CLINICAL ORAL IMPLANTS RESEARCH

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New 3D technologies applied to assess the long-term clinical effects of misfit of the full jaw fixed prosthesis on dental implants

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Abstract

Objectives: To assess implant:suprastructure misfit in patients with an edentulous jaw restored by an implant-retained fixed dental prosthesis (FDP) and its association with biologic and mechanical adverse events over an extensive period.

Material and methods: Thirty patients with an edentulous mandible treated with implant-supported prosthetics before 2000 were examined clinically in 2012. Each patient had received 4 to 6 implants to retain a FDP made from acrylic and three different metal alloys, that is, Ag-Pd, Pd-Ag, and Au type IV. The implant intra-oral locations were recorded digitally by use of an intra-oral scanner, and the intaglio surface of the detached FDP was recorded using a desktop scanner. The fit was estimated by digital matching of the STL files using industrial metrological software. The average misfit was correlated with the average marginal bone loss and the prevalence of screw loosening or fractures, using the patient as the statistical unit.

Results: Over an average of 19 years (range 12 to 32), 5 implants had been lost in 4 participants (96.7% implant survival) and 8 eight prostheses (26.7%) had been remade. Anaverage misfit was 150 μm (SD 35, range 95–232, CI 138–163). An average marginal bone loss of 2.2 mm (SD = 0.7) had occurred (range 0.6 to 5.8 mm) for individual implants. The correlation between framework misfit and marginal bone loss was weak (R^2 = 0.04) (P = 0.29). The prostheses with a history of screw-related adverse events showed average misfit of 169 μm (SD = 32) vs. those with no history of screw-related adverse events, that is, 134 μm (SD = 30) (P = 0.005, Student's t-test). Fourteen of the 30 participants had experienced at least one incidence of screw loosening or fracture of prosthetic or abutment screw(s) over the period of follow-up. The occurrence among the frameworks fabricated with different metal alloys did not differ (P > 0.05, Fisher's exact test).

Conclusions: Combining STL files with best-fit algorithms to appraise misfit is feasible using metrological software. The effect of misfit between the superstructures on its supporting implants up to ~230 μm on the long-term clinical outcomes appears to be minor, apart from a slightly higher risk of screw-related adverse events.

The clinical consequence of an ill-fitting metal framework on one or multiple implants has been extensively debated over four decades (Skalak 1983; Smedberg et al. 1996; Sahin & Cehreli 2001; Monteiro et al. 2010), albeit with limited direct clinical evidence. In the nineties, reported high frequencies of implant system component fractures were associated with alleged misfit (Jemt 1991; Naert et al. 1992; Kallus & Bessing 1994), although redesigns of the components largely alleviated the problem. Numerous laboratory studies using alternative research strategies have shown that a lack of passivity between the matching surfaces of the framework to the respective implants platforms can be directly translated into internal stresses in the implant body—crestal bone—implant system components—prosthesis complex. It has been hypothesized that these internal stresses are prime causes for subsequent biological and mechanical adverse events (Goodacre et al. 2003; Heckmann et al. 2004). Along this line of thought, many ingenious approaches have been attempted to maximize passive fit, albeit to what extent this is achievable at all has been questioned (Tan 1995).

Some evidence of the association between prosthesis misfit and bone response has been

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generated in animal studies, but the interpretation with regard to clinical connotation is unclear (Jemt et al. 2000; Duyck et al. 2005; Rungruanganunt et al. 2013). The correlation between the degree of passivity of fit of implant-supported FDPs and the rate of mechanical and biological adverse events over extended time clinically remains to be investigated. Recent developments within optical scanning technologies based on faster and affordable microchips combined with improved metrology algorithms open up for applying this tool in clinical dental research (Tahmaseb et al. 2010, 2011). The purpose of this clinical study was to assess the metal framework accuracy against its supporting implant abutments in patients with an edentulous jaw restored by an implant-retained fixed dental prosthesis (FDP) and its association with biological and mechanical adverse events over an extensive period. The null hypothesis was that the amount of marginal bone loss and the rate of mechanical adverse events in FDPs are not correlated with the average numerical misfit value of the metal framework of FDPs against the implant abutments.

