A Clinical Study of the Efficacy of Gold-Tite Square Abutment Screws in Cement-Retained Implant Restorations

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Purpose: *The purpose of this study was to record the effectiveness of Gold-Tite square abutment screws, tightened to 35 Ncm with a torque indicator, in maintaining a clinically stable implant/abutment connection.* ***Materials and Methods:*** *The study consisted of 73 patients who were treated with 110 Osseotite implants. All patients were restored with either pre-machined titanium or customized UCLA hexed abutments. All abutments were fabricated per the Gold Standard ZR abutment design of Implant Innovations. All of the abutment screws were Gold-Tite square abutment screws. They were torqued to 35 Ncm with a torque indicator at the time of abutment connection. All crown restorations were cemented to the abutments. Patients were followed for at least 1 year post-occlusal loading.* ***Results:*** *Four patients with 6 implants were lost between the 6- and 12-month recall appointments. Clinical assessments of implant/restoration mobility were made by the author. One abutment screw was found to be loose at the 12-month recall appointment, representing a 99% survival rate.* ***Discussion:*** *These results add to the growing evidence that abutment screws with enhanced surfaces may provide increased screw/implant contact, higher rotational values, and calculated preload values.* ***Conclusion:*** *The use of the Gold-Tite square abutment screws, torqued to 35 Ncm, maintained a stable implant/abutment connection that was successful in clinical practice for this minimal evaluation period.* (INT J ORAL MAXILLOFAC IMPLANTS 2003;18:273–278)

Key words: *bone screws, dental abutments, dental cement, dental implants, dental prostheses, torque*

The biology of osseointegration of dental implants has been well documented in edentulous, partially edentulous, and single-tooth situations.[1–4] Originally, the external-hex, commercially pure, titanium implant was used only in the treatment of edentulous patients. The initial purpose of the external hex was to allow surgeons to drive the implant into position after the osteotomy site had been prepared; it was not designed as an antirotational device for single implant restorations.[5] The height of the external hex was established at 0.7 mm. Modifications have included increasing the height of the external hex from 0.7 mm to 1.2 mm.[6]

Initially, implant research was concentrated on the biology of osseointegration. Brunski and Skalak stated that a key problem in all implant designs is the "fixation problem," ie, how to hold the implant in bone.[7] Osseointegration of dental implants is now thought to be a predictable, long-term phenomenon with success rates in the high 90% range.[2,8–10]

The attachment of a restoration to an implant can be accomplished through screw retention, cementation, or a combination of both. One distinct advantage of screw retention over cement retention is retrievability of the restoration.[11] However, in screw-retained restorations that use both abutments and cylinders, the weakest link of the restoration involves the retaining screw between the abutment and cylinder, because the retaining screw in this connection is significantly smaller than the screw that connects the abutment to the implant. Repair/replacement of cylinder-retaining screws in this type of restoration is generally less complicated than repair/replacement of abutment screws.[12]

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Loosening of the cylinder-retaining screw occurs at the lowest loads when compared to all other structural components.[12] The percentage of cylinder-retaining screw loosening has been reported from 5% to 49%.[2,13–15]

Screw connections must remain stable (tight) to avoid clinical problems. Becker and Becker hypothesized that a CeraOne abutment (Nobel Biocare USA, Yorba Linda, CA) with a high-pretension abutment screw may reduce the incidence of screw loosening in implant restorations.[10] Tan and Nicholls have stated that the implant/abutment screw joint preload of external-hex implants is dependent on abutment design, screw diameter, material, tightening torque, and torque controller speed.[16]

Clinicians may also cement a crown restoration to an abutment that has been attached directly to an implant with an abutment screw. This technique provides excellent esthetics, as the screw access hole is covered by the crown restoration. This technique also enables clinicians to have optimal control of occlusal contacts.[17] Abutment screws in cement-retained restorations must provide a long-term stable implant/abutment connection because a loose screw cannot be accessed easily. Laney and coworkers reported abutment screw loosening in 10 of 92 patients (10.8%) who received single-tooth, implant-retained restorations replacing premolars or incisors.[9]

Screw loosening seems to occur most often with single-tooth implant restorations. Jemt and associates reported that 74% of abutment screws loosened over a 3-year period, even though the implant restorations directly engaged the external hex of the implants.[3] Becker and Becker replaced molar teeth with screw-retained crowns.[10] Twenty-one 3.75-mm-diameter, one 4-mm-diameter, and two 5-mm-diameter implants were used. All of the restorations involved abutments, cylinders, abutment-retaining screws, and gold cylinder-retaining screws. Approximately 62% of the restorations were reported as being stable over the course of the study (1 year). Fourteen percent of the screws were reported as loose once, approximately 10% were loose twice, and 14% were reported as loose 3 times.

