

Resistance of ITI Implant Connectors to Multivectorial Fatigue Load Application

H. W. Anselm Wiskott, DMD, MS, MSD, PD^a/Antonello F. Pavone, DMD^a/Susanne S. Scherrer, DMD, PD^a/
Roger R. Renevey, CDT^b/Urs C. Belser, DMD, Prof Dr Med Dent^c

Purpose: In an effort to provide patients with mechanically optimized implant connectors, this study was designed to assess the relative fatigue resistance of five types of connectors for the ITI implant system: (1) standard (screw-on) abutments torqued to 35, 70, and 140 Ncm; (2) metal Octa connectors torqued to 35 Ncm; (3) ceramic Octa connectors torqued to 15 and 35 Ncm; (4) cemented cast-on abutments; and (5) an experimental screw-retained composite core. **Materials and Methods:** To duplicate the alternating and multivectorial intraoral loading patterns, the specimens were subjected to the rotating cantilever beam test. The implants, their connectors, and abutments were spun around their longitudinal axes while a perpendicular force was applied to the external end. The objective was to determine the force level at which 50% of the specimens would survive 10⁶ load cycles. The mean force levels at 50% failure and their 95% confidence intervals were determined using staircase analysis. **Results:** The fatigue resistances of the standard (screw-on) abutment, metal Octa connector, and ceramic Octa connector torqued to 35 Ncm were within a few percent of one another. The fatigue resistance of the cemented cast-on abutment was approximately half that of the screwed connectors, and the experimental screw-retained composite core's resistance was about 30%. Increasing the preload in the standard abutments and ceramic Octa connectors increased their fatigue resistance. **Conclusion:** Preloaded screwed components were mechanically superior to cemented cast-on abutments and screw-retained composite buildups. For the screw-on connectors, augmenting preload (ie, torque) augmented the resistance to fatigue loading. *Int J Prosthodont* 2004;17:672-679.

In a classic study by Schwartz et al,¹ prosthodontic failures were classified as either of biologic or mechanical origin. The same dichotomy also applies to implants, in that all elements of the implant-connector assemblage may be subjected to mechanical failures.

Fractures of implant cylinders, abutments, and/or screws, as well as decementation of crowns and screw loosening, have been reported.² In an early study, a total of 1,997 implants were followed over a period of 15

years: 54 maxillary and 15 mandibular implants fractured, resulting in an overall fracture rate of 3.5%.³ In another investigation, among 133 implants placed in 50 patients, 2 abutments fractured.⁴ Depending on the system and duration of observation, reported implant fracture rates range from 0.1%⁵ to 0.6%.⁶ A number of reports also cite screw loosening as a frequent mishap. Between 18% and 88% of the implants investigated carried screws that needed retightening at the recall visits.⁷⁻⁹ In a study on the overall mechanical failure rate of implants versus natural teeth after 5 years of function,¹⁰ mechanical complications occurred on 20% of all implants (vs 6% of the teeth). Of the units, 3% lost retention, 7% experienced screw loosening, and 11% presented minor fractures and chipping of the porcelain.

Consolidating the data from the various studies to survival estimates is nearly impossible because of the heterogeneity in test durations, systems, clinical

^aResearch Associate, Division of Fixed Prosthodontics, University of Geneva School of Dentistry, Switzerland.

^bCertified Dental Technician, Geneva, Switzerland.

^cProfessor and Chair, Division of Fixed Prosthodontics, University of Geneva School of Dentistry, Switzerland.

Correspondence to: Dr Anselm Wiskott, School of Dental Medicine, 19 Rue Barthélemy-Menn, 1205 Geneva, Switzerland. Fax: + 41 22 382 91 73. e-mail: Anselm@Wiskott.com

applications (single-tooth or multiunit restorations, fixed-removable anchorage), and patient populations. Furthermore, a number of systems were improved by their manufacturers, and older data may not apply to more recent designs. Nevertheless, a broad reading of the literature yields a combined mechanical failure rate of approximately 1% at 5 years.

