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TAG Implants- Dimensional Tolerances & Accuracy Gap in Implants/Abutments Internal Hexagon Connection

Daniel Baruc[1*], Hila Cohen[2], Erez Yakuti[3], Tsachie Clay[4]

[1]R&D Director - T.A.G Medical Products Corporation, Dental Division, Gaaton, Israel
[2]Eng. - T.A.G Medical Products Corporation, Dental Division, Gaaton, Israel
[3]T.A.G Medical Products Corporation, Gaaton, Israel
[4]CTO - T.A.G Medical Products Corporation, Dental Division, Gaaton, Israel

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***Corresponding author**: Daniel Baruc

Abstract **Original Research Article**

Passive and precise fit in the implant/ abutment connection is an important and primordial parameter for the longevity of implant-supported prostheses. This paper presents a long follow up of tight tolerances on dental implants and abutments tolerances in order to guarantee the repeatability of the parts measurement and their perfect adjustment.

The aim of this study is to: 1) Measure the implant and abutment hexagonal dimensions. 2) Measure the rotational misfit between implant and abutments. 3) Verify the stability of the dimensions during a long run production.The quality of the connection between an implant and an abutment is depending of the surface finish of the six facets sides, the circumscribed circle dimension and their tolerances. The follow up indicate that with high level of quality control you can assure in long-term a high accuracy of all the components that is one of the parameters that induce to a significantly better long-term stability in the clinical application.

Keywords: TAG Implants, Dimensional, Implants/Abutments, Internal Hexagon Connection.

INTRODUCTION

The clinical application of implants and prosthetic components obtained by different manufacturing processes lacks of technological foundation: the dimensional tolerance of individual parts and their assembly accuracy have not any standardization [1]. 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 [9]. No standardization in the tolerances of the implant/abutment interface has been established [6, 8]. For reliable proper functioning of mechanical parts, it is necessary that the dimensions, shape and mutual position of the surfaces of their different parts are met with some precision [1]. With the common production processes, it is not possible to measure the geometrical properties data with absolute precision. The actual areas of the produced parts therefore differ from ideal surfaces prescribed in drawings.

Deviations of actual surfaces are divided into four groups to enable assessment, prescription and control the degree of precision allowed during production:

- Deviations of dimensions
- Deviations of the form
- Deviations of the position
- Deviations of the roughness of the surface

The choice of a suitable fit is important particularly in terms of measuring instruments, gauges and tools used in production. Micro-gap between implant and abutment can produce biological and mechanical problems. The marginal fit and size of micro gap at the implant /abutment interface value will influence the level of bacterial leakage [2,5]. A large micro-gap at the implant-abutment interface has been reported to result in adverse effects such as peri-implantitis and/or fatigue failures [7]. Mechanicals failures included screw loosening, wear and abutment rotation or fracture [3].The capacity of repeatability in the production requires a high level of quality control especially when we need close tolerances. Surface quality and machining tolerance are dependent of machine precision [4], milling parameters, cutting fluid (coolant) and tools characteristics.

PURPOSE

The purpose of this work is to measure the tolerances of the interface between internal hexagon implants with corresponding abutments from the production and compare with identical measurements from the virtual model to obtain threshold values. These values may be a valuable tool for evaluating increasing misfit caused by fabrication, processing, and wear.

