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#### Method to improve passive fit of frameworks on implant-supported prostheses: An in vitro study

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| Availability:   |  |  |  |
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| Published version:  |  |  |  |
| DOI:10.1016/j.prosdent.2016.01.006  |  |  |  |
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Elsevier Editorial System(tm) for The Journal of Prosthetic Dentistry Manuscript Draft

Manuscript Number: JPD-D-15-00798R1

Title: Proposal of a method to improve passive fit of frameworks on implant-supported prostheses: an in-vitro study.

Article Type: Clinical Research

Section/Category:

Keywords: Dental Implants; Jig; Misfit Implant; Oral Prostheses; Framework

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Order of Authors: Carlo Manzella, DDS Tutor; Cristina Bignardi, Engineer, PhD Associate Professor; Valerio Burello, Master Dental Technician; Stefano Carossa, MD. DDS Full professor; Gianmario Schierano, MD DDS

Abstract: Statement of problem.

The passivity of the superstructure to the abutments of implant-supported prostheses is necessary for implant-prosthesis success. Improvements are needed in the methods of verifying passivity. Purpose. The purpose of this in vitro study was to evaluate an inexpensive, easy to make, and user friendly jig to verify the position of the implant abutment replicas of the definitive cast and to avoid framework misfit before fabrication. Material and methods. Eighty stone jigs were constructed on a metal base for the in vitro tests. The horizontal, vertical, and angled positions of the implants replicas were created to simulate misfits. The jigs were

fitted on the abutment replicas, and their ability to identify misfits was evaluated. A statistical analysis was not indicated, since the probability of fracture of the stone jig was 0 or 1. Two mathematical models were built using CAD software (SolidWorks Premium; Dassault Systèmes SolidWorks Corp), and the finite element method was used (Ansys; ANSYS Inc) to simulate the structural behavior of 2 implant configurations (4 and 6 implants).

Results. Horizontal misfits of 150  $\mu$ m, vertical misfits of 50  $\mu$ m, angled misfits of 1 degree were detected during the in vitro tests. Different loads and bone quality in the mathematical models did not change stress in the prosthesis configurations on 4 or 6 implants in a relevant way. Conclusions. The fabricated jig was easily able to detect the misfits in accordance with the defined parameters.

Stephen F. Rosenstiel Editor The Journal of Prosthetic Dentistry

Torino, January 08 2016

Dear Editor,

we are uploading you the revised paper entitled "Proposal of a method to improve passive fit of

#### frameworks on implant-supported prostheses: an in-vitro study ".

We have answered one by one to the reviewers comments.

Thank you so much for considering our manuscript.

Author's contribution

Carlo Manzella<sup>a</sup> carlo.manzella@unito.it "Concept/Design, Data collection, executor of the trials"

Cristina Bignardi<sup>b</sup> cristina.bignardi@polito.it "Mathematical analyses, Drafting article"

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Best regards,

Gianmario Schierano

Gianmario Schierano, MD DDS University of Torino Surgical Science Department CIR Dental School. Via Nizza 230 10126 Torino (Italy) Tel: +39-011-6331536, Fax: +39-011-6331513 e-mail: gianmario.schierano@unito.it Dear Cheryl Sullivan,

Editorial Manager of "The Journal Prosthetic Dentistry"

#### Torino, October 12, 2015

I want inform you that I sent to your prestigious journal, like corresponding author, the manuscript entitled "Proposal of a new method to improve passive fit of frameworks on implant-supported prostheses: an in-vitro study", authors C. Manzella, C. Bignardi, V. Burello, S. Carossa, G. Schierano.

Kindly, I ask you to include in the author's list the professor Stefano Carossa as fifth name. The reason is that he worked for drafting and critical revision of the manuscript.

All the authors are agree to include him and every of them will send you an agreement mail.

Author's contribution

Carlo Manzella <sup>a</sup> carlo.manzella@unito.it "Concept/Design, Data collection, executor of the trials"

Cristina Bignardi <sup>b</sup> cristina.bignardi@polito.it "Mathematical analyses, Drafting article"

Valerio Burello <sup>c</sup> valerio.burello@unito.it "Builder of the jig, executor of the trials"

Stefano Carossa <sup>a</sup> stefano.carossa@unito.it "Drafting article. Critical revision of article"

Gianmario Schierano <sup>a</sup> gianmario.schierano@unito.it "Concept/Design. Data collection and Drafting article"

Thank you so much for your consideration.

