

The Effect of Aging on the Accuracy of Spring-Style Mechanical Torque Limiting Devices for Dental Implants

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Abstract

Objective: Recently, a wide variation has been reported in delivery of the target torque by spring-style mechanical torque limiting devices (MTLDs) but the effect of aging on their accuracy has not been independently evaluated. The purpose of this study was to determine the effect of aging on the accuracy of spring-style MTLDs.

Methods: In this in-vitro experimental study, 15 new spring-style MTLDs were selected of three different manufacturers. To measure their accuracy, the peak torque was measured in 10 sequences by a Tohnichi torque gauge before and after 1000 times of use. In each sequence, 10 repetitions of peak torque values were registered. The intra-class correlation coefficient (ICC) was calculated and Repeated Measures ANOVA and two-way ANOVA were applied to calculate and compare the absolute error values between the three understudy groups.

Results: The absolute error value was in the range of -3.5(-3) Ncm for 3i group, -2.5 (1) Ncm for ITI and -4-+2 Ncm for Nobel Biocare group. The latter value showed a significant difference with the two former values ($p<0.05$). All samples in the ITI group had error values within 10% of the clinically acceptable range. About 5% of measurements (maximum of 11.4%) in Nobel Biocare and 9% of measurements (maximum of 14.53%) in the 3i group showed error values greater than the 10% range.

Conclusion: Aging decreased the accuracy of spring-style MTLDs. The magnitude and trend of reduction in accuracy were variable among different groups.

Key words: Accuracy, Aging, Application times, Dental implant, Mechanical Torque Limiting Devices (MTLDs), Spring-style, Torque.

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Introduction:

Delivery of controlled torque is the first technique used in dentistry for screw tightening. The manufacturers of MTLDs have recommended specific target torques for abutment screw tightening. The target torque is the most suitable torque that can deliver an optimal preload for each screw and prevent screw loosening or fracture by providing adequate clamping force (1-5). Delivery of

optimal peak torque value or target torque maintains the screw joint integrity (6-8). Application of a preload lower or greater than the optimal limit can cause technical complications such as screw loosening, screw fracture, corrosion of screw threads or separation of screw joint (9-17).

Inaccuracies have been reported for all hand, mechanical and electronic torque drivers due to errors by the operator or the device (18-23).

Despite the reported inaccuracies, MTLDs are

necessary for the delivery of peak torque (11, 8, 6, 19). The peak torque is the output torque of the MTLT when the torque indicator on the gauge shows the target torque value.

Sterilization and clinical service (aging) affect the accuracy of MTLTs (24-31). Extensive deviation of delivered peak torque from the target torque by some friction-style MTLTs has been reported in several studies (24, 26).

Vallee *et al.* in 2008 evaluated the accuracy of new MTLTs in delivering the target torque and showed that spring-style MTLTs were more accurate than friction-style devices ($P < 0.001$). The mean absolute difference between the measured torque and the target torque values was 0.82 Ncm for spring-style and 3.83 Ncm for friction-style devices. The accuracy of MTLTs correlates with their type (friction- or spring-style) and their manufacturing company (8).

Cehreli *et al.* in 2004 compared the accuracy of 15 spring-style MTLTs (ITI) in three groups: one new group ($n=5$) and two used groups (50-200 times versus 500-1000 times of use) and reported the torques delivered by group 3 devices to be 1-1.5 Ncm lower than those of other groups for the 35-Ncm target torque. New devices applied higher torque values than devices used for 1000 times ($p < 0.05$) (28).

McCracken *et al.* in 2010 evaluated the variability of torque applied by MTLTs in service in a US dental school. In their study, MTLTs with unspecified duration of clinical service and different sterilization cycles were evaluated. The researchers reported that some of the toggle-type torque wrenches delivered unacceptably high torque values in clinical service (24). Santos *et al.* (2011) (29) in their study on 4 types of spring-style MTLTs with a maximum clinical service of 2 years stated that when 20 Ncm torque was applied, 62.5% of delivered values were accurate (within 10% of the target value); whereas, for 32 Ncm torque, only 37.5% of target values were achieved.

