

Original Article

Evaluation of the effect of diode laser for debonding ceramic brackets on nanomechanical properties of enamel

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ABSTRACT

Background: The heat from laser can lead to the destruction of organic components of enamel and consequently changes in the mechanical properties of enamel. The purpose of this study was to evaluate the effect of diode laser on the nanomechanical properties of enamel in the process of debonding the ceramic brackets.

Materials and Methods: In This *in vitro* study Eighteen ceramic brackets were bonded on the intact premolars in 3 groups of 6 (one control and two study groups). To debond the brackets in the study groups, laser diode was used for 3 s with 1W and 3W power. Shear bond strength and adhesive remnant index were recorded for all groups. Hardness and elastic modulus were measured in 1–31 μ depth from enamel surface in each debonded area. Analysis of variance was used for determining the difference in shear bond strength (SBS), hardness, and elastic modulus and was followed by *post hoc* Tukey's honest significant difference test. One-sample *t*-test was used to compare the changes in the pulp temperature with the standard threshold (5.5°C). The significance level was set at %5 in this study.

Results: SBS was significantly greater in the control group compared to the study groups. There was no significant difference in the average of hardness and elastic modulus of enamel between the groups. Pulp temperature elevation in the study groups was significantly < 5.5°C (*P* = 0.000).

Conclusion: The diode laser with either 1W or 3W power for 3 s is effective in debonding the ceramic brackets without any detrimental effect on the pulp or mechanical properties of enamel. In regard to the pulp health, the 1W power laser is rather recommended for debonding the ceramic brackets than the 3W laser power.

Key Words: Brackets, dental debonding, diode laser, hardness, shear strength

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INTRODUCTION

Ceramic brackets are one of the best choices for patients and the most acceptable appliances in orthodontics.^[1-3] Besides the esthetic advantage, these brackets are completely durable and are resistance to color change. However, these brackets have some

disadvantages. The main clinical problem of these brackets is the risk of damage to the enamel during bracket debonding^[4] that arises from the high bonding strength between the adhesive and ceramic bracket.^[5,6] Fractures and cracks are among the damages that

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enamel suffers and leads to esthetic concern or expensive operative treatments.^[7] Moreover, the inherent brittleness of ceramic brackets makes the usual debonding methods ineffective for these brackets.^[8] Several ways have been proposed to solve this problem. One of these methods is to use thermal energy to soften the adhesive at the adhesive/bracket interface. A very convenient way to deliver a controlled amount of heat to ceramic brackets is using laser.^[9] Diode laser is one of the most commonly used lasers in dentistry. This laser is small, lightweight, inexpensive, and most importantly portable.^[10,11]

Laser softens the adhesive by increasing the temperature in brackets and teeth.^[9] Heat can damage the proteins of enamel matrix,^[12] change the mechanical properties of enamel, and make it susceptible to iatrogenic damages. Although the organic components make up a small percentage of enamel, they are very important in determining the mechanical properties of enamel such as hardness and elastic modulus.^[12,13] One of the best methods to evaluate mechanical properties of materials with sizes as small as a tooth and biologic hard tissues is Nanoindentation test.^[14-16] Although the previous studies have evaluated the effects of diode laser on debonding ceramic brackets and dental pulp, they have not examined its radiation effects on enamel mechanical properties such as hardness and elastic modulus.^[3,7,17] The aim of this study was to evaluate the effects of diode laser for ceramic bracket debonding on the mechanical properties of the enamel by nanoindentation test while the pulp temperature changes were monitored.

MATERIALS AND METHODS

This *in vitro* study was done in Oral and Dental Diseases Research Center in Kerman University of Medical Sciences and Central Laboratory of Isfahan University of technology. In this study, 12 healthy maxillary premolars extracted for the orthodontic treatment purposes were used. The number of samples was specified based on previous studies. Selection criteria included no decalcification or cracking of the enamel surface. After cleaning the roots, teeth were saved in a balanced saline solution of HANK (Gibco, Life Technologies, USA) to reduce demineralization.^[4] All teeth were vertically buried to the CEJ area in blocks of self-cured acrylic resin (Dentsply Ltd., Surrey, England) so that the crowns were out of acryl.

Before bonding, access cavity to the pulp chamber was created by high-speed handpiece (Pana-Max, NSK, Japan) with coolant and to facilitate the placement of K-Type thermocouple (K-Type, Gumo, Germany), pulp tissue was removed by endodontic file. Buccal surface of all teeth was cleaned with pumice without fluoride, polished by rubber cup, rinsed, and dried by moisture- and oil-free air.