Best regards

Gianmario Schierano

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Tel: +39-011-6331536, Fax: +39-011-6331513 e-mail: gianmario.schierano@unito.it Reviewer #1:

1. Missing references in introduction.

## Recent articles suggested are included in the introduction

2. Please add photo of thermoplastic disk.

### The photo of thermoplastic disk has been included

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### Reviewer #2:

1. There was no abstract submitted for my review.

• • • •

2. The first nine paragraphs in the introduction were each 1 sentence. Please combined into fewer paragraphs.

## The first nine paragraphs in the introduction are combined into fewer paragraphs.

3. The conclusion's last sentence that the jig CAN prevent complications should be changed to MAY. The study did not show any prevention on complications.

We are agree with the reviewer's sentence "The study did not show any prevention on complications", because this is an "in vitro study" and the goal is to develop an inexpensive, easy to make, and user-friendly device to serve as a precise method to check the position of the implant replicas of the definitive cast to avoid a misfit framework before fabrication. So, CAN is changed to MAY in the conclusion's last sentence

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de Vasconcellos DK, Kojima AN, Mesquita AM, Bottino MA, Ozcan M. A microstrain comparison of passively fitting screw-retained and cemented titanium frameworks. J Prosthet Dent 2014;112:834-8.

## Recent articles suggested are included in the text.

#### Title

Proposal of a method to improve passive fit of frameworks on implantsupported prostheses: an in-vitro study.

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Acknowledgements

The authors wish to thank Enid Rosenstiel for the support in the revision language of the manuscript.

#### **Key Words**

Dental Implants; Jig; Misfit Implant; Oral Prostheses; Framework

#### **INTRODUCTION**

The long-term reliability of an implant system is related to the ability of the system to bear occlusal forces without inducing excessive stress-strain states in the periimplant bone region and to avoid failures in the screw and framework.<sup>1,2</sup> The passivity of the superstructure on the abutments of implant-supported prostheses is an important aspect of their success.

The cause of fixed implant-supported framework misfit is usually multifactorial and can occur in the x-, y- or z-axis dimension.<sup>3-9</sup> Riedy <sup>9</sup> said that one of the important questions asked by clinicians was: "What precision of fit is achievable in clinical practice and is the fit different when frameworks are fabricated using different techniques?"

Several authors have attempted to define an acceptable level of abutment framework misfit. However, to date, no universal guidelines defining an acceptable fit have been established,<sup>10,11</sup> nor has the term "passive fit" ever been defined in biomechanical terms.<sup>12-14</sup>

Over time, some authors have suggested that misfits may be minimized, achieving an acceptable passive fit with the splinted impression technique, low fusing metal casts, or casting frameworks in sections.<sup>15-24</sup> Although the challenge of applying advanced technology, such as a computer numerically controlled (CNC) milling technique for the improvement of framework fit is ongoing, the problem still remains.<sup>14,25,26</sup> Verifying the position of the implant on the definitive cast must correspond with the x-, y- and z-axis dimensions of the position of the implant in the oral cavity before making the framework. Methods which make use of metal,<sup>27-29</sup> resin,<sup>23,30-33</sup> and polymeric<sup>34</sup> materials are available to verify the position of the implants in the definitive cast and in the oral cavity. However, the fabrication of these devices can be difficult and expensive. Moreover, any dimensional change in the material used may invalidate the desired precision.

The purpose of this study was to develop an inexpensive, easy to make, and userfriendly device to serve as a precise method to check the position of the implant replicas of the definitive cast to avoid a misfit framework before fabrication.

#### MATERIAL AND METHODS

For this in vitro study, a  $10.5 \times 8 \times 2$  cm aluminum and brass base with 6 implant host sites (Ø 3.5 mm) was prepared with a computer-controlled drilling, tapping, and milling machine (VMC480P; Bridgeport, positioning error of ±5 µm and repeatability of 2 µm for all axes). Six 13-mm-long, 3.75-mm-wide external hexagon implants (Dummy Brånemark System MkIII Groovy; Nobel Biocare Italiana) were screwed into the base with a torque of 50 Ncm using a torque controller device (OsseoSet # 200 SI-923 230V; Nobel Biocare). The implants were placed so as to represent the ideal tooth arch position and were numbered from 1 to 6. A T-shaped brass device containing implant #4 was made using the spark erosion process. The device ran horizontally in a T-shaped guide cut in the aluminum base. The brass element was held tightly by applying a torque of 10 Nm to a lateral screw with a wrench (Usag 810/50; SWK Utensilerie S.r.l.) with the T-shaped brass element at the bottom of the guide. This position was defined as the standard position (SP). Multiunit abutments (Brånemark System RP 4 mm high; Nobel Biocare) were placed, and a torque of 35 Ncm was applied to each abutment screw with the torque controller device.

