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Tolerance analysis for cast vs machined dental implants

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Abstract

The paper addresses the dimensional tolerance and assembly accuracy of prosthetic components obtained by different manufacturing processes. The success of single tooth implant replacements hangs on the stability of the hexagonal connection, but no standard control procedures are available for its evaluation. The research aims at proposing a new protocol for the dimensional assessment of implant-abutment connections, based on non-contact measurement and statistical data processing. The procedure is applied to machined- and cast-on abutments, as well of the matching implants. Samples are measured using an optical measuring microscope and data are processed to obtain the international tolerance (IT) grade. The rotational misfit is then calculated using the apothems of the external and the internal hexagon. As to the results, all the components are classified between IT8 and IT9 and the maximum rotational misfit is around 4° for all the assemblies, inferior to the critical limits for the screw joint stability. An objective dimensional characterization of prosthetic components and assemblies is reported, which is the basis for their reliability in clinical applications. From a wider perspective, an original measuring protocol is proposed, independent of parts assembly and based on international tolerances.

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Keywords: accuracy; assembly; tolerancing; methodology

1. Introduction

Dental implant prostheses require the fabrication of many components, to be employed in both the clinical and laboratory phases. The prosthetic abutments have been considerably improved with the introduction of custom CAD-CAM components, but traditional abutments such as machined titanium abutments, totally calcinable resin abutments and partially calcinable abutments with a machined connection to the implant (UCLA type) are still the most widespread solutions.

The life of the restoration in implant prostheses can be affected by biological or technical complications. From the technical point of view, screw loosening of implant restorations has been reported as the most common restorative complication, especially in single units in the premolar and molar areas [1-3]. Jemt et al. observed screw loosening in 49% of maxillary implant prostheses and 20,8% of mandibular prostheses over a 3-year period [2].

In single tooth restorations, Jemt and colleagues observed that 57% of the abutment screws loosened during the first year, and only 37% remained stable throughout a 3-year follow-up [1]. A more recent literature review reported a decreased incidence of screw loosening: 12.7% at a 5-year follow-up according to Jung et al. [4]; but the screw-joint still appears to be the weakest part of the implant-prosthesis complex [5].

The inherent machining tolerance of all the implant components must be reduced to a minimum, to ensure intimate fit between the coupling surfaces of the abutment and the implant and avoid many mechanical and biological complications [6,7]. Yet, the producers do not provide a statement of dimensional tolerances, either for single parts or assemblies. Lack of prosthesis accuracy at the implant-abutment interface has been related by many authors both to screw loosening and screw fracturing [3,8,9]. Technical complications are then more frequent than biological ones [4].

Several in vitro and clinical studies demonstrated the correlation between the rotation of the abutment and the prosthetic screw loosening and have underlined the importance

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to reduce to a minimum the implant-abutment misfit, to avoid mechanical complications [3,4,10-16].

Despite its relevance, a definite measuring protocol for the rotational misfit (RM) between implant and abutment is lacking in literature; only few studies suggest non-objective procedures based on assembly [15,16]. The present research aims at filling this shortage.

The purpose of this study is to develop an original, non-contact analytical protocol for the dimensional assessment of implant-abutment connections. By extending concepts (which owe their origin to fine mechanics) to the dental field, the authors propose an evaluation of coupling precision without assembly, through the measurement of the male- and female parts. In particular, the RM can be analytically derived by the apothems of the two hexagons [14]. Moreover, this study aims at applying the dimensional measurements to calculate the international tolerance (IT) grade of components. IT grade has never been stated for dental components, but it is worldwide accepted as an accuracy indicator, fundamental to ensure parts' standardization and acceptance.

To show the potential results, in this study the protocol is applied to evaluate the dimensional tolerances and the assembly accuracy of widely used prosthetic components.

2. Experimental

The study focuses on the type of connection known as external hexagon, which means that the male external hexagon is on the implant and the female internal one on the abutment. Since it is the most used and studied configuration, the results can be easily compared with previous researches. The regular dimension (3.75mm diameter) of the implant is chosen and the experimental plan includes all the abutments that can be coupled with the considered implant (Figure 1). All the components are produced by Keystone Dental, Burlington, MA, USA.