Material and methods

The protocol of this retrospective clinical study was approved by the Research Ethics Board of the University of Toronto (Ref. 2011-#26777). All patients with an edentulous mandible treated with implant-supported prosthetics in the period between 1978 and 2000 in the Graduate Prosthodontic Clinic of the University of Toronto, Faculty of Dentistry were in 2012 invited to attend a clinical examination at the clinic (n = 136). Each patient had received 4 to 6 implants (Brånemark system, Nobel Pharma AB, subsequently Nobel Biocare AB, Gothenburg, Sweden) to retain FDPs made from metal and acrylic. All other implant system components were from the same manufacturer. The prefabricated abutments were secured to the implants with titanium abutment screws torqued to 35 n Cm. All FDPs were attached to titanium cylindrical transmucosal abutments with gold prosthetic screws using 15 n Cm. The fabrication of FDP followed the process described in detail elsewhere (Zarb & Jansson 1985). In brief, a metal framework was casted from a wax-up made on abutment analogues in a master stone model. During 1978 to 2000, three different metal alloys had been used to fabricate the FDPs: Silver–Palladium (65:35%), Albacast or Palliag (n = 9), Palladium–Silver (70:30%) A37 NOBLE or Degubond Ultra (n = 13), and type IV gold (58% Au) Esteticor Implant 58 or Stabilor G (n = 8).

For the patients consenting to participation, the general information and medical/dental history were gathered retrospectively from the patient charts. Any history of mechanical adverse events such as prosthetic/abutment screw loosening/fracture and incidences of cracks, chippings and fractures in resin teeth, acrylic body, and metal framework of prostheses was recorded. Thorough intra-oral examinations were carried out by an experienced prosthodontist to assess the clinical status of the implants and the superstructure. Periapical radiographs were taken of all supporting implants using a long-cone parallel technique on the day of recall.

The FDP and surrounding tissues were first assessed intra-orally, and loose and fractured abutment and/or prosthetic screws were noted. The FDP was next unscrewed and removed from the patient's mouth to be cleaned in an ultrasonic bath. Any fractured screw parts were carefully removed using a variety of techniques. Stability of each individual implants was assessed by torquing the abutment screws attaching the abutments to the respective implants. In case of abutment screw breakage, new screws were used and torqued as per the manufacturer's instructions. The extraoral FDP was inspected in a stereomicroscope for any obvious flaws before the extra-oral scanning process.

The intra-oral locations of the implant abutments were recorded using a handheld digital scanner (iTero, Align Technology, Inc., San Jose, California, USA). Stents made from acrylic were fabricated on the patients' original master stone models prior to the intra-oral recording appointment (Fig. 1a and b). The acrylic stents were friction-fitted against the transmucosal abutments while letting the abutment platforms projecting through the holes devised on the stent (Fig. 2). The manufacturer's instructions for recording were followed, and a consistent series of digital images was captured using the Itero clinical software (ver. 3.7.0.26 → 4.1.0.61). The point cloud file was sent online to the manufacturer, and the converted file was returned and examined using the Itero laboratory software. A stereolithographic data file was exported from the Itero laboratory software, in a standard tessellation language (STL) format compatible with 3Shape.

The intaglio surface of the detached FDP was recorded using a desktop scanner (D810 Scanner, 3Shape A/S, Copenhagen, Denmark) (Fig. 1c and d). According to the manufacturer, the D810 scanner has a maximum error of 16 μm over a 60 mm scan length and a maximum probing error of 2 μm. The intaglio surface of the detached FDP was prepared according to the manufacturer's

