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RESEARCH ARTICLE

Tactile misfit detection ability at the implant-abutment interface of internal connection dental implants: an in-vitro study

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ABSTRACT

Objective: The aim of this *in-vitro* study was to investigate the tactile assessment ability at the implant impression-taking stage.
Methods: Thirty clinicians (18 novices, 12 experts) were included for a tactile fit assessment by using a used/new probe (tip diameter 100 µm/20 µm). Six implant replicas and related impression copings of two internal connection implant systems were used, each with a perfect fit (0 µm) and defined vertical micro gaps of 8, 24, 55, 110 and 220 µm at the interface. Statistical analysis was performed using descriptive methods and non-parametric tests with a focus on specificity (ability to detect perfect fit), sensitivity (ability to detect misfit), and predictive values. P-values <5% were considered statistically significant.
Results: The tactile assessment showed a mean total sensitivity for the Straumann and Nobel Biocare systems of 83% and 80% with a used probe, and 91% and 92% with a new probe, respectively. The mean total specificities were 33% and 20% with a used probe and 17% and 3% with a new probe, respectively. No statistical significance was observed between novice and expert clinicians concerning their tactile assessment ability.
Conclusions: The ability to detect a perfect fit (specificity) with a probe was very poor for both implant systems and impaired with the use of a new probe. The use of a new probe improved the gap detection ability (sensitivity) significantly at the expense of the specificity. A combination of additional chairside techniques with training and calibration could improve clinicians' ability to correctly assess the fit/misfit at the implant-abutment interface.

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1. Introduction

Implant-supported fixed dental prostheses (FDPs) are a reliable and safe treatment option for partially and edentulous patient prosthetic rehabilitation with excellent and high success rates up to 20 years of follow-up [1–4]. Considering the implant-prosthodontics restorative phases, clinical and laboratory workflow requires multiple manuals and/or digital steps during the reconstruction design and fabrication. Good teamwork between the dentist, dental technician and in many cases an external milling centre is essential to get high precision of the reconstructions regarding the implant-abutment fit. While the framework fit may be assessed in the dental laboratory on the master model with specialized microscopes and digital tools, the clinician's possibilities for the intraorally scenario are limited to visual, tactile, and radiographic assessment methods [5].

The passive fit of single or multiple unit reconstruction between the abutment and the implant has been essentially considered a clinical long-term success key point [6], however, clinical evidence is currently limited [7]. Marginal gap or misfit detection at the implant-impression coping interface is a common clinical task in implant-prosthodontic treatment. The existence of unrecognizable misfits during the impression-taking phase will cause an incorrect transmission of the implant's three-dimensional position to the master cast, resulting in uncontrolled stresses on the implant-abutment interface of prosthetic components and the peri-implant tissues. These stresses can lead to biological complications, such as bacterial microleakage, plaque accumulation resulting in mucositis or peri-implantitis [8–10] and/or technical complications such as loosening of the prosthetic screws and/or abutment loosening, implant system component fractures and implants or prostheses loss [11–15]. In 1983 Professor Brånemark defined the passive fit, suggesting a 10 µm gap as the norm to enable bone maturation and remodelling in response to occlusal loads [16]. In the early nineties, Jemt defined the passive fit as a condition that will

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not cause any long-term clinical complications and in addition, it was suggested that discrepancies smaller than 150 µm were acceptable [17]. Nevertheless, from those initial investigations, different values and definitions were reported, investigated, discussed, and subsequently frequently quoted in the literature as being theoretical or empirical. Those values have been reported without clear evidence and it has also been suggested that clinicians are used to combine them to minimize misfits [16–19].

