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Removal Torque of Immediately Loaded Transitional Endosseous Implants in Human Subjects

Harel Simon, DMD[1]/Angelo A. Caputo, PhD[2]

Purpose: *Transitional implants were designed to support provisional restorations and to allow for load-free osseointegration of conventional implants while a patient was provided with immediate esthetics and function. The purpose of this study was to evaluate the removal torque values of immediately loaded transitional implants in human subjects.* ***Materials and Methods:*** *Thirty-one 1.8-mm-diameter transitional implants were placed in 4 patients to support provisional restorations and were subjected to immediate loading. Removal torque values were recorded using a modified ITI torque driver, which was calibrated on an Instron test machine. Torque values were subjected to analysis of variance and post hoc comparisons of means (P < .05).* ***Results:*** *Twenty-six implants were removed intact with torque values between 10.5 and 22.9 Ncm, while 5 fractured at the bone crest at values between 27.1 and 35.4 Ncm. Mean torque values increased with time in function. These values were significantly lower in the maxilla (16.1 ± 4.8 Ncm) than in the mandible (24.0 ± 7.3 Ncm).* ***Discussion:*** *Results suggest that these transitional implants may be safely removed from the maxilla after 7 to 15 months, but there is a risk of implant fracture during removal from the mandible after 10 months.* ***Conclusion:*** *Removal torque levels for these implants indicate varying degrees of integration even though they were subjected to immediate loading.* (INT J ORAL MAXILLOFAC IMPLANTS 2002;17:839–845)

Key words: *dental implants, failure torque, immediate loading, osseointegration, removal torque, transitional implants*

The introduction of transitional endosseous implants provided the option of immediate fixed provisionalization for implant patients rather than immediate removable dentures. Transitional implants are narrow-diameter implants that are placed temporarily to support provisional restorations. They are placed in a non-submerged fashion in a single-stage surgery and are designed to be immediately loaded. Typically, transitional implants are placed between conventional implants and allow for their load-free osseointegration, while the patient is provided with immediate esthetics and function.[1] The transitional implants usually are removed with a manual tool at the end of the provisionalization period. The conventional implants are then restored employing the usual techniques according to the preliminary treatment plan. Transitional implants generally are made of commercially pure titanium or titanium alloy and are designed as 1-piece implants composed of root and crown replacement segments. These implants have a self-threading tapered screw design with diameter of 1.8 to 2.4 mm and embedment length between 7 and 14 mm.

The literature regarding transitional implants consists mainly of case reports[1–8] and animal histologic studies.[9] These studies have demonstrated the osseointegration of transitional implants with various degrees of bone-to-implant contact.[4,5,9] Questions remain as to the strength of that osseointegration and whether such implants can be removed easily and safely from a patient's mouth.

[1]Resident, Advanced Prosthodontics, UCLA School of Dentistry, Los Angeles, California.
[2]Professor and Chairman, Biomaterials Science Section, Division of Advanced Prosthodontics, Biomaterials, and Hospital Dentistry, UCLA School of Dentistry, Los Angeles, California.

Reprint requests: Dr Harel Simon, 1400 Midvale Ave #101, Los Angeles, CA 90024. Fax: +310-479-2972. E-mail: sims1@hotmail.com

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Fig 1 A 21-mm, 1-piece transitional implant, with a 14-mm threaded portion for implantation into bone and a 7-mm prosthetic extension to support the restoration.

A removal torque test was suggested as a means to evaluate the strength of osseointegration of conventional implants.[10] Removal torque studies have been performed mainly on animals, predominantly the tibiae and femurs of rabbits.[10–16] Few studies have examined intraoral sites in animal models, such as the baboon,[17,18] dog,[19] and miniature pigs.[20,21] Human studies of removal torque for conventional implants are very rare. One such study by Tjellström and coworkers[22] reported the removal of 9 non-loaded titanium craniofacial implants from the mastoid process of a human volunteer. The only reported human intraoral removal torque study to date was performed by Sullivan and associates, who measured the removal torque of 2 non-loaded conventional implants in a human volunteer.[23] No data have been reported regarding the removal torque of implants subjected to any type of loading, whether delayed or immediate loading.

Further, no human or animal studies are available regarding the torque required to remove transitional implants. The purpose of this investigation was to evaluate the removal torque value of immediately loaded transitional implants in human subjects.