MATERIALS AND METHODS

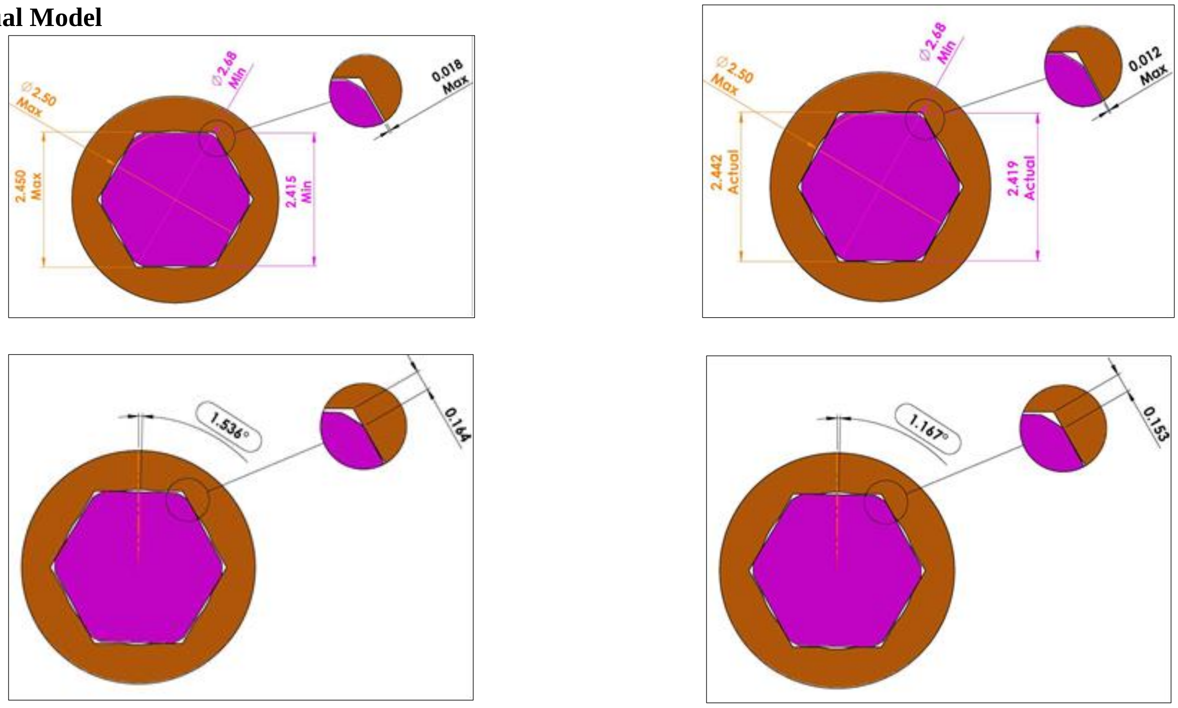
100 implants and 100 abutments with internal-hexagon connections from TAG Dental production were studied. All the components from the internal hexagon have been measured digitally (COM-Germany Model ATOS Core 45). Measurements from the production were compared with identical dimensions from the virtual model to obtain threshold values. The six hexagon facets of the 100 implants have been measured 2 by 2 to check the accuracy of the broch and the repeatability of the hexagon.Twice the apothem was measured on each hexagon through an optical measuring microscope. The data were processed to obtain the micro gap µ between the 2 hexagons. The circumscribed circle of the hexagon was measured as parameter that influenced the rotational misfit.

The RM (rotational misfit) was then calculated using the apothems of the external and the internal hexagon. Gap between implant/abutment were measured with a coordinate measuring machine (COM-Germany Model ATOS Core 45). The measured tolerances ranged from 0 to 15 microns. Machining tolerances between implant components should be included in future studies of accuracy, because it is an inherent characteristic of the component itself.

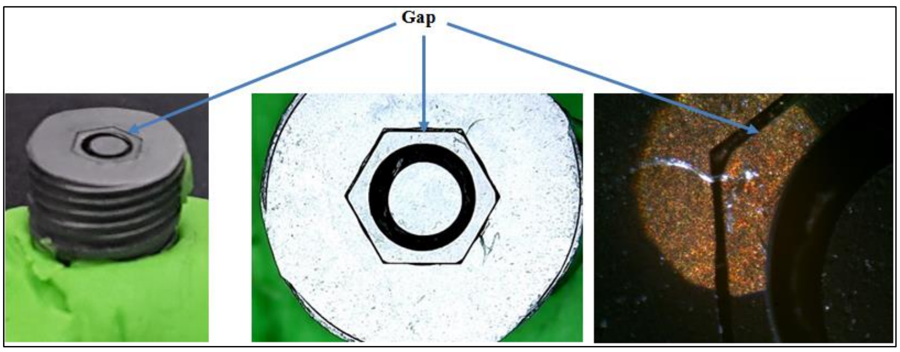
COM- Acceptance/Reverification Test According to VDI/VDE 2634, Part 3

Parameter	Maximum deviation	Limit
Probing error (size)	-0.0029 mm	0.0060 mm
Sphere spacing error	0.0015 mm	0.0040 mm
Length measurement error	0.0004 mm	0.0100 mm