Perfect passive fit has been defined to be achieved theoretically when the opposing surfaces of the implants and the prosthetic framework gap are in maximum spatial consistency, with no component of stress after all screws are tightened, provided that the implant and the abutment surfaces are made perfectly smooth [9]. Therefore, the smallest possible misfit should be the objective of all types of reconstructions; however, it has not been possible to determine a threshold, neither for a maximum size of space or micro gap in the implant-abutment interface nor for a tension level (screw, framework, implant-bone complex). In this sense, a 100% passive frame adjustment is clinically difficult to achieve [18], especially in multi-unit implant reconstructions and presumably a more accurate frame adjustment will reduce the risk of biological and technical complications in the medium and long term [20]. Several methods such as visual and tactile with alternating finger pressure, tactile with screw retention, one screw test, and radiographic and tactile fit by using an explorer probe have been proposed to determine the gap or misfit at the implant-abutment interface. Nevertheless, the radiological evaluation can present some limitations, such as superimposing or magnifying the image, and therefore can lead to false positives. Among them, the tactile fit assessment at the implant-abutment interface by using an explorer probe (a new probe or a used probe) is one of the most common methods for fit evaluation in implant-prosthodontics [21]. It should be mentioned that this method is especially useful in submucosal situations for interfaces that cannot be directly visualized. However, the sensitivity of this method is limited by the size of the probe tip and the clinician's discriminatory tactile ability and experience [22,23]. Nevertheless, this method allows for determining the fit along the entire contour of the implant and the abutment in a simple, fast, cheap and non-invasive way.

Considering the increase of the implant reconstructions demand among dentists and patients and that nowadays there is no standardization regarding fit assessment methods, the ability to assess the FPD fit is still questionable. In this respect data on the clinical ability to detect the presence or absence of a gap at the implant-abutment interface are lacking and quantitative fit guidelines do not exist. Therefore, achieving passive fit may be currently based on clinical experience but not on any scientific evidence.

The aim of the present study was to investigate the tactile assessment ability by means of specificity (Ability to detect a good fit, i.e. no gap) and the sensitivity (ability to detect a misfit i.e. interface gap) of novice and experienced dentists in order to extrapolate the smallest detectable vertical gap at the implant-impression coping interface using the tactile fit (with a used and a brand-new probe) assessment method. The null hypothesis was that there would be no statistically significant differences in the tactile misfit assessment ability by means of specificity (Ability to detect a good fit, i.e. no gap) and sensitivity between two implant systems, new and used explorer probing tips, novice and expert dentists.

2. Materials and methods

2.1. Study design

The present study was designed and performed as an in-vitro comparative study at the Department of Reconstructive Dentistry and Gerodontology, University of Bern in order to determine the tactile assessment abilities at the impression-taking phase. According to the Swiss federal law on human research (Humanforschungsgesetz, HFG, Switzerland), the approval of the ethics committee of the Canton of Bern (KEK, Nr.:reg2016-00244) was not required.

2.2. Participants

Thirty dentists (15 females, 15 males) from the Department of Reconstructive Dentistry and Gerodontology, University of Bern with at least three years of experience with dental implants were divided into expert or novice clinicians depending on the number of reconstructions restored in their professional clinical career (≤100 reconstructions: 18 novices, VS >100 reconstructions: 12 experts).

2.3. Sample preparation

Two sample blocks were used placing 6 Straumann (STR) implant analogues (RN synOcta analogue, diameter 4.1 mm, restorative platform 4.8 mm, grey with red stripe, 048.124) and 6 Nobel implant analogues (Implant replica tri-channel, NobelReplace RP, diameter 4.3 mm, No. 29500, Nobel Biocare, Göteborg, Sweden). The implant analogues were fixed in a resin bloc, and each was marked with A-F by one dental technician (Daniel Vallata, Vallata Dentaltechnik, Grenchen, Switzerland). Afterwards, six Straumann (STR) impression posts (RN SynOcta Impression cap, red, open tray, diameter 4.1 mm, No. 048.010, Straumann, Basel, Switzerland) and six Nobel Biocare (NOB) impression posts (Impression Coping Closed Tray, NobelReplace RP, diameter 4.3 mm, Nobel Biocare, Gothenburg, Sweden) were screwed on the implant analogues (Figure 1). In order to create and simulate artificial gaps at the implant-abutment junction interfaces, two foils were inserted with standard thicknesses between the implant and the impression post from two different sides to prevent an oblique gap. The interfaces with perfect fit (0 µm) and defined vertical microgaps of 8, 24, 55, 110 and 220 µm were created using the following materials (Figure 2).

- 0µm: No material interposition between the components.
- 8µm: One layer of shim-stock foil (Hanel, Langenau, Germany).

