

Original Article

The effect of sterilization and number of use on the accuracy of friction-style mechanical torque limiting devices for dental implants

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ABSTRACT

Background: Mechanical torque limiting devices (MTLDs) are necessary tools to control a peak torque and achieving target values of screw component of dental implants. Due to probable effect of autoclaving and number of use on the accuracy of these devices, this study aimed to evaluate the effect of sterilization and number of use on the accuracy of friction-style mechanical torque limiting devices (F-S MTLDs) in achieving their target torque values.

Materials and Methods: Peak torque measurements of 15 new F-S MTLDs from three different manufacturers (Astra Tech, BioHorizons, Dr. Idhe) were measured ten times before and after 100 steam sterilization using a digital torque gauge. To simulate the clinical situation of aging (number of use) target torque application process was repeated 10 times after each sterilization cycle and the peak torque values were registered. Comparison of the mean differences with target torque in each cycle was performed using one sample t test. Considering the type of MTLDs as inter subject comparison, One-way repeated measure ANOVA was used to evaluate the absolute values of differences between devices of each manufacturer in each group ($\alpha = 0.05$).

Results: The results of this study in Dr. Idhe group showed that, mean of difference values significantly differed from the target torque ($P = 0.002$) until 75 cycles. In Astra Tech group, also mean of difference values with under estimation trend, showed a significant difference with the target torque ($P < 0.001$). Mean of difference values significantly differed from the target torque with under estimation trend during all the 100 cycles in BioHorizons group ($P < 0.05$).

Conclusion: The torque output of each individual device stayed in 10% difference from target torque values before 100 sterilization cycles, but more than 10% difference from the target torque was seen in varying degrees during these consequent cycles.

Key Words: Calibration, dental implants, equipment failure, torque

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INTRODUCTION

Torque control is the primary method used in implant dentistry for tightening abutment screws.^[1] Tightening torque and the coefficient of friction at the abutment screw-implant thread interface are the most important factors in determining the preload developed in the

implant complex.^[2] Studies have demonstrated that a lower joint preload causes significantly greater micromotion in the joint, resulting in joint failure and loss of function.^[3] Manufacturers of mechanical torque devices specify the torque to which the screws need to be tightened to achieve the intended preload, as a target torque. Two types of mechanical torque devices are common in clinical use. These two types are toggle type or friction-style and beam type or spring-style. Accuracy of mechanical torque limiting devices (MTLDs) is essential to prevent connection related complications.

The literature offers little information on the possible influence of steam sterilization on the accuracy of

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friction-style mechanical torque limiting devices (F-S MTLDs).^[4-6] It is stated that except for the effect of autoclaving on the 10Ncm friction-style torque wrench, sterilization procedures did not adversely affect the accuracy of the new F-S MTLDs.^[4] But high variability in delivered peak torque have been reported in clinical service of these devices.^[5,6] Gutierrez *et al.*,^[5] tested 35 F-S MTLDs following 3 years of clinical services for torque delivery accuracy. Their results showed that many of the tested devices were not accurate in delivering the target torque and maximum torque difference was higher than the manufacturer's designated torque value for 10 Ncm devices. McCracken *et al.*,^[6] reported that the mean applied torque of F-S MTLDs was not significantly different from spring-style devices, but greater range of values and variability were seen in F-S MTLDs after clinical use.

In general, manufacturers recommend sterilizing the F-S MTLDs in the broken or toggled position or dismantling of devices following the use of an approved lubricant before sterilization. The effect of such pre-sterilization process has not yet been clarified on the accuracy of F-S MTLDs.

Due to high inaccuracy reported in F-S MTLD and unknown effect of sterilization procedures (considering the broken position or dismantling of devices, with the use of an approved lubricant) and number of use on their accuracy, this study aimed to investigate the effect of sterilization procedures and number of use on the accuracy of F-S MTLDs.

The null hypothesis was that there would be no significant difference in the accuracy of F-S MTLDs considering sterilization procedures and number of use.

MATERIALS AND METHODS

15 new F-S MTLDs from three different implant manufactures were evaluated [Figure 1] to determine the effect of pre-sterilization procedures before steam sterilization on their accuracy (within %10 of the target value). Five samples from each of the three types of selected F-S MTLDs were tested:

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

Target torque was 25 Ncm for Astra Tech devices and 30 Ncm for BioHorizons and Dr. Idhe devices. Total specimen size of fifteen devices was selected according to other studies^[4,7] and considering the effect size of 0.37 Ncm, SD = 0.13 and β using 2-level factorial design.

