Evaluation of UCLA Implant-Abutment Sealing

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Purpose: To evaluate the effect of the presence of a prefabricated cobalt-chromium (CoCr) margin in a universal castable long abutment (UCLA) on the sealing capability and fit of the implant-abutment interface. Materials and Methods: One-hundred twenty external hexagon implants (SIN) were divided into two groups (n = 60 each) to receive UCLA abutments from six manufacturers (n = 10 each) either with or without a CoCr margin (n = 60 each). Abutments were cast and 12 groups were formed: M (Microplant), I (Impladen), S (SIN), Sv (Signo Vinces), T (TitaniumFix), and B (Bionnovation). Sealing was determined by placing 0.7 µL of 0.1% toluidine blue in the implant wells before abutment torquing. Implant-abutment samples were placed into 2.0-mL vials containing 0.7 mL of distilled water to maintain the implant-abutment interface, and aliquots of 100 µL of water were retrieved at 1, 3, 6, 24, 48, 72, 96, and 144 hour incubation times for measurement of absorbance in a spectrophotometer, and returned for repeated measurements. Two-way ANOVA (P < .05) and Tukey's test were used. Scanning electron microscopy (SEM) was used for observation of the implant-abutment fit. Results: Groups M, Sv, and T without the CoCr margin resulted in complete release of toluidine blue at 1 hour, whereas I, S, and B did so at 3, 24, and 96 hours, respectively. Complete leakage in abutments with the prefabricated margin occurred at 6 hours for S; 24 hours for Sv, T, and B; and 72 hours for M and I. Implant-abutment gaps were observed in all groups. A poorer fit was depicted for groups M and T without the CoCr margin. Conclusion: Complete leakage was observed for all UCLA abutments regardless of the presence of the CoCr margin. Implant-abutment gaps were observed in all groups. INT J ORAL MAXILLOFAC IMPLANTS 2014;29:113-120. doi: 10.11607/jomi.3217

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comprehensive efforts to characterize biologic and technical complication rates have been recently made in systematic reviews involving implant-supported single crowns¹ and fixed dental prostheses.² Remarkably, irrespective of prosthetic reconstruction type, a significant amount of extra chairtime seems necessary for prosthetic repair over years of service. In addition, it has been shown that biologic outcomes are most commonly reported, whereas evaluations of prostheses and patient satisfaction are scarce.³

Typically, an implant-supported rehabilitation is comprised by an endosseous implant that connects to a transmucosal abutment to receive a single- or multiple-unit prosthetic restoration. The location of this connection can be either submerged, at the bone crest level, or nonsubmerged. Regardless of the location and type of connection (internal or external), it is important that the best implant-abutment fit is achieved in order to favor stress distribution between the connecting components and hinder microorganism colonization at this interface. Therefore, to maintain connection stability, it is important that the unclamping forces induced by functional loading do not exceed the connecting clamping force between

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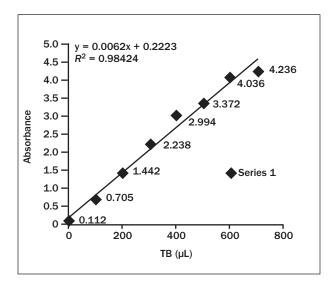


Fig 1 Calibration curve determined through linear regression by placing TB increments of 0.1 μ L to 0.7 μ L (best line fit) using a fraction of a color marker volume in water.

the implant and abutment obtained by torquing the connecting screw.⁷⁻⁹ Considering the behavior of bolted joints, the clamping force between two surfaces is maximized and most stable when no gaps are present between them.¹⁰

The placement of the implant-abutment interface at the level of alveolar bone has been associated with the presence of inflammatory cell infiltrate and bone loss.¹¹ It has been demonstrated that following implant surgery, remodeling occurs and may lead to a reduction in bone dimension, both horizontally and vertically.¹² Some studies have shown that implant components and bone appear to tolerate some degree of lack of fit,13-15 but the degree of marginal fit that can be considered clinically acceptable has not been established. 16-18 Several methods have been proposed to characterize the implant-abutment interface fit. Studies have most frequently investigated the sealing capability by observing bacterial^{4-6,19} or color marker migration toward or from the implant well.4 Direct observations of the implant-abutment interface have also been performed by radiograph,²⁰ scanning electron microscopy (SEM),^{21,22} and hard x-ray synchrotron radiation.²³ Another possibility is a crosssectional analysis and evaluation of the misfit taken as a function of implant radius, which allows a more comprehensive observation of adaptation along the implant-abutment interface.²⁴ It has generally been shown that most implant-abutment interfaces do not result in a sealed connection.