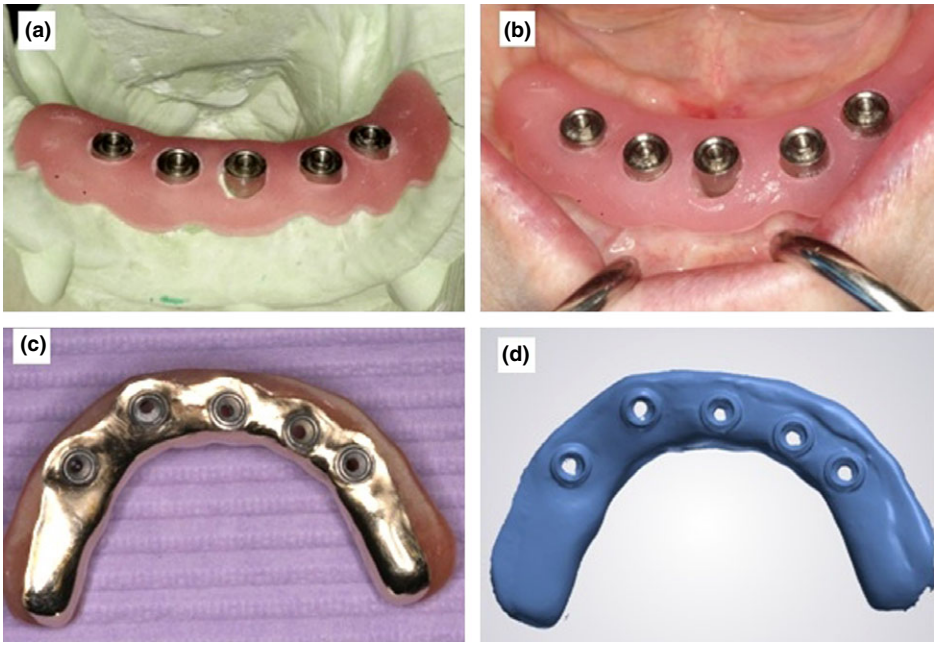

Fig. 1. (a and b) Customized acrylic stent made on stone model used intra-orally to facilitate intra-oral digital recording (iTero, Align Technology, Inc., San Jose, California, USA); (c and d) virtual model of the intaglio surface of the prosthesis recorded extra-orally using a desktop scanner (D810 scanner, 3Shape A/S, Copenhagen, Denmark).

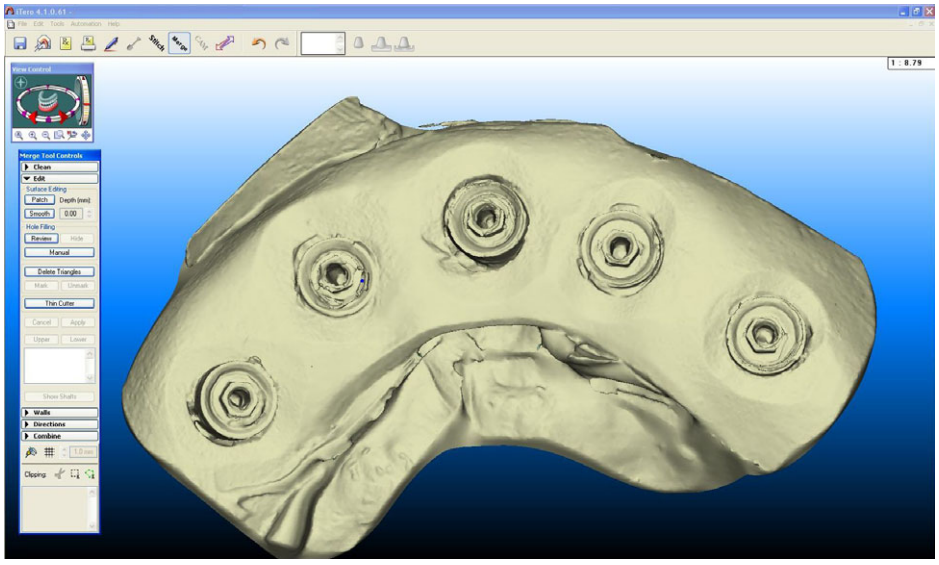

Fig. 2. Itero clinician software (iTero, Align Technology, Inc., San Jose, California, USA) screen picture, showing the abutment platforms penetrating through the acrylic stent.

instructions with white VITA Powder before placing the device in the scanner. The 3D model was inspected and verified using the 3Shape Dental designer software (ver. 2.6 & 2.7).

After having been cleaned and scanned, the FDP was reattached to the abutments using brand new gold prosthetic screws using the 15 N cm screw torque as per the manufacturer's recommendation. The screw holes were filled with a cotton pellet or plastic tape, topped with a light-curable composite resin (Tetric; Ivoclar Vivadent, Schaan, Liechtenstein), and adjusted and polished. The occlusion was readjusted with anterior and cuspid guidance in medio-laterotrusion and freedom in centric using shim stock and/or articulator paper.

The fit of the metal framework to the matching transmucosal abutments was estimated by digital matching of the two STL files of paired 3D virtual models using an industrial metrological software (Convince™ Premium, 3Shape A/S, Copenhagen, Denmark). Utilizing a 3-point registering system, the virtual models (i.e., the intaglio surface of FDP and the respective transmucosal abutments) were aligned after selecting three specific points on the FDP interface and the corresponding points on the transmucosal abutments. Generating 3D geometric dimension and tolerance (GD&T) mapping, the software allowed for a point-to-point distance 3D measurement for any given region-of-interest (ROI) (i.e., the interface of the FDP and the transmucosal abutments). Hence, "difference maps" could be generated for the region-of-interest (ROI) which in this study is the interface between the FDP and transmucosal abutments (Fig. 3). The misfit value calculated by the software was an average measure for all implants in each patient. To measure the misfit and obtain only positive values, the best fit among the implant-suprastructure was chosen, thus ensuring that the fit against the other implants had only positive discrepancies. Otherwise, the misfit numbers would be both positive and negative. If more than one abutment–bridge connection was considered passive the choice would be more or less arbitrary, and the average misfit was numerically adjusted for the fit against the reference implant. The average misfit represented the total misfit for all supporting implants. This number was compared with the average bone loss of all implants supporting that specific FDP. These differences, based on a configurable color-coded scale map ranging between 0 and 500 micrometers (μm), reflect the misfit of the FDP and hence its deviation from a full passivity.

