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In-Vitro Investigation of Fatigue and Fracture Behavior of Transmucosal versus Submerged Bone Level Implants Used in Fixed Prosthesis

Saverio Cosola [1,*], Paolo Toti [2], Enrico Babetto [3], Ugo Covani [1,4], Miguel Peñarrocha-Diago [1] and David Peñarrocha-Oltra [1]

[1] Oral Surgery Unit, Department of Stomatology, Faculty of Medicine and Dentistry, University of Valencia, 13, 46010 Valencia, Spain; covani@covani.it (U.C.); miguel.penarrocha@uv.es (M.P.-D.); david.penarrocha@uv.es (D.P.-O.)
[2] Tuscan Stomatologic Institute, Foundation for Dental Clinic, Research and Continuing Education, 55041 Camaiore, Italy; capello.totipaolo@gmail.com
[3] Sweden & Martina's Department of Engineering Research, 35020 Due Carrare, Italy; EBabetto@sweden-martina.com
[4] School of Dentistry, Saint Camillus International University of Health and Medical Sciences, 00131 Rome, Italy
* Correspondence: s.cosola@hotmail.it; Tel.: +39-0584-618414

Abstract: Background: The present in vitro study aimed to investigate the fatigue performance of different dental fixtures in two different emergence profiles. Biological failures are frequently reported because the problem canonly be solved by replacing a failing implant with a new one. Clinicians addressed minor mechanical failures, such as bending, loosening or the fracture of screws, abutment, or the entire prosthesis, by simply replacing or fixing them. Methods: Transmucosal and submerged bone-level dental implants underwent fatigue strength tests (statical and dynamical performance) by a standardized test: UNI EN ISO 14801:2016. Two types of emergence profiles (Premium sub-crestal straight implant with a cylindrical-shaped coronal emergence or Prama one-piece cylindrical-shape implant with transmucosal convergent neck and hyperbolic geometry) were tested, and dynamic fatigue were run to failure. Data was analyzed by a suitable statistical tool. Results: The Wöhler curve of 0.38 cm Premium group c2, appeared to be significantly different from that of the 0.38 cm Prama group c3 (nonparametric one-way ANOVA χ^2 = 6; degree of freedom = 1; probability = 0.0043) but not from that of the 0.33 cm Premium group c1 (nonparametric one-way ANOVA χ^2 = 0.62; degree of freedom = 1; probability = 0.4328). Fatigue performance of configuration 2 was one and a half times better than that of configuration 3. Group c3 had a better ultimate failure load (421.6 ± 12.5 N) than the other two settings i.e., c1 (324.5 ± 5.5 N) and c2 (396.3 ± 5.6) reaching almost a nonsignificant level. Conclusions: It was observed that a transmucosal implant design could provide the highest resistance to static fracture. On the other hand, an equicrestal implant design could increase dynamic endurance.

Keywords: transmucosal implant; submerged bone-level implant neck; fatigue test; implant fracture

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1. Introduction

Edentulous patients havebeen successfully rehabilitated through teeth replacement with dental implants supporting prostheses. Studies havedocumented the risks of impact fracture to dental implants and components [1,2]. Even if the adults were not prone to direct impact forces on their prostheses, the constant activity of biting and chewing, taken together, make fatigue fractures or deformations of the dental implants and related components much more likely [3].

The major problem clinicians face is that of a single implant-supported dental crown which hasscrew joint instability between the abutment/superstructure and the dental implant, and so, theincidence of mechanical failure increases [2,4]. The causes of fracture

or permanent deformation occur when excessive bending of the restoration exertsa force on the screw which is larger than the screw yield strength, or when the loss of preload (via small micromovements) reducesthe contact force between the abutment/superstructure and the dental implant body [4].

The investigation of Gehrke and co-workers suggested that no significant difference was highlighted in the fracture energy between the implant-abutment system and the transmucosal single-piece implant system [5], but their results were not validated through comparison of the two systems using static and dynamic fatigue tests.