Virtual Model



Production parts measurement



Cross section of an implant / abutment assembled at the hexagonal connection

Data

Implant internal Hex. [mm]					Abutment [mm]		
IA1-33013-9		LOT 14M01					
Element	Hex1	Hex 2	Hex 3	Hex AVG	Sample #	Hex dimension	P/N & LOT
Nominal	2.44	2.44	2.44	2.44	Nominal	2.42	
MIN Tol	-0.01	-0.01	-0.01	-0.01	MIN Tol	-0.005	
MAX Tol	0.005	0.005	0.005	0.005	MAX Tol	0.01	
sample 1	2.446	2.439	2.449	2.445	sample 1	2.419	PF1-0077-9 15K03 WO1500074767
sample 2	2.444	2.436	2.449	2.443	sample 2	2.419	
sample 3	2.446	2.441	2.447	2.445	sample 3	2.416	
sample 4	2.447	2.442	2.442	2.444	sample 4	2.417	
sample 5	2.436	2.445	2.436	2.439	sample 5	2.42	
sample 6	2.435	2.446	2.436	2.439	sample 6	2.419	
sample 7	2.436	2.443	2.433	2.437	sample 7	2.418	
sample 8	2.439	2.428	2.448	2.438	sample 8	2.415	
sample 9	2.445	2.438	2.451	2.445	sample 9	2.418	
sample 10	2.445	2.451	2.435	2.444	sample 10	2.42	
sample 11	2.448	2.445	2.445	2.446	sample 11	2.417	PF1-0073-9 15K04 WO1500074759
sample 12	2.432	2.446	2.43	2.436	sample 12	2.419	
sample 13	2.446	2.445	2.442	2.444	sample 13	2.421	
sample 14	2.438	2.433	2.445	2.439	sample 14	2.42	
sample 15	2.44	2.453	2.43	2.441	sample 15	2.415	
sample 16	2.432	2.435	2.442	2.436	sample 16	2.42	
sample 17	2.441	2.444	2.431	2.439	sample 17	2.423	
sample 18	2.435	2.442	2.435	2.437	sample 18	2.42	
sample 19	2.437	2.433	2.445	2.438	sample 19	2.421	
sample 20	2.437	2.43	2.449	2.439	sample 20	2.419	
sample 21	2.431	2.443	2.431	2.435	sample 21	2.416	PF1-0081-9 15E06 WO1500238168
sample 22	2.443	2.439	2.45	2.444	sample 22	2.416	
sample 23	2.448	2.444	2.445	2.446	sample 23	2.418	
sample 24	2.448	2.444	2.445	2.446	sample 24	2.423	
sample 25	2.444	2.449	2.438	2.444	sample 25	2.415	
sample 26	2.437	2.435	2.446	2.439	sample 26	2.422	
sample 27	2.444	2.449	2.434	2.442	sample 27	2.42	
sample 28	2.444	2.449	2.445	2.446	sample 28	2.425	
sample 29	2.445	2.449	2.438	2.444	sample 29	2.424	
sample 30	2.434	2.43	2.442	2.435	sample 30	2.424	
sample 31	2.436	2.435	2.45	2.44	sample 31	2.415	PF1-0069-9 15E06 WO1500238163
sample 32	2.441	2.438	2.448	2.442	sample 32	2.418	
sample 33	2.435	2.436	2.438	2.436	sample 33	2.417	
sample 34	2.443	2.437	2.448	2.443	sample 34	2.419	
sample 35	2.441	2.446	2.437	2.441	sample 35	2.418	
sample 36	2.444	2.44	2.451	2.445	sample 36	2.418	
sample 37	2.442	2.439	2.443	2.441	sample 37	2.418	
sample 38	2.445	2.445	2.445	2.445	sample 38	2.417	
sample 39	2.435	2.444	2.434	2.438	sample 39	2.419	
sample 40	2.439	2.434	2.443	2.439	sample 40	2.419	
sample 41	2.44	2.436	2.448	2.441	sample 41	2.417	PF1-0069-9 15E04 WO1500238162
sample 42	2.443	2.436	2.449	2.443	sample 42	2.415	
sample 43	2.453	2.449	2.446	2.449	sample 43	2.417	
sample 44	2.433	2.441	2.431	2.435	sample 44	2.417	
sample 45	2.434	2.432	2.444	2.437	sample 45	2.415	
sample 46	2.445	2.449	2.433	2.442	sample 46	2.415	
sample 47	2.443	2.435	2.448	2.442	sample 47	2.415	
sample 48	2.442	2.441	2.45	2.444	sample 48	2.419	
sample 49	2.445	2.453	2.436	2.445	sample 49	2.415	
sample 50	2.45	2.447	2.445	2.447	sample 50	2.416	