Six titanium copings (Temporary Coping Multi units; Nobel Biocare) were screwed onto the multiunit abutments, and 6 plastic mixing tips (Ø 5.6 mm, height 11 mm) were cut and inserted to cover the titanium temporary abutments. A 3-mm-thick thermoplastic disk was used (Imprelon; Scheu-Dental) to form a polymeric model (Fig. 1).

An impression was made with a model duplication polyvinyl siloxane (Elite Double; Zhermack SpA) and poured with Type IV dental gypsum (GC Fujirock EP; GC Corp) to create a duplicate of the polymeric model.

The gypsum frameworks were 8 mm high and 3 mm thick. 80 identical jigs made with Type IV dental gypsum, all in the standard position, were prepared (Fig. 2).

Starting from the SP, the lateral position, height, and angle of multiunit abutment #4 were changed to simulate horizontal, vertical, and angular misfits. Horizontal misfits were simulated by inserting a thickness gauge (0.05-1.00 mm, 20; Blatt) between the aluminum and T-shaped brass piece. The brass element was always stabilized by applying a torque of 10 Nm to the lateral screw.

Vertical misfits were simulated by mounting several multiunit abutments, which were consecutively shorter than the commercial 4-mm-high abutment, on the #4 implant. The cylinder base of the 4-mm-high multiunit abutment was sectioned on the side mating with the implant to obtain shorter abutments of 150, 100, 50, and 30  $\mu$ m by using a computer-controlled drilling, tapping, and milling machine (VMC480P; Bridgeport, positioning error ±5  $\mu$ m and repeatability 2  $\mu$ m for all axes). An electronic micrometer (Mitutoyo, linear height 600; stroke 0-25 mm; measurement sensitivity 1  $\mu$ m) was used to verify the height of the customized cylinders.

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3

Angular misfit was simulated by replacing the T-shaped brass element with a new T-shaped brass element. The implant host in position #4 was drilled using a computercontrolled lathe with the same coordinates as used previously while adding an angle of 1 degree (Fig. 3).

A 35-Ncm torque was applied to all the abutment screws using the torque controller. The T-shaped brass element was always at the bottom of the T-guide in the standard position. The jigs were screwed onto the abutments, following the protocol of Jemt.<sup>35</sup> If a jig fractured after the screws had been tightened, this indicated a misfit (Fig. 4).

Ten jigs were tested with a 50- $\mu$ m horizontal misfit, 10 with a 100- $\mu$ m horizontal misfit, and 10 with a 150- $\mu$ m horizontal misfit (misfits measured compared with the SP). In the vertical plane, the tests involved replacing the 4-mm-high multiunit abutment on implant #4 with a shorter modified one; 10 jigs were screwed onto a misfit of 150  $\mu$ m, 10 onto one of 100  $\mu$ m, 10 onto one of 50  $\mu$ m, and 10 onto one of 30  $\mu$ m from the SP. The last 10 jigs were tested with an angular misfit of 1 degree from the SP. Five jigs of each group were tested by a dentist and the other five by a student, to avoid operator skill improvement with time.

A statistical analysis was not appropriate, since the probability of fracture of the stone jig was 0 or 1.

Two mathematical models were built with software (CAD SolidWorks Premium; Dassault Systèmes SolidWorks Corp), and a finite element method (FEM) analysis was carried out with software (Ansys; ANSYS Inc) to simulate the structural behavior of the 2 implant configurations (4 and 6 implants).

Model geometries are shown in Figures 5 and 6. The mechanical characteristics are reported in Table 1, and all are hypothesized to be isotropic with linear elastic behavior.

The models were fixed at the base of the bone structure so as to impede any movement, the cylinders inserted into the jigs were loaded, and a coaxial compression force equal to that derived from the tightening torque ( $F_s$ ) was applied to all the cylinders. Three different load conditions were applied to the extreme right cylinder. Only the coaxial compression force equal to that deriving from the hypothesized tightening torque ( $F_s$ ) (the same as applied to all the other cylinders); the force of the load condition ( $F_s$ ) plus a force equal to that of 10 N applied directly longitudinally on the jig ( $F_1$ ); and the force of the load condition ( $F_s$ ) plus a force equal to that of 10 N applied directly transversally on the jig ( $F_1$ ). The second and third load conditions shown on the 6implant model (Fig. 7) simulated a possible offset of the tightening wrench to the screws, which induces a bending moment on the cylinder-jig-abutment-bone system.

