

Evaluation of the Accuracy and Related Factors of the Mechanical Torque-Limiting Device for Dental Implants

Mahmood Kazemi¹, Ahmad Rohanian¹, Abbas Monzavi^{2✉}, Mohammad Sadegh Nazari³

¹Assistant Professor, Department of Prosthodontics, Faculty of Dentistry, Tehran University of Medical Sciences, Tehran, Iran

²Associate Professor, Department of Prosthodontics and Dental Implant Research, Faculty of Dentistry, Tehran University of Medical Sciences, Tehran, Iran

³Dentist

Abstract

Objective: Accurate delivery of torque to implant screws is critical to generate ideal preload in the screw joint and to offer protection against screw loosening. Mechanical torque-limiting devices (MTLDs) are available for this reason. In this study, the accuracy of one type of friction-style and two types of spring-style MTLDs at baseline, following fatigue conditions and sterilization processes were determined.

Materials and Methods: Five unused MTLDs were selected from each of Straumann (ITI), Astra TECH and CWM systems. To measure the output of each MTLD, a digital torque gauge with a 3-jaw chuck was used to hold the driver. Force was applied to the MTLDs until either the friction styles released at a pre-calibrated torque value or the spring styles flexed to a pre-calibrated limit (target torque value). The peak torque value was recorded and the procedure was repeated 5 times for each MTLD. Then MTLDs were subjected to fatigue conditions at 500 and 1000 times and steam sterilization processes at 50 and 100 times and the peak torque value was recorded again at each stage.

Results: Adjusted difference between measured torque values and target torque values differed significantly between stages for all 3 systems. Adjusted difference did not differ significantly between systems at all stages, but differed significantly between two different styles at baseline and 500 times fatigue stages.

Conclusion: Straumann (ITI) devices differed minimally from target torque values at all stages. MTLDs with Spring-style were significantly more accurate than Friction-style device in achieving their target torque values at baseline and 500 times fatigue.

Key Words: Dental Implantation; Torque; Calibration

✉ Corresponding author:

A. Monzavi, Department of Prosthodontics and Dental Implant Research, Faculty of Dentistry, Tehran University of Medical Sciences, Tehran, Iran

monzavia@sina.tums.ac.ir

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INTRODUCTION

Nowadays, implant dentistry is considered as a choice of treatment [1]. Though similar to

conventional treatment, it is accompanied with complications [2,3], which are classified into two groups of mechanical and biological prob



Fig 1. Three Straumann (ITI), Astra TECH and COWELLMEDI (CWM) implant devices



Fig 2. Mark-10 digital force/torque indicator model BGI

lems. Screw loosening is one of the most common mechanical complications of implant treatment [1,4-11]. Several factors including inserting torque value, occlusion, thread embedment, misfit, cantilever, design of anti-rotational features, platform dimensions, and screw materials have been studied as reasons in this phenomenon.

The torque value between the factors mentioned above allied with platform dimensions and thread embedment phenomenon have been known as effective factors [4, 8, 12, 13]. Hand screw drivers and mechanical and electrical torque drivers are available devices for exerting torque to the screw joint of an implant complex.

Although using hand drivers is simple, comfortable and also the most common method in the primary stage of the screw tightening process, its use shows much variety among clinicians [4]. Therefore, this method is not advised for final screw tightening [4, 7, 14]. Mechanical and electronic torque drivers are available to apply desired torque to the screw joint. According to the manufacturer's recommendation, mechanical devices have a margin of error from 3 to 6% [4, 5, 10, 15] and they could also be sterilized with autoclave.

Calibration is recommended for this group of

devices annually [4, 5, 10, 15]. Studies have showed that generated torque by these devices could be affected by frequent use and sterilization process [4, 8, 10, 17]. The aim of the current study was to evaluate the accuracy of three different mechanical torque-limiting devices after frequent use and sterilization process.

