

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

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Abstract

Objective: High variability in delivering the target torque is reported for friction-style mechanical torque limiting devices (F-S MTLDs). The effect of aging (number of use) on the accuracy of these devices is not clear.

The purpose of this study was to assess the effect of aging on the accuracy ($\pm 10\%$ of the target torque) of F-S MTLDs.

Materials and Methods: Fifteen new F-S MTLDs and their appropriate drivers from three different implant manufacturers (Astra Tech, Biohorizon and Dr Idhe), five for each type, were selected. The procedure of peak torque measurement was performed in ten sequences before and after aging. In each sequence, ten repetitions of peak torque values were registered for the aging procedure. To measure the output of each device, a Tohnichi torque gauge was used.

Results: Before aging, peak torque measurements of all the devices tested in this study failed within 10% of their preset target values. After aging, a significant difference was seen between raw error values of three groups of MTLDs ($P < 0.05$). More than 50% of all peak torque measurements demonstrated more than 10% difference from their torque values after aging.

Conclusion: Within the limitation of this study, aging as an independent factor affects the accuracy of F-S MTLDs. Astra Tech MTLDs presented the most consistent torque output for 25 Ncm target torque.

Key Words: Dental Implants; Aging; Torque

Journal of Dentistry, Tehran University of Medical Sciences, Tehran, Iran (2013; Vol. 10, No.1)

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Received: 3 September 2012

Accepted: 5 December 2012

INTRODUCTION

Increasing initial tension in the screw known as preload, without exceeding its yield strength

stabilizes the screw joint [1]. An integral part of this process in dental implant screws is tightening screws to an appropriate torque or target



Fig 1. The friction-style mechanical torque limiting devices tested.

value [2,3]. It is demonstrated that application of insufficient preload, affects the stability of screw joint at implant abutment connection [4]. It is stated that connection-related complications (screw loosening or fracture) are among the most frequent technical complications that affect the survival rates of fixed implant supported prosthesis [5-9]. Hand, electronic and mechanical torque drivers are available for tightening screws and applying torque to the screw joint. It is demonstrated that hand held drivers are dependent on the experience level of the operator and are inconsistent, unpredictable and generally less than the target torque [10-12]. While accuracy of new and used electronic torque controllers has been reported without significant difference [13], unpredictable torque level with great range of errors (1% to 165% from the target torque) is also demonstrated in these devices [14]. Mechanical torque limiting devices (MTLDs), eliminating operator variability, are recommended as a common device to ensure consistency in tightening implant components to specific target torque. Two types of MTLDs are common in clinical use. These two types are toggle type or friction-style and beam type or spring-style.

Beam type or spring-style MTLDs apply a torque to the screw with spring action. This type does not have a release mechanism and MTLDs (F-S MTLDs) refer to those wrenches that use a ball detent system to disengage the lever arm at the desired torque and then by flipping the head of the wrench to the side, limit the torque applied.

Sterilization and aging seems to affect the accuracy of MTLDs [15-17].

Despite the evaluation of independent influence of steam sterilization on the accuracy of friction-style and spring-style MTLDs [18,19], the independent effect of aging has not been evaluated.

The accuracy of new MTLDs has been examined in few studies [20-22].

By comparing peak torque values of different MTLDs, Standlee and colleagues (2002) concluded that the mean torque values of new spring-style and friction-style MTLDs were within 10% of their respective torque levels [20]. Cehreli (2004) examined the accuracy of fifteen new and used spring-style MTLDs, and showed that new devices applied higher torque values than used

devices (sterilized up to 1000 times) for the 35 Ncm torque target ($P < 0.05$) [21].



Fig 2. The peak torque values of each friction-style mechanical torque limiting devices (F-S MTLDs) presented on the torque indicator of the gauge for each device were registered using a magnifier

Vallee and colleagues (2008) assessed the accuracy of new MTLDs and showed that spring-style MTLDs were more accurate than friction-style MTLDs in delivering the target torque ($P < 0.001$). The accuracy of MTLDs were dependent not only on the wrench style, but also on the manufacturer [22]. Some F-S MTLDs in clinical service delivered unacceptably high torque values [15,16]. Due to the high variability in peak torque delivery, the purpose of this study was to assess the accuracy ($\pm 10\%$ of the target torque) of new F-S MTLD, before and after aging.

