

Accuracy of Electronic Implant Torque Controllers Following Time in Clinical Service

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Tightening of the screws in implant-supported restorations has been reported to be problematic, in that if the applied torque is too low, screw loosening occurs. If the torque is too high, then screw fracture can take place. Thus, accuracy of the torque driver is of the utmost importance. This study evaluated 4 new electronic torque drivers (controls) and 10 test electronic torque drivers, which had been in clinical service for a minimum of 5 years. Torque values of the test drivers were measured and were compared with the control values using a 1-way analysis of variance. Torque delivery accuracy was measured using a technique that simulated the clinical situation. In vivo, the torque driver turns the screw until the selected tightening torque is reached. In this laboratory experiment, an implant, along with an attached abutment and abutment gold screw, was held firmly in a Tohnichi torque gauge. Calibration accuracy for the Tohnichi is $\pm 3\%$ of the scale value. During torque measurement, the gold screw turned a minimum of 180 degrees before contact was made between the screw and abutment. Three torque values (10, 20, and 32 N-cm) were evaluated, at both high- and low-speed settings. The recorded torque measurements indicated that the 10 test electronic torque drivers maintained a torque delivery accuracy equivalent to the 4 new (unused) units. Judging from the torque output values obtained from the 10 test units, the clinical use of the electronic torque driver suggests that accuracy did not change significantly over the 5-year period of clinical service. (INT J ORAL MAXILLOFAC IMPLANTS 2001;16:394-399)

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A common problem associated with implant restorations is abutment screw loosening. Early studies of implant-supported restorations indicated abutment screw loosening on the order of 31% during the first year.¹ The nature of loosening or displacement of prosthetic components is complex, since it can be attributed to several causes, including inadequate screw tightening, inadequate prosthesis fit, poorly machined components, or excessive load-

ing and screw design.² Jörn us and colleagues³ suggested that the probable cause of unintentional screw loosening is inadequate tightening. However, excessive torque that exceeds the yield strength of the screw creates permanent deformation in the screw shank, leading to screw fracture over time arising from the load fatigue associated with mastication forces.⁴ When a screw is tightened, a tensile force (preload) is created in the shank of the screw. This preload should be as great as possible, because it creates a contact force between the abutment and the implant. The greater this contact force between abutment and implant, the more stable the anchorage.³⁻⁶

With the introduction of the CeraOne abutment (Nobel Biocare, Yorba Linda, CA) came a new gold alloy abutment screw. Because it is a gold alloy, this screw has a higher yield strength, allowing a higher torque value; this leads in turn to a higher preload in the screw shank and a more stable joint.^{7,8} At the same time, Nobel Biocare introduced a new electronic torque driver, series DEA 020. This device allows the application of known or preset torques to specified alloy screws.

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Accurate torque delivery requires the use of calibrated torque devices that can consistently deliver the desired torque. Incorrect torque can be applied to the fastening screws as a result of the age of the device, frequency of use, debris in the operating mechanism, and corrosion of the spring in the handle of the torque wrench, all of which may lead to an error in torque value as large as 455%.⁹ Standlee and Caputo¹⁰ investigated the torque accuracy of 7 electronic torque drivers, all of which had been in clinical service for several years, and found that errors in torque delivery could be as high as 165%.

Thus, the purpose of this study was to determine the accuracy of electronic torque controllers that had been in clinical service for a minimum period of 5 years, and to compare these older units to new or unused controllers.

METHODS AND MATERIALS

Several torque controllers are currently available; however, only the DEA 020 electronic torque controller (Nobel Biocare) was tested in this study. This system consists of a handpiece that is connected to an electronic control unit having 4 different torque settings (10, 20, 32, and 45 N-cm). Each of these torques can be applied to the implant screws at 1 of 2 speed settings, low or high. All torque controllers tested in this study were evaluated at both speed settings, but only the 10, 20, and 32 N-cm torque values were used. This provided 6 separate speed/torque setting test sequences for each controller. In addition, each controller was tested after being subjected to a steam-autoclaving sterilization cycle.

Control Values

The control values against which the test controller values were compared were those obtained by testing 4 new units (unused) supplied by the manufacturer. Each controller was tested at 10, 20, and 32 N-cm, at both the low- and high-speed settings.

