

UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

ILANA SANTOS RAMALHO

**Influence of abutment fabrication method and fixation mode on the
three-dimensional fit and reliability of implant-supported
prostheses**

**Influência do método de fabricação de pilares e modo de fixação na
adaptação tridimensional e confiabilidade de próteses sobre
implantes**

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Orientador: Prof. Dr. Estevam Augusto Bonfante

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“Se você pode sonhar, você pode fazer.”

Walt Disney

ABSTRACT

Influence of abutment fabrication method and fixation mode on the three-dimensional fit and reliability of implant-supported prostheses

Objectives. To evaluate the effect of abutment fabrication method on the three-dimensional fit at the implant-abutment interface and its correlation with stress at fatigue failure of prostheses. Probability of survival (reliability) and fractography to characterize failure modes were also performed for cemented and screw-retained prostheses.

Methods. Central incisor crowns were milled to restore implants and divided in 3 cemented and 3 screwed-retained groups, as follows (n=21/group): [Digital-Sc]: milled one-piece monolithic abutment/crown; [TiB-Sc]: milled crowns cemented onto Ti-base abutments; [UCLA]: screw-retained crown using UCLA abutments; [Digital-Ce]: milled two-piece assembly comprised by screwed monolithic abutment and a cemented crown; [TiB-Ce]: milled coping cemented onto Ti-base abutments to receive a cemented crown; [UCLA-Ce]: UCLA abutments that received an overcast coping and a cemented crown. Volume measurements were performed to assess the internal misfit using silicone replica of the implant/abutment interface area three-dimensionally reconstructed after microcomputed tomography (μ CT). Implant/crown systems were subjected to step-stress accelerated life testing (SSALT) in water. The use-level probability Weibull curves and reliability for a mission of 50,000 cycles at calculated stress at failure of 2,300, 3,300 and 4,300 MPa were plotted. Fractographic analysis was performed with scanning electron microscopy. Internal misfit was analyzed through one-way ANOVA following post-hoc comparisons by Tukey test ($P<0.05$). Correlation between misfit volume and the stress at fatigue failure was assessed by Pearson test.

Results. Similar misfit volumes were observed for TiB-Sc (0.458 mm^3), TiB-Ce (0.461 mm^3), UCLA (0.471 mm^3) and UCLA-Ce (0.480 mm^3), which were significantly lower than Digital-Sc (0.676 mm^3) and Digital-Ce (0.633 mm^3). The mean β values were: 1.68, 1.39, 1.48, 2.41, 2.27 and 0.71 for Digital-Sc, TiB-Sc, UCLA, Digital-Ce, TiB-Ce and UCLA-Ce, respectively, indicating that fatigue was an accelerating factor for failure of all groups, except for UCLA-Ce. Higher stress at failure decreased the

reliability of all groups, more significantly for screw compared to cement-retained groups, especially for Digital-Sc that demonstrated the lowest reliability. The failure mode was restricted to abutment screw fracture. A negative correlation was observed between misfit values and stress at failure ($r = -0.302$, $P=0.01$).

Conclusions. Ti-Base and UCLA abutments exhibited better internal fit at the implant/abutment interfaces compared to full commercial lab fabrication process (CAD-CAM custom abutments). An impairment of the mechanical resistance according to different levels of internal misfit was observed, since the higher the volume of misfit, the lower the stress at failure during fatigue. Probability of survival decreased at higher stress, especially for screw compared to cement-retained groups, and failures were confined to abutment screws.

Keywords: Dental Implant-Abutment Designs. Dental Implant-Abutment Interface. Dental Implants. MicroCT. Reliability. Computer-Aided Design.

RESUMO

Influência do método de fabricação de pilares e modo de fixação na adaptação tridimensional e confiabilidade de próteses sobre implantes

Objetivos. Avaliar o efeito do método de fabricação de pilares sobre a adaptação tridimensional na interface implante-pilar e sua correlação com o estresse à fratura por fadiga das próteses. Probabilidade de sobrevivência (confiabilidade) e fractografia para caracterizar modos de falha também foram realizadas para próteses cimentadas e parafusadas.

Métodos. Coroas de incisivos centrais foram confeccionadas para restaurar implantes e divididas em seis grupos, sendo 3 grupos parafusados e 3 cimentados (n=21/grupo): [Dig-Par] – coroa fresada monolítica parafusada; [TiB-Par] – coroa fresada cimentada sobre pilar Ti-Base e parafusados ao implante; [UCLA] – coroa fundida sobre UCLA parafusada; [Dig-Cim] – pilar fresado parafusado para receber coroa fresada cimentada; [TiB-Cim] – pilar fresado e cimentado sobre Ti-Base para receber coroa cimentada; [UCLA-Cim] – pilar fundido sobre UCLA parafusado para receber coroa cimentada. Mensurações de volume foram realizadas para avaliar o desajuste interno usando réplica de silicone na área da interface implante/pilar reconstruída tridimensionalmente após a microtomografia computadorizada (μ CT). Os espécimes foram submetidos ao teste de fadiga acelerada progressiva na presença de água. As curvas de probabilidade de Weibull e a confiabilidade para missões de 50.000 ciclos a 2.300, 3.300 e 4.300 Mpa foram plotadas e calculadas em função do estresse. A análise fractográfica foi realizada com microscopia eletrônica de varredura. O desajuste interno foi analisado através de ANOVA seguida de comparações múltiplas pelo teste de Tukey ($P < 0,05$). A correlação entre o volume de desajuste e o estresse à fratura por fadiga foi avaliada pelo teste de correlação de Pearson.

Resultados. Volumes de desajuste semelhantes foram observados para TiB-Par (0,458 mm³), TiB-Cim (0,461 mm³), UCLA (0,471 mm³) e UCLA-Cim (0,480 mm³), que foram significativamente menores que Dig-Par (0,676 mm³) e Dig-Cim (0,633 mm³). Os valores médios de β foram: 1,68, 1,39, 1,48, 2,41, 2,27 e 0,71 para Dig-Par, TiB-Par, UCLA, Dig-Cim, TiB-Cim e UCLA-Cim, respectivamente, indicando que

o acúmulo de danos em função da fadiga foi um fator de aceleração para as falhas em todos os grupos, exceto para UCLA-Cim. Maior estresse à fratura diminuiu a confiabilidade de todos os grupos, mais significativamente para os grupos parafusados comparado aos cimentados, especialmente para o Dig-Par, que demonstrou a menor confiabilidade. O modo de falha predominante foi a fratura do parafuso do pilar. Uma correlação negativa foi observada entre os valores de desajuste e estresse à fratura ($r = -0,302$, $P = 0,01$).

Conclusões. Os pilares do tipo Ti-Base e UCLA exibiram melhor ajuste interno na interface implante/pilar comparado com os pilares fresados em laboratório comercial (customizados CAD-CAM). Observou-se um comprometimento da resistência mecânica de acordo com os diferentes níveis de desajuste interno, visto que quanto maior o volume de desajuste, menor o estresse à fratura durante a fadiga. Probabilidade de sobrevivência diminuiu em nível maior de estresse, especialmente para os grupos parafusados em comparação com os cimentados, e as falhas foram confinadas aos parafusos do pilar.

Palavras-chave: Implantes dentários. MicroCT. Confiabilidade. Projeto Auxiliado por Computador.

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1 INTRODUCTION

1 INTRODUCTION

Implant-based therapy is a predictable and reliable treatment modality in the rehabilitation of missing or lost teeth ^{1, 2}. The literature on dental implants has advanced remarkably over the last decade, and recent reports have been shown success rates upwards of 95% ³. Although high success rates are commonly reported for such treatment ^{1, 4}, the less common report of cumulative survival rates suggests that the actual failure rates of dental implants are likely to be higher than the rates published in the clinical literature and therefore success may be inflated ³.

According to a recent systematic review ⁴, the total number of technical complications was statistically similar for internal and external connections, with a 5-year complication rate of 10.1% and 12.4%, respectively. Also, it has been reported that the most common complication is abutment screw fracture, with a cumulative rate of 10.4% in 5 years and a twofold increase to 20.4% in 10 years ⁵. Such findings emphasize that treatment with implants, despite its advantages, should predict complications, time, and additional cost for maintenance ¹.

Considering that complication rates increase over time ⁶, indicating that the fatigue damage accumulation degrades prostheses strength, it is essential to acknowledge that technical complications in implant dentistry are prevalent, and the importance of their characterization in preclinical studies has been increasingly valued ^{7, 8}. In this context, the use of *in vitro* mechanical testing methods to characterize the implant-prostheses complex becomes paramount, since clinical studies demand proper design, long-term follow-up, and robust data from many volunteers would need to be statistically addressed to provide meaningful results ⁸. The use of *Step-stress Accelerated Life Testing* (SSALT) for reliability and failure mode analysis of several implant restorative scenarios has been widely reported ⁹⁻¹³.

Given the vast possibility of a combination between variables in an implant-supported rehabilitation, the selection of restorative components and crown fixation mode must be considered as a factor for long-term clinical success ^{14,2}. For improved performance, abutments should present the best fit at the implant connection ¹⁵, since higher values of misfit between components may increase microleakage and

mechanical stress on connection structures and surrounding tissues ¹⁶⁻¹⁸. Depending on the level of misfit, it may lead to mechanical problems, such as damage to the internal threads, screw preload loss or screw fracture ^{16, 19}. Additionally, biologic complications due to the microorganism colonization of the implant well may eventually participate in the multifactorial role of peri-implant tissue inflammation, which can cause pain, bone strain, marginal bone loss, and in the worst scenario the loss of osseointegration ^{17, 18, 20, 21}.

There has been little information presented on the three-dimensional internal gap misfit between abutments fabricated through different techniques connected to implants with internal connection. The methods commonly used to measure marginal and internal discrepancies of restorations involve direct visualization or sectioning of the specimens, followed by measurement of the interface using scanning electron microscopy (SEM) ^{22, 23}, optical microscopy ²⁴, travelling microscope ^{25, 26} among others. These measurements commonly involve human error that, along with the non-standardized evaluation sites make interpretation and comparison between studies a challenge ^{27, 28}. In recent years, micro-computed (μ CT) tomography has gained popularity in implantology ²⁹⁻³¹ because it allows the non-destructive and three-dimensional (3D) evaluation of the materials, promoting a feasible quantitative and qualitative analysis of marginal or internal misfit ³². Additionally, 3D reconstruction software may be used for the volumetric quantification of the misfit and internal/marginal gaps at the implant–abutment interface.

The selection of the implant abutment for each patient case is an essential part of the implant-prosthetic treatment phase. Firstly, a fundamental distinction needs to be made between ‘prefabricated’ or ‘stock’ and ‘custom-made’ abutments. The former comprises a standard geometry commercial abutment. Several prefabricated abutments are available in the market, which vary in indication and design, generally being indicated when the implant is placed in an almost ideal prosthetic position. Although the claimed better fit of stock abutments provided by the industry, which demand approval by regulatory agencies, their customization may be limited, considering each patient’s difference in peri-implant soft tissue emergence profile. Therefore, the need for custom abutments is gradually increasing over the years.

Opportunities for individualization include the use of custom-made abutments fabricated through either a conventional casting procedure using universal casting long abutments (UCLA) or through a digital workflow using the computer-aided design/computer-aided manufacturing (CAD/CAM) technology. In the latter, two customization options are available: 1) full digital lab fabrication process: a one-piece monolithic abutment/crown may be designed and milled in a commercial laboratory by CAD/CAM system (currently feasible for external or internal non-conical connections); or 2) hybrid fabrication process: an industrially manufactured abutment system receives custom CAD/CAM restoration fabricated by a commercial laboratory (final crown or custom core).

The UCLA-type abutment is one of the most versatile abutments produced by conventional casting procedures. Although the indications may vary, the UCLA-type abutment is practically universal and at a lower cost when compared to other prefabricated abutments. However, the castable base of the abutment that will adapt to the implant undergoes distortions during the casting procedures, impairing the fit and passivity at the implant/abutment connection, thus causing mechanical and biological problems, as previously reported ^{19, 33, 34}. In order to minimize such effect, castable UCLA abutments with metallic base should be used because the metal (Co-Cr) suffers minor changes during casting as its melting point is higher than the temperature used for investment heating and compatible with the temperature for alloy injection ^{25, 35}, which in theory preserves the fit provided by the industry.

CAD/CAM technology has introduced several advantages for fabricating abutments and has been suggested as an improvement over the conventional methods ^{36, 37}. The benefits of employing a fully digital laboratory fabrication process for abutments and prostheses include customization and rapid chair-side or commercial laboratory fabrication regardless of industry abutment availability. Such a technology is well known to allow the high-precision machining of prefabricated blocks of various materials including ceramics, composite resin, acrylic resin and metal alloys ³⁶. Despite the evident advantages of abutments produced by a full digital workflow, the internal fit of such abutments is roughly dependent on several variables involved in the accuracy of milling of the CAD/CAM systems unit and the selected milling strategy ⁵. Also of concern is the fact that milling of abutments by commercial labs is not yet controlled by international standards or norms, as it is for

industry-provided prefabricated abutments, which undergo standard quality assurance and quality control evaluation.

A potential workaround has been recently introduced where industry-fabricated Titanium-base (or Ti-base) abutments and their inclusion in CAD/CAM libraries allowing the rapid fabrication of either a customized milled core (e.g: zirconia) or the crown by commercial laboratories. This concept is based on a titanium connector featuring a female component that connects to the implant well and an external configuration with geometry available for insertion in most CAD/CAM systems where monolithic or bilayered restorations of any given material can be cemented chairside ³⁸⁻⁴⁰. The main advantage and rationale for use of Ti-base abutments comprise the maintenance of industry provided fit of the female part, in contrast to UCLA abutments where overcasting and post processing (e.g. aluminum oxide blasting) change the titanium surface topography and fit ²⁵. Also, retrievability is maintained when cementing the final prostheses directly to Ti-base since CAD/CAM blocks are provided with screw access holes that allow extra-oral bonding and excess cement removal, eventually reducing cementation induced peri-implantitis ⁴¹⁻⁴³.

