

Determination of accuracy and tolerance of critical dimensions in RODO abutments

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EXECUTIVE SUMMARY

Geometric and dimensional analysis was used to establish the dimensional tolerances for RODO Medical's abutment interfaces for Nobel, Neodent and Straumann implants. This ensures compatibility, fit, and performance equivalent to the FDA-cleared abutments for each of the implant brands. Fatigue testing has validated these tolerances and they have been cleared by the FDA. These high-quality components make the dental treatment outcomes more predictable with fewer failure incidents.

INTRODUCTION

Dimensional analysis ensures RODO Medical's precision machined abutment is compatible with most commercial dental implant fixtures. These abutments accept Smileloc – a shape memory sleeve that has 2 sets of arms that switch between the “engaged” and “disengaged” positions that lock and unlock the restoration, respectively. Currently, RODO abutments are designed to fit with commercially-available implant platforms. The presented geometric and dimensional analysis ensures the compatibility of RODO abutments with several of the top-selling dental implant brands. .

BACKGROUND

Reverse engineering techniques are employed to extract dimensional information for components that need to be duplicated or modified when computer-

aided design (CAD) models are unavailable or unusable [1]. This information is also used to design custom parts that interface with commercially available products for which the manufacturer is unable or unwilling to provide design specifications. An essential element of designing and manufacturing mechanical components is tolerancing. Tolerance can be defined as the permissible variation of a physical dimension from its nominal value and is important to determine for the proper assembly and performance of interfacing parts. Failure to consider tolerances of two interacting parts can negatively impact their stability and durability. This is especially true if the intent is to manufacture a commercial product from data collected using reverse engineering techniques. In these cases, an important goal of reverse engineering is to extract tolerance data from measurements, which is often done by performing dimensional anal-



ysis on several specimens of the same product to elucidate normal manufacturing variations [2]. Reverse engineering was employed to design RODO abutments that precisely match commercially available dental implants.

MATERIALS & METHODS

To design RODO abutments using reverse engineering, the following FDA-cleared implants and their approved abutments were used: Straumann’s Bone Level (BL) Narrow CrossFit (NC) and Regular CrossFit (RC) implants; Neodent’s Cone Morse (CM) implants; and Nobel’s Internal Conical 3.0, Internal Conical Narrow Platform (NP), Internal Conical Regular Platform (RP), and Internal Conical Wide Platform (WP), and Tri-Channel Narrow Platform (NP), Tri-Channel Regular Platform (RP), Tri-Channel Wide Platform (WP), and Tri-Channel 6.0 implants.

Reverse engineering techniques were used to create CAD models of RODO abutments for FDA-cleared implants. CAD images from the transverse and coronal views of FDA-cleared abutments and abutment screws for Nobel implants are shown in Figure 1 as

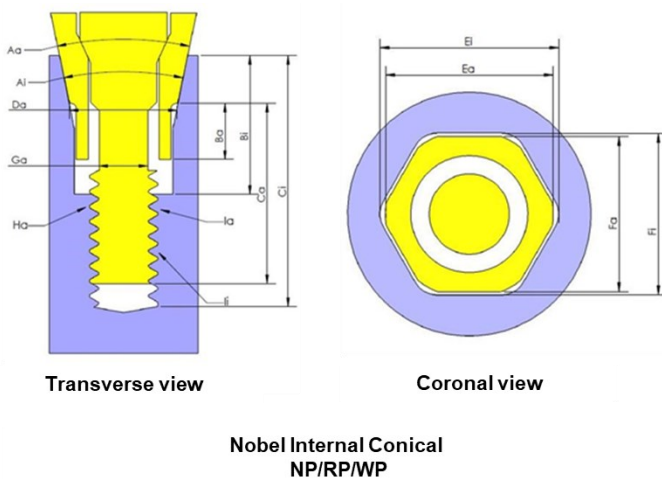


Figure 1. Transverse and coronal views of FDA-cleared abutments and abutment screws for Nobel implants.

an example. The CAD images are shown in contrasting colors such that the gaps between components of the system are displayed in white. Abutment features are noted with subscript “a”, while matching implant features are noted with subscript “i”. Some of the features deemed critical to fit and performance of the abutment-implant interface were: taper angle (A_a), engaging feature length across abutment flats and height (F_a and B_a , respectively). Taper angle and engaging feature height was measured on specimens using a digital optical metrological system (Micro-Vu Corp., Windsor, CA). The length across the abutment engaging flats was measured using a high-precision micrometer. For each feature, a minimum of 6 specimens from at least 2 different lots was measured and the average dimension, standard deviation, upper and lower tolerance limits were recorded along with the manufacturer’s information, part number, and lot number. A summary of the implants measured is shown in Table 1, and a summary of sample size for FDA-cleared abutments for each implant line is shown in Table 2.