A group of 5 Titanium implants is considered. Besides, three groups of 5 abutments each are analyzed: UCLA abutments before casting procedures (named group 1), the same premachined abutments after the cast-on procedure (group 2) and totally machined titanium abutments, identified as group 3. As to UCLA abutments, traceability is ensured for each specimen to allow comparison before and after the casting procedure. Table 1 summarizes the experimental groups. In the calcinable abutments the pre-machined part is obtained in a platinum-palladium gold alloy and the expendable part in a polymeric resin; then group 2 specimens are obtained by

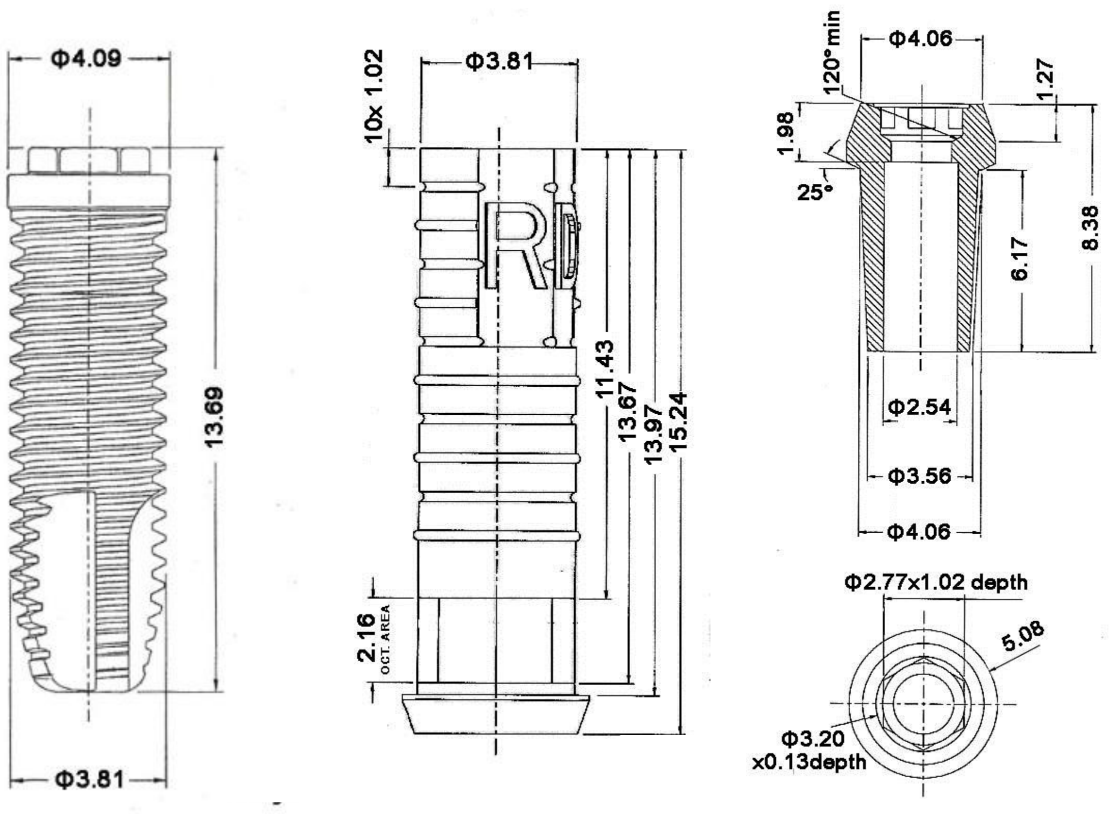

Fig. 1. (a) Restore RBM 3.75x13mm implant; (b) Premachined UCLA ab. before casting; (c) Restore COC abutment straight

casting a different silver-copper gold alloy (Ney-Oro CB, Denstply Ceramco, York, PA, USA) on the pre-machined part.

The abutments of group 1 are named with numbers from 1 to 5 and the measuring order is maintained, to allow traceability and comparison before and after the casting procedure for each specimen. To obtain the group 2 specimens, after measuring group 1, wax is applied to the premachined collar region of the abutments, to simulate a similar custom made profile for all the abutments.

The five patterns are assembled into a tree and invested in a fine-grain carbon-free investment composed of quartz, cristobalite and magnesium oxide bonded by ammonium phosphate (Castorit all speed, Dentaurum, Ispringen, Germany). The tree is then subjected to the wax burnout cycle, comprising a ramp rate of 3°C/min up to 700°C, with two isothermal steps at 250°C and 570°C for 45 minutes plus a final stabilization of 30 minutes. The described cycle allows the thermal expansion of the investment and the complete removal of the expendable part. The castings are allowed to bench-cool, divested, polished by blasting with 50µm plastic beads and in the end pickled in acid solution at 40°C (Neacid, Degussa Dental GmbH&Co. KG, Hanau-Wolfgang, Germany).

