.793–9.376). The mean implant loading time was 11.8 years (range: 5–22 years). Details of patient, implant and restoration characteristics are reported in Table 1.
The area under the curve (AUC) was 0.613 (95% CI: 0.464–0.762) if the IDRA-risk category was associated with peri-implantitis at the most recent follow-up (Figure 2A). On the other hand, when a composite of all eight IDRA vectors was associated with a diagnosis of peri-implantitis, the AUC was 0.750 (95% CI: 0.638–0.862) (Figure 2B).

### Discussion

The aim of the present study was to evaluate a recently proposed risk assessment tool to assist clinicians in the identification of patients at low, moderate and high risk of developing peri-implant diseases. Based on the reported results, the null hypothesis of no difference in prevalence of peri-implantitis between the moderate- and high-risk groups could not be rejected. Indeed, despite an increased tendency in the risk of developing peri-implantitis within patients categorized as high risk (OR 2.7, 95% CI: 0.793–9.376), this difference did not reach statistical significance.

Among the eight vectors that constitute the implant disease risk assessment (IDRA) tool, six are patient-related, while only two (i.e. distance from the RM of the implant-supported FDP to the alveolar bone level and implant prosthesis-related factors) are implant-restoration related. It seems that three vectors (i.e. history of periodontitis, bone loss/age and periodontal susceptibility) are...
strictly linked with each other, indicating the strength of evidence for history of periodontitis as a major risk factor for peri-implantitis.

On the other hand, in the IDRA tool the implant-related factors are represented only by two vectors and appear to have a lower impact for the final IDRA-risk assessment, due to less evidence for these factors as risk indicators.

Moreover, an important clinical aspect, such as the quality of the peri-implant soft tissue seal (i.e. presence or absence of attached and keratinized mucosa) (Roccuzzo et al., 2016), was not included in the IDRA tool, due to emerging or inconclusive evidence.

One important aspect of the present investigation is the fact that the majority of the patients (n = 63; 80%) included in the analysed cohort had a history of periodontal disease which was identified as a major risk factor for peri-implantitis in the 2017 World Workshop on the Classification of Periodontal and Peri-implant diseases (Karoussis et al., 2003; Ramaunskaitė & Juodzbalys, 2016; Roccuzzo et al., 2010, 2012). However, it must be pointed out that implant placement was always performed after completion of nonsurgical/surgical periodontal therapy as reflected by the low mean full-mouth BOP score of 10.9% and the mean full-mouth number of sites with PPD ≥5 mm of 3.8/patient at time of reconstruction delivery in this unique patient sample at the University of Bern re-habilitated with only one implant system. Moreover, in the present study all patients were compliant and enrolled in an individually tailored SPT programme carried out by experienced dental hygienists. More specifically, SPT visits included a diagnostic process followed by full-mouth removal of supra- and submucosal dental biofilms and calculus using hand instruments or ultrasonic devices and oral hygiene reinforcement. Supportive therapy in conjunction with high levels of plaque control was identified as important factors in the prevention of peri-implantitis and implant loss (Roccuzzo et al., 2014).

As the cohort of 79 patients analysed represented only moderate- and high-risk IDRA patients, it is evident that a cohort of low-risk IDRA patients was not included.

In addition, the evaluation of patients experiencing tooth loss due to trauma, caries or agenesis rather than periodontitis, might provide additional valuable information to investigate low IDRA-risk patients. In the recruitment process of the present study, only one patient with low IDRA-risk was identified with absence of peri-implant disease. For statistical reasons, however, that patient was excluded from the analysis. Hence, it is clear that the present study yields a selection bias in the patient’s material with absence of a low-risk IDRA group. Therefore, in order to fully validate the IDRA tool, low-, moderate- and high-risk patient cohorts should be included and evaluated prospectively.

Moreover, limitations of the present study should be highlighted including the retrospective design and the low number of included patients. A post hoc power calculation using the same distribution of risk and level of disease yielded a sample size of n = 120 patients necessary to reach statistical significance when comparing moderate- with high-risk IDRA groups.