Experimental data indicate that the force vectors applied to teeth during function are multivectorial.^{11,12} That is, they may range from fully vertical (along the longitudinal axis of the implant)¹³ to horizontal (perpendicular to the longitudinal axis). The transverse forces are considered most detrimental because of the relative weakness of the components in tension and shear combined with the bending moment resulting from the crown's length.¹⁴ Furthermore, the teeth are subjected to continuously alternating cycles of buccolingual and linguobuccal forces.¹¹

One experimental technique geared at generating alternating transverse stresses is the rotational fatigue test. Such tests were introduced to industry in the mid-18th century in the wake of the development of axles for railroad stock. In its simplest form, the test consists of spinning a specimen while holding it at one end and loading it at the protruding end. This will subject the specimen to alternating cycles of tension and compression¹⁵; the technique is therefore often referred to as the rotating cantilever beam test. During the procedure, the "inner" end of the specimen is held in a chuck or collet while a force is applied to the "outer" end via a ball-bearing. In industry, this experimental approach has been used in varying degrees of sophistication,¹⁶ and it appears to apply equally well to the testing of prosthetic components in dentistry.^{17,18} Indeed, because of the multivectorial nature of the functional or para-functional forces applied to the teeth, actuator-driven fatigue testing systems are unable to reproduce the complex force patterns that are active clinically. By contrast, a rotating-bending system will subject each component to a field of force vectors that encompass the 360 degrees of the circumference. Hence, it is postulated that data gained using rotational fatigue tests have a superior pertinence relative to single-axis testing designs.

In an effort to provide patients with optimized implant connectors, this study was undertaken as part of a project aimed at correlating in vitro data with clinical survival rates. To this end, five types of connectors for the ITI implant system (Straumann) were evaluated. The following connectors were assessed as to their fatigue resistance under rotational cyclic loading: (1) a standard biconal implant-abutment connector, (2) a metal-to-metal Octa connector (Straumann), (3) a metal-to-ceramic Octa connector (Straumann), (4) a cemented biconal connector, and (5) an experimental screw-retained composite buildup. The null hypothesis was

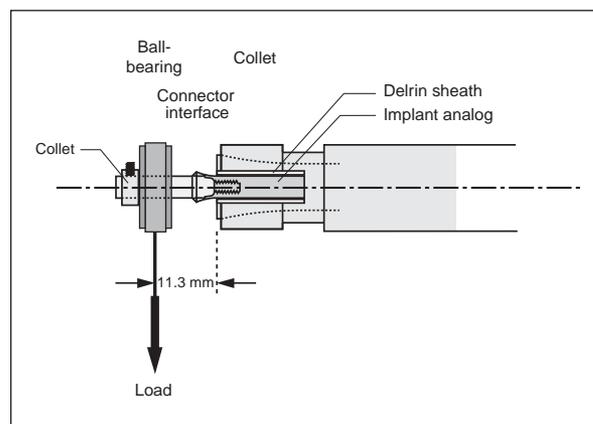


Fig 1 Principle of rotating-beam fatigue test. Implant analog is clamped into a collet and rotated. Abutment analog is connected to the implant and configured so a ball-bearing can be affixed to the protruding end. This generates cycles of tension and compression inside the structure, fatiguing the connector and leading to its final breakage. The lever between the polished portion of the implant and the point of force application is kept constant at 11.3 mm for all configurations tested.

that the five connector designs would respond equally under fatigue loading.

Materials and Methods

The rotating-beam principle was applied in the present experiment (Fig 1). The principle requires that a concentric arrangement be established between the longitudinal axis of the implant, the connector, and the ball-bearing. One end of the test specimen is clamped into a collet and rotated, while a perpendicular force vector (F) is applied to the other end via a ball-bearing. Then, the specimens are spun using a specially constructed machine, and the fatigue resistance of the connectors is expressed as the force level at which 50% of the specimens survive 10^6 load cycles without breakage and 50% fail (F_{50}).