Along with the plethora of implant restorative components available, the fixation modes of the implant-supported restoration can be either screwed, cemented, or a combination of both. There is a rich literature on the advantages and disadvantages of the prosthesis retention systems ^{42, 44-50}. A current consensus has been published ⁵⁰ and, in general, the clinical recommendations for screw retention include: implants placed in a prosthetically ideal position, with the presence of minimal interarch space (4 mm); FDPs (fixed dental prostheses) with a cantilever design; long-span FDPs; in esthetic areas, where provisionalization of implants is required to enable soft tissue conditioning and emergence profile improvement or when retrievability is desired. Also, the cement retention is recommended in the following situations: for short-span prostheses with margins at or above the mucosa level, to compensate for improperly inclined implants, for cases where an easier control of occlusion without an access hole is desired (e.g. narrow-diameter crowns)⁵⁰. Although less technical complications of cement-retained relative to screw-retained crowns has been reported ⁵¹, the performance of hybrid systems that combine extra-orally cemented and screw-retained crowns warrants investigation.

Considering the increased use of customizable abutments in restorative dentistry and given that, once under function in the mouth, any restorative system's strength will degrade over time due to fatigue damage accumulation, the characterization of the internal fit at the implant/abutment connection of abutments fabricated by a commercial laboratory (milled or cast) compared to abutments provided by the industry, as well as the impact of misfit levels on the mechanical performance of prostheses still requires investigation. Therefore, the overall objective of this work was to evaluate the effect of abutment fabrication method on the three-dimensional fit at the implant-abutment interface and its correlation with stress at fatigue failure of prostheses. Probability of survival (reliability) and fractography to characterize failure modes were also performed for cemented and screw-retained prostheses.

2 ARTICLES

2 ARTICLES

The articles below were written according to the Journal of Prosthetic Dentistry instructions and guideline for article submission.

- **ARTICLE 1 – Abutment fabrication method affects the three-dimensional fit of the implant-abutment connection**
- **ARTICLE 2 – Implant-abutment fit influences the mechanical performance of single-crown prostheses**

2.1 ARTICLE 1

Abutment fabrication method affects the three-dimensional fit of the implant-abutment connection

ABSTRACT

Purpose. To three-dimensionally (3D) evaluate the internal fit at the implant-abutment interface of abutments fabricated through different workflows using a combination of the silicone replica technique and micro-computed tomography (μ CT).

Materials and Methods. Thirty abutments were fabricated to restore internal connection implants that were divided in 3 groups according to abutment fabrication method, as follows: 1) Full-Digital (abutment machined by CAD/CAM system); 2) Ti-Base (prefabricated standard Ti-Base abutments); and 3) UCLA (UCLA-type abutments) ($n=10$ /group). Linear and volume measurements were performed to assess the internal misfit using silicone replica of the implant/abutment interface misfit area three-dimensionally reconstructed after μ CT. The internal discrepancy in 3 different regions of interest ($Gap_{superior}$, $Gap_{marginal}$ and Gap_{center}) was assessed. Data were statistically evaluated through analysis of variance and Tukey test ($P<.05$).

Results. Ti-Base and UCLA abutments presented significantly lower volume of misfit (0.49mm^3 , $CI:\pm 0.045\text{mm}^3$ and 0.48mm^3 , $CI:\pm 0.045\text{mm}^3$, respectively) and mean internal gap ($25.20\mu\text{m}$, $CI:\pm 3.14\mu\text{m}$ and $27.97\mu\text{m}$, $CI:\pm 3.14\mu\text{m}$, respectively) relative to Full-Digital group (0.70mm^3 , $CI:\pm 0.045\text{mm}^3$ and $34.90\mu\text{m}$, $CI:\pm 3.14\mu\text{m}$) ($P<.001$), without significant difference between each other ($P=.825$). While Gap_{center} was significantly higher for the Full-Digital group ($P<.001$), $Gap_{superior}$ and $Gap_{marginal}$ did

not demonstrate significant differences among groups. All regions were statistically similar within groups, except for the Gap_{center} in the Full-digital group that exhibited higher mean values compared to the other regions (P=.000). The three-dimensional measurement for quantification of internal discrepancy was strongly associated to the two-dimensional measurements.

Conclusion. Ti-Base and UCLA-type abutments exhibited better internal fit at the implant/abutment interfaces compared to fully digitalized workflow (CAD-CAM custom abutments). Three-dimensional reconstruction software may be used for the volumetric quantification of the misfit and internal/marginal gaps at the implant–abutment interface.

Keywords: Dental Implant-Abutment Interface. CAD/CAM. UCLA. Internal Fit. MicroCT.

INRODUCTION

On the basis of the osseointegration phenomenon,¹ implant-based therapy is an established treatment modality in dental practice, providing high success ratios.^{2,3} Given the wide possibility of combination between variables in an implant-supported rehabilitation, the abutment fabrication method should be carefully evaluated, since the implant/abutment connection is one of the most important factors for prostheses stability and long-term success.³ Misfit between such components is recognized as a major concern because it may lead not only to mechanical problems,^{4,5} such as damage to the internal threads and screw loosening, but also to biologic complications due to the microorganism colonization in the inner part of the implant

that may eventually cause the inflammation of peri-implant tissues, and consequently, pain, bone strain, marginal bone loss, and in the worst scenario the loss of osseointegration.⁶⁻⁹

Firstly, a fundamental distinction needs to be made between 'prefabricated' or 'stock' and 'custom-made' abutments. The former comprises a standard commercial abutment, not customizable. The custom-made abutments may be produced by casting (such as the UCLA-type abutments) or may be entirely designed and milled by using the computer-aided design/computer-aided manufacturing (CAD/CAM) process. Since the prefabricated abutments may not provide ideal peri-implant soft tissue emergence profiles, the need of custom abutments is gradually increasing over the years.

The UCLA-type abutment is one of the most versatile custom abutments produced by conventional casting procedures. Although the indications may vary, the UCLA-type abutment is practically universal and at a lower cost when compared to prefabricated abutments. However, the castable base of the abutment that will adapt to the implant undergoes distortions during the casting procedures, impairing the fit and passivity at the implant/abutment connection, thus causing mechanical and biological problems, as previously reported.^{5, 10, 11} In order to minimize such effect, castable UCLA abutments with metallic base should be used because the metal (Co-Cr) suffers minor changes during casting as its melting point is higher than the temperature used for investment heating and compatible with the temperature for alloy injection,^{12, 13} which in theory preserves the fit provided by the industry.

CAD/CAM technology has introduced several advantages for fabricating abutments and has been suggested as an improvement over the conventional methods. The benefits of employing a fully digital workflow are undeniable, including

clinical time reduction, freedom in the selection of machining material, high level of customization, reduced laboratory technique sensitivity and, last but not least, independence of the professional in relation to the industry of prefabricated components. Such a technology is well known to allow the high-precision machining of prefabricated blocks of various materials including ceramics, composite resin, acrylic resin and metal alloys. Despite the evident advantages of abutments produced by a full digital workflow, the control of internal misfit is not yet controlled by international standards or norms (as it is for prefabricated abutments) and is dependent on several variables involved in the milling of the CAD/CAM systems.

In an attempt to overcome this issue, a recently introduced concept based on industrially manufactured abutment systems that receives custom milled restorations resulting in hybrid abutments has received interest.¹⁴ Also known as Ti-base abutments, this concept is based on a titanium connector featuring a female element that connects to the implant and an external configuration with geometry stored in a CAD/CAM system in which monolithic or bilayered restorations of any given material can be cemented chairside.^{15, 16} In addition to the aforementioned advantages to the full digital workflow, the main advantages of such concept comprise the maintenance of industry provided fit of the female part and the opportunity of performing the extra-oral bonding procedure and excess cement removal, achieving a final bond area polishing that decreases soft tissue reaction due to remnants of cement.^{17, 18}

The methods commonly used to measure marginal and internal discrepancies of restorations involve direct visualization or sectioning of the specimens, followed by measurement of the interface using scanning electron microscopy (SEM),^{19, 20} optical microscopy,²¹ travelling microscope,^{13, 22} among others. These measurements commonly involve human error that, along with the non-standardized evaluation sites

make interpretation and comparison between studies a challenge.^{23, 24} In recent years, micro-computed (μ CT) tomography has gained popularity in implantology²⁵⁻²⁷ because it allows the non-destructive and three-dimensional (3D) evaluation of the materials, promoting a feasible quantitative and qualitative analysis of marginal or internal misfit.²⁸

Moreover, there has been little information presented on the three-dimensional internal gap misfit between abutments fabricated through different techniques connected to implants with internal connection. Three-dimensional reconstruction software may be used for the volumetric quantification of the misfit and internal/marginal gaps at the implant–abutment interface. Therefore, the purpose of this study was to evaluate the effect of different workflow for abutment fabrication on the internal fit at the implant/abutment interface and to correlate the two- and three-dimensional misfit measurements. The null postulated hypotheses were: (i) the abutment fabrication methods have no influence on the internal fit at the implant/abutment connection and (ii) there is no statistically significant relationship between the two- and three-dimensional misfit measurements.

MATERIAL AND METHODS

Specimen preparation

Thirty abutments were fabricated to restore internal nonconical connection implants (4 x 10 mm, IH, Novo Colosso; Emfils) that were divided in 3 groups, according to fabrication method, as follows (n = 10/group) (Fig. 1):

- *Fully digitalized workflow* [Full-Digital]: abutment machined by CAD/CAM system and directly screwed to the implant. The implant geometry
-

previously stored in the CAD software (Ceramill® mind; Amann Girrbach) was used to design the abutments, which were then milled using CoCr discs (Ceramill sintron®; Amann Girrbach).

- *Pre-fabricated Ti-base* [Ti-base]: prefabricated standard Ti-Base abutments (non-rotational Ti-Base, Colosso; Emfils).
- *Conventional workflow* [UCLA]: screw-retained abutment using custom-cast long abutments (UCLA). For standardized abutment anatomy, they were designed in the same CAD software (Ceramill® mind; Amann Girrbach) as for Full-Digital group and milled in wax (Ceramill® wax; Amann Girrbach) pattern followed by conventional casting procedures using UCLA-Type abutments (Castable non-rotational in CoCr base with plastic sleeve abutment, Colosso; Emfils).

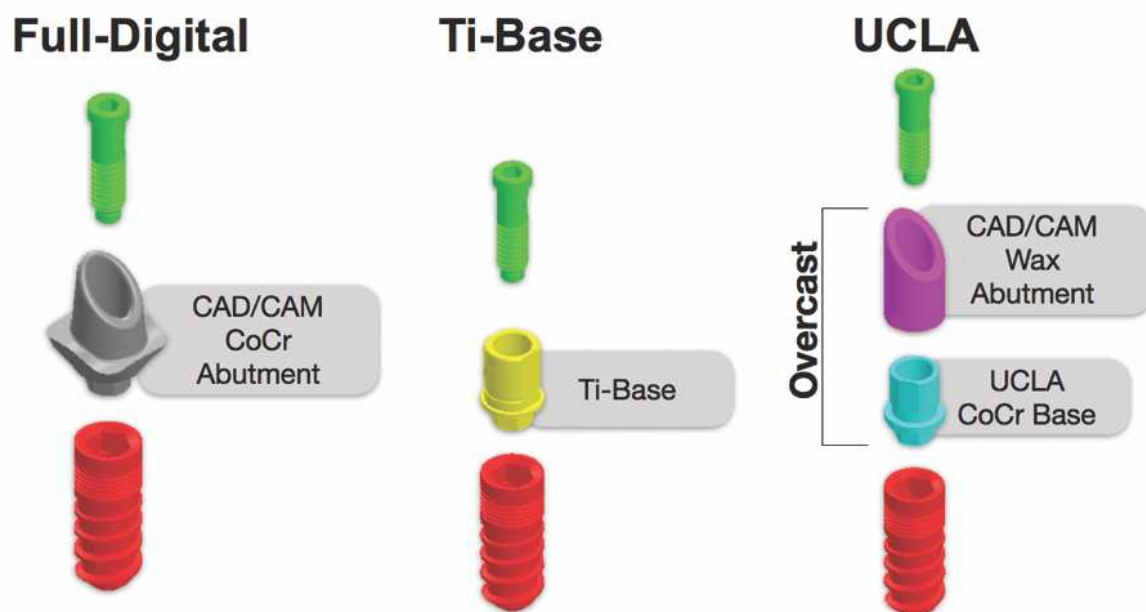


Figure 1. Workflow of the specimen preparation according to the fabrication methods.

Fit evaluation

Linear and volume measurements were performed to assess the internal misfit at the implant-abutment connection using silicone replica three-dimensionally reconstructed after micro-computed tomography (μ CT) (μ CT 40; Scanco Medical). All implants were vertically embedded in an acrylic resin (Orthoresin; Degudent) and plastic tube ($\text{\O}25$ mm x 35 mm) with the implant's platform positioned at the same level of acrylic resin. The implants were filled with a medium-bodied consistency silicone impression material (ExpressTM XT Regular Body; 3M Oral Care) and the abutments were then tightened with torque recommended by the manufacturer (32 N.cm) using a digital torque gauge (Tohnichi BTG150CN-S; Tohnichi America). After the impression material had set, the abutment was untightened and carefully removed from the implant while the thin polyvinyl siloxane film remained on the inner surface of the implant. Then, the polyvinyl siloxane film was gently removed from the implant. At this point, to ensure greater stability of the replica specimen, the excess of impression material drawn into the screw hole was not eliminated (Fig. 2A-B).

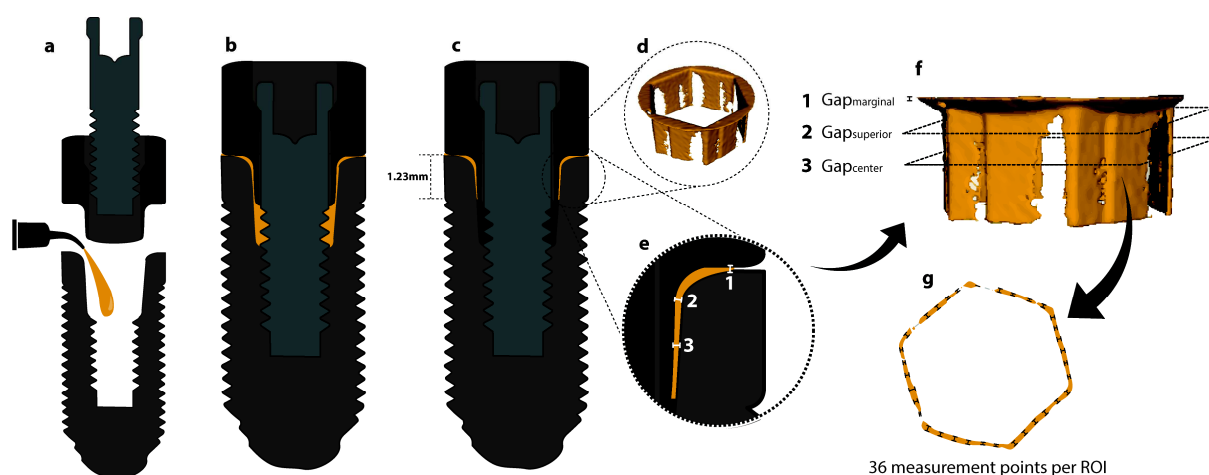


Figure 2. Schematic of the internal fit evaluation. (a) Silicone impression material inserted into the implant. (b,c) To obtain similar volumes for analysis across groups, the excess of impression material drawn into the screw hole was removed by means of Amira software and the ROI was defined by cropping the silicone replica image data at the equivalent height to the first implant thread (1.23 mm from the implant platform). (d) 3D reconstruction of the silicone replica. (e,f) ROIs for linear measurements. (g) Section of replica specimen image data showing the predetermined equidistant measurement points per ROI.