Bonding of brackets

The buccal surface of the crown of each tooth was then divided to mesial and distal sides by a hypothetical center line. Eighteen monocrystalline ceramic brackets (Radiance, American orthodontics, USA) were bonded randomly on mesial or distal sides (6 sides, either mesial or distal, remained free) by curing a transbond XT composite resin (Transbond XT, 3M Unitek, Monrovia, California, USA) with LED (Demi, Kerr Co., USA) for 40 s (10 s for each side of bracket) [Figure 1] after removing the excess resin. Surfaces had been etched with 35% phosphoric acid gel (Transbond XT, Eching Gel, 3M Unitek, Monrovia, California, USA) for 15 s, rinsed for 20 s, and then dried by moisture- and oil-free air before bonding the brackets. The samples were then kept in distilled water bath set at 37°C for 24 h. Following thermocycling for 1000 cycles and temperatures between 5°C and 55°C, the brackets were divided into 3 groups of 6 (control, 1w, and 3w power laser), randomly.

Shear bond strength test and Adhesive Remnant Index test for control group

The teeth were placed in testometric machine (10KN, M350-10CT, Testometric, England) so that the bracket's slot was horizontal. In control group, a sharp Chisel blade was placed at the enamel/bracket's base interface and the machine was set at the speed of 0.5 mm/min. The debonding force was measured in terms of Newton and converted to mega Pascal unit (MPa) through dividing the force by the area



Figure 1: Bonded brackets on buccal surface.

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of bracket's base. After debonding, the enamel surfaces and the brackets' base were examined by stereomicroscope (ST30B2 L, Motic, Spain) with $\times 10$ and they were rated based on the amount of adhesive remaining on the enamel surface and Adhesive Remnant Index (ARI) criterion.

ARI scoring from 0 to 3 is as follow:

Zero: No adhesive left on the surface and the bond break occurred between the adhesive and enamel.

1. Less than half of adhesive left on the tooth surface
2. At least, half of the adhesive left on the tooth surface
3. All of the adhesive left on the tooth surface and the bond break occurred between the adhesive and the bracket's base.^[7]

Shear bond strength test, Adhesive Remnant Index test, and the pulp temperature changes in the study groups

Following placing a K-type thermocouple inside the pulp chamber of the teeth, brackets of test groups were subject to either 1 Watt (1W group) or 3 Watt (3W group) power. Diode laser (Diode 940 nm, Epic 10, Biolase, CA, USA) irradiation was applied directly to the center of bracket for 3 s [Figure 2], and immediately, the chisel blade was placed at the enamel/bracket's base interface and the debonding force was recorded. Pulp chamber temperature was recorded by thermocouple before and after laser radiation. Furthermore, the base of the teeth and brackets' base, regarding to residual adhesive, were scored according to ARI. Again, the samples were buried in acrylic resin. Then, the samples were cut at the level of bracket's slot by a diamond saw at

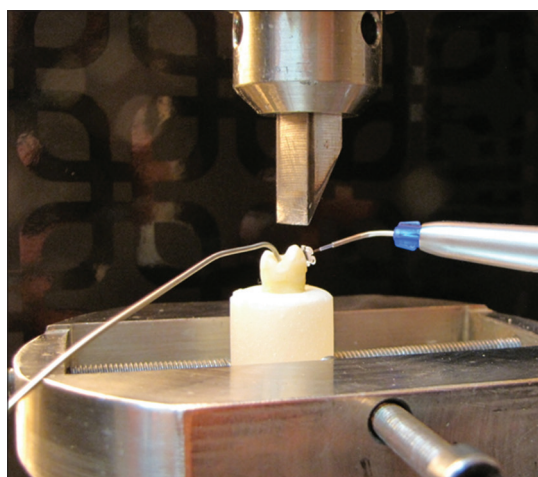


Figure 2: Fixed sample on testometric machine accompanied with laser and thermocouple.

low speed and with cooling water (TC 300, Vafaei industrial, Tehran, Iran). The surface of cervical half was polished using a grit 3000 sandpaper (991A softflex, Matador, Germany) and eventually diamond paste with particle sizes of 3 and 1 μ .

The nanoindentation test

The nanoindentation test was done by CSM indentation tester (Nano-Hardness Tester, CSM, Switzerland) with maximum load of 10 mN by a diamond Berkovich indenter tip. Each test consisted of three parts: 10 s loading up to a maximum amount, 1 s holding in the maximum load, and 10 s for unloading. In this study, our indentation was done in the depth of 1–31 μ from the enamel surface (7 points at intervals of 5 μ) in all surfaces from which the bracket was debonded.