RESULTS & DISCUSSION

To ensure proper fit, dimensions for the RODO abutment’s implant interface features were not allowed to impinge on the matching implant’s interface features, which could compromise the performance of the implant, the abutment, or the entire abutment-implant system. Additionally, the selected tolerances for critical features of the RODO abutment’s implant interface were all within ranges measured on FDA-cleared abutments (Table 3). Tolerances define realistic size and shape limits for as-

Table 1. Measured Implants

Manufacturer	Implant Platform	n	lots
Neodent	Cone Morse	6	6
	NobelActive	18	16
Nobel Biocare	Nobel Replace	18	18
	NobelSpeedy	12	12
Straumann	Bone Level Narrow Crossfit	6	6
	Bone Level Regular Crossfit	6	6

Table 2. Measured FDA-cleared Abutments for Each Implant Line

Manufacturer	Implant Platform	n	lots
Neodent	Cone Morse	10	9
	Internal Conical 3.0	6	2
Nobel Biocare	Internal Conical NP	11	10
	Internal Conical RP	14	5
	Internal Conical WP	6	6
	Tri-Channel NP	6	5
	Tri-Channel RP	7	7
	Tri-Channel WP	8	8
	Tri-Channel 6.0	9	4
Straumann	Bone Level Narrow Crossfit	14	8
	Bone Level Regular Crossfit	10	8

Abbreviations: *Narrow Platform (NP); Regular Platform (RP); Wide Platform (WP).*

Table 3. Critical dimensions for FDA-cleared abutments compatible with a presentative implant system and the selected RODO tolerances.

	A _a (°)	B _a (mm)	F _a (mm)
Measured Min.	29.6	2.05	2.31
Measured Max.	30.6	2.30	2.37
Avg. Measured Value	30.1	2.24	2.33
Std. Deviation	0.3	0.06	0.01
RODO Min.	29.9	2.08	2.33
RODO Max.	30.5	2.28	2.37

sembled parts. The design requires that the components fit together tightly. Components that do not

have adequate fit contribute to screw loosening, and abutment screw loosening is one of the most common causes of implant-supported restoration failure [3]. Therefore, it is critical that components have been designed to fit and work together long-term.

There are several design features that are critical to the performance of the RODO abutments, including the taper angle and engaging feature flats and height. The engaging feature flats on the RODO abutment (Feature F_a in Figure 1 coronal view) provide rotational resistance equivalent to that of FDA-cleared abutments while not impinging on implant feature F_i. Anti-rotational features have previously been shown to significantly help maintain abutment screw preload and prevent loosening [4-6]. Loosening is important to minimize since motions between the abutment and the implant can cause wear and premature failure of the components. The presence of a taper has also been shown to have an effect on screw loosening since the tapered-interference fit helps to provide a secure connection between the abutment and the implant by the large contact pressure and resulting frictional resistance at the implant –abutment interface [7,8]. Additionally, the taper angle provides resistance to bending forces and increases the strength of the implant-abutment joint [9,10]. It should be noted that torque efficiency – the ratio between the loosening torque and the tightening torque, which is a measure of screw loosening prevention – and joint strength are competing design criteria since the fracture resistance of the implant collar is increased with greater taper angles while torque efficiency is decreased [7,9].

Implant Engaging Feature

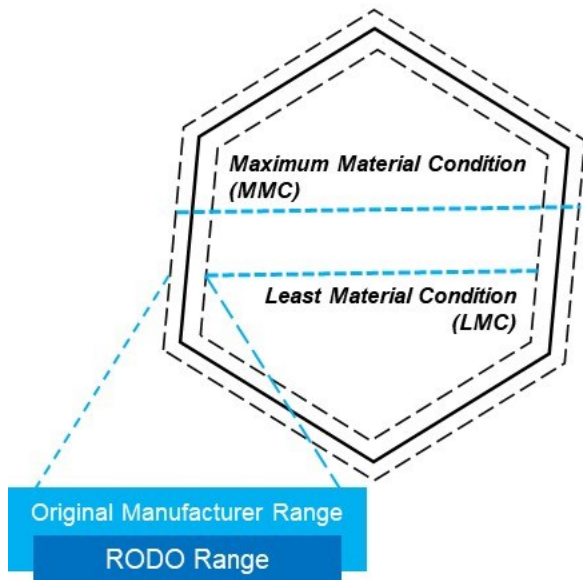


Figure 2. RODO abutments have been designed with tighter tolerances for implant engaging features than FDA-cleared abutments.