Recently, sealing tests of external hexagon implantabutment interfaces showed that stock abutments from different manufacturers presented similar leakage in temporal observations.²⁵ In this study, it was hypothesized that customized universal castable long abutments (UCLAs) from several manufacturers would present improved sealing due to the presence of a prefabricated cobalt chromium (CoCr) margin at the interface compared to UCLA abutments without it. This study tested the following hypotheses: (1) the sealing capability of implant-abutment connections with a prefabricated CoCr margin will present improved resistance to microleakage at several incubation times compared to connections without this margin and (2) subsequent SEM observation of the implant-abutment marginal fit would reflect the results from the sealing testing, where groups presenting higher leakage would also present a qualitatively poorer interface fit.

MATERIALS AND METHODS

Sample Preparation

One-hundred and twenty 4.1-mm-diameter external hexagon implants (SIN) were randomly divided into two groups (n = 60 each) to receive UCLA abutments from six different manufacturers. One group comprised implants receiving customized UCLA abutments with a prefabricated CoCr margin and a remaining body of plastic, and the other group comprised full plastic UCLA abutments from the same manufacturers (n = 60 each). The groups were as follows: group M (Microplant), group I (Impladen, Prodem), group S (SIN,), group SV (Signo Vinces), group T (Titanium Fix, AS Technology Componentes Especiais), and group B (Bionnovation Biomedical).

Abutments from both groups were sent to a commercial laboratory to be waxed and cast in a CoCr alloy

(Wirobond-280, Bego) by an experienced technician who was blind to abutment brand. A total of 12 groups were formed according to the presence or absence of the prefabricated CoCr margin. Abutments were seated and screwed on their respective implants and torqued to 32 Ncm using a torquemeter (SIN), following the manufacturer's recommendation.

Sealing Capability Test

The implants and their abutments were first subjected to a sealing capability test and then to SEM observation of the interface. To quantify the range of the color marker, toluidine blue (TB) that implants could leak to distilled water, a calibration curve was determined through linear regression. TB increments of 0.1 to 0.7 μ L (best line fit) were added with an automated pipette (Eppendorf Research Pro) to 0.7 mL of distilled water placed in 2.0-mL vials. The absorbance of TB dissolved in water (Fig 1) was quantified with a spectrophotometer calibrated to a wavelength of 560 nm (Fluostar Optima; BMG, Labotech).

The maximum amount of 0.7 µL was determined from a previous study,²⁵ which indicated that this volume was enough to fill the implant well and remain free from contact with the apical region of the abutment screw. Samples from each increment were analyzed in the spectrophotometer calibrated to a wavelength of 560 nm to acquire the absorbance values, which were used to compose the absorbance curve. The starting point to formulate the absorbance curve was pure distilled water without color marker (blank). The calibration curve was determined by linear regression (best line fit) considering the absorbance as a function of TB amount.

Subsequently, 0.7 µL of TB was dispensed at the most apical portion of the implant well by means of an automated pipette. Implants were vertically held by a vise connected to the bench to allow abutments to be torqued to 32 Ncm, as per manufacturer recommendations, using a torque wrench (TMEC, SIN—Sistema de Implante Nacional). The connected implants were placed into 2.0 mL vials (Eppendorf Research Pro) filled with 1.5 mL of distilled water assuring that only the implant-abutment interface remained immersed, and not the interface between the abutment and screw. The capped vials containing the implants were kept at room temperature throughout testing.

Samples of $100~\mu L$ (n = 3 for each implant) were acquired at 1, 3, 6, 24, 48, 72, 96, and 144 hour incubation times using an automated pipette. Each sample was transferred from the respective vial to a microplate (TPP 96, Techno Plastic Products AG) for absorbance evaluation. Immediately after measurements, the contents of the microplate were returned to the vials containing the implants. When a group presented total leakage

of TB, no subsequent absorbance measurement was made. The arithmetic average of the three absorbance values was determined and used for statistical analyses. Repeated measures analysis of variance (ANOVA) at 95% level of significance and Tukey test for multiple comparisons were utilized.

SEM Observation

Specimens were subjected to marginal fit evaluation in the SEM (Model 3500S, Hitachi Ltd.) at a 15-Kv acceleration voltage and 35× magnification. The inspection involved qualitative observation of representative areas of the implant-abutment interface fit. Specimens of all groups were subjected to the same imaging protocol where they were first evaluated across the observable interface and images of representative sections of the interface were acquired, as perpendicular as possible to the junction.