MATERIALS AND METHODS

Study Population

The implants used in this study were commercially pure titanium 1.8-mm-diameter screws with tapered ends (Modular Transitional Implants, Dentatus USA, New York, NY). These 1-piece implants are available in 7-, 10-, and 14-mm lengths for implantation, each with a 7-mm prosthetic extension (Fig 1).

The study population was composed of 4 patients varying in age from 45 to 74 years who were undergoing prosthodontic reconstruction with implants. Transitional implants had been in place and subjected to immediate loading by means of partial- or full-arch provisional restorations for periods of 7 to 15 months prior to removal. Thirty-one transitional implants, with embedment lengths of 10 mm (n = 17) and 14 mm (n = 14), that were considered to be clinically integrated were included (Table 1). The implants were placed according to the manufacturer's instructions in the anterior and posterior regions of the maxilla, mandible, or both arches of the patients. All the restorations were in occlusion from the day of implant placement. The occlusal scheme developed was mutually protected articulation. All implants were clinically stable prior to removal, in the sense that they could not be moved with reasonable manual force.

Torque Device Calibration

The torque-measuring device used was a manual implant torque driver (ITI Straumann, Waltham, MA). A scale with 0.5-mm gradations and a plastic stopper were added to the device for precise readings and to facilitate intraoral recording (Fig 2). The torque device was calibrated on an Instron test machine (Canton, MA) using a miniature lathe to transfer rotation generated by the torque driver to the pulley of the lathe, which was connected by a cable to the load cell of the Instron machine. Torque applied by the driver was converted to force units measured by the test machine load cell. Calibration was made under 4.3× magnification (Carl Zeiss, Thornwood, NY), and the device demonstrated a resolution of ± 1 Ncm. The calibration was performed 3 times to construct a curve and assure reproducibility and was confirmed between patient intraoral removals. The test setup was evaluated for the effects of inertia and internal friction; when placed in tension at crosshead speeds of 0.05, 5, and 20 inches/minute, maximum torque values of 0.25 Ncm were observed.

Removal Torque Measurement

The transitional implants were removed from each patient, after completion of second-stage surgery for the conventional implants, under local anesthesia using the torque device (Fig 3). The timing of removal was dictated by the patient's treatment plan. To decrease bias in the data recording procedure, all removals and torque measurements were performed by one operator, who was not aware of implant lengths or time in function until the completion of each procedure.

Torque values were recorded intraorally using 4.3× magnification loupes and were verified extraorally with the stopper on the scale. Millimeter values from the scale were converted to Ncm using the calibration curve (Fig 4).

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Table 1 No. and Distribution of Implants

	Implant embedment length			Arch		
Patient	10 mm	14 mm	Total	Maxilla	Mandible	Total
1	0	4	4	4	0	4
2	2	2	4	4	0	4
3	3	2	5	0	5	5
4	12	6	18	10	8	18
Total	17	14	31	18	13	31

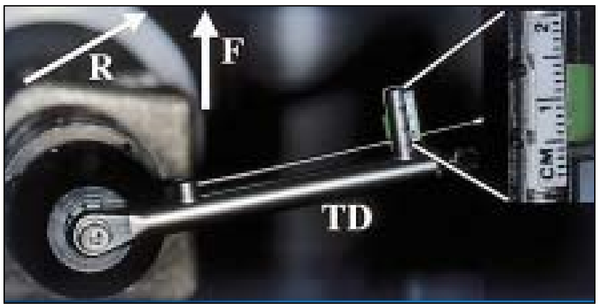

Fig 2 Calibration of torque device. Rotation generated by the torque device (TD) is transferred to the pulley of the lathe (radius R), which is connected by cable to the load cell of the Instron machine (F). A 0.5-mm gradation scale and a stopper were included to facilitate intraoral recording *(inset).*

Fig 3 *(Right)* Removal of implants using torque device.