The proposed measuring procedure is based on the hexagon width or twice the apothem, named D in Figure 2. The nominal value of D is D_{ni}=2.698mm, for the considered implants, and D_{na}=2.716mm, for the abutments; the same for all the groups. It is noteworthy that abutments produced by different manufacturing processes and materials are dimensionally undifferentiated by the producer. The authors propose an original measuring protocol based on the mechanical concept of dimensional tolerance [17], new to the dental field.

The measuring procedure is sketched in Figure 2 and described in the following.

- Measuring of 5 points on each side of the hexagon for every specimen of the four groups.
- Fitting of a line to the points coordinates with the LSM (least square method).
- Calculation of the distance between each pair of opposite parallel lines, obtaining the three values D1- D3 for each abutment and implant.
- Computation of the mean value for D and its standard deviation (SD) among the 5 specimens of each group.
- Calculation of the mean dimensional deviation ε with respect to the nominal value D_n ($\varepsilon_j=(D_j-D_n)$), and of its standard deviation within each group.
- Calculation of the number of tolerance units n, its mean, standard deviation and the value corresponding to 95% of the observations for each group.
- Definition of the IT grade for each group by comparing the n number matching 95% of the observations with the chart of tolerance grades.

The adopted approach introduces the maximum number of tolerance units for 95% of the observations as a quality index, which is justified because the distribution of n is not log-normal and the tolerance grade establishes the maximum error allowed for each dimension.

Table 1. Measured specimens.

Reference	Description	Material		
implants	Restore RBM 3.75x13mm	CP3 Titanium (ASTM F67)		
group 1	Premachined UCLA abut. before casting	Pt-Pd gold alloy / Derlin® resin		
group 2	Group 1 after cast-on procedures	Pt-Pd gold alloy / Ag-Cu gold alloy		
group 3	Restore COC abutment straight	Grade 5 Titanium (Ti-6Al-4V)		

	Au	Pd	Pt	Ag	Cu
Pt-Pd gold alloy	60	20	19		
Ag-Cu gold alloy	59	4		22.5	13.5

The results of the dimensional measurements are processed to evaluate the RM between the external hexagon of the implant and the internal hexagon of the abutment. The rotational misfit is calculated by coupling every implant with all the abutments and applying geometrical formulas to the measured apothems of the hexagons [14]. If the minimum of the three values $D_{1\text{-}3}$ is considered for the implant (smallest male) and the maximum one for the abutment (largest female), a maximum value of RM is obtained for each implant-abutment combination. RM_{max} corresponds to the most critical orientation of implant and abutment during assembly. Instead, taking into account the mean value D for both the implant and the abutment leads to an average RM (RM_{av}). Every combination between the group of implants (5 specimens) and one group of abutments (5 specimens) leads to 25 values for both RM_{max} and RM_{av}. The mean, the standard deviation and the 95th percentile of both angles are computed for each of the three assemblies.

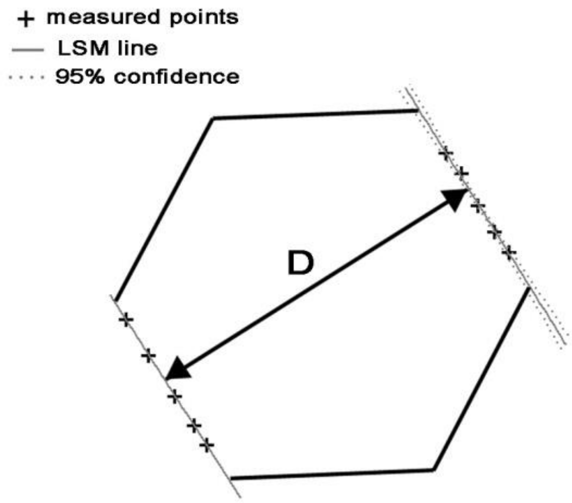

Fig. 2. Sketch of the measuring procedure for the hexagon width D.

The measures are done with the optical measuring microscope [18] Kestrel 200 by Vision Engineering, equipped with Quadra-check metrology software. Uncertainty for the nominal values of the considered specimens results in 7µm.