Biological failures aremore frequently reported because the problem could only be solved by replacing the failing implant with a new one (reporting the brand of the manufacturer) [6,7]. By contrast, the clinician can address minor mechanical failures, such as loosening or fracture of screws, abutment, or the entire prosthesis, by replacing or fixing them [8,9]. If, for whatever reason, there was a fracture or damage toeither the implant body or shoulder, which could jeopardize the stability of the prosthesis again, the dental implant could be replaced [1]. Therefore, mechanical in-vitro studies describing the results of fatigue fracture tests of different types and with implant systems may be very important to deepen understanding of the topic. The null hypothesis is that aone-piece cylindrical-shaped implant with a transmucosal convergent neck and hyperbolic geometry, and anabutment/implant system with a subcrestal straight cylindrical-shaped neck, would show similar behavior.

2. Materials and Methods

In this in vitro study three different types of implant emergence profiles, such as one transmucosal and two submerged bone level configurations, were investigated. These were small (configuration 1, c1) and standard diameter (configuration 2, c2) abutment/implant systems with a subcrestal straight cylindrical-shaped neck, and a standard diameter one-piece cylindrical-shaped implant with a transmucosal convergent neck (configuration 3c3).

2.1. Equipment/Setting

Three samples were checked in different settings. Statical performance offracture behavior to acquire a value of the maximum breakout force was evaluated, then the behavior of a set of specimens per each configuration was tested registering breakages during a cycle of loading, according to ISO 14801: 2016 standards [10]. As shown in Figure 1, the test involved applying a known force (a fraction of the breakout force) at a known distance along a lever arm 1.1 cm from the site of force application, i.e., hemispheric support to the nominal bone level.

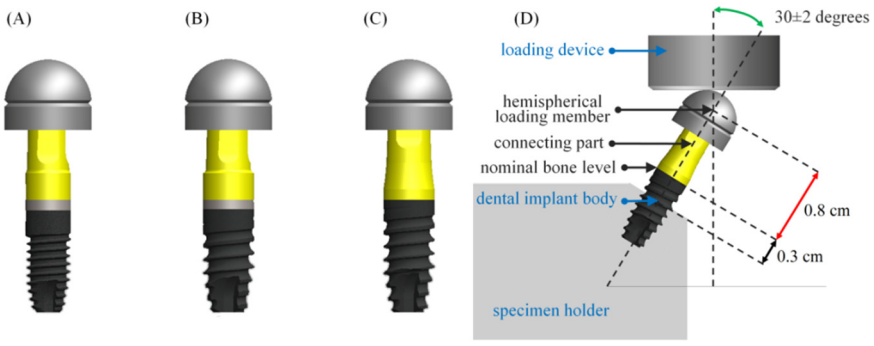


Figure 1. Three configurations: (**A**) c1; (**B**) c2; (**C**) c3. (**D**) Schematic of test set-up for systems (ISO14801:2016).

In the static load test, the maximum breakout forces were calculated, known as Ultimate Failure Loads (UFLs), which are functions of the specimens' bending moments (BMs). Each implant, as soon as the test was over, was checked and photographed. Any metal fracture or displacement (higher than 0.4 cm) was considered to be a fatigue failure.

2.2. Dental Implant Materials

The following settings were applied to eleven to thirteen dental implants of a single brand and two types (Prama and Premium, Sweden & Martina, Padua, Italy) (Table 1 and Figure 2).

Table 1. Implants and equipment employed in the study with UFL, BMs, and failure eventsfor the statical performance test. (A) c1: 0.33 cm subcrestal abutment-level finishing line with a cylindrical-shaped coronal emergence profile. (B) c2: 0.38 cm subcrestal abutment-level finishing line with a cylindrical-shaped coronal emergence profile. (C) c3: 0.33 cm abutment-level finishing line on diameter of cylindrical endosseous shape and transmucosal convergent neck with hyperbolic geometry.