MATERIALS AND METHODS

This comparative study included three implant systems: Straumann (ITI), COWELLMEDI (CWM) with Spring-style torque wrench devices and Astra TECH implant system with friction style torque wrench device (fig 1). Evaluation of generated torque by devices was done by means of torque evaluating electrical machine, Mark-10 digital force/torque indicator model BGI (mark 10 corporation-USA) with an accuracy of full scale 0.1% (fig 2). The first stage included evaluating the accuracy of unused or new devices and comparing the three systems. In this stage, by attaching the screw driver to the torque indicator, when one practitioner exerted tightening abutment torque to the head of screw driver (fig 3), another practitioner recorded the maximal generated torque by every device ten times consecutively.



Fig 3. Practitioner exerting tightening abutment torque to the head of the screw driver

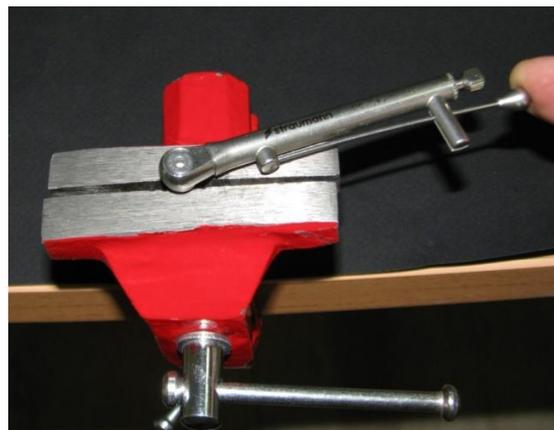


Fig 4. The metal clip has been fixed

Then the mean and standard deviation of conclusion for every device was calculated.

The aim of the next two stages was evaluating the effect of frequent use or fatigue in three conditions; baseline (primary accuracy), after 500 times of use and after 1000 times of use (fatigue condition).

In order to create 500 and 1000 times of use (fatigue condition) for the devices, a screw driver in the region of the shank was attached to a bench metal clip then tightening abutment torque was exerted by means of each device to the head of the screw drivers while the metal clip was fixed (fig 4).

Then the torque generated by every device after 500 and 1000 times of use was recorded by a torque indicator with the method mentioned above. In the final stages, the devices were sterilized for 50 and 100 times by autoclave (class C primary Italia) according to the manufacturer's instruction (134°C, 0.9 bar pressure and 18 minutes).

Then the torque generated by devices was recorded as mentioned before. In this study, quantitative data were recorded in the form of mean and standard deviation.

The absolute difference was defined as the algebra difference of exerted tightening abutment torque (target torque) by the practitioner from the measured generated torque indicator

and the adjusted difference was defined by the following formula:

$$\text{Adjusted difference} = \frac{\text{Absolute difference}}{\text{Target torque}} \times 100$$

Statistical analysis was performed using non-parametric analysis and SPSS 18 for Windows (SPSS/PC 18.0; SPSS Inc, Chicago, Ill, USA). Comparison between conditions for each device was done with the Friedman test. Comparison between devices in each condition was performed by Kruskal-Wallis test and U Mann-Whitney test was used for comparison between conditions for different styles and the level of significance was considered at $p < 0.05$.

RESULT

Adjusted difference between the stages for Straumann (ITI) devices was not equal ($P=0.002$) This was caused by the difference between the mean difference of 1000 times use with the final stage (adjusted $P=0.003$) and baseline stages (adjusted $P=0.001$).

Adjusted difference between the stages of the study was not equal for Astra devices ($P=0.001$). It was caused by the difference between the mean differences of the third stage with 1000 times use+50 times sterilization (ad