To function as rotating beams, the connectors were configured as cylinders to which the ball-bearings carrying the loads were affixed. For intergroup comparisons, the lever length was kept constant for all connectors tested. Technical aspects of the machinery and ancillary controls were described in a previous report.¹⁹

Implant Analogs

The present study addressed connectors for the ITI implant system. More specifically, the standard 4.1-mm-diameter implant was selected as the common implant base. To this effect, implant analogs were machined to the specifications shown in Fig 2. While the external

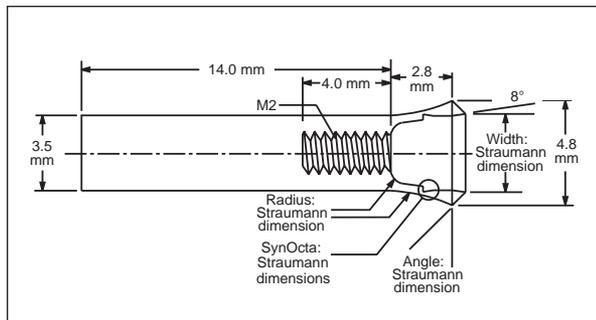
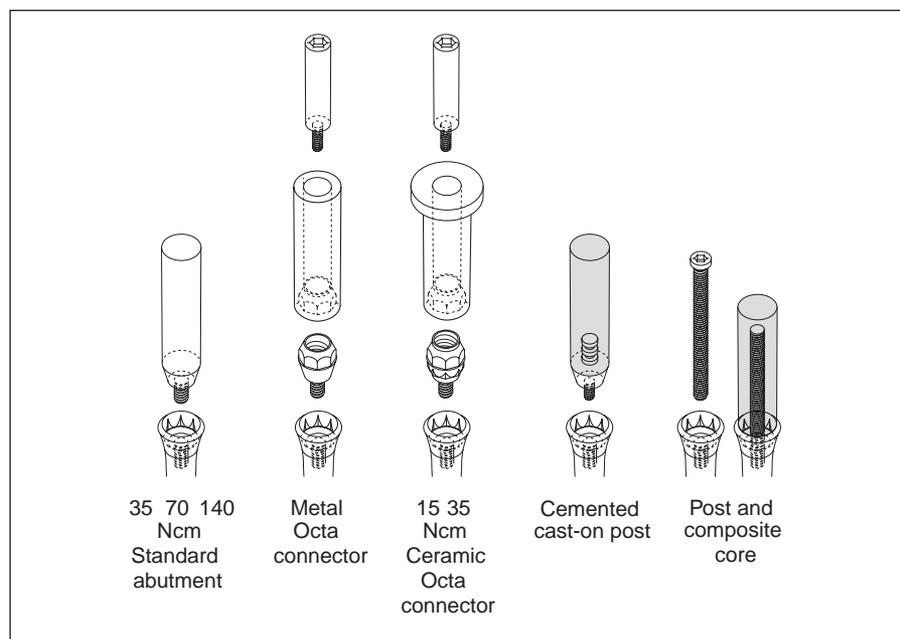


Fig 2 (left) Schematics of implant analog. A number of dimensions are proprietary information of the manufacturer; these were made into the specimens by Straumann.

Fig 3 (below) Connectors and abutment analogs used. To comply with the rotating-beam principle, abutments are configured as cylinders.



dimensions of the ITI implants are readily accessible, many particulars (tolerances, internal lengths, radii of internal angles) are proprietary information of the manufacturer. Therefore, the implant analogs were manufactured by Straumann with the mandate of adjusting the proprietary dimensions, machining techniques, and thermal treatments. Standard manufacturing procedures were applied, with two exceptions: (1) no external thread was machined into the implant corpus; and (2) no sandblasted and acid-etched coating (SLA, Straumann) was added to the surface. All implant analogs were provided with an internal SynOcta coupling (Straumann).