Configuration	Fixture	Abutment	Material	Ultimate Failure Load (UFL in [N])	Bending Moment, (BM in [N·cm])	Failure Mode
C_1	A-ZT-330-130	A-MD-330-2	CP-Ti grade 4	324.5 ± 5.5	178.50 ± 3.04	deformation
C_2	A-ZT-380-130	A-MD-380-2	CP-Ti grade 4	396.3 ± 5.6	217.95 ± 3.09	deformation
C_3	LA-ZT-380-130	A-ABU-330-1	CP-Ti grade 4	421.6 ± 12.5	231.88 ± 6.87	deformation

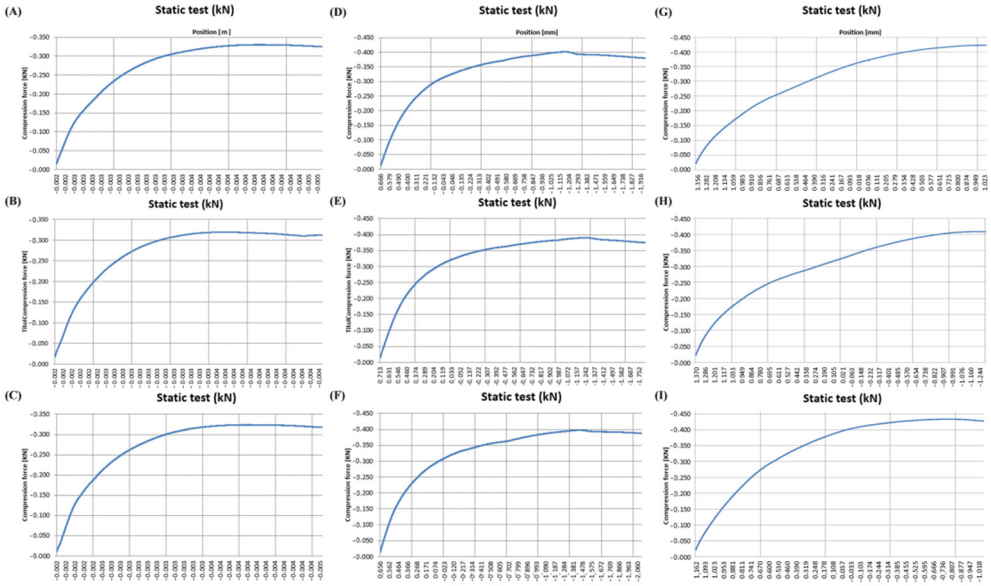


Figure 2. View of displacement curves for (**A**–**C**) c1; (**D**–**F**) c2; (**G**–**I**) c3 with permanent deformations to the right sides of the graphs.

c1: Subcrestal 0.33 cm implant diameter, 0.33 cm abutment diameter. Abutment finishing design on standard abutment/implant system with subcrestal straight cylindrical-shaped neck.

c2: Subcrestal 0.38 cm implant diameter, 0.38 cm abutment diameter. Abutment finishing design on abutment/implant system with subcrestal straight cylindrical-shaped neck.

c3: Transmucosal 0.38 cm implant diameter, 0.33 cm abutment diameter. Implant finishing design on the standard one-piece cylindrical-shaped implant with transmucosal convergent neck and hyperbolic geometry.

2.3. Procedures

Static Load Test

The bed for an in vitro implant lodging was formedinto a poly-methyl methacrylate (PMMA) piece (Plexiglas®, Röhm GmbH, Darmstadt, Germany). to simulate, as far as possible in vivo conditions, following themanufacturers' recommendations Implants were positioned with a torque up to 100Ncm, allowing a coronal portion of the implant to protrude through the opening of the PMMA exactly 0.3 ± 0.05 cm below the abutment-

implant interface. The standardized experimental analysis established a lever arm size of 0.8 ± 0.05 cm from the abutment-implant junction to the center of the hemisphere.

Three repeated samples for each of the configurations were submitted to static fatigue overstress by a fatigue test machine (Instron ElectroPuls® E10000, Instron Industrial Products, Bucks, UK) with the following set-up: 30 ± 2 stress-angle degrees between the axis of the dental implant and the direction of the loading device, and 2 mm/min load rate with the application of a preload force of 20 N.

In this context, it was important to emphasize that the standard protocol ISO14801:2016 was used for in silico studies, with angles of inclination from 30 to 45 degrees [11–13]. That value of 30° was chosen because tilted implants in some clinical studies were positioned with an inclination ranging between 10 and 30 degrees [14,15]. The increasing load was applied to the static sample until it was fractured or displaced.