The direct exploitation of the results is eased by fixing the maximum RM (clockwise plus counter-clockwise) and drawing the admitted tolerance on the hexagon dimensions. As an example, the maximum rotation limit can be set at 5

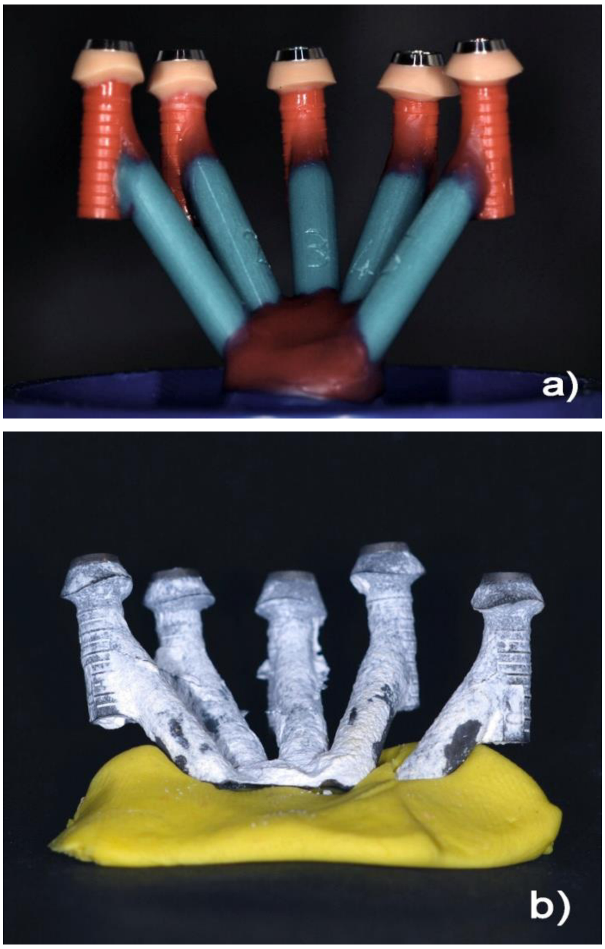

Fig. 3. a) Abutments assembled into the tree ready to be cast-on; b) Cast tree after divesting.

degrees, as proposed by some authors to ensure the stability of the screw connection. In this case, if the nominal width of the implant D_{ni} is considered, the maximum tolerable clearance between the abutment and the implant is 33 μm.

3. Results

Figure 3 shows two production steps of group 2 specimens. The results of the measuring procedure are reported in Tables 2 and 3. Table 2 shows the hexagon width D calculated for the implants and the three groups of abutments and the dimensional deviation with respect to the nominal value D_n. The next two columns in the table indicate the mean, SD and 95th percentile of the number of tolerance units n. In the last column the IT grade is indicated for the four groups. Figure 4 shows the exact positioning of the considered specimens within the chart of international tolerance grades.

Table 3 shows the mean, standard deviation and value corresponding to 95% of observations for RM_{max} and RM_{av} (° - decimal notation), obtained considering the group of implants combined with each group of abutments. The values corresponding to 95% of the observations are specified, since this is an important indicator in the field of dimensional accuracy and tolerance calculation. As regards RM_{max}, the absolute maximum value is indicated as well, being the upper limit of the rotational misfit for the considered assembly.

Table 2. Hexagon width D, dimensional deviation ε, number of tolerance units n and IT grade measured on the implants and the abutments.

	D [mm]	**ε [mm]**	**n**	**IT**
	mean (SD)	*mean (SD)*	*mean (SD) [95th %]*	
implants	2.680 (.004)	0.018 (.004)	34 (7.7) [43]	**IT9**
group 1	2.725 (.004)	0.008 (.004)	16 (7.4) [25]	**IT8**
group 2	2.707 (.003)	-0.009 (.004)	17 (9.1) [29]	**IT8**
group 3	2.725 (.003)	0.009 (.004)	17 (8.4) [28]	**IT8**

