Implant dentistry has become an accepted therapeutic method to treat partial/complete edentulism worldwide. Success/survival rates of dental implants are high, resulting in favorable long-term results.1,2 The stability of peri-implant tissue is one of the most important prerequisites for the long-term success of implant dentistry. Soft tissue seals can affect soft tissue around implants. Micromobility between the surgical/prosthetic parts used in implant dentistry can lead to destruction of the soft tissue seal, potentially leading to microbial invasion.3

Peri-implantitis following microbial invasion may modify the implant surface, making re-ossosintegration extremely challenging.4 implant loss results in prosthetic reconstruction removal as well. A fresh new implant surface might improve the chance for re-ossosintegration. A new two-piece dental implant with a replaceable thin titanium sleeve was designed. The purpose was to renew the implant surface in order to improve the chances for re-ossosintegration.3 Regeneration procedures may be performed. The original restoration is restored. Peri-implant disease is treated without the need to replace the original prosthetic restoration.

Microcomputed tomography (micro-CT) is a relatively new modality to investigate mechanical deformations. The purpose of this study was to assess the microgap at the implant-sleeve connection of a new two-piece dental implant with a replaceable sleeve. Materials and Methods: Implants were assembled with 25-degree angulated abutments. Micro-CT was used to assess implant-sleeve connection gaps under the following mechanical conditions: (1) unloading; (2) compressive 10,000 cyclic loading with 400 N; (3) static compressive load of 200 N or 400 N for 24 hours. Results: The mean gap in the unloaded sample was 2.9 ± 0.9 μm. The mean gap difference after cyclic compressive load was 0.3 ± 0.15 μm, demonstrating a negligible effect for the cyclic loading. Under static compressive load, there was no increase in microgap size at 200 N. At 400 N, a significant (P < .05) increase was noted. While the mean values increased by 1.9 μm, the most pronounced significant increase in mean microgap was noted in the direction of force application (5.1 ± 2.14 μm), while a significant decrease in mean microgap (1.2 ± 1.47 μm) was noted on the opposite side. Conclusion: The mechanical behavior of the implant-sleeve connection under static and dynamic loads was found to be within the previously reported range of implant dentistry. Int J Oral Maxillofac Implants 2021;36:451–459. doi: 10.11607/jomi.8563

Keywords: cyclic loading, dental implant, micro-CT, microgap, static loading
angle, power source, and filter thickness) are standardized. The obtained images are processed by dedicated reconstruction software, making it possible to observe any internal and external components. Through the sequential analysis of axial sections, the microgap (a thin circular radiolucency) between the two near surfaces may be measured. Consequently, the resolution of the micro-CT device used is critical and may otherwise limit accurate gap measurement.

The aim of the present in vitro study was to characterize the mechanical behavior of the implant-sleeve connection with x-ray 3D microtomography, under static and dynamic loads.

**MATERIALS AND METHODS**

**Dental Implant Description**

New Generation Implant (NGI) 100 (Implant-B, NGT) is composed of two modules: an implant body, which resembles a regular implant, and a thin titanium sleeve (Fig 1). The implant and the sleeve are preassembled during manufacturing in a configuration identical to a regular implant (Fig 2).

**Sleeve**

The sleeve is cylindrical on the outside with a hexagon at the top of it. The outer dimensions of the sleeve are 4.4 mm in length with a diameter of 4.2 mm. The sleeve wall thickness is approximately 0.2 mm. The outer surface is sandblasted and acid-etched. The inner side of the sleeve is a machined cone without any surface treatment. The potential treatment sequence is described in Fig 3. The implant is inserted similarly to standard implants. When peri-implant disease occurs and intervention is required, the restoration is removed. A specific extractor is used to remove the sleeve. Mechanical, biologic, or biochemical cleaning of the bone and soft tissue is performed. A fresh, noncontaminated, new desired sleeve replaces the extracted contaminated one, without requiring full replacement of the implant and the prosthetic parts it supports. The sleeve is intended to be used for bone regeneration following vertical bony deficiencies of 4 to 6 mm. Theoretically, such a sleeve could be used endlessly. Practically, no more than one to two renewals through an implant’s lifetime are expected, according to the progression of peri-implant disease.
Sample Mounting
NGI 100 4.2-mm-diameter, 13-mm-length implants were tested (Fig 4a). Implants were embedded into Teflon holders (Fig 4b). Angulated 25-degree straight abutments, EI-7025 (ETGAR), were attached to the implants. The entire implant-abutment assembly was mounted onto the Deben Microtest CT5000-TEC mechanical testing stage (Fig 4c).