Preliminary tests had shown that the analogs should not be clamped directly into the metal collet. Under these conditions, the neck of the implants broke because of stress concentration at the implant-collet interface. Therefore, the implants were cushioned using a 1-mm-thick acetal sheath (Delrin 300AS, DuPont). The specimens were spun at 1,000 rpm (16.7 Hz) to a maximum of 10^6 load cycles.

Connectors

Five type of connectors were tested (Fig 3):

- *Standard abutment*: Standard ITI “screw-on” abutments (part No. 048.542) were duplicated as cylinders with a 16-degree cone and an M2 thread at one end. These components were machined of grade IV titanium. As some of the dimensions and manufacturing techniques are proprietary, the components were specifically fabricated by Straumann for the present project. In a first test group, the components were torqued to 35 Ncm, in a second group to 70 Ncm, and in a third group to 140 Ncm.
- *Metal Octa connector*: Octa components (part No. 048.404) were inserted into the implant and torqued to 35 Ncm. The corresponding abutments were fabricated by casting an Au-Pd alloy (Qualibond 2, Qualident) cylinder onto a prefabricated gold coping featuring an internal octagon (part No. 048.631).

Table 1 Example of Data Arrangement for Staircase Analysis (Cemented Cast-on Posts)*

| Applied force (N) | Load level (<i>l</i>) | No. of failures (<i>n_l</i>) | <i>in_l</i> | <i>l²n_l</i> |
|-------------------|-------------------------|--|-----------------------|-----------------------------------|
| 35 | 2 | 4 | 8 | 16 |
| 30 | 1 | 4 | 4 | 4 |
| 25 | 0 | 2 | 0 | 0 |

*With $n = \sum n_l$; $A = \sum in_l$; and $B = \sum l^2 n_l$.

The M2 screw that fastened the abutment analog was torqued to 35 Ncm.

- *Ceramic Octa connector*: The ceramic components were first machined of In-Ceram zirconium dioxide blanks (Vita) to specifications and then infiltrated using the proprietary Zirconia Glass Powder. These specimens were fabricated for this study by Straumann. At the outset, Octa components (part No. 048.602) were tightened to 35 Ncm onto the implant analog. Then, the M2 screws of a first group of ceramic components were tightened to 15 Ncm, and a second group to 35 Ncm, onto the Octa connectors.
- *Cemented cast-on post*: These connectors were based on cemented components (Cast-on Post, part No. 048.424) that were luted into the threaded openings of the implants. These components feature a 16-degree cone, an M1.6 thread that fits passively into the implant's M2 thread, and a stabilizing stud for the overcast metal. They are machined of nonoxidizing alloy (Au 60%, Pt 19%, Pd 20%, Ir 1%) with a melting range of 1,400 to 1,490°C. The cylindrical abutment analogs were cast onto the component using an Au-Pd alloy (Qualibond 2). For cementation into the implants, the abutment analogs were guided using a paralleling device that ensured colinearity between the implants and abutments.¹⁹ The connectors were cemented with a dual-cure composite cement (Variolink II, Ivoclar Vivadent).
- *Screw-retained composite core*: As a low-cost alternative to machined components, the experimental configuration shown on the right side of Fig 3 was tested. First, M2 stainless-steel screws were inserted into the implants and torqued to 35 Ncm. Then, the screw heads were cut, and composite cores (Luxacore, DMG) were built and polymerized around the screw using a transparent plastic mold. To avoid undue stress concentrations on the composite material during loading, the core was shielded against the ball-bearing using a Delrin sheath.