Tests for cyclical performance to fracture followed ISO guidelines. Two samples were submitted to dynamic fatigue overstress with the required mean value of the UFL by the same fatigue test machine. The setting used in the static loading tests for the two samples in each of the configurations were submitted to the dynamic fatigue overstress test with the required mean value of the UFL by the same fatigue test device and setting geometry used in the static loading tests (Figure 1).

The test was run with the following UFL percentages decreasing in 10% increments from: 80% to zero. The frequency of the applied loading was 15 Hz. An individual dental implant survived the loading test if it reached 5 million cycles; otherwise, it was a failure. The number of cycles was registered.

2.4. Statistical Analyses

Results of statical and cyclical performance to fracture were analyzed by a matrix laboratory (Database and Statistics Toolbox, MatLab 7.11; The MathWorks, MA, USA). Descriptive statistics were calculated by a statistical toolbox (Database and Statistics Toolbox, MatLab 7.11; The MathWorks, MA, USA). The normality of data distribution was not verified (Shapiro-Wilk test). Scheffe's multiple comparisons test was applied during the analysis of static load groups. The effects on dynamical performance to fracture were evaluated with nonparametric one-way analysis of variance tests (such as Friedman's one). All significance was recorded. All measurements were given as means and standard deviations. The level of significance was set at 0.01.

3. Results

The mean values of UFLs and the bending moments of each of the three configurations can be seen in Table 1 and Figure 2. The c3 (0.38 cm cylindrical endosseous shape and transmucosal convergent neck) showed better and nonsignificant UFLs (421.6 ± 12.5 N) than the other two settings i.e., c1 (0.33 cm subcrestal abutment implant-level, 324.5 ± 5.5 N) and c2 (0.38 cm subcrestal abutment implant-level, 396.3 ± 5.6). No fracture of the implant was registered even if all evident defects or deformations of the implant necks and bodies were recorded (Figure 3).

Data showing the number of cycles registered until the specimens failed are givenin Figure 4.

A Wöhler function encoded the dependence of a parameter, i.e., the expected number of cycles before failure under the loading sequences with decreasing load levels. In contrast to the statical performance offracture results, the c2 setting allowed for survival (5 Megacycles)for a loading force of 169 N (ultimate failure load at 50%). This was better than the c1 (ultimate failure load at 40%: 130 N) and c3 settings (ultimate failure load at 40%: 169 N). Moreover, the function of the 0.38 cm Premium was significantly different from that of the 0.38 cm Prama group (nonparametric one-way ANOVA χ^2 = 6; degree of freedom = 1; probability = 0.0043) but not from that of the 0.33 cm Premium group (nonparametric one-way ANOVA χ^2 = 0.62; degree of freedom = 1; probability = 0.4328). The fatigue-life of configuration 2 was one and a halftimes better than that of configuration 3. No conclusions

cannot be drawn between configurations 1 and 2, even if the narrow implants showed excellent resistance to shear stress. Examples of failures are shown in Figure 5.