Four tightening torques of 10 Ncm, 15 Ncm, 20 Ncm, and 25 Ncm were considered and 2 types of bone quality, one of which corresponded to that of a Young modulus equal to 18 GPa and one that was 10-fold less (1.8 GPa).

#### RESULTS

None of the jigs tested on horizontal misfits of 50 and 100  $\mu$ m fractured. However, all the jigs tested with 150- $\mu$ m horizontal misfits did fracture. All the jigs tested with 50-, 100-, and 150- $\mu$ m misfits fractured. The vertical test was done on a customized abutment simulating a 30- $\mu$ m misfit, and none of the 10 jigs tested fractured. Ten stone jigs were used for the 1-degree angular misfit test, and all fractured. The jigs showed the same behavior in each test.

The results for all the numeric models and all load configurations were analyzed in terms of the changes and maximum value of the equivalent von Mises stress, which is indicative of the overall tension of the structure under constraints and loads to the various blocking torques and with different bone quality.

The resulting data demonstrated that the tightening torque had a strong influence on the shift in both the types of bone hypothesized but only on the y-shift component, which is that which determines the placement of the implant into the bone. The results of the simulation for strain/stress in the jig as to the load conditions, the hypothesized bone quality, and the number and arrangement of the implants showed that the maximum stresses always reached the interface between the cylinders under the most loaded condition, that is, the one where horizontal forces are also applied (both longitudinal and transversal) in correspondence with the interface cylinder/abutment at the point where the cylinder comes out of the jig.

The maximum stresses were influenced by the tightening torque of 10 Ncm, 15 Ncm, 20 Ncm, and 25 Ncm, that is, with a linear increase in the torque. The maximum stress values were reached with 4 to 6 implants under load conditions b, that is, when a force equal to that of 10 N was also applied directly longitudinally to the jig along with the coaxial compression force of the cylinder, which is equal to that derived from the hypothesized tightening torque. The bone quality influenced the state of stress of the jig: in the presence of a 90% reduction in the Young modulus, the maximum stress increased to about 6%. The presence of a more yielding bone and, consequently, the structure to which it is blocked (abutment-cylinder-jig), allowed for more shifts both in collapse and in flexion but had a marginal influence on the stress of the jig if a rigid shift of the connected cylinders was allowed. The maximum Von Mises stress value reached by the jig was in the range of 35 to 45 MPa. This means that no substantial

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variations were found in the stress with variations in implant configuration, load, and bone quality.

#### DISCUSSION

The dimensions of the jig (8 mm high and 3 mm thick) (Patent # 1412488), were chosen after having made several attempts to find a good compromise between sensitivity and aptitude of handling without accidental fractures, especially when bearing in mind its clinical application. The tests were carried out leaving an even longer time interval than that recommended by the manufacturers so as to increase the strength of the gypsum.

At the beginning the trial jigs were made of 1-mm-thick but the stone jigs could not be removed from the impression without fracture as they were too thin. The same procedure was then used with a 2-mm thickness, but, even after doubling the thickness, the jigs could only be removed from the impression with extreme care and even then not always.

The in vitro results showed that vertical misfits can be detected with values smaller (up to 50  $\mu$ m) than those of horizontal misfits (up to 150  $\mu$ m). This may be because of the horizontal displacement of each temporary coping multiunit on the mating surface of each abutment within the range of the machining tolerances.<sup>36,37</sup>

An offset of only 1 degree caused fracture in all jigs. This finding is in agreement with Winter,<sup>12</sup> who stated that an angular misfit is the most damaging to a prosthetic implant. The jigs showed the same behavior in each in vitro test, whether carried out by a dentist, a technician, or a student.

The mathematical models showed that the tightening torque, the presence of flexion forces due to the tightening of the screws when they were not perfectly coaxial to the cylinders, and the bone quality influenced the stress on the jigs.

Even under the highest stress conditions, shifts always showed values below those that led to fractures in vitro. For example, in the 4-implant model, the maximum shift component reached by the extreme right cylinder, that is, the one that determines placement of the implant into the bone, was equal to that of 30  $\mu$ m, with a cylinder tightening torque equal to that of 25 Ncm, a transversal force equal to that of 10 N, and a bone quality hypothesized to correspond to a Young modulus equal to 1.8 GPa.