Groups and Number of Implants
Twelve implants were used in the study. Each implant was subjected to different tests. The types of measurements conducted on each of the 12 implants are described in Table 1. I1 to I12 is the implant’s number; 0 N = measurement prior to any loading; 200 N or 400 N = measurements at a static load of 200 or 400 N; ac1K400, ac3K400, ac10K200 = the measurements conducted after the cyclic loading of 1,000, 3,000, and 10,000 cycles with 400 or 200-N compression force, respectively.

**Table 1** Grouping of Measurements Conducted on 12 Implants

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X-ray Microtomography
X-ray tomography was collected using Zeiss Xradia 520 Versa 3D X-ray microscope at 150 keV, 10 W voltage, and power at the x-ray source. The implant-abutment assembly fixed on the in situ mechanical testing setup was mounted on a sample rotation stage of the x-ray microscope, enabling collection of x-ray transmission images at a range of sample orientations around a vertical rotation axis (Fig 4d). These x-ray projections were
converted into visible light by a scintillator screen and captured onto a CCD camera, either directly or after a magnification with an objective lens. The recorded projection images had pixel dimensions of 1,024 × 1,024 in overview scans or 2,048 × 2,048 in scans of the entire sleeve area.

Overview tomographic scans, which cover the entire sample mounted onto the in situ test stage, were recorded in 401 projections with 43-μm pixel size using a 0.4× objective. Tomographic scans of the entire sleeve of 4.2-mm diameter were recorded using a 4× objective and consisted of 801 projections with 2.145-μm pixel size translating into 4.4 × 4.4-mm field of view. Single x-ray projections of areas 1 to 4 (Figs 4 and 5) were recorded with 20× objective at 0.418-μm pixel size, corresponding to approximately half of the nominal resolution limit, 0.9 μm, for the given objective lens.

All tomographic projections were collected over the sample orientation range spanning 360 degrees in order to minimize beam-hardening artifacts. These projection series were then reconstructed into 3D tomographic maps by a filtered back-projection algorithm implemented in the microscope control software.

The influence of the compression force moment was assessed as follows. A typical implant, embedded in a Teflon holder with a 25-degree angulated abutment mounted to its top, is shown in Fig 5a. A compressive load was applied between the Teflon holder and the tip of the abutment. Due to a bending moment, created by the compression force applied to the angulated abutment in a loaded implant, which was maximal in the plane formed by the axis of symmetry of the implant and the tip of the abutment, it was reasonably assumed that maximum displacement occurs in the same implant-abutment plane (Fig 5b). Overview tomographic scans provided 3D images of implants mounted on the in situ mechanical test stage, enabling precise measurement of the implant-abutment plane orientation relative to the detector plane, represented by angle φ on a schematic drawing in Fig 5c. Consequently, the sample stage was rotated by the amount –φ, thereby bringing...
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the implant-abutment plane parallel to the detector plane. This enabled measurement of the implant-sleeve gaps in the maximum displacement plane from single x-ray projections (Fig 5d).

Implant-sleeve gaps were measured under the following mechanical conditions: (1) unloaded sample; (2) after compressive 1,000 cyclic loading with 400 N (Fig 6); (3) after static compressive load of 200 N or 400 N for 24 hours, during which the compression force was kept constant.

Gap Width Measurement from Single Projections

Coaxial cylinder geometry in implant areas 1 to 4, where the outer cylinder is the sleeve and the inner cylinder is the implant, enables gap width measurement from single projections (Fig 7a). The implant-sleeve gap is schematically represented by the gap between the cylinders. A simulated x-ray projection and its intensity profile generated by transmission of radiographs through such geometry are shown in Fig 7b. The gap widths between the cylinders are equal to the distance between the local minimum and the maximum in the intensity profile as shown in Figs 7c and 7d.

Software

Gap width measurements from single projections were made in ImageJ software (National Institutes of Health). Programs for simulation of single projection measurements shown in Fig 7 and result analysis were written in MATLAB (MathWorks). Tomographic virtual cuts and 3D volume rendering were made in Avizo 9.4 (Thermo Fisher Scientific).

Statistical Analysis

The Student t test was used to evaluate differences between loaded and nonloaded groups. The independent variable was loading, and the dependent variable was the microgap. The results were considered significant if P was < .05.
Gaps in areas 1 to 4 in nine unloaded implants ranged from 2 to 7.8 μm with a mean of 2.9 ± 0.9 μm (Fig 8a). Per implant sleeve area (Fig 8b), the microgap mean values were 2.9 ± 0.8 μm, 2.6 ± 0.5 μm, 2.6 ± 0.4 μm, and 3.3 ± 1.5 μm for areas 1, 2, 3, and 4, respectively. The larger mean microgap in area 4 may be attributed to an exceptionally large microgap of 7.8 μm measured in implant 4.