Each replica specimen was scanned using a micro-computed tomography scanner (μ CT 40; Scanco Medical). Five specimens at a time were placed in the sample holder. The instrument was operated at medium resolution (16 μ m/slice) using 70 kVp (114 μ A) resulting in approximately 380 slices per sample. All data were exported in a DICOM-format and imported into Amira software (Amira, version 5.5.2; VSG) for quantification of implant-abutment internal discrepancy, which was represented by the thickness of the medium-body polyvinyl siloxane. Three-dimensional (3D) rendering of the image set was performed using a standard “silicone mask” in Amira software. The same software was used to remove all silicone excess and define the region of interest (ROI) (Fig. 2C). To ensure that the replica specimens of different groups were all cut in an identical fashion and to obtain

similar volumes for analysis, the ROI was defined by cropping the silicone replica image data at the equivalent height to the first implant thread (1.23 mm from the implant platform) (Fig. 2C). A uniform threshold for silicone was determined across all groups using the Otsu algorithm ROIs. The volume of misfit was calculated using the “Material Statistics” software function after 3D reconstruction of the silicone replica (Fig. 2D).

The internal discrepancy was assessed by measuring the thickness of the silicone replica image data using 108 predetermined equidistant points that were divided into three different ROIs. Gap_{marginal} was defined as the vertical distance between the points representing the implant platform and the abutment margin (36 measurements). Gap_{center} was defined as the mean value of the 36 measurements in the middle part of the internal hexagon. Gap_{superior} was defined as the mean value of the 36 measurements in the superior part of the internal hexagon (Fig. 2E-G).

The Shapiro-Wilk statistical test for normality and Levene test for homogeneity revealed normal distribution for data. Data from three-dimensional measurements (volume of misfit) were statistically evaluated through one-way analysis of variance (ANOVA) and data from two-dimensional measurements were statistically evaluated through two-way ANOVA with fixed factors of abutment fabrication method (Full-Digital, Ti-Base and UCLA) and region (Gap_{center} , Gap_{superior} and Gap_{marginal}) following post-hoc comparisons by Tukey test. The level of significance was set at $P=.05$. Data are presented as a function of mean values with the corresponding 95% confidence interval (CI). Also, the Pearson correlation test was used to assess the association between the measurement methods used in this study for fit evaluation. All analyses were accomplished using SPSS (IBM SPSS 23; IBM Corp.).

RESULTS

Regarding to three-dimensional (3D) analysis, one-way ANOVA showed a significant difference between groups with respect to volume of misfit ($F=32.086$, $P=.000$) (Table 1). Tukey post hoc test showed that Ti-base and UCLA abutments presented significantly lower volume of misfit (0.49 mm^3 , $CI:\pm 0.045 \text{ mm}^3$ and 0.48 mm^3 , $CI:\pm 0.045 \text{ mm}^3$, respectively) relative to full digitalized workflow (0.70 mm^3 , $CI:\pm 0.045 \text{ mm}^3$)($P=.000$), without significant difference between each other ($P=.825$)(Fig. 3).

Table 1. One-way ANOVA was used to find any significant difference in the volume of misfit of studied groups. The level of significance was set at $P < .05$.

	Sum of Squares	<i>df</i>	Mean Square	<i>F</i>	Significance	Observed Power
Volume						
Between groups	9.296	1	9.296	32.086	0.000	1.0
Within group	0.307	2	0.154			1.0
Total	9.733	30				
$R^2 = 0.704$ (corrected $R^2 = 0.682$)						

Table 2. Two-way ANOVA was used to find any significant difference between the fixed factors fabrication method and region and their interactions. The level of significance was set at $P < .05$.

Source of Variation	Sum of Squares	<i>df</i>	Mean Square	<i>F</i>	Significance	Observed Power
Fabrication method	1494.613	2	747.306	10.006	0.000	1.0
Region	687.359	2	343.679	4.602	0.013	0.8
Fabrication method*Region	2760.858	4	690.215	9.241	0.000	1.0
Total	88570.054	90				
$R^2 = 0.450$ (corrected $R^2 = 0.395$)						

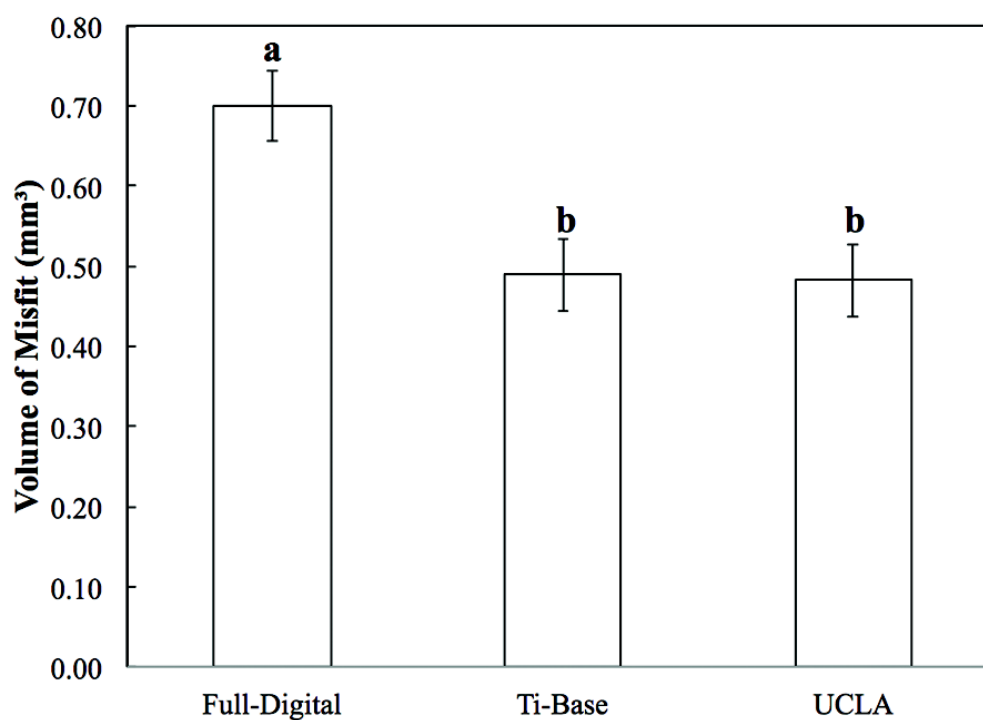


Figure 3. Misfit values from three-dimensional analysis as a function of mean and 95% confidence interval. Abutment fabrication method have influenced volume of misfit. Full-Digital presented higher volume of misfit compared to other groups. *Different letters indicate significant difference between groups ($P < .05$).

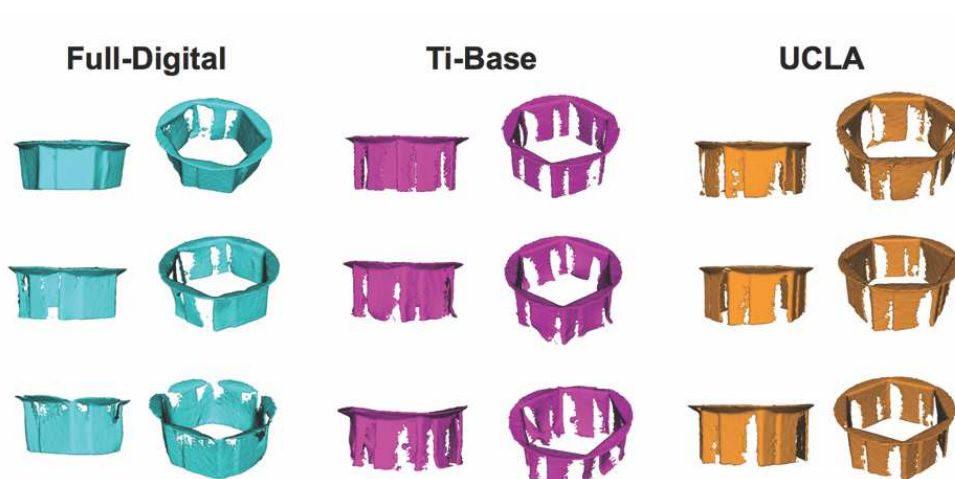


Figure 4. 3D reconstruction of three representative samples of each group showing presence of internal gaps and empty spaces (correspondent to gaps inferior to $1 \mu\text{m}$).

Three-dimensional reconstruction of the silicone replica detected gap sized from 1 μm and above with good accuracy. Qualitative 3D image analysis of internal misfit at the implant-abutment interface depicted higher internal gaps for Full-Digital compared to Ti-Base and UCLA, which can be observed due to thicker silicone layer and fewer empty spaces (correspondent to gaps inferior to 1 μm) (Fig. 4).

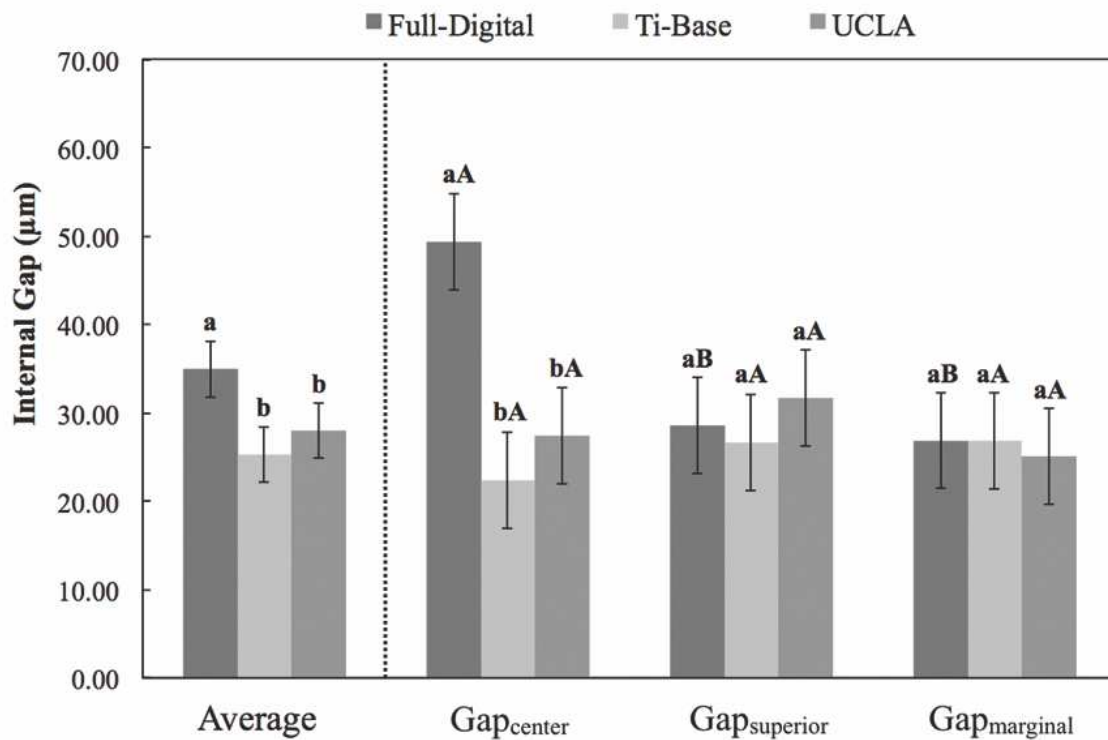


Figure 5. Misfit values from two-dimensional analysis as a function of mean and 95% confidence interval. The average internal gap values were calculated by the mean values of the three ROIs (Gap_{center}, Gap_{superior} and Gap_{marginal}). Full-Digital group exhibited statistically higher average internal gap values compared to Ti-Base and UCLA groups. While Gap_{center} was significantly higher for the abutments fabricated with the full-digitalized workflow, Gap_{superior} and Gap_{marginal} did not demonstrate significant differences among groups. All regions were statistically similar within groups, except for the Gap_{center} in the Full-digital group that exhibited higher mean values compared to the other regions. *Different lowercase letters mean statistical difference between groups ($P < .05$). *Different uppercase letters mean statistical difference between regions within groups ($P < .05$).

Results from linear measurements of the internal discrepancy at the implant/abutment connection are shown in Figure 5. The factors 'abutment fabrication method' and 'region' and their interaction were statistically significant ($P < .05$) (Table 2). The pairwise comparison of different workflow was performed for each region of interest separately. The Full-Digital group exhibited the highest average internal gap ($34.90 \mu\text{m}$, $\text{CI}:\pm 3.14 \mu\text{m}$), which was significantly different from the Ti-base and UCLA groups ($25.21 \mu\text{m}$, $\text{CI}:\pm 3.14 \mu\text{m}$ and $27.97 \mu\text{m}$, $\text{CI}:\pm 3.14 \mu\text{m}$, respectively) ($P < .05$), which were not significantly different between each other ($P = .219$) (Fig. 5). Regarding to internal gap in the different ROIs, $\text{Gap}_{\text{center}}$ was significantly higher for the abutments fabricated with the full-digitalized workflow compared to the others ($P < .001$). $\text{Gap}_{\text{superior}}$ and $\text{Gap}_{\text{marginal}}$ did not demonstrate significant differences among groups ($P > .05$) (Fig. 5). All regions were statistically similar within groups, except for the $\text{Gap}_{\text{center}}$ in the Full-digital group that exhibited higher mean values compared to the other regions ($P < .001$).

The Pearson correlation coefficient value illustrated that there is a strong correlation between the two-dimensional and the three-dimensional gap measurements ($r = 0.835$, $P < .001$).

DISCUSSION

The present study revealed that the abutment fabrication method influenced the internal fit at the implant-abutment interface. Additionally, the three-dimensional measurement for quantification of internal discrepancy was strongly correlated to two-dimensional measurements. Therefore, both null hypotheses were rejected.