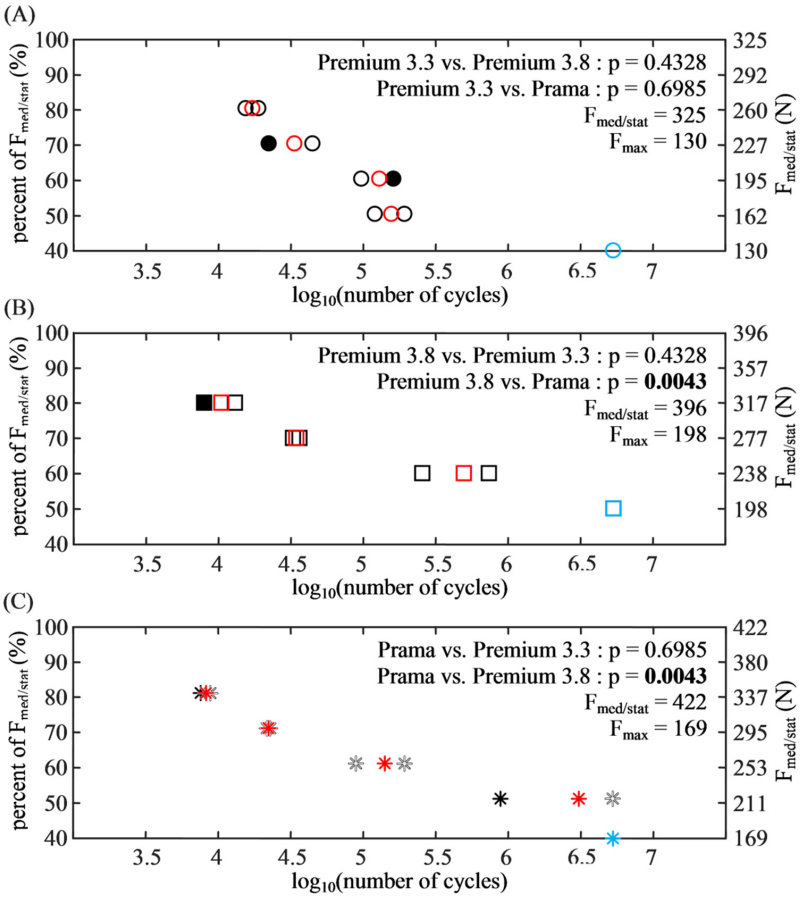


Figure 3. Cyclical performance to fracture. Significant differences occur between the groups in bold. Red marks arethe mean values; cyan marks arethe maximum values of the force to achieve five million cycles. (**A**) c1 circle; (**B**) c2 square; (**C**) c3 asterisk. Black empty mark: simple sudden fracture of the specimen. Black full mark: both deformation and fracture of the specimen.

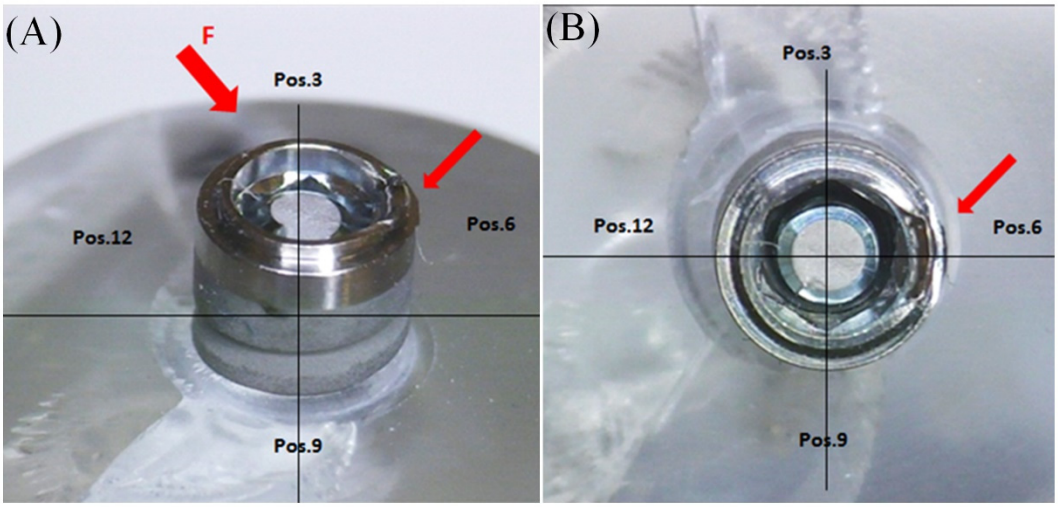
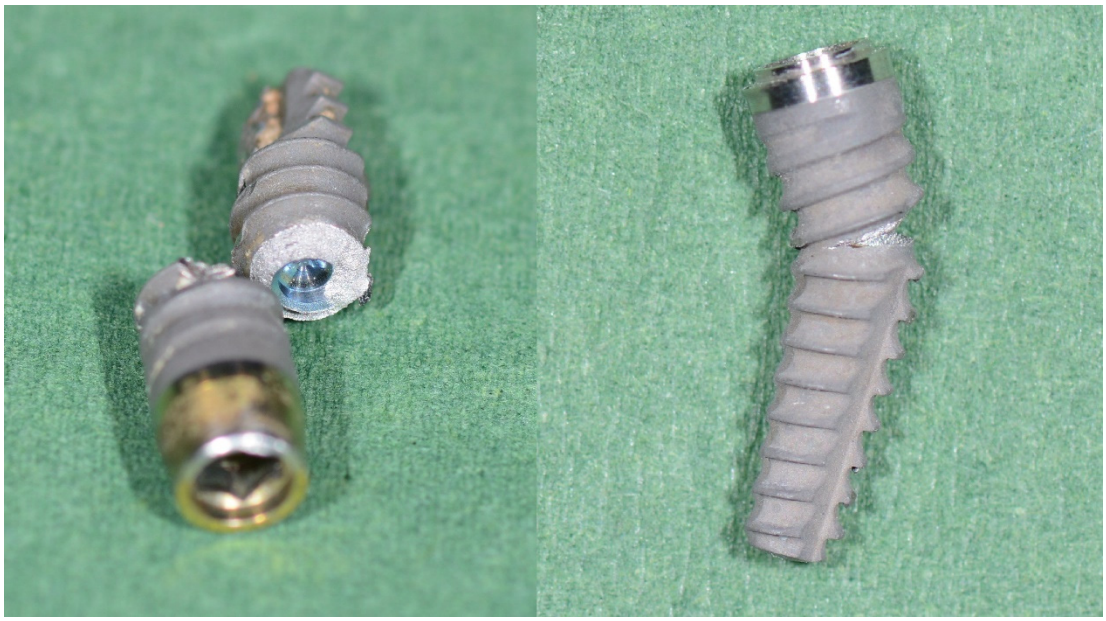