Statistical analysis

To analyze the data and obtain the results, the SPSS spreadsheet (SPSS Inc., Chicago, IL, USA) was used. The significance level was set at %5 in this study. The ARI, shear bond strength (SBS), changes in pulp temperature, hardness, and elastic modulus data were tested for normal distribution by Kolmogorov–Smirnov that they were normally distributed in this study. The mean value for SBS, hardness, and elastic modulus for all groups were compared with one-way ANOVA and was followed by *Post hoc* Tukey's honest significant difference test. Chi-square test was used to compare the ARI percentage in different groups.

One-sample *t*-test was used to compare the changes in pulp temperature in groups with the standard threshold of 5.5°C and independent *t*-test was used to compare the relative pulp temperature changes between groups

RESULTS

Descriptive data for SBS are shown in Table 1. The statistical analysis showed a significant difference between the control group and other groups ($P = 0.008$) but not between the two groups of 1W laser and 3W laser ($P = 0.826$). Table 2 shows the descriptive statistics for ARI between different

Table 1: Descriptive statistics for shear bond strength (MPa) in groups

Group	n	Mean \pm SD	Minimum	Maximum
Control	6	26.55 \pm 3.66	30.40	30.76
Laser 1 watt	6	19.37 \pm 2.83	15.50	22.12
Laser 3 watt	6	17.89 \pm 5.92	11.43	28.29

SD: Standard deviation

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groups. The comparison of ARI scores showed no significant difference between groups ($P = 0.123$).

Statistical analysis showed no significant difference for the mean value of hardness ($P = 0.482$) and elastic modulus ($P = 0.472$) between any of the groups (control, 1W, and 3W). Results can be seen in Figures 3 and 4. In all groups, hardness and elastic modulus of enamel up to 1 μ thick from the enamel surface were lower in comparison with deeper layers, but this was not statistically significant. Elastic modulus of enamel decreased in test groups, as compared to the control group, but this difference was not statistically significant.

Radiating diode laser with either power of 1W or 3W for 3 s elevated the pulp temperature, but it was significantly $<5.5^\circ$ ($P = 0.000$). Also comparing pulp temperature changes between the two test groups (1W laser and 3W laser) showed a significant difference ($P = 0.000$) in such a way that the amount of temperature elevation in the group of 1W laser (0.6 ± 0.16) was significantly less than the group of 3W laser (2.35 ± 0.76) [Table 3].

DISCUSSION

According to this study, the laser diode with either 1W or 3W power for 3 s is effective in reducing bond strength and consequently in debonding the ceramic brackets without any detrimental effect on the pulp or mechanical properties of enamel.

Previous studies have shown that lasers can be effective in reducing the debonding force of ceramic brackets.^[3,7,9,17] The heat resulted from the laser can damage the enamel matrix protein. Hardness

and elastic modulus are strongly influenced by the organic components. Identifying the mechanical changes of enamel at micron level after debonding the orthodontic brackets is important for determining the iatrogenic damages to the enamel during debonding.^[15,18,19] In this study, the debonding force of ceramic brackets was significantly lower in the two test groups (1W and 3W) compared to the control group, but there was no significant difference between the test groups which is consistent with other related studies. In this study, we used a monocrystalline bracket. Feldon *et al.* showed that the diode laser with either 3W or 5W power significantly lowered the bond strength of monocrystalline (not polycrystalline) ceramic bracket because its uniform crystalline structure

Table 2: Descriptive statistics for Adhesive Remnant Index score in groups

Groups	ARI score				Number of samples in each group
	ARI=0	ARI=1	ARI=2	ARI=3	
Control (%)	2 (33.3)	1 (16.6)	0 (0)	3 (50)	6
Laser 1 watt (%)	0 (0)	0 (0)	1 (16.6)	5 (83.3)	6
Laser 3 watt (%)	1 (16.6)	3 (50)	0 (0)	2 (33.3)	6

ARI: Adhesive Remnant Index

Table 3: Thermal changes of pulp (°C)

Groups	Pulp temperature (mean)			
	Before lasing	After lasing	Thermal changes	SD
Laser 1 watt	17.75	18.35	0.6	0.16
Laser 3 watt	17.98	20.33	2.35	0.76