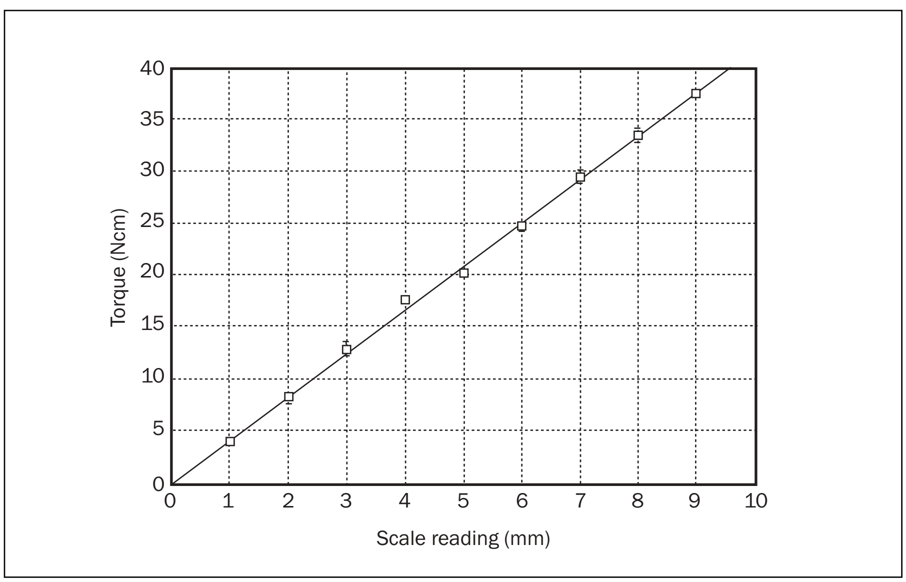

Fig 4 Calibration curve. The device demonstrated a linear relationship between the scale reading and measured torque.

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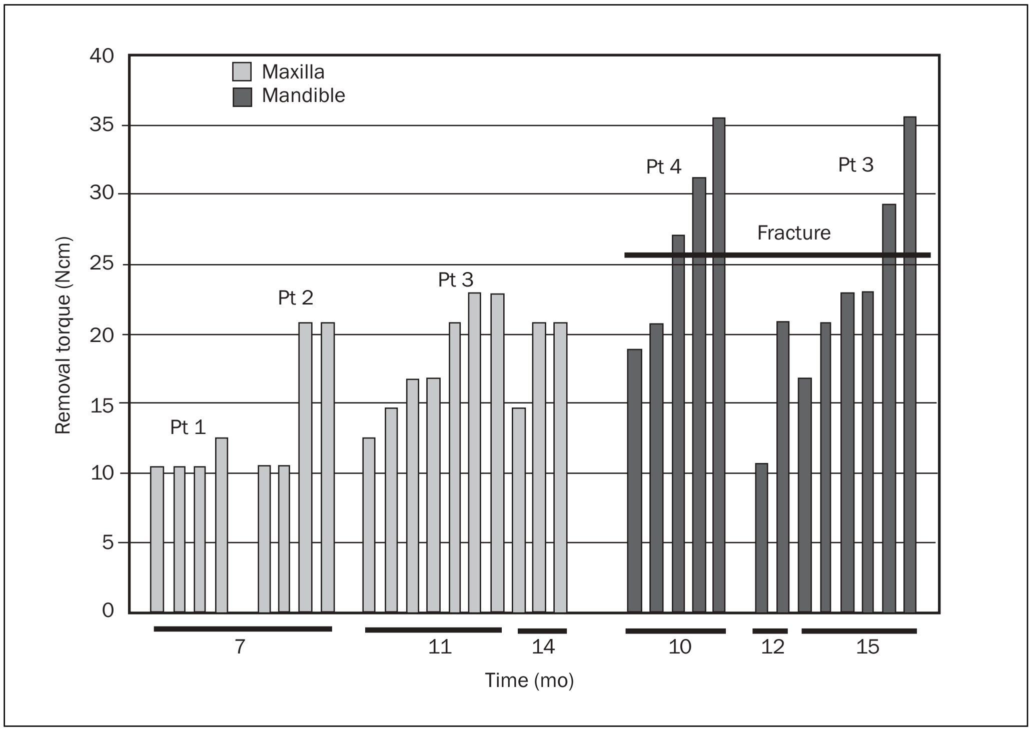

Fig 5 Distribution of mean removal torque values.

Removal of implants was completed with a manual key. At the end of the procedure, each patient was provided with a new provisional restoration supported by the conventional implants.

Statistics

The removal torque values were subjected to analysis of variance (ANOVA). Post hoc comparisons of means were performed using *t* tests, with *P* values adjusted for multiple comparisons (Bonferroni method). Significance levels were set at $P < .05$.

RESULTS

A summary of the torque values recorded in each arch of each patient at any period of time is presented in Fig 5. The recorded torque values were between 10 and 35 Ncm, with a mean of 19 ± 7 Ncm. Twenty-six of the transitional implants were removed intact, with torque values between 10.5 and 22.9 Ncm (Figs 6a to 6c). Five implants fractured upon removal in 2 patients (Fig 6d). The torque values for these implants were the highest recorded: between 27 and 35 Ncm. Fractures occurred only in the mandible and after 10 months or more in function.