The peak torque measurement was tested ten times before and after 1, 5, 10, 20, 50, 75, and 100 steam sterilization cycles (134°C, 0.9 bar vacuum pressure and 18 min) using the digital torque gauge (Tohnichi torque gauge, Tohnichi CO., Tokyo, Japan) [Figure 2]. The torque gauge was calibrated by the manufacturer to be accurate within $\pm 2\%$ of the full scale. Drivers for each respective device were clamped in 3-jaw chuck of torque gauge. After connection of the torque device to the driver, torque indicator on the gauge was set to zero. The torque gauge was fixed in a wise for stability. Each device was tested by applying the torque slowly; over 4 s.^[8] Force was applied to the F-S MTLDs until the release at a pre-calibrated target torque value. The torque was applied by one operator that was blind of measured values and the other operator registered the peak torque values. The sequence for testing the devices was randomized. Devices of each group were prepared before each sterilization cycle, as recommended by manufacturers. Astra Tech and Dr. Idhe devices were dismantled, cleaned, dried and lubricated at the proposed site, and then the parts were assembled before sterilization [Figures 3 and 4]. For BioHorizons, devices were lubricated with the bended handle [Figure 5].

To simulate the clinical situation of aging, the procedure of target torque application was repeated



Figure 1: Friction-style mechanical torque limiting devices tested. X, Astra Tech — Y, BioHorizons — Z, Dr Idhe mechanical torque limiting devices

10 times after each sterilization cycle and the peak torque values were registered. Before each autoclaving cycle, to simulate the contamination of these devices during surgical and prosthetic procedures, devices were immersed in artificial saliva (Bioextra, Solarfarma, Knokke, Belgium) and then disinfected, for 15 min with the 2% phenols and aldehyde-free, non-fixing disinfectant (Deconex 53 plus, Borer Chemie AG, Zuchwil, Switzerland). Devices were packed and then were put through the steam autoclave (Techno- Gaz/, Europa BXP/Parma, Italy).

Mean and range of difference between the measured torque and the targeted torque values were evaluated, considering sterilization cycles and number of use. Absolute difference is the difference in Ncm taken without regard to the sign between the measured torque value and the targeted torque value. Furthermore, algebraic absolute values of these differences were calculated.

Descriptive statistical analysis was used and a comparison of mean of difference with target torque in each cycle was performed with one sample *t* test. One-way repeated measure ANOVA, considering the type of MTLDs as a between subject comparison, was used to evaluate the absolute values of difference between devices of each manufacturer in each studied group ($\alpha = 0.05$).

RESULTS

Descriptive values of mean, standard deviation, minimum, and maximum difference between the measured torque and the targeted torque values for each group of friction-style mechanical torque devices are summarized in Tables 1-3.

In Astra Tech group [Table 1] mean of difference values significantly differed from the target torque



Figure 2: The digital torque gauge (Tohnichi, Japan)



Figure 3: Dismantling of the components in Dr. Idhe devices



Figure 4: Dismantling of the components Astra Tech devices



Figure 5: For BioHorizons devices lubrication and bending of the handle could be considered

($P = 0.04$) until 75 cycles, usually with under estimation trend. Under estimation increased until the 100 cycle that achieved to maximum difference values and showed a significant difference with the target torque ($P < 0.001$). Maximum absolute values of difference were 3.35 Ncm (13.4% difference from the target torque) in Astra Tech devices and they showed more than 10% difference from the target torque on 16% of measured peak torque in one device (Figure 6).

Considering steam sterilization and number of use, the results of this study in BioHorizons

group [Table 2] showed that, mean of error values significantly differed from the target torque with under estimation trend during all the 100 cycles ($P < 0.05$). Maximum absolute value of difference was 7.75 Ncm (25.83% difference from the target torque) in this group. BioHorizons devices showed more than 10% difference from the target torque on 76% of measured peak torque in all of the five devices.

Considering sterilization and number of use, the results of this study in Dr. Idhe group [Table 3] showed that, mean of difference values significantly differed from the target torque ($P = 0.002$) until 75 cycles and then,

Table 1: Differences between peak torque and target values (absolute, mean, and range in Ncm) before (X0) and during 100 times of steam sterilization cycles (X1-X100) for Astra Tech devices

Measurement time	Absolute difference (minimum-maximum)	Minimum	Maximum	Mean difference (SD)
X0	1.44 (0.70-2)	-2	-0.7	-1.44 (0.50)
X1	1.28 (0.60-2.2)	-2.20	-0.60	-1.28 (0.65)
X5	0.81 (0.15-1.14)	-1.40	-0.15	-0.81 (0.56)
X10	0.44 (0-0.95)	-0.95	0.50	0.44 (0.36)
X20	0.87 (0.10-1.65)	-1.65	0.10	-0.84 (0.71)
X50	0.75 (0.15-1.25)	-1.25	-0.15	-0.75 (0.47)
X75	1.34 (0.90-1.75)	-1.75	-0.90	-1.34 (0.37)
X100	2.35 (1.50-3.35)	-3.35	-1.50	-2.35 (0.68)