sample 51	2.444	2.439	2.451	2.445	sample 51	2.419	PF1-0077-9 15K01 WO1500074765	
sample 52	2.448	2.445	2.441	2.445	sample 52	2.419		
sample 53	2.45	2.447	2.446	2.448	sample 53	2.416		
sample 54	2.448	2.445	2.447	2.447	sample 54	2.418		
sample 55	2.44	2.447	2.431	2.439	sample 55	2.419		
sample 56	2.438	2.435	2.442	2.438	sample 56	2.419		
sample 57	2.437	2.435	2.448	2.44	sample 57	2.417		
sample 58	2.428	2.435	2.428	2.43	sample 58	2.418		
sample 59	2.445	2.437	2.454	2.445	sample 59	2.42		
sample 60	2.449	2.447	2.443	2.446	sample 60	2.42		
sample 61	2.437	2.435	2.45	2.441	sample 61	2.418	PF1-0073-9 15K05 WO1500074760	
sample 62	2.44	2.436	2.446	2.441	sample 62	2.417		
sample 63	2.439	2.437	2.45	2.442	sample 63	2.422		
sample 64	2.439	2.437	2.45	2.442	sample 64	2.422		
sample 65	2.437	2.445	2.431	2.438	sample 65	2.419		
sample 66	2.441	2.434	2.445	2.44	sample 66	2.419		
sample 67	2.438	2.436	2.447	2.44	sample 67	2.422		
sample 68	2.435	2.437	2.44	2.437	sample 68	2.422		
sample 69	2.429	2.433	2.433	2.432	sample 69	2.422		
sample 70	2.43	2.433	2.438	2.434	sample 70	2.422		
sample 71	2.451	2.452	2.439	2.447	sample 71	2.417	PF1-0073-9 15K03 WO1500074758	
sample 72	2.435	2.432	2.45	2.439	sample 72	2.419		
sample 73	2.436	2.443	2.434	2.438	sample 73	2.421		
sample 74	2.436	2.443	2.434	2.438	sample 74	2.418		
sample 75	2.445	2.441	2.451	2.446	sample 75	2.42		
sample 76	2.45	2.453	2.439	2.447	sample 76	2.422		
sample 77	2.444	2.435	2.448	2.442	sample 77	2.419		
sample 78	2.445	2.439	2.451	2.445	sample 78	2.422		
sample 79	2.438	2.446	2.437	2.44	sample 79	2.422		
sample 80	2.445	2.449	2.438	2.444	sample 80	2.418		
sample 81	2.442	2.454	2.436	2.444	sample 81	2.423	PF1-0081-9 15E04 WO1500238166	
sample 82	2.447	2.447	2.443	2.446	sample 82	2.423		
sample 83	2.445	2.451	2.438	2.445	sample 83	2.421		
sample 84	2.455	2.448	2.445	2.449	sample 84	2.42		
sample 85	2.436	2.436	2.448	2.44	sample 85	2.422		
sample 86	2.443	2.45	2.437	2.443	sample 86	2.422		
sample 87	2.432	2.437	2.438	2.436	sample 87	2.42		
sample 88	2.444	2.44	2.454	2.446	sample 88	2.417		
sample 89	2.434	2.439	2.439	2.437	sample 89	2.423		
sample 90	2.436	2.431	2.445	2.437	sample 90	2.418		
sample 91	2.442	2.443	2.434	2.44	sample 91	2.415	PF1-0081-9 15E05 WO1500238167	
sample 92	2.437	2.447	2.436	2.44	sample 92	2.417		
sample 93	2.452	2.447	2.445	2.448	sample 93	2.417		
sample 94	2.446	2.436	2.452	2.445	sample 94	2.417		
sample 95	2.443	2.447	2.436	2.442	sample 95	2.42		
sample 96	2.445	2.449	2.436	2.443	sample 96	2.419		
sample 97	2.448	2.447	2.444	2.446	sample 97	2.418		
sample 98	2.449	2.442	2.445	2.445	sample 98	2.415		
sample 99	2.445	2.452	2.429	2.442	sample 99	2.415		
sample 100	2.445	2.436	2.453	2.445	sample 100	2.415		
MAX sample				**2.449**		**Average**	**2.419**	
MIN sample				**2.43**				
AVERAGE sample				**2.442**				

RESULTS

Worse case tolerance is indicated as

- Max implant tolerance and min abutment tolerance
- min circumscribed circle of the abutment hexagon

From the drawing

- Max tolerance = 30 µ (on Diameter)
- Max gap 15 microns
- Rotational misfits is 1.54º

Results measurement

- Max tolerance = 23 µ (on Diameter)
- Max gap 12 microns
- Rotational misfits is 1.17º

Verification by random samples of the final stock compare to others well knows companies show the accuracy of our connection.

Implant/abutment fitting - TAG - MIS - Zimmer				
IMPLANT measurement (mm)			ABUTMENT measurement (mm)	
Company	sample	Hex Average	sample	Hex Average
TAG	1	2.445	1	2.42
	2	2.444	2	2.419
MIS	1	2.443	1	2.42
	2	2.444	2	2.41
Zimmer	1	2.442	1	2.41
	2	2.445	2	2.43

CONCLUSION

Within the limits of this study, consistencies of the hexagons were found for all implants and abutments tested. When the theoretically gap is Max 15µ and rotational misfit of 1.54º we find that when measuring the components the Max tolerance is 12µm and rotational misfit of 1.17º. Comparing the theoretical with the measuring tolerances shows the high quality of TAG products in their accuracy due to machine precision, milling parameters, tools characteristics and the high quality control. This confirms the repeatability of the production process. The quality of the TAG production is able to stand to those tolerances.

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