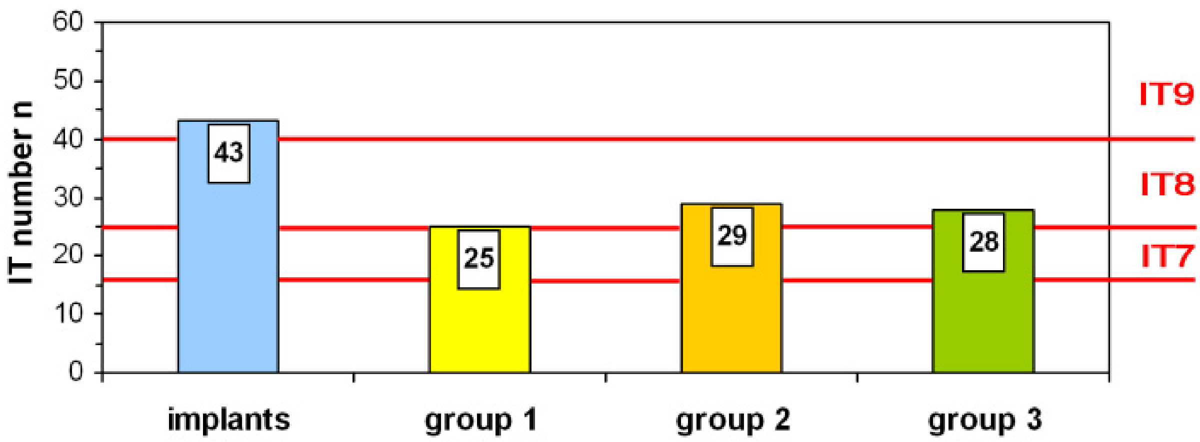

Fig. 4. IT positioning of the implants and the three groups of abutments.

Table 3. Maximum and average rotational misfit for all the implant-abutment assemblies.

	RM$_{max}$ [°]			**RM$_{av}$ [°]**	
	mean (SD)	*Max.*	*95th %*	*mean (SD)*	*95th perc.*
implants-group 1	3.90 (0.323)	4.38	4.30	3.42 (0.324)	3.87
implants-group 2	2.75 (0.388)	2.66	3.51	2.01 (0.303)	2.50
implants-group 3	3.96 (0.318)	3.44	4.54	3.42 (0.309)	3.84

4. Discussion

Several studies have investigated the effect that the rotational freedom of the abutment on the anti-rotational device of the implant (i.e. an external hexagon in the most common implant systems) has on implant prosthetic restorations. It has been proved that movements of the abutment on the implant can lead to the prosthetic screw loosening and to overload and damage in single tooth restorations. Binon et al demonstrated a decrease by 26% of the number of cycles required to cause screw loosening when the RM was increased from 2 to 3 degrees [10-12].

Many clinical researches draw the same conclusions. According to Jorneus et al, screw joint stability improves when the rotational misfit is decreased [13]. Some authors suggest that the fit between the external hexagon of the implant and the internal one of the abutment should permit less than 5 degrees of rotational movement to hold a stable screw joint [14].

Assuming the relevance of the RM in the implant-abutment connection, some authors suggested its evaluation through assembly tests on different types of abutments. Lang et al. studied the fit of 4 different Branemark system (Nobel Biocare) abutments, showing a maximum RM of the abutment around the implant hexagon of less than 3.5 degrees [15]. Vigolo and colleagues studied with the same protocol the amount of rotation of Procera (Nobel Biocare) titanium, alumina and zirconia abutments, finding a RM of less than 3 degrees for all of them [16].

To sum up, the scientific community agrees that the RM of the hexagonal connection is a decisive point for the success of single implant restorations and should be minimized. The literature is not unanimous on the maximum limit to avoid complications, about 5 degrees seem acceptable for external hexagon implant systems.

Differing from the cited references, the authors of the present study believe that a measuring system based on parts assembly has limits both due to the contact deformations of the hexagons, that cannot be measured, and to the specific positioning of the two components, that can influence the measures. For this reason, they propose and apply here a protocol based on measuring the dimensions of the hexagon through a non-contact system. Then, data processing allows calculating both the IT grade and the RM for any abutment-implant assembly.

Commenting upon the results in Table 3, all the specimens display very good repeatability, being the standard deviation on the hexagon dimensions of few µm. The cast-on abutments (group 2) exhibit a negative dimensional deviation, meaning that they are on average smaller than the nominal dimension.

As to IT classification, which opens the way to standardized quality control in the dental field, all the abutments can be classified in IT8, whereas the implants show larger tolerances and fall into IT9.

The rotational misfit is lower than the reported clinically-accepted limit of 5° for all the implant-abutment combinations, with absolute maximum values a bit over 4° but on average around 3.5°.

5. Conclusions

An innovative objective and analytical measuring protocol has been developed to calculate the IT grade for dental implants and implant components, based on the international standards.

All the studied abutments fall into IT8, whereas the implants are less accurate and can be classified in IT9.

A new procedure has been proposed for the assessment of the rotational misfit in external hexagon connections, independent of part assembly. The average and maximum rotational misfit have been calculated for external hexagon implants combined with totally machined- and cast-on abutments. The measured rotational misfit is clinically acceptable for all the studied implant-abutment assemblies.

In future developments of the research the developed measuring protocol will be applied to dental components produced with different processes and materials.

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