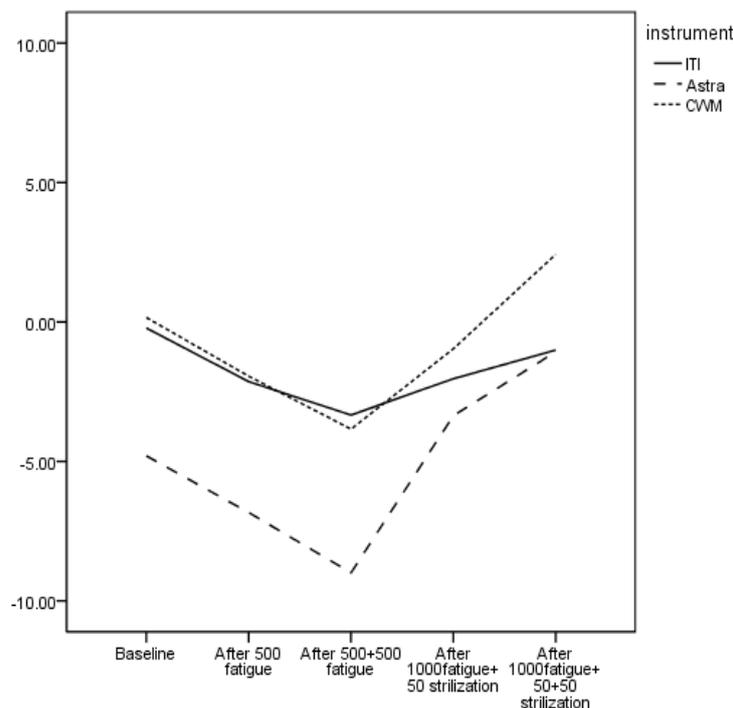


Fig 5. The diagram of adjusted difference (percentage) of the devices during different stages of the study

justed P=0.03) and with 1000 times use+100 times sterilization (adjusted P=0.001).

Adjusted difference between the stages for the study of CWM devices was not equal (P=0.004).

This difference was between the mean difference of the third stage with the final stage (adjusted P=0.003) (Table 1) (Fig 5).

Adjusted differences between devices were not expressive in any stages of the study statistically (P=0.009 in baseline stage, 0.09 for 500 times use, 0.15 for 500+500 times use, 0.54 for 1000 times use+50 times sterilization and 0.81 for the final stage).

Adjusted difference between Astra devices as a device that works with friction style with two other devices that work with spring style were compared in every stage. The amount of P-value calculated 0.05 after 500 times use, which represents the generated torque by Astra devices, was far from target torque. In the other stages, there was no difference statistically between the two styles (P= 0.14, 0.62 and 0.62, respectively) (Table 2) (Fig 6).

DISCUSSION

Comparison of the results showed that in the baseline stage or in unused devices and in 500

Table 1. Adjusted Difference (Percentage) of Devices During Different Stages of the Study as Mean (Std. Deviation)

Device	ITI	Astra	CWM
Baseline	-0.22 (0.78)	-4.80 (2.06)	0.16 (0.82)
500 Use	-2.14 (1.46)	-6.83 (1.73)	-1.94 (9.72)
500+500 Use	-3.34 (1.40)	-8.99 (1.58)	-3.84 (10.42)
1000 Use +50 Sterilization	-2.03 (1.56)	-3.36 (2.13)	-0.96 (10.73)
1000 Use +50 +50 Sterilization	-1.01 (1.12)	-1.07 (1.35)	2.42 (12.54)

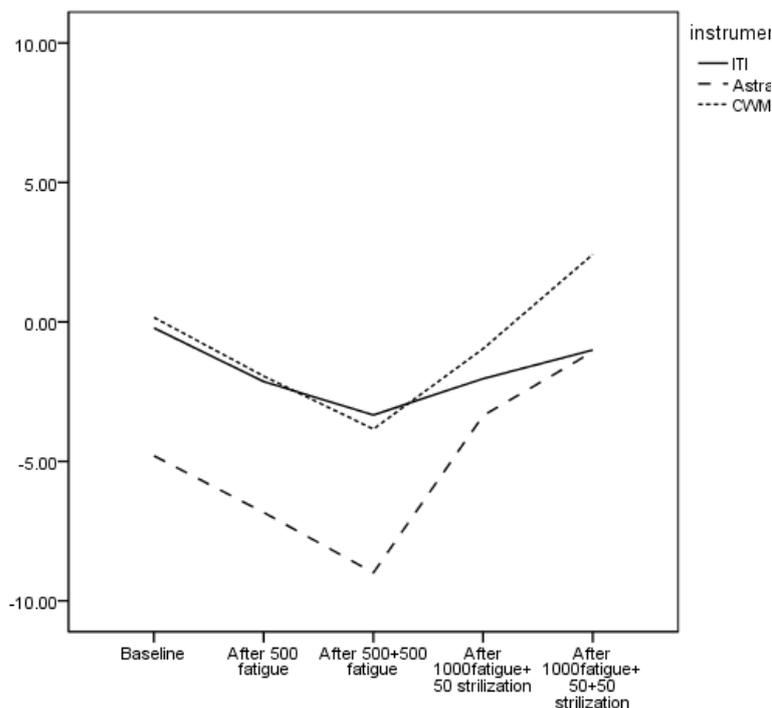


Fig 6. The diagram of adjusted difference (percentage) of the by two styles during different stages of the study

times use although no expressive difference was separately observed between the three systems statistically when comparing 2 styles, devices with spring style mechanism were more accurate than devices with friction style mechanism.