Given the multifaceted and highly complex set of clinical scenarios, the ability of prefabricated abutments to meet these requirements is very limited. Hence, the

rationale behind the selection of the abutments used in this study is based on the increasing need of custom abutments to attend such complex clinical sets. These allow the clinician to improve prostheses emergence profile, to customize cervical margins similar to the anatomy of a natural root, and to compensate for inadequate implant angulation. Such abutments are individually shaped according to the anatomical needs of the respective implant site.^{14, 29, 30} Nowadays, besides the custom castable abutments fabricated through a conventional casting workflow, customized abutments can also be fabricated out of different materials such as metal alloys or ceramics by means of CAD/CAM manufacturing systems.^{14, 30} Considering that the abutment/implant interface exerts remarkable influence on the future success and long-term stability of implant-supported rehabilitations, it becomes paramount to investigate the effect of different abutment fabrication methods on the internal fit at the implant-abutment connection.

The results of the present study revealed that abutments fabricated with fully digitalized workflow resulted in less favourable internal fit at the implant/abutment interface compared to Ti-Base and UCLA-type abutments, without significant differences between each other. This assertion is true for both the three-dimensional volume data and the two-dimensional data obtained by linear measurements. It is noteworthy that the qualitative findings of the three-dimensionally reconstructed images along with linear measurements of the internal discrepancies in the ROIs depicted that the $\text{Gap}_{\text{center}}$ was the main responsible for the statistically higher misfit values for Full-Digital group, since such region consisted of approximately a twofold increase in gap values compared to the other regions of interest ($\text{Gap}_{\text{superior}}$ and $\text{Gap}_{\text{marginal}}$ were statistically similar for all groups).

Possible explanations for the worse fit found in the Full-Digital group could be associated to several factors relative to the milling process, such as the wear of milling instruments, the change in the radius of the instruments during the milling procedure,³¹ the incompatible size of the milling drill with the corresponding implant angles³² and, more importantly, tolerances set in producing CAD/CAM screw-retained abutments/crowns, which can play a key role in the final fit.²¹ Mobilio et al.²¹ evaluated the marginal vertical fit along implant/abutment interface of a prefabricated abutment and three customized CAD/CAM screw-retained crowns with three different “tolerance” values. The results of such investigation demonstrated that reducing the tolerance of 10 microns lower than the manufacturer values is equal to increasing the attrition and, consequently, the vertical gap between the components.

The similarity between the misfit values of the Ti-Base and UCLA abutments can be explained by the well-controlled conditions in which such abutments were industrially produced. It is worthwhile to mention that, in the current study, UCLA abutments with metallic base were used and the customized wax patterns were milled in the CAD/CAM system followed by conventional casting procedures, which could contribute to the favorable internal fit depicted in this group. Previous investigations^{11, 13} showed that prefabricated abutments, which include UCLA abutments with a CoCr base that are customized in a laboratory, are superior in adaptation to those cast from plastic burnout patterns. Conversely, Rismanchian et al.²⁰ found that premachined abutments exhibit smaller microgaps than those of Cast On and Castable abutments, and stated that the reasons for the increased microgap on the fitting surfaces of such abutments may be due to lack of after casting finishing and polishing procedures. Despite the controversies, finishing procedures of UCLA

abutments should be standardized and refined by laboratories to avoid discrepancies in fit.¹³

In contrast to studies reporting data on marginal/internal gaps between two different surfaces, a volume of misfit (mm^3) at the implant/abutment interface was also measured in this study. Similarly, Lops et al.³³ calculated the volume of contact (mm^3) to investigate the accuracy of fit between an internal conical connection implant and prefabricated and CAD/CAM abutments, using a multisensored opto-mechanical coordinate measuring machine. In contrast to our results, lower mean values of volume of interference for the CAD/CAM abutments (0.108 mm^3) were found in comparison to the prefabricated abutments (0.134 mm^3). Although direct comparison is not feasible, given the different implant geometry and methodology used in such investigation, the authors emphasized the 3D measurement method as a more helpful approach compared to the 2D measurement for the comparison between different abutment groups.

From a technical standpoint, gaps between the implant and the abutment are inevitable in fitting the different parts. Such components cannot be accurately matched because of the precision limit during manufacturing process and therefore, some amount of microleakage will unavoidably occur regardless of the type of connection and the size of the microgaps.^{7, 20, 34} Accordingly, the magnitude of these gaps and its clinical significance has been receiving significant attention^{7, 9, 11, 12, 25, 35, 36} and different methodologies have been utilized for such investigation.^{4, 5, 11, 21, 25, 27, 33, 35} The size of the microgap at implant/abutment connection has been reported as a wide range of 1 to $60 \mu\text{m}$,^{11, 13, 21, 37} and it is dependent, among other factors, on the implant system and the torque used to fix abutments.^{7, 38} Although gaps from different magnitudes have been identified along with proportional levels of

microleakage at different implant abutment configurations, it is important to bear in mind that no internal or external implant-abutment screwed connection has 100% bacterial seal.³⁹

Several measuring analytical techniques for gap determination in implant-supported rehabilitations are described in the literature, which include measurement of the specimens by direct visualization under a microscope; or embedded and sectioned specimens and silicone replica analyzed under scanning electron microscopy (SEM),^{19, 20} optical microscopy,²¹ microtomography,^{19, 27} travelling microscope,^{13, 22} among others. Although such techniques are well established, most authors agree that these methodologies provide limited information,^{33, 40, 41} and it is impossible to use these methods *in vivo* considering their destructive approach. Accordingly, with the development of digital technology, three-dimensional analysis methods has been explored, such as 3D nonlinear finite element analysis (FEA)¹⁹ and microcomputed tomography.^{19, 42} The three-dimensional measurement for quantification of internal discrepancy was strongly associated to the two-dimensional measurements. By using this technique we have demonstrated that microgaps up to 1 μm width could be measured in two and three dimensions; in the latter case, the microgaps at the implant/abutment interface could be reconstructed onto a three-dimensional rendering image, which can provide insight into the most critical areas of misfit. Oka et al.⁴¹ proposed a methodology to evaluate the fitting accuracy of prostheses three-dimensionally (3D) using a combination of the silicone replica technique and μCT in comparison with a conventional 2D silicone replica method (stereomicroscopy) and demonstrated that 3D virtual images of the replica accurately reflected its real-life morphology.

Considering the lack of studies about the influence of different fabrication methods of abutments on the fit at the implant/abutment interface, this study showed that the fully digitalized workflow resulted in worse internal fit compared to the casting methods (UCLA) and Ti-Base abutments. It is important to mention that there is currently no international standard method for the adaptability evaluation between the implant body and abutments (ISO/NP 22683 under development). Future research to investigate the impact of gap sizes to biomechanical performance is warranted.

CONCLUSIONS

Within the limitations of this study, the following conclusions may be drawn:

- Prefabricated Ti-Base and UCLA-type abutments exhibited better internal fit at the implant/abutment connection compared to abutments fabricated through a full digitalized workflow (CAD-CAM custom abutments);
 - The three-dimensional measurement (volume of misfit) for quantification of internal discrepancy was strongly associated to the two-dimensional measurements.
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2.2 ARTICLE 2

Implant-abutment fit influences the mechanical performance of single-crow prostheses

ABSTRACT

Objectives. To evaluate the three-dimensional fit of abutments fabricated by the industry to those either milled or cast by a commercial laboratory and to correlate the implant-abutment connection fit with stress at fatigue failure of prostheses. Probability of survival (reliability) and fractography to characterize failure modes were also performed for cemented and screw-retained prostheses.

Methods. One-hundred and twenty-six maxillary central incisor crowns were milled to restore implants and divided in 3 cemented and 3 screwed-retained groups (n=21/each), as follows: [Digital-Sc]: milled one-piece monolithic abutment/crown; [TiB-Sc]: milled crowns cemented onto Ti-base abutments; [UCLA]: screw-retained crown using UCLA abutments; [Digital-Ce]: milled two-piece assembly comprised by screwed monolithic abutment and a cemented crown; [TiB-Ce]: milled coping cemented onto Ti-base abutments to receive a cemented crown; [UCLA-Ce]: UCLA abutments that received an overcast coping and a cemented crown. Implant-abutment volume misfit was assessed by micro-computed tomography using the silicone replica technique. Implant/crown systems were subjected to step-stress accelerated life testing (SSALT) in water. The use-level probability Weibull curves and reliability for a mission of 50,000 cycles at calculated stress at failure of 2,300, 3,300 and 4,300 MPa were plotted. Fractographic analysis was performed with scanning electron microscopy. Internal misfit was analyzed through one-way ANOVA

following post-hoc comparisons by Tukey test ($P < 0.05$). Correlation between misfit volume and the stress at fatigue failure was assessed by Pearson test.

Results. Similar misfit volumes were observed for TiB-Sc (0.458 mm^3), TiB-Ce (0.461 mm^3), UCLA (0.471 mm^3) and UCLA-Ce (0.480 mm^3), which were significantly lower than Digital-Sc (0.676 mm^3) and Digital-Ce (0.633 mm^3). The mean β values were: 1.68, 1.39, 1.48, 2.41, 2.27 and 0.71 for Digital-Sc, TiB-Sc, UCLA, Digital-Ce, TiB-Ce and UCLA-Ce, respectively, indicating that fatigue was an accelerating factor for failure of all groups, except for UCLA-Ce. Higher stress at failure decreased the reliability of all groups, more significantly for screw compared to cement-retained groups, especially for Digital-Sc that demonstrated the lowest reliability. The failure mode was restricted to abutment screw fracture. A negative correlation was observed between misfit values and stress at failure ($r = -0.302$, $P = 0.01$).

Conclusions. Abutments milled by a commercial lab presented higher misfit compared to those provided by the industry and a moderate correlation was observed between higher misfit and lower stress at failure during fatigue. Probability of survival decreased at higher stress, especially for screw compared to cement-retained groups, and failures were confined to abutment screws.

INTRODUCTION

Although high success rates are commonly reported for implant-supported prostheses,^{1, 2} the less common report of cumulative survival rates suggest that success may be actually lower than reported and is therefore inflated.³ Because complication rates increase over time,⁴ indicating that the fatigue damage accumulation degrades prostheses strength, it is important to acknowledge that technical complications in implant dentistry are very common and the importance of

their characterization in preclinical studies has been increasingly valued.^{5, 6} According to a systematic review and meta-analysis, the most common complication is abutment screw fracture, with a cumulative rate of 10.4% in 5 years and a twofold increase to 20.4% in 10 years.⁷ Such findings emphasize that treatment with implants, despite its advantages, should predict complications, additional time and cost for maintenance.²

The implant/abutment connection is one of the most important factors for prostheses stability.⁸ Therefore, the selection of restorative components must be considered a paramount factor for long-term clinical success.⁹ For improved performance, it is important that abutments present the best fit at the implant connection,¹⁰ since higher values of misfit between such components may increase mechanical stress on connection structures and surrounding tissues, which may cause not only mechanical problems,^{11, 12} such as screw preload loss or screw fracture, but also to biologic issues due to the bacterial contamination eventually participating in the multifactorial role of peri-implant tissue inflammation.¹³⁻¹⁶

Several 'prefabricated' or 'stock' abutments are available in the market, which vary in indication and design. Although the claimed best fit of stock abutments provided by the industry, which demand approval by regulatory agencies, their customization may be limited considering each patient's difference in peri-implant soft tissue emergence profile and prosthetic needs. Opportunities for individualization include the use of custom-made abutments fabricated through either a conventional casting procedure using universal casting long abutments (UCLA) or through a digital workflow. In the latter, two customization options are available: 1) not only the crown but also the entire abutment, may be designed and milled in a commercial laboratory (full digital lab fabrication process) by using the computer-aided design/computer-

aided manufacturing (CAD/CAM) system (currently feasible for external or internal non-conical connections); or 2) an industrially manufactured abutment system (Ti-base) with libraries inserted in CAD/CAM systems receives custom CAD/CAM restoration fabricated by a commercial laboratory (final crown or custom core).

The benefits of employing a fully digital laboratory fabrication process for abutments and prostheses include customization and rapid chair-side or commercial laboratory fabrication regardless of industry abutment availability; however, the internal fit of such abutments is roughly dependent on several variables involved in the accuracy of milling of the CAD/CAM systems unit and the selected milling strategy. Also of concern is the fact that milling of abutments by commercial labs is not yet controlled by international standards or norms, as it is for industry-provided prefabricated abutments, which undergo standard quality assurance and quality control evaluation. A potential workaround has been recently introduced where industry-fabricated Ti-base abutments and their inclusion in CAD/CAM libraries allow the rapid fabrication of either a customized milled core (e.g. zirconia) or of the crown by commercial laboratories. This concept is based on a titanium connector featuring a female component that connects to the implant well and a external configuration with geometry available for insertion in most CAD/CAM systems where monolithic or bilayered restorations of any given material can be cemented chairside.¹⁷⁻¹⁹ The main advantage and rationale for use of Ti-base abutments comprise the maintenance of industry provided fit of the female part, in contrast to UCLA abutments where overcasting and post processing (e.g. aluminum oxide blasting) change the titanium surface topography and fit.²⁰ Also, retrievability is maintained when cementing the final prostheses directly to Ti-base since CAD/CAM blocks provided with screw access holes are used allowing extra-oral bonding and excess cement removal,

which seems advantageous to reduce chances of potential cementation induced peri-implantitis.²¹

Along with the plethora of implant restorative components available, the fixation modes of the implant-supported restoration can be either screwed, cemented, or a combination of both. There is a rich literature on the advantages and disadvantages of each prosthesis retention systems.²²⁻²⁹ A current consensus has been published²⁹ and, in general, the clinical recommendations for screw retention include: implants placed in a prosthetically ideal position, with the presence of minimal interarch space (4 mm); FDPs (fixed dental prostheses) with a cantilever design; long-span FDPs; in esthetic areas, where provisionalization of implants is required to enable soft tissue conditioning and emergence profile improvement or when retrievability is desired. Also, the cement retention is recommended in the following situations: for short-span prostheses with margins at or above the mucosa level, to compensate for improperly inclined implants, for cases where an easier control of occlusion without an access hole is desired (e.g. narrow-diameter crowns).²⁹ Although less technical complications of cement-retained relative to screw-retained crowns has been reported³⁰, the performance of hybrid systems that combine extra-orally cemented and screw-retained crowns warrants investigation.