- 24µm: Three layers of shim-stock foil (Hanel, Langenau, Germany).
- 55µm: A sheet protector (Lyreco Deutschland GmbH, Barsinghausen, Germany).
- 110µm: A clear plastic folder (Lyreco Deutschland GmbH, Barsinghausen, Germany).
- 220µm: Two layers of clear plastic folder.

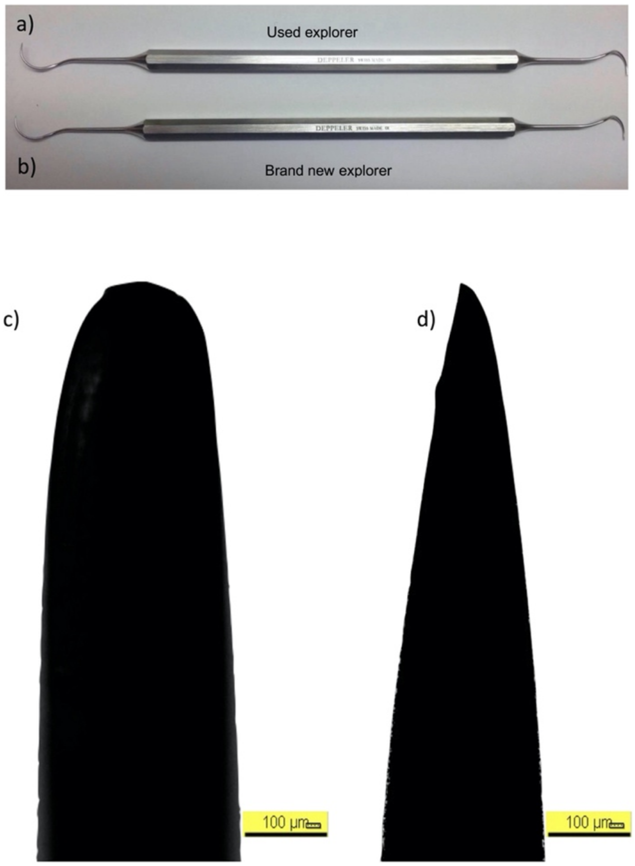

Figure 1. Overview (a, b) and close-up picture with increased contrast (c, d) of a used and brand-new explorer (Deppeler explorer S3C).

Once the gaps were created, the impression posts were tightened by hand (approximately 10 Ncm) with the specific screwdriver by the same calibrated investigator (L.P). To simulate submucosal conditions for the marginal gap position, the interface area at the implant-abutment interface of the sample blocs was covered with a fibrous web at the implant neck level.

2.4. Clinical fit assessment

The implant-impression post-tactile fit assessments were performed in a standardized sequence led by the same investigator (L.P.) using a used explorer probe and a brand-new explorer probe (Deppeler explorer S3C, Rolle Switzerland). The included participants started with the Straumann-sample bloc and then on it with the left side specimen. They were first given a used probe and had to judge in a submucosal situation whether there was a gap or not. The misfit evaluation was performed around the entire contour of the implant-abutment (buccal, palatinal, mesial and distal) and the misfit was defined as presence [yes (1)] or absence [no (0)].

The assessment was then repeated with a brand-new probe. It was ensured that the two material strips (between the interfaces) were hidden (Figure 3). Once the assessment was performed, individuals kept in mind all the information they collected and recorded. For the present study, Specificity was defined as the ability to detect a good fit (i.e. no gap) and sensitivity as the ability to detect misfit (i.e. interface gap).

2.5. Statistical analyses

Data analysis was performed with descriptive methods and group comparisons were done with non-parametric tests using the SPSS software (SPSS 23.0, Chicago, IL, USA) and Microsoft Excel for Mac 2011 (Excel Version 14.4.6). For the