In a laboratory study by Martin and coworkers,[18] 4 different types of abutment screws at 20 and 32 Ncm of torque were tested. Rotational angle measurements and removal torque values were obtained. Removal torque values were used to indirectly calculate preload values. Preload is created when torque is applied to a screw during tightening. The preload creates tension between the threads of the system components (implant and screw). This force produces a clamping force between the screw head and the screw seat. Optimal preload has been recognized as 75% of the screw's yield strength. This allows for high tension in the system, with a safety factor for additional loads.[19] The greatest preload values were calculated for abutment screws with a 24-carat, 0.76-μm coating. The authors concluded that abutment screws with enhanced surfaces reduced friction and generated greater rotational angles and preload values than abutment screws without surface treatments.[19]

The purpose of this study was to evaluate the clinical efficacy of implant restorations cemented to abutments for at least 1 year post-occlusal loading. All abutments were secured to the external hex of implants with gold-palladium abutment screws coated with a 0.76-μm layer of 24-carat gold. All abutment screws were torqued to 35 Ncm with a torque indicator. The crowns were cemented to the abutments with temporary cement.

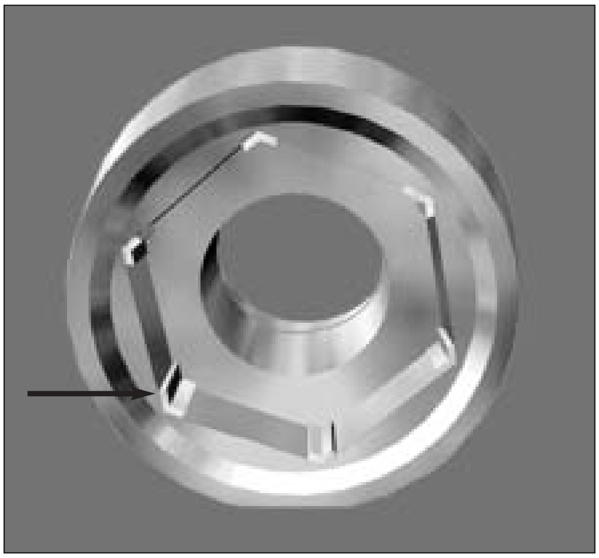
MATERIALS AND METHODS

This was a clinical study conducted in a large multi-specialty medical center setting. Seventy-three patients participated (51 women and 22 men whose ages ranged from 17 to 72 years, with a mean age of 48.7 years). All of the patients were restored with single-unit, cement-retained implant restorations fabricated by the author. The patients were admitted to the study consecutively. The implants were placed by 1 of 4 oral/maxillofacial surgeons and 1 periodontist. Seventy-five maxillary and 35 mandibular Osseotite implants were placed (Implant Innovations, Palm Beach Gardens, FL). Eighty implants were placed using the traditional 2-stage surgical protocol; 30 implants were placed using the single-stage surgical protocol. All of the implants osseointegrated successfully. Osseointegration was defined as the absence of macroscopic implant mobility, pain, radiographic bone loss in excess of 1 mm at 12 months post-occlusal loading, and soft tissue swelling/infection. Patients were followed for at least 1 year after placement of the implant-retained restorations.

All of the final impressions were made directly to the implants. Impressions were made at least 6 weeks post-placement of the implants. Implant laboratory analogs with the appropriate restorative platforms were connected to the undersurface of the implant impression copings consistent with the pick-up impression technique. Master casts were developed in die stone (GC Fujirock EP, GC Europe, Leuven, Belgium) per the manufacturer's instructions by 1 dental laboratory technician (Fig 1). Restorations were fabricated by 1 of 2 dental

Fig 1 Representative master cast with implant lab analog.