Table 2: Mean differences between peak torque and target values (absolute, mean, and range in Ncm) before (X0) and during 100 times of steam sterilization cycles (X1-X100) for BioHorizons devices

Measurement time	Absolute difference (minimum-maximum)	Minimum	Maximum	Mean difference (SD)
X0	0.79 (0.40-1)	-1	0.40	-0.26 (0.61)
X1	1.66 (0.15-4.2)	-4.2	0.15	1.57 (2.10)
X5	2.12 (0.05-4.45)	-4.45	-0.05	-2.12 (1.97)
X10	2.35 (0.75-4)	-4	-0.75	-2.35 (1.41)
X20	2.92 (0.60-5.35)	-5.35	0.60	-2.47 (2.67)
X50	4.94 (3.15-6.75)	-6.75	-3.15	-4.94 (1.61)
X75	4.15 (1.1-6.35)	-6.35	-1.10	-4.15 (3.03)
X100	4.74 (2.60-7.75)	-7.75	-2.60	-4.74 (2.46)

Table 3: Differences between peak torque and target values (absolute, mean, and range in Ncm) before (X0) and during 100 times of steam sterilization cycles (X1-X100) for Dr Idhe devices

Measurement time	Absolute difference (minimum-maximum)	Minimum	Maximum	Mean difference (SD)
X0	0.65 (0.20-0.80)	-0.80	0.50	-0.13 (0.53)
X1	1.43 (0.40-3.15)	0.4	3.15	1.43 (1.21)
X5	1.65 (0.15-2.90)	0.15	2.90	1.65 (1.22)
X10	2.18 (0.80-2.85)	0.8	2.85	2.18 (0.97)
X20	1.89 (0.25-2.50)	-0.25	2.50	1.68 (1.11)
X50	1.49 (0.55-2.35)	-0.55	2.35	0.87 (1.13)
X75	1.56 (0.40-2.10)	-0.40	2.10	1.39 (1.01)
X100	1.98 (0.70-3.75)	-2.05	3.75	0.13 (2.68)

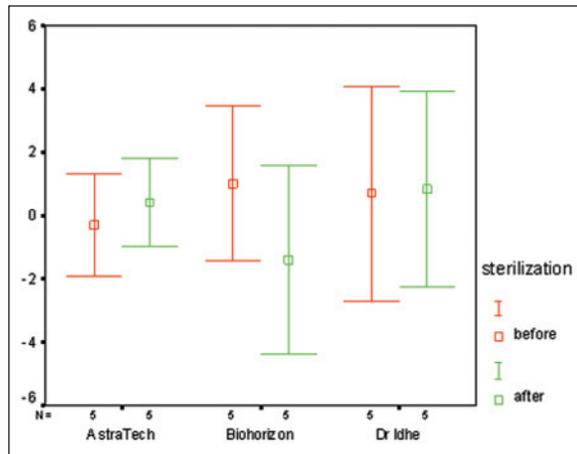


Figure 6: Error bar and 95% confidence interval of mean raw error compared to target torque for 3 groups of friction-style torque limiting devices, zero level showing target torque for each group (Astra Tech, BioHorizon, Dr. Idhe)

despite the increase of difference, values with both under and over estimation trend of target torque value evaluation, significant difference of mean values was not seen. Maximum absolute values of difference was 3.75 Ncm (12.5% difference from the target torque) in Dr. Idhe group. After 100 cycles, more than 10% difference from the target torque was seen on 10% of measured peak torque in one device.

DISCUSSION

The data support rejection of the first null hypothesis as there was a statistically significant difference of torque values ($P < 0.05$ for BioHorizons and Dr. Idhe and $P < 0.001$ for BioHorizons and Astra Tech). Accuracy of MTLTD is essential to prevent connection related complications. Connection related complications have been reported among the most frequent technical complications that affects the survival rates of fixed implant supported prosthesis.^[9-13] Peak torque values within 10% of the target torque was proposed as a clinically suitable torque.^[6,8] After 100 autoclave cycles the maximum torque value measured in the current study showed 12.5% and 13.4% and 25.83% difference from the target torque in Dr. Idhe, Astra Tech and BioHorizons group respectively.