Analytic Procedure

The five connectors were evaluated with respect to their fatigue resistance at 10^6 cycles (the reasoning

behind this number has been reported elsewhere²⁰). The fatigue resistance (F_{50}) was defined as the force level (1 kg F \approx 10 N) at which 50% of the specimens survived 10^6 load applications and 50% failed. F_{50} was determined using a procedure originally designed for the analysis of "quantal" (ie, fail or not fail) data²¹ and referred to as the "staircase" or "up-and-down" method.²²⁻²⁴ The technique requires that a series of specimens be tested in sequence. At the outset of the trial, the first specimen is loaded to a level set according to the best estimate of the experimenter. After 10^6 cycles, the experimenter checks whether the specimen is intact (a "run-out") or whether it has broken. A new, fresh specimen is then cycled for another 10^6 cycles at a load decreased by 5 N if the first specimen failed or increased by 5 N if it ran out. The third specimen is again loaded depending on the outcome of the previous test, and so forth for all specimens in the series. This leads to a characteristic up-and-down pattern of run-outs and failures, hence the name staircase method.

The number of specimens in each series was dependent on the progress of the test. Indeed, seven of eight combinations developed a confined up-and-down pattern after 10 runs. In these instances, the number of specimens was limited to 10. In the cast-on post series, the tenth specimen broke the previously established confinement. Therefore, 10 additional runs were performed.

After the data were collected, they were tabulated as shown in Table 1. The analysis is always based on the least frequent event (failure or run-out). When F_0 (the lowest level at which failure occurred) was set to 25 N, F_{50} was calculated as:

$$F_0 + F_{incr} \left[\frac{A}{n} \pm \frac{1}{2} \right]$$

where + = test based on run-outs; and - = test based on failures; and the standard deviation (SD) was calculated as:

$$1.62 F_{incr} \left[\frac{nB - A^2}{n^2} + 0.029 \right] \quad \text{if} \quad \frac{nB - A^2}{n^2} \geq 0.3$$

and

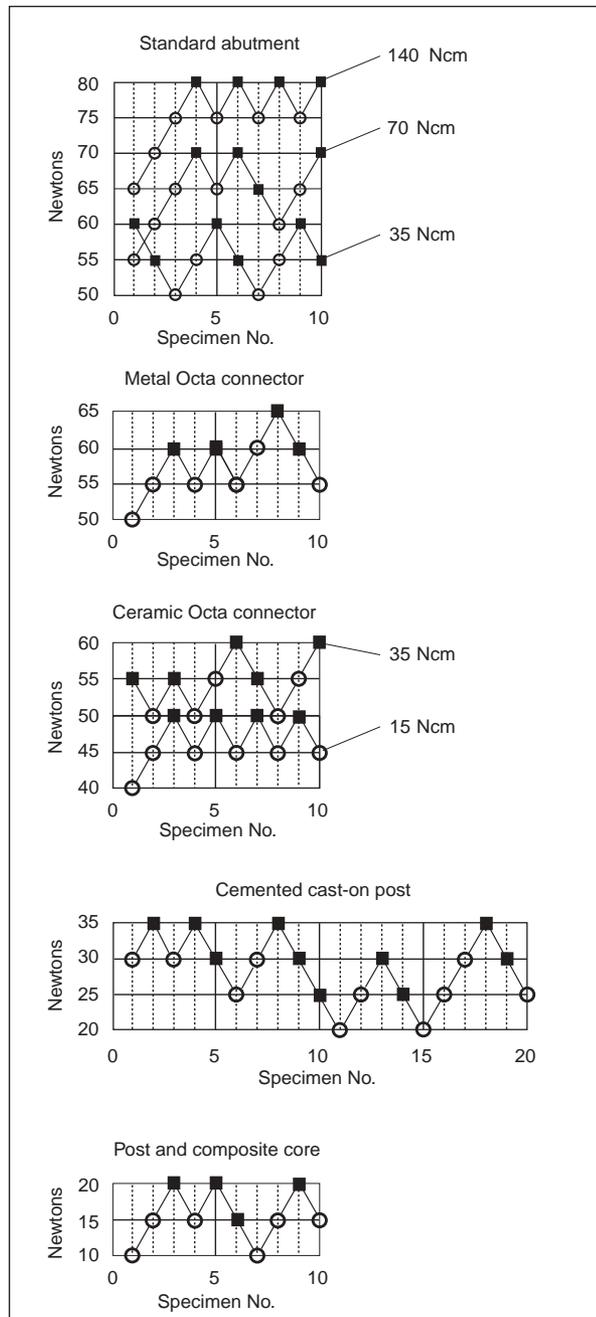


Fig 4 Staircase data for connectors investigated. The tenth specimen of the cemented cast-on post series escaped the previously established upper and lower confinements; therefore, an additional 10 specimens were tested.