ANOVA showed that there were no significant differences in removal torque as a function of location in either the mandible or the maxilla. Further, implant length was not a significant determinant of removal torque. However, mean torque values were significantly lower in the maxilla (16.1 ± 4.8 Ncm) compared to the mandible (24.0 ± 7.3 Ncm) (Fig 7). With respect to length of time in function, maxillary torque values at 7 months (13.3 ± 3.8 Ncm) were significantly lower than at 11 to 14 months (18.3 ± 4.7 Ncm). No significant differences were seen between the implants that functioned for 11 months and those that were in function for 14 months (Fig 8). A short-term group of implants (ie, 7 months) was not available for the mandible. However, no significant difference existed between the 10-, 12-, and 15-month periods (Fig 8). A scatter plot of the data is presented in Fig 9.

DISCUSSION

The specific torque-measuring device used in this study (ITI Straumann) is an intraoral device, which was selected because of its properties established by Standlee and associates.[24] That study demonstrated that torque levels of the device were within 10% of target values regardless of usage history of the device. The measured torque values varied linearly along the superimposed scale and were easily

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Figs 6a to 6c Post-removal appearance of implants.

Fig 6a Intact implant.

Fig 6b Deformed implant.

Fig 6c Bone attached to threads.

Fig 6d Fractured implant.

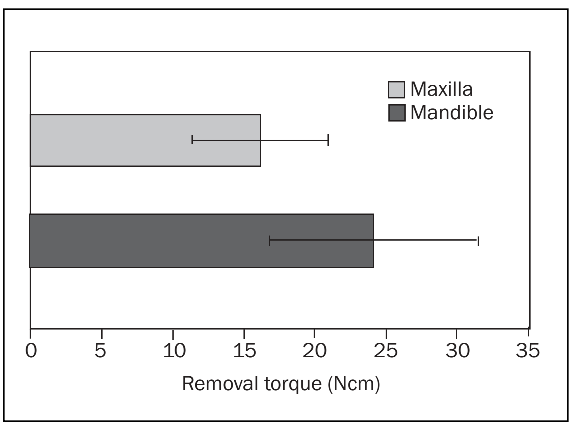

Fig 7 Removal torque distribution by arch.

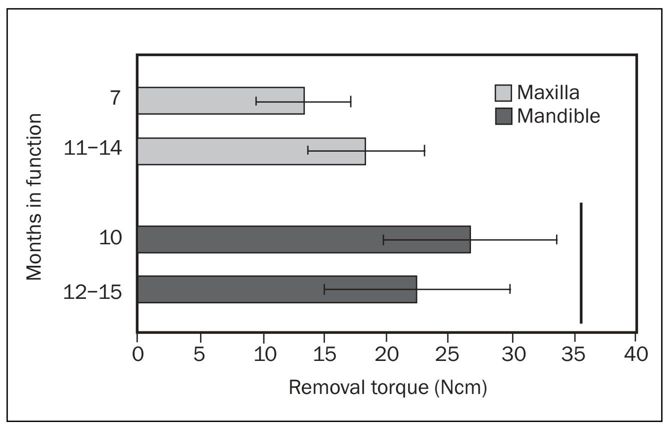

Fig 8 Removal torque distribution according to time in function.

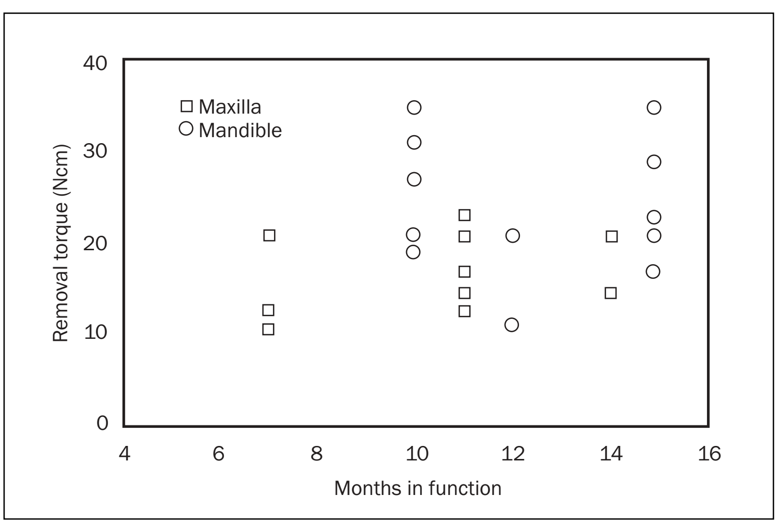

Fig 9 Scatter plot of the removal torque data.