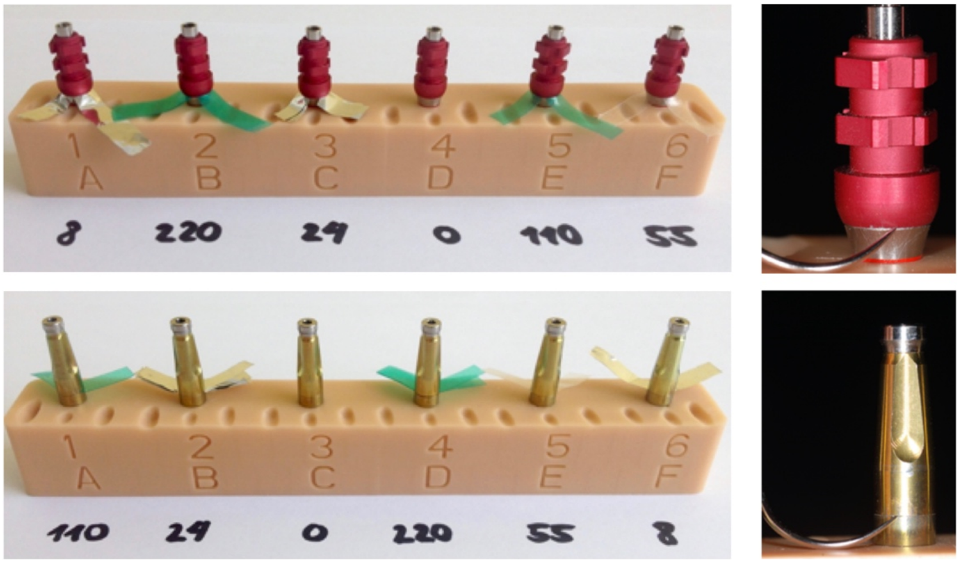

Figure 2. Simulated artificial gaps implant-abutment junction interfaces. Perfect fit (0 µm) and defined vertical microgaps of 8, 24, 55, 110 and 220 µm.

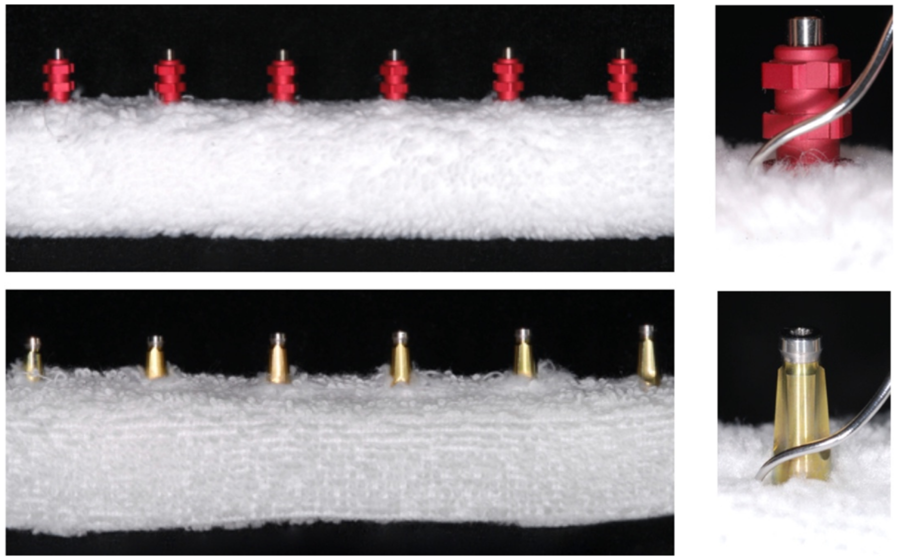

Figure 3. Probing fit scenario mimicking a submucosal situation for implant-impression coping interface.

Table 1. Sensitivities and specificities (%) of the tactile assessments with the used and new probes for the two implant systems.

		Used probe			New probe		
		Straumann	Nobel	Total	Straumann	Nobel	Total
Sensitivity	8 µm	90	60	75*	97	83	90*
	24 µm	47	67	57	63	87	75
	55 µm	77	80	78	97	90	93
	110 µm	100	93	97	100	100	100
	220 µm	100	100	100	100	100	100
	Total (µm)	83	80	81	91	92	92
Specificity		33	20	27**	17	3	10**

*$p = .018$ (Chi-square test); **$p = .018$.

assessments (detectability of a gap/no gap) the specificity, sensitivity and positive/negative predictive values were calculated, and the proportions were compared with the chi-square test. *P*-values smaller than 0.05 were considered statistically significant.