SD: Standard deviation

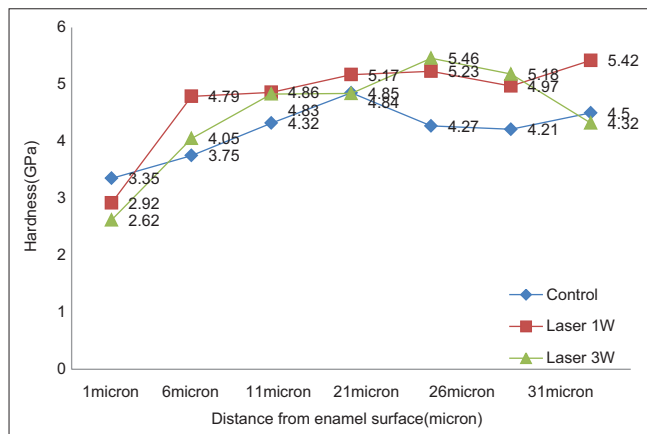


Figure 3: Mean value of hardness at different distance from enamel surface.

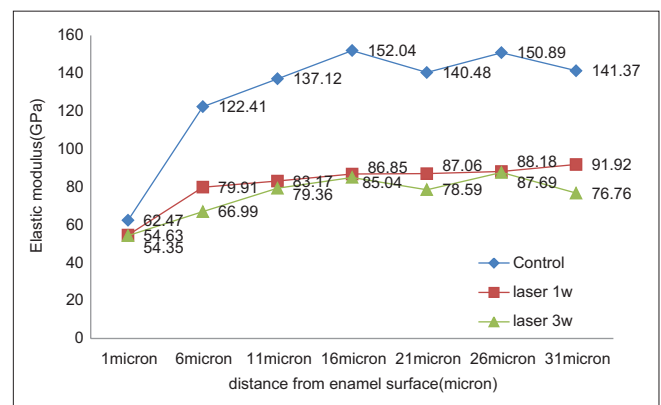


Figure 4: Mean value of elastic modulus at different distance from enamel surface.

results in high transmissibility of the bracket and minimizes the loss of energy.^[3]

Similar results have been reported by Almohaimed and Halim. In their study, precoated brackets (APC plus APCII) and laser with 3W power for 3 s were used. They stated that a laser with 3W power for 3 s is effective in debonding the ceramic bracket.^[17]

Yassaei *et al.* used diode laser with 2.5W power for 10 s in debonding the polycrystalline ceramic bracket and stated that using this laser reduces the risk of damage to the enamel such as crack.^[7]

In this study, diode laser with 1W power (in addition to 3W) for 3 s was used for debonding the ceramic which is the minimum power and energy used in similar studies. Although the debonding force for radiance bracket, when using diode laser with 1W power, is higher than 3W power, but this difference is not statistically significant, and it seems that diode laser with 1W power in debonding the ceramic bracket is effective as much as the 3W power is.

Comparing the ARI score between the groups (control, 1W laser, and 3W laser) showed no significant difference between the groups. This finding is consistent with the studies of Yassaei *et al.* and Feldon *et al.* but it was in contrast with the results obtained from the study of Almohaimed *et al.* which showed that the laser diode increased the ARI Score^[3,7,17] which can be due to the difference in the structure of base of brackets used in these two studies.

In this study, although there was no significant difference between the groups regarding the ARI Score, but the ARI Score 3 was the most frequent. This finding is consistent with the studies of Romano *et al.* and Fernandez and Canut who showed the highest bond failure at the adhesive/bracket interface.^[20,21] Furthermore, in the samples with ARI score 1, the remaining adhesive pattern was in conformity with peripheral areas of the bracket. This finding might be related to the structure of radiance bracket. Radiance bracket base has the exclusive pattern of “Quad matte.” This technology provides a strong bond in the center of the bracket, while the peripheral edges of the bracket base are smooth that makes bracket debonding easier and more predictable.^[22]

In this study, the mean of pulp temperature elevation in test groups was compared with the results of Zach and Cohen’s study. Their study revealed that if the pulp temperature elevates for more than 5.5°C, 15%

of the sample teeth will show necrosis.^[23] Serebro *et al.* and Goodis *et al.* also stated that elevating the pulp temperature up to 5.5°C is tolerable.^[24,25]

In our study, the pulp temperature elevation after laser radiation for 3 s, with either 1W or 3W power, was significantly <5.5°C which was consistent with the studies of Yassaei *et al.* and Feldon *et al.*

These results can be attributed to this fact that the absorption coefficient of diode laser in enamel is low; thus, the surface energy increases and decreases quickly during and after laser exposure, respectively, and leaves no detrimental effect on the pulp.^[26] Anyway, in these studies, measurements were carried out at room temperature that is lower than the temperature inside the mouth. Hence, it might be slightly different from what is actually happening in clinical conditions.