The null hypothesis was that there would be no significant difference in the absolute value of errors (absolute difference between peak torque and target torque) after aging in each group of F-S MTLD.

The second null hypothesis was that there would be no significant difference in the absolute value of errors after aging among the three groups of F-S MTLDs.

MATERIALS AND METHODS

New F-S MTLDs from three different implant manufacturers were collected to determine their accuracy by comparing their peak torque with their target torque values (Figure 1).

Five MTLDs from each of the three types were selected and their respective drivers were tested:

- 1- Astra Tech (25 Ncm, Hader SA, La Chaux-de-Fonds, Switzerland)
- 2- Biohorizon (30 Ncm, Dynatorq ITL, Irvine, California, USA)
- 3- Dr Idhe (15-60 Ncm, Dr Idhe Dental, Eching/Munich, Germany).

Target torque was 25Ncm for Astra Tech MTLDs and 30 Ncm for Biohorizon and Dr Idhe MTLDs. The total specimen size of fifteen MTLDs were selected according to other studies [18,19,21,22] and considering the minimum effect size of 0.41Ncm, $SD=0.13$ and $\beta=0.2$, using 2-level factorial design and using minitab 14. Each manufacturer was given an abbreviation and each MTLD was randomly assigned a number from 1 to 5 and then labeled accordingly: Astra Tech (X1 to X5), Biohorizon (Y1 to Y5), Dr Idhe (Z1 to Z5). The sequence for testing MTLDs was also randomized. The Tohnichi torque gauge (Tohnichi, 6-BTG (-S), Japan) was used to measure the peak torque values of each MTLD. The torque gauge was new and calibrated by the manufacturer to be accurate within $\pm 2\%$ of the full scale. The driver for each respective MTLD was selected. Drivers were clamped in a 3-jaw chuck of torque gauge. After connection of the MTLD to the driver, torque indicator on the gauge was set to zero. The torque gauge was fixed in a vice for stability. Each MTLD was tested by applying the torque slowly for over 4 seconds [16,20]. Force was applied to the MTLDs until release and flipping of the head of the wrench to the side at a precalibrated torque value. The torque was applied by one operator that was blind to the measured values and the other operator registered the peak

torque values presented on the torque indicator of the gauge for each MTLT using a magnifier (Figure 2). The procedure of peak torque measurement was performed in ten sequences before aging. In each sequence, ten repetitions of peak torque values was registered. Totally, the procedure was repeated 100 times for each MTLT in three selected types. For the aging procedure, 1000 applications of target torque in 100 sequences, with at least 3 hours of delay between each sequence were performed using Tohnichi torque gauge. This 3 hours of delay was considered for simulating sterilization procedures in the clinical situation. The procedure of peak torque measurement was repeated after aging. The mean and range of difference between the measured torque value and the target torque values were evaluated before and after aging. Descriptive statistical analysis was used and a 2 way repeated- measure ANOVA was performed to assess the difference in accuracy among the three groups of friction-style MTLTs after aging. For pair wise comparison, Bonferroni post hoc test was used.

The distribution of absolute difference was not normal, though to compare the absolute difference values after aging in each group, the non parametric Wilcoxon signed rank test was used. P values less than 0.05 were considered as significant.

RESULT

Repeated measures ANOVA before aging demonstrated that peak torque values decrease with the number of repetitions and this decrease was significant until twenty times repetition of torque value measurements ($P<0.05$) and then did not show any significant difference until the end of the measurements (1000 times in 100 sequences) (Figure 3). For pair wise comparison Bonferroni post hoc test was used (Table 1-3).

According to this test, Biohorizon and Dr Idhe MTLTs, showed significant differences in the fifteen first repetitions of torque value measurements ($P<0.05$) and then they were comparable but showed significant difference with Astra Tech MTLTs ($P<0.05$).