In addition to reducing micromovements that can lead to wear, proper fit between implants and abutments helps to reduce the size of microgaps that exist at their interface. Microgaps are susceptible to infiltration by oral fluids, glycoproteins, and microorganisms, which can further exacerbate disharmony between the two components. First, oral fluids can act as lubricants that reduce friction between the abutment and implant and enable micromovements [11]. Additionally, oral fluids and microorganisms can cause corrosion and loss of surface material comprising the contact area between the two components. Several studies have reported that the acidic metabolic byproducts of microorganisms have caused increased corrosion rates [12-14] as have therapeutic substances like bleaching agents and fluorides.

For the aforementioned reasons, RODO abutments have been designed with a range between the least material condition (LMC) and maximum material condition (MMC) that falls well within measurements taken during reverse engineering. This ensures that RODO components will always have equivalent or tighter tolerances than components from original equipment manufacturers they are meant to interface with (Figure 2). Importantly, these tolerances have undergone fatigue testing and have been validated by receiving FDA clearance.

REFERENCES

1. Thompson WB, Owen JC, St Germain HJD, Stark SR, Henderson TC. Feature-based reverse engineering of mechanical parts. *IEEE Transactions on Robotics and Automation* 1999;15(1):57-66.
2. Curtis SK, Harston SP, Mattson CA. Characterizing the Effects of Learning When Reverse Engineering Multiple Samples of the Same Product. *Journal of Mechanical Design* 2013;135(1).
3. Jung RE, Zembic A, Pjetursson BE, Zwahlen M, Thoma DS. Systematic review of the survival rate and the incidence of biological, technical, and aesthetic complications of single crowns on implants reported in longitudinal studies with a mean follow-up of 5 years. *Clinical Oral Implants Research* 2012;23:2-21.
4. Aboyousef H, Weiner S, Ehrenberg D. Effect of an antirotation resistance form on screw loosening for single implant-supported crowns. *Journal of Prosthetic Dentistry* 2000;83(4):450-455.
5. Binon PP, McHugh MJ. The effect of eliminating

- implant/abutment rotational misfit on screw joint stability. *International Journal of Prosthodontics* 1996;9(6):511-519.
6. Binon PP. The effect of implant/abutment hexagonal misfit on screw joint stability. *International Journal of Prosthodontics* 1996;9(2):149-160.
 7. Bozkaya D, Muftu S. Mechanics of the taper integrated screwed-in (TIS) abutments used in dental implants. *Journal of Biomechanics* 2005;38(1):87-97.
 8. Bozkaya D, Muftu S. Mechanics of the tapered interference fit in dental implants. *Journal of Biomechanics* 2003;36(11):1649-1658.
 9. Wang K, Geng JP, Jones D, Xu W. Comparison of the fracture resistance of dental implants with different abutment taper angles. *Materials Science & Engineering C-Materials for Biological Applications* 2016;63:164-171.
 10. Norton MR. An in vitro evaluation of the strength of an internal conical interface compared to a butt joint interface in implant design. *Clinical Oral Implants Research* 1997;8(4):290-298.
 11. Apaza-Bedoya K, Tarce M, Benfatti CAM, Henriques B, Mathew MT, Teughels W, Souza JCM. Synergistic interactions between corrosion and wear at titanium-based dental implant connections: A scoping review. *Journal of Periodontal Research* 2017;52(6):946-954.
 12. Souza JCM, Ponthiaux P, Henriques M, Oliveira R, Teughels W, Celis JP, Rocha LA. Corrosion behaviour of titanium in the presence of *Streptococcus mutans*. *Journal of Dentistry* 2013;41(6):528-534.
 13. Souza JCM, Henriques M, Oliveira R, Teughels W, Celis JP, Rocha LA. Do oral biofilms influence the wear and corrosion behavior of titanium? *Biofouling* 2010;26(4):471-478.
 14. Oliveira MN, Schunemann WVH, Mathew MT, Henriques B, Magini RS, Teughels W, Souza JCM. Can degradation products released from dental implants affect peri-implant tissues? *Journal of Periodontal Research* 2018;53(1):1-11.