Under the same load conditions, but with a bone quality hypothesized to correspond to a Young modulus of 18 GPa, the same shift component was observed to be 9  $\mu$ m. In the presence of a 90% reduction in the bone Young modulus, the vertical shift of the cylinder was 3-fold, but the values reached were lower than those the gypsum jig resisted in in vitro tests.

The horizontal transversal shift of the jig variation is less appreciable than the variation in the tightening torque. In the 4-implant model, the maximum value reached by the extreme right cylinder is equal to that of 13  $\mu$ m at a tightening torque of 25 Ncm, a transversal force equal to that of 10 N, and a bone quality hypothesized to correspond to a Young modulus of 1,8 GPa. This component is also affected by the quality of the bone (under the same load conditions, but with bone hypothesized to have a Young modulus of 18 GPa, it was equal to 6.5  $\mu$ m). However, the "horizontal" shifts, in both cases, were lower than those observed for the gypsum jig in vitro. In all models tested and under all load conditions, the maximum component of longitudinal shift reached by the cylinders at the extreme right was modest and always lower than both the vertical and transversal component.

As to the maximum equivalent stresses, variations in the load conditions, that is, tightening torque and flexion forces with different bone quality for configurations with 4 and 6 implants, were observed in a restricted value range (35-45 MPa). These values were not much lower than the fracture stress of the gypsum. This implies that even small variations in the surrounding conditions, such as a more yielding bone support, might well cause the jig to fracture more easily.

In a recent in vivo study, the jig was tested by 7 different operators with different implant prosthesis experience on 58 patients requiring maxillary edentulous rehabilitation (38) or rehabilitation of an edentulous mandible (20) (275 total implants: 185 maxillary and 90 mandibular) with a fixed bridge on a titanium framework constructed using the CNC milling technique.

At the first attempt, 55% of the jigs had at least 1 fracture, that is a total of 32 jigs, 22 in the maxilla and 10 in the mandible, with a confidence interval (CI) of 95% 42.5-67.3. After the jigs had been corrected, no fractures were noted for a 100% success rate, with a CI of 95% 0-6.2. Operator experience did not influence the outcome of the in vivo tests. <sup>38</sup>

#### CONCLUSION

The purpose of this study was to create an inexpensive, easy to make, and userfriendly device to verify the position of the implant replicas of the definitive cast so as to avoid misfit frameworks before construction.

The jig was easily able to detect misfits in vitro in accordance with the parameters defined in the literature. Operator experience does not influence the outcome of this procedure, and different loads and/or bone quality in the mathematical model do not change any stress in prosthesis configurations on 4 or 6 implants. Indeed, the new jig

may prevent the onset of complications in the edentulous maxilla and in mandible rehabilitation supported by implants.

#### REFERENCES

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|          | Material | Young Modulus (MPa) | Poisson ratio |
|----------|----------|---------------------|---------------|
| Bone     | Bone     | 1800 or 18000       | 0.3           |
| Implant  | Titanium | 100000              | 0.3           |
| Jig      | Gypsum   | 34710               | 0.3           |
| Abutment | Titanium | 100000              | 0.3           |
| Cylinder | Titanium | 100000              | 0.3           |

**Legend figures:** 

Figure 1. Thermoplastic disk and polymeric model of jig

Figure 2A., Impression of polymeric model of jig made from polyvinyl siloxane.

B, Type IV dental gypsum poured into the impression.

**Figure 3.** Implant #4 is angled at 1 degree. Note gaps between implants and temporary coping multiunit.

**Figure 4.** Fracture of stone indicates jig detected a misfit. Note circled thickness gauge simulating a horizontal misfit.

**Figure 5.** Mathematical model of four-implant configuration; dimensions are in mm.

Figure 6. Mathematical model of six-implant configuration; dimensions are in mm.

**Figure 7.** A, Six-implant configuration with extreme right loaded with force  $F_s$  resulting from torque, same as applied to all other cylinders, and a force  $F_1$  longitudinal to jig. B, Six-implant configuration with extreme right loaded with force  $F_s$  resulting from torque, same as applied to all other cylinders, and a force  $F_t$  transversal to jig.













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| Table 1. Mechanical characteristics of materials |          |                     |               |  |
|--|----------|---------------------|---------------|--|
|  | Material | Young Modulus (MPa) | Poisson ratio |  |
| Bone   | Bone     | 1800 or 18000       | 0.3           |  |
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| Cylinder   | Titanium | 100000              | 0.3           |  |