Considering the increased use of customizable abutments in restorative dentistry and given that, once under function in the mouth, any restorative system's strength will degrade over time due to fatigue damage accumulation, the characterization of the internal fit at the implant/abutment connection of abutments fabricated by a commercial laboratory (milled or cast) compared to abutments provided by the industry, as well as the impact of misfit levels on the mechanical performance of prostheses still requires investigation. Therefore, the objective of this

study was to evaluate the three-dimensional fit of abutments fabricated by the industry to those either milled or cast by a commercial laboratory and to correlate the implant-abutment connection misfit with stress at fatigue failure of prostheses. Probability of survival (reliability) and fractography to characterize failure modes were also performed for cemented and screw-retained prostheses. The null postulated hypotheses were: (i) the fabrication process of implant-supported prostheses has no influence on the internal misfit at the implant-abutment connection; (ii) the abutment fabrication method and crown fixation mode have no influence on the reliability; (iii) the internal misfit at the implant abutment interface has no influence on the stress at fatigue failure.

MATERIAL AND METHODS

Specimen preparation

One-hundred and twenty-six maxillary central incisor crowns were milled to restore implants and divided in 3 cemented and 3 screwed-retained groups (n=21/each), as follows: [Digital-Sc]: milled one-piece monolithic abutment/crown; [TiB-Sc]: milled crowns cemented onto Ti-base abutments; [UCLA]: screw-retained crown using UCLA abutments; [Digital-Ce]: milled two-piece assembly comprised by screwed monolithic abutment and a cemented crown; [TiB-Ce]: milled coping cemented onto Ti-base abutments to receive a cemented crown; [UCLA-Ce]: UCLA abutments that received an overcast coping and cemented crown (Table 1 and Figure 1).

Table 1. Detailed description of the groups used in this study.

Fixation Mode	Group	Fabrication Method	Description	Specification
Screwed (Sc)	Digital-Sc	Fully Digital	One-piece monolithic abutment and crown produced by CAD/CAM and screw-retained to the implants. The implant geometry previously stored in the CAD software was used to design the one-piece assembly, which were then milled using CoCr discs.	<p>CAD software (Ceramill® mind, Amann Girrbach)</p> <p>CoCr discs (Ceramill sintron®, Amann Girrbach)</p> <p>Ti-Base (non-rotational Ti-Base, Colosso, Emflis, Itu, Brazil)</p> <p>Resin cement (RelyX™ Ultimate Adhesive Resin Cement, 3M)</p> <p>Universal adhesive (Scotchbond Universal, 3M)</p> <p>Wax discs (Ceramill® wax, Amann Girrbach, Curitiba, Brazil)</p> <p>UCLA-Type abutments (Castable non-rotational in CoCr-base with plastic sleeve abutment, Colosso, Emflis, Itu, Brazil)</p> <p>Temporary cement (RelyX Temp® 3M Oral Care)</p>
	TIB-Sc	Partial Digital	CAD/CAM produced crowns directly cemented onto prefabricated Ti-base abutments. The Ti-Base geometry previously stored in the CAD software was used to design the crowns, which were milled using CoCr discs and cemented onto Ti-Base abutment using a resin cement with universal adhesive for treatment of titanium substrates.	
	UCLA	Conventional	Screw-retained crown using custom-cast abutments (UCLA). For standardized crown anatomy, they were designed in the same CAD software and milled in wax pattern followed by conventional casting procedures using UCLA-Type abutments.	
Cemented (Ce)	Digital-Ce	Fully Digital	Two-piece assembly comprised by monolithic abutment produced by CAD/CAM and screwed to the implants to receive a cemented crown. The same CAD software was used to design the abutment and crown, which were milled using CoCr discs. CAD/CAM crowns were cemented onto digital abutments with a temporary cement.	<p>CAD software (Ceramill® mind, Amann Girrbach)</p> <p>CoCr discs (Ceramill sintron®, Amann Girrbach)</p> <p>Ti-Base (non-rotational Ti-Base, Colosso, Emflis, Itu, Brazil)</p> <p>Resin cement (RelyX™ Ultimate Adhesive Resin Cement, 3M)</p> <p>Universal adhesive (Scotchbond Universal, 3M)</p> <p>Wax discs (Ceramill® wax, Amann Girrbach, Curitiba, Brazil)</p> <p>UCLA-Type abutments (Castable non-rotational in CoCr-base with plastic sleeve abutment, Colosso, Emflis, Itu, Brazil)</p> <p>Temporary cement (RelyX Temp® 3M Oral Care)</p>
	TIB-Ce	Partial Digital	Coping produced by CAD/CAM system and cemented onto prefabricated standard Ti-Base abutments to receive a cemented crown. The Ti-Base geometry previously stored in the CAD software was used to design the copings, which were milled using CoCr discs and cemented onto Ti-Base abutment using a resin cement with universal adhesive for treatment of titanium substrates. CAD/CAM crowns were cemented onto abutments with a temporary cement.	
	UCLA-Ce	Conventional	Screw-retained abutment using custom-cast abutments (UCLA) to receive a cemented crown. For standardized abutment anatomy, they were designed in the same CAD software and milled in wax pattern followed by conventional casting procedures using UCLA-Type abutments. Crowns were cemented onto abutments with a temporary cement.	

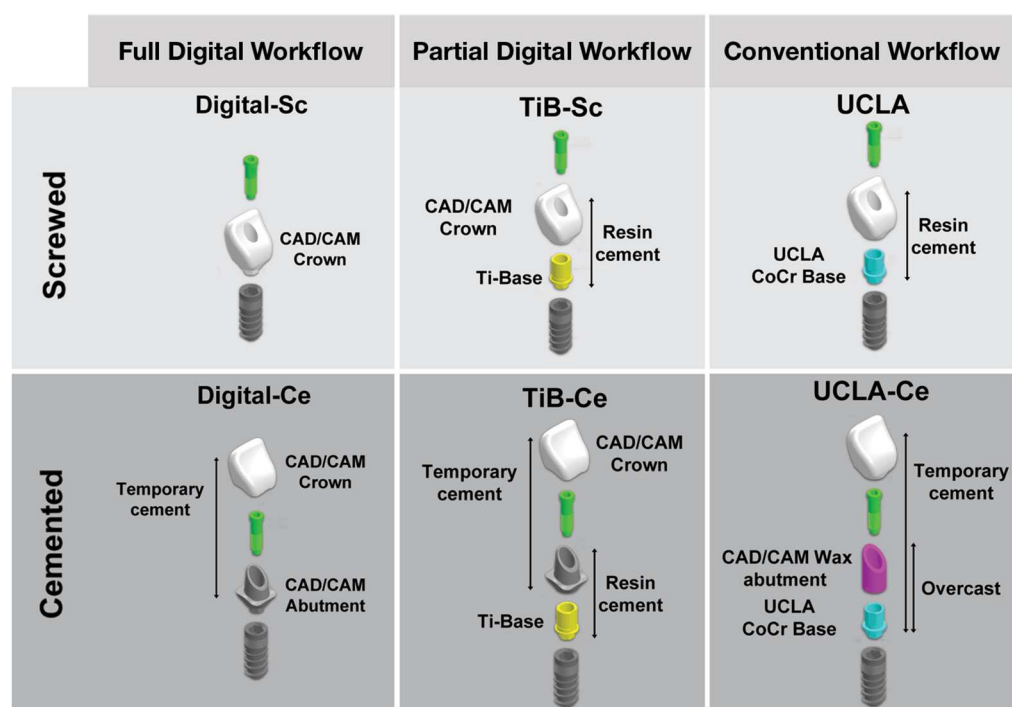


Fig. 1. Schematic diagram of experimental groups according to the abutment fabrication methods and crown fixation modes.

Prior to experimental tests, all implants were vertically embedded in an acrylic resin (Orthoresin, Degudent, Hanau-Wolfgang, Germany) and plastic tube ($\text{\O}25$ mm x 35 mm) with the implant's platform positioned at the potting surface.

3-Dimensional misfit evaluation

Volume measurements were performed by one direct and another indirect micro-computed tomography scanning (μCT) technique to assess the internal misfit at the implant-abutment connection. First, direct volume scanning was performed for a single implant-abutment assembly of each group (μCT SkyScan 1272, Bruker, Belgium). Because of the low time-cost effectiveness of direct μCT scanning of metallic interfaces, an impression of the implant-abutment connection was made for μCT scanning comparison by means of the silicone replica technique. The implants

were filled with a regular-body consistency polyvinyl-siloxane impression material (Express™ XT Regular Body, 3M Oral Care, St. Paul, MN, USA) and the abutments were then torqued as per manufacturer's instructions (32 N.cm) using a digital torque gauge (Tohnichi BTG150CN-S, Tohnichi America, Northbrook, USA). After impression material setting, the abutment was untightened and carefully removed from the implant while the thin polyvinyl siloxane film remained in the inner surface of the implant. Then, the polyvinyl siloxane film was gently removed from the implant well. To avoid distortion of the replica specimen, the excess impression material drawn into the screw hole was not eliminated.

Each replica specimen was scanned using a μ CT scanner (μ CT 40, Scanco Medical, Basserdorf, Switzerland). Five specimens at a time were placed in the sample holder. The instrument was operated at medium resolution (16 μ m/slice) using 70 kVp (114 μ A) resulting in approximately 380 slices per sample. All data were exported in a DICOM-format and imported into Amira software (Amira, version 5.5.2, VSG, Burlington, MA, USA) for quantification of implant-abutment internal discrepancy, which was represented by the thickness of the regular-body polyvinyl siloxane. Three-dimensional (3D) rendering of the image set was performed using a standard "silicone mask" in Amira software. The same software was used to remove all silicone excess and define the region of interest (ROI). To ensure that the replica specimens of different groups and those directly scanned were all measured equally, the same ROI was defined by cropping the silicone replica image data at the equivalent height to the first implant thread (1.23 mm from the implant platform). A uniform threshold for silicone was determined across all groups using the Otsu algorithm ROIs. The volume of misfit was calculated using the "Material Statistics" software function after 3D reconstruction of the silicone replica.

Mechanical testing and reliability analysis

To design the profiles for the step-stress accelerated life testing (SSALT), three specimens of each group underwent single load-to failure (SLF) testing⁶ in a universal testing machine (Model 5566, Instron, Norwood, MA, USA) equipped with a 10-kN load cell. A uniaxial compression load was applied at the incisal edge of the crown using a flat tungsten carbide indenter ($r=3.18$ mm), 30° off-axis at a crosshead speed of 1 mm/min following the ISO 14801:2007 (Dentistry-Implants-Dynamic fatigue test for endosseous dental implants).^{6, 31-35}

Based on the mean load to failure from SLF results, the remaining 18 specimens of each group were randomly distributed into three step-stress profiles as follows: mild ($n = 9$), moderate ($n = 6$), and aggressive ($n = 3$) (aspect ratio distribution 3:2:1, respectively).⁶ Such profiles refer to the increasingly step-wise rapidness in which a specimen is fatigued to reach a certain level of load, meaning that specimens assigned to a mild profile will be cycled longer to reach the same load of a specimen assigned to either moderate or aggressive profiles. A servo-all-electric system (TestResources 800L, Shakopee, MN, USA) was used for SSALT under water (load orientation and indenter as in SLF test) at 9 Hz. All specimens were subjected to fatigue until failure (fracture or bending of the abutment or implant), or suspension (no failure at the maximum 900 N load level).^{6, 31-35}

Bending moment (M) and stress (σ) values were calculated as follows:

$$M = y \times F \quad (1)$$

Where y is the moment arm, defined as $l \times \sin \theta$ (for most dental setting tests $\theta=30^\circ$), where l is the distance from the center of the crown to the clamping plane. Since force is expressed in N, bending moment is typically reported in N·mm. For determination of stress leading to failure (MPa), subsequent calculation included:

$$\sigma_{Stress} = \frac{My}{I}, \quad (2)$$

where M represents the bending moment, y is the perpendicular distance from the center of the inertia moment and I is the area moment of inertia, described by the area of the screw cross-section as:

$$I_{circle} = \frac{\pi.d^4}{64} \quad (3)$$

where d is the circle diameter.

Findings were recorded as stress, number of cycles, and step-stress profile in which the specimen failed during accelerated life testing for the reliability calculations.

Use-level probability Weibull curves (probability of failure versus number of cycles) using a cumulative damage and power law relationship were calculated (Alta Pro 7; Reliasoft, Tucson, AZ, USA) with use stress of 3300 MPa. The reliability (the probability of an item functioning for a given amount of time without failure) for completion of a mission of 50,000 cycles (using 90% two-sided confidence intervals) at 2300, 3300 and 4300MPa was determined for group comparisons. The use level probability Weibull analysis provides the beta (β) value, which describes the failure rate behavior over time. Beta value lower than 1 ($\beta < 1$) indicates that the failure rate decreases over time and is associated with “early failures” or failures related to egregious flaws; β value approximately 1 ($\beta \sim 1$) determines that failure rate does not vary over time and is associated with failures of a random nature; and, β higher than 1 ($\beta > 1$) means that failure rate increases over time and is linked to fatigue damage. As per $\beta < 1$ for one tested group, a probability Weibull 2-parameter contour plot (Weibull modulus [m] vs characteristic stress [η]) was calculated using final stress to failure or survival of groups (90% confidence intervals).^{6, 36}

Failure mode analyses

Failed specimens were first inspected in a polarized-light stereomicroscope (MZ-APO Stereomicroscope, Leica Micro Imaging, Thornwood, NY, USA) to analyze and classify the modes of failure. Most representative failed samples were also imaged under a scanning electron microscope (SEM) (Hitachi S-3500, Hitachi Instruments, Tokyo, Japan) for qualitative fractography.

The statistical analyses from internal fit evaluation and fatigue load to failure were accomplished using SPSS (IBM SPSS 23, IBM Corp., Armonk, NY). Shapiro-Wilk statistical test for normality revealed normal distribution for data ($P>0.05$), which were statistically evaluated through one-way analysis of variance (ANOVA) following post-hoc comparisons by Tukey test. The level of significance was set at $P=0.05$ and data are presented as a function of mean values with the corresponding 95% confidence interval (CI). Also, the Pearson correlation test was used to assess the association between the volume of misfit at the implant-abutment interface and the load in which the specimens failed.