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recorded in the current investigation with the aid of a plastic stopper. These attributes rendered the device clinically suitable for accurate measurements of removal torque in this study.

It has been shown histologically that transitional implants can become osseointegrated.[4,5,9] In the present study, 55% of the implants demonstrated torque values above 20 Ncm. These narrow-diameter implants would be considered successful according to the 20-Ncm reverse-torque test of Sullivan and coworkers used to evaluate the osseointegration of conventional implants.[23] If such transitional implants were to be utilized for longer-term applications, such as anchorage for orthodontic purposes, a similar test would have to accommodate the narrow diameter. A lower value as a criterion for osseointegration may be expected based on the findings of Ivanoff and associates that removal torque decreases with decreasing implant diameter.[25] According to results of the present study, the minimum torque required to remove a clinically successful transitional implant 7 months after placement was 10.5 Ncm.

A considerable number of implants placed in the mandible and implants that were in function for longer periods demonstrated torque values above the 20-Ncm level. Removal torque values of 20 Ncm may be beyond the maximum torque that can be produced manually with 5 different screwdrivers, as shown by Gross and coworkers.[26] Therefore, these implants may require additional instrumentation for removal. Careful use of a hemostat or a similar instrument could provide the proper lever arm to apply adequate torque for removal of these implants.

This investigation showed significantly higher removal torque levels in the mandible than in the maxilla for the transitional implants evaluated. These findings are consistent with those of Carr and coworkers, who demonstrated the same tendency for non-loaded implants placed in mandibles of baboons versus those placed in their maxillae.[17] Removal torque was also shown to be correlated to cortical bone thickness in a cadaver study performed on extraoral bone.[27] A possible explanation may be that the quality of bone in the mandible—a combination of cortical bone and dense cancellous bone—is better than that of the maxilla.[28] A radiographic study in humans demonstrated better bone quality in the mandible compared to the maxilla.[29] Consequently, the difference in removal torque between the arches seen in the present study may be explained by the difference in bone quality between the maxilla and mandible.

Implant fractures occurred in this study only at high torque values in the mandible, indicating that fracture was the result of strong integration rather than inherent weakness of the implants. Removal torque values of these implants would have been higher had the implants remained intact. These higher values would have resulted in higher mean torque for the mandible and a larger difference between arches.

Increasing implant embedment length should theoretically increase the torque value because of a larger surface area in contact with bone. However, the previously mentioned cadaver study demonstrated no significant correlation between removal torque and implant embedment length.[27] The current investigation is in agreement with these findings, suggesting that other factors play a more important role in removal torque levels compared to implant length.

Speculation exists as to the relationship between insertion torque of implants into bone and the subsequent removal torque levels.[21,30,31] The relationship between insertion and removal torques for the transitional implants evaluated in this investigation is not known. However, it should be noted that the implants were placed in accordance with the manufacturer's protocol, which currently does not specify insertion torque level. Since insertion torque was not measured, its effect on the results of this study is not known.

The results of this study are consistent with those of Johansson and associates, who demonstrated increased removal torque with time during 12 months following the placement of non-loaded titanium implants in the rabbit tibia.[11] The increased torque was explained by an increase in bone-implant contact with time. Continuing bone formation at the implant interface was also demonstrated radiographically in humans during the first 2 years following placement.[32] These findings suggest that the osseointegration process continues for a year or more after implant placement and that premature loading of implants should be avoided. However, the present study indicates that the osseointegration process may continue even though the implants were subjected to immediate loading.

CONCLUSIONS

The results of this study suggest that for the narrow-diameter transitional implants evaluated:

1. Because of stronger integration, the risk of fracture increased during attempted removal from the mandible after 10 or more months.
2. Implants in function up to 15 months were safely removed from the maxilla.

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3. Stronger integration was observed in the mandible compared to the maxilla.
4. Integration in the maxilla increased with time.
5. Removal torque levels of these implants indicated varying degrees of integration, even though they were subjected to immediate loading.

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