In the majority of studies evaluating the effect of

duration of service (aging) on the accuracy of MTLTs, number of applications and sterilization cycles have not been specified and considering their retrospective designs, the reported results have been controversial (24, 28, 29).

To date, no study has investigated the independent effect of application times (aging) on the accuracy of MTLTs. Considering the reported differences between the peak torque and the target torque values in MTLTs and the effect of their type (manufacturing company) on their accuracy, the present study was designed to determine the effect of application times (aging) on the accuracy of spring-style MTLTs for dental implants.

Methods:

In this in-vitro experimental study, 5 new spring-style MTLTs of three different manufacturing companies including Nobel Biocare (Goteborg, Sweden), 3i (Biomet 3i, Palm Beach Gardens, FL, USA) and ITI (Straumann, Basel, Switzerland) (Figure 1) along with their respective drivers were selected for the assessment of the effect of number of applications on the accuracy of peak torque relative to the desired target torque value.



Figure 1- Spring-style MTLTs: Nobel Biocare (up), 3i (middle) and ITI (down)

The sample size ($n=15$, 5 samples in each group) was calculated based on similar studies (24, 26, 27) as well as the results of Vallee *et al.* study in 2008 (8) with the consideration of absolute error

value, minimum effect size of 0.41 Ncm, pooled standard deviation of 0.13 and $\beta=2$ using 2-level factorial design. Each MTLD in each group was given an abbreviation and randomly allocated a number from 1 to 5:

Nobel Biocare (X1-X5), ITI (Y1-Y5) and 3i (Z1-Z5).

The sequence of testing was randomized as well. Tohnichi torque gauge (Tohnichi, 6-BTG-S, Japan) was used for the measurement of applied peak torque value. Tohnichi torque gauge was calibrated by the manufacturer to be accurate within $\pm 2\%$ of the full scale. The driver for each respective MTLD was clamped in a 3-jaw chuck of the Tohnichi torque gauge. The torque wrench was then connected to the driver, and the torque indicator on the gauge was set to zero and measurement of peak torque was started. Use of Tohnichi torque gauge has been thoroughly explained in previous studies (24, 25).

Each spring-style MTLD (20) was connected to its respective driver and tested by gently applying the torque within 4 seconds (23). Application of force was continued until the flexing of bow and reaching the desired peak torque value (Figure 2). Force was applied by one operator and another operator read and recorded the peak torque value registered by the Tohnichi torque gauge using a magnifier.



Figure 2- Force was applied until the flexing of bow and reaching the desired target torque value

The measurement of peak torque value for each sample was made in 10 sequences. In each

sequence, 10 repetitions of peak torque values were recorded and after a 3-hour time interval, another 10 repetitions were carried out. In general, each specimen underwent 100 measurements.

After the assessment of the primary accuracy in reaching the target torque value, each specimen was reached to the target torque for 1000 times in 100 consecutive sequences in order to simulate clinical service. The target torque for all 3 understudy groups was 35 Ncm. Target torque was applied to each specimen in 100 sequences for 10 repetitions each. The minimum time interval between the sequences was 3 hours. After 1000 applications, the peak torque was measured in each MTLD for 10 consecutive sequences (10 repetitions each) for a total of 100 repetitions using Tohnichi torque gauge. The mean and range of difference as well as the absolute error value between the peak torque value and the target torque were calculated for each specimen (the absolute difference: ABSDIFF). Furthermore, the percentage deviation between the measured peak torque and the target torque for each sample was calculated as follows:

$$\text{Percentage deviation: PERDEV} = \frac{\text{Absolute error value}}{\text{Torque}} \times 100$$

Using Repeated Measures ANOVA, the difference in accuracy between the three groups of spring-style MTLDs after 100 sequences of use (a total of 1000 applications) was evaluated. Type I error was considered as $P < 0.05$. The null hypothesis of the study was that aging would have no effect on the accuracy of spring-style MTLDs.

Results:

At baseline, Repeated Measures ANOVA showed that significant differences existed between the three groups in terms of error value and the raw error value in the ITI group was significantly smaller than in the other two

groups ($P < 0.001$). Bonferroni post hoc test was used for pair wise comparison of groups; according to which, percentage deviation and absolute difference were not significantly different among the three groups.