RESULTS

Fit evaluation

Regarding three-dimensional (3D) analysis of the internal fit at the implant-abutment interface, one-way ANOVA revealed that there was a statistically significant difference in volume of misfit between the different abutment fabrication methods ($F=24.81$, $P=0.000$). Results from post-hoc comparisons showed that TiB-Sc (0.458 mm³, CI:0.039 mm³), TiB-Ce (0.461 mm³, CI:0.039 mm³), UCLA (0.471 mm³, CI:0.039 mm³) and UCLA-Ce (0.480 mm³, CI:0.039 mm³) groups presented similar volume of misfit (all, $P>0.438$), which were significantly lower than Digital-Sc (0.676

mm³, CI:0.039 mm³) and Digital-Ce (0.633 mm³, CI:0.039 mm³)(not significantly different from each other, $P=0.646$)(Figure 2). Qualitative 3D image analysis and quantitative data from the direct and indirect μ CT scanning techniques depicted similar results of internal misfit at the implant-abutment interface (Figure 2 and 3). It was observed higher internal gaps for groups produced with a full digital lab fabrication process (Digital-Sc and Digital-Ce) compared to a hybrid fabrication process (TiB-Sc and TiB-Ce) and a conventional (UCLA and UCLA-Ce) workflow, which can be observed due to thicker silicone layer and fewer empty spaces (correspondent to gaps inferior to 1 μ m) (Figure 3).

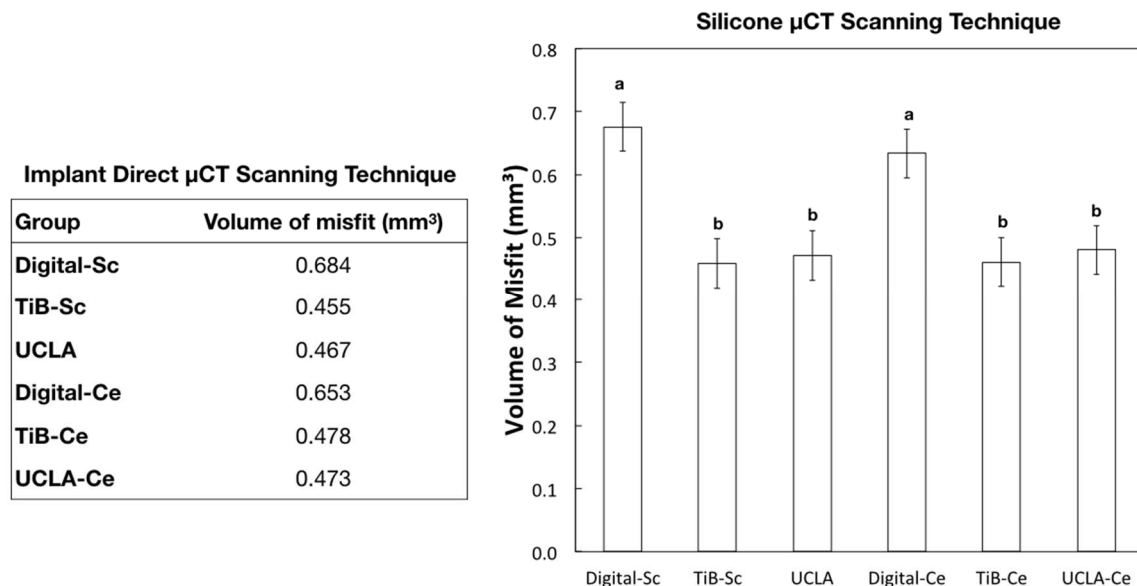


Fig. 2. Quantitative data from the direct and indirect Silicone μ CT scanning techniques showing similar results of internal misfit at the implant-abutment interface. Column graphs showing misfit values as a function of mean and 95% confidence interval. Implant-retained prostheses fabrication methods have influenced the volume of misfit at the implant-abutment interface. *Different letters indicate significant difference between groups ($P<0.05$).

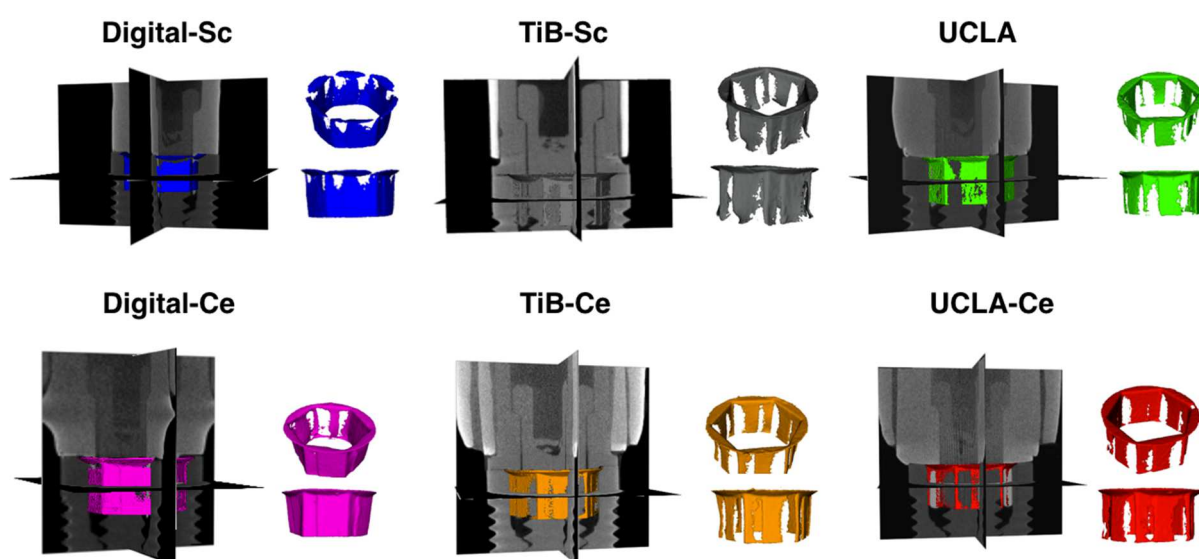


Fig. 3. Comparative images of the 3D reconstruction of one representative sample per group - from the direct and indirect silicone μ CT scanning techniques - showing the presence of internal gaps and empty spaces (correspondent to gaps inferior to 1 μ m).

Reliability analysis

All samples failed after SSALT. The failure mode was similar for all groups, restricted to abutment screw. The use level probability Weibull (90% confidence bounds) showing the probability of failure vs. number of cycles at 3300 MPa of set stress is presented in Figure 4. The mean β values (confidence interval range) derived from use level probability Weibull calculation were: 1.68 (1.13-2.49) for Digital-Sc, 1.39 (0.93-2.07) for TiB-Sc, 1.48 (0.89-2.46) for UCLA, 2.41 (1.64-3.53) for Digital-Ce, 2.27 (1.56-3.31) for TiB-Ce and 0.71 (0.41-1.23) for UCLA-Ce (Table 2). Except for the latter, such values indicated that for all groups, failure rate increases over time, associated with fatigue damage accumulation. For UCLA-Ce, failure is commonly associated with “early failures” or failures that occur due to egregious flaws.

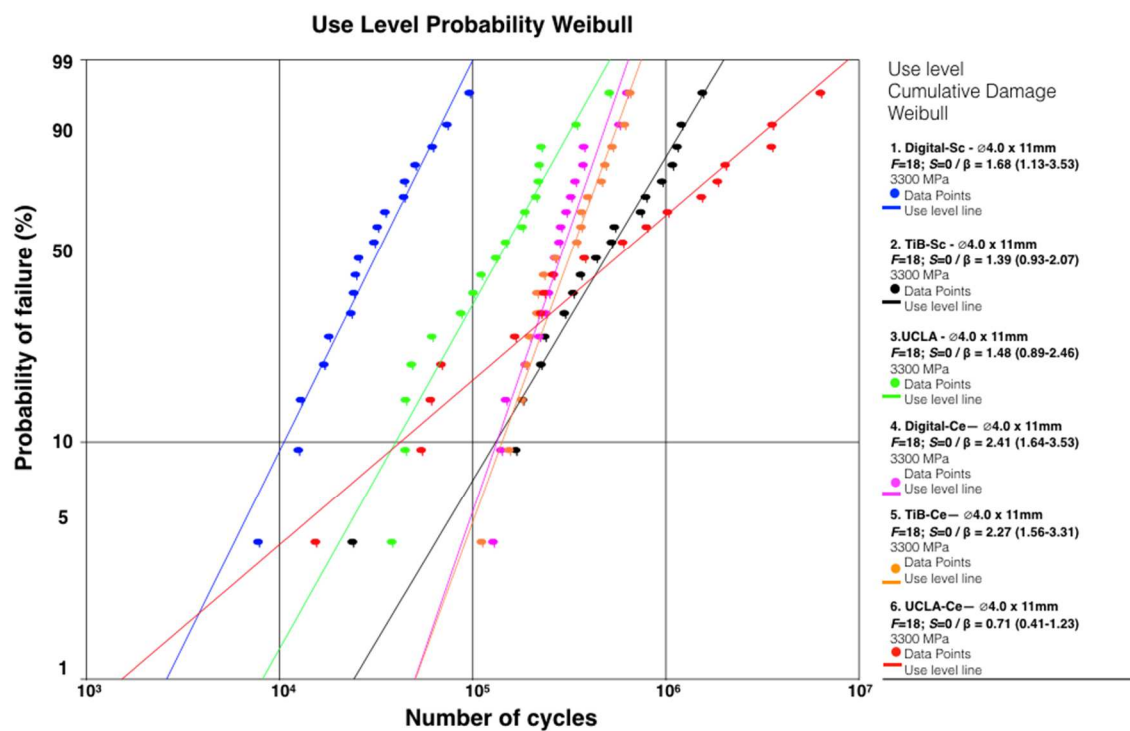
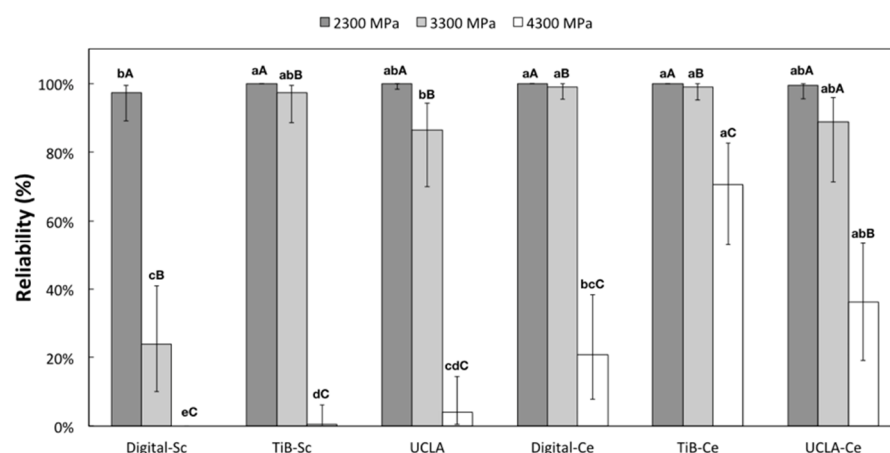


Fig. 4. Use level probability Weibull (90% confidence interval) showing the probability of failure versus time at 3300 MPa of set stress.

The calculated reliability (probability of the implant-supported incisor operating for a given amount of time without failure) with 90% confidence intervals for a mission of 50,000 cycles at 2300, 3300 and 4300 MPa are shown in Figure 5. At 2300 MPa, all groups showed high reliability (above 97%), with Digital-Sc (97.32%) presenting the lowest values (statistically similar to UCLA-Ce). While all groups kept their survivability higher than 86% at a set stress of 3300 MPa, a significantly reduced reliability was demonstrated by Digital-Sc (~24%). An increase in stress to 4300 MPa significantly decreased the reliability to 0%, 0.49% and 4.12% for screwed groups (Digital-Sc, TiB-Sc and UCLA, respectively) and 20.93%, 70.68% and 36.08% for cemented groups (Digital-Ce, TiB-Ce and UCLA-Ce, respectively) with statistically lower and higher survival for Digital-Sc and TiB-Ce, respectively, compared to all other groups (without difference between TiB-Ce and UCLA-Ce). At such stress

scenario, the pairwise comparisons between cemented and screwed crowns presenting the same fabrication method depicted that the cemented systems always presented higher reliability than screwed ones.

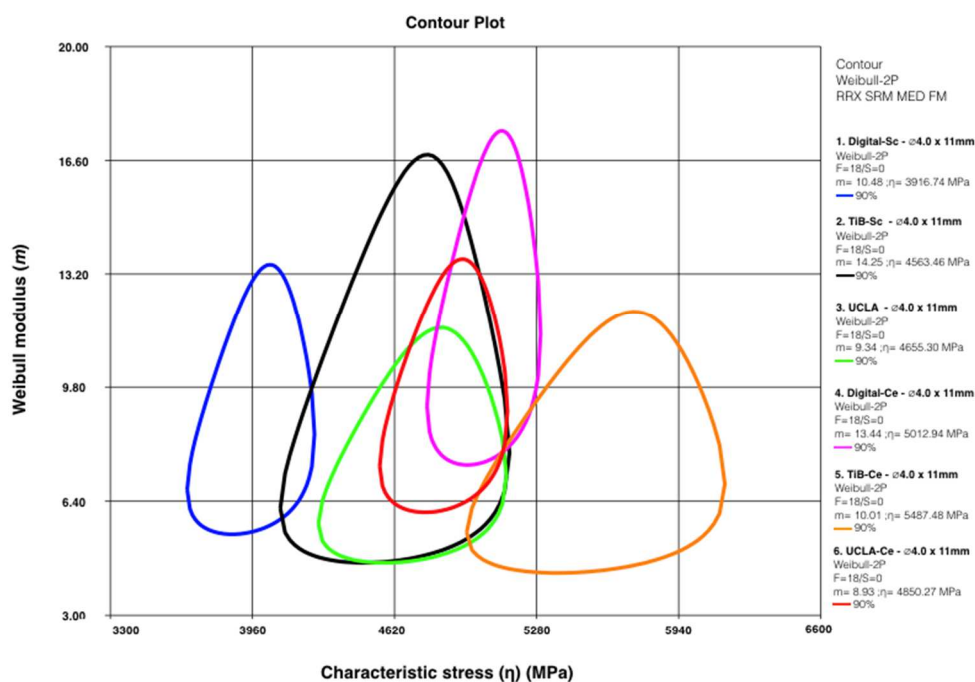


	Digital-Sc		TiB-Sc		UCLA		Digital-Ce		TiB-Ce		UCLA-Ce							
	Lower Bound	Reliability	Upper Bound	Lower Bound	Reliability	Upper Bound	Lower Bound	Reliability	Upper Bound	Lower Bound	Reliability	Upper Bound						
2300 MPa	89.10	97.32 ^{ba}	99.36	99.92	100 ^{aA}	100	98.31	99.78 ^{abA}	99.97	99.97	100 ^{aA}	100	99.83	99.99 ^{aA}	100	95.51	99.37 ^{abA}	99.91
3300 MPa	10.07	23.87 ^{cb}	40.91	88.59	97.29 ^{abB}	99.38	70.02	86.35 ^{bbB}	94.13	95.33	99.01 ^{ab}	99.79	95.16	99.02 ^{ab}	99.8	71.39	88.81 ^{abA}	95.91
4300 MPa	0	0 ^c	0	0	0.49 ^{cdC}	6.23	0.52	4.12 ^{cdC}	14.45	7.84	20.93 ^{bcC}	38.27	52.95	70.68 ^{ac}	82.75	19.06	36.08 ^{abB}	53.42
Beta	1.13	1.68	2.49	0.93	1.39	2.07	0.89	1.48	2.46	1.64	2.41	3.53	1.56	2.27	3.31	0.41	0.71	1.23

Fig. 5. Calculated reliability (%) for a given mission of 50,000 cycles at a set stress of 2300, 3300 and 4300 MPa. *Different lowercase letters mean statistical difference between groups at the same load level. Different uppercase letters mean statistical difference between load levels. Differences between groups were identified based on the non-overlap of 90% two-sided confidence interval.