Table 1. Mean Standard Deviation and Range of Difference Between Peak Torque and Target Values in 100 Times of Accuracy Measurement for Astra Tech Mechanical Torque Limiting Devices Before and After Aging

| | Measurement Times | Absolute Difference | Minimum | Maximum | Mean Difference (\pm SD) |
|-----|-------------------|---------------------|---------|---------|-----------------------------|
| 1 | Before | 0.3 | 0 | 1 | 0.3 ± 0.45 |
| | After | 1.5 | -2 | -1 | -1.5 ± 0.5 |
| 5 | Before | 0.4 | -1 | 0 | -0.4 ± 0.55 |
| | After | 2 | -2.5 | -1.5 | -2 ± 0.35 |
| 10 | Before | 0.5 | -1 | 0 | -0.50 ± 0.50 |
| | After | 2 | -2.5 | -1.5 | -2 ± 0.35 |
| 20 | Before | 1.6 | -2.5 | -1 | -1.60 ± 0.65 |
| | After | 2.8 | -3 | -2 | -2.8 ± 0.44 |
| 50 | Before | 0.4 | -2 | -0.5 | -1.40 ± 0.57 |
| | After | 2 | -2.5 | -1.5 | -2 ± 0.35 |
| 100 | Before | 1.1 | -2.5 | -0.5 | -1.1 ± 0.82 |
| | After | 2.9 | -3.5 | -2 | -2.9 ± 0.55 |

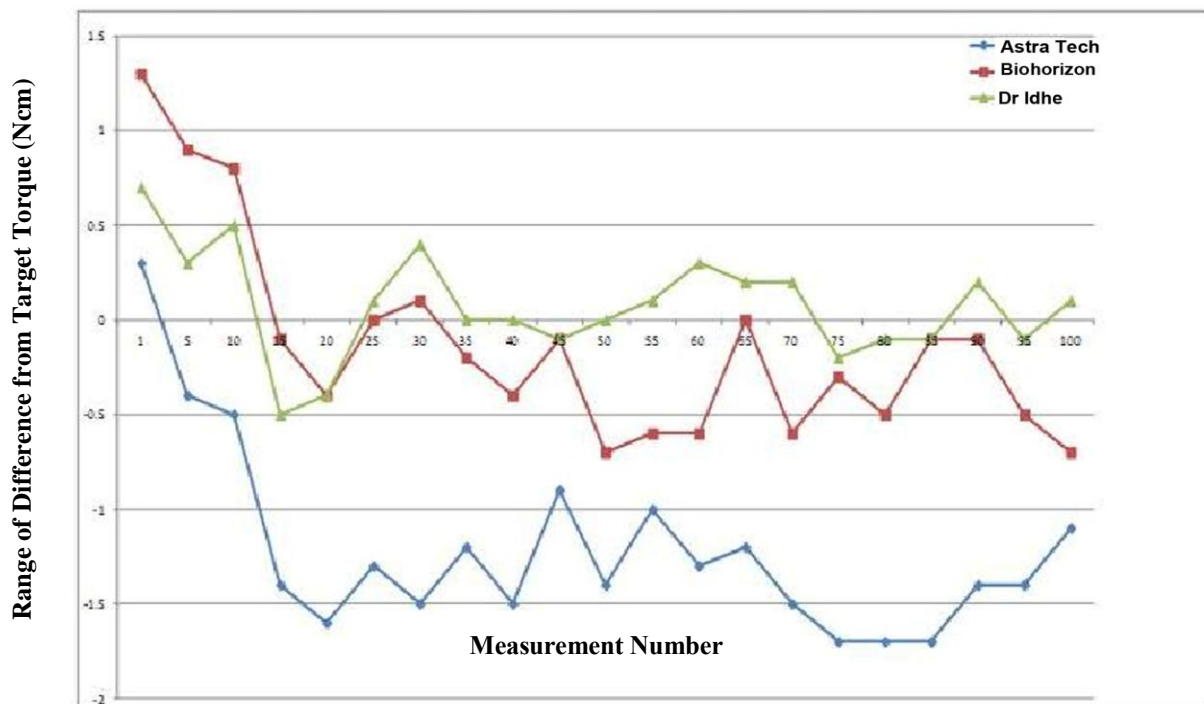


Fig. 3. Mean of difference between peak torque and target torque values in one to hundred times of measurement for three groups of friction-style mechanical torque limiting devices tested before aging. Zero level, showing target torque for three Astra Tech, Biohorizon and Dr Idhe groups

The mean difference of Astra Tech MTLDs was always lower than the target torque compared to the two other groups.

Repeated measures ANOVA after aging did not show any significant difference of peak torque values with the increased number of peak torque measurement. After aging, the difference between target torque and peak torque values increases.

A significant difference was seen between raw error values (absolute value of difference between peak torque and target torque) of the three groups studied ($P < 0.05$). Peak torque values were almost always higher than the target torque for Dr Idhe group and always lower than the target torque for Astra Tech and Biohorizon groups (Figure 4).