### Table 4

|                  | Peri-implant health and peri-implant mucositis | Peri-implantitis | Total | OR (95% CI) | p-value | RR (95% CI) | p-value |
|------------------|-----------------------------------------------|-----------------|-------|------------|---------|------------|---------|
| Moderate IDRA-risk | 30 (88.2%)                                    | 4 (11.8%)       | 34 (100%) | 2.727 (0.793–9.376) | n.s. | 2.267 (0.801–6.415) | n.s. |
| High IDRA-risk    | 33 (73.3%)                                    | 12 (26.7%)      | 45 (100%) |            |         |            |         |
| Total            | 63 (79.7%)                                    | 16 (20.3%)      | 79 (100%) |            |         |            |         |

**Figure 2**

(a) Receiver Operator Characteristic (ROC) curve of the development of peri-implantitis in patients categorized with moderate or high IDRA-risk. (b) ROC curves for the combination (Composite) of single vectors used in the IDRA tool in patients categorized with moderate or high risk.
Furthermore, even though the included patients were all treated in a specialist university setting with similar protocols and strict supervision, some differences cannot be excluded as those protocols were applied by different clinicians over a 17-year period of time (i.e. 1998–2015). All clinical and radiographic measurements used to calculate the IDRA-risks were collected from the patients’ dental charts by a single experienced clinician (S.D.R). Based on the follow-up period extending up to 22 years, no calibration was performed among the other clinicians and dental hygienists involved in data acquisition.

Finally, due to the characteristics of a department of periodontology in a university setting and to the fact that most of the included patients experienced periodontal disease, the generalizability of the obtained data might be questioned. In the cohort of patients in the present study, the IDRA vectors playing the greatest part in determining higher risk were History of Periodontitis, Perio Susceptibility and BL/Age, as the other vectors (i.e. BOP%, PPD ≥5 mm, SPT, RM-Bone and Prosthesis Factors) were all within the influence of the clinician and were intentionally optimized as part of treatment within a specialist university clinic setting.

Therefore, additional studies with different patient characteristics (i.e. no history of periodontal disease, lack of compliance with SPT) and settings (i.e. private practice) should be performed to evaluate the IDRA in predicting the risk for peri-implantitis in different patient populations and clinical scenarios (Mir-Mari et al., 2012).

Analysis of future patient samples with the IDRA tool should include the impact of the single vectors and their respective degree of grading on both the level of risk and the ability to predict peri-implantitis.

In the present analysis, both the presence of bone loss at baseline with an AUC of 0.739 and the distance from the restoration margin to the bone with an AUC of 0.662 reflected the best ability to predict peri-implantitis while periodontal susceptibility and implant prosthesis-related factors only yielded AUCs of 0.576 and 0.531, respectively. Consequently, different degrees of grading of the last two vectors may be considered necessary to improve the ability of the IDRA tool to predict peri-implantitis in patients with a history of periodontitis. With respect to periodontal susceptibility, an accurate differential diagnosis between stage III and stage IV periodontitis was not always possible based on the available clinical and radiographic data.

As available in the online software (http://www.ircohe.net/IDRA), future studies should assess the impact of the number of probing sites (i.e. 2, 4 or 6/implant) on the calculated IDRA-risk.

In conclusion, within the limitations of the present retrospective study, the IDRA algorithm might represent a promising tool to assess patients at moderate or high risk of developing peri-implantitis.

CONFLICT OF INTEREST

The authors do not report any conflicts of interest related to the present study. A.R. is the recipient of a 3-year scholarship from the Clinical Research Foundation (CFR) for the Promotion of Oral Health, Brienz, Switzerland.

AUTHOR CONTRIBUTIONS

G.E.S; N.P.L; and L.J.H.M conceived the idea; S.D.R and A.R. collected and analysed the data and contributed to the writing; C.A.R performed data analysis and contributed to the writing; N.P.L, G.E.S, L.J.H.M and A.S contributed to the writing.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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**SUPPORTING INFORMATION**

Additional supporting information may be found online in the Supporting Information section.

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