$$1.53F_{incr} \quad \text{if} \quad \frac{nB - A^2}{n^2} < 0.3$$

where F_{50} = mean force level at which 50% of specimens ran out and 50% failed; F_0 = lowest load level at

which failure occurred; F_{incr} = chosen force in increments or decrements of 5 N; $n = \sum n_i$ (n_i = number of failures for each load level; Table 1); $A = \sum in_i$ (i = load level); and $B = \sum i^2 n_i$. In the present example (cemented cast-on posts), $F_{50} = 28.5$ N and $SD = 4.77$.

To determine significant differences, the mean failure loads were fitted with 95% confidence intervals (CI) according to the technique described by Collins.²⁵ Means with overlapping intervals were considered equivalent.

Results

The staircase data generated for each abutment combination are shown in Fig 4. The fatigue resistance of each connector combination expressed as the mean force level at which 50% of the samples survived 10^6 cycles and 50% failed (F_{50}) is shown in Fig 5, which also details each mean's 95% CI. All screw-retained connectors (ie, the all-metal as well as ceramic abutment analogs) tightened to 35 Ncm presented mean failure loads in the $57 \text{ N} \pm 5\%$ range. The resistance of the cemented cast-on posts was about 50% of the screw-retained connectors, and that of the experimental post and composite cores was about 30%. For both the standard abutment and the ceramic Octa connector, increasing torque increased the mean failure load. For the eight combinations tested, the standard abutment, metal Octa connector, and ceramic Octa connectors torqued to 35 Ncm presented overlapping CIs, indicating a lack of statistically significant difference.

None of the screws loosened during the experiment. All screwed connectors failed in the screw threads. For the standard abutments, failure occurred in the first thread at the cone base. For the Octa connectors, it was the screw that fastened the abutment analog that fractured. The cemented cast-on posts fractured at the insertion of the M1.6 screw into the cone base. The screw-retained composite cores failed by brittle fracture of the cores.

Discussion

The largest stress amplitude a material can sustain for an infinite number of cycles is termed its fatigue limit. The existence of such a fatigue limit has been demonstrated for steels, for which it can be extrapolated after 10^7 load cycles.²⁶ In most applications, however, the structure's life is limited and therefore characterized by a (conventional) endurance limit. This value is defined as the largest stress amplitude for which 50% of the specimens will sustain a predetermined number of load cycles. In this respect, the F_{50} parameter as determined in the present study may be considered the endurance limit of each connector combination. However, the connectors were characterized in terms of loads (ie, forces)

