Dimensional Tolerances and Assembly Accuracy of Dental Implants and Machined Versus Cast-On Abutments

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ABSTRACT

Background: The clinical application of prosthetic components obtained by different manufacturing processes lacks technological foundation: the dimensional tolerance of individual parts and their assembly accuracy are not known. The rotational misfit (RM) of the hexagonal connection is critical in single-tooth implant restorations, but no standard control procedures are available for its evaluation.

Purpose: The research aimed at proposing a new protocol for the dimensional assessment of implant-abutment connections, based on noncontact measurement and statistical data processing. The procedure was applied to machined- and cast-on abutments, as well of the matching implants.

Materials and Methods: Three groups of five abutments each were studied: machined titanium abutments, pre-machined calcinable abutments before casting procedures and the same specimens after casting. A group of five corresponding implants was considered as well. Twice the apothem was measured on each hexagon through an optical measuring microscope. The data were processed to obtain the international tolerance (IT) grade. The RM was then calculated using the apothems of the external and the internal hexagon.

Results: All the components were classified between IT8 and IT9, and the maximum RM was around 3–4° for all the assemblies, inferior to the critical limits for the screw joint stability.

Conclusion: An original measuring protocol was developed, independent of parts assembly and based on ITs. An objective dimensional characterization of prosthetic components and assemblies has been achieved, which is the basis for their reliability in clinical applications.

KEY WORDS: abutment, accuracy, assembly, dental implant, dimensional tolerances

Throughout the procedures associated with implant prosthesis fabrication, many different dental implant components are 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 duration 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 and colleagues[2] observed screw loosening in 49% of maxillary implant prostheses, and 20.8% of mandibular prostheses over a 3-year period. In single-tooth restorations, Jemt and colleagues[1] observed that 57% of the abutment

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screws loosened during the first year, and only 37% remained stable throughout a 3-year follow-up. A more recent literature review reported a decreased incidence of screw loosening: 12.7% at a 5-year follow-up according to Jung and colleagues;[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. Scientific evidence is lacking to demonstrate the need of precision between implant and prosthetic components for long-term osseointegration;[2] however, 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 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 nonobjective procedures based on assembly.[15,16] The present research aimed at filling this shortage.

The purpose of this study was to develop an original, noncontact analytical protocol for the dimensional assessment of implant-abutment connections. Transferring to the dental field concepts that are typical of fine mechanics, 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 aimed 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 was applied to evaluate the dimensional tolerances and the assembly accuracy of widely used prosthetic components.

MATERIALS AND METHODS

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

A group of five titanium implants has been considered. Besides, three groups of five abutments each were analyzed: UCLA abutments before casting procedures (named group 1), the same pre-machined abutments after the cast-on procedure (group 2), and totally machined titanium abutments, identified as group 3. As to UCLA abutments, the specimens were considered both before and after the casting procedure to investigate eventual dimensional changes. Table 1 summarizes the specimens' main characteristics. 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 were obtained by 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 were named with numbers from 1 to 5, and the measuring order was 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 was applied to the pre-machined collar region of the abutments, to simulate a similar custom-made profile for all the abutments.

The five patterns were 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 was 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 and 570°C for 45 minutes, plus a final stabilization of 30 minutes. The described cycle allows the