As one group showed β value lower than 1, the probability Weibull distribution was determined using fatigue stress to failure data of the groups. The calculated Weibull modulus (m) and characteristic stress (η), which indicates the stress in which 63.2% of the specimens may fail, are depicted in the contour plot (Figure 6). The probability Weibull distribution presented values of 10.48 (7.71-14.25) for Digital-Sc,

14.25 (11.16-18.19) for TiB-Sc, 9.34 (7.02-12.44) for UCLA, 13.44 (9.99-18.08) for Digital-Ce, 10.01 (7.6-13.17) for TiB-Ce, and 8.93 (6.57-12.14) for UCLA-Ce, without significant differences between each other. While Digital-Sc demonstrated the lowest characteristic stress values (3916 MPa), TiB-Ce showed the highest values (5487.48 MPa), both significantly different from others. Furthermore, UCLA, UCLA-Ce and TiB-Sc displayed statistically similar characteristic stress values (Figure 6).



	Digital-Sc	TiB-Sc	UCLA	Digital-Ce	TiB-Ce	UCLA-Ce
Characteristic stress (η) (CI)	176.87 ^D (169.48-184.58)	206.08 ^C (198.25-214.21)	211.69 ^{BC} (201.53-222.19)	227.86 ^B (220.66-235.29)	249.43 ^A (237.5-261.87)	220.46 ^{BC} (210.64-230.74)
Weibull modulus (m) (CI)	10.48 ^A (7.71-14.25)	14.25 ^A (11.16-18.19)	9.34 ^A (7.02-12.44)	13.44 ^A (9.99-18.08)	10.01 ^A (7.6-13.17)	8.93 ^A (6.57-12.14)

Fig. 6. Contour plot showing “ m ” as an indicator of reliability (Weibull modulus) vs. characteristic stress (η), which indicates the stress in which 63.2% of the specimens of each group may fail. Differences between groups were identified based on the non-overlap of 90% two-sided confidence interval.

The Pearson correlation coefficient value illustrated that there is a negative correlation between the volume of misfit and the stress in which the specimens failed ($r = -0.302$, $P=0.01$), which means that the higher the volume of misfit, the lower the fatigue stress to failure (Figure 7).

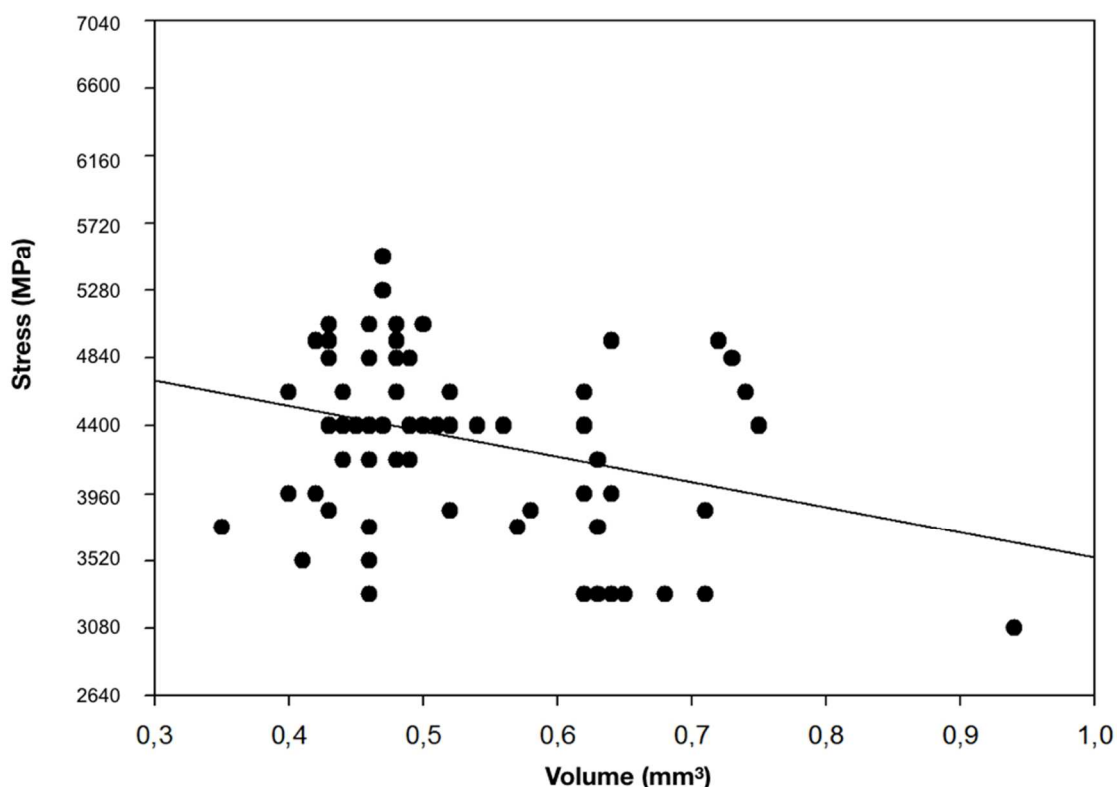


Fig. 7. Scatter plot of stress and volume of misfit, $r = -0.302$, $P=0.01$.

Failure mode

For all groups, failure mode chiefly comprised abutment screw fracture. Observation of the polarized light and scanning electron microscope (SEM) micrographs of the fractured surface of the abutment screws allowed the consistent identification of fractographic marks, such as compression curl, fatigue striations, dimples, which indicated the fracture origin and the direction of crack propagation (Figure 8).

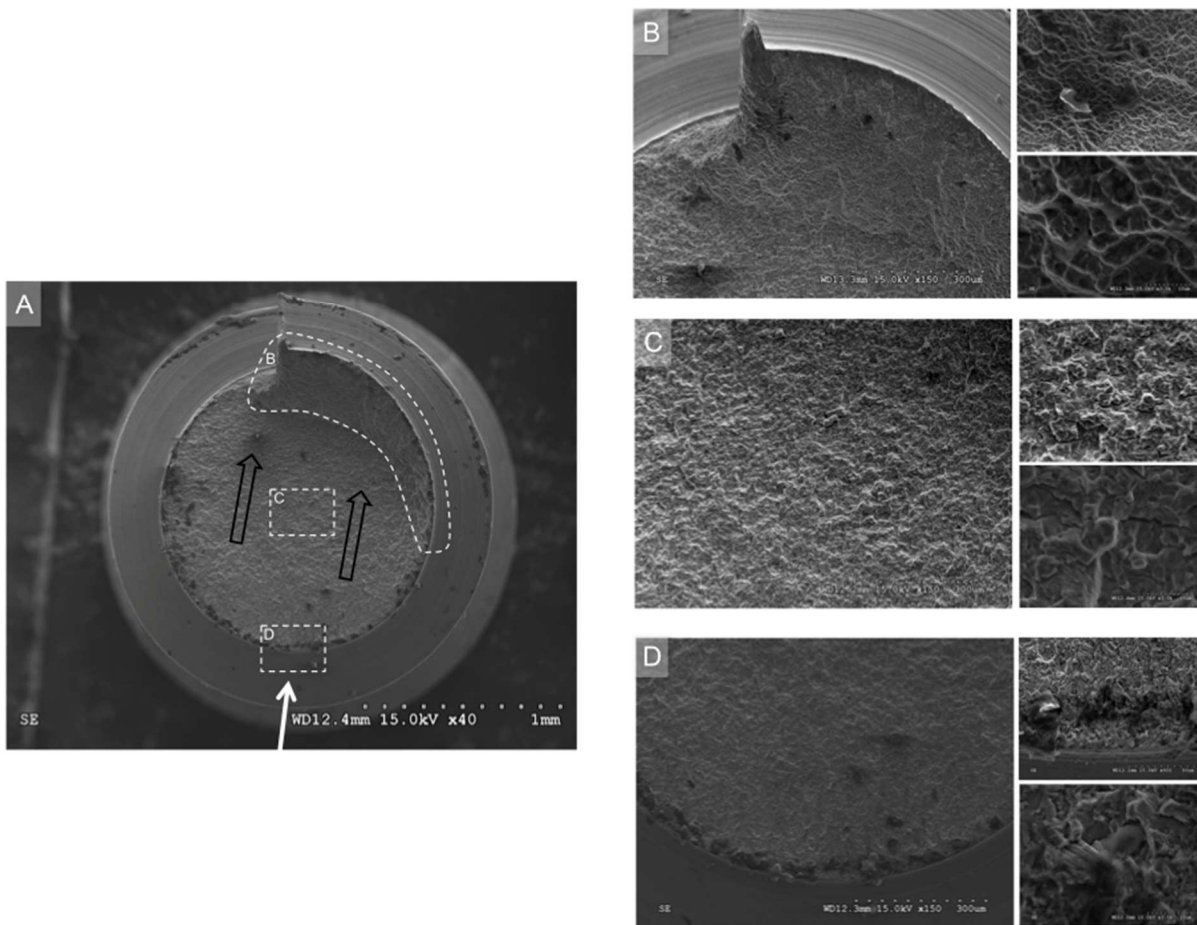


Fig. 8. (A) SEM micrograph (40x magnification) of a representative failed abutment screw after SSALT. The main dotted marked area (top) shows a compression curl, which evidences fracture origin (dotted bottom square-D) at the opposite tensile side (white arrow), indicating the direction of crack propagation (dcp) (black arrows) from lingual to buccal. (B, C and D) Higher magnification (150x, 350x and 2,500x) of the fractured surface shows fractographic features of ductile metals such as dimples created by microvoid coalescence (B) and fatigue striations (pointer in D) that mark the crack-front position with its successive stress cycles.

DISCUSSION

The present study sought to evaluate the three-dimensional fit of abutments fabricated by the industry compared to those either milled or cast by a commercial laboratory and to correlate the implant-abutment connection misfit with stress at fatigue failure of prostheses. Also, the probability of survival (reliability) and fractography to characterize failure modes were performed for cemented and screw-retained prostheses. The results demonstrated that the three-dimensional internal fit at the implant/abutment interface was influenced by the fabrication method of implant-retained restorations. An impact on the mechanical performance was also observed, since the higher the volume of misfit between the implant and the abutment, the lower the strength of the implant-supported rehabilitations. Besides, the results of this study showed that fatigue accelerated the failures of all groups, except for UCLA-Ce, as evidenced by the resulting β value. The reliability of such systems was influenced by the fabrication method and crown fixation mode. Therefore, all postulated null hypotheses were rejected.

The need for custom abutments is gradually increasing over the years. To achieve aesthetic, biological and functional success in implant rehabilitation, it is often necessary to improve prostheses emergence profile, by customization of the abutment to the anatomical needs of the respective implant site³⁷⁻³⁹ and/or compensate for inadequate implant angulation. In this study, two customized restoration designs fabricated through different process were investigated: (a) monolithic-abutment-crown, where the abutment and crown are manufactured as one-piece that is directly screwed to implant (Digital-Sc and UCLA) or bonded to a titanium base then screwed to the implant (TiB-Sc) or (b) a core with a separate crown, where the abutment is screwed to implant (Digital-Ce and UCLA- Ce) or

bonded to titanium base first (TiB-Ce), then screwed to the implant followed by cementation of a crown. While the former design would be better indicated for implants placed in an ideal three-dimensional position, the latter would be indicated for implants in a not ideal position. Regarding the fabrication process, besides the custom castable abutments fabricated through a conventional casting workflow (by using UCLA-type abutments), customized abutments can also be fabricated out of different materials such as metal alloys or ceramics using CAD/CAM manufacturing systems.^{37, 39} Such a technology has been suggested as an improvement over the conventional methods since numerous advantages in the fabrication of implant-supported rehabilitations were introduced, which include reduced clinical time, high precision machining of prefabricated blocks of any given material, reduced laboratory technique sensitivity and, consequently, high capacity of customization.^{36, 37} However, despite the advantages mentioned above of employing a fully digital workflow, the control of internal misfit is not yet controlled by international standards or norms (as it is for prefabricated abutments) and is dependent on several variables involved in the milling strategies of the CAD/CAM systems.⁴⁰⁻⁴² In this scenario, recently introduced abutments, known as Ti-base, have been designed to be CAD/CAM-friendly and to allow rapid fabrication of prostheses with maximal fit at the implant-abutment connection.³⁷ In essence, Ti-base is a prefabricated abutment with a hybrid concept of cemented and screwed fixation in the same prostheses where the implant-abutment connection is used with the precision as delivered from the manufacturer.

The literature on the fit accuracy of abutments milled in commercial laboratory CAD/CAM systems is controversial, either supporting or not a comparable internal fit relative to prefabricated ones.⁴³⁻⁴⁶ In this study, the qualitative and quantitative

findings of the three-dimensional internal fit evaluation demonstrated that groups produced by a complete laboratory digital workflow (Digital-Sc and Digital-Ce) depicted higher values of internal misfit relative to groups produced by hybrid digital (TiB-Sc and TiB-Ce) and conventional (UCLA and UCLA-Ce) workflows (not significantly different from each other). While the reasons for the worse fit found in the Digital-Sc and Digital-Ce group can be explained by several factors relative to the milling parameters and strategies,⁴⁰⁻⁴² the similarity between the misfit values of the TiB-Sc, TiB-Ce, UCLA, and UCLA-Ce can be explained by the well-controlled conditions in which such abutments were industrially manufactured.