3. Results

3.1. Specificity (ability to detect a good fit, i.e. no gap)

The mean total specificities of the Straumann (STR) and Nobel Biocare (NOB) systems were 33% and 20% with a used probe and 17% and 3% with a new probe, respectively. Sensitivities and specificities percentages are presented in Table 1. The mean total specificities of the used vs new probes were 27% vs 10% ($p = .018$). The subgroup specificities of the used vs new probes were 28% vs 11% (STR, novice), 42% vs 25% (STR, expert), 11% vs. 0% (NOB, novice), and 33% vs 8% (NOB, expert).

3.2. Sensitivity (ability to detect misfit, i.e. interface gap)

In general, the sensitivity increased with the gap sizes for both implant systems using a blunt or a new probe. The mean total sensitivity of the Straumann and Nobel System was 83% and 80% with a used probe and 91% and 92% with a new probe, respectively (Table 1). The mean total sensitivities of the used vs new probes were 75% vs 90% for 8 µm ($p = .030$), 57% vs 74% for 24 µm, non-significant (n.s.), 78% vs 94% for 55 µm ($p = .018$), 96% vs 100% for 110 µm (n.s.), and 100% vs 100% for 220 µm (n.s.), respectively. The 8 µm gap sub-group sensitivities of the used vs new probes were 89% vs 94% (STR, novice), 92% vs 100% (STR, expert), 56% vs 89% (NOB, novice) ($p = .025$), and 67% vs 75% (NOB, expert). The 24 µm gap sub-group sensitivities of the used vs new probes were 50% vs 72% (STR, novice), 42% vs 50% (STR, expert), 61% vs 89% (NOB, novice), and 75% vs 83% (NOB expert). The 55 µm gap sub-group sensitivities of the used vs new probes were 83% vs 100% (STR, novice), 67% vs 92% (STR, expert), 78% vs. 83% (NOB, novice), and 83% vs 100% (NOB, expert). All 110 and 220 µm gap sub-group sensitivities of the used vs new probes were 100% with the exception of the NOB/expert group using the worn probe at 110 µm (83%). No statistical significance ($p > 0.05$) was found between novices and experts concerning the specificity and sensitivity of the tactile gap assessment. The positive predictive values (proportion of positive values depending on the prevalence) with the old/new probe were 86/85% for the Straumann system vs 83/83% for the Nobel Biocare implant system. These proportions did not differ significantly between the systems. The negative predictive values were tendentially higher for the Straumann system (28/28% vs 17/7%) specifically using a new probe.

4. Discussion

The aim of the present study was to investigate the tactile assessment ability of dentists in order to extrapolate the smallest detectable vertical gap at the implant-impression post/coping interface using the tactile assessment method. For both experience levels, implant systems and probing tips, only at the 110 and 220 µm specimens, the tactile assessment was shown to have clearly detection of the gap at the interface (100% specificities, exception: Nobel, used probe, experts 83%), therefore, the null hypothesis of the tactile assessment was rejected. The study findings revealed that the created microgaps in the proposed dimensions (0–220 µm) are difficult to be quantified for both clinician's experience levels, the assessed implant systems and probing tips. Only at the 110 and 220 µm specimens, the tactile assessment was shown to clearly have detection ability of the gap at the implant-abutment interface (100% specificities, exception: Nobel, used probe, experts 83%). The tactile assessment with a new probe was considered accurate. The acceptable misfit values were smaller than the estimated misfit assessment abilities. Considering the level of experience, the expert group generally estimated smaller values for the used and new probe than the novices.

The impression-taking procedure plays a major role in the whole prosthetic rehabilitation process and in this sense, the fit of the impression post is directly related to the precision of definitive reconstruction fabrication [7]. A literature review investigated the misfit of implant prostheses and its impact on the final clinical outcomes, reported in agreement with the current study that in chairside, only major misfits >150 µm may be diagnosed clearly with tactile and radiographic assessment methods [7]. Christensen reported that clinicians found subgingival marginal openings as large as 120 µm, acceptable [24]. Another in-vitro evaluated the accuracy of fit in full-arch implant fixed prostheses and the authors mentioned, that misfits over 50 µm may not be detectable with a visual inspection and tactile test [25]. Therefore, relying only on tactile probe assessment may not be enough for the fit evaluation of implant reconstructions.