Marginal bone loss around the implants was measured on digitized periapical radiographs using freely available software (ImageJ; US National Institutes of Health, Bethesda, MD, USA). Calibration was performed by correcting for the known distance between implant–abutment interface and the first thread (1.2 mm) and the standard distance between the threads (0.6 mm) in the Brånemark system implants.

The misfit between the abutment and FDP was correlated with the marginal bone loss using the Pearson product moment correlation test (Pearson's correlation). Moreover, a Student's t-test was used to compare the average misfit of frameworks in patients who had a clinical history of screw loosening or fracture of abutment and/or prosthetic screws versus those without such incidences. The

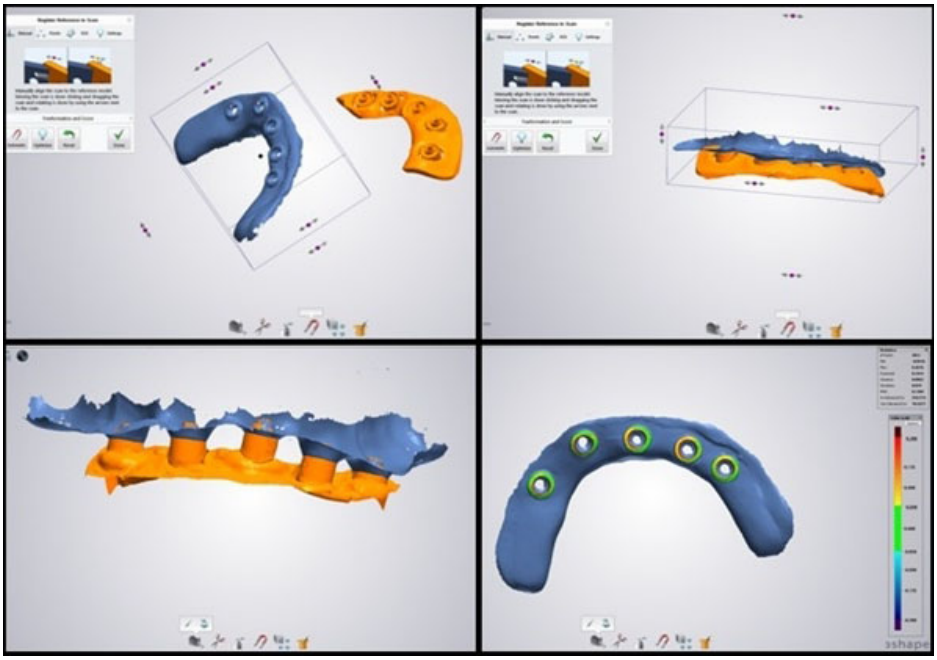

Fig. 3. Alignment (automatic best fit) of the 3D models of the transmucosal abutments in patient's mouth (intra-oral digital recording, orange) and the intaglio surface of the detached FDP (extraoral digital recording, blue) through 3-point registration using metrological software (Convince™, 3Shape A/S, Copenhagen, Denmark). The region-of-interest (ROI) representing the interface between the two matched virtual models is shown in green.

rate of one or more screw-related adverse events in the frameworks versus the different types of metal alloys used for the framework was assessed by use of Fisher's exact tests. In all statistical tests, the patient formed the statistical unit (n = 30) and not the individual implants (n = 148). Underlying assumptions of normality of the data was verified, before using parametric statistical tests. All statistical analyses were conducted using SPSS (version 19, SPSS Inc., Chicago, IL, USA).

Results

Thirty patients of the 136 invited responded to the study invitation. The 30 participants had received 153 implants 12 to 32 years earlier (average 19, SD = 6). At the time of implant placement, the participants had an average age of 54 years (ranging from 28 to 74 years), while it was 73 (SD = 11) years at the time of examination. The major reasons for not partaking in the clinical study were unknown address (n = 29), decease or health issues (n = 25), disinterest (n = 18) or simply no response for unknown reasons (n = 24).