Torque Measurements

To measure the torque output of each controller, a model 9BTG-A Tohnichi torque gauge (Tohnichi America, Los Gatos, CA) was used. To simulate the clinical protocol used with the torque controller, an actual implant (standard implant 3.75 in diameter by 13 mm long RP, SDCA 018-0; Brånemark System, Nobel Biocare) was modified by creating 2 flat surfaces, each 3 mm in width, on the threaded cylindrical section of the implant. When this implant was secured in the 3-jaw chuck of the Tohnichi torque

gauge (Fig 1), these flat surfaces prevented implant rotation under torque when the implant was clamped in the torque gauge. Next, a 3-mm collar height Nobel Biocare CeraOne abutment (SDCA 334-0) was placed on top of the implant, and a gold CeraOne abutment screw (catalog no. 25235) was then used to connect the abutment to the implant.

The Tohnichi torque gauge is calibrated at the factory to be accurate within $\pm 3\%$ of the scale value. The accuracy of the Tohnichi torque gauge was tested prior to data collection. An L-shaped rod with a groove to locate load location was clamped in the chuck of the gauge. With the gauge lying horizontally, accurately known loads were placed on this cantilever. With a known distance from the groove to the center of the 3-jaw chuck, the applied torques could be calculated. These known torque values were compared with the values recorded by the torque indicator on the gauge. The error was found to be within the $\pm 3\%$ specification given by the manufacturer.

The steps used in testing each electronic torque controller were as follows.

1. The implant was clamped in the 3-jaw chuck of the Tohnichi torque gauge (Fig 1).
2. The torque indicator on the gauge was set to zero. This indicator rotated to mark the peak torque value delivered and remained there following torque removal.
3. The controller was set to the required torque and speed settings. The driver head in the handpiece of the controller was then used to torque the gold screw to the preset torque value. Care was taken to ensure that the driver head was collinear with the implant during torque application (Fig 2).
4. While the torque controller handpiece was held in one hand and the gauge was held in the other hand (Fig 2), the controller rheostat (pedal) was activated. When the electronic sound (beep) was heard, the rheostat pedal was released. During this operation, the gold screw turned a minimum of half a rotation before the full torque value was attained. This was done to simulate clinical conditions.
5. The peak torque value registered by the torque indicator was read and recorded.
6. Steps 1 to 5 were repeated 10 times for each torque controller, and all torque readings were done by the same investigator.
7. When the control units were tested, only 1 handpiece was used for all 4 units. This allowed torque variation to be attributed to the controller alone and not to any of the other components.



Fig 1 The modified implant is secured into the 3-jaw chuck of the Tohnichi gauge.



Fig 2 The handpiece is held collinear with the Tohnichi gauge.

With this torque-measuring protocol, a total of 10 repetitions for each of the 6 torque value/speed combinations (10, 20, and 32 N-cm at high and low settings) were recorded for each torque controller, giving 60 torque values for each controller.

Along with the torque data for each controller, additional information was collected: (1) age of the controller (in months), and (2) any recalibration since purchase.

Statistical Analysis

To compare the test controllers with the control units, a 1-way analysis of variance was performed to compare the torque values associated with each of the 6 combinations tested. This required 6 statistical tests to compare the same torque value/speed combination across all test and control units. In addition, a Pearson's correlation coefficient test was performed to compare the age of the test controllers with torque output values; this was expressed as a percentage error above or below the preset or standard values.

RESULTS

Tables 1 and 2 provide the test information on the torque values delivered by both torque controller sets. The values in Table 1 are for the 10 test controllers, which had been in clinical service for a minimum of 5 years, and the values in Table 2 are for the 4 new controllers, which had never been in clinical practice.

Three torque settings were investigated: 10, 20, and 32 N-cm. In addition, both the high- and low-speed settings were checked for each of the 3 torque

values, giving a total of 6 combinations within which torque values were evaluated. The mean value for each torque value/speed combination is given under the columns marked 10, 20, and 32 N-cm for both torque driver sets. Each of the torque values given in Tables 1 and 2 is the mean of 10 individual readings. However, the global means and global standard deviations given at the bottom of each table are those calculated for the entire set of readings for that controller set. The global values in Table 1 were each calculated from 100 readings, and those for Table 2 were each calculated from 40 readings.

Range of Torque Values Measured

Table 3 provides the maximum and minimum mean torque values measured for each of the 6 torque value/speed combinations used. Each torque value in this table was calculated from the data for 1 torque controller alone (Tables 1 and 2) and represents the highest mean torque measured (maximum), or the lowest mean torque value measured (minimum). These torque values are not from the same unit. Values of maximum and minimum torque values are given for both the test and control units.