In this study, there was no significant difference in the mean of hardness and elastic modulus between the groups and between layers. Although the enamel hardness in the groups irradiated with laser was slightly increased compared to control group, it was not statistically significant.

Iijima *et al.* examined the effect of CO₂ laser in debonding the ceramic bracket on the mechanical properties of the enamel. The results showed that the hardness and elastic modulus of enamel were not affected by CO₂ laser irradiation^[12] which is consistent with our results on the diode laser. In Iijima’s study, the hardness and elastic modulus of the enamel up to 1 μ thick from the enamel surface were significantly lower than deeper layer (1–1000 μ) which is consistent with our results; so that in our study, the hardness and elastic modulus of the enamel were also decreased in the superficial 1 μ thick layer after debonding the bracket, but it was not statistically significant.

Iijima *et al.* examined the effect of debonding the bracket on nanomechanical properties of the enamel using self-etch and conventional-etch adhesives. They showed that in conventional etch group, the superficial 1 and 5 μ thick layers had significant lower hardness and elastic modulus than deeper layers.^[19] These results suggest that the mechanical properties of the enamel surface decreased after debonding when conventional etch method was used.

According to these studies, it seems that the reduced hardness and elastic modulus in the superficial 1 μ

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thick layer in our study was also because of using the conventional etch for bonding the brackets.

Alavi *et al.* examined the effect of bonding the bracket by Er: YAG laser on the nanomechanical properties of the enamel. The results showed that the enamel hardness of superficial 1–21 μ thick layers and elastic modulus of superficial 1–6 μ thick layers in the Er: YAG laser group were significantly higher than the conventional etch and control groups (intact enamel) which could be associated with the changes resulted from the Er: YAG laser on the enamel surface.^[18,27]

Dental enamel contains 85%–95% hydroxyapatite crystals, 8%–12% water, and 2%–3% organic components. Hardness and elastic modulus are different for each tooth because mechanical properties vary according to the mineral content of the enamel, age, and the individual health. These values also vary based on the location (distance from the enamel surface), the magnitude of force, indenter type, organic components, and the direction of enamel rods. These factors may explain the differences in the studies.^[18]

The results of this study show that the use of diode laser in ceramic bracket debonding has no significant effect on the mechanical characteristics of the enamel surface such as hardness and elastic modulus. This was, however, an *in vitro* study and the results may, therefore, be unlike the results of clinical studies. It is also recommended that to evaluate the efficiency of diode laser with 1W power for 3 s which is the lowest energy used in the studies so far, some studies with larger sample sizes may be beneficial.

CONCLUSION

1. Diode laser with 3W and 1W power for 3 s is effective in reducing the bond strength of monocrytalline ceramic bracket
2. It seems that the diode laser with 1W power for 3 s can be effective in debonding the monocrytalline ceramic bracket
3. The heat resulted from the diode laser, whether with 3W or 1W power for 3 s, has no destructive effect on the pulp and 1W laser is safer than 3W laser for the pulp
4. Diode laser with 1W and 3W power does not make significant change in the nanomechanical properties of the enamel; therefore, under the conditions of this study, diode laser with 1W power

is recommended for debonding the monocrytalline ceramic bracket.

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Conflicts of interest

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or nonfinancial in this article.