Table 1 shows the calculated mean absolute

error value (ABSDIFF) and standard error for the three groups of MTLs (ITI, Nobel Biocare, 3i) and demonstrates the deviation of peak torque from the target torque value. ICC was calculated as well which was 0.698 for Nobel Biocare, 0.654 for 3i and 0.984 for ITI group.

Table 1- The mean absolute error value (ABSDIFF) and standard error in the three groups of spring-style MTLs at baseline (before aging)

The manufacturing company	Standard absolute error value	Mean absolute error value
Nobel BioCare	1.36	0.056
ITI	0.75	0.034
3i	1.44	0.098

The descriptive error values or the difference between the measured peak torque and the target torque (mean, SD, maximum, minimum),

ABSDIFF and PERDEV for each group of MTLs are summarized in Tables 2-4.

Table 2- Summary of the descriptive error values for Nobel Biocare MTLs in 100 measurements after 1000 applications

Times of measurement	Absolute error value (Ncm)	PERDEV	Minimum (Ncm)	Maximum (Ncm)	Mean difference (SD)
1	1.1	3.14	-1.5	2	0.3 (1.44)
5	0.6	1.71	0	2	0.6 (0.89)
10	1	0.57	-1.5	1	-0.2 (1.15)
20	1	1.71	-2	1	-0.6 (1.33)
50	1.2	2.29	-1	2	0.8 (1.15)
100	1.5	3.14	-3	1	-1.1 (1.95)

Table 3- Summary of descriptive error values for ITI MTLs in 100 measurements after 1000 applications

Times of measurement	Absolute error value (Ncm)	PERDEV	Minimum (Ncm)	Maximum (Ncm)	Mean difference (SD)
1	0.8	2.29	-1.5	1	0.3 (1.44)
5	1.1	3.14	-2	-0.5	0.6 (0.89)
10	0.9	2.57	-2	0	-0.2 (1.15)
20	1.5	4.29	-2	-0.5	-0.6 (1.44)
50	1.3	1	-2	-1	0.8 (1.15)
100	1.4	4.00	-2.5	-0.5	-1.1 (1.95)

Table 4- Summary of the descriptive error values for 3i MTLs in 100 measurements after 1000 applications

Times of measurement	Absolute error value (Ncm)	PERDEV	Minimum (Ncm)	Maximum (Ncm)	Mean difference (SD)
1	1.5	4.29	-5	0	-1.5 (2.03)
5	0.5	1.42	-3.5	2	-0.5 (2.65)
10	1.6	2.29	-2.5	2	-0.8 (1.82)
20	1.8	1.14	-2.5	3	0.4 (2.22)
50	1.4	2.86	-4	1	-1 (1.90)
100	1.8	3.43	-3.5	1.5	-1.2 (1.86)

A significant difference in accuracy was detected before and after aging in each group ($p < 0.001$). But, in 100 times of accuracy testing after aging, no significant difference was noted in the trend of changes.

In 3i and Nobel Biocare groups, the error value was zero or towards over-estimation of the target

torque. In the ITI group, both over-estimation and under-estimation of the actual target torque value were noted; but, the mean difference between the peak torque and target torque tended towards the under-estimation of the actual target torque (Figure 3).