The limitation of samples can be the probable reason for the less expressive difference in comparison between the three systems.

These results were in accordance with the study of Vallee et al. [4] that of course, were done on assessing unused devices of six systems; Zimmer, life core, Astra tech with friction style and Straumann (ITI), Nobel biocare and 3i with spring style. The difference level in baseline condition in the study conducted by Vallee et al. for both friction style and spring style mechanisms was more than our study, and

Table 2. Adjusted Difference (Percentage) of the Two Styles During Different Stages of the Study as Mean (Std. Deviation)

Device	Friction Style	Spring Style
Baseline	-4.80 (2.06)	-0.03 (7.23)
500 Use	-6.83 (1.73)	-2.04 (6.56)
500+500 Use	-8.99 (1.57)	-3.90 (7.01)
1000 Use +50 Sterilization	-3.36 (2.13)	-1.50 (7.25)
1000 Use +50 +50 Sterilization	-1.17 (1.35)	-0.71 (8.59)

variation of systems could be the probable reason for this phenomenon.

The conclusions of a study performed by Standlee et al. [16] showed that the mean torque of Straumann (ITI) devices was in the margin error of 10 %, while the current study showed that it is in the range of less than 5% of target torque. This conclusion was according to the producer's recommendation.

This difference can be the results of different torque evaluating devices in the two studies. Nevertheless, the conclusions of the two studies have indicated the minor variability of Straumann (ITI) devices.

In CWM devices, although the mean was in the range of 5% of target torque, the standard deviation was more than the margin error of 5%, while the Astra device has a mean torque near to the range of 5% and the margin of standard deviation was more than the producer's recommendation. The conclusions of the study showed that between the stages of the study, there was an expressive difference statistically for three systems. Straumann (ITI) devices were sensitive to fatigue expressively, yet they were in the margin error of the producer's recommendation.

These results were in accordance with the results of a study carried out by Cehreli et al. [8]. Although in the current study fatigue has been defined experimentally and in the study of Cehreli et al. it has been defined in the form of frequent use in clinic and in both studies a decrease in exerted torque was observed (1.5 Ncm decrease in Cehreli et al. study and 1.1 Ncm, in our study), after sterilization, an increase in generating torque of all devices was observed.

This increase was statistically expressive in comparison to 1000 times use. Difference in Astra devices was more than the other devices that may be explained by the sensitivity of Astra system devices to sterilization in comparison to Straumann (ITI) and CWM devices. But after sterilization, no expressive difference with the baseline stage was demonstrated in

the three systems. Dellinges et al. [17] showed that the sterilization process with autoclave causes an increase in the range of torque. Although increase of the range did not show an expressive difference, this difference between the two studies may be the result of difference in the type of included systems and frequent use (fatigue condition) in the current study.

CONCLUSION

According to the limitations of the current study such as in vitro condition of fatigue and limitation of the included systems, we can conclude that:

- 1) Devices with spring style mechanism were more accurate in comparison to devices with friction style mechanism in baseline and 500 times use, although this difference was not observed in the other stages.
 - 2) CWM devices after 100 times sterilization had the lowest reliability.
 - 3) Straumann (ITI) devices in the baseline stage had the highest reliability and they also had the nearest mean to the target torque, although the difference with the two other systems was not expressive.
 - 4) The sensitivity of Astra system devices to sterilization was more in comparison to Straumann (ITI) and CWM devices and the sensitivity of Straumann (ITI) system devices to frequent use (fatigue condition) was more in comparison to Astra and CWM devices.
- We suggest calibration of all new devices before use and a plan for periodic calibration of the devices by the manufacturer is necessary.

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