Eleven implants were subjected to at least 1,000 cycles, 30 seconds each, of 400-N compression load (Fig 8c). The mean ± SD gap width calculated over all measurements and per area are given in Table 2. Microgap differences before and after cyclic loading were negligible with a mean microgap of 0.3 ± 0.15 μm, demonstrating a negligible effect for the cyclic loading. Similarly, the microgap differences between the four tested areas were negligible, demonstrating no side preference for increased microgap, despite the use of a 25-degree abutment.

**RESULTS**

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Five implants were subject to a static compression loading of 200 N or 400 N over 24 hours, during which the compression force was kept constant.

Areas 1 to 4 of each sample were labeled consistently with the orientation of the abutment, such that the abutment tip was always located on the side of areas 3 and 4, as shown in Figs 4 and 5. According to this geometry, the gaps in areas 1 to 4 experienced an uneven horizontal component of the applied force, resulting in a wider distribution of the gap width changes (Fig 6).

The mean gap widths before and during the static loading of 200 N and 400 N are given in Table 3. At 200-N loading, there was no increase in microgap size compared with unloaded implants. The values were the same regardless of the area involved. At 400-N loading, a significant ($P < .05$) increase was noted in the mean microgap size compared with unloading. While the mean values increased by 1.9 µm, the most pronounced significant increase in mean microgap was noted in area 1 ($5.1 ± 2.14$ µm), while area 4 displayed a significant decrease in mean microgap ($1.2 ± 1.47$ µm).

As expected, the gaps in areas 1 and 2 experienced larger widening compared with areas 3 and 4, with the mean gap width in area 4 even narrowed by 1.2 µm.

## DISCUSSION

In this study, in vitro tests using cyclic (1,000 cycles) and static (200 N and 400 N for 24 hours) loading and micro-CT were conducted to assess microgaps along the implant-sleeve interface of a novel implant design NGI 100. This implant comprises a 0.2 cm² renewable surface assembled with a press-fit 4.2-mm-length conical connection. The load was applied using a 25-degree abutment, connected to the implant via an internal hexagonal connection.

Several study limitations were encountered. The cyclic loading experiment was conducted under limiting conditions of the loading mechanical test stage available with the micro-CT system. Specifically, the test stage was not designed for fast compression experiments, limiting the loading period to a minimum 30 seconds/cycle. As a result, unfortunately, it has not been possible to conduct this study according to the ISO14801:2016 standard.

Due to the mechanical stage limitations, the cyclic frequency was $1/30 = 0.033$ Hz. The sample was clamped between two metal plates as with the bottom of the Teflon holder in direct contact with the compression plate.

Due to limited time on the micro-CT system and long CT scan times (approximately 24 hours/scan), it was not possible to conduct entire CT scans for gap measurement of all 12 samples with a sufficient signal-to-noise ratio without degrading the spatial resolution. Therefore, the present study resorted to measurements of gaps from single long-exposure raw projections (radiographs), not slices from reconstructed tomograms, as depicted in Figs 5 and 7 and described in the Gap Width Measurement from Single Projections section of Materials and Methods. This approach was possible due to the coaxial composition of the imaged implant area, as shown schematically in Fig 7. This approach allowed the authors to reduce the measurement time per sample dramatically, enabling measurement of 12 samples.

The spatial resolution of the micro-CT system (ZEISS Xradia 520 Versa; analysis of raw projection images was done in ImageJ [National Institutes of Health] and with custom written software in MATLAB) with the selected objective lens is approximately 0.9 µm, as stated in the Materials and Methods section, which is one-third or less of the gaps measured (with an exception of a single gap measured at 2.5 µm). The range values given in the tables are the standard deviations of the measured values in implants as specified in Table 2.

Temperatures of the sample stage as well as the ambient temperatures within the micro-CT chamber were provided by the micro-CT system and automatically recorded with each projection. The reported temperatures ranged between 29.9°C and 30.5°C.

One of the factors contributing to the development of peri-implant mucositis and peri-implantitis may be the penetration of bacterial colonies and products into the peri-implant surroundings from the implant-abutment connection, compromising the long-term survival of implants. Implant manufacturers have since pursued decreasing the amount of bacterial microleakage, whenever

### Table 3  Gap Widths Measured in 5 Implants Before and During Static Compression Loading of 400 N at the End of the Extended Compression Period