RESULTS

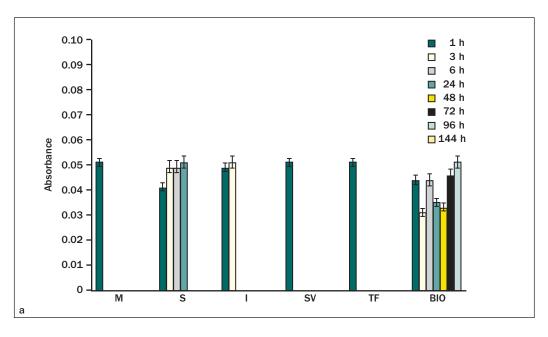
The calibration absorbance curve was linear with respect to the TB 0.1 μ L increments (up to 0.7 μ L) dissolved in 2.0 μ L of distilled water presenting an R^2 of 0.98424 (Fig 1).

Two-way ANOVA repeated measures (time, margin, and manufacturers) showed that there was no significant difference in the release of TB between groups presenting the prefabricated CoCr margin (P > .05) and groups without it (P > .05). The absorbance means and 95% confidence intervals as a function of incubation time for the different implant abutment systems are presented in Figs 2a and 2b.

As a general trend, all implant abutment systems, regardless of the presence of the prefabricated CoCr margin, presented an increase in absorbance as a function of time, with a significant difference observed between incubation times for some groups (P < .05). However, the fastest complete release of TB occurring at 1 hour was observed for groups M, Sv, and TF without the CoCr margin. Group I without the margin resulted in the complete release of TB at 3 hours, followed by groups S at 24 hours and B at 96 hours (Fig 2a).

Groups with the CoCr margin presented no statistical difference (P < .059) compared with groups where the margin was absent. However, total release of TB generally occurred after longer incubation times (Fig 2b). For group S, maximum release occurred at 6 hours followed by groups SV, TF, and B at 24 hours. Groups M and I showed the complete release at 72 hours (Fig 2b).

SEM observation showed the presence of gaps in all groups even at low magnifications (Figs 3 and 4). An evidently larger misfit was observed for groups M (Fig 3a) and TF (Fig 3e) without the CoCr margin.



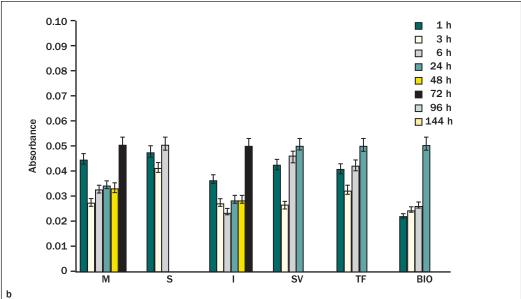


Fig 2 Color marker release as a function of incubation time for groups (a) without and (b) with the 2-mm CoCr shoulder. M: Microplant; S: SIN; I: Impladen; SV: Signo Vinces; TF: Titanium Fix; BIO: Bioinnovation.

DISCUSSION

Despite the high success rates of dental implantology, the quest to reduce long-term biological complications has fostered the development of new implant designs aimed to maintain long-term peri-implant tissue health. Changes in implant geometry and surface treatment as well as the trend toward the use of internal implantabutment connections have shown that the current criteria for implant treatment success should be recon-

sidered in light of industrial and clinical advances.²⁶ Remarkably, decades after the launch of the external hexagon system, this connection design is still the most used worldwide.^{21,27} An evaluation of the market share of implant connections in Brazil, where all the evaluated components in this study were fabricated, showed that the external hexagon represents 58% of the sales, followed by internal conical connections (27%), and internal hexagon (15%).²⁸

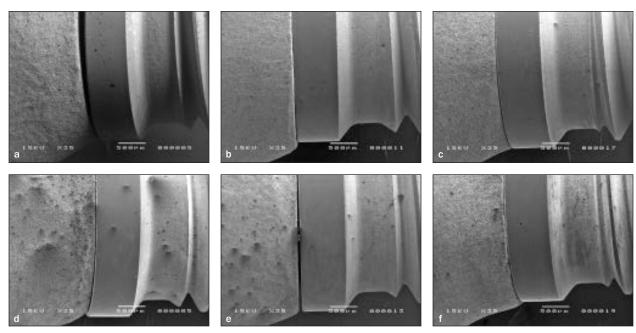


Fig 3 SEM micrographs of the implant-abutment interface for groups without a 2-mm CoCr shoulder: (a) Microplant, (b) Impladen, (c) SIN, (d) Signo Vinces, (e) Titanium Fix, (f) Bioinnovation.