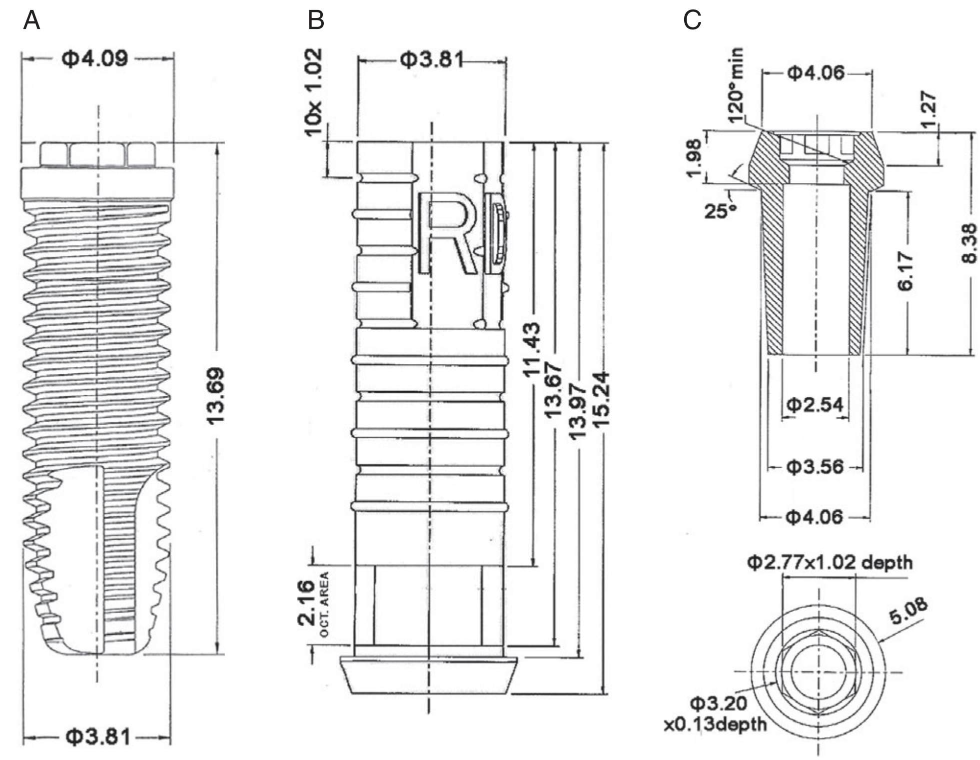


Figure 1 (A) Restore RBM 3.75 × 13 mm implant, (B) pre-machined UCLA ab. before casting, and (C) restore COC abutment straight. All dimensions in mm.

thermal expansion of the investment and the complete removal of the expendable part. The Ag-Cu gold alloy was fused in a ceramic crucible with a propane-oxygen torch. The castings were allowed to bench-cool, divested, polished by blasting with 50 μm plastic beads and in the end pickled in acid solution at 40°C (Neacid, Degussa Dental GmbH&Co. KG, Hanau-Wolfgang, Germany).

As described in the introduction, the proposed measuring procedure is based on the hexagon width or twice the apothem, named *D* in Figure 2. The nominal value of *D* for the considered implants is $D_{ni} = 2.698$ mm and for the abutments is $D_{na} = 2.716$ mm, the same for all the groups. It is important to notice that abutments produced by different manufacturing processes and materials are dimensionally undifferentiated by the producer.

The authors propose an original measuring protocol transferring to the dental field the mechanical concept of dimensional tolerance.[17] Engineering

TABLE 1 Measured Specimens and Chemical Composition (%) of the Gold Alloys

Reference	Description	Material
Implants	Restore RBM 3.75 × 13 mm	CP3 Titanium (ASTM F67)
Group 1	Pre-machined UCLA abutment 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

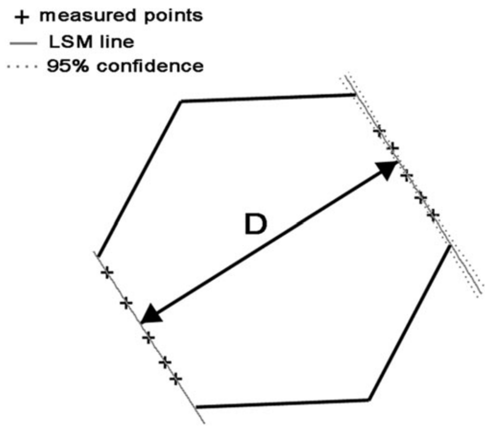


Figure 2 Sketch of the measuring procedure for the hexagon width *D*.

tolerance grades relate the dimensional deviation of a measure to the magnitude of the nominal value, establishing classes of dimensional accuracy.

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

- Measuring of five points on each side of the hexagon for every specimen of the four groups;
- Fitting of a line to the point coordinates with the least square method;
- Calculation of the distance between each pair of opposite parallel lines, obtaining the three values D_1–D_3 for each abutment and implant;
- Computation of the mean value for D and its SD among the five 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 SD within each group;
- Calculation of the number of tolerance units n, its mean, SD, 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.

The results of the dimensional measurements were processed to evaluate the RM between the external hexagon of the implant and the internal hexagon of the abutment. The RM was calculated coupling every implant with all the abutments, applying geometrical formulas to the measured apothems of the hexagons.[14] If the minimum of the three values D_{1-3} 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 (five specimens) and one group of abutments (five specimens) leads to 25 values for both RM_{max} and RM_{av}. The mean, SD, and the 95th percentile of both angles were computed for each of the three assemblies.

The measures were done with the optical measuring microscope[18] Kestrel 200 by Vision Engineering, equipped with Quadra-check metrology software. The system ensures good accuracy, thanks to 0.5 μm stage repeatability in X and Y-axes. The measurement uncertainty for a confidence interval of 95% can be calculated using Equation 1,

$$U_{95}2D = 7 + \left(6.5 \cdot \frac{D}{1{,}000}\right)[\mu\text{m}] \qquad (1)$$

where D is the measured length in mm.