Sterilization in saturated steam under pressure is considered to be the most certain method for destroying all forms of microbial life. Instruments suffer however, from corrosion during autoclaving due to hot steam medium.^[14-16] Dellenges and Curtis^[4] demonstrated that

sterilization procedures did not adversely affect the accuracy of the new DynaTorq wrench system for target torque value of 20 and 30Ncm. However, the results of the current study demonstrated higher variability of DynaTorq ITL devices in BioHorizons group. The maximum torque value measured in BioHorizons group showed 25.83% difference from the target torque. This can be related to the effect of lubrication and simulated clinical use in the current study.

Gutierrez *et al.*,^[5] evaluated the torque delivery accuracy of 35 F-S MTLTDs. All of the devices had been in clinical service for a minimum of 1 month or a maximum of 3 years. Corrosion of the spring in the handle of the torque wrench was found to be the reason for the largest value seen for 10 Ncm torque wrench (455% higher than the manufacturer's designated torque value). They presented spring corrosion as a leading factor to excessively high torque delivery resulting from lack of spring flexibility. Their results showed largest values of 17% for the 30 Ncm torque wrench and 58.6% for the 35 Ncm devices.^[5] Sterilization procedures were not clearly pointed in this study. In the current study, maximum difference values, considering sterilization procedures and number of use, were higher for BioHorizons group (7.75 Ncm/25.83% differences for the target torque of 30 Ncm).

Aging as an independent factor affects the accuracy of F-S MTLTDs.^[17] It is stated that the number of uses producing wear, is probably not the major factor of inaccurate torque delivery. Evaluating the peak torque delivery of frictional style torque wrenches used routinely in dental practice, any correlation between age of the torque wrenches and peak torque delivery have been rejected.^[5] This finding support our results that demonstrated low variability of peak torque values in some of the tested devices considering 100 cycles of sterilization and number of use. Higher variability was seen in BioHorizons devices. Vallee *et al.*,^[7] demonstrated the accuracy of MTLTDs were dependent not only on the wrench style, but also on the manufacturer. This finding supports our results that demonstrated higher variability in BioHorizons devices.

Under estimation of target torque on peak torque delivery was seen in the majority of tested devices in the current study. Dental implant screw joints tightened to lower preload values, cannot achieve the mechanical integration in implant abutment interface.^[18]

McCracken *et al.*,^[6] assessing the accuracy of mechanical torque devices at clinical service for 18

months to 7 years and with maximum 700 times of clinical use in an institutional environment, showed their capability of producing accurate torque values within 10% of their target torque. However, higher standard deviation (16.1 Ncm) and range of values (55.9%) were seen among the friction-style devices comparing with spring-style devices. Heating process that congeals the lubricant inside the friction-style wrench, jamming the action and increasing the applied torque, was stated as a probable cause of creating inaccuracy of F-S MTLDs in an institutional environment with proposed frequent calibration of these devices.^[6] Current results showed that mean absolute values of difference did not differ significantly between Astra Tech and Dr. Idhe group, but they were significantly lower than BioHorizons group $P < 0.05$. In the analysis of data, absolute values of difference (extremes) are more reliable than the mean difference values to show probable clinical complications.^[8] Lubrication of Astra Tech and Dr. Idhe devices was performed meticulously, in multiple sites after dismantling of the devices. They seem less sensitive to the effect of lubrication and corrosion. High variability was seen in BioHorizons devices. Lubrication of these devices was performed in a single site at broken position.

Some studies have used new devices to evaluate the effect of sterilization on the accuracy of these devices.^[4,19] F-S MTLDs of current *in vitro* study were also new and had not been exposed to clinical procedures (aging). Other studies use torque wrenches in clinical services to investigate their accuracy but, due to the lack of data on the exact age and the actual number of sterilization cycles and maintenance of mechanical torque devices, their results will not apply to every clinical situation.^[5,6,20] Continuous education and regular studies on the efficacy of different sterilizing techniques to overcome the infectious hazards are strongly emphasized.^[21] Considering the combined effect of sterilization methods and number of use, will help to determine a clinical guideline to determine the maintenance requirement of this devices for accurate torque delivery (within 10% of their preset target values).^[22]

CONCLUSION

- The torque output of each individual device stayed in 10% difference from target torque values before 100 sterilization cycles.

- Mean difference values differed significantly from the target torque in Astra Tech group ($P < 0.01$) and BioHorizons group ($P < 0.05$). However, in Dr. Idhe devices, mean difference showed a significant difference only until 75 cycles ($P = 0.002$) and then, despite the increase of difference, significant difference of mean values was not seen.
- Absolute values of difference did not differ significantly between Astra Tech and Dr. Idhe group but they were significantly lower than BioHorizons group ($P < 0.05$).
- Low range of variability was seen in all of the tested devices in Dr. Idhe group.

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