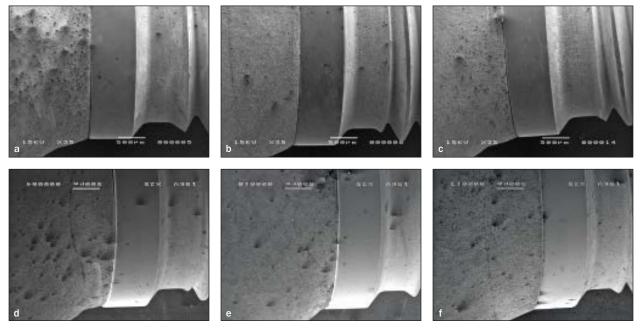


Fig 4 SEM micrographs of the implant-abutment interface for groups with a 2-mm CoCr shoulder: (a) Microplant, (b) Impladen, (c) SIN, (d) Signo Vinces, (e) Titanium Fix, (f) Bioinnovation.

The present in vitro study evaluated the sealing capability and marginal fit of one external hexagon implant system using customized UCLA connections with or without a prefabricated margin, each from six different manufacturers by spectrophotometric quantification of microleakage. 4,24,25 Of clinical significance is that irrespective of the presence of the prefabricated CoCr margin, all systems presented, at some observation time point, leakage of the color marker placed in the implant

well. However, two groups that did not present the prefabricated margin revealed a consistently larger gap that resulted in the fastest complete color marker release. Interestingly, another system, also without the prefabricated margin, presenting total color marker release at 1 hour depicted gaps visually smaller and similar to other groups, which suggests that microscopic marginal observation of implant-abutment interfaces alone fails to be an accurate predictor of sealing capability.

Extrapolation of the present findings that indicated unimpeded leakage of toluidine blue from the implant well to the external media, to the clinical scenario, which may include a two-way path for a variety of bacteria under loading, should be made with caution. However, such bidirectional fluid leakage and bacterial penetration has been described for implant-abutment systems also in the absence of mechanical loading.^{29–31} Specific evaluations on internal conical implant-abutment connections have also pointed out their inability to hinder endotoxin leakage from the implant well.³² When dynamic loading was incorporated into bacterial leakage testing (E Coli, which measures 1.1 to 1.5 µm in diameter and 2 to 6 µm in length), all five evaluated implant systems, including external and internal connections, showed bacterial leakage.³³

Explanations for the presence of an implant-abutment gap include imprecise machining of implant parts, excessive torque during abutment installation leading to part distortion, and improper male-female adaptation among others.34 Taking into consideration the careful adaptation and torque applied to the implants with or without a CoCr margin in this study, the leakage of the color marker was probably because of imprecise machining of the implant male hexagon part and/or abutment female hexagon. When placed at or below the crestal bone level, the presence of this interface may be critical to the health of peri-implant tissues.³⁵ Although some companies recommend the casting of abutments without the CoCr shoulder for the final restoration, our data suggest that even in a less sensitive connection type, ie, the external hex, a very poor fit can be expected. This may be aggravated in internal connections where casting and slight distortions may compromise the fit and close contact between the implant walls and abutment surface. Therefore, regardless of implant-abutment connection type, abutment configurations omitting a metal shoulder may be indicated exclusively for provisional restorations.

From a mechanical standpoint, oblique loads are mainly born by the abutment screw in external hexagon systems, whereas in internal connections a shift in load distribution occurs toward the implant walls, abutment, and screw. Therefore, less micromovement seems to occur in internal connections, which ultimately leads to a higher probability of survival when subjected to fatigue loading.³⁶ In addition, most internally connected systems present a mismatch between the abutment diameter and the implant at the crestal level, a concept known as platform-switching. Such configuration places the implant-abutment gap away from the bone with a directly proportional relationship between the amount of mismatch and the level of bone preservation reported to occur in a randomized clinical trial.^{37,38} Therefore, considering that screwed internal connections have also been shown to fail in providing a hermetic implant-abutment seal,⁴ the use of the platform-switching concept seems to be more suitable for internal compared to external connections in terms of probability of survival, as recently reported.³⁹

The differences in hardness and moduli between CoCr alloy (E = 210 GPa, ASTM F75) and CP Ti (E = 100GPa, ASTM F67) may be a factor accelerating the failure of a restored implant system, which is yet to be elucidated. A somewhat similar scenario occurs with Y-TZP abutments (E = 210 GPa) connected to Ti CP or Ti6Al4V implants (E = 110 GPa, ASTM F136) where a disparity in modulus is found. Although Y-TZP is a ceramic, its transformation toughening effect makes the comparison with a metal such as CoCr alloy fair from the mechanical properties standpoint. A recent short-term (5 years) randomized clinical trial⁴⁰ as well as a systematic review have indicated not statistically different survival rates between Ti and Y-TZP abutments, 41 indicating that no current evidence is available to infer the impact of material differences between implants and abutments on prosthesis longevity. Longer follow-ups are desired, especially with CoCr alloy abutments, for further clarification.