Uncertainty for the nominal values of the considered specimens (D_n is around 2.7 mm) results in 7 μm.

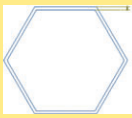
To ease the direct exploitation of the results, Table 2 was calculated by fixing the nominal width of the implant D_{ni} and varying the width of the abutment by adding different values of the side clearance. The table allows fixing the maximum RM (clockwise plus counterclockwise) and drawing the admitted tolerance on the hexagon dimensions.

If the maximum rotation limit of 5° is accepted to ensure the stability of the screw connection, as proposed by some authors, the maximum tolerable clearance can be calculated. For the specific dimensions considered in the present research and the assumed limits, the apothem difference between the abutment and the implant should not overcome 33 μm.

RESULTS

Figure 3 shows two production steps of group 2 specimens.

TABLE 2 Rotational Misfit (RM) in the Implant-Abutment Connection for Different Values of the Side Clearance between the Hexagons

 Side clearance $(D_a - D_{ni})/2$ (μm)	 RM (°)
50	7.76
45	6.94
40	6.13
35	5.33
30	4.54
25	3.76
20	2.99
15	2.22
10	1.47
5	0.73

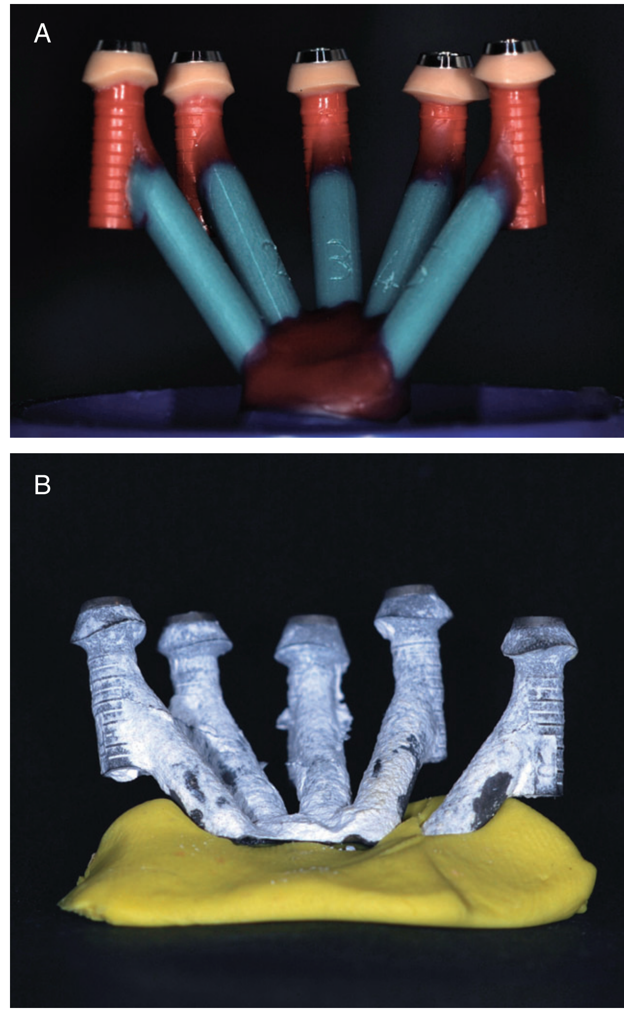


Figure 3 (A) Abutments assembled into the tree ready to be cast-on, and (B) cast tree after divesting.

One of the five obtained abutments was evidently defective, so it was excluded from the measurements. Further analysis will be carried out to investigate the reasons for the process failure.

All the specimens were measured ensuring the axis to be orthogonal to the measuring plane. Figure 4 shows, as an example, the appearance of an implant during the measuring phase.

The results of the measuring procedure are reported in Tables 3 and 4. Because the failed sample was rejected, the results for group 2 are referred to only four abutments.

Table 3 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 5 shows the exact positioning of the considered specimens within the chart of IT grades.

Table 4 shows the mean, SD, 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 have been specified, because this is an important indicator in the field of dimensional accuracy and tolerance calculation. As regards RM_{max}, the absolute maximum value has been indicated as well, being the upper limit of the RM for the considered assembly.