Figure 4. (**A**) Lateral and occlusal (**B**) views of failures in the statical performance to fracture of a 0.38 cm implant diameter, 0.33 cm subcrestal abutment finishing line, and a cylindrical-shaped coronal emergence profile.



(**A**) (**B**)

Figure 5. Failure modes in dynamic load test for Prama (**A**) and Premium (**B**).

4. Discussion

Since the one-piece cylindrical-shaped implant with a transmucosal convergent neck and hyperbolic geometry and the abutment/implant system with sub-crestal straight cylindrical-shaped neck showed significantly different behavior, the null hypothesis was rejected. A progressive crack propagation with fracture of the implant body occurred when the dental implant under mechanical fatigue no longer had the physical endurance to withstand repeated stress loading conditions. To decrease the incidence of negative events, some authors tried to reduce mechanical failure rates by modifying the features of the implant systems under investigation, such as diameter and screw joint design, and/or the shape, length, material, and number of the components [16,17]. Studies suggested that the use of orthodontic mini dental implants (MDI) and small diameter implants (SDI),necessary to achieve skeletal expansion, could lead to complications such as fracture, mucositis and ulceration [18,19]. Even though many other factors, such as different surgical procedures (techniques of drilling in the opposite rotatory direction to conventional drills) or various surgery devices for implant positioning, e.g., electromagnetic instruments (Magnetic mallet®, Osseotouch, Turbigo, Milano, Italy https://www.osseotouch.com/) or piezosurgical devices (Piezosurgery®touch, Mectron, Carasco, Italy), (KaVo SONICflex® KaVo Italia srl, Genoa, Italy) could affect postimplant osseodensification and, in turn, implant fracture [20].

Implant transmucosal designs were launched as a result of clinical studies attesting that the crestal implant/abutment interface, as well as the type of connections, platforms, and surface properties of the components, had great effects on biological dimensions and the amount of soft tissue inflammation, as well as on the marginal bone levels around implants [21]. As regards transmucosal designs, it was suggested that concave designs might reduce the compression around the healing peri-implant connective tissue and promote cell adhesion [22]. Moreover, in the following phases of healing, a narrow design seemed to reduce marginal bone loss, providing a wider/horizontal space versus the smaller space of the conventional flared transmucosal components [23].