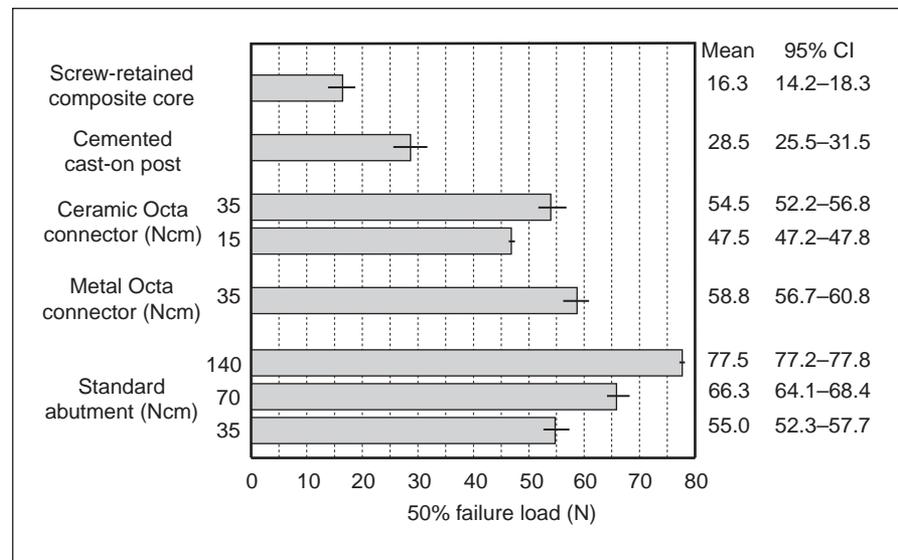


Fig 5 Fatigue resistance of connectors subjected to rotating-bending test \pm 95% confidence intervals (CI). Three groups emerge: (1) screwed connectors torqued to 35 Ncm; (2) cemented cast-on posts; and (3) experimental screw-retained composite core abutments.

sustained at 10^6 cycles. Because of the complex geometry of the specimens, these data could not be normalized to stress values (MPa) (as would be expected for a “true” endurance limit). Hence, the force values gathered are only valid within the present experimental configuration. To allow comparisons with future experimental groups, the tests on other connector systems that are in progress at this time are conducted while maintaining the geometric configuration constant.

Choosing an appropriate analytic procedure to determine a component’s fatigue resistance is a tricky issue. Indeed, both the precision of the results as well as the practicality of the test are to be considered.

Fatigue tests are classified into three regimens²⁷: (1) low-cycle fatigue, which spans the range between 1 and 10^4 cycles; (2) limited endurance, which spans fatigue lives between 10^4 and 10^7 cycles; and (3) unlimited endurance, that is, 10^7 cycles and above. While the unlimited endurance regimen essentially applies to industrial structures such as rotors and turbines, tests conducted in the limited endurance range do approximate the lifespan of clinical restorations and can be regarded as conclusive. Therefore, drawing full-range S-N diagrams²⁸ makes little sense for prosthodontic structures whose predictable lifetime is in the $10^6 - 2 \cdot 10^7$ cycles range,²⁰ in effect excluding both the low-cycle and unlimited endurance fatigue regimens. The same comment applies to Weibull distributions as proposed by Baran et al.²⁹

While the mean, SD, and CI derived from staircase procedures are codified, the number of specimens required is not. Pertinent results are obtained after some

reversals are observed in the test series, that is, the series stabilizes within an upper and lower boundary. Hence, the experimentalist needs to determine: (1) an appropriate increment or decrement (F_{incr} in the present study), and (2) the required number of reversals for the test to be considered complete. The choice of the increment or decrement is most delicate, since a small value will to some extent raise the accuracy level of the result but may unduly augment the number of specimens needed to satisfy criterion 2. In the authors’ estimate, the 5 N F_{incr} value chosen for the present study is somewhat on the crude side but still allows a clear distinction between the test groups while minimizing the number of specimens needed.

As applied, the staircase procedure assumes normality in data distribution, yet fatigue data are known to be skewed in their distribution, and normality is only established when the log of the data is plotted. Collins’s²⁵ and Hardenbergh’s³⁰ numeric treatment (as applied in the present analysis) does not adjust the data to their logarithms. Hence, a minor error was introduced into the computations of SDs and CIs.