<table>
<thead>
<tr>
<th>Measurement</th>
<th>All areas (µm)</th>
<th>Area 1 (µm)</th>
<th>Area 2 (µm)</th>
<th>Area 3 (µm)</th>
<th>Area 4 (µm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 N</td>
<td>2.9 ± 0.9</td>
<td>3.3 ± 1.0</td>
<td>2.9 ± 0.6</td>
<td>2.3 ± 0.3</td>
<td>4.0 ± 2.2</td>
</tr>
<tr>
<td>200 N</td>
<td>2.9 ± 0.3</td>
<td>3.1 ± 0.2</td>
<td>2.9 ± 0.5</td>
<td>2.9 ± 0.4</td>
<td>3.0 ± 0.1</td>
</tr>
<tr>
<td>400 N</td>
<td>4.8 ± 3.2</td>
<td>8.4 ± 4.1</td>
<td>5.2 ± 2.7</td>
<td>2.8 ± 0.3</td>
<td>2.8 ± 0.5</td>
</tr>
<tr>
<td>Difference (400 N – 0 N)</td>
<td>1.9 ± 1.03</td>
<td>5.1 ± 2.14</td>
<td>2.3 ± 1.37</td>
<td>0.5 ± 0.21</td>
<td>1.2 ± 1.47</td>
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</table>
introducing novel implant systems, by minimizing the implant-abutment connection microgap, hoping to maximize peri-implant bone stability. Minimum microgaps may prevent oral fluids from reaching the inner part of the implant-sleeve connection. Such oral fluids could carry bacteria and small molecules in the implant-sleeve interface, which may serve as a reservoir, endangering the health of the peri-implant sulcus, or may further advance apically beyond the implant-sleeve connection directly into the bone, jeopardizing osseointegration, or inside the implant, as found by some in vivo studies for implant-abutment connections.

Within the range of cyclic and static loads tested in the present study, the maximum mean gap size was 4.8 ± 3.2 µm, which may not be large enough for the invasion of bacteria, the size of which can reach 6 µm. Previous studies demonstrated that implant-abutment connections are smaller with conical connections vs nonconical connections. Moreover, conical connections resisted mechanical deformation and bacterial invasion in a superior way to nonconical connections. The numerical results in the present study are in accordance with these previous studies. The small implant-sleeve connection microgaps in all four tested areas may be attributed to the 4.2-mm-long larger taper-shaped contact area in the implant-sleeve connection.

In the incisor region of the participating subjects, the mean occlusal force was found to be approximately 193 N, and the mean occlusal force in the molar region was 350 N. For patients with implant-supported prostheses, the mean occlusal force value was 188 N and 323 N in the incisor and molar regions, respectively. This is the reason for choosing 200 N and 400 N as load forces in the present study. While almost no changes are noted when a force of 200 N is applied, mean microgaps of less than the size of large bacteria are noted even when 400-N force load is applied. Due to the small microgaps obtained in the present study, it can be presumed that the implant-sleeve connection of the novel implant may withstand the mechanical deformations following application of participating subjects using implant-supported prostheses.

There is a lack of standardization concerning the fit between implant system parts (e.g., implant-abutment connection). Consequently, comparisons between studies are extremely limited. Cross-sectional measurement is the most popular. The acceptable vertical microgap of the implant-abutment connection is still missing. A vertical misfit of 4 to 10 µm was found between machined titanium abutments and implants. The use of four areas in the present study allowed insight into the horizontal discrepancies at different height levels. It demonstrated that when angulated abutments are used, the microgap will decrease in the angulated direction while it will increase in the opposite area, as the horizontal microgap is measured more apically. Thus, the greater amount of load increases the gap width. Similarly, application of force at different regions results in different gap widths due to moment variations related to different distances from the center of force applied.

Future investigations will need to provide better information, not only about horizontal and vertical microgaps per se, but also about horizontal and/or vertical microgaps as a function of the angle in which force is applied. This is definitely one of the variables influencing the microgap.

As demonstrated in the present study, x-ray microtomography is efficient and may turn out to be one of the best tools for the detection of microgaps between implant parts with either the implant-sleeve connection or implant-abutment connection. Compared with other methods investigating microgaps, it allows 3D image evaluations in a noninvasive and nondestructive technique. Several limitations have to be considered. In the present study, long x-ray tomography acquisition times (several hours per tomogram) limited the number of samples that could be scanned. Another significant limitation is the period of a single cycle during the cyclic loading. The mechanical test setup used in the experiment was not designed for fast compression experiments, limiting the loading period to a minimum 30 seconds/cycle. Hence, this study has been limited to a maximum 10,000 cycles.

It can be speculated that a fresh new surface replacing a contaminated implant surface may be a new treatment approach for peri-implantitis that may allow re-osseointegration. A new two-piece dental implant might solve peri-implant disease by removing the contaminated surface, enabling re-osseointegration, and ensuring long-term stability of the implant without endangering the prosthetic reconstruction. Since the first rule of medicine is “primum non nocere,” the present study demonstrates that the microgap in such an implant design does not impose the hazard of increased plaque accumulation, so instead of solving peri-implant disease, it might initiate it. Future studies will hopefully demonstrate efficiency in re-osseointegration.

**CONCLUSIONS**

Within the limitations of this study, the mechanical behavior of the implant-sleeve connection under static and dynamic loads was found to be within the acceptable range of the implant-abutment connection. Bacterial plaque accumulation may be prevented. The load and its direction affect the gap.
ACKNOWLEDGMENTS

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REFERENCES