REFERENCES

1. Guignone BC, Silva LK, Soares RV, Akaki E, Goiato MC, Pithon MM, *et al.* Color stability of ceramic brackets immersed in potentially staining solutions. *Dental Press J Orthod* 2015;20:32-8.
2. Rosvall MD, Fields HW, Ziuchkovski J, Rosenstiel SF, Johnston WM. Attractiveness, acceptability, and value of orthodontic appliances. *Am J Orthod Dentofacial Orthop* 2009;135:276.e1-12.
3. Feldon PJ, Murray PE, Burch JG, Meister M, Freedman MA. Diode laser debonding of ceramic brackets. *Am J Orthod Dentofacial Orthop* 2010;138:458-62.
4. Pont HB, Özcan M, Bagis B, Ren Y. Loss of surface enamel after bracket debonding: An *in vivo* and *ex vivo* evaluation. *Am J Orthod Dentofacial Orthop* 2010;138:387.e1-9.
5. Shashwath M, Shetty N, Reddy A, Patil AK. Aesthetic trends in orthodontics. *J Dent Peer* 2013;1:128.
6. Tehranchi A, Fekrazad R, Zafar M, Eslami B, Kalhori KA, Gutknecht N, *et al.* Evaluation of the effects of CO₂ laser on debonding of orthodontics porcelain brackets vs. the conventional method. *Lasers Med Sci* 2011;26:563-7.
7. Yassaei S, Soleimani A, Nik ZE. Effects of diode laser debonding of ceramic brackets on enamel surface and pulpal temperature. *J Contemp Dent Pract* 2015;16:270-4.
8. Ahrari F, Heravi F, Fekrazad R, Farzanegan F, Nakhaei S. Does ultra-pulse CO₂ laser reduce the risk of enamel damage during debonding of ceramic brackets? *Lasers Med Sci* 2012;27:567-74.
9. Azzeh E, Feldon PJ. Laser debonding of ceramic brackets: A comprehensive review. *Am J Orthod Dentofacial Orthop* 2003;123:79-83.
10. Marković D, Rakašević D, Trišić D. Application of high-power diode laser and photodynamic therapy in endodontic treatment-review of the literature. *Balk J Den Med* 2015;19:71-4.
11. Srivastava VK, Mahajan S. Diode lasers: A magical wand to an orthodontic practice. *Indian J Dent Res* 2014;25:78-82.
12. Iijima M, Yasuda Y, Muguruma T, Mizoguchi I. Effects of CO₂ laser debonding of a ceramic bracket on the mechanical properties of enamel. *Angle Orthod* 2010;80:1029-35.
13. Cuy JL, Mann AB, Livi KJ, Teaford MF, Weihs TP. Nanoindentation mapping of the mechanical properties of human molar tooth enamel. *Arch Oral Biol* 2002;47:281-91.

14. Ayatollahi M, Karimzadeh A. Nano-indentation measurement of fracture toughness of dental enamel. *Int J Fract* 2013;183:113-8.
15. Iijima M, Muguruma T, Brantley WA, Mizoguchi I. Comparisons of nanoindentation, 3-point bending, and tension tests for orthodontic wires. *Am J Orthod Dentofacial Orthop* 2011;140:65-71.
16. Sakamoto M. Estimations of mechanical properties of bones using nanoindentation. *Clin Calcium* 2016;26:81-91.
17. Almohaimeed M, El Halim SA. Diode laser de-bonding of pre-coated ceramic brackets. *J Am Sci* 2013;9(5s):177-81.
18. Alavi S, Birang R, Hajizadeh F, Banimostafae H. Effect of bracket bonding with Er: YAG laser on nanomechanical properties of enamel. *Dent Res J (Isfahan)* 2014;11:49-55.
19. Iijima M, Muguruma T, Brantley WA, Ito S, Yuasa T, Saito T, et al. Effect of bracket bonding on nanomechanical properties of enamel. *Am J Orthod Dentofacial Orthop* 2010;138:735-40.
20. Fernandez L, Canut JA. *In vitro* comparison of the retention capacity of new aesthetic brackets. *Eur J Orthod* 1999;21:71-7.
21. Romano FL, Tavares SW, Nouer DF, Consani S, Borges de Araújo Magnani MB. Shear bond strength of metallic orthodontic brackets bonded to enamel prepared with self-etching primer. *Angle Orthod* 2005;75:849-53.
22. Available from: <http://www.americanortho.com/radiance.html>. [Last accessed on 2016 Apr 15].
23. Zach L, Cohen G. Pulp response to externally applied heat. *Oral Surg Oral Med Oral Pathol* 1965;19:515-30.
24. Goodis HE, Schein B, Stauffer P. Temperature changes measured *in vivo* at the dentinoenamel junction and pulpodentin junction during cavity preparation in the *Macaca fascicularis* monkey. *J Endod* 1988;14:336-9.
25. Serebro L, Segal T, Nordenberg D, Gorfil C, Bar-Lev M. Examination of tooth pulp following laser beam irradiation. *Lasers Surg Med* 1987;7:236-9.
26. Yussif NM. Evaluation the Effect of Diode Laser 980 nm in Caries Prevention. CU Theses; 2012.
27. Mine A, Yoshida Y, Suzuki K, Nakayama Y, Yatani H, Kuboki T, et al. Spectroscopic characterization of enamel surfaces irradiated with Er: YAG laser. *Dent Mater J* 2006;25:214-8.