A recent systematic review summarized the available methodologies on implant-abutment-framework misfit, and they concluded that despite the technological advances, reliable clinical methods to assess these misfits are currently unavailable, a clear relationship between the misfit and the resulting strain-stress has not been substantiated and there is still a lack of consensus on the tolerable misfit clinical threshold [26]. A recent study on the microgap evaluation by using Scanning Electronic Microscope in conical connection implants for single reconstructions fabricated with different materials and techniques were reporting microgaps values from 0.12 to 85.97 µm [27]. In addition, poor misfit detection at the implant-impression post or abutment section may potentially correlate with the microleakage of different bacterial species that could be detected at different gap levels [8]. Although the microgap assessment was not performed with an explorer probe, the reported data can serve as reference values when evaluating the implant-abutment misfit [27].

Considering the limitations of the present study, the *in-vitro* set-up was the major issue since the intraoral conditions may influence all the assessment results. In this sense, further studies including *in vivo* conditions can give additional information. When the simulated gaps can represent realistic misfit levels that could occur clinically during the impression-taking procedure with mucosal interposition or a wrong engaging process between the impression post and the dental implant. It is noteworthy, that the background and level of experience of the clinician can attribute to errors in fit assessment, as was observed in the present study and previously reported [28]. Considering that the *in vitro* set-up was given, additional specimen groups in which the clinicians screw the impression post and afterwards the fit was assessed could give further information.

Another limiting factor was the artificial mucosa used in the present study setup. The direct tactile assessment of the interface was hidden with the fibrous web, but the viscosity was for sure not comparable to the real mucosal tissues. Thus, it may have been easier to access the implant interface as compared to clinical reality. Further studies with silicones as gingival mimic material, ex-vivo or animal specimens will give additional results. In addition, the inclusion of external and conical connection implants with different placement depths as additional comparison groups can give a wider scenario to extrapolate the obtained results to the current clinical situations. Although the study was based on the impression-taking phase, the absence of individualized post abutments or restoration can be a potential limitation since the tactile misfit detection may not be as simple when the implant reconstruction is present and can be dependent on the shape and the emergence from the implant shoulder.

When the clinical implications of the present study are considered, to reliably confirm passive fit or detect a misfit or a gap at the implant-impression coping interface of tissue and bone level implants is difficult independently of the level of clinical experience. It should be noted that a new probe improves the detection ability (sensitivity) significantly at the expense of the specificity, hence a new probe may be recommended or at least a probe that does not have a worn tip.

In addition, the specificity and sensitivity to determine an acceptable fit or a non-acceptable misfit by using an explorer probe alone may not be sufficient on a routine basis, especially in situations with difficult direct accessibility to the interface area, such as deep-placed implants, individualized impression posts or implant reconstruction shape and the emergence or cases of multiple implants. The specificity and sensitivity to determine a good fit or misfit with one clinical method alone, may not be sufficient on a routine basis, but it could be improved by combining with additional chairside techniques (periapical radiographs and or the one screw test), especially in situations with difficult direct accessibility to the interface area, such as bone level implant systems or in cases of multiple implants. Systematic training and calibration of professionals especially in a specialization program could significantly improve the theoretical knowledge and practical assessment abilities.

5. Conclusions

Within the limitations of the present *in vitro* study and based on the obtained results it can be concluded that: The ability to detect a perfect fit (specificity) with an explorer probe, was very poor for both implant systems used in the present study and was impaired with the use of a new probe. The ability to detect a gap at the interface (sensitivity) with a probe was poor-fair for 24 and 55 µm and good-excellent for large gaps of 110 and 220 µm. It improved significantly in small gaps <55µm with the use of a new probe. The positive predictive values for the tactile gap detections ranged from 83 to 86% compared to 7 to 28% for the negative predictive values. Considering the specificity results, a combination of the tactile misfit detection with additional chairside techniques (periapical radiographs and or the one screw test) and further systematic and calibrated training in implant-prosthodontics may significantly improve the assessment abilities.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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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