The 30 mandibular FDPs were supported by 148 implants. While none of the implants was found to be mobile at the day of recall, 5 implants (of 153) were lost in 4 patients over the average 19-year follow-up period (96.7% implant survival). A total number of 8 prostheses (26.7%) had been remade (prosthesis failure) due to mechanical adverse events over the observation period.

The calculated average value for the misfit between the interface of the FDP (n = 30) and the transmucosal abutments was 150 μm (SD 35, range 95–232, CI 138–163).

The radiographic assessment at the day of clinical examination revealed that an average marginal bone loss of 2.2 mm (SD = 0.7) had occurred over the follow-up period with bone losses ranging from 0.6 to 5.8 mm for individual implants.

The Pearson's coefficient (r) for the correlation between the average value of framework misfit and the average marginal bone loss was 0.199 (Fig. 4), indicating that there is only a weak relationship between the two variables (R^2 = 0.04). The corresponding P-value (two-tailed probability) for the correlation between the marginal bone loss and the framework misfit was not statistically significant (P = 0.29).

A review of the patients' charts combined with the data from the intra-oral examination at the recall session suggests that 46.7% of the patients (14 of 30 prostheses) experienced at least one incidence of screw loosening/fracture (prosthetic and/or abutment screws) over the period of follow-up. A student's t-test revealed that the prostheses with a history of screw-related adverse events showed an average misfit of 169 μm (SD = 32), which was more than the average misfit of the prostheses with no history of screw-related adverse events, that is, 134 μm (SD = 30) (P = 0.005, Student's t-test) (Fig. 5).

The occurrence of one or more screw-related adverse events among the frameworks fabricated with different metal alloys (i.e., Ag-Pd, Pd-Ag, Au Type IV) did not differ (P > 0.05, Fisher's exact test).

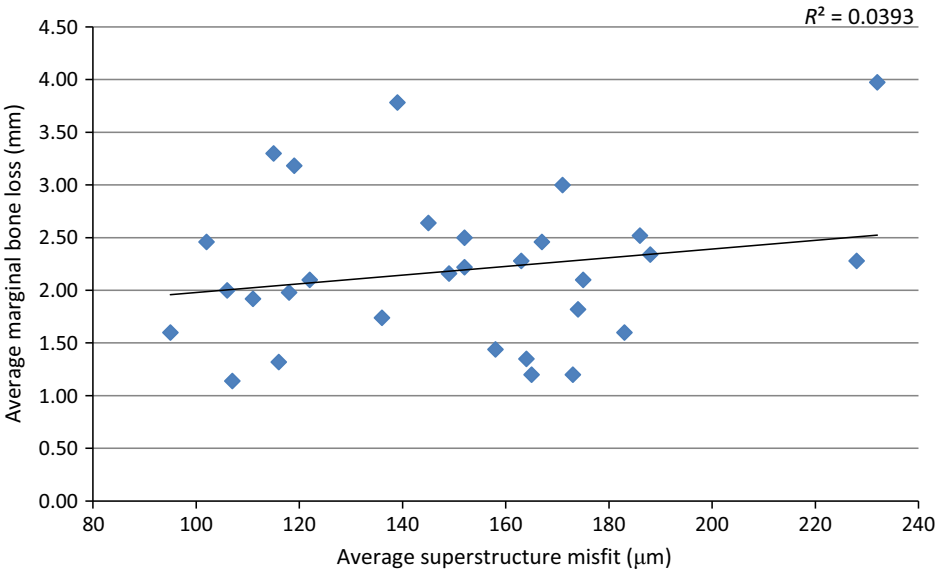

Fig. 4. Correlation between the average framework misfit against the supporting implants (μm) and the average marginal bone loss around the supporting implants (mm) over the full observation period (range 12 to 32 years) (n = 30). Diagonal line represents the regression line.