For pair wise comparison, Bonferroni post hoc test was used.

According to this test, Biohorizon and Astra Tech MTLDs did not show significant difference after aging ($P < 0.001$).

According to this test, Biohorizon and Astra Tech MTLDs did not show significant difference, but showed significant difference with Dr Idhe group ($P < 0.05$).

To compare the absolute difference values (error) after aging in each group, the non parametric Wilcoxon signed rank test was used. The results demonstrated significant difference of error in Astra Tech and Biohorizon MTLDs after aging.

DISCUSSION

The data support rejection of the first null hypothesis, as there was significant difference between the absolute difference of peak torque and target torque values (error) after aging in



Fig4. Mean of difference between peak torque and target torque values, during one to hundred times of measurement for 3 groups of friction-style mechanical torque limiting devices tested after aging. Zero level, showing target torque for three Astra Tech, Biohorizon and Dr Idhe groups

Astra Tech and Biohorizon MTLDs ($P < 0.001$). The data also support rejection of the second null hypothesis, as there was a statistically significant difference of absolute error values after aging between the three groups ($P < 0.05$). Before aging, statistically significant differences were found among the three types of F-S MTLDs ($P < 0.05$), but all the devices tested in this study delivered fairly consistent torque output within 10% of their preset target values. Vallee's findings on the accuracy of new F-S MTLDs showed all the recorded torque values lower than the target torque (in 50 consecutive measurements) [22].

However, our results showed that only recorded values of Astra Tech MTLDs always demonstrated a lower peak torque range than target torque values. Peak torque values decreased until twenty times repetition of torque value measurements in all the three study groups

($P < 0.05$) before aging. After aging, the difference between target torque and peak torque values increased. Evaluation of the range of this difference demonstrated the decrease of peak torque values for Astra Tech (-3.5,-1 Ncm) and Biohorizon (-4,-1Ncm) torque devices. This decrease demonstrated a predictable pattern for these two groups (always-2 Ncm lower than target torque). After aging, the increase of torque output was seen for Dr Idhe torque wrenches in the range of (-1, 5Ncm), with no predictable pattern. More than 50% of all torque wrenches in this study demonstrated more than 10% difference from their torque values. Maximum difference values were 16% for Astra Tech in 64% of peak torque measurements, 15% for Biohorizon in 52.7% of peak torque measurements and 16.7% for Dr Idhe torque limiting devices in 34% of peak torque measurements.

In this study, instead of using aggregate measures, the range of error was evaluated, which can demonstrate the torque values measured in 10% suitable torque range, with more confidence.

Extreme values in peak torque measurements were evaluated. The extremes are torque values that will most likely cause problems [20]. Peak torque values within 10% of the target torque were proposed as a clinically suitable torque [16,20].

Standlee demonstrated the ability of new F-S MTLDs in producing consistent torque values that did not vary more than 10% from target torque values [20]. This might confirm the present findings that demonstrated that all the devices tested in this study delivered fairly consistent torque output within 10% of their target values before aging.

As yet, a gold standard for clinically suitable torque has not been defined and the safety zone for inevitable errors of mechanical torque limiting devices has not been determined.

McCracken et al., measuring the variability of F-S MTLDs in clinical service, showed their capability of producing accurate torque values within 10% of their target torque, but high variability was seen and frequent calibration recommended [16].

After aging, peak torque values of mechanical torque limiting devices did not show any significant difference with the increased number of peak torque measurements. Gutierrez et al. evaluated the peak torque delivery of friction-style torque wrenches used routinely in dental practice. They did not find any correlation between the age of torque wrenches and peak torque delivery [15].

Table 2. Mean Standard Deviation and Range of Difference Between Peak Torque and Target Values in 100 Times of Accuracy Measurement for Biohorizon Mechanical Torque Limiting Devices, Before and After Aging