One objection to the present experimental configuration (Fig 1) is that the connectors were subjected to forces normal to the longitudinal axis of the implant. Compressive or oblique forces were not considered. Our approach is justified insofar as a general consideration in structural design is that the resistance to compressive forces is 0.5 to 1.0 order of magnitude superior to the same material’s resistance in tension.³¹ Hence, the structural durability of a component is essentially jeopardized by tensile (and shear) forces

rather than compressive loading. Although the present experimental configuration ignores compressive forces, via the force parallelogram, it does account for the tensile component of oblique force systems.³²

Many authors have studied the strength of implant connectors by subjecting the connectors to univectorial load applications. This leads to rather strange deformations of the implant or abutment components,³²⁻³⁵ an observation that, to the authors' knowledge, is never made clinically. In the present experiment, whenever a screw was used to secure the connector, the connecting screws broke without observable bending or fissuring of either the implant or connector. The cemented cast-on posts failed after fracture of the cemented thread, which is also consistent with clinical observations. The screw-retained composite core restorations were purely experimental and have never been used clinically. The authors interpret the close correspondence between the failure modes observed in the present experiment and clinically observed fractures as an indication of the pertinence of the rotating cantilever beam principle.

In its present mode of operation, the experimental setup was unable to detect screw loosening. Whenever this occurrence preceded failure, it remained unnoticed. For connector combinations featuring preloaded screws, the joint always failed in the screws and possibly blurred an effect of the abutment. This applies especially to the ceramic abutment, as alterations in shape (such as decreasing the diameter or generating zones of stress concentrations) might have made the abutment fragile to the extent that fracturing would occur in the abutment and not in the connector screw. This may be the object of another study in which the shape and dimensions of the abutments would be investigated.

This study showed that the fatigue resistance of the screw-retained components was vastly superior to that of the cemented cast-on post and the experimental post and composite core designs. Furthermore, the screw-retained components tightened to 35 Ncm all failed at the same load. This is surprising in view of the heterogeneity in designs and materials. Indeed, the biconal connection of the standard abutment did not test stronger than either Octa combination. In the latter combinations, the mechanically weaker Octa connector was subjected to a reduced lever length (and fractured), while the mechanically stronger biconal implant-Octa connector was subjected to a longer lever (and withstood the applied fatigue loading). The magnitude of the stresses generated inside these structures, however, is unknown and must be investigated using numeric (ie, finite element) models.³⁶

The fatigue resistance of the screw-retained metal or ceramic connectors was markedly increased when the screw was preloaded to 70 Ncm and 140 Ncm. This

effect is known and can be explained via the joint diagram of bolted connectors.³⁷ Augmenting preload increases the static tension on the screw but simultaneously decreases the amplitude of the cyclic loads applied to it, thereby shielding the screw against fatigue failure. According to Norton,³⁸ the effect is not related to cold-welding phenomena between the abutment and implant as suggested earlier.³⁹ The increase in strength with increasing torque was also observed for the ceramic Octa connector. This is at variance with the findings of others, who could not evidence any difference between CeraOne and EsthetiCone connectors (Nobel Biocare) tightened to $\pm 20\%$ of the manufacturer's recommended preload value.¹⁸

The 140 Ncm torque value is somewhat theoretic and was selected to determine whether fatigue resistance would further increase with increasing torque. Although high removal torques were reported,⁴⁰ 140 Ncm may exceed the strength of the "average" bone-implant interface.⁴¹ Therefore, augmenting torque beyond 35 Ncm will augment the fatigue resistance of the connector, but may also jeopardize osseointegration while the abutment is tightened into the implant.

Preangled components were not evaluated here, but these components may also be subjected to rotation-bending tests. Obtaining concentricity for such specimens requires specific crown analogs that must be machined on a lathe.

Conclusion

This study demonstrated the superior resistance of preloaded screwed components relative to cemented or passively tightened connectors. The ceramic connectors resisted almost equally well to fatigue loading as the metal components. This finding is intriguing in view of the inherent brittleness and low fracture toughness of these materials.⁴² It should be remembered, though, that the specimens used herein were optimized as to their fabrication, and the same strength values may not apply to everyday laboratory procedures.

The null hypothesis of no difference between the five connector designs was rejected. Preloaded screwed components were twice as resistant as cemented cast-on abutments and three times as resistant as screw-retained composite buildups when subjected to multivectorial fatigue loading. For the screw-on connectors, augmenting preload (ie, torque) augmented the resistance to fatigue loading.

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