Statistical Results

A comparison of the mean torque values for the 6 torque value/speed combinations (Tables 1 and 2) showed no significant differences. Here, only equivalent torque value settings for the test and control units were compared. There was no significant correlation between delivered torque and time in clinical service (Table 1) for all torque value/speed combinations. Thus, the years in clinical service did not correlate with inaccuracy.

Table 1 Mean Torque Values for the 10 Test Controllers

		Test controller torque values (N-cm)*					
		10 N-cm		20 N-cm		32 N-cm	
Controller	Age (y)	High speed	Low speed	High speed	Low speed	High speed	Low speed
1	5	14.7	11.9	20.8	19.0	33.0	31.5
2	8	13.5	10.4	17.4	16.2	29.0	26.2
3	6	10.2	9.8	20.9	18.1	33.8	30.9
4	6	12.7	10.3	20.2	18.3	34.0	31.0
5	6	10.9	10.8	19.8	19.1	30.6	28.4
6	7	13.1	10.6	23.6	21.4	36.9	35.3
7	8	12.1	10.2	19.2	17.1	31.7	27.6
8	7.5	13.9	12.0	20.0	19.9	31.5	29.7
9	6	10.0	10.1	17.8	17.1	29.9	28.5
10	5	13.9	11.8	24.6	19.8	38.0	32.9
Global mean [†]		12.5	10.8	20.4	18.6	32.8	30.2
Global SD [†]		1.8	2.3	2.9	1.0	1.6	2.7

*All values are the mean of 10 sequential readings on each controller.

[†]Mean and SD for 100 readings, ie, 10 for each controller.

Table 2 Torque Values for the New Controllers

		New controller torque values (N-cm)*					
		10 N-cm		20 N-cm		32 N-cm	
Controller	Age (y)	High speed	Low speed	High speed	Low speed	High speed	Low speed
1	0	12.2	10.4	19.5	17.0	29.9	26.7
2	0	14.8	9.9	18.4	15.9	24.9	26.7
3	0	14.7	11.1	23.2	19.1	31.3	29.6
4	0	13.4	10.8	21.5	17.6	32.2	28.5
Global mean [†]		12.9	10.5	20.8	17.5	30.8	27.8
Global SD [†]		1.6	0.6	1.8	1.6	1.5	1.8

*All values are the mean of 10 sequential readings on each controller.

[†]Mean and SD for 100 readings, ie, 10 for each controller.

Table 3 Maximum and Minimum Torque Values for the Test and Control Units

		Extreme torque values (N-cm)*					
		10 N-cm		20 N-cm		32 N-cm	
Controller	Extremes	High speed	Low speed	High speed	Low speed	High speed	Low speed
Control	Maximum	14.8	11.1	23.2	19.1	32.2	29.6
Control	Minimum	12.2	9.9	18.4	15.9	24.9	26.7
Test	Maximum	14.7	12.0	24.6	21.4	38.0	35.3
Test	Minimum	10.0	9.8	17.4	16.2	29.0	26.2

*All values are the mean of 10 sequential readings on each controller.

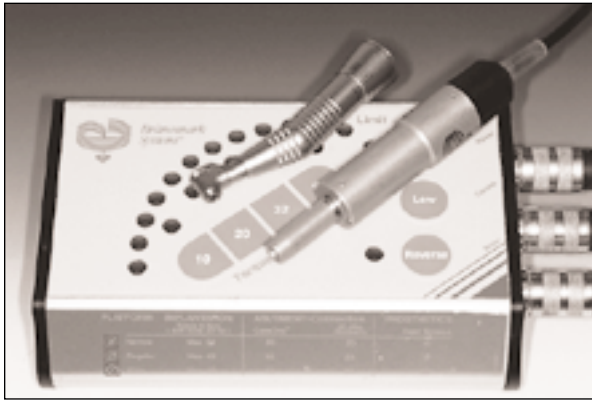


Fig 3 The DEA 020 electronic torque controller (Nobel Biocare).

DISCUSSION

Matching Controller Units and Controller Motors

Each torque controller has 3 components: (1) the handpiece, (2) the controller motor, and (3) the controller unit (Fig 3). This allowed an interchange of components to determine any effect on the torque delivered. For the 4 new units, controller motor #1 was tested when connected to controller units #2, 3, and 4; controller motor #2 was tested when connected to controller units #1, 3, and 4; and so on. The torque values delivered were consistent for all combinations, indicating that these components could be interchanged without compromising torque accuracy.