Fig 2 *(Right)* Schematic illustration of micro-stop contacts *(arrow)* that have been machined into the corners of the abutment with the Gold Standard ZR design. The micro-stop contacts prevent rotation between the abutment and implant.



laboratory technicians. The abutments for the implant-retained restorations were either customized UCLA hexed abutments or preparable machined titanium abutments (Implant Innovations). All implant restorative components were purchased from Implant Innovations. Custom abutments were fabricated with an alloy that consisted of 52% gold and 37.5% palladium (Eclipse, Ney Dental International, Bloomfield, CT). Two coats of die spacer (SuperPen, Belle de St. Claire, Chatsworth, CA) were applied to the abutments prior to fabrication of the crowns. The definitive crowns were fabricated with alloy that consisted of 56% gold, 20% silver, 4% palladium, and 17% copper (Ney Oro 60, Ney Dental International) for the all-metal crowns and the aforementioned 52% gold alloy for the porcelain/metal crowns.

The Gold Standard ZR feature is unique to certain abutments manufactured by Implant Innovations[20] (Fig 2). All of the abutments used in this study were manufactured with the Gold Standard ZR feature.

At the restoration insertion appointments, healing abutments were removed from the implants and the custom abutments were placed using square try-in screws (UNITS, Implant Innovations). Radiographs were made to verify that all of the abutments were completely seated onto the external hex of the implants (Fig 3). A computer program was used to measure the location of the alveolar crest on the mesial and distal surfaces of the implant relative to the implant restorative platforms (Dexis Provisional Dental System, Palo Alto, CA). All measurements were made by the author and were accurate to 0.1 mm. The definitive crowns were tried in and

Fig 3 Radiograph demonstrating an abutment seated onto an external-hex implant replacing the mandibular left second premolar.

adjusted as needed relative to interproximal contacts, gingival contours, and occlusal contacts. Lateral working contacts were permitted. Balancing interferences were eliminated.

The square try-in screw was removed and the definitive abutment screw (Fig 4a) was placed (Gold-Tite square screw, UNISG, Implant Innovations). All abutment screws were torqued to 35 Ncm with a torque indicator (Fig 4b, Restorative Torque Indicator, RTI2035, Implant Innovations). The definitive crowns were polished and cemented to the abutments with temporary cement (Dycal, LD Caulk Division, Dentsply International, Milford, DE). Patients were scheduled for follow-up visits at 1, 6, and 12 months post-insertion of the implant-retained restorations. Digital radiographs were taken at the 12-month visits (Dexis Provisional

Fig 4a Occlusal and lateral view of Gold-Tite square abutment screw.

Fig 4b Restorative torque indicator.

Dental System). The same computer program was used to measure the distances between the implant restorative platforms and the crest of the alveolar bone mesial and distal to the implants. All measurements were made by the author.

All analyses were based on the intent-to-treat principle for each implant. The critical level for a 2-sided test of each hypothesis was .05. Continuous variables were analyzed using the 1-sample *t* test and are reported as means and standard deviations. Binomial data were analyzed using the binomial test. All analyses were conducted using SPSS software version 10.1 (SPSS, Chicago, IL).

RESULTS

Four patients with 6 implants were lost to follow-up during the course of the study (all 4 relocated out of the area). In the remaining 104 restorations, 1 abutment screw became loose. In this instance, the implant-retained restoration remained cemented to the abutment and had to be removed with a hemostat. Neither the abutment screw nor the abutment was damaged. This implant-retained restoration replaced the mandibular left first molar; the second molar was also missing but was not replaced.

No significant bone loss was detected on the digital radiographs at 12 months post-occlusal loading compared to the location of the alveolar crest and the implant restorative platform at the abutment connection appointment. The average distance between mesial and distal alveolar crests and implant restorative platforms was 0.23 and 0.18 mm, respectively. The average amount of bone loss over the 12-month observation period was 0.45 mm (± 0.16). The average bone loss on mesial surfaces was 0.59 mm (± 0.18), and the average bone loss on distal surfaces was 0.31 mm (± 0.13). No implant showed bone loss greater than 0.8 mm on any of the digital radiographs. There was no macroscopic mobility or pain noted for the 104 implants that had complete data. One abutment screw was found to be loose (1%). The survival rate for loose screws in this study was significantly better than the 90% and 74% survival rates that have been reported in other research (P = .047 and .002, respectively).[3,9] Additionally, there were no implant failures for the 1-year observation period. This was significantly better than a 97% survival rate (P = .017). The same values were observed for the pain and mobility variables.