The existence of micro gaps between implant and abutment has been described in several studies.^{14, 16, 47-51} Such interface comprises a paramount factor in the long-term success of any implant rehabilitation.⁸ Biological implications of the micro gap at the implant-abutment connection are related to the bacterial colonization which, as a bacterial reservoir, could influence the remodelling of the peri-implant bone and the long-term health of the peri-implant tissues.¹³⁻¹⁶ It must be recognized that as of now, there are no endosseous dental implant systems that can provide a complete seal at the implant–abutment interface⁵² and so this is still an important clinical issue. Mechanical implications are more related to micro-movements and possible loosening or fracturing of abutment screws.^{11, 12} In the present study, the volumetric results of internal fit affected the mechanical performance of the investigated systems since the volume of misfit between the implant and abutment was negatively related to the fatigue stress of the implant-supported rehabilitation, which means that specimens with higher internal gaps failed at lower fatigue stress. The impairment of the mechanical resistance according to different levels of internal

misfit, although seldom investigated, was confirmed by other authors using different methods.^{11, 53, 54}

Several measuring analytical techniques for gap determination in implant-supported rehabilitations are described in the literature.^{55, 56, 40, 57, 20, 58} Although many of these techniques are well established, most authors agree that these methodologies provide limited information,^{43, 59, 60} and it is impossible to use these methods *in vivo* considering their destructive approach. Accordingly, with the development of digital technology, three-dimensional analysis methods have been explored, such as microcomputed tomography, as used in our study.^{55, 61} By using the silicone replica technique we have demonstrated that microgaps up to 1 μm width could be measured and reconstructed in a three-dimensional rendering image, providing insight into the most critical volumes of misfit. Besides, qualitative and quantitative data from the direct implant scanning and the silicone replica scanning techniques showed similar values. Statistical analysis was not performed to compare direct and the indirect silicone replica techniques, given that only one sample for each group was evaluated in the former technique. However, our findings of similar measurements between these two techniques are in agreement with Oka et al.⁶⁰ that evaluated the fitting accuracy of prostheses three-dimensionally using a combination of the silicone replica technique and μCT in comparison with a conventional 2D silicone replica method (stereomicroscopy). Their study showed that 3D virtual images of the replica accurately reflected their *in situ* misfit.

In addition to the implant-retained prostheses fabrication method, the fixation mode influenced the reliability of the groups at higher stress scenario. A general trend was observed for increased reliability of cement-retained prostheses at higher stress, regardless of the fabrication method. From a mechanical standpoint, the

finding concerning higher reliability for cement-retained implant-supported prostheses compared to screw-retained prostheses has been previously reported in fatigue studies^{32, 62, 63} and was confirmed by a clinical study⁶⁴. It can be inferred that the presence of the cement between the crown and abutment increases the interaction due to the intimate contact created by the filling cementing media, which potentially reduces misfit and micromotion between parts. A review of clinical studies showed the survival of cement-retained single crowns was 93%, compared to 83% for implant-supported screwed crowns for follow-up periods commonly longer than 6 years.⁶⁵

Based on fractographic features of failed specimens observed in polarized-light and scanning electron microscopy, all fractures were characterized by plastic deformation, suggesting ductile fractures. From a clinical standpoint, failure modes of all groups could be considered repairable, since they did not affect the implant integrity, as observed in previous *in vitro*⁶² and clinical studies.^{66, 67} As a consequence, expected long-term maintenance of the investigated systems would likely be limited to the abutment screws. Considering that at 3300 MPa (equivalent to 150 N) all groups kept their survivability higher than 86%, except for the screwed monolithic digital abutment/crown (Digital-Sc = 24%), the investigated systems showed sufficient resistance required for the clinical application under loadings within the maximum bite force for incisors (65N⁶⁸ to 100N).⁶⁹ However, long-term randomized clinical trials are always highly desired to obtain information on the longevity and complication modes of new implant-abutment restorative systems.

CONCLUSIONS

Within the limitations of this study, the following conclusions may be drawn:

- Implant-supported prostheses milled by a commercial laboratory (Digital-Sc and Digital-Ce) exhibited poorer internal fit at the implant/abutment connection compared to those either cast or fabricated by the industry (TiB-Sc, TiB-Ce, UCLA and UCLA-Ce);
- All groups presented high reliability at 2300 MPa. At higher stress TiB-Ce demonstrated the highest reliability;
- Failure mode chiefly comprised abutment screw fracture;
- Higher misfit values negatively influenced the stress in which the specimens failed.

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3 DISCUSSION

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The overall objective of this study was to evaluate the influence of abutment fabrication method on the reliability and the three-dimensional fit at the implant-abutment interface of implant-supported prostheses. The correlation between misfit levels with stress at fatigue failure of prostheses was also performed. The results demonstrated that not only the three-dimensional internal fit at the implant/abutment interface but also the reliability of the studied systems was influenced by the fabrication method of implant-retained restorations. An impact on the mechanical performance was observed, since the higher the volume of misfit between the implant and the abutment, the lower the strength of the implant-supported rehabilitations. Therefore, all postulated null hypotheses were rejected.

The rationale behind the selection of the abutments used in this study is based on the increasing need of custom abutments to attend the multifaceted and highly complex set of clinical scenarios. Custom abutments are individually shaped according to the anatomical needs of the respective implant site⁵²⁻⁵⁴ and allow the clinician to improve prostheses emergence profile, and to compensate for inadequate implant angulation. In this study, two customized restoration designs fabricated through different process were investigated: (a) monolithic-abutment-crown, where the abutment and crown are manufactured as one-piece that is directly screwed to implant (Digital-Sc and UCLA) or bonded to a titanium base then screwed to the implant (TiB-Sc) or (b) a core with a separate crown, where the abutment is screwed to implant (Digital-Ce and UCLA-Ce) or bonded to titanium base first (TiB-Ce), then screwed to the implant followed by cementation of a crown. While the former design would be better indicated for implants placed in an ideal three-dimensional position, the latter would be indicated for implants in a not ideal position.

Considering that the abutment/implant interface exerts remarkable influence on the future success and long-term stability of implant-supported rehabilitations, it becomes paramount to investigate the effect of different abutment fabrication methods on the internal fit at the implant-abutment connection. As regards the fit accuracy of abutments milled in commercial laboratory CAD/CAM systems, the

literature is controversial, either supporting or not a comparable internal fit relative to the prefabricated ones.⁵⁵⁻⁵⁸ In this study, the qualitative and quantitative findings of the three-dimensional internal fit evaluation demonstrated that groups produced by a fully digital laboratory fabrication process (Digital-Sc and Digital-Ce) depicted higher values of internal misfit relative to groups produced by a hybrid fabrication process (TiB-Sc and TiB-Ce) and conventional (UCLA and UCLA-Ce) workflow (not significantly different from each other). Possible explanations for the worse fit found in the fully digital groups could be associated to several factors relative to the milling process, such as the wear of milling instruments, the change in the radius of the instruments during the milling procedure,⁵⁹ the incompatible size of the milling drill with the corresponding implant angles⁶⁰ and, more importantly, tolerances set in producing CAD/CAM screw-retained abutments/crowns, which can play a key role in the final fit.²⁴ Mobilio et al.²⁴ evaluated the marginal vertical fit along implant/abutment interface of a prefabricated abutment and three customized CAD/CAM screw-retained crowns with three different “tolerance” values. The results of such investigation demonstrated that reducing the tolerance of 10 microns lower than the manufacturer values is equal to increasing the attrition and, consequently, the vertical gap between the components.

The similarity between the misfit values of the Ti-Base and UCLA abutments can be explained by the well-controlled conditions in which such abutments were industrially produced. It is worthwhile to mention that, in the current study, UCLA abutments with metallic base were used and the customized wax patterns were milled in the CAD/CAM system followed by conventional casting procedures, which could contribute to the favorable internal fit depicted in this group. Previous investigations^{25, 34} showed that prefabricated abutments, which include UCLA abutments with a CoCr base that are customized in a laboratory, are superior in adaptation to those cast from plastic burnout patterns.

In contrast to studies reporting data on marginal/internal gaps between two different surfaces, a volume of misfit (mm^3) at the implant/abutment interface was also measured in this study. Similarly, Lops et al.⁵⁵ calculated the volume of contact (mm^3) to investigate the accuracy of fit between an internal conical connection implant and prefabricated and CAD/CAM abutments, using a multisensored opto-mechanical coordinate measuring machine. In contrast to our results, lower mean

values of volume of interference for the CAD/CAM abutments (0.108 mm³) were found in comparison to the prefabricated abutments (0.134 mm³). Although direct comparison is not feasible, given the different implant geometry and methodology used in such investigation, the authors emphasized the 3D measurement method as a more helpful approach compared to the 2D measurement for the comparison between different abutment groups.

Several measuring analytical techniques for gap determination in implant-supported rehabilitations are described in the literature, which include measurement of the specimens by direct visualization under a microscope; or embedded and sectioned specimens and silicone replica analyzed under scanning electron microscopy (SEM),^{22, 23} optical microscopy,²⁴ microtomography,^{22, 31} travelling microscope,^{25, 26} among others. Although such techniques are well established, most authors agree that these methodologies provide limited information,^{55, 61, 62} and it is impossible to use these methods *in vivo* considering their destructive approach. Accordingly, with the development of digital technology, three-dimensional analysis methods has been explored, such as 3D nonlinear finite element analysis (FEA)²² and microcomputed tomography.^{22, 63} By using this technique we have demonstrated that microgaps up to 1 μm width could be measured in two and three dimensions; in the latter case, the microgaps at the implant/abutment interface could be reconstructed onto a three-dimensional rendering image, which can provide insight into the most critical areas of misfit. Besides, qualitative and quantitative data from the direct implant scanning and the silicone replica scanning techniques showed similar values. Statistical analysis was not performed to compare direct and the indirect silicone replica techniques, given that only one sample for each group was evaluated in the former technique. However, our findings of similar measurements between these two techniques are in agreement with Oka et al.⁶² that evaluated the fitting accuracy of prostheses three-dimensionally using a combination of the silicone replica technique and μCT in comparison with a conventional 2D silicone replica method (stereomicroscopy). Their study showed that 3D virtual images of the replica accurately reflected their *in situ* misfit.

From a technical standpoint, gaps between the implant and the abutment are inevitable in fitting the different parts. Such components cannot be accurately matched because of the precision limit during manufacturing process and therefore,

some amount of microleakage will unavoidably occur regardless of the type of connection and the size of the microgaps.^{20, 23, 64} Accordingly, the magnitude of these gaps and its clinical significance has been receiving significant attention^{18, 20, 29, 34, 35, 65, 66} and different methodologies have been utilized for such investigation.^{16, 19, 24, 29, 31, 34, 55, 65} The size of the microgap at implant/abutment connection has been reported as a wide range of 1 to 60 μm ,^{24, 25, 34, 67} and it is dependent, among other factors, on the implant system and the torque used to fix abutments.^{20, 68} Although gaps from different magnitudes have been identified along with proportional levels of microleakage at different implant abutment configurations, it is important to bear in mind that no internal or external implant-abutment screwed connection has 100% bacterial seal⁶⁹ and so this is still an important clinical issue. Biological implications of the micro gap at the implant-abutment connection are related to the bacterial colonization in the apical portion of the abutment screw, which, as a bacterial reservoir, could influence the remodelling of the peri-implant bone and the long-term health of the peri-implant tissues.^{17, 18, 20, 21} Mechanical implications are more related to micro-movements and possible loosening or fracturing of abutment screws.^{16, 19} In the present study, the volumetric results of internal fit affected the mechanical performance of the investigated systems since the volume of misfit between the implant and abutment was negatively related to the fatigue stress of the implant-supported rehabilitation, which means that specimens with higher internal gaps failed at lower fatigue stress.

Additionally, when evaluating the calculated reliability for the tested groups, all groups showed comparable reliability (above 97%) at 2300 MPa. However, at higher stress (3300 MPa) while all groups kept their survivability higher than 86%, significantly lower reliability was demonstrated by Digital-Sc (~24%). Within the same fixation mode, the full digital groups presented the lowest reliability values (0% - Digital-Sc and 20.93% - Digital-Ce) at 4300 MPa of set stress. The impairment of the mechanical resistance according to different levels of internal misfit, although seldom investigated, was confirmed by other authors.^{16, 30, 70}

In addition to the implant-retained prostheses fabrication method, the fixation mode influenced the reliability of the groups at higher stress scenario. It was observed a general trend for better reliability of cement-retained prostheses at higher

stress, regardless of the fabrication method. From a mechanical standpoint, the finding concerning higher reliability for cement-retained implant-supported prostheses compared to screw-retained prostheses has been previously reported in fatigue studies^{10, 11, 71} and was confirmed by a clinical study⁷². It can be inferred that the presence of the cement between the crown and abutment increases the interaction due to the intimate contact created by the filling cementing media, which potentially reduces misfit and motion between parts and thereby improving the mechanical performance of cement-retained systems. In an extensive review, the survival of cement-retained single crowns was 93%, compared to 83% for implant-supported screwed crowns for follow-up periods commonly longer than 6 years.⁷³

Based on fractographic features of failed specimens observed in polarized-light and scanning electron microscopy, all fractures were characterized by material tearing and exhibited gross plastic deformation, suggesting ductile fractures. From a clinical standpoint, failure modes of all groups could be considered repairable, since they did not affect the implant integrity, as observed in previous *in vitro*⁷¹ and clinical studies.^{74, 75} As a consequence, expected long-term maintenance of the investigated systems would likely be limited to the abutment screws. Considering that at 3300 MPa of set stress (equivalent to 150 N) all groups kept their survivability higher than 86%, except for the screwed monolithic digital abutment/crown (Digital-Sc = 24%), the investigated systems showed sufficient resistance required for the clinical application under loadings within the physiologic range for incisor area, where the loads are reported to be approximately 65 N⁷⁶ to 100 N.⁷⁷ However, long-term randomized clinical trials are always highly desired to obtain information on the longevity and complication modes of new implant abutments.

4 CONCLUSION

4 CONCLUSION

Within the limitations of this study, the following conclusions may be drawn:

- Implant-supported prostheses milled by a commercial laboratory (Digital-Sc and Digital-Ce) exhibited poorer internal fit at the implant/abutment connection compared to those either cast or fabricated by the industry (TiB-Sc, TiB-Ce, UCLA and UCLA-Ce);
 - All groups presented high reliability at 2300 MPa (up to 97%), however at higher stress Digital-Sc decreased the reliability to 0% and TiB-Ce (71%) demonstrated higher reliability than other groups;
 - Failure mode chiefly comprised abutment screw fracture;
 - Higher misfit values negatively influenced the load in which the specimens failed.
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