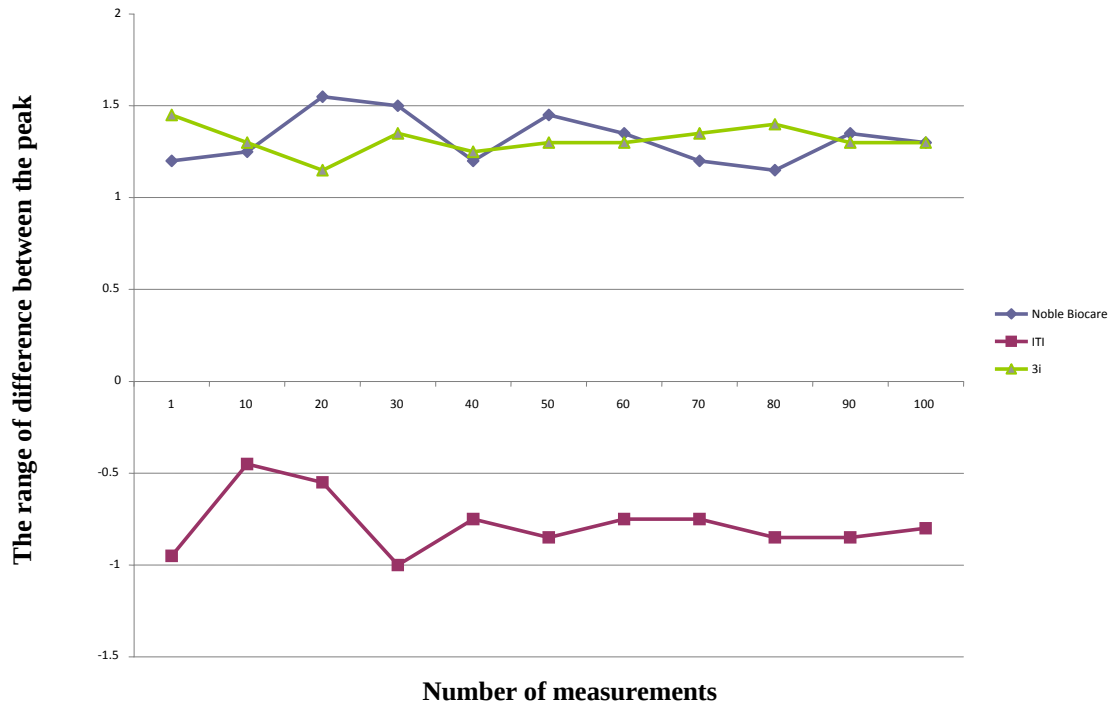


Figure 3- The mean difference between the peak torque and target torque in 100 measurements after aging

For all three groups of Nobel Biocare, ITI and 3i, level zero was indicative of target torque for each group.

ABSDIFF and PERDEV for the ITI group were in the range of -2.5 to +1 Ncm relative to the target torque. These values were in the range of -5 to +3 Ncm after 1000 measurements in the 3i group and in the range of -4 to +2 Ncm in the Nobel Biocare group. The latter values (Nobel

Biocare) were significantly different from the values in the first two groups ($p < 0.05$).

Table 5 shows the calculated mean absolute error value and standard error in the three groups of MTLs and indicated the deviation of peak torque from the target torque value.

Intra Class Correlation Coefficient (ICC) was calculated as well and was 0.951, 0.941 and 0.598 for the ITI, Nobel Biocare and 3i groups, respectively.

Table 5- The calculated mean absolute error value (ABSIFF) and standard error in the three groups of spring-style MTLs after aging

The manufacturing company	Standard error	ABSIFF
Nobel Biocare	1.07	0.120
ITI	1.17	0.115
3i	1.71	0.103

Discussion:

Considering the presence of significant differences between the mean absolute error values, the difference in ICCs between the three groups as well as the evident clinical differences, the present study results revealed that times of application (aging) in all groups decreased the accuracy and the amount of this reduction was variable in different groups. Thus, the null hypothesis of the study was rejected.

In the three understudy groups, the ABSIFF and PERDEV after 1000 applications showed a specific trend mainly towards the over-estimation of target torque for the two groups of Nobel Biocare and 3i. In the ITI group both over- and under-estimation existed but the observed trend was mainly towards under-estimation. Assessment of the accuracy of spring-style MTLDs before 1000 applications showed a difference within 10% of the clinically acceptable range of the target torque. The Nobel Biocare and 3i samples exceeded the 10% clinically acceptable range in 5% (maximum of 11.4%) and 9% (maximum of 14.53%) of measurements, respectively. Error value and greater variance of the measured values in 3i group indicate the need for further evaluation of 3i samples. Borderline values (maximum and minimum) are particularly important in the measurement of peak torque value because they are potentially capable of causing clinical problems. Consideration of these borderline values is more important than the evaluation of mean value (26).