| | Measurement Times | Absolute Difference | Minimum | Maximum | Mean Difference (\pm SD) |
|-----|-------------------|---------------------|---------|---------|-----------------------------|
| 1 | Before | 0.7 | 0 | 2 | 0.70 \pm 0.76 |
| | After | 1.9 | -2.5 | -1.5 | -1.9 \pm 0.42 |
| 5 | Before | 0.3 | 0 | 1 | 0.30 \pm 0.45 |
| | After | 1.8 | -2.5 | -1 | -1.8 \pm 0.57 |
| 10 | Before | 0.5 | 0 | 1 | 0.50 \pm 0.50 |
| | After | 2.1 | -3.5 | -1.5 | -2.1 \pm 0.82 |
| 20 | Before | 0.4 | -1.5 | 0 | 0.4 \pm 0.65 |
| | After | 2.6 | -4 | -1.5 | -2.6 \pm 0.96 |
| 50 | Before | 0.3 | -1 | 0.5 | 0 \pm 0.61 |
| | After | 1.5 | -2 | -1 | -1.5 \pm 0.5 |
| 100 | Before | 0.1 | -1 | 1 | 0.10 \pm 0.74 |
| | After | 2.7 | -3 | -2 | -2.7 \pm 0.44 |

They concluded that the number of uses producing wear is probably not the major factor of inaccurate torque delivery. This finding supports our results that demonstrated a lower variability of peak torque values in comparison with other studies evaluating the accuracy of torque devices in clinical services [15,16].

Steam sterilization is the only routine method used for all torque wrenches used. Therefore, corrosion of the moving parts was found to be the reason of inaccurate values, as high as 455% of the stated target torque [15]. Congealation of the lubricant inside the friction-style torque wrench is proposed to increase the applied torque [16]. Separate and combined effect of steam sterilization and aging must be determined before consideration of other methods of sterilization. Clinical methods of calibration must also be considered.

The number of peak torque measurements for testing accuracy vary from five [16,17], seven [21], ten [15,18,20] to fifty [22] and finally 100 times [19] in different studies.

In this study, torque values were measured 100 times in 10 sequences. In each sequence, 10 consecutive measurements, with 3 hours delay between each sequence were made, simulating the clinical procedure of sequential screw tightening.

MTLDs of the current in vitro study were new and had not been exposed to clinical or sterilization procedures. Considering the independent influence of the number of use as aging, is a new point of view.

Generally, aging in the clinical situation is stated as a combined effect of the number of use and sterilization cycles without defining the exact number of use or sterilization cycles [16, 17, 21].

While other studies used torque wrenches in clinical services to investigate their accuracy, their results will not apply to every clinical situation, because too many confounding variables associated with sterilization, maintenance and use exist that cannot be checked and defined precisely [16].

Table 3. Mean, Standard Deviation and Range of Difference Between Peak Torque and Target Values in 100 Times Accuracy Measurement for Dr. Idhe Mechanical Torque Limiting Devices Before and After Aging

| Measurements Time | Absolute Difference | Minimum | Maximum | Mean difference (\pm SD) | |
|-------------------|---------------------|---------|---------|-----------------------------|------------------|
| 1 | Before | 3.1 | 1 | 2 | 1.30 \pm 0.45 |
| | After | 1.7 | 0 | 3 | 1.7 \pm 1.1 |
| 5 | Before | 0.9 | 0.5 | 2 | 0.90 \pm 0.65 |
| | After | 2 | 0 | 3.5 | 2.0 \pm 1.37 |
| 10 | Before | 0.8 | 0 | 2 | 0.8 \pm 0.76 |
| | After | 2.4 | 0 | 5 | 2.4 \pm 1.92 |
| 20 | Before | 0.6 | -1 | 0.5 | -0.4 \pm 0.65 |
| | After | 2.1 | -1 | 3.5 | 1.6 \pm 1.98 |
| 50 | Before | 0.7 | -1 | 0 | -0.70 \pm 0.44 |
| | After | 2.4 | 0 | 4 | 2.1 \pm 1.6 |
| 100 | Before | 0.8 | -1 | 0.5 | -0.70 \pm 0.67 |
| | After | 1.8 | -1 | 3 | 1.1 \pm 1.78 |

Future observations may be needed to simulate clinical situation and control the confounding variables such as sterilization, aging and maintenance [19]. Considering the independent and combined effect of sterilization methods and aging will give a clinical guideline to determine the calibration frequency needs of these devices.

CONCLUSION

Within the limitation of this study, aging as an independent factor affects the accuracy of F-S MTLDs. Astra Tech MTLDs presented the most consistent torque output for 25 Ncm target torque.

ACKNOWLEDGMENTS

This work has been sponsored by the Dental Research Center; Research Institute of Dental Sciences of Shahid Beheshti University of Medical Sciences, Tehran, Iran and the authors would like to express their appreciations to Dr Mohammad Javad Kharazi Fard for the statistical evaluation.

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