Screw/Implant Test Setup

When used in vivo, the torque driver turns a screw that has not been tightened into the implant. This allows rotation of the screw prior to complete torque development. It has been suggested that the torque driver needs this initial rotation to sense the delivered torque. Use of the current test setup, wherein a gold screw was tightened into an implant, completely simulated the in vivo situation.

Controller Sterilization

Very little information was available regarding the number of times each handpiece had been sterilized in the dental office. The statement made consistently by these dentists was that these torque drivers were used weekly, with several stating that the use rate was as high as 10 times per week. However, the

only consistent information here was that the handpiece was sterilized prior to each in vivo use. With this lack of detailed information, no statistics could be run on torque accuracy versus the number of sterilization cycles.

Recalibration Since Initial Purchase

Of the 10 test units, none had been sent in for recalibration. Thus, all 10 units in Table 1 had been in clinical service without recalibration since the time of purchase.

Age of the Test Controller

Table 1 provides not only the torque values measured for each of the 10 test units, but also the number of years each had been in clinical service. For the 10 units tested, the shortest time in clinical service was 5 years, and the longest time was 8 years. Table 1 shows that the extreme torque values (maximum or minimum) measured for each test controller were not seen in the units that had been in clinical service the longest.

Order of Testing

Six individual combinations were measured for each torque unit tested: 3 torque values (10, 20, and 32 N-cm), each at 2 speed settings (high and low). Each of these 6 combinations was measured 10 times, and the average torque values were computed (Tables 1 and 2). These 6 combinations were not measured in the same order for all controllers. A random number table for these combinations was generated that provided the order in which these torque values were measured for both the test series and the control series.

Angulation of Screw Driver with Respect to the Implant Long Axis

In the mouth, and for implants placed in the posterior of the mouth, it is possible that the screw driver head may be placed at an angle to the long axis of the implant when it is in contact with the gold screw, because of the height of the handpiece head plus the attached screw driver. It was thus deemed necessary to measure another set of torque values with the screw driver oriented at an angle to the long axis of the implant. The angle between these 2 components was defined by contact between the screw driver and the top of the CeraOne abutment when the screw driver was in contact with the gold screw. One test torque controller was used for this test, with all 6 combinations evaluated. For each combination, there was no significant difference between the torque values measured in this way and the comparable values seen in Table 2.

Use of One Screw for All Tests

For all torque testing, only 1 gold screw was used. This CeraOne gold screw was chosen because it has the capacity to withstand all 3 test torque values (10, 20, and 32 N-cm). One might expect that the threads of this screw would wear, becoming smoother with time and use, and that the head of the screw would also become smooth because of repeated contact with the abutment. This potential change in status of the gold screw head and threads would in no way have any effect on the torque-measuring capability of the torque controller. Perhaps the number of rotations that the screw experiences may change with time and use resulting from the smoother surface conditions, but the torque-measuring capacity of the controller is completely independent of this additional screw rotation.

Evaluation of Maximum Torque Values Measured

Using a digital torque gauge, Haack and coworkers¹¹ applied torques of 20 and 32 N-cm to titanium and gold screws, respectively. Their results showed that the tensile stress or load in the screw shank at the recommended torque values was 56% of yield strength for the titanium screws and 57.5% of yield strength for the gold screws. These results indicate that the screw shank is well below yield when the required torque is applied. For the present study, maximum torque values for both the test and control units are given in Table 3. Percent yield values can be assigned to these maximum torques using the data provided by Haack and coworkers.¹¹ For the 24.6 N-cm maximum torque value (Table 3), a 70.8% yield stress was determined. For the 38.0 N-cm maximum torque value (Table 3), a 68.3% yield stress was determined. Thus according to Haack and coworkers, the torque values determined from this evaluation induce a stress in the screw shank for both the 20 and 32 N-cm values that is lower than yield stress. However, screw threads increase stress, and stresses at the thread level may indeed be above yield for all torque values given here.

CONCLUSIONS

The torque output of 10 torque controllers that had been in clinical practice in the Seattle, Washington, area for a minimum of 5 years was measured. For

each controller, 10 torque readings were recorded at each of 6 torque value/speed settings. In addition, 4 new controllers were evaluated at the same settings. These torque output data were subjected to a 1-way analysis of variance, wherein like settings were compared, providing 6 statistical calculations. From the torque values recorded, the following conclusions may be stated.

1. No significant difference was found between the mean torque values measured for the 10 test units and the mean torque values found for the 4 control (new) units.
2. There was also no correlation between the torque output of the test units and the number of years in clinical service.

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