Sterilization and aging affect the accuracy of MTLDs (24-31). Cehreli *et al.* in their study in 2004 on spring-style MTLDs reported a significant decrease in the applied torque by manual torque devices used for 1000 times in comparison to new MTLDs but this decrease was within the range of 1.5 Ncm (28). Considering the small range of changes despite the consideration of sterilization, their study

results confirmed our findings. McCracken *et al.* (2010) reported higher variability of torque produced by toggle-type devices in clinical service at a US dental school compared to the beam wrenches (24). However, they did not mention the effect of application times or sterilization on this variability; which shows the difference between the peak torque and the target torque values. The mentioned study has limited generalizability due to its retrospective nature and unspecified application times, sterilization cycle and type of MTLDs (in terms of the manufacturing company). But, it is in agreement with our obtained results in terms of limited range of change in the accuracy of torque delivered by these devices.

In our study, the trend of changes in accuracy or error value did not show a significant association with times of application; which is in accord with some previous studies (24, 26). But, aging as an independent variable irrespective of the effect of sterilization in two understudy groups (Nobel Biocare and 3i) caused more than 10% difference from the clinically acceptable range of the target torque in 5% and 9% of cases, respectively. Recent studies on the friction-style MTLDs have indicated that application times (aging) as an independent factor can affect the accuracy of these devices and more than 50% of all peak torque measurements showed more than 10% difference from their torque values after aging (32).

There is no gold standard for a clinically acceptable peak torque but some studies consider 10% difference range between the peak torque and target torque as the clinically acceptable torque range (24, 27, 29). Santos *et al.* in 2011 reported the accuracy of spring-style MTLDs with a maximum clinical service of 2 years to be alarmingly low (29). However, small sample size, measurement repetitions, unspecified details regarding the method of sterilization and device preparation steps, duration of service (1 month to 3 years) and

application times make the generalization of results difficult. Furthermore, their criterion for the assessment of accuracy was the inclusion of output peak torque within 10% of the target torque value. When using 20 Ncm torque, 62.5% of the measured values were accurate; whereas this rate was 37.5% for 32 Ncm torque. In our study, 5% of measurements (maximum of 11.4%) in Nobel Biocare group and 9% (maximum of 14.53%) in 3i showed error values greater than the 10% clinically acceptable error range of the target torque and a tendency towards over-estimation was mainly observed in mean measurements. Lower error values in our study may be due to not assessing the sterilization factor.

Some researchers working on the accuracy of MTLDs have collected samples from clinical centers to involve operator-related factors as well as the clinical setting conditions. However, all these studies have mentioned limited generalizability of their results due to the retrospective nature of their studies, lack of information regarding times of application and sterilization process, and interaction between the two independent variables of clinical service (aging) and sterilization. As the result, wide variations in accuracy and unacceptably high values have been reported in some studies (24, 26). Independent assessment of application times and sterilization and the interaction of the two can better elucidate the trend of variation in accuracy of MTLDs and provide a clear guideline for proper application of these devices in the clinical setting. In the present study, the accuracy of spring-style MTLDs was assessed and the effect of aging in this respect was investigated. Future studies need to focus on the role of sterilization and the interactive effect of aging and sterilization on the accuracy of these

devices.

Conclusion:

1. Considering the presence of significant differences in the absolute error values and ICCs among the three groups, we may conclude that aging (application times) in all groups decreased the accuracy and the amount and trend of this reduction were variable in the three groups.
2. In all groups, over- or under-estimation of the actual value was observed after 1000 times of use. But the mean measured values tended towards under-estimation.
3. A predictable pattern of change was not observed in any of the three understudy groups
4. Measurements in ITI MTLDs were within 10% of the acceptable error range. Also, 5% and 9% of measurements in Nobel Biocare and 3i groups showed error values over the 10% clinically acceptable range of target torque, respectively
5. Higher error value and variance in 3i group necessitate further investigations

Independent assessment of the effect of sterilization and its interaction with aging can enhance our clinical knowledge in this respect

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Conflict of Interest: “None Declared”

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