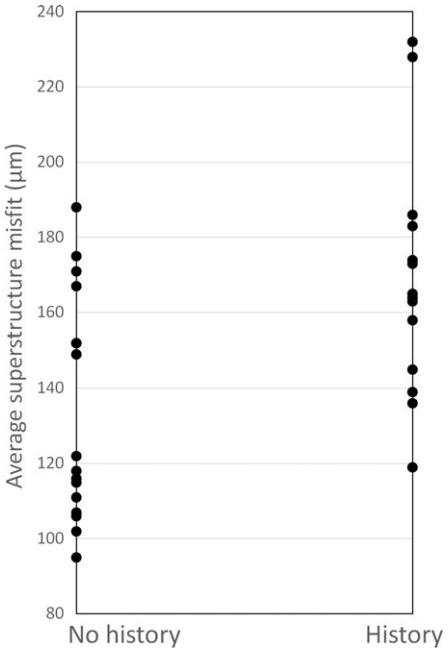

Fig. 5. Framework misfit in prostheses without (left) and with (right) a history of one or more screw-related complications (Average μm) over the full observation period (range 12 to 32 years) (n = 30).

Discussion

A common practical problem inherent with most full mouth intra-oral digital impression methods is that any movements in the observation field, for example, flowing saliva or some activity of the tongue or vestibule will disturb the recording, sometimes to the extent that the software is unable to stitch together series of digital images. Another critical element is that the surfaces to be recorded cannot be too smooth because the 3D software in such situations is unable to incrementally build the series of digital images during the acquisition process. After some experimentation with various rubber dam and custom impression tray materials, it was realized that the best solution was acrylic stents that masked the mucosa while letting the transmucosal abutments projecting through the holes.

To assess the effect of misfit in clinical studies, most authors have attempted to measure the gap between the framework and abutments. This is mostly for practical reasons because it is not possible to evaluate the distribution of internal stress in a superstructure and implants. It has been proposed that vertical gaps up to 100 micrometers can

be readily closed after torquing the retaining screws (Smedberg et al. 1996; Jemt & Lekholm 1998). One may infer that the traditional methods to measure the vertical gap between the framework and abutments may not accurately represent the internal stress in the superstructure. The application of a modern 3D intra-oral scanner combined with a laboratory scanner and software that is designed to estimate the discrepancy between the virtual 3D models of the framework and abutments can efficiently solve the aforementioned problem.

The maximal amount of clinically acceptable misfit remains unknown. While Brånemark assumed that a misfit of frameworks within the range of 10 μm was necessary to secure "the adequate remodeling stimulus"(Brånemark 1983), other investigators considered discrepancies within the range of 100 to 200 μm as clinically acceptable (Jemt 1991, 1996; Tiossi et al. 2008; Wettstein et al. 2008).

The overall misfit value of the FDP on its supporting implants in the current study sample was within the range of 95 to 232 μm. The misfit did not correlate with the amount of marginal bone loss after an average of 19 years of follow-up. How much static force was exerted on the implants and surrounding bone by the non-passive superstructures included in this study remains unknown. One may hypothesize that the prosthetic gold screws could have absorbed some of the misfit-induced strain and decreased the strain transferred to the implant–bone interface. The other important issue deserving attention is the range of misfit in this study (95 to 232 μm) with little or no relation to biological and technical adverse events. It has been previously proposed that there might be a safe range of misfit beyond which the static forces can potentially cause marginal bone loss (Jemt 1996). This investigator used a type of 3D photogrammetric technique to estimate superstructure passivity and found an average of 91 ± 51 μm misfit, but found no correlation between fit and bone loss after 5 years of follow-up. It is essential to understand that the results of this study do not preclude the incidence of progressive bone loss in cases where the passivity of the superstructure is worse than the aforementioned range of misfit. Furthermore, the physiologic tolerance level of an ill-fitting superstructure will be greatly affected by factors such as bone quality, dynamic occlusal forces, the size of implants, and implant surface characteristics.

Unlike biological adverse events, it was observed that prostheses with greater amount of average framework misfit experienced a higher incidence of the screw-related adverse events (screw loosening/fracture). This result is in agreement with previous clinical studies (Kallus & Bessing 1994; Wennerberg & Jemt 1999). It is known that he elastic recovery force of the screws provides for the preload, which secures the connection between the superstructure and the abutments. In a non-passive superstructure, the torquing forces provide the same level of preload. Nonetheless, it may be hypothesized that tightening a non-passive superstructure on the transmucosal abutments imposes an uneven distribution of tensile stresses on the shank and threads of prosthetic screws resulting in an uneven screw elongation. Such an uneven strain of the prosthetic screws can eventually cause screw-related adverse events including screw loosening and screw fracture.

The current study reports the average misfit values and bone level loss, using the patient as the statistical unit ($n = 30$). Albeit statistical power is lost, the presented statistical tests in this paper assume independence among variables. Further studies are underway that assess relationships on the implant level, which require more sophisticated statistical approaches that take into account the effects of clustered data within each patient.

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