DISCUSSION

The results of this study demonstrated satisfactory clinical survival (99%) when custom or preparable abutments were fastened to external-hex implants with Gold-Tite square abutment screws at 35 Ncm using a torque-indicating instrument. All of the abutments had the Gold Standard ZR machined feature.

These results add to the growing evidence that screws with enhanced surfaces (0.76-µm layer of 24-carat gold on a gold-palladium alloy or titanium alloy with a proprietary surface treatment) as opposed to screws without enhanced surface treatments may provide increased screw/implant contact, higher rotational values, and calculated preload values. These features can result in improved clinical performance of the implant restorations.[18]

These data compare favorably with more recent reports that included appropriate torque and improved screw surfaces and designs.[21,22] Levine and coworkers[21] examined 135 posterior single-unit implant restorations. They reported an overall crown-retaining screw loosening of 22.2% over an average observation period of 40.1 months. They reported that only 1 screw-retained crown became loose more than once and suggested that the tightening forces applied to occlusal screws in their study were adequate to retain crowns to implants.

Eckert and Wollan performed a comprehensive retrospective review of 1,170 endosseous implants placed in partially edentulous patients.[22] Restorations included in this review had to be completed prior to March 1997. They noted that prosthetic complications decreased significantly after June 1, 1991. This was the date when components designed specifically for partially edentulous patients were introduced. Their comprehensive statistical analyses indicated that prosthetic failures with older components occurred 2.096 times more frequently than prosthetic failures with new, more modern components.

Clamping forces associated with screw fasteners in a biologic system are extremely complex. Hagiwara and Ohashi[23] noted that increased clamping forces were associated with the coefficient of friction between the threads in a system in an inverse relationship: as the friction between the threads decreases, the preload distributed through the system increases. The 0.76-µm, 24-carat gold layer plated to the abutment screws used in this study is considered to be a dry lubricant. This reduced the friction between the gold-palladium abutment screw and the commercially pure titanium implant.[24]

The author performed all of the clinical prosthetic procedures for all of the patients in this study. All of the screws were torqued to 35 Ncm with one torque-indicating instrument. Tan and Nicholls have noted that variability in measured preloads of abutment screws was caused by operator manipulation of torque controllers, specifically in the manner in which the driver tip engaged the screw and how the torque was applied.[16] In the present study, the author was as consistent as clinically possible when seating the square driver tip into the square head of the abutment screw.

Previous clinical reports have demonstrated varying levels of screw loosening in implant restorations.[2,3,6,8–10,21,22] The studies do not always report or compare data from studies with similar screw designs. Early reports did not indicate known amounts of torque applied to the screws, because torque indicators/controllers were not available commercially. Also, earlier reports were concerned with first-generation screws. The present clinical study followed patients restored with single-unit implant restorations cemented to abutments (Gold Standard ZR design) with 1 type of abutment screw with an enhanced surface for 1 year post-occlusal loading. Satisfactory survival rates were seen relative to the stability of the implant/abutment connection.

CONCLUSIONS

In this in vivo study, gold-palladium abutment screws with Gold-Tite surface coatings were used in conjunction with custom and preparable abutments and tightened to 35 Ncm of torque. They remained successfully in function when followed for 1 year post-occlusal loading. Short-term (1-year) survival rates may not be indicative of long-term survival rates. Temporary cement can be used to successfully retain crown restorations to implant abutments when followed regularly. Further study is needed relative to the biomaterials, fastener systems, and loads found in the biologic systems in which endosseous implants are used to anchor dental prostheses.

ACKNOWLEDGMENTS

The author gratefully acknowledges the assistance of Paul Havlik and Kathy Sandy of the Gundersen Lutheran Medical Foundation, La Crosse, Wisconsin.

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