However, very recent review papers suggest there isno evidence for differences in marginal bone loss or implant survival rate between standard and narrow implants [24], or between bone-level and transmucosal dental implants, after a period of follow-up v from 12 to 60 months [25]. Some authors suggest that both asecond surgery, required

for uncovering a submerged implant, and the connection/reconnection of the healing screw and prosthesis, could be factors that affect healing and stability of the peri-implant environment [26]. Nevertheless, in the absence of definitive evidence attesting whether transmucosal or submerged healing might have a more favorable long-term influence, we must assume similar behavior regarding the stability of the hard and soft peri-implant tissues for both procedures [27,28].

The present study showed data of two different implant systems from a single manufacturer and compared their load-bearing capacity.

Mean results of static fracture resistance tests (excluding those from narrow implants) ranged between 390 N and 434 N and were in line with previous studies describing transmucosal implants with or without a ferrule effect (0.38 cm with UFL from 362 N to 445 N) and standard/wide-diameter implants (0.4 cm or higher with UFL of 565.64 ± 185.46 N) [29,30].

Itisclear from Figure 2 that the transmucosal and equicrestal standard diameter implants behaved differently in the presence of a gradual progressive force, with the transmucosal design showing slightly nonsignificant higher resistance. The dynamic endurance of the equicrestal configuration appeared to be better than that of the transmucosal configuration. The equicrestal configuration could endure dynamic stress by as much as a half or more (ranging from 1.26 to 3.46) when compared to the transmucosal configuration. This was a significant difference.

The study of Khraisat and coworkers attested that the internal conical implant/abutment joint of immediate transmucosal implant systems had higher resistance to mechanical fatigue than the hex-mediated butt joint of equicrestal implant systems. Although the results were obtained from dental implants of different trademarks, they partially confirmed the present findings.

Mechanical data for transmucosal implant systems were not available, and the recorded information about the classification of fracture patterns in implants and their association with clinical factors is sparse or lacking. The study of Lee and co-workers did not find any significant association between the implant length and fracture rate, showingthat in the case of peri-implant bone resorption, the more powerful lever arm of a long implant did not cause meaningfully relevant screw or component fractures [1].

On the contrary, the study of Pérez-León and coworkers found a difference between the transmucosal implants and the bone-level implant group when fatigue strength exponentswere analyzed. The sensitivity to cyclic stress of the transmucosal implants was higher than the bone level implants, suggesting that a screw-retained implant-supported crown with atransmucosal part in the worst possible scenario might fail at a very low load-bearing (about 150 N) in a very short time (about 80,000 cycles) [31]. These results arein line with the findings of the present paper, showinga higher sensitivity to cyclic stress of the transmucosal configuration.

The main limitations of this study were the small sample size and the unmodifiable test setting. The mechanical strength tests on commercially pure titanium dental implants had to fulfill a unique mandated protocol (UNI EN ISO 14801:2016) which requires a standard number of specimens to be investigated for each configuration [10,32].

The fatigue test equipment used for the present study wasadjusted to ensure that the location, direction and magnitude of the applied force waskept constant and carefully monitored. This procedure ensures that the method delivers reliable research results and decreases consistently the error in terms of bias and variance despite the wide range of components.

If a technician is correctly qualified, they may set up this machine for fatigue testing tomimic occlusal and lateral forces. A limitation is that there is no generalization from the in vitro to the clinical phase in the present experimental conditions used.

5. Conclusions

It was observed that a transmucosal implant design could provide the highest resistance to fracture. An equicrestal design increased dynamic endurance. According to the

standard UNI EN ISO 14801:2016, the tests didnot always match clinical practice because they depended on the machine settings used. Other studies are needed to confute or confirm the present results, because it is possible that the same implant and mechanical tests configurations may provide different data when external conditions are different, or the software or machines usedare different (i.e., hydraulic or electric).

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Institutional Review Board Statement: None because the study did not involve human or animal samples or subjects. Instead, it is an invitro study on medical devices.

Informed Consent Statement: None because it is an invitro study.

Data Availability Statement: The files were encrypted in a dedicated database (.mat) available if requested to corresponding author.

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Conflicts of Interest: All the authors and authors' institutions declare that there were no competing interests nor personal relationships with other people or organizations who might inappropriately influence their actions. One author (E.B.) has a job relationship with Sweden & Martina, Padua, Italy.

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