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 and colleagues[10–12] evaluated the amount of freedom between the implant hexagonal extension and the UCLA abutment counterpart, finding a direct correlation between the hexagonal misfit and screw loosening after cyclic loading. These

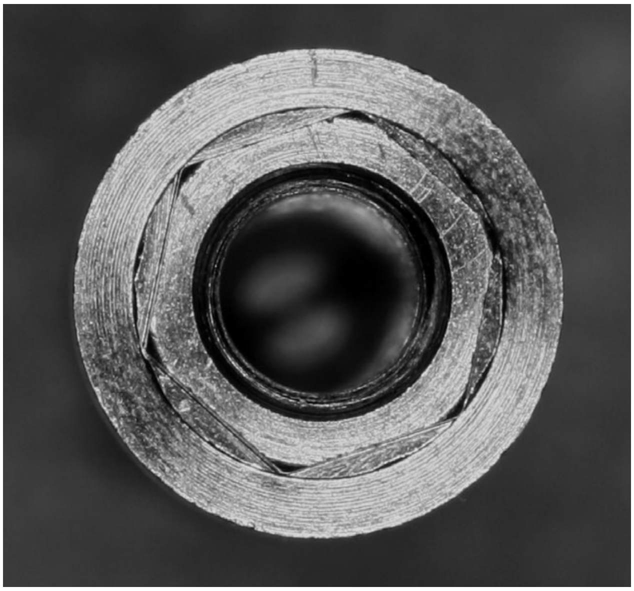


Figure 4 Implant during the measurements with the optical measuring microscope.

studies demonstrated a decrease by 26% of the number of cycles required to cause screw loosening when the RM was increased from 2 to 3°.

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

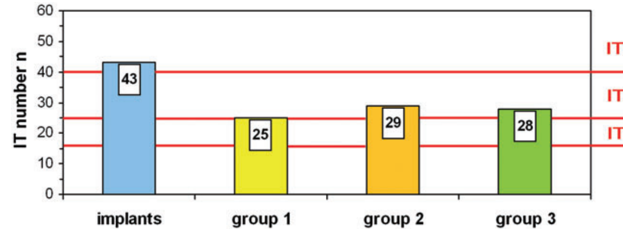


Figure 5 International tolerance positioning of the implants and the three groups of abutments.

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 and colleagues[15] studied the fit of four different Brånemark System (Nobel Biocare) abutments, showing a maximum RM of the abutment around the implant hexagon of less than 3.5°. Vigolo and colleagues[16] studied with the same protocol the amount of rotation of Procera (Nobel Biocare) titanium, alumina, and zirconia abutments, finding an RM of less than 3° for all of them.

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° seem acceptable for external hexagon implant systems.

Differing from the cited references, the authors of the present study believe that a measuring system based

TABLE 3 Number of Measurements *N*, Hexagon Width *D*, Dimensional Deviation ε, Number of Tolerance Units *n*, and International Tolerance (IT) Grade Measured on the Implants and the Abutments

		D (mm)	ε (mm)	*N*		
	N	Mean (SD)	Mean (SD)	mean (SD)	95th Percentile	IT
Implants	15	2.680 (0.004)	−0.018 (0.004)	34 (7.7)	43	IT9
Group 1	15	2.725 (0.004)	0.008 (0.004)	16 (7.4)	25	IT8
Group 2	12	2.707 (0.003)	−0.009 (0.004)	17 (9.1)	29	IT8
Group 3	15	2.725 (0.003)	0.009 (0.004)	17 (8.4)	28	IT8

TABLE 4 Maximum and Average Rotational Misfit (RM) for All the Implant-Abutment Assemblies

	RM_{max} [°]			RM_{av} [°]	
	Mean (SD)	Max. value	95th Percentile	Mean (SD)	95th Percentile
Implants – group 1	3.90 (0.323)	4.38	4.30	3.42 (0.324)	3.87
Implants – group 2	2.75 (0.388)	3.51	3.36	2.01 (0.303)	2.50
Implants – group 3	3.96 (0.318)	4.54	4.38	3.42 (0.309)	3.84

on parts assembly has limits both caused by 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, a protocol has been developed and applied based on measuring the dimensions of the hexagon through a noncontact system. Then, data processing allowed calculating both the IT grade and the RM for any abutment-implant assembly.

Commenting upon the results in Table 3, all the specimens displayed very good repeatability, being the SD on the hexagon dimensions of few µm. The cast-on abutments (group 2) exhibited 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 could be classified in IT8, whereas the implants showed larger tolerances and fell into IT9.

The RM was 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°.

CONCLUSIONS

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

All the studied abutments fell 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 RM in external hexagon connections, independent of parts assembly. The average and maximum RM have been calculated for external hexagon implants combined with totally machined and cast-on abutments. The measured RM 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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