Another potential subject of concern is the possibility of galvanic corrosion, occurring due to the contact between two dissimilar metals in an electrolytic solution.⁴² The composition of the CoCr alloy used in the abutment of our study includes the following: C = 0.042, Si = 0.36, Mn = 0.40, Cr = 27.56, Ni = 0.17, Fe = 0.24, Co = 65.82, Mo = 5.13, and N = 0.165. These amounts follow the ASTM F75 standard for Cobalt-based alloys. However, galvanic corrosion represents an important concern and has been addressed in several studies. An investigation concerning the CoCr alloy susceptibility to galvanic corrosion when in contact with commercially pure Ti, Ti alloys, and steel alloys, found that the CoCr alloy and Ti couple was stable when subjected to an electrochemical open-circuit potential measurement test and a potentiostatic passive film-corrosion measurement test.⁴³ Another study evaluated the galvanic corrosion between Ti and several alloys including CoCr by electrochemical means, scanning electron microscopy (SEM), and Auger spectrometry. Very low corrosion rates (10⁻⁶ to 10⁻⁸) were found for CoCr alloys, which were not different from high noble alloys.44 Specific evaluations using artificial saliva as the medium at 37°C of the combination between CoCr frameworks fixed to titanium dental implants were made. After electrochemical testing, morphologic evaluations of the surface and sections detected galvanic corrosion activity, however to insignificant levels. Authors also emphasized that the clinical perception of metallic taste, suggesting ongoing galvanic corrosion activity, may be elicited with currents averaging 75 μA/cm.^{2,45} The maximum current density level observed for CoCr alloys was $11.6~\mu\text{A/cm}^2$, which is substantially inferior to the levels required to trigger such sensations. The concern of biologic and mechanical risks of galvanic corrosion between predominantly base alloys and Ti should not be overlooked. From a biologic standpoint, the implications of electrical corrosion and their potential effect on perimplant tissues are yet to be elucidated. However, if formulated as per ASTM F75, as in the present study, galvanic corrosion, if present, may be clinically negligible, but certainly deserves close observation. Lastly, from a mechanical standpoint, a recent systematic review has indicated abutment screw loosening as the chief complication in implant restorations, whereas no complications related to galvanic corrosion were reported.

The magnitude of the implant-abutment gap has received significant attention in the past,5,49 and different methodologies have been utilized for such investigation.^{8,9,24,50} The implant-abutment connection type has been one of the design parameters commonly changed by implant manufacturers. Rationales for changing the implant-abutment connection design include an attempt to establish better prosthetic stability and to decrease the implant-abutment gap that has been reported to occur in many implant systems. 5,24,49 Internal connections presenting improved sealing capability⁴ have also been shown to result in a higher probability of survival.⁵¹ Therefore, an adequate fit between components seems to influence the overall system's mechanical performance. Locking taper connections have been shown to provide a bacterial seal through cold welding occurring at the implantabutment connection,⁵ and remarkably high characteristic strength and reliability have been observed for crowns placed on such a system. 52,53 Future studies addressing interface fit of custom abutments in external connections in tandem with fatigue testing to elucidate failure mechanisms and reliability are warranted. A recent investigation incorporating the use of hard x-ray synchrotron radiation under load application has been described in the evaluation of implant-abutment interfaces. Such an analytical tool allows not only qualitative imaging but also quantitative measurements of the interface under static and dynamic loading, presenting an interesting potential for future characterization of the implant-abutment mating zone.²³

Our first hypothesis, which postulated that the sealing capability of implant-abutment connections with a prefabricated cobalt-chromium (CoCr) margin would present improved resistance to microleakage compared to connections without it, was rejected. Since SEM observation showed different levels of fit in UCLA abutments without the prefabricated margin and the same levels of lack of sealing, the second hypothesis was also rejected.

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The